Références (voir pdf complets plus bas)
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https://www.inesss.qc.ca/outils-cliniques/outils-cliniques/soutenir-la-prise-de-decision-partagee.html

Chaire de recherche du Canada sur la décision partagée et l'application des connaissances / Canada Research Chair in Shared Decision Making and Knowledge Translation
http://www.decision.chaire.fmed.ulaval.ca/

Formation à distance gratuite sur la conception d'outils d'aide à la prise de décision partagée / Free distance learning course on the design of shared decision aid tools
https://www.boitedecision.ulaval.ca/formations/conception-outils/

Outil d'aide à la décision partagée pour le dépistage du cancer du sein chez les femmes sans risque accru / Breast Cancer Screening for Women Not at Increased Risk
https://canadiantaskforce.ca/tools-resources/cancer-du-sein-mise-a-jour/outil-daide-a-la-prise-de-decision-partagee-personnes-agees-de-40-a-49-ans/?lang=fr

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BMJ Open

Effectiveness of case management interventions for frequent users of healthcare services: a scoping review

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ABSTRACT

Objective: Frequent users of healthcare services are a vulnerable population, often socioeconomically disadvantaged, who can present multiple chronic conditions as well as mental health problems. Case management (CM) is the most frequently performed intervention to reduce healthcare use and cost. This study aimed to examine the evidence of the effectiveness of CM interventions for frequent users of healthcare services.

Design: Scoping review.

Data sources: An electronic literature search was conducted using the MEDLINE, Scopus and CINAHL databases covering January 2004 to December 2015. A specific search strategy was developed for each database using keywords 'case management' and 'frequent use'.

Eligibility criteria for selecting studies: To be included in the review, studies had to report effects of a CM intervention on healthcare use and cost or patient outcomes. Eligible designs included randomised and non-randomised controlled trials and controlled and non-controlled before–after studies. Studies limited to specific groups of patients or targeting a single disease were excluded. Three reviewers screened abstracts, screened each full-text article and extracted data, and discrepancies were resolved by consensus.

Results: The final review included 11 articles evaluating the effectiveness of CM interventions among frequent users of healthcare services. Two non-randomised controlled studies and 4 before–after studies reported positives outcomes on healthcare use or cost. Two randomised controlled trials, 2 before–after studies and 1 non-randomised controlled study presented mitigated results. Patient outcomes such as drug and alcohol use, health locus of control, patient satisfaction and psychological functioning were evaluated in 3 studies, but no change was reported.

Conclusions: Many studies suggest that CM could reduce emergency department visits and hospitalisations as well as cost. However, pragmatic randomised controlled trials of adequate power that recruit the most frequent users of healthcare services are still needed to clearly confirm its effectiveness.

Strengths and limitations of this study

- This article is the first to review the evidence of case management (CM) for a general population of frequent users of healthcare services.
- Although CM activities were well described in the studies, key elements associated with successful CM interventions were scarcely discussed and will deserve more attention in further studies.
- Emergency department visits of frequent users show a natural decrease over time and regression to the mean may bias outcomes measured in before–after studies.
- Pragmatic randomised controlled trials of adequate power and using good case finding strategies are still needed.

INTRODUCTION

Industrialised countries have recognised that a small number of patients account for a large proportion of healthcare costs.[1–3] These patients use emergency department (ED) repeatedly, but their definition varies across studies.[4 5] They also frequently use hospital services for increasingly complex health needs[6–8] arising from factors such as multimorbidity, psychiatric comorbidities and psychosocial issues, or a combination of these factors.[7 9 10] Requiring care and services from many partners in the health and social services care system as well as the community care network, frequent users are more likely to encounter difficulties in the integration of care[11] and more at risk for incapacity and mortality.[12] Healthcare providers often feel limited in their interventions with this clientele because of patients' complex needs, fragmentation of care and the episodic nature of their visits to ED.[13] In this context, patients receive suboptimal care and healthcare systems are overwhelmed by the rising costs.[14]

To address this issue, case management (CM) is the most frequently performed intervention to reduce healthcare use and cost,

and to provide better care.[4 5 15] CM is a collaborative approach used to assess, plan, facilitate and coordinate care to meet patient and family health needs through communication and available resources with the intent to improve individual and health system outcomes.[16] CM has been shown to improve satisfaction and quality of life[17] and to reduce costs associated with frequent users of services.[1 4–6 17–20] The National Case Management Network of Canada[16] defined six standards of practice in CM: (1) determining and verifying patient eligibility for CM; (2) assessing patient needs; (3) documenting patient goals and priorities in a concerted strategy of intervention; (4) planning and adjusting services included in individualised service plans, including patient education and self-management support; (5) periodically reassessing patient needs and progresses; and (6) supporting transition process.

Three systematic reviews[4 5 15] reported the effectiveness of CM interventions among frequent ED users and concluded they had variable benefits on clinical, social and organisational outcomes such as ED use and cost. Two reviews reported different kinds of interventions, including CM. Althaus *et al*[4] included studies conducted before 2010, while the review by Soril *et al*[15] did not report patient outcomes. Finally, the third review by Kumar and Klein[5] looked at effectiveness of CM interventions but included articles concerning specific subgroups of patients such as psychiatric populations or patients with psychosocial problems.

Considering that many relevant studies[13 21–24] were not included in these reviews, we aimed, in our review, to examine evidence regarding the effectiveness of CM interventions among a more encompassing population of frequent users of healthcare services.

METHODS

Scoping review methodology is recognised as a process of mapping the main concepts of a research area to their source and evidence available in the literature.[25 26] It also serves to identify gaps in the field and provide recommendations for implementation.[25] This scoping review followed the five key phases of Arksey and O'Malley:[25] (1) identifying the research question; (2) identifying relevant studies; (3) selecting studies; (4) charting the data; and (5) collating, summarising and reporting the results.

Research question

Based on the expertise of our research team and an initial review of the literature, we defined the following research question:

> What is the evidence for the effectiveness of CM interventions among frequent users of healthcare services?

Search strategy

We conducted an electronic literature search of the MEDLINE, Scopus and CINAHL databases for English and French articles published between January 2004 and December 2015. The following MeSH terms and key words were used: case management, disease management, patient care management, patient care planning, health care services misuse, utilization review, frequent attend$, frequent consult$, frequent use$, high utilize$, high consult$, high attend$, high use, repeat use, frequent flyer, heavy use$, repeat$, recidivist, revolving door, misuse and hyperuse. We also examined reference lists of reviewed articles for additional relevant articles (hand searching). The search identified 2717 potentially relevant articles.

Study selection

To be included in the review, studies had to (1) report effectiveness of an intervention of CM for adult frequent users of healthcare services and (2) describe some form of comparison between patients who receive CM to those who do not receive the intervention (ie, randomised and non-randomised controlled trials, before–after studies) or between patients in preintervention and postintervention (same patients). The outcomes of interest were healthcare use and cost as well as patient-reported measures, such as quality of life and patient experience of care. To increase homogeneity and comparability among studies, we excluded studies limited to psychiatric, geriatric, paediatric, homeless, addicted patients or focusing on a single disease.

First, titles and abstracts were reviewed by one team member (ML) to exclude articles that were not eligible. At this stage, we excluded references clearly not meeting our inclusion criteria and retained all other references for analysis. In case of doubt, the full article was submitted to other team members (CH and M-CC) for a more detailed evaluation. Disagreement among team members (ML, CH and M-CC) was resolved by consensus. Forty-two articles were retained for detailed evaluation by team members (ML, CH and M-CC) and one additional reference was identified by hand searching. Of these 43 articles, 32 were excluded: 13 evaluated CM intervention designed for a specific population of frequent users (psychiatric, geriatric, paediatric, homeless or addicted patients), nine were disease-oriented interventions (mainly on diabetes, chronic obstructive pulmonary disease, rheumatoid arthritis, stroke and heart failure), eight evaluated interventions other than CM, one did not target frequent users and one was a commentary paper. A final sample of 11 articles was retained for data extraction (figure 1).

Data extraction

For each paper included, we collected descriptive characteristics such as first author and year of publication, study location and population, setting, aim and design of the study, characteristics of the intervention (including type of activities and case manager profession), length of follow-up and data about effectiveness of the intervention.

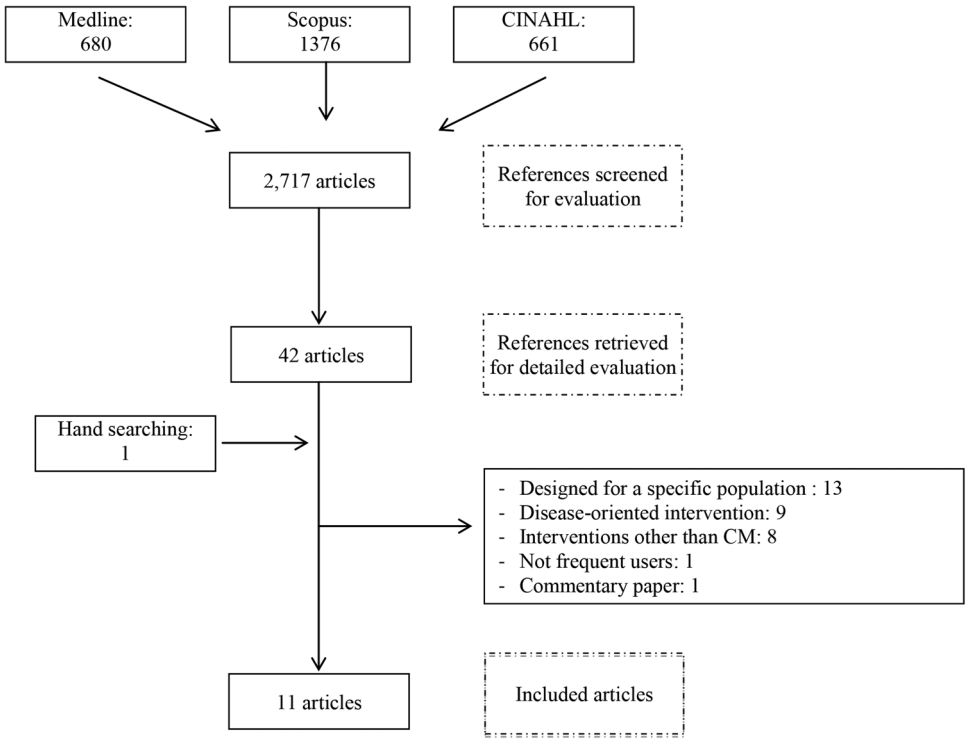

Figure 1 Scoping review flow chart of search results.

RESULTS

Description of the included studies

The characteristics of the 11 included papers are shown in table 1.[10 13 21–24 27–31] Two papers were randomised controlled trials, three were non-randomised controlled studies and six were before–after studies. The number of participants varied from 10 to 2742, their mean age ranged from 35 to 65 years and the proportion of female varied from 36% to 74%. Most studies were carried out in the USA (n=8). CM intervention was conducted in ED (n=6), primary care (2), in-patient (1) and emergency medical services (EMS) (2).

Definitions of frequent users varied across the 11 studies and were based on number of patient ED visits (ranging from 3 visits in a month to 10 visits in a year),[10 13 27–31] number of patient admissions (ranging from two to more than four admissions in a year),[23 30] number of EMS uses (10 transports or more in 1 year or the top 25 frequent users),[21 24] annual hospital cost ($4000 and more in a year)[22] and opinion of the healthcare staff.[10 24] Three studies recruited low-income, uninsured frequent users.[27 30 31] Nurses were the case manager in four studies,[23 27 28 31] social workers in two studies[30 31] and paramedic staff in one study,[24] but majority of the studies (n=5) did not specify who the case manager was.

The CM intervention also varied across studies (table 2). All interventions assessed patient needs as well as planned and adjusted services included in individualised service plans. The majority determined and verified patient eligibility (n=10), supported transition process (n=8), reassessed patient needs and progress (n=7), and provided patient education and self-management support (n=6). Few studies documented patient goals and priorities (n=3) (see online supplementary appendix 1).

As indicated in table 3, all studies reported the use of care as an outcome, six studies evaluated healthcare cost[21–24 27 30] and three studies investigated the impact of a CM intervention on patient quality of life.[22 23 31] Only one study evaluated healthcare use and cost as well as patient quality of life.[23]

Healthcare use and cost

Among all the studies included, two described results of a randomised control trial.[22 23] In a study of 2742 patients with high levels of in-patient healthcare expenditures, Segal *et al*[22] showed an increase in healthcare cost mainly due to the extra costs for care planning and CM. However, the experimental group included only 5% of patients at risk of future hospital admission. This could indicate a problem in the selection of their patients who should represent frequent users. In a randomised controlled trial of 96 patients, Sledge *et al*[23] observed a trend towards reduced admission, ED use and total healthcare cost in the experimental group, but they found that the difference was not significant, probably due to a lack of power.

Three articles presented non-randomised controlled studies.[27 28 30] Shah *et al*[30] conducted a study with 258 low-income, uninsured patients and demonstrated that ED use as well as cost had significantly decreased, but no difference was reported for in-patient admissions. The authors attributed positive results to patient engagement, frequent in-person contacts, liaison with social

Table 1 Characteristics of the studies included

Source (location)	Design	Setting	Population	N	Outcomes
Crane *et al*[27] (USA)	Non-randomised controlled study	ED	Low-income, uninsured frequent ED users (6 ED visits/year)	I=36 C=36	▶ ↓ ED use ▶ ↓ Total healthcare cost—ED and admission charges
Lee and Davenport[10] (USA)	Before–after study (pilot study)	ED	Frequent ED users (≥3 ED visits/month) associated with symptoms of unresolved pain, drug seeking or lack of primary care physician	50	No change on ED use
Peddie *et al*[28] (New Zealand)	Non-randomised controlled study	ED	Frequent ED users (≥10 ED visits/year)	I=87 C=77	No change on ED use
Phillips *et al*[29] (Australia)	Before–after study	ED	Frequent ED users (≥6 ED visits/year)	60	▶ ↑ ED use ▶ ↑ Primary care engagement ▶ ↑ Community care engagement ▶ ↑ Housing stability ▶ No change on admission ED disposition, ED length of stay, ED triage category, drug and alcohol use and EMS use
Pillow *et al*[13] (USA)	Before–after study	ED	Top 50 chronic ED frequent users (a total of 94 ED visits/month and 31 admissions/month)	50	▶ ↓ ED use* ▶ No change on admission
Rinke *et al*[21] (USA)	Before–after study (pilot study)	EMS	Top 25 frequent EMS users	10	▶ ↓ EMS cost* ▶ ↓ EMS use*
Segal *et al*[22] (Australia)	Randomised controlled trial	In-patient services	Frequent users of in-patient services ($≥4000 during a 2-year period)	I=2074 C=668	▶ ↑ Total healthcare cost* ▶ ↑ Hospital-based outpatient cost* ▶ No change on admission cost, medication cost, quality of life and mortality
Shah *et al*[30] (USA)	Non-randomised controlled study	Primary care services	Low-income, uninsured frequent ED and inpatient users (≥4 ED visits or admissions, or ≥3 admissions, or ≥2 admissions and 1 ED visit/year)	I=98 C=160	▶ ↓ ED use ▶ ↓ ED cost ▶ ↓ Admission cost ▶ No change on admission and ▶ Admission length of stay
Sledge *et al*[23] (USA)	Randomised controlled trial	Primary care services	Frequent users of in-patient services (≥2 admissions/year)	I=47 C=49	No change on admission, ED use, total healthcare cost, quality of life and patient satisfaction
Tadros *et al*[24] (USA)	Before–after study (pilot study)	EMS	Frequent EMS users (≥10 EMS transports/year, or referred by fire and EMS personnel)	51	▶ ↓ Dispatch priority* ▶ ↓ EMS cost* ▶ ↓ EMS mileage* ▶ ↓ EMS task time* ▶ ↓ EMS use* ▶ ↓ Healthcare cost*—EMS, ED and admission cost ▶ ↓ Paramedic transport code* ▶ No change on admission*, admission cost*, admission length of stay*, ED cost and ED use
Wetta-Hall[31] (USA)	Before–after study	ED	Low-income, uninsured frequent ED users (≥3 ED visits/6 months)	492	▶ ↓ ED use ▶ ↑ Quality of life ▶ No change on health locus of control

*Not stated if the outcome was significant or not.
C, Control group; ED emergency department; EMS, Emergency Medical System; I, intervention group.

Table 2 CM activities described in the included studies

CM activity	Crane *et al*[27]	Lee and Davenport[10]	Peddie *et al*[28]	Phillips *et al*[29]	Pillow *et al*[13]	Rinke *et al*[21]	Segal *et al*[22]	Shah *et al*[30]	Sledge *et al*[23]	Tadros *et al*[24]	Wetta-Hall[31]
Determining and verifying patient eligibility	+	+	+	+	+	+	+		+	+	+
Assessing patient needs	+	+	+	+	+	+	+	+	+	+	+
Documenting patient goals and priorities							+	+			+
Providing patient education and self-management support	+					+		+	+	+	+
Planning and adjusting services included in individualised service plans	+	+	+	+	+	+	+	+	+	+	+
Reassessing patient needs and progress	+				+	+	+	+	+		
Supporting transition process	+				+	+	+	+	+	+	

CM, case management.

Table 3 Outcomes measured in the included studies

Outcome	Number of studies
Use of care	11
ED	9
ED length of stay	1
Admission	4
Admission length of stay	2
EMS	3
Primary care services	1
Care cost	6
ED	2
Admission	3
EMS	2
Healthcare services (primary, secondary and supportive care)	4
Hospital-based outpatient services	1
Medication	1
Other	6
Quality of life	3
Community care engagement	1
Drug and alcohol use	1
ED disposition	1
EMS dispatch priority	1
EMS task time	1
EMS mileage	1
Health locus of control	1
Housing status	1
Mortality	1
Paramedic transport code	1
Patient satisfaction	1
Primary care engagement	1
Triage category (ED)	1

ED, emergency department; EMS, Emergency Medical System.

resources, and close relationships between case managers, local hospitals and providers at local clinics. However, a possible bias in favour of patients more willing to engage in the management of their health was noted. A study with 36 patients in the experimental group by Crane *et al*[27] also demonstrated a reduction in ED use and healthcare cost ranging from US$ 1167 per patient per month to US$ 230 ($p<0.001$) in combined ED and inpatient hospital charges. The authors identified many factors contributing to the effectiveness of their CM intervention: long and frequent medical visits without limitation on the number, identification and resolution by the care team of barriers and frustrations in accessing medical care, emotional support provided to the patient by the group meetings, and personal qualities and competence of the care manager who gaining patient trust. However, of the 147 frequent users contacted, only 36 accepted to participate, probably the more motivated patients, something that could be seen as a possible bias. Another limitation could be attributed to the analysis of the data that came from only one hospital, although frequent users are known to seek care at multiple EDs. On the other hand, Peddie *et al*[28]

conducted a non-randomised controlled study with 164 frequent ED users and found no reduction in ED visits. After 4 years of follow-up, the percentage of patients in the experimental group still attending ED at least once a year in the fourth year was similar to the control group (respectively 64% vs 65%). The fact that the control group was an historical one, that is, individuals acted as their own controls, and possible lack of power could explain this result.

Six articles described results of before–after studies.[10 13 21 24 29 31] Four articles demonstrated a reduction of healthcare use and cost,[13 21 24 31] and two of them reported no change in ED use or admission.[13 24] Pillow *et al*[13] conducted a study with the top 50 chronic ED frequent users. By using data from one hospital, they reported a trend towards a reduction in ED use, but no significant change on admission. The main factors contributing to their repeat visits according to the CM team were psychiatric disease, substance abuse, malingering, medication non-compliance and unstable housing. In the same way, a before–after study of 60 patients by Phillips *et al*[29] reported an increase in ED use. Seventy-three per cent of the patients presented either substance misuse or psychosocial issues as their primary problem, and only 27% had chronic medical problems. In a study of 492 low-income, uninsured frequent ED users, Wetta-Hall[31] demonstrated a reduction in ED use. The author associated this result to the advocacy role of the CM team who facilitated participant access to medical care, prescription medications and social services. Rinke *et al*[21] (n=10) and Tadros *et al*[24] (n=51) observed a reduction in EMS cost and use among frequent EMS users. However, Tadros *et al*[24] reported no change on admission as well as ED use and cost. Finally, in a pilot study with 50 patients, Lee and Davenport[10] found no change in ED use.

Patient-reported outcomes

Among the three studies reporting quality-of-life outcomes,[22 23 31] two randomised controlled trials reported no change,[22 23] one of them included only 5% of patients at risk of future hospital admission[22] and the other possibly lacked power with a sample of 96 patients.[23] One before–after study found an improvement in patient quality of life.[31] Wetta-Hall[31] demonstrated that the physical dimension of quality of life improved significantly after the CM intervention ($p<0.001$). However, the mental dimension of the quality-of-life score showed minimal change. Physical dimension of quality of life probably improved due to the fact that the participants had access to medical care, prescription medications and social services. According to the author, mental dimension of quality of life did not change because it was not the focus of the CM intervention. Moreover, life circumstances of a low-income, less educated and uninsured population did not change between preintervention and postintervention.

Patient outcomes such as drug and alcohol use, health locus of control and patient satisfaction were evaluated in three studies,[23 29 31] but no change was reported.

DISCUSSION

This scoping review identified 11 studies evaluating the effectiveness of CM interventions among frequent users of healthcare services. Two non-randomised controlled studies[27 30] and four before–after studies[13 21 24 31] reported positive outcomes on healthcare use or cost. However, a selection bias may have been present in four studies because their participants were probably more motivated to change behaviour given their willingness to participate in the intervention.[21 27 30 31] In addition, four studies included a small sample of patients (≤51),[13 21 24 27] and three studies conducted their analyses on data from only one hospital.[13 24 27] On the other hand, five studies presented mitigated results.[10 22 23 28 29] One of the randomised controlled trials[23] was unable to detect a difference in healthcare cost and use, while the other demonstrated an increase in healthcare cost[22] but raised issues concerning case finding. One before–after study[29] found an increase in ED use, but this was probably due to high levels of participants with substance abuse or psychosocial problems. A non-randomised controlled study[28] and a before–after study[10] reported no change in ED use, but possibly lacked power. Patient outcomes such as drug and alcohol use, health locus of control, patient satisfaction and psychological functioning were evaluated three studies, but no change was reported.[23 29 31]

A majority of the studies included a detailed description of their intervention and CM activities were clearly identified. 'Documenting patient goals and priorities' was the activity less frequently reported. Many interventions did not consider patient health objectives in individualised services plan[13 21 23 24 27 28] even if goal setting is recognised as an important component of CM.[16] Although CM activities were well described in the studies included, key elements associated with successful CM interventions were scarcely discussed. Considering their complexity, it is essential to understand the main mechanisms underlying CM activities and go beyond the cause–effect relationship by including a process evaluation considering the influence of contexts on outcomes.[32] An explanatory analysis on how CM intervention works, in what populations/subpopulations, and in what circumstances and contexts is necessary to identify modifiable factors influencing intervention effects.[33] These results would be very relevant for researchers and decision-makers who plan to implement CM interventions.

The studies included pointed out several problems in assessing the efficacy of CM interventions designed to manage frequent users. First, ED visits of frequent users show a natural decrease over time[23 28 34 35] and regression to the mean may bias outcomes[36] measured in

before–after studies that demonstrated a reduction in ED use.[13 27 30 31] Pragmatic randomised trials may help to attribute a reduction in use of care for frequent users of CM interventions and produce results that can be generalised to clinical practice settings, more than in a traditional controlled randomised trial.[37] Second, case finding, that is, the identification of participants who will benefit the most from the intervention, could also affect results as shown in the study by Segal *et al*[22] where experimental groups included only 5% of patients at risk of future hospital admission. In addition to the identification of frequent users based on data from hospital electronic medical records, opinion of healthcare providers is recommended to properly identify patients likely to be willing and able to participate in a CM intervention.[38] Finally, many of the included studies had a small sample of frequent users[10 23 28 29] and could result in a lack of power where effects are harder to detect. The fact that frequent users are vulnerable populations who may be reluctant to participate[39] and represent only a small proportion of patients[1–3] could explain the low sample size of the included studies.

Our review has some limitations. Conducting a meta-analysis of the effectiveness of CM interventions for frequent users of healthcare services would have contributed to fill gaps in the possible lack of power of some included studies, but the heterogeneity across studies in terms of definition of frequent users, healthcare settings and CM interventions makes direct comparisons difficult. Another limitation of a scoping review is the potential omission of relevant articles, as well as any unpublished material. Our search strategy relied on key words assigned by authors and may have missed relevant studies on the effectiveness of CM. However, our search strategy was adapted for different databases, and enabled an exhaustive literature review. Moreover, we identified further articles through hand searching. Finally, it would be interesting to conduct an evaluation of the quality of the studies included. However, the scoping review method does not imply an evaluation of quality because it aims to provide a description of available research rather than determine robust or generalisable findings.

CONCLUSION

In conclusion, our review suggests that CM could reduce ED visits and hospitalisations as well as cost, but additional studies still need to clearly confirm its effectiveness. Pragmatic randomised controlled trials of adequate power and the recruitment of well-defined frequent users of healthcare services are needed. The effectiveness of CM to improve patient outcomes such as self-management and experience of care would also have to be evaluated.

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Characteristics of Case Management in Primary Care Associated With Positive Outcomes for Frequent Users of Health Care: A Systematic Review

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ABSTRACT

PURPOSE Case management (CM) interventions are effective for frequent users of health care services, but little is known about which intervention characteristics lead to positive outcomes. We sought to identify characteristics of CM that yield positive outcomes among frequent users with chronic disease in primary care.

METHODS For this systematic review of both quantitative and qualitative studies, we searched MEDLINE, CINAHL, Embase, and PsycINFO (1996 to September 2017) and included articles meeting the following criteria: (1) population: adult frequent users with chronic disease, (2) intervention: CM in a primary care setting with a postintervention evaluation, and (3) primary outcomes: integration of services, health care system use, cost, and patient outcome measures. Independent reviewers screened abstracts, read full texts, appraised methodologic quality (Mixed Methods Appraisal Tool), and extracted data from the included studies. Sufficient and necessary CM intervention characteristics were identified using configurational comparative methods.

RESULTS Of the 10,687 records retrieved, 20 studies were included; 17 quantitative, 2 qualitative, and 1 mixed methods study. Analyses revealed that it is necessary to identify patients most likely to benefit from a CM intervention for CM to produce positive outcomes. High-intensity intervention or the presence of a multidisciplinary/interorganizational care plan was also associated with positive outcomes.

CONCLUSIONS Policy makers and clinicians should focus on their case-finding processes because this is the essential characteristic of CM effectiveness. In addition, value should be placed on high-intensity CM interventions and developing care plans with multiple types of care providers to help improve patient outcomes.

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INTRODUCTION

In developed countries, the bulk of health care system expenses is attributable to a small proportion of the population. Specifically, frequent users of health care services account for approximately 10% of the population but upward of 70% of health care expenditures.[1-3] Many frequent users have chronic physical diseases that are further complicated by mental health comorbidities and/or social vulnerabilities, which increase their overall health care needs.[4,5] These individuals are more likely to experience fragmentation of care,[6,7] suffer from disability,[8] and have a general decrease in quality of life[9] and an increased risk of death.[10,11]

A variety of interventions have been developed to improve the health and social care of frequent users, the most common of which are case management (CM), individualized care plans, patient education and counseling, problem solving, and information sharing.[12-17] Case management is a promising and effective intervention to improve the health and social care of frequent users[12-17]; it is a collaborative approach to ensure, coordinate, and integrate care and services for patients, in which a case

manager evaluates, plans, implements, coordinates, and prioritizes services on the basis of patients' needs in close collaboration with other health care providers.[18] Many literature reviews have reported the effectiveness of CM interventions, citing such benefits as reductions in emergency department (ED) visits and hospital admissions, overall reductions in expenditures, and improved patient outcomes such as quality of life and patient satisfaction.[12-15,19,20] However, CM is a complex intervention, with various characteristics interacting in a nonlinear manner.[21,22] To design and implement effective CM interventions, we need to understand the characteristics of CM that are associated with positive outcomes. The objective of the present study was to conduct a systematic review to identify characteristics of CM that yield positive outcomes among adult frequent users with chronic disease in primary care.

METHODS

We conducted a systematic review including quantitative, qualitative, and mixed methods studies, with a data-based convergent synthesis design.[23] This type of design, combining the strengths of quantitative and qualitative research, helps to develop a rich and deep understanding of complex health interventions.[23,24] Our complete methods are detailed in a peer-reviewed systematic review protocol that is registered on PROSPERO (CRD42016048006).[25]

Eligibility Criteria

The eligibility criteria were as follows: (1) population: adult frequent users (aged ≥18 years) with physical chronic disease and receiving care in primary, secondary, tertiary, or community care settings, (2) intervention: CM in a primary care setting (including ED) with a postintervention evaluation, and (3) primary outcomes: integration of services, health care system use, financial cost, and patient outcomes (eg, self-management, patient experience of care, health-related quality of life, etc). To increase homogeneity of the sample of included studies and comparability of CM characteristics between studies, pediatric, frail elderly, and homeless populations were excluded because these populations might have distinct sets of needs. In addition, specific disease-oriented CM interventions were excluded because primary care aims to improve whole-person health.

Information Sources and Search Strategy

A bibliographic database search was conducted of the online databases MEDLINE, CINAHL, Embase, and PsycINFO for empirical studies (experimental, quasi-experimental, qualitative, and mixed methods studies) published in English or French and limited to the past ~20 years (ie, 1996 to September 2017). An information specialist for Cochrane Canada Francophone developed and ran specific search strategies for each database, combining the search concepts "frequent use" and "evaluation studies." The MEDLINE search strategy is presented in Supplemental Appendix 1 (http://www.AnnFamMed.org/content/17/5/448/suppl/DC1/). Relevant studies were identified via a hand search of the reference lists of studies selected via the electronic search to be included in the review. To capture more information on CM interventions, companion documents (eg, protocols, reports, website pages, news articles) for each included study were retrieved by searching Google, ResearchGate, Scopus, and PubMed, as well as e-mailing the corresponding authors.

Study Selection and Data Extraction

Four reviewers participated in the study selection using Covidence systematic review software. Two independent reviewers (L.L., M-J.C; see acknowledgment in end copy for reviewers listed in this section) screened titles and abstracts using the eligibility criteria, and 2 other independent reviewers (M.S., V.G.) assessed full texts of the selected studies for eligibility. At both stages, discrepancies were resolved by a third reviewer (M.L.). Eligible studies were retained for data extraction and methodologic quality assessment. Two reviewers extracted the following data using a standardized data extraction form: study characteristics (eg, first author, year of publication, country, setting, design); definition of frequent users; population characteristics such as age and sex; sample size; type, objective, frequency, and content of intervention; length of intervention sessions; duration of patient follow-up; case-finding process; health care providers involved; intervention offered to control group; data analysis; outcome characteristics and assessment instruments; and intervention effectiveness according to reported outcomes (quantitative or qualitative). Data extraction was double-checked by a second reviewer.

Quality Appraisal and Data Synthesis

Two independent reviewers used the Mixed Methods Appraisal Tool (MMAT)[26-29] to assess eligible studies and determine an overall methodologic quality score for each. When necessary, disagreements between reviewers were resolved by a third reviewer. The MMAT was specifically designed to concomitantly appraise studies with diverse designs and has been validated and reliability tested.[26-29] We used the 2011 version of the MMAT, which includes 2 initial screening questions and 19 items. Studies that did not meet the 2 initial screening questions were deemed not empirical and were excluded. We performed a sensitivity analysis to assess the effect of methodologic quality on the results

by replicating the analysis without the low-quality studies (MMAT score ≤25%).[30] The MMAT has recently been updated and revalidated using a conceptual framework on the quality of qualitative, quantitative, and mixed methods studies included in mixed studies reviews[31]; qualitative research[32] with MMAT users worldwide; and a Delphi study with international experts.[33] This led to the 2018 version of the MMAT.[34] We used the original version for the present study.

Sufficient and necessary characteristics of CM interventions were identified using configurational comparative methods (CCM)[35]; this is used to study a small to intermediate number of cases (eg, 5-50), among which an outcome of interest has been identified,[36] allowing for the integration of quantitative and qualitative results.[23] The use of CCM helps to identify configurations, that is, a combination of conditions that produces the presence or absence of the outcome of interest across cases. This allows for reduction of the complexity of data sets in small N situations by using Boolean algebra[37] to explore different combinations of conditions and to identify necessary and sufficient conditions associated with the outcome of interest. A necessary condition is one that is always present when the outcome occurs, that is, the outcome cannot occur without this condition. A condition (or combination of conditions) is considered sufficient to produce an outcome if the outcome always occurs when the condition (or combination of conditions) is present.[38] In the present study, the characteristics of CM interventions were the conditions we explored. Supplemental Appendix 2 (http://www.AnnFamMed.org/content/17/5/448/suppl/

Table 1. Description of Included Studies

First Author, Year, (Country)	Design	Setting	Population (CM Intervention Inclusion Criteria)
Adam et al,[40] 2010 (USA)	Nonrandomized trial	Primary care clinic	≥8 clinic visits/year with multiple comorbidities (physical, psychiatric and psychosocial issues)
Bodenmann et al,[41] 2017 (Switzerland)	Randomized controlled trial	ED	≥5 ED visits/year
Brown et al,[42] 2005 (USA)	Before-after study	Primary care clinic	≥1 hospital admission/year, ≥1 chronic condition, and life expectancy judged to be greater than 3 years
Crane et al,[43] 2012 (USA)	Nonrandomized trial	ED	≥6 ED visits/year; low family income
Edgren et al,[44] 2016 (Sweden)	Randomized controlled trial	ED	≥3 ED visits/6 months, deemed at risk of high health care use and considered to be receptive to intervention
Grimmer-Somers et al,[45] 2010 (Australia)	Mixed methods study	Primary care centers	Vulnerable frequent users
Grinberg et al,[46] 2016 (USA)	Qualitative study	Transitional primary care – postdischarge	≥2 hospital admissions/6 months with at least 3 of the following criteria: ≥2 chronic conditions; ≥5 outpatient medications; lack of access to health care services; lack of social support; mental health comorbidity; substance abuse or use; homeless
Grover et al,[47] 2010 (USA)	Before-after study	ED	≥5 ED visits/month or concern about ED use raised by staff or identified by California prescription-monitoring program
Hudon et al,[48] 2015 (Canada)	Qualitative study	Primary care clinics	≥3 ED visits and/or hospital admissions/year, ≥1 chronic condition, and identified by family physician as a frequent user likely to benefit from intervention

C = control group; CM = case management; ED = emergency department; I = intervention group; PCP = primary care provider; Qual = qualitative study; Quant = quantitative study; UK = United Kingdom; USA = United States of America.

N	Main Characteristics of the Intervention	Outcome	Methodological Quality Score, %
I: 12 C: 8	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include referral to mental health services, review of medication, and care coordination. The PCP presented the care plan to the patient and amended it if needed.	↓ Clinic visits ↑ Well-being ↑ Patient satisfaction ↑ Quality of care ↑ No show or cancelled appointments No change in hospital admission and ED use	100
I: 125 C: 125	Interdisciplinary mobile team developed care plan based on patient's evaluation. Care plan could include assistance for financial entitlements, education, housing, health insurance, and domestic violence support, as well as referral to mental health services, substance abuse treatment, or a PCP. Team also provided care coordination, counseling on substance abuse (if needed) and use of medical services. They also facilitated communication between health care team members.	No significant changes in ED visits	75
17	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include referral for diagnostic testing or specialists' services and a review of medication. The team also provided care coordination, psychological support, self-management support, and disease management.	↓ ED visits ↓ Hospital admissions ↓ Length of stay No change in health care costs	25
I: 34 C: 36	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include referral for diagnostic testing or specialists' services and review of medication. The team also provided group and individual medical appointments, telephone access to care manager, and group sessions on life-skills support.	↓ ED visits ↓ ED and inpatient costs ↑ Employment status	75
I: 8,214 C: 3,967	Nurse case manager developed, with patient, a care plan based on patient's evaluation. Care plan could include self-management support, patient education, and referrals to other health and social services. Via regular contact by telephone, case manager provided self-management support to patient. They also facilitated communication and supported interactions with health care providers and social services.	↓ Outpatient care ↓ Inpatient care ↓ ED visits ↓ Health care costs	25
Quant: 37 Qual: Unknown	Interdisciplinary care team developed, with patient, care plan based on patient's evaluation. Care plan could include referrals to other health and social services, self-management support, patient education, goal setting, and involvement in peer-led community group. The team also provided support for language, literacy, social support, and transport barriers.	↓ ED use ↓ Hospital admissions ↓ Length of stay ↓ Inpatient cost ↓ Outpatient attendance ↑ Patient reflection on their health and other needs ↑ Patient goal-setting	50
30	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include access to primary care, review of medication, medical appointment accompaniment, assistance for transport, and financial entitlements. The team also provided care coordination and health navigation after hospital discharge.	↑ Patient motivation ↑ Self-management ↑ Healing relationships	100
85	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include referrals to outpatient and social services as well as restriction of narcotics prescriptions. Patients received letters to inform them of the care plan but had no contact with the team. The care plan was entered in the patient's medical records in the ED for easy access to information by the ED staff.	↓ ED use ↓ Radiation exposure from diagnostic imaging ↑ Efficacy of referral No change in hospital admissions or most common chief complaint	75
25 patients 8 family members	Nurse case manager developed, with patient and other health care providers, a care plan based on patient's evaluation. Care plan could include referrals to health and social services and interdisciplinary team meetings (including the patient). The case manager also provided self-management support and care coordination.	↑ Access to care ↑ Communication ↑ Care coordination ↑ Patient involvement in decision-making ↑ Care transition	50

continued

DC1/) provides definitions of CCM terms.

The CCM followed the 6 steps described by Rihoux and Ragin[35] (a complete description of each step is detailed in Supplemental Appendix 3, http://www.AnnFamMed.org/content/17/5/448/suppl/DC1/): (1) building a raw data table, (2) constructing a truth table, (3) resolving contradictory configurations, (4) conducting Boolean minimization using fuzzy set/qualitative comparative analysis (fs/QCA) software, (5) bringing in the logical remainders cases (TOSMANA software was used to create a visual representation of our results), and (6) interpreting the results. Following best practices in CCM, the selection of conditions used in the analysis, and the way each condition was defined, was informed by case-based knowledge (data extraction) and CM theory.[38] The number of conditions was limited so that the ratio between the number of possible logical combinations of conditions and the number of cases was kept sufficiently low.[37,39] For example, for the thematic synthesis step of the present review, we identified main characteristics of CM interventions in the included studies (Table 1). Of those, we identified 4 initial conditions that were most commonly reported in the included studies (informed by the team's experience with CM and prior research on CM for frequent users). The definitions of these conditions were developed iteratively by drawing from prior research, going back to the cases to explore how they were defined, and drawing on the substantive and field knowledge of the team members. One condition (effective communication between health care providers) was removed because it was not reported or we were not able to

Table 1. Description of Included Studies *(continued)*

First Author, Year, (Country)	Design	Setting	Population (CM Intervention Inclusion Criteria)
McCarty et al,[49] 2015 (USA)	Before-after study	ED	≥25 ED visits/year or identified by ED staff as frequent user likely to benefit from intervention
Peddie et al,[50] 2011 (New Zealand)	Nonrandomized trial	ED	≥10 ED visits/year
Pope et al,[51] 2000 (Canada)	Before-after study	ED	Frequent users who had the potential for high ED use, with at least 2 of the following criteria: chronic condition, complex medical condition, substance abuse user, violent behavior or abusive behavior
Reinius et al,[52] 2013 (Sweden)	Randomized controlled trial	ED	≥3 ED visits/6 months with the ability to participate in the study based on medical history, number of medications prescribed, and social factors
Roberts et al,[53] 2015 (USA)	Before-after study	Transitional primary care – postdischarge	≥2 hospital admissions/6 months or ≥3 hospital admissions/year with ≥1 chronic condition
Shah et al,[54] 2011 (USA)	Nonrandomized trial	Primary care center	≥4 ED visits or hospital admissions or ≥3 hospital admissions or ≥2 hospital admissions and 1 ED visit/year, with low family income, uninsured, and not eligible for public health insurance program
Skinner et al,[55] 2009 (UK)	Before-after study	ED	≥10 ED visits/6 months or identified by senior health care providers as putting a high demand on unscheduled care services (or at future risk) and who could benefit from intervention
Sledge et al,[56] 2006 (USA)	Randomized controlled trial	Primary care center	≥2 hospital admissions/year
Spillane et al,[57] 1997 (USA)	Randomized controlled trial	ED	≥10 ED visits/year
Stokes-Buzzelli et al,[58] 2010 (USA)	Before-after study	ED	Top 100 frequent ED users, or identified as frequent users deemed appropriate for intervention
Weerahandi et al,[59] 2015 (USA)	Nonrandomized trial	Transitional primary care – postdischarge	≥1 hospital admission/1 month or 2 hospital admissions/6 months

C = control group; CM = case management; ED = emergency department; I = intervention group; PCP = primary care provider; Qual = qualitative study; Quant = quantitative study; UK = United Kingdom; USA = United States of America.

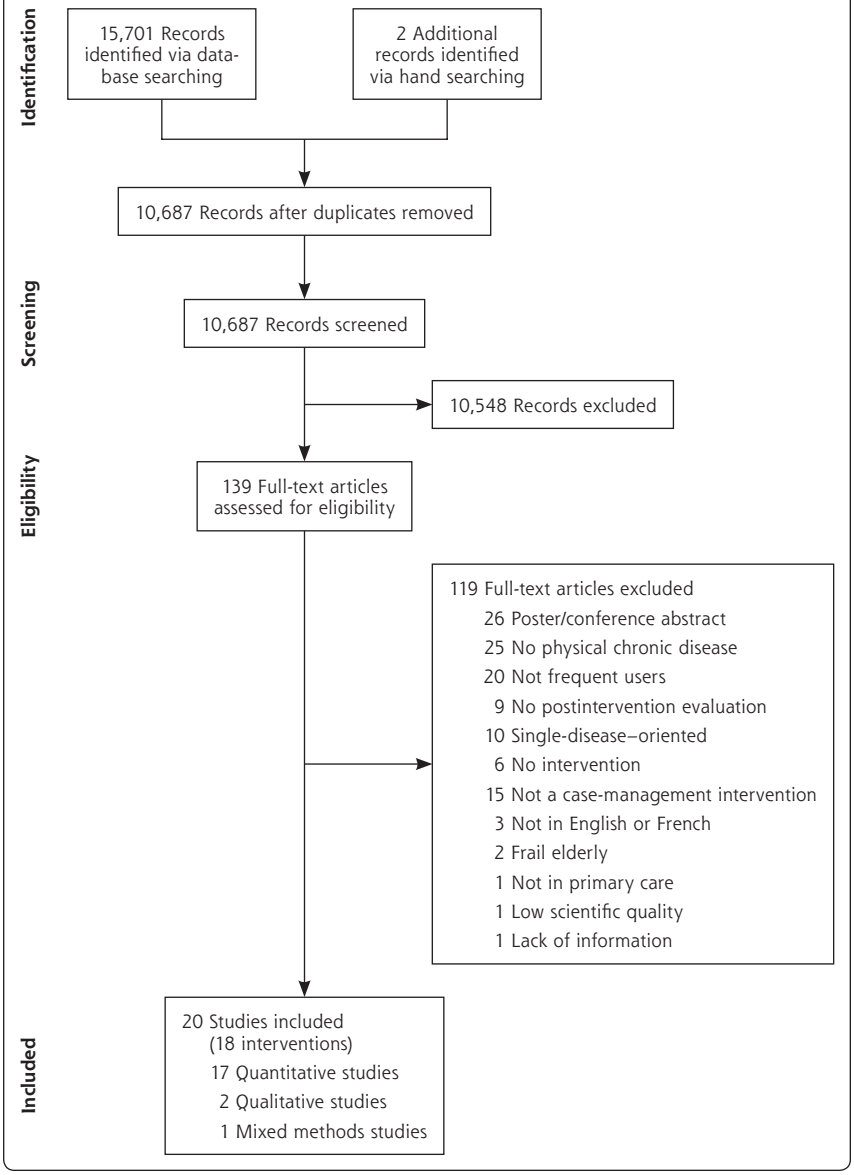
N	Main Characteristics of the Intervention	Outcome	Methodological Quality Score, %
23	Interdisciplinary care team developed, with patient, a care plan based on patient's evaluation. Care plan could include referrals to health care and social services, goal setting, crisis intervention, restriction of narcotic prescriptions, assistance for transport, financial entitlements, and housing. The team also provided care coordination and supported interactions with community services.	↓ ED visits	50
I: 87 C: 77	Interdisciplinary care team developed care plan based on patient's evaluation. The care plan could include referrals to a PCP and interdisciplinary team meeting (including the patient).	No change in ED visits	25
24	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include referrals to health care and social services, restriction of narcotic prescriptions, restriction of ED use, limited interaction with ED staff, and escort by a security guard in the ED. The team also provided counseling and supported interactions with community services.	↓ ED visits	25
I: 211 C: 57	Same intervention as Edgren et al (2016)[44]	↓ Outpatient care ↓ ED visits ↓ Length of stay ↓ Health care costs ↑ Health status ↑ Patient satisfaction No change in inpatient care, hospital admissions, or mortality	50
198	Interdisciplinary care team developed, with patient, care plan based on patient's evaluation. Care plan could include goal setting, review of medication, assistance for transport, financial entitlements, and housing. The team also provided self-management support, patient education, health navigation, and care coordination.	↓ ED visits ↓ Hospital admission ↓ Health care costs	75
I: 98 C: 160	Case manager developed, with patient, care plan based on patient's evaluation. Care plan could include referrals to health and social services, goal setting, assistance for transport, financial entitlements, and housing. The case manager also provided care navigation, facilitated communication with health care providers, supported interactions with community services, and provided care transition.	↓ ED visits ↓ Health care cost No change in hospital admissions or length of stay	50
57	Interdisciplinary care team developed care plan based on patient's evaluation. The care plan could include referrals to health care services.	↓ ED visits	75
I: 47 C: 49	Same intervention as Brown et al (2005)[42]	↑ Clinic visits No change in health care use or costs, functional status, patient satisfaction, or medication-taking adherence.	50
I: 27 C: 25	Interdisciplinary care team developed care plan based on patient's evaluation. Care plan could include care recommendation and treatment guidelines for ED staff such as limitation of diagnostic tests and restriction of narcotics prescriptions. The team also provided psychosocial services, care coordination, and liaison with a PCP.	No change in ED visits	75
36	Interdisciplinary care team developed care plan based on patient's evaluation. The care plan could include care suggestions and treatment guidelines (eg, restriction of narcotics prescriptions) for ED staff.	↓ ED visits ↓ ED contact time ↓ Laboratory tests ordered ↓ ED costs	75
I: 579 C: 579	Social worker case manager, with patient and other health care providers, developed care plan based on patient's evaluation. Care plan could include referrals to health care and social services, counseling for mental health problems, self-management support, patient activation, assistance with insurance, and medical appointment accompaniment. The case manager also provided care coordination and care transition and facilitated communication between health care providers.	No change in hospital admissions	50

conclude its absence/presence across all cases. Finally, the definitions of the 3 remaining main conditions were used to develop a codebook that was independently tested for clarity and comprehensiveness by reviewers outside the team. The final list of conditions and outcomes is presented in Supplemental Appendix 4 (http://www.AnnFamMed.org/content/17/4/448/suppl/DC1/).

RESULTS

We identified 10,687 unique records, of which 10,548 did not meet the inclusion criteria (Figure 1). Among the 139 full-text articles selected, 117 were excluded based on the inclusion criteria, 1 was excluded because it did not meet the 2 initial MMAT screening questions,[60] and another was excluded from the CCM analysis, owing to lack of information about the conditions (characteristics) of CM intervention in the documents.[61] Thus, 20 studies (18 CM interventions) were included in the synthesis. Table 1 presents a description of these studies. Seventeen were quantitative (7 before-after studies, 5 nonrandomized controlled trials, and 5 randomized controlled trials), 2 were qualitative, and 1 was a mixed methods study. Twelve were conducted in United States, 2 each in Sweden and Canada, and 1 each in Switzerland, Australia, New Zealand, and the United Kingdom. The studies included 17 to 12,181 participants, with a mean age range of 20 to 66 years. The proportion of men varied from 23% to 75%. All of the studies included development and implementation of a care plan, 15 involved an interdisciplinary team,[40-43,45-47,49-51,53,55-58] and 11 were conducted in an ED setting.[41,43,44,47,49-52,55,57,58]

Figure 1. Study selection process.



For the majority of studies (n = 17), CM intervention participants were identified using a threshold of number of health care visits.[40-44,46-50,52-57,59] To determine eligibility, 9 studies required patients be evaluated by a health care provider to assess their likelihood of benefiting from the CM intervention.[42,44,47-49,51,52,55,58] Ten studies included patients with a complex/vulnerable situation such as the presence of physical, psychiatric, and/or psychosocial issues.[40,42,43,45,46,48,51-54] The methodologic quality of the included studies ranged from 25% to 100% (median, 50%).

Fifteen studies reported positive outcomes such as health and functional status,[52] patient satisfaction,[40,52] self-management,[45,46,48] ED[42-45,47,49,51-55,58] and clinic visits,[40,44,45,52] hospital admission[42,44,45,53] and length of stay,[42,45,52] and ED[43,44,52-55,57,58] and inpatient cost.[43,44,45,52-54] Regarding the conditions, 16 studies implemented a high-intensity CM intervent

ion[40-46,48,49,51-54,56,57,59] including at least 3 of the following criteria: caseload of fewer than 60 patients, ≥50% of the time spent face-to-face with the patient, initial assessment in person, and multidisciplinary team meetings or frequent contact with the patient. Fifteen studies identified patients who could benefit the most from the CM[40,42-49,51-55,58] on the basis of their identification as frequent users (with no clear definition) with complex care needs or based on providers' assessment that the CM intervention would be beneficial. Finally, 17 studies included a multidisciplinary/interorganizational care plan[40-43,45-51,53,55-59] documenting patient needs and goals as well as the available resources to respond to patients' needs and including at least 2 health care providers from disciplines other than the family physician or case manager.

Table 2 shows 5 configurations for which the case-finding condition was always present when a positive outcome occurred. In addition, the CCM revealed that the multidisciplinary/interdisciplinary care plan and the CM intensity conditions were often present when a positive outcome occurred. These results remained the same when we removed the studies with low methodologic quality.[42,44,50,51] Supplemental Appendix 5 (http://www.AnnFamMed.org/content/17/5/448/suppl/DC1/) illustrates the relation between the conditions and the outcomes based on the results presented in Table 2.

The analysis revealed that the case-finding characteristic (ie, high frequency of health care visits) and complexity of health care needs are necessary to produce a positive outcome. Moreover, in our cases, positive outcomes were associated with the following 2 sufficient characteristics when each was combined with this necessary condition: high-intensity CM intervention and presence of a multidisciplinary/interorganizational care plan.

DISCUSSION

Our findings suggest that CM should be offered to patients such as those who are uninsured, have a low income, or who a health care provider deems in need and who frequently use health care services and have complex health care needs. Such appropriate case finding should be combined with a high-intensity intervention and/or the presence of a multidisciplinary/interorganizational care plan.

Previous research,[60,62-64] as well our prior thematic analysis review on key factors of CM interventions,[65] have recognized the importance of appropriate patient identification. Previous studies, however, have defined the appropriateness of patient identification on the basis of patients' risk of frequent health care use and associated cost to health care systems.[63,66,67] In addition to these criteria, our present results recommend a case-finding process based also on patient complex care needs (eg, combination of physical, psychiatric, and social conditions; poverty, polymedication, lack of social support, or clinical judgment).[68] A combination of quantitative (eg, prediction tools and thresholds) and qualitative (eg, clinical judgment) techniques might be the best approach to identify patients for whom CM interventions will likely be most beneficial.[64]

The association between high-intensity CM and its effectiveness has been examined in other populations. In a systematic mixed studies review exploring the relations between positive outcomes and barriers to CM implementation designed for patients with dementia and their caregivers in home care programs, high-intensity CM identified with CCM was shown to be a necessary and sufficient condition to produce positive clinical outcomes and to reduce health care use.[69] Similar to our present results, the importance of small caseload, regular follow-up, and multidisciplinary team meetings was highlighted.[69] In addition, reviews on the effect of CM in reducing hospital use,[70] and on the effectiveness of interventions in reducing ED use,[16] reported that regular in-person contacts with a case manager, a criterion for high-intensity CM, might contribute to positive patient outcomes. However, others[62] have reported equivocal

Table 2. Truth Table

Case-Management Intensity	Case Finding	Multidisciplinary/ Interdisciplinary Care Plan	Positive Outcome	No. of Cases	Cases
1	1	1	1	9	Adam et al,[40] Brown et al,[42] Crane et al,[43] Grimmer-Somers et al,[45] Grinberg et al,[46] Hudon et al,[48] McCarty et al,[49] Pope et al,[51] Roberts et al[53]
1	1	0	1	3	Edgren et al,[44] Reinius et al,[52] Shah et al[54]
0	1	1	1	3	Grover et al,[47] Skinner et al,[55] Stokes-Buzzelli et al[58]
1	0	1	0	4	Bodenmann et al,[41] Sledge et al,[56] Spillane et al,[57] Weerahandi et al,[59]
0	0	1	0	1	Peddie et al[50]

results regarding the effect of high-intensity CM for patients with complex care needs and highlighted that evidence from CM interventions remains unclear. This might explain why our present CCM analysis did not identify high-intensity CM intervention as a necessary condition to produce positive outcomes.

Multidisciplinary teams have been recognized as an important part of CM interventions,[18] providing the opportunity to learn from each other and offering holistic and comprehensive care for patients with complex care needs.[62-64,71,72] As the coordinator of the multidisciplinary team, the case manager must ensure that patients receive coordinated and integrated care processes that guarantee quality and cost effectiveness.[63] To this end, the development and implementation of a care plan is a strategy used by the case manager and best suited to align the goals of the different health care services.[63] Our present review suggests that a care plan provided by health care providers from different disciplines, combined with appropriate case finding, is a strategy that will more likely be effective and result in positive CM outcomes.

To our knowledge, this is the first systematic review aimed at identifying characteristics of CM interventions associated with positive outcomes. Whereas a meta-analysis of quantitative results would have led to an estimate of the magnitude of the effect of CM, it would not have revealed the characteristics that are necessary and sufficient to yield the effect size. The present review used an innovative method of data analysis, CCM, which allowed us to combine quantitative, qualitative, randomized, and uncontrolled study designs in a single analysis scheme to clarify how CM leads to positive outcomes. All steps of this systematic review were confirmed by at least 2 members of the team to ensure reproducibility of the results. In addition, the systematic review process lends credence to our results, as does our sensitivity analysis, which showed that the methodologic quality of the included studies did not affect the results.

Limitations

In the present review, all outcomes were considered equal and were not analyzed individually. Second, we considered all of the eligible CM intervention studies regardless of methodologic quality. The sensitivity analysis, however, indicated that the studies with low methodologic quality did not influence the results. Third, given that the majority of the studies were implemented at a single site, results might not be generalizable to multisite health care settings. Fourth, the present review did not address the knowledge gap concerning who should deliver CM or where. Fifth, even though frequent users are a primary target of case management research, the present review did not evaluate case management for individuals with complex health care needs who are not frequent users. Finally, the primary publications often did not include enough contextual information to make a broader consideration of context possible.

CONCLUSIONS

On the basis of our results, we recommend that policy makers and clinicians focus on their case-finding processes because these comprise the essential characteristic of effective CM. Moreover, value should be placed on high-intensity CM intervention (ie, small caseload, frequent face-to-face contact with the patient, initial assessment in person, and/or multidisciplinary team meetings) and developing care plans with multiple types of care providers to help improve patient outcomes. All policy makers and clinicians directly or indirectly involved in CM now or in the future should consider adapting their decisions or practices accordingly. Further research could address how different primary care settings (eg, ED vs clinic) influence CM outcomes.

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Mini-review

Barriers and facilitators to implementing shared decision-making in clinical practice: Update of a systematic review of health professionals' perceptions

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ABSTRACT

Objective: To update a systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice as perceived by health professionals.
Methods: From March to December 2006, PubMed, Embase, CINHAL, PsycINFO, and Dissertation Abstracts were searched. Studies were included if they reported on health professionals' perceived barriers and facilitators to implementing shared decision-making in practice. Quality of the included studies was assessed. Content analysis was performed with a pre-established taxonomy.
Results: Out of 1130 titles, 10 new eligible studies were identified for a total of 38 included studies compared to 28 in the previous version. The vast majority of participants ($n = 3231$) were physicians (89%). The three most often reported barriers were: time constraints (22/38) and lack of applicability due to patient characteristics (18/38) and the clinical situation (16/38). The three most often reported facilitators were: provider motivation (23/38) and positive impact on the clinical process (16/38) and patient outcomes (16/38).
Conclusion: This systematic review update confirms the results of the original review.
Practice implications: Interventions to foster implementation of shared decision-making in clinical practice will need to address a range of factors.

1. Introduction

With the increased emphasis on engagement of patients as partners in their care as evidenced by research priorities of national funding agencies [1] there is a rapidly growing body of new knowledge regarding new decision-making models. Consequently, shared decision-making, defined as a decision-making process jointly shared by patients and their health care providers, is attracting increased interest. Nonetheless, shared decision-making has not yet been widely adopted by health care professionals. This is why in 2004–2005, we sought to systematically review studies that reported on health professionals' perceived barriers and facilitators to implementing shared decision-making in their clinical practice [2].

Systematic reviews are "scientific tools which can be used to summarise, appraise, and communicate the results and implications of otherwise unmanageable quantities of research." It is of particular value in bringing together a number of separately conducted studies, sometimes with conflicting findings, and synthesizing their results [3]. Systematic reviews are deemed essential for identifying effective interventions but also for identifying important gaps in knowledge that need to be prioritized in future studies. However, systematic reviews are most useful if they are up to date. The updating process of systematic reviews is defined as "a discrete event aiming to search for and identify new evidence to incorporate into a previously completed systematic review [4,5]." Indeed, as science evolves with the accumulation of new research and publications, there may be reversal of the evidence concerning an intervention previously considered to be effective or new interventions proven to be effective. Ignoring these changes could undermine the validity of existing systematic reviews. For example, within 2 years of their publication, it is estimated that only 3% of systematic reviews published in peer-reviewed journals had been updated thus suggesting an important lack of rigour in the robustness of the existing knowledge [4]. Based on evidence, experts have recently pointed out that "The first step in assessing whether or not a given systematic review is up to date is to consider: (1) the age of the

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review, (2) the availability of new relevant trials, and (3) the number of participants in the new trials. The second step is to assess the importance of the topic by ascertaining the burden of disease and pace of development of the field [4,5]. Therefore, in line with these recommendations, this paper reports on the update of our systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice as perceived by health professionals [2].

2. Methods

2.1. Search strategy

Covering the period from March to December 2006, PubMed, Embase, CINHAL, PsycINFO, and Dissertation Abstracts were searched.

2.2. Selection criteria

A study was eligible for inclusion in the review if: (1) it reported on original collection of data and (2) participants included health professionals, including those in training programs who are responsible for patient care (residents, fellows, and other pre-licensure healthcare professionals) [6] and (3) results included perceived barriers and/or facilitators to shared decision-making. Shared decision-making was defined in an inclusive manner as a joint process between health professionals and patients for making health-related decisions [7], or as decision support interventions such as decision aids [8], or as the active participation of patients in decision-making. We did not restrict our search and inclusion of studies to those reporting as their main objective the assessment of barriers and facilitators to shared decision-making. Thus, we included studies that provided usable data for either of these two outcomes: barriers or facilitators to shared decision-making as perceived by health professionals. No study design was excluded, and only studies in French and English were assessed. When more than one publication described a single study and each presented the same data, we included only the most recent publication. However, when more than one publication described a single study but each presented new and complementary data, we included them all.

2.3. Study identification and data extraction

One individual (KG) screened all references. Two reviewers (KG and SR) extracted data independently using a data extraction sheet. At the time this review was conducted and to the best of our knowledge, there was no taxonomy for assessing barriers and facilitators to the implementation of shared decision-making in clinical practice. Therefore, a data extraction sheet was created by using a template analytic approach, beginning with a basic set of codes based on *a priori* theoretical understanding and expanding on these codes by readings of the text. The beginning set of *a priori* codes was based on a taxonomy of barriers and facilitators to implementing clinical practice guidelines in actual practice [9,10]. This taxonomy had been used successfully to study factors affecting general practitioners' decisions about plain radiography for back pain by Espeland and colleague (2003), who concluded that it compared well to other taxonomies [10]. Following previous work by one of the authors [11], we further enriched this taxonomy with some attributes of innovations (Table 1) [12]. Discrepancies between the reviewers were resolved through iterative discussions with FL. Themes were ordered according to the number of studies in which they were identified.

Study characteristics were abstracted and included: country of origin, year and language of publication, main objective of the study, use of a conceptual framework to assess barriers and/or facilitators to the implementation of shared decision-making in practice, design of study within which barriers and facilitators were elicited, characteristics of participants, response rate, and methodological approach, including data collection strategies. For the purpose of this review, a conceptual framework was defined as a set of concepts (words describing mental images of phenomena) and the propositions (statements about the concepts) that integrate the former into a meaningful configuration [13]. Therefore, we sought to determine in the eligible papers if the authors were referring to and/or citing a conceptual framework for assessing barriers and facilitators to implementing shared decision-making in clinical practice as perceived by heath professionals.

2.4. Quality assessment

Quality of the studies was assessed using Qualsyst validated tools [14,15] by two reviewers (KG and SR) independently. This framework was selected because its authors provide reviewers with an extensive manual for quality scoring of quantitative, qualitative and mixed methods studies. The manual also includes definitions and detailed instructions [14]. Discrepancies were resolved through iterative discussion with FL. As the review did not involve human subjects, ethical approval for the study was not sought.

3. Results

3.1. Included studies

Out of the new 1130 titles that were identified over the 9-month period we covered, 10 new eligible studies were identified for a total of 38 included studies compared to 28 in the previous version [2]. However, the following results include the aggregated findings from the previous review and this review. This means that overall, for all years available, from PubMed, Embase, CINHAL, PsycINFO and Dissertation Abstracts, we screened a total of 10,710 references (9580 + 1130) and assessed the full text of 294 (170 + 124) documents (Fig. 1). A total of 41 publications [11,16–55] relating to 38 unique studies met our inclusion criteria, among which were two unpublished doctoral dissertations [17,26]. Three publications presenting additional but distinct data were from the same randomized controlled trial [19–21], and two were from the same cross-sectional study [39,40]. Thus, we abstracted data from each one of them.

3.2. Study characteristics

The characteristics of included studies are shown in Table 2. Studies were published in English, except for one that was published in French [38]. Most studies originated in the United Kingdom ($n = 13$) [19–24,27,29,32–34,41,43,50,54], followed by the United States ($n = 11$) [16,17,25,26,28,30,36,39,40,51–53], Canada ($n = 6$) [11,18,31,37,47,48], Netherlands ($n = 2$) [35,44], France ($n = 1$) [38], Mexico ($n = 1$) [42], Australia ($n = 1$) [45], Norway ($n = 1$) [46], Germany ($n = 1$) [49] and China ($n = 1$) [55]. More than half of the publications were published in or after 2004 ($n = 26$) [18,20,21,27,34–55].

Five studies were explicit in their use of a conceptual framework pertaining to the assessment of barriers and/or facilitators to the implementation of best practices in clinical practice [26,37, 46–48]. Study designs within which barriers and facilitators were elicited included: cross-sectional ($n = 31$) [11,16–18,22–31,33–36,38–40,43–48,50,53–55], randomized controlled trial ($n = 6$) [19–21,32,37,49,51,52], and before-and-after ($n = 1$)

Table 1
Taxonomy of barriers and facilitators and their definitions

Knowledge	
Lack of awareness	Inability to correctly acknowledge the existence of shared decision-making (SDM) [9]
Lack of familiarity	Inability to correctly answer questions about SDM content, as well as self-reported lack of familiarity [9]
Forgetting	Inadvertently omitting to implement SDM [16]
Attitudes	
Lack of agreement with specific components of shared decision-making	
Interpretation of evidence	Not believing that specific elements of SDM are supported by scientific evidence [9]
Lack of applicability	
Characteristics of the patient	Lack of agreement with the applicability of SDM to practice population based on the characteristics of the patient [9]
Clinical situation	Lack of agreement with the applicability of SDM to practice population based on the clinical situation [9]
Asking patient about his/her preferred role in decision-making	Lack of agreement with a specific component of SDM such as asking patients about their preferred role in decision-making [9]
Asking patient about support or undue pressure	Lack of agreement with a specific component of SDM such as asking patients about support and/or undue pressure [9]
Asking about values/clarifying values	Lack of agreement with a specific component of SDM such as asking patients about values [9]
Not cost-beneficial	Perception that there will be increased costs if SDM is implemented [10]
Lack of confidence in the developers	Lack of confidence in the individuals who are responsible for developing or presenting SDM [9]
Lack of agreement in general	
"Too cookbook"—too rigid to be applicable	Lack of agreement with SDM because it is too artificial [9]
Challenge to autonomy	Lack of agreement with SDM because it is a threat to professional autonomy [9]
Biased synthesis	Perception that the authors were biased [9]
Not practical	Lack of agreement with SDM because it is unclear or impractical to follow [10]
Overall lack of agreement with using the model (not specified why)	Lack of agreement with SDM in general (unspecified) [9]
Lack of expectancy	
Patient's outcome	Perception that performance following the use of SDM will not lead to improved patient outcome [9]
Health care process	Perception that performance following the use of SDM will not lead to improved health care process [[10]
Feeling expectancy	Perception that performance following the use of SDM will provoke difficult feelings and/or does not take into account existing feelings [10]
Lack of self-efficacy	Belief that one cannot perform SDM [9]
Lack of motivation	Lack of motivation to use SDM or to change one's habits [9]
Behaviour	
External barriers	
Factors associated with patient	
Preferences of patients	Perceived inability to reconcile patient preferences with the use of SDM [9]
Factors associated with shared decision-making as an innovation	
Lack of triability	Perception that SDM cannot be experimented with on a limited basis [12]
Lack of compatibility	Perception that SDM is not consistent with one's own approach [12]
Complexity	Perception that SDM is difficult to understand and to put into use [12]
Lack of observability	Lack of visibility of the results of using SDM [12]
Not communicable	Perception that it is not possible to create and share information with one another in order to reach a mutual understanding of SDM [12]
Increased uncertainty	Perception that the use of SDM will increase uncertainty (for example, lack of predictability, of structure, of information) [12]
Not modifiable/way of doing it	Lack of flexibility to the extent that SDM is not changeable or modifiable by a user in the process of its adoption and implementation [12]
Factors associated with environmental factors	
Time pressure	Insufficient time to put SDM into practice [12]
Lack of resources	Insufficient materials or staff to put SDM into practice [10]
Organizational constraints	Insufficient support from the organization
Lack of access to services	Inadequate access to actual or alternative health care services to put SDM into practice [10]
Lack of reimbursement	Insufficient reimbursement for putting SDM into practice [10]
Perceived increase in malpractice liability	Risk of legal actions is increased if SDM is put into practice [10]
Sharing responsibility with patient[a]	Using SDM lowers the responsibility of the health professional because it is shared with patient

[a] Only for the facilitator assessment taxonomy.

[42]. Response rates were reported in 16 studies and varied from 42% to 97% [11,16–18,22,23,26,30–33,37,38,43,46,48,55].

Four studies did not report the number of participants [28,32,49,54]. In those that did, this number varied from 6 to 914. Overall, in studies that reported the number of participants, most of the participants were physicians (3231 out of a total of 3624) [11,16–27,29–31,33–36,38–48,50–53,55]. Most studies used qualitative methods exclusively ($n = 21$) [11,16,22–24,27–29,32–36,39–41,43–45,47,50,54]. Eleven used quantitative methods exclusively [17,18,25,30,31,38,46,49,51,52,55], and six used

Table 2
Characteristics of included studies

Study, publication year, country	Principal objective of the study	Method, study design, data collection	Response rate	Participants	Quality score
O'Connor et al. (1997) [31], Canada	To examine the variations in physicians' opinions about the appropriateness and content of patient decision aids for women with node-negative breast cancer, and the criteria for evaluating the effectiveness of such aids	Quantitative, Cross-sectional, Questionnaire	87%	144 oncologists	94%
Elwyn et al. (1999) [22] UK	To explore the view of general practice registrars about involving patients in decisions and to assess the feasibility of using the SDM model by means of simulated practice	Qualitative, Cross-sectional, Focus group	87%	39 general practice registrars	85%
Hammond et al. (1999) [25], USA	To explore the perceptions of health care providers regarding who is responsible for selected role functions in decision-making	Quantitative, Cross-sectional, Questionnaire	Not reported	5 administrators, 47 nurses, 11 physicians, 15 psychologists, social workers, 37 psychiatric technicians and 5 therapists	94%
Howell (1999) [26], USA	To ascertain primary care and specialty physicians' ideas about more informed, actively involved patients as partners in health and medical care decisions—and the impact they believe consumers/patients being more informed and taking a more active partnership role in health and medical care decisions will have	Mixed methods, Cross-sectional, (a) Questionnaire, (b) Interviews	(a) 42%, (b) Not reported	(a) 914 physicians (379 in primary care and 535 specialists), (b) 13 primary care physicians, 7 specialty physicians, and 1 clinical psychologist	97%
Elwyn et al. (2000) [23], UK	To explore and understand what constitutes the appropriate involvement of patients in decision-making within consultation, to consider previous theory in this field, and to propose a set of competences and steps that would enable generalists to undertake SDM in their clinical practice	Qualitative, Cross-sectional, Focus group	80%	6 general practitioners	85%
Holmes-Rovner et al. (2000) [16], USA	To determine the feasibility of SDM programmes in fee-for-service hospital systems, including physicians' office and in-patient facilities	Qualitative, Cross-sectional, Observation	97%	13 nurses, 7 social workers and administrators, and 14 physicians	75%
McKeown et al. (2002) [30], USA	To explore patients' and physicians' views of their roles in decision-making and to determine perspectives of residents and patients on the amount of control each should have in health care decisions	Quantitative, Cross-sectional, Questionnaire	63%	45 residents in 7 residency programs	100%
Keefe et al. (2002) [28], USA	To enhance medical student learning about common clinical preventive services and to teach students how to inform and involve patients in SDM about those services	Qualitative, Cross-sectional, Focus group	Not reported	Medical students	15%
Stapleton et al. (2002) [32], UK	To examine the use of evidence-based leaflets on informed choice in maternity services	Qualitative, Randomized controlled trial, Interviews, Observation	Not reported	Health professionals in 13 maternity units	65%
Graham et al. (2003) [11], Canada	To investigate physicians' perceptions of three patient decision aids and to identify factors perceived to encourage or discourage their possible uptake	Qualitative, Cross-sectional, Interviews	48%	20 family physicians, 12 gynaecologists, 16 respirologists and 19 medical specialists	80%
Araki (2003) [17], USA	To elicit physicians' opinions about the notion of a patient decision aid that could be used in SDM	Quantitative, Cross-sectional, Questionnaire	42%	248 endometriosis specialists and 112 generalists in gynaecology	100%
Ford et al. (2003) [24], UK	To identify the elements and skills required for a successful evidence-based patient choice consultation	Qualitative, Cross-sectional, Interviews	Not reported	11 general practitioners, 10 hospital consultants, 5 nurse practitioners, 11 academics, 8 lay people	75%
Lewis et al. (2003) [29], UK	To explore the views of clinicians and lay people about the minimum benefit needed to justify drug treatment to prevent heart attacks, and to explore the rationale behind treatment decisions	Qualitative, Cross-sectional, Interviews	Not reported	4 general practitioners, 4 practice nurses and 18 lay people	80%

Table 2 (*Continued*)

Study, publication year, country	Principal objective of the study	Method, study design, data collection	Response rate	Participants	Quality score
Stevenson et al. (2003) [33], UK	To explore the views of general practitioners of the practical application of SDM in their own and other participants' real life practice	Qualitative, Cross-sectional, Focus group	55%	11 general practitioners	60%
Davis et al. (2003) [19], Edwards et al. (2004) [20], (2005) [21], UK	To explore, from paired doctor–patient interviews, participants' perceptions of SDM in the consultation and the level of consensus between the participants in the consultation process and to identify the experiences and views of professionals skilled in SDM and risk communication, exploring the opportunities and challenges for implementation	Mixed methods, Randomized controlled trial, Questionnaire, Focus group, Interviews	Not reported	20 general practitioners	85%
Charles et al. (2004) [18], Canada	To explore the extent to which Ontario breast cancer specialists report practising SDM with their patients, their comfort level with this approach, and perceived barriers and facilitators to implementation	Quantitative, Cross-sectional, Questionnaire	Surgeons 72%, Oncologists 79%	232 surgeons and 102 oncologists	89%
Jones et al. (2004) [27], UK	To explore the way in which general practitioners in the UK manage the dual responsibilities of treating individual patients and making the most equitable use of National Health Service resources in the context of the policy of greater patient involvement in decision-making	Qualitative, Cross-sectional, Focus group, Interviews	Not reported	24 general practitioners	80%
Thistlewaite et al. (2004) [34], UK	To explore whether newly qualified doctors feel adequately trained to discuss management with patients, their attitudes towards the concept of sharing decisions about treatment with patients and their strategies for coping with managing patients	Qualitative, Cross-sectional, Interviews	Not reported	36 pre-registration house officers	80%
Wetzels et al. (2004) [35], Netherlands	To determine specific barriers to the involvement of older patients in general practice care and to identify variations between countries	Qualitative, Cross-sectional, Interviews	Not reported	233 general practitioners in 11 European countries	80%
Bajramovic 2004 [45], Australia	To explore beliefs and expectations of general practitioners, consumers and pharmacists in relation to concordance to allow further exploration of the implementation of principles of concordance in Australia	Qualitative, Cross-sectional, Focus group, Interviews	Not reported	9 pharmacists and 10 general practitioners	75%
McGuire et al. (2005) [36], USA	To identify and characterize physicians' attitudes toward patient participation in decision-making and to gain insight into how they consequently think about and structure the decision-making process	Qualitative, Cross-sectional, Interviews	Not reported	53 academic and private practice physicians from primary care and surgical specialties	70%
Stacey et al. (2005) [37], Canada	To elicit the barriers and facilitators influencing the provision of decision support by call center nurses for callers facing values-sensitive health decisions and to explore the magnitude of these barriers and facilitators as perceived by the nurses	Mixed methods, Randomized controlled trial, Questionnaires, Focus group, Interviews	52,8% (barriers questionnaire)	108 registered nurses	85%
Andre et al. (2005) [38], France	To describe how paediatric residents involve children during medical decision-making and evaluate the relationship between practice patterns and residents' characteristics	Quantitative, Cross-sectional, Questionnaire	75%	45 paediatric residents	94%
Kim et al. (2005) [42], Mexico	To report on a field test in Mexico that assessed the tool's effectiveness in changing the counselling and decision-making process, and collected feedback from providers and clients	Mixed methods, Before and after, Focus group, Interviews, Observation	Not reported	9 doctors, 2 nurses and 2 social workers	79%
Naik et al. (2005) [39], Schulman-Green et al. (2006) [40], USA	To examine experiences of older persons and their clinicians with shared decision-making and their willingness to use an SDM instrument	Qualitative, Cross-sectional, Focus group	Not reported	5 nurses and 6 physicians	70%

Thomson et al. (2006) [41], UK	To pilot test a decision aid for hypertension treatment based on decision analysis that incorporated guidance on the best options for patients, based on their personal preferences	Qualitative, Cross-sectional, Questionnaire	Not reported	2 consultant cardiologists, 2 general practitioners, 2 specialist nurses, 2 practice nurses	45%
Seale et al. (2006) [43], UK	To report the views of 21 general adult psychiatrists working in UK about their experiences of consultations involving discussion of antipsychotic medication	Qualitative, Cross-sectional, Interviews	66%	21 consultant psychiatrists	70%
Suurmond et al. (2006) [44], Netherlands	To describe several barriers to SDM in an intercultural context	Qualitative, Cross-sectional, Interviews	Not reported	18 physicians	60%
Ruland 2006 [46], Norway	To investigate the perceived usefulness of a support system designed to improve patient-centred symptom management for cancer patients at the point of care	Quantitative, Cross-sectional, Questionnaire	Nurses 79%, Physicians 72%, Total 78%	65 nurses + 12 physicians	100%
Towle et al. (2006) [47], Canada	To investigate the practice, experiences and views of motivated and trained physicians as they attempt to implement informed and SDM in routine practice and to identify and understand the barriers they encounter	Qualitative, Cross-sectional, Focus group, Observation	Not reported	6 family physicians	90%
Légaré et al. (2006) [48], Canada	To describe primary health care professionals' views on barriers and facilitators for implementing the Ottawa Decision Support Framework in their practice	Mixed methods, Cross-sectional, Focus group	75%	118 primary health care professionals (64 clinical teachers, 50 residents and 4 other health professionals)	100%
Hamann et al. (2006) [49], Germany	The study reported here aimed at assessing an intervention designed to facilitate SDM among acutely ill in-patients with schizophrenia	Quantitative, Randomized controlled trial, Questionnaires	Not reported	Nurses and psychiatrists	96%
Lester et al. (2006) [50], UK	To describe the views on, potential for, and types of patient involvement in primary care from the perspectives of primary care health professionals and patients with serious mental illness	Qualitative, Cross-sectional, Focus group	Not reported	39 GPs and 8 practice nurses	90%
Sullivan et al. (2006) [51] USA	To test the effects on physicians' self-reported attitudes and behaviour of a SDM training for opioid treatment of chronic pain	Quantitative, Randomized controlled trial, Questionnaire	Not reported	45 physicians	83%
Siminoff et al. (2006) [52], USA	This study was designed to examine the impact of a novel decision aid, Adjuvant! on treatment decisions made during consultations between oncologists and patients with breast cancer, and its implications for practice	Quantitative, Randomized controlled trial, Questionnaire	Not reported	58 oncologists	92%
Saba et al. (2006) [53], USA	Communication has been researched either as a set of behaviours or as a facet of the patient-physician relationship, often leading to conflicting results. To determine the relationship between these perspectives, we examined SDM and the subjective experience of partnership for patients and physicians in primary care	Mixed methods, Cross-sectional, Observation	Not reported	10 physicians	94%
Wirrmann et al. (2006) [54], UK	The objectives were to: (1) Identify what makes decisions difficult for urology patients, (2) Understand concepts of decision support and decision quality, (3) Understand the role of patient decision aids, (4) Demonstrate skills in decision support using a clinical decision support protocol, (5) Develop self-appraisal skills in evaluating decision support provided to patients	Qualitative, Cross-sectional, Interviews	Not reported	Health professionals (oncologists, urologists and nurses)	85%
Zhang at al. (2006) [55], China	To investigate the attitudes of Chinese doctors towards the difficulties they have concerning the involvement of patients in decision-making about treatment	Quantitative, Cross-sectional, Questionnaire	62%	488 doctors (70% internal medicine, 22% general surgery, 8% gynecology)	71%

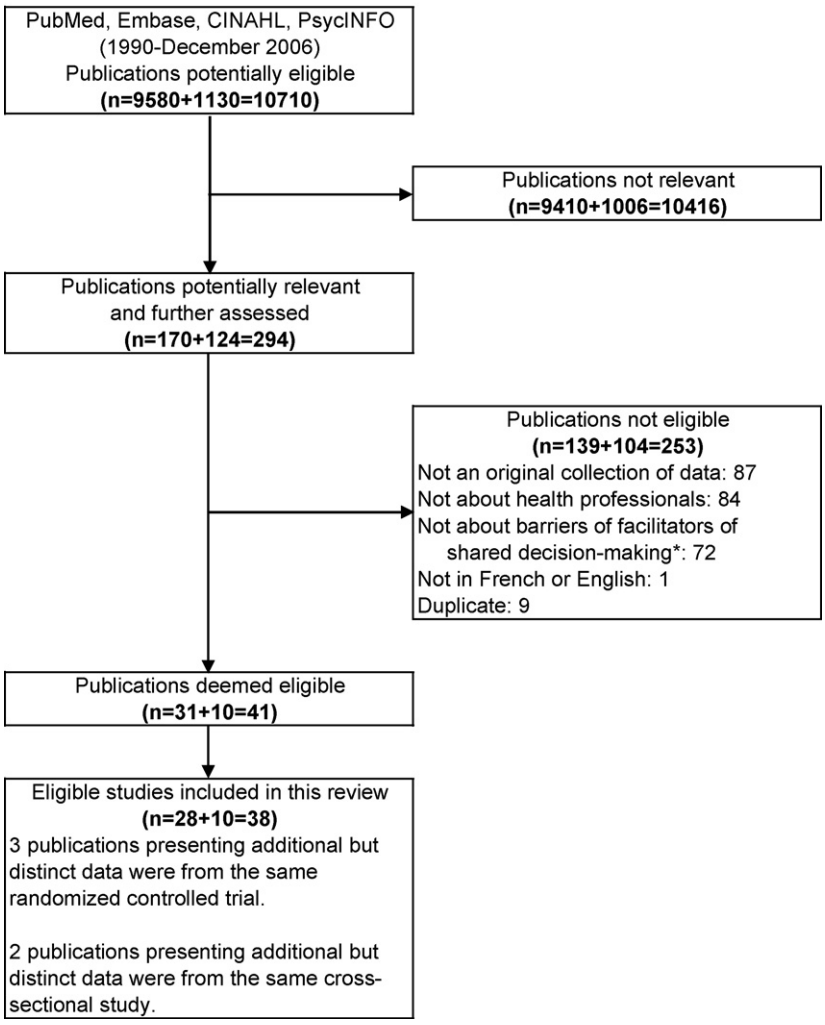

Fig. 1. Study flow diagram.

mixed methods [19–21,26,37,42,48,53]. Data collection strategies included individual interviews ($n = 16$) [11,19–21,24,26,27,29,32,34–37,42–45,54], questionnaires ($n = 15$) [17–21,25,26,30,31,37,38,41,46,49,51,52,55], focus groups ($n = 13$) [19–23,27,28,33,37,39,40,42,45,47,48,50], and observation ($n = 5$) [16,32,42,47,53].

3.3. Quality assessment of included studies

Except for two studies [28,41], most qualitative studies had an average score of 50% or more. It is interesting to note that only one qualitative study explicitly provided an account of reflexivity [48]. Overall, quantitative and mixed methods studies had an average score of 50% or more.

3.4. Barriers and facilitators

Seven studies focused solely on identifying barriers [25,29,33,38,44,45,50], while four focused solely on identifying facilitators [31,43,46,51]. Most focused on both barriers and facilitators ($n = 27$) [11,16–24,26–28,30,32,34–37,39–42,47–49,52–55]. Fig. 2 summarises the barriers and facilitators that were reported based on the number of studies in which they were identified. In order of frequency, the three most often identified barriers were: time pressure ($n = 24$) [11,16,18–24,26,27,32,33,35,36,38–42,45,47,48,50,53–55], lack of applicability due to patient characteristics ($n = 18$) [11,16,18–22,27,32–34,38–40,44,47–50,54,55] and lack of applicability due to the clinical situation ($n = 16$) [11,18–23,30,32–34,38–40,44,47,48,50,55].

In order of frequency, the three most often identified facilitators were: motivation of health professionals ($n = 22$) [16,17,19–21,23,24,26–28,32,34,36,37,39,40,42,43,46–48,51,53–55], the perception that shared decision-making will lead to a positive impact on patient outcomes ($n = 16$) [17,18,22,26,31,35–37,39–41,46–48,51,52,54] and the perception that shared decision-making will lead to a positive impact on the clinical process ($n = 15$) [11,16–21,26,30,35,36,39,40,42,46,48,51,54].

4. Discussion and conclusion

4.1. Discussion

Results of this updated systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice as perceived by health professionals are important because they inform researchers, educators and clinicians interested in shared decision-making on two key aspects: (1) how rapidly the knowledge base of this relatively new research field is growing and (2) what factors will need to be addressed for implementing shared decision-making in clinical practice effectively. More specifically, our results validate that there were enough new relevant studies over a period of 9 months (an increase of 40% in the number of eligible trials) and enough

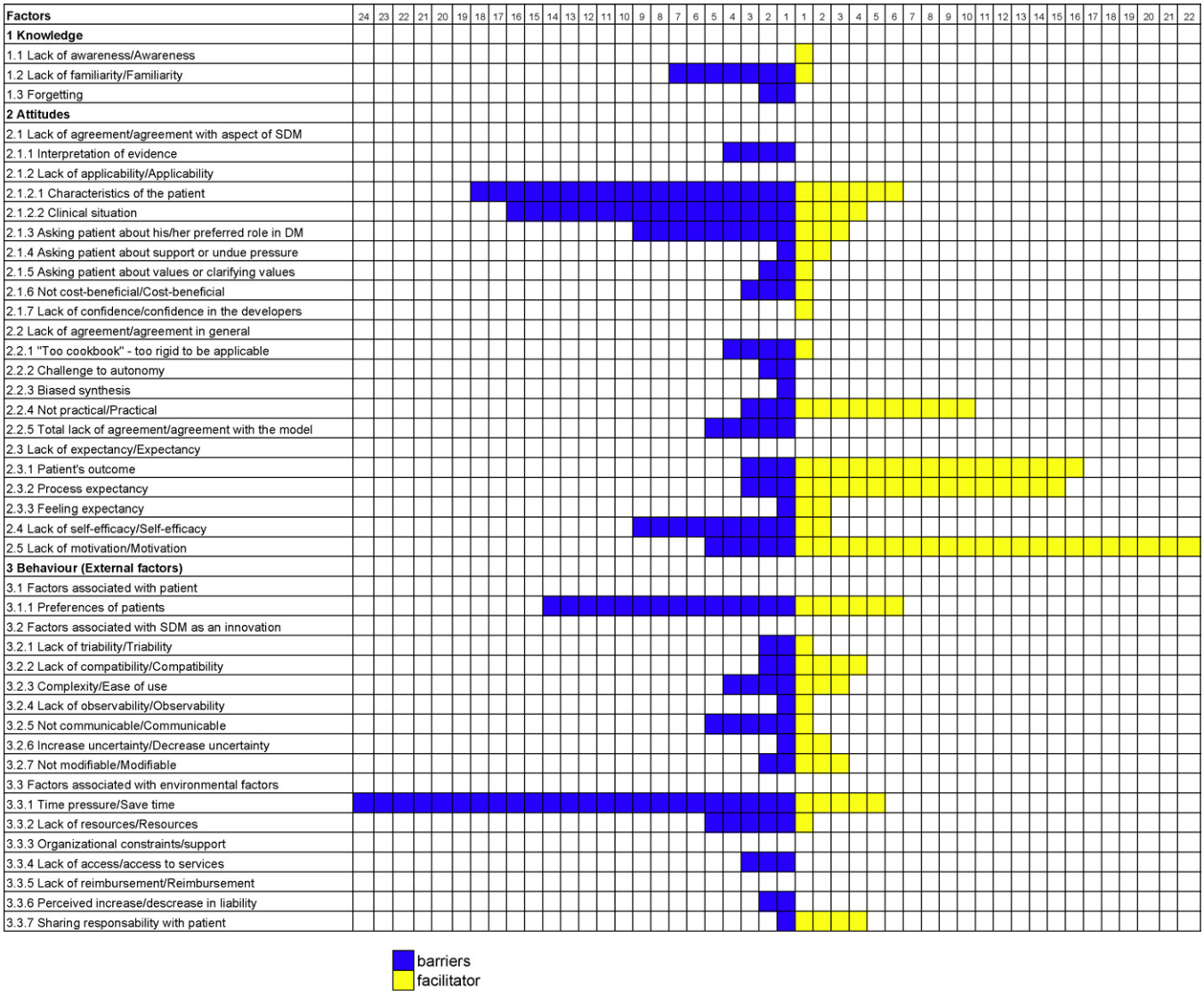

Fig. 2. Number of studies in which the perceived barriers and facilitators to implementation of shared decision-making in clinical practice have been identified.

participants in the new trials (an increase of 30%) to justify updating our systematic review. Moreover, at least three out of the 10 new studies originated from countries that had not been identified in the previous review: Norway, Germany and China. This is important because it provides evidence that shared decision-making as a topic of interest is gaining recognition in more diverse cultures and health care systems, including those of Asia. Also, this update provides evidence that the pace of development in the field of shared decision-making is quite rapid: 10 new eligible studies in less than 1 year. However, interestingly, the new eligible studies did not change the results of the previous systematic review thus suggesting saturation of the information provided by the existing sources of data [56]. A few reasons could explain why and are presented below.

Time constraints remain the most often cited barrier for implementing shared decision-making in clinical practice across many different cultural and organizational contexts. Although, there is no robust evidence that compared to usual care, more time is required to engage in shared decision-making in clinical practice, this universal perceived barrier seems unavoidable [57,58]. Indeed, there is a general consensus that the growing demands and expectations of informed health consumers and societies are putting a lot of pressure on limited resources, including human resources [59]. Therefore, it remains essential that future studies investigate whether engaging in shared decision-making actually takes more time or not than usual care.

Lack of agreement with the applicability of shared decision-making to the population in a practice, based on the characteristics of the patient, was the second most often cited barrier for implementing shared decision-making in practice [9]. Lack of agreement with the applicability of shared decision-making to the practice population, based on the clinical situation was the third most often cited barrier [9]. These results suggest that health professionals might be screening *a priori* which patients will prefer or benefit from shared decision-making. This is of some concern because physicians may misjudge patients' desire for active involvement in decision-making [60]. Therefore, as suggested in our previous review, future interventions will need to target the public and patients directly and not depend solely on health professionals' evaluation of the patient desire for active participation in decisions. In other words, patient-mediated interventions will need to be considered in order to foster the implementation of shared decision-making in clinical practice.

Again, we observed that the three most frequently reported facilitators to implementing shared decision-making in clinical practice remain the same and were: (1) motivation of health professionals, (2) their perception that putting shared decision-making into practice will lead to improved patient outcomes and (3) their perception that putting shared decision-making into practice will lead to improved health care processes. These results suggest that health professionals need to be able to perceive that the use of shared decision-making with their patients will have positive outcomes on the patients themselves or on the processes of care. Unfortunately, to the best of our knowledge, evidence of the impact of shared decision-making on health indicators is still lacking that could provide health professionals with more convincing arguments [61]. On the other hand, Hack et al. showed that in a group of 205 women who suffered from breast cancer, quality of life at the end of a 3-year follow-up was significantly related to reports of having experienced involvement in treatment decision-making, but not to reports of preferred involvement, or congruence between preferred and experienced involvement. In other words, notwithstanding what the preferred role in making decision was, women who had been active in making treatment decisions had a higher probability of better quality of life at the end of the 3-year follow-up [62].

Other interesting results from this update are as follows. Three English-speaking countries (UK, Canada and US) with a shared historical background still lead in the number of studies they contributed to. In 1 year, 2006, 14 studies were published; up from 6 in each of the following years: 2003, 2004 and 2005. This suggests that this field of research is expanding very rapidly. Nonetheless, there has been no sign that a more interprofessional approach to SMD has yet occurred, with close to 90% of all participants being physicians [63].

Notwithstanding its interesting results, the update of our systematic review has some limitations. First, although we searched systematically and thoroughly for articles on perceived barriers and/or facilitators of implementing shared decision-making in clinical practice by health professionals, this is still not a well-indexed field of research. Therefore, it is possible that some eligible studies were not included in this review. Second, we continued using our previously existing taxonomy to classify barriers and facilitators [9]. It is possible that the use of another taxonomy to content-analyse the data might have modified our results [10]. However, the taxonomy did allow us to categorize most of the material collected, giving us no reason to invalidate its use. Third, as in our initial review, we did not systematically contact the authors of the included studies to verify data interpretation.

4.2. Conclusion

In this update of a systematic review on the barriers and facilitators to implementing shared decision-making in clinical practice as perceived by health professionals, we showed that this field of research was growing exponentially. Nonetheless, gaps in knowledge remain for effective implementation of shared decision-making in clinical practice and would need to be prioritized in future studies.

4.3. Practice implications

Although the implementation of shared decision-making in clinical practice is a relatively recent phenomenon of interest [64], the update of our previous systematic review suggests that this field is expanding very rapidly. However, many gaps in knowledge remain, some more crucial than others. For example, the difference in time required to involve patients in decision-making compared to usual care needs to be the object of well-conducted future studies. For clinicians, one key message is to be careful not to assume, based on patients' sociodemographics or the type of clinical situation, that they are not fit for shared decision-making. Health professionals would gain by asking one simple question to their patients: what role do they want to play in making decisions about their health? However, the impact of shared decision-making on health professionals themselves remains unknown and requires more study.

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Contributors: FL conceived the study, supervised SR and KG, validated the methods, validated the article selection, analysed the results, and wrote the first draft of the paper. SR acted as the information specialist who updated the search strategies. SR and KG selected the articles, assessed the quality of the included studies, first-coded all included articles, helped in analysing the results, and reviewed the paper. IG validated the methods, helped refined the taxonomy of barriers and facilitators, helped in analysing the results, and participated actively throughout the writing of the paper. All approved the final version of the paper. FL is its guarantor.

Conflict of interest

All authors declare that they have no conflicting financial interests.

Two of the authors of this review, IG and FL, are the authors of two of the included studies.

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Are you SURE?

Assessing patient decisional conflict with a 4-item screening test

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ABSTRACT

OBJECTIVE To assess the reliability and validity of the 4-item SURE (Sure of myself; Understand information; Risk-benefit ratio; Encouragement) screening test for decisional conflict in patients.

DESIGN Cross-sectional study.

SETTING Four family medicine groups in Quebec and 1 rural academic medical centre in New Hampshire.

PARTICIPANTS One hundred twenty-three French-speaking pregnant women considering prenatal screening for Down syndrome and 1474 English-speaking patients referred to watch condition-specific video decision aids.

MAIN OUTCOME MEASURES Cronbach α was used to assess the reliability of SURE. A factorial analysis was performed to assess its unidimensionality. The Pearson correlation coefficient was computed between SURE and the Decisional Conflict Scale to assess concurrent validation. A *t* test procedure comparing the SURE scores of patients who had made decisions with the scores of those who had not was used to assess construct validation.

RESULTS Among the 123 French-speaking pregnant women, 105 (85%) scored 4 out of 4 (no decisional conflict); 10 (8%) scored 3 (≤3 indicates decisional conflict); 7 (6%) scored 2; and 1 (1%) scored 1. Among the 1474 English-speaking treatment-option patients, 981 (67%) scored 4 out of 4; 272 (18%) scored 3; 147 (10%) scored 2; 54 (4%) scored 1; and 20 (1%) scored 0. The reliability of SURE was moderate (Cronbach α of 0.54 in French-speaking pregnant women and 0.65 in treatment-option patients). In the group of pregnant women, 2 factors accounted for 72% of the variance. In the treatment-option group, 1 factor accounted for 49% of the variance. In the group of pregnant women, SURE correlated negatively with the Decisional Conflict Scale ($r = -0.46$; $P < .0001$); and in the group of treatment-option patients, it discriminated between those who had made a choice for a treatment and those who had not ($P < .0001$).

CONCLUSION The SURE screening test shows promise for screening for decisional conflict in both French- and English-speaking patients; however, future studies should assess its performance in a broader group of patients.

EDITOR'S KEY POINTS

- *Decisional conflict* refers to a patient's uncertainty about the course of action to take when the choices involve risk, loss, regret, or a challenge to personal life values.
- The 4-item SURE (Sure of myself; Understand information; Risk-benefit ratio; Encouragement) screening test was developed to help health professionals identify patients with clinically significant decisional conflict as quickly as possible.
- Results of this study indicate that the SURE screening test has acceptable psychometric properties and is suitable for screening for decisional conflict in patients facing clinical decisions in primary care. As such, the tool can improve how decisions are made in family medicine, benefiting patient outcomes as a result.

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Êtes-vous « SURE »?

Évaluer le conflit décisionnel chez les patients à l'aide d'un test de dépistage en 4 volets

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RÉSUMÉ

OBJECTIF Évaluer la fiabilité et la validité du test SURE servant à dépister le conflit décisionnel chez les patients (SURE est l'acronyme en anglais pour : sûr de soi; comprendre l'information; rapport risques-avantages; encouragement).

TYPE D'ÉTUDE Étude transversale.

CONTEXTE Quatre groupes de médecine familiale au Québec et un centre médical universitaire rural au New Hampshire.

PARTICIPANTS Groupe de 123 femmes enceintes francophones envisageant le dépistage du syndrome de Down et 1 474 patients anglophones référés pour visionner une vidéo sur l'aide à la décision liée à leur maladie.

PRINCIPAUX PARAMÈTRES ÉTUDIÉS On a utilisé le coefficient α de Cronbach pour évaluer la fiabilité de SURE. On a effectué une analyse factorielle pour mesurer son unidimensionnalité. On a calculé le coefficient de corrélation de Pearson entre SURE et l'Échelle du conflit décisionnel pour évaluer la validation concurrente. Pour évaluer la validation du construct, on a effectué un test t comparant les résultats SURE des patients qui avaient pris leur décision avec ceux des personnes qui ne l'avaient pas prise.

RÉSULTATS Parmi les 123 femmes enceintes francophones, 105 (85%) ont eu des résultats de 4 sur 4 (aucun conflit décisionnel); 10 (8%) ont eu un résultat de 3 (≤3 indique un conflit décisionnel); 7 (6%) ont eu 2; et 1 (1%) a eu un résultat de 1. Parmi les 1 474 patients anglophones du groupe envisageant les options de traitement, 981 (67%) ont eu des résultats de 4 sur 4; 272 (18%) ont eu 3; 147 (10%) ont eu 2; 54 (4%) ont eu 1; et 20 (1%) ont eu 0. La fiabilité de SURE était modérée (α de Cronbach de 0,54 chez les femmes enceintes francophones et de 0,65 chez les patients du groupe des options de traitement). Dans le groupe des femmes enceintes, une part de 72% de la variation était attribuable à 2 facteurs. Dans le groupe des options de traitement, 1 facteur expliquait 49% de la variation. Dans le groupe des femmes enceintes, il y avait une corrélation négative entre SURE et l'Échelle du conflit décisionnel (r = -0,46; P<,0001); dans le groupe des options de traitement, le test faisait une distinction entre ceux qui avaient fait un choix de traitement et ceux qui n'avaient pas décidé (P<,0001).

CONCLUSION Le test de dépistage SURE est prometteur pour évaluer le conflit décisionnel chez les patientes francophones et les patients anglophones; par contre, les études futures devraient mesurer son efficacité dans un groupe plus large de patients.

POINTS DE REPÈRE DU RÉDACTEUR

- Le conflit décisionnel désigne l'incertitude des patients entourant la marche à suivre quand leurs choix comportent des risques, une perte, un regret éventuel ou un conflit avec des valeurs de vie personnelles.
- Le test de dépistage en 4 volets SURE (sûr de soi; comprendre l'information; rapport risques-avantages; encouragement) a été conçu pour aider les professionnels de la santé à identifier aussitôt que possible les patients qui vivent un conflit décisionnel important sur le plan clinique.
- Les résultats de cette étude indiquent que les propriétés psychométriques du test de dépistage SURE sont acceptables et que ce test convient dans le dépistage du conflit décisionnel chez les patients aux prises avec des décisions cliniques en soins primaires. Comme tel, l'outil peut améliorer la façon dont les décisions sont prises en médecine familiale et, par conséquent, les résultats chez les patients.

Cet article a fait l'objet d'une révision par des pairs.
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Most primary health care decisions occur in contexts of uncertainty. Because the probability of risks and benefits in a population cannot be directly attributed at the individual level, uncertainty is inevitable when making decisions in family medicine. In a study of shared decision making in primary care, 54% of 924 patients who had made decisions with their doctors stated that they were uncertain about which option was best.[1] It is clear from this that both family physicians and their patients must manage uncertainty when making clinical decisions.[2]

Decisional conflict refers to an individual's perception of uncertainty about the course of action to take when the choices involve risk, loss, regret, or a challenge to personal life values.[3] In lay terms, it indicates an individual's level of comfort with a decision.[4] The Decisional Conflict Scale (DCS)[4] is a unique research-oriented tool that assesses decisional conflict in patients. Unlike the Physician Reaction to Uncertainty scale[5] and the Ambiguity Aversion Medical scale,[6] which were developed to assess the actors' predisposition to uncertainty (a trait), the DCS assesses individual perceptions of uncertainty about which course of action to take (a state). The DCS counts 16 items and has been translated and validated in Dutch,[7] French,[8] and Spanish.[9] The DCS scores correlate with scores for patient knowledge, treatment and screening intentions,[4] and decisional regret,[10] as well as the patient's blaming of his or her doctor for a negative outcome.[11] Physicians can use the DCS to reduce the downstream effects of unresolved decisional conflict by evaluating decisional conflict in their patients and providing appropriate support.[12] However, the time required to administer the DCS discourages its use.[13] For that reason, we sought to develop a tool that would help health professionals identify patients with clinically significant decisional conflict as quickly as possible. We accordingly developed the 4-item SURE (Sure of myself; Understand information; Risk-benefit ratio; Encouragement) screening test for decisional conflict in patients and used a 2-step process to assess its reliability and validity.

METHODS

Creating the 4-item SURE test

We based our selection of the 4 items on core concepts of the Ottawa Decision Support Framework, which are relevant at all stages of decision making: feeling uncertain, feeling informed, feeling clear about values, and feeling supported in decision making.[14] A fifth core concept (ie, the perceived effectiveness of the choice made) was not applicable to all stages of decision making. The wording of the French and the English questions was developed concurrently and framed in a positive manner to match the acronym SURE. The resulting 4-item test was field-tested with experts and graduate students taking clinical courses in decision support. **Table 1** shows the French and English versions of the 4-item SURE screening test.

Table 1. The SURE test: *A) English and B) French versions. A response of yes scores 1 and a response of no scores 0; a score of < 4 is a positive result for decisional conflict.*

A)	
SURE ACRONYM IN ENGLISH	ENGLISH VERSION OF TEST
Sure of myself	Do you feel SURE about the best choice for you?
Understand information	Do you know the benefits and risks of each option?
Risk-benefit ratio	Are you clear about which benefits and risks matter most to you?
Encouragement	Do you have enough support and advice to make a choice?
B)	
SURE ACRONYM IN FRENCH	FRENCH VERSION OF TEST
Sûr	Êtes-vous certain de ce qui constitue le meilleur choix pour vous?
Utilité de l'information	Est-ce que vous connaissez les bénéfices et risques de chacune des options?
Risques-bénéfices à balancer	Avez-vous le sentiment de savoir ce qui est le plus important pour vous à l'égard des risques et bénéfices?
Encouragement	Avez-vous suffisamment de soutien afin de faire votre choix?

Clinical setting, study participants, and data collection

Between April 2007 and December 2008, 2 distinct data-collection processes were performed in a stepwise approach, using convenience samples. The first group of consecutive patients consisted of French-speaking pregnant women who were considering prenatal screening for Down syndrome; they were recruited from 4 family medicine groups in Quebec city. Women were eligible if they were between the ages of 18 and 34 years, had no family history of genetic disorders, had not experienced pregnancies in which fetuses had suffered from genetic disorders, and were between 8 and 12 weeks pregnant. Women whose pregnancies were at risk were excluded. Patients were told that the study aimed at describing shared decision making in the context of prenatal screening. After their first routine prenatal

consultations, the women provided sociodemographic information and completed a self-administered 16-item DCS. Each item was measured on a 5-point Likert scale (1 = strongly agree and 5 = strongly disagree). The women also completed the self-administered 4-item SURE test (**Table 1**) with 2 response categories: yes (score = 1) and no (score = 0).

The second group consisted of consecutive English-speaking patients at a rural academic medical institution (ie, the Dartmouth Hitchcock Medical Center in New Hampshire) who were referred to watch condition-specific video decision aids as part of their standard process of care. The conditions addressed by the videos were chronic low back pain, spinal stenosis, herniated disk, hip osteoarthritis, knee osteoarthritis, prostate cancer treatments, early-stage breast cancer surgery, and breast reconstruction after cancer. The video for each condition provided information about treatment options, discussed the potential benefits and risks of each option, invited the viewer to consider the values he or she associated with each option, and reviewed the importance of patient involvement in decision making. After watching the video decision aids, study participants completed a self-administered questionnaire, which included the 4-item SURE questions. They did not complete the 16-item DCS.

Data processing and analysis

In both groups of patients, we performed descriptive data analyses and assessed the internal reliability of the SURE test by computing Cronbach α. The tetrachoric correlation coefficient was used to assess item-to-item correlations and the Pearson correlation coefficient was used to assess item-to-total correlations. Because decisional conflict is a state rather than a trait, it was not appropriate to assess intrarater reliability over time. Also, as the SURE test is a self-administered instrument, interrater reliability was similarly irrelevant. Factor analysis was performed using the principal components analysis method for factor extraction, with varimax orthogonal rotation. The number of factors retained was based on the minimum eigenvalue of 1 criterion.

In the group of French-speaking pregnant women, we computed the mean DCS score by adding the values for all items, dividing the sum by 16, and multiplying the product by 25. The DCS scores ranged from 0 (no decisional conflict) to 100 (high decisional conflict). Previous research shows that women whose scores exceed 37.5 experience clinically significant decisional conflict.[4] Totals of the SURE test were computed by adding the response scores of the 4 questions. We then assessed the criterion validity of the SURE test with the DCS by using a Pearson correlation coefficient—the hypothesis being that SURE scores would correlate negatively with DCS scores. (A perfect score on the SURE test indicates no decisional conflict; while a high score on the DCS indicates high decisional conflict.) In the group of treatment-option patients, treatment intentions were dichotomized (ie, those who made a choice about treatment versus those who were unsure about treatment), and SURE items were summarized as the frequency (percentage) of endorsed responses. Construct validity by extreme groups was assessed using a *t* test procedure—the hypothesis being that SURE would discriminate between patients who made choices of treatment and patients who did not. All calculations were performed using Statistical Analysis System version 9.1. Patients were not compensated financially. The study was approved by the institutional review boards of the institutions where data collection took place.

RESULTS

Participant characteristics

We approached 180 French-speaking pregnant women registered at family medicine clinics in Quebec and requested their participation. Of these women, 21 were ineligible and 11 declined to participate. Of the 148 women recruited (response rate of 82%), 141 completed the DCS and 123 completed the SURE test. **Table 2** summarizes participants' sociodemographic characteristics. Of the 141 participants who completed the DCS, 7 presented clinically significant decisional conflict. Of the 123 participants who completed the SURE test, 105 (85%) scored 4 out of 4, 10 (8%) scored 3, 7 (6%) scored 2, and 1 (1%) scored 1.

Table 2. Patient characteristics: *Mean (SD) age was 28.6 (3.51) years for French-speaking pregnant patients in Quebec and 59.3 (13.2) years for English-speaking patients facing treatment decisions in New Hampshire.*

CHARACTERISTIC	FRENCH-SPEAKING PATIENTS N = 123, N (%)	ENGLISH-SPEAKING PATIENTS N = 1474, N (%)
Female	123 (100)	765 (52)
Education*		
• University	62 (50)	671 (46)
• Some college education or a high school diploma	56 (46)	689 (47)
• Less than a high school diploma	5 (4)	96 (7)

*Education category for English-speaking patients does not add to 100 owing to missing data.

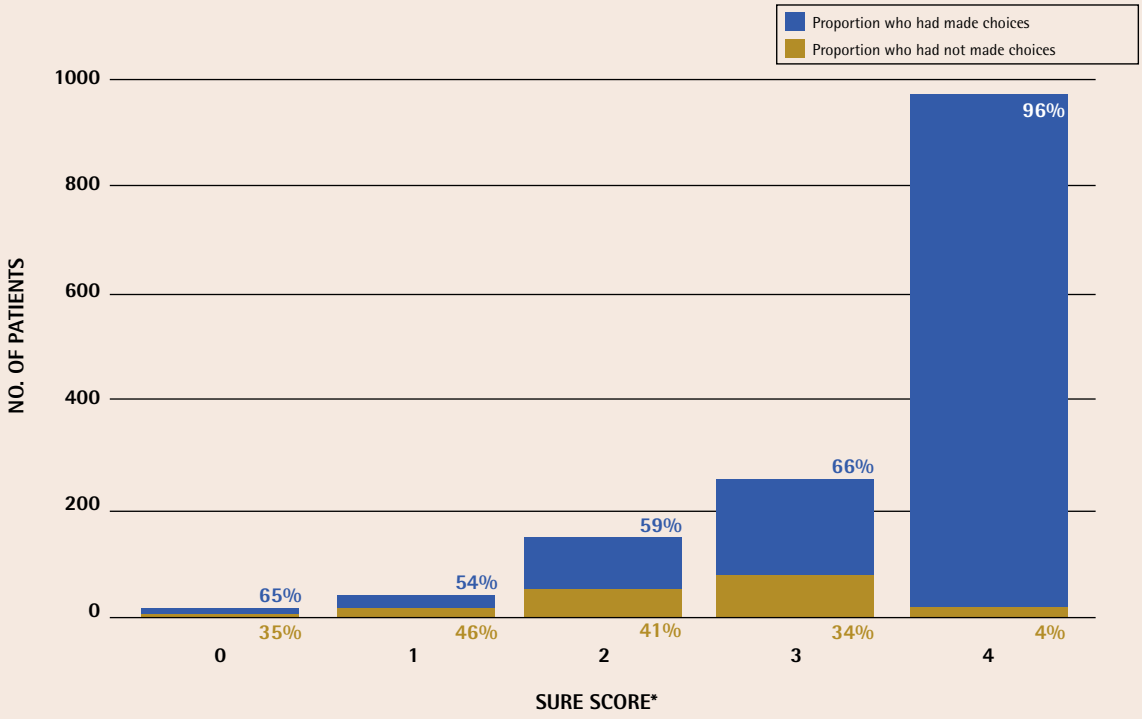
The English-speaking patients in the treatment-option group were systematically distributed video decision aids and SURE questionnaires. A total of 1474 patients (34%) completed and returned the questionnaire. Of these 1474 patients, 981 (67%) patients scored 4 out of 4; 272 (18%) scored 3; 147 (10%) scored 2; 54 (4%)

scored 1; and 20 (1%) scored 0 (**Figure 1**). **Table 3** summarizes patients' yes responses to the 4-item SURE questions.

Reliability of SURE

The internal reliability of SURE was moderate (Cronbach α was 0.54 in French-speaking pregnant women and 0.65 in English-speaking treatment-option patients). In the group of pregnant women, removing 1 item (ie, support) produced a higher value (Cronbach α=0.61). In the group of treatment-option patients, all item-to-item correlations were positive and ranged from 0.46 to 0.71. Item-to-total correlation results are presented in **Table 4**. In pregnant women, 1 item (ie, support) was negatively correlated with 2 items (ie, knowledge and values) and was poorly correlated with the total score. This item showed no variance in this group of respondents.

Figure 1. The SURE scores of patients in the treatment-option group (N=1474) and the proportion of them who had made and not made treatment choices



*A score of ≤3 indicates decisional conflict.

Table 3. Percentage of participants responding yes to each of the 4-item SURE questions, by condition

PATIENTS AND CONDITIONS	N	YES RESPONSES, %			
		SURE OF MYSELF	UNDERSTAND INFORMATION	RISK-BENEFIT RATIO	ENCOURAGEMENT
French-speaking pregnant women, N=123					
• Prenatal screening	123	87	98	94	98
English-speaking treatment-option patients, N=1474					
• Hip osteoarthritis	160	80	99	95	94
• Knee osteoarthritis	292	75	98	95	90
• Herniated disk	177	76	99	93	93
• Spinal stenosis	295	71	95	90	84
• Chronic back pain	171	75	89	89	80
• Prostate cancer	204	59	96	90	77
• Breast cancer reconstruction	86	74	97	93	86
• Early-stage breast cancer surgery	89	60	96	87	84

Table 4. Item-to-total Pearson correlation coefficient results for the 2 participant groups

PARTICIPANT GROUP	CORRELATION WITH TOTAL			
	SURE OF MYSELF	UNDERSTAND INFORMATION	RISK–BENEFIT RATIO	ENCOURAGEMENT
French-speaking pregnant women, N = 123	0.47	0.32	0.59	0.07
English-speaking treatment-option patients, N = 1474	0.46	0.33	0.45	0.49

Concurrent and construct validation

As expected, in the group of French-speaking pregnant women, the SURE score correlated negatively with the DCS score (r = -0.46; P < .0001). Also as expected, in the English-speaking treatment-option group, patients who had not made choices about treatment (n = 225) had lower mean (SD) SURE scores than those who had (n = 1249) (2.6 [1.0] vs 3.6 [0.8], respectively; P < .0001). More specifically, among the treatment-option patients who scored 4 on the SURE test, only 4% had not made treatment choices compared with 34% of patients who had scored 3, 41% of patients who had scored 2, 46% of patients who had scored 1, and 35% of patients who had scored 0 (**Figure 1**).

A factorial analysis of the SURE test in the group of pregnant women indicated that 2 factors accounted for 72% of the variance. Three items (ie, knowledge, value, and certainty) loaded under 1 factor. The other item (ie, support) loaded under the second factor. As expected, in the treatment-option group, 1 factor accounted for 49% of the variance.

DISCUSSION

Our findings suggest that the SURE test has acceptable psychometric properties and is suitable for screening for decisional conflict in French- and English-speaking patients facing clinical decisions in primary care. As such, the tool can improve how decisions are made in family medicine, benefiting patient outcomes as a result. We expect this phenomenon to occur in a 2-step process.

First, to the best of our knowledge, SURE is the only clinically oriented instrument that helps physicians identify patients experiencing clinically significant decisional conflict. In developing the 4-item test, our team drew inspiration from the 4-item CAGE questionnaire (Have you ever felt that you should *cut* down on your drinking? Have people *annoyed* you by criticizing your drinking? Have you ever felt bad or *guilty* about your drinking? Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover [*eye*-opener]?) used for screening for alcohol abuse in clinical practice.[15] The literature reports that CAGE's short format makes it more attractive to busy clinicians than the longer version and thereby increases its use.[16,17] It is not unlikely that the 4-item SURE test will act similarly, making clinicians more willing to seek to identify patients experiencing substantial decisional conflict.

Second, the downstream effects of unresolved clinically significant decisional conflict in patients[4,10,11] suggest that the use of SURE in clinical practice has the potential to improve patient outcomes. In the group of French-speaking pregnant women who had consulted with their family physicians, testing revealed that 7 (6%) of them were experiencing clinically significant decisional conflict regarding prenatal screening for Down syndrome. This relatively high incidence suggests real benefits to coupling the use of the SURE tool with a decision support system so that positive test results (a score of 3 or less) trigger physicians to help patients make decisions or refer patients to appropriate resources.

Limitations

Notwithstanding the interest of our findings, our study has several limitations. First, we reported on data collections that occurred independently. The drawbacks of this procedure are offset by the fact that it produced a larger sample size with more descriptive data and better evidence of the tool's acceptability (2 languages and 2 countries) than would otherwise be possible. It also allowed us to assess the tool's relevance in different clinical situations. Second, in the group of French-speaking pregnant women, we observed a less-than-optimal value of Cronbach α and could not confirm SURE's unidimensionality. This suggests that there might be a need to modify 1 item (ie, support). However, it is possible that the lack of variance in the SURE scores (most individuals had perfect scores) might have contributed to this observation, as the magnitude of a reliability coefficient is highly dependent on the homogeneity of subjects in a group. Thus, it is possible that we underestimated the true reliability of the SURE test. For this reason, it is important that future studies assess the performance of SURE in groups with a larger proportion of patients experiencing clinically significant decisional conflict.

Conclusion

Results from this study suggest that the SURE test is suitable for screening for decisional conflict in French- and English-speaking patients with a variety of health conditions. Future research should assess the performance of the SURE test with a more diverse group of patients.

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Contributors
All authors contributed to concept and design of the study; data gathering, analysis, and interpretation; and preparing the manuscript for submission.

Competing interests
None declared

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Validating a conceptual model for an inter-professional approach to shared decision making: a mixed methods study

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Keywords
conceptual model, decision coaching, inter-professionalism, primary care, shared decision making, validity

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Abstract

Rationale, aims and objectives Following increased interest in having inter-professional (IP) health care teams engage patients in decision making, we developed a conceptual model for an IP approach to shared decision making (SDM) in primary care. We assessed the validity of the model with stakeholders in Canada.

Methods In 15 individual interviews and 7 group interviews with 79 stakeholders, we asked them to: (1) propose changes to the IP-SDM model; (2) identify barriers and facilitators to the model's implementation in clinical practice; and (3) assess the model using a theory appraisal questionnaire. We performed a thematic analysis of the transcripts and a descriptive analysis of the questionnaires.

Results Stakeholders suggested placing the patient at its centre; extending the concept of family to include significant others; clarifying outcomes; highlighting the concept of time; merging the micro, meso and macro levels in one figure; and recognizing the influence of the environment and emotions. The most common barriers identified were time constraints, insufficient resources and an imbalance of power among health professionals. The most common facilitators were education and training in inter-professionalism and SDM, motivation to achieve an IP approach to SDM, and mutual knowledge and understanding of disciplinary roles. Most stakeholders considered that the concepts and relationships between the concepts were clear and rated the model as logical, testable, having clear schematic representation, and being relevant to inter-professional collaboration, SDM and primary care.

Conclusions Stakeholders validated the new IP-SDM model for primary care settings and proposed few modifications. Future research should assess if the model helps implement SDM in IP clinical practice.

Introduction

Given today's drive to integrate health care services, foster patient-centred care and engage patients as partners in their own care, finding effective ways to involve patients in decision making has become crucial [1]. According to the literature, shared decision making (SDM) is an approach whereby practitioners and patients communicate around decisions, referring to the best available evidence and deliberating upon the consequences of each option [2–4]. In the process, patients' autonomy is respected, patients are helped to establish their values and preferences, and final treatment decisions are reflected through agreement between patients and their practitioner(s) rather than a unilateral decision.

In most Western health care systems, care is increasingly planned and delivered by inter-professional (IP) teams [5–7]. Inter-professionalism refers to the process in which professionals from different disciplines collaborate in an integrated approach to patient care [5,6]. Key elements of IP collaboration include: the engagement of two or more health professionals from different disciplines, a common goal, collaborative relationships, integrated and cohesive care, symmetrical power, shared knowledge, interactions over time, an understanding of each professionals' role, interdependence among professionals, and a supportive organizational environment [5,8].

Given that most primary care decisions are made by the patient and more than one health care professional, SDM models should acknowledge the involvement of multiple players including IP teams [9]. However, most SDM conceptual models are limited to the clinical encounter between a patient and a single doctor [10]. Nonetheless, an IP approach to SDM has the potential to help primary health care teams collaborate in involving patients in decision making and help improve the quality of decisions by fostering integrated health care services and continuous care across health sectors [11]. More use of SDM could increase the quality of care, reduce variations in practice, and close the gap between the care that patients need and want and the care that they actually receive [12].

A conceptual model is an important element of the research process [13]. An IP-SDM conceptual model has the potential to broaden the perspective of SDM researchers beyond the patient–doctor dyad to include an IP approach. The model could also assist researchers interested in IP to focus on the essential elements that patients need as they move through the decision-making process within specific clinical pathways [14,15]. Finally, an IP-SDM model might help health care teams set clear goals for their patients and contribute to the design of medical and health sciences education curricula. Consequently, our team drew on a detailed theory analysis of SDM models [10] and conducted a stepwise consensus-building exercise to develop a new IP-SDM model that health care teams can use to achieve SDM [16].

Briefly, this new IP-SDM model addresses the three levels of health care systems. The model captures the influence of factors at the micro level (individuals), as well as the influence of systemic factors at both the meso level (health care teams within organizations) and the macro level (broader policies and social contexts). At the individual level, the patient presents a health problem that requires a decision. The patient then moves through a structured process to make an informed, preference-sensitive decision while interacting with one or more health care professionals and family members. The model acknowledges the contribution of each person's role and recognizes two particular roles that can be shared among health care professionals on the team: the role of decision coach (a person who supports the patient's involvement in decision making) and the role of first contact person (a person who identifies the health problem and the decision that must be made). Following our development of the model and consistent with our research protocol [17], the present study aimed to explore the validity of the model in the context of primary care.

Methods

Participants

Using a snowball strategy [18], we selected participants from the following categories: (1) stakeholders from Canadian organizations that represented health professionals, medical education and the health care policy environment; (2) patients that represented a health consumers' perspective; and (3) clinicians from primary health care teams who were either familiar or unfamiliar with the concepts of inter-professionalism and/or SDM. Using our personal networks and networks of colleagues not directly involved in our project, we intentionally targeted participants from each of these three categories in two Canadian provinces: Québec and Ontario. All participants completed a consent form. There was no financial compensation.

Data collection

To help participants better understand the proposed IP-SDM model, we produced a short video illustrating an IP-SDM approach. The video depicts a pregnant woman, her husband and an IP team (a doctor and a nurse) making a decision regarding prenatal screening for Down syndrome. The video is based on a scenario that the research team developed from audiotaped consultations of family doctors and pregnant women [19].

Table 1 briefly describes the storyline.

A member of the research team conducted the interviews (individual or group). All group interviews with health care teams took place at their clinic. Individual interviews were either conducted face-to-face or by telephone. We developed a semi-structured interview guide, which was used for both the individual and group interviews. The interviewer began by describing the IP-SDM model and explaining its core concepts and the relational statements linking the concepts. Next, the interviewer presented the video to the participants. The interviewer then asked a series of open-ended questions and asked informants to: (1) suggest changes to the model that could make the model clearer and/or easier to implement; (2) identify barriers and facilitators to the implementation of an inter-professional approach to SDM in clinical practice; and (3) appraise the model using nine criteria that were based on elements known to be important to developing a theory [20,21]. Each criterion was rated on a 7-point Likert scale ranging from strongly disagree (1) to strongly agree (7), with neutral in the middle. Participants also provided basic sociodemographic information about themselves. All interviews (individual and group) were audiotaped and transcribed verbatim.

Table 1 The video vignette: a clinical example of the IP-SDM model at the individual level

Step 1. 'The patient and the health condition' or 'Equipoise'. A pregnant woman accompanied by her husband meets her family doctor for her first prenatal visit. The family doctor indicates that she will need to decide whether or not to have prenatal screening for Down syndrome.
Step 2. 'Exchange of information' about the options. The nurse provides the pregnant woman with written information on prenatal screening. The health care team of the clinic is aware of this information.
A few weeks later, the pregnant woman and her husband meet the nurse again. The nurse assesses their understanding of the information they were given, corrects any misperceptions and answers their questions. The nurse involves both the woman and her husband in this exchange.
Step 3. 'Values clarification'. The nurse assesses the values of the woman and her husband regarding prenatal screening for Down syndrome by asking them which outcomes are the most important to them.
Step 4. 'Feasibility of the options'. The nurse reviews the feasibility of the options with the couple in light of accessibility and costs.
The nurse informs the family doctor of the woman and her husband's understanding of the information and describes what matters most to each of them. She also confirms that the options that the couple is considering are feasible. The nurse states that the husband has different values from his wife but that both understand each other's point of view and agree to proceed with prenatal screening for Down syndrome using the blood test.
Step 5 'Preferred/actual choice'. The pregnant woman and her husband meet the family doctor for a second time and convey their decision that the woman will undergo prenatal screening test for Down syndrome.
Step 6 'Implementation'. The family doctor completes the requisition for blood work and tells the couple when to expect the results.

IP-SDM, inter-professional shared decision making.

Data analysis

For the qualitative data, two research assistants performed thematic data analysis using NVivo Version 8 to collect, organize and analyse the data. When analysing the data, the research assistants were guided by a coding framework based on known barriers and facilitators to the implementation of SDM [22] and on concepts that the literature associated with IP collaboration [5,7,8]. As well, inductive thematic analysis was used if the data suggested a new theme to be added. Reviewers independently coded two interviews using this coding framework and compared their results. After reaching consensus on coding using the framework, they divided the remaining transcripts for analysis. Results were summarized for each level of the health care system (the micro, meso and macro levels). The principal investigators reviewed and validated the results. For quantitative data, the research team performed simple descriptive statistical analyses using the Statistical Analysis System (SAS Institute, Cary, NC, USA), Version 9.1.3.

Team consensus on a revised IP-SDM model

All team members were sent a summary of participants' suggested changes to the initial IP-SDM model. Team members either forwarded their feedback or teleconferenced to discuss the changes and reach consensus on changes required. Finally, a graphic artist helped design the revised model (Fig. 1).

Results

Participants

The individual interviews and group interviews were conducted from January to April 2009. Seventy-nine health care professionals and other stakeholders were approached and participated in either an individual interview ($n = 15$) or group interview ($n = 7$). Most group interviews were composed of a diverse set of health care professionals working as a team. Table 2 describes the characteristics of the participants, who represented all levels of the health care system: the micro level ($n = 63$), the meso level ($n = 6$) and the macro level ($n = 10$). The median duration was 83 minutes (SD = 18.7 minutes) for individual interviews and 65 minutes (SD = 12.4 minutes) for group interviews.

Of 79 participants, 38 (48%) saw the video. The rest could not watch the video because of technical limitations (a screen was not available, interview time was too short). All participants were given a detailed description of the IP-SDM model that has been developed previously by the team.

Participants' proposals of changes to the model with the research team's response

Participants' suggested changes to the IP-SDM model and the research team decisions to incorporate them are summarized in Table 3. The main changes were to place the patient at the centre of the model, enlarge the concept of family to include significant others, clarify what was meant by outcomes, make the concept of time more explicit, merge the three levels of health care (micro, meso and macro), and explain how two new items influenced the SDM process: emotions and the physical environment. The next paragraphs describe the revised model with attention to the rationale for making the changes.

The environment

'Environment' refers to the global context in which IP-SDM takes place. To illustrate that an IP approach to SDM within clinical encounters is not free of the influence of environmental factors, the top of the revised model (Fig. 1) lists the two interpenetrated categories of meso and macro-level factors: social norms, organizational routines and institutional structure. Social norms include cultural values, routines and policies within society, the health care team, and the patient-family team, all of which influence the decision-making process. In health care organizations, organizational routines are activities that exhibit four characteristics: memory, adaptation, values and rules [23]. Institutional standards are defined as state-level policies that constrain organizations and individuals, including elected officials, government agencies, the public administration, the legislature and the legal system. Neo-institutionalism holds that institutional standards are public supra-organizational, and exist legally for the social good. Examples of institutional standards that impact health decision making are federal, provincial and municipal government rules

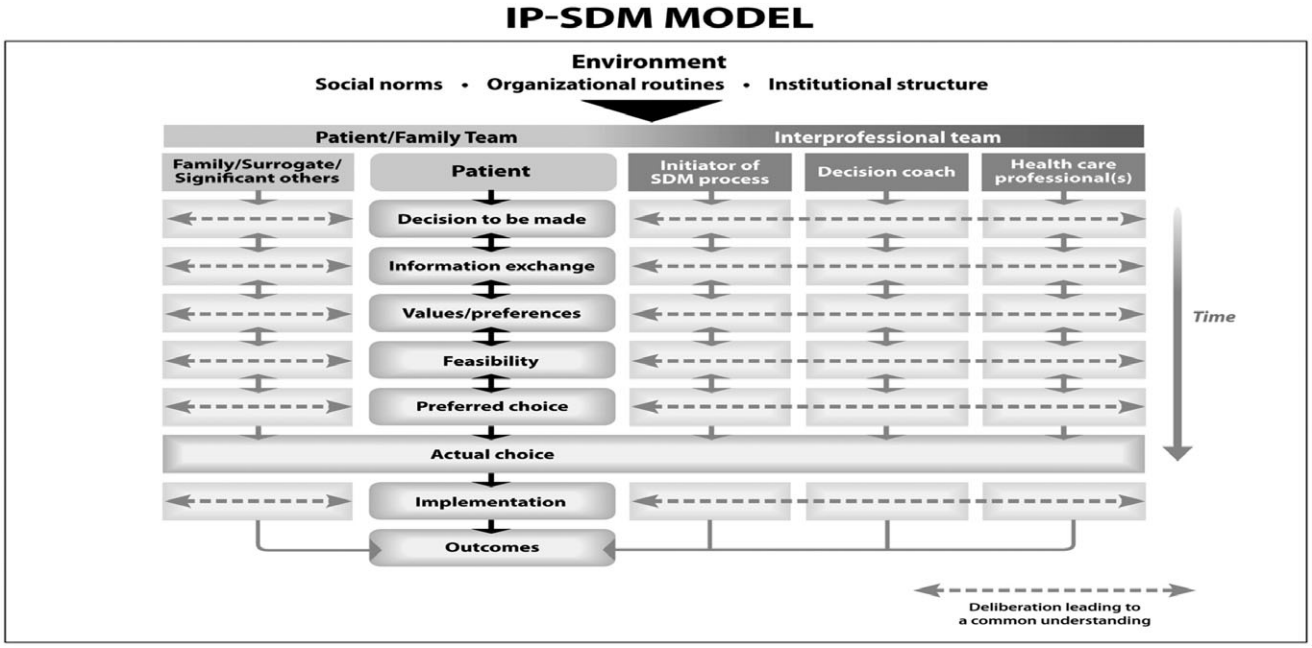

Figure 1 Inter-professional shared decision-making model. IP-SDM, inter-professional shared decision making.

Table 2 Participants' characteristics and interview modalities

Characteristic	Micro	Meso	Macro	Total
Gender: *n* (%)				
Female	49 (78)	4 (67)	9 (90)	62 (79)
Male	14 (22)	2 (33)	1 (10)	17 (21)
Age: *n* (%)				
Under 30 years	9			9 (11)
30 to 39 years	19			19 (24)
40 to 49 years	14	3	1	18 (23)
50 to 59 years	10	3	7	20 (25)
60 years and older	4		1	5 (6)
Missing data	7		1	8 (10)
Profession: *n* (%)				
Doctor	27			27 (34)
Resident	6			6 (8)
Nurse	8			8 (10)
Clinical nurse	1			1 (1)
Social worker	3			3 (4)
Occupational therapist	1			1 (1)
Pharmacist	1			1 (1)
Audiologist	1			1 (1)
Speech therapist	1			1 (1)
Manager	3	6	10	19 (25)
Patient representative	3			3 (4)
Missing data	8			8 (10)
Interview modality: *n*				
Individual interview	3	6	6	15
Group interview	6	0	1	7

and policies that constrain resources or legislate requirements for consent; accreditation standards; and practice guidelines set by professional bodies.

Actors and their roles

Figure 1 depicts the patient as central to the decision-making process. The initiator of the SDM process plays another central role. The role of initiator can be played by any health care professional – doctor, nurse practitioner, pharmacist – who identifies the health problem and makes explicit the decision to be made. A third key role is the decision coach, who is trained to support the patient's involvement in decision making. The last column of the Fig. 1 refers to health care providers. For the SDM process to be IP, at least two health care providers from different professions must collaborate with the patient either concurrently or sequentially. Finally, the family category (the first column) includes relatives, surrogates and/or other people who are important to the patient and can influence the decision-making process. The family member can support the patient and/or add pressure and make the process more difficult. A surrogate decision maker participates in decision making on behalf of the patient in situations where the patient cannot be involved (for example, if the patient has severe mental illness or is unconscious).

Steps in the SDM process

The SDM process begins with the 'Decision to be made': the initiator of the SDM process makes explicit that a choice needs to be made and identifies more than one option. We had initially labelled this stage 'Equipoise,' which Elwyn *et al*. define as a situation in which more than one option exists (including the option of status quo) and in which the pros and cons of each option

Table 3 Participants' proposed changes to the IP-SDM model and the responses of the research team

Category	Proposed change	Level			Research team's response
		Micro	Macro	Meso	
Actor/role					
Patient	Make the patient's presence clearer and more central; make explicit that the patient is a decision maker	X	X	X	Patient moved to central position
	Change 'patient' to 'client,' 'consumer' or 'person with a health condition'	X	X	X	Retained the term 'patient'
First contact person	Specify that this role can be played by any health professional involved		X		Added
Decision coach	Make the coaching aspect explicit		X		Added
Family member(s)	Make the concept more inclusive (e.g. include significant others, the patient's social support network, the patient's social network)	X		X	Changed
Health professional(s)	Include non-regulated health care providers: change 'health care professionals' to 'health care providers' and divide into regulated and non-regulated providers		X		Retained the definition of 'professional' selected for the study
SDM process					
Decision point situation	'Equipoise' is a confusing concept: force the term, change to another concept that is easier to understand, keep 'decision point' only or use 'portrayal of options'	X	X	X	Kept 'decision to be made' only
Implementation	Make the box bigger to show that this step takes more time than other steps		X		Made box size consistent throughout the model
Health outcomes	Clarify the type of outcome (patient health outcome versus an outcome related to the IP process). For example, remove the term 'health' and add information about what the model means by 'outcomes'		X		Kept 'outcomes' only and expanded description
General modifications	Avoid verbs in labelling the steps. Choose names that are more inclusive and explain names when describing the model		X		Verbs were removed
	Highlight the notion of time to represent the fact that time affects all levels		X		Concept of time was expanded
Meso/macro level					
General modifications	Add the meso/macro level as a background to the micro level Add the environment to the micro level		X		The three levels were merged
Environment	Add 'health professional regulators' to the environment		X		Not applicable after merging the two figures
	Add the patient and family to the section 'IP team members'	X			Patient/Family Team added at the same level as inter-professional team
	Represent collaboration between the patient and his/her family or relatives	X			Patient and family moved side-by-side
Additional items	Discuss the relevance of adding the concept of 'outcomes' in the meso/macro section			X	Not applicable after merging the two figures
IP team	Mention that the elements are examples and that the list is not exhaustive		X		In accompanying document, mention that 'health care professionals' is an inclusive term
Figures					
Pyramid	Use bubbles (concentric circles) instead of a pyramid			X	Not applicable after merging the two figures
Arrows	Add feedback loops to represent that IP SDM is not a linear process; discuss the iterative process. State that decisions can be revisited if the results of the first decision fail to meet expectations	X	X	X	Add arrows that represent the iterative process and feedback loop
	Add an arrow or a circle to represent interactions between the health professionals involved in the SDM process Add arrows to represent deliberation between silos	X	X		Added a dotted line between steps of the SDM process

Table 3 *Continued*

Category	Proposed change	Level			Research team's response
		Micro	Macro	Meso	
Squares	Represent the steps as circles instead of squares to express the overlap/iterative nature of the process		X		Too difficult to represent graphically
Diamond shapes	Enlarge the diamond shape in the background to clarify that all elements of the model have equal importance		X		Not applicable after merging the two figures
Missing elements	Add the physical environment (e.g. the availability of meeting rooms, access to technology)		X		Included in the description of institutional structure
	Add the box 'Follow-up and revisiting or readjusting if needed' between 'Implementation' and 'Health outcomes' or after 'Health outcomes'	X			Judged unnecessary
	Include a new box to represent affective and emotional aspects, the unconscious dimension of decision making that SDM should take into account	X			Added to the description of Information exchange

IP-SDM, inter-professional shared decision making.

must be weighed [24]. We changed the name of this stage to 'Decision to be made' after participants found the term 'equipoise' too confusing.

The next step in the process is to exchange information about the options ('Information exchange'). The health professional(s) and the patient share information about potential harms and benefits, including evidence-based information such as educational material and patient decision aids. We expanded this step to include information on the affective and emotional aspects of the decision after participants expressed the opinion that the affective and emotional aspects of the decision-making process may not be explicitly stated but are important to consider.

Participants did not suggest changes regarding the clarification of values and preferences, the feasibility of the options, the preferred choice or the actual choice. They agreed that it was important to acknowledge not only the patient's values and preferences but also to acknowledge the impact of values and preferences of others involved in the decision-making process, including family, surrogates, decision coach, initiator and other health care professionals. They suggested that we modify 'health outcomes' for 'outcomes' to be more inclusive of other outcomes, which may impact decision making.

Interactions between steps in the process and individuals

The iterative nature of the IP-SDM process is represented by the two-way arrows between the steps of the process. These arrows also express the possibility for patients to revisit a decision. Revisiting decisions was considered more likely to occur when an initial choice does not produce the desired health outcome or when chronic conditions are involved (e.g. depression or hot flashes).

Barriers and facilitators to implementing the IP-SDM model in clinical practice

Table 4 summarizes participants' perceptions of barriers and facilitators to implementing IP-SDM in clinical practice. The three most often reported barriers were time constraints, insufficient resources and an imbalance of power among health professionals. The three most often reported facilitators were education and training in IP and SDM, motivation to achieve an IP approach to SDM, and a mutual knowledge and understanding of the disciplinary roles (the practices, expertise, responsibilities, skills and values). Some barriers and facilitators reported by participants were specific to an IP approach. The barriers most frequently reported were an imbalance of power between health professionals, practicing in silos, and disagreeing about roles and responsibilities. The most frequently reported facilitators in the context of an IP approach to SDM were mutual knowledge and understanding of disciplinary roles, trust and respect.

The three most common organizational barriers were organizational routines, the costs of implementation and the organization's lack of responsiveness to the IP-SDM model. The three most often reported organizational facilitators were the organization's responsiveness to the model, support by the organization and pre-existing organizational routines consistent with IP and/or SDM.

Participants' critical appraisal of the model

Most participants agreed or strongly agreed that the IP-SDM model was logical (73.4%), testable (62.0%), and relevant to SDM (83.5%), inter-professionalism (77.2%) and primary care (59.5%). More than half also agreed or strongly agreed that the schematic representation of the model was clear (55.7%). Fewer participants agreed or strongly agreed that the concepts were clear (50.6%), that the relationships between the concepts were clear (46.8%), and that they would be willing to test the model in a clinical setting (40.5%). Results did not vary significantly by the level of the health care system (micro, meso, macro) that participants represented ($P > 0.05$) or by participants' gender ($P > 0.05$). Also, there were no significant differences associated with the interviewers ($n = 3$) who led the interviews (individual and group) ($P > 0.05$). Based on results from the theory appraisal, in particular participants' feedback that the graphical presentation of the model was complicated and difficult to

Table 4 Frequency of participants' mention of barriers and facilitators to IP-SPM

Factors	Number of interviews (individual or group) in which the factor was mentioned as a barrier ($n = 15$)	Number of interviews (individual or group) in which the factor was mentioned as a facilitator ($n = 15$)
1. Knowledge		
1.1 Unaware/aware of IP-SDM	3	
1.2 Familiar/unfamiliar with IP-SDM	2	
1.3 Lack of education and training/education and training about IP-SDM		11
1.4 Level of knowledge about IP-SDM		1
1.5 Unstandardized/standardized information regarding IP-SDM		1
2. Attitudes		
2.1 Lack of agreement/agreement with a specific component of IP-SDM		
2.1.1 Disbelief/belief that IP-SDM is supported by the evidence	1	1
2.1.2 IP-SDM is inapplicable/applicable		
2.1.2.1 Patient characteristics are inappropriate/appropriate for IP-SDM	3	3
2.1.2.2 Clinical situation is inappropriate/appropriate for IP-SDM		3
2.2 Lack of general agreement/general agreement with IP-SDM		
2.2.1 IP-SDM threatens/enhances professional autonomy	2	2
2.2.2 IP-SDM is impractical/practical	1	
2.2.3 IP-SDM is irrelevant/relevant	1	
2.2.4 Overall lack/overall agreement with IP-SDM	1	
2.3 Expectation of difficult feelings/positive feelings from applying IP-SDM		
2.3.1 Patient outcomes will suffer/benefit from IP-SDM	5	3
2.3.2 Health care processes will suffer/benefit from IP-SDM	1	1
2.4 Lack of motivation/motivation to apply IP-SDM	6	7
2.5 Unresponsiveness/responsiveness to using IP-SDM		6
3. Behaviour (external factors)		
3.1 Factors associated with patients		
3.1.1 Patients' preferences	4	
3.1.2 Patients' culture and values	1	
3.2 Factors associated with IP-SDM as an innovation		
3.2.1 IP-SDM cannot/can be tried on an experimental basis		4
3.2.2 IP-SDM is complex/easy to use	1	
3.3 Factors associated with the environment		
3.3.1 IP-SDM is time-intensive/saves time	15	4
3.3.1.1 IP team members' schedule too full/regularly scheduled IP team meetings	7	3
3.3.1.2 IP-SDM requires the practitioner to choose among tasks	1	
3.3.1.3 Intervention time too short/sufficient to apply IP-SDM without harming patient's health	3	
3.3.2 Insufficient/sufficient resources to apply IP-SDM	10	5
3.3.2.1 Insufficient/sufficient technological and information resources to apply IP-SDM		4
3.3.3 Insufficient/sufficient access to services necessary to apply IP-SDM	1	
3.3.4 Lack of reimbursement/reimbursement for applying IP-SDM	5	1
3.3.5 Ethical issues (confidentiality of patient data, risk of malpractice suits)	3	1
3.3.6 Imbalance/balance of power between health professionals and patients	1	
3.3.7 Geographical location of team members (different locations/proximity)	3	2
4. Organization		
4.1 General organizational constraints/facilitators	3	
4.2 Organizational structures and routines	8	4
4.2.1 Different working schedules	2	
4.3 High/low implementation costs	4	1
4.4 Insufficient/sufficient support from the organization	2	5
4.5 Unfavourable/favourable paradigms in the organization	1	1
4.6 Lack of responsiveness/responsiveness by the organization	3	6
4.7 Ministerial unwillingness/willingness		1
4.8 Approach not embedded/embedded within the organization		2
4.9 No leaders/leaders within the organization		1
4.10 Unfavourable/favourable legislation		1
4.11 Revised accreditation standards		1

Table 4 *Continued*

Factors	Number of interviews (individual or group) in which the factor was mentioned as a barrier ($n = 15$)	Number of interviews (individual or group) in which the factor was mentioned as a facilitator ($n = 15$)
5. Barriers/facilitators associated with IP collaboration		
5.1 Division of labour		
5.1.1 Protecting fields of expertise	1	
5.1.2 Practicing in silos	6	
5.1.3 Lacking/sharing knowledge of different disciplinary frameworks	4	7
5.1.4 Disagreeing/agreeing over roles and responsibilities	5	
5.1.5 Sharing responsibilities increases/decreases the work		4
5.1.6 IP-SDM uses professionals' skills and strengths inefficiently/efficiently	1	
5.2 Interactions		
5.2.1 Lack of effective communication/effective communication	2	1
5.2.2 Lack of shared working methods/shared working methods	1	
5.2.3 Lack of/presence of a shared health care philosophy regarding patients' needs		1
5.2.4 Interpersonal incompatibility/compatibility	1	
5.2.5 Imbalance/balance of power between professionals	9	2
5.2.6 Lack of trust/trust	4	5
5.2.7 Lack of respect/respect		4
5.2.8 Lack of/presence of team cohesion (appreciation of others' contributions)	1	3
5.2.9 Lack of/presence of continuous interactions	2	
5.3 Environment		
5.3.1 Unstable teams (movement of staff)/stable teams	4	3

IP-SDM, inter-professional shared decision making.

understand, we revised the model and developed a companion document that defines the concepts used in the model and makes the relational statements between them explicit (document available upon request).

Discussion

Our IP-SDM model for primary care was developed using a comprehensive process that included theory analysis and group consensus methods and has been reviewed by key stakeholders from three levels of the health care system. Overall, it was positively received though less than half of the participants agreed or strongly agreed that its concepts and the relationships were clear. Participants found the model to be logical, testable and relevant to SDM, inter-professionalism and useful in primary care. They proposed changes that were reviewed by team members and integrated in a revised model. They also identified barriers and facilitators to implementing the model in clinical practice. Participants' suggestions to improve the clarity of the model included enlarging the concept of family to include significant others, changing the term 'equipoise' and clarifying types of outcomes.

Very few conceptual models are designed with the approach we have detailed here. In proposing new conceptual models, developers usually only refer to the literature and their own expert judgment. However, potential users' assessment of a model can provide important insight on how an initial model designed from a literature review and expert opinion should be modified to better guide clinical practice. Accordingly, we had 79 participants assess the validity of our model in order to apply it in clinical practice. This was very useful given that some of participants' proposed changes reinforced what we had intended to accomplish (e.g. put the patient at the centre of the process) but had not yet achieved in the earlier version. Our experience thus confirms the great value of adding this layer of feedback to the elaboration of a conceptual model before its implementation.

The participation of 79 individuals in our study also confirmed the assertion of scholars from inter-professionalism [25] and SDM that stakeholders from all levels of the health care system are demonstrating increased interest in these two domains. In addition, our study devised an innovative method of presenting our initial IP-SDM model to action-oriented individuals: the video vignette. Without this solution, it was more difficult to explain how a conceptual model could translate into clinical practice.

Team members accepted most of the changes proposed by participants and revised the model accordingly. Changes that were not accepted often came from only one single individual interview or group interview but were not supported by other research. For example, one group interview suggested we change the term 'patient' to the term 'client,' 'consumer,' or 'person facing a decision'. Studies have found, however, that patients want to be called 'patients' [26]. Another suggestion was to include non-regulated health care providers as IP team members influential in the SDM process. However, we limited the description of individuals involved in SDM to regulated professions because it is easier to identify these individuals and we are planning to work with regulated health care professionals to implement the model within the Canadian health care system. Finally, participants' feedback helped the model better represent the transition between the patient-family

team and the IP team. In other words, depending on the setting, patients and family may be more or less integrated into the IP team.

Consistent with the findings of other implementation studies, the most frequently reported barrier to the potential implementation of this IP-SDM conceptual model in clinical practice was time constraints [27,28]. Time, as well as insufficient human, material and/or financial resources were also identified in a recent synthesis of barriers and facilitators influencing implementation of SDM in clinical practice [22]. Indeed, a key condition for a successful collaborative practice is the availability of time to interact and spaces to meet [29]. Although time is considered a barrier, research has shown that engaging patients in decision making does not necessarily produce a statistically significant increase in the time necessary to interact with patients: rather, in SDM, time is employed differently, with more time spent on discussing the decision than on giving information [30–32]. Indeed, some participants felt that sharing responsibilities would rather optimize efficacy and save time.

Another barrier identified in our study was the imbalance of power between the health professionals whom participants considered influential in achieving an IP approach to SDM. This finding is not surprising, given that one of the key elements necessary to achieving IP collaboration in clinical practice is symmetry of power [25]. Actually, equality between professionals is one of the basic characteristics of a collaborative practice; research has shown that collaboration is hindered by power differences based on gender stereotypes and social status [29]. In reality, however, participants reported that the doctor's symbolic authority is still very strong.

Our results are congruent with the literature on inter-professionalism. For example, the most frequently reported facilitator to implementing the initial IP-SDM model was education and training. This is supported by other research that contends training for inter-professionalism is essential [33]. Indeed, the need for adequate training is a common implementation strategy identified in both SDM and IP literature [19,34]. Besides education and training in IP and SDM, the motivation to achieve an IP approach to SDM and mutual knowledge and understanding of disciplinary roles are other facilitators identified in the literature on IP collaboration. Also, patient decision aids may have a role to play in fostering an IP approach to SDM [35,36] as they have been shown to increase the adoption of SDM-related behaviours in health care professionals [37].

Overall, the revised IP-SDM model proposes that the patient and his or her family (including significant others) are a distinct and active part of the SDM team. As such, they collaborate with the IP team throughout the SDM process. The IP team is composed of health care professionals who care for the patient and influence the SDM process through their roles and relationships. Their roles include two unique ones to this model: the initiator of the SDM process and the decision coach. To be effective, the IP team must develop a collaborative relationship with authentic, constructive and honest communication mutual trust and respect among team members as well as between team members and the patient. The team must provide integrated and cohesive care and share power among its members. The team members must be able to exercise their partnership and share their knowledge regularly and without interruptions, communicating information systematically throughout the therapeutic process and using well-designed information and communication technologies. Broader factors are likely to affect the ability of the IP team to collaborate with the patient in decision making. For this reason, the organization will likely need to modify the environment of practice in order to facilitate the implementation of an IP approach. Finally, professional regulatory and institutional standards may need to be adapted to facilitate an IP approach to patient care.

Our study has limitations. First, we used a snowball strategy to identify potential participants. Our findings are therefore dependant on who agreed to participate and do not necessarily represent the perspectives of all stakeholders. Second, only 48% of the participants watched the video. It is therefore possible that those who watched the video understood the initial IP-SDM model differently from those who did not. In other words, not all participants may have responded to the same model and concepts. Our mixed methods study design permitted us to further explore this issue by further examining the results from the nine theory criteria (the quantitative results) that showed no difference between those who watched the video and those who did not.

Implications for practice, education and future research

Our study fills an important gap in the knowledge about how IP teams can engage patients and patients' significant others in the decision-making process [38]. The revised IP-SDM model stresses the importance of facilitating communication between the individuals involved in various phases of the decision-making process, with a view of sharing knowledge and ultimately developing a common understanding of the issues at stake. It makes explicit the role of a decision coach and family members and includes the principal elements of IP collaboration. Educators of inter-professionalism may want to refer to this model to foster the practice of SDM by IP teams. However, further research is needed to better understand how IP teams collaborate to achieve SDM, determine types of relationships that are essential to IP-SDM processes, and identify interventions to facilitate implementation of an IP approach to SDM in routine clinical practice.

Conclusion

Our research team drew on health professionals' and other stakeholders' assessment of our new IP-SDM conceptual model to revise the newly proposed model. The revised model merges the micro, meso and macro levels in an integrated version that can help inform an IP approach to SDM in primary care. Future research should focus on how this conceptual model can help health professionals engage patients in SDM as part of an IP team. This research could address the barriers and build upon the facilitators identified in this study.

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ABSTRACT

Background

Shared decision making (SDM) can reduce overuse of options not associated with benefits for all and respects patient rights, but has not yet been widely adopted in practice.

Objectives

To determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM.

Search methods

For this update we searched for primary studies in *The Cochrane Library*, MEDLINE, EMBASE, CINAHL, the Cochrane Effective Practice and Organisation of Care (EPOC) Specialsied Register and PsycINFO for the period March 2009 to August 2012. We searched the Clinical Trials.gov registry and the proceedings of the International Shared Decision Making Conference. We scanned the bibliographies of relevant papers and studies. We contacted experts in the field to identify papers published after August 2012.

Selection criteria

Randomised and non-randomised controlled trials, controlled before-and-after studies and interrupted time series studies evaluating interventions to improve healthcare professionals' adoption of SDM where the primary outcomes were evaluated using observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM).

Data collection and analysis

The three overall categories of intervention were: interventions targeting patients, interventions targeting healthcare professionals, and interventions targeting both. Studies in each category were compared to studies in the same category, to studies in the other two categories, and to usual care, resulting in nine comparison groups. Statistical analysis considered categorical and continuous primary

outcomes separately. We calculated the median of the standardized mean difference (SMD), or risk difference, and range of effect across studies and categories of intervention. We assessed risk of bias.

Main results

Thirty-nine studies were included, 38 randomised and one non-randomised controlled trial. Categorical measures did not show any effect for any of the interventions. In OBOM studies, interventions targeting both patients and healthcare professionals had a positive effect compared to usual care (SMD of 2.83) and compared to interventions targeting patients alone (SMD of 1.42). Studies comparing interventions targeting patients with other interventions targeting patients had a positive effect, as did studies comparing interventions targeting healthcare professionals with usual care (SDM of 1.13 and 1.08 respectively). In PROM studies, only three comparisons showed any effect, patient compared to usual care (SMD of 0.21), patient compared to another patient (SDM of 0.29) and healthcare professional compared to another healthcare professional (SDM of 0.20). For all comparisons, interpretation of the results needs to consider the small number of studies, the heterogeneity, and some methodological issues. Overall quality of the evidence for the outcomes, assessed with the GRADE tool, ranged from low to very low.

Authors' conclusions

It is uncertain whether interventions to improve adoption of SDM are effective given the low quality of the evidence. However, any intervention that actively targets patients, healthcare professionals, or both, is better than none. Also, interventions targeting patients and healthcare professionals together show more promise than those targeting only one or the other.

PLAIN LANGUAGE SUMMARY

A review of the ways in which healthcare professionals can be helped to involve their patients in the healthcare decision making process

When there are several treatments possible, healthcare professionals can involve patients in the process of making decisions about their care so that the patients can choose care that meets their needs and reflects what is important to them. We call this 'shared decision making'. Although the results are better when patients are involved, healthcare professionals often do not involve their patients in these decisions. We wanted to know more about what can be done to encourage healthcare professionals to share decision making with their patients. In our review we identified 39 studies that tested what activities work in helping healthcare professionals involve their patients more in the decision-making process. We learned that any such activity was better than none, and that activities for healthcare professionals and patients together worked somewhat better than activities just for patients or just for healthcare professionals. However, given the small number of studies and the differences across the studies, it was difficult to know which activities worked best. This review suggested ways to better evaluate how much healthcare professionals involve patients in healthcare decisions so that we can understand this process better in the future.

SUMMARY OF FINDINGS

Summary of findings for the main comparison.

Interventions targeting patients compared with usual care for improving the adoption of shared decision making by healthcare professionals				
Outcomes*	**Type of outcome**	**Median of the standardized mean difference or median of the risk difference (range)**	**No of measures (studies**)**	**Quality of the evidence (GRADE)**
Observer-based SDM measures	Continuous measure	Unavailable data	3 (1)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	**0.21 (0.04 to 0.50)**	6 (4)	Very low [1,2,3]
	Categorical measure	-0.02 (-0.28 to -0.01)	5 (4)	Very low [1,2,3]
	Qualitative quote	Unavailable data	0 (0)	
Interventions targeting patients compared with another intervention targeting patients for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**1.13 (1.04 to 1.21)**	2 (2)	Very low [1,2,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	**0.29 (-0.05 to 0.63)**	6 (2)	Very low [1,2,3]
	Categorical measure	0.04 (-0.21 to 0.12)	11 (8)	Low [1,2]
	Qualitative quote	0 significant study on 3	3 (3)	Very low [1,2,4]
Interventions targeting healthcare professionals compared with usual care for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**1.08 (0.38 to 2.07)**	4 (3)	Very low [1,2,3,4,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	0.11	1 (1)	Very low [1,2]

	Categorical measure	0.05 (0.00 to 0.09)	3 (2)	Low [2,3]
	Qualitative quote	0 significant study on 1	1 (1)	Very low [2,4]
Interventions targeting healthcare professionals compared with another intervention targeting patients for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	-0.12	1 (1)	Very low [1,2]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Interventions targeting healthcare professionals compared with another intervention targeting healthcare professionals for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	-0.3	1 (1)	Very low [2,4,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	**0.20 (-0.09 to 0.48)**	7 (2)	Very low [1,2,3]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Interventions targeting both patients and healthcare professionals compared with usual care for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	**2.83**	4 (2)	Very low [1,2,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant stdy on 1	1 (1)	Very low [2,4]
Patient-reported SDM measures	Continuous measure	0.16	3 (3)	Very low [1,2]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant study on 2	2 (2)	Very low [1,2,4]
Interventions targeting both patients and healthcare professionals compared with another intervention targeting patients for improving the adoption of shared decision making by healthcare professionals				

Observer-based SDM measures	Continuous measure	**1.42**	1 (1)	Very low [2,4,5]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	0.09 (-0.06 to 0.73)	5 (3)	Very low [1,2,3]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant measure on 2	2 (1)	Very low [2,4]
Interventions targeting both patients and healthcare professionals compared with another intervention targeting healthcare professionals for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	0.06	1 (1)	Very low [1,2]
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	1 significant study on 1	1 (1)	Very low [1,2,4]
Interventions targeting both patients and healthcare professionals compared with another intervention targeting both patients and healthcare professionals for improving the adoption of shared decision making by healthcare professionals				
Observer-based SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	-0.04	1 (1)	Very low [1,2]
	Qualitative quote	Unavailable data	0 (0)	
Patient-reported SDM measures	Continuous measure	Unavailable data	0 (0)	
	Categorical measure	Unavailable data	0 (0)	
	Qualitative quote	Unavailable data	0 (0)	

* Where studies reported more than one measure for each endpoint, the primary measure (as defined by the authors of the study) or the median measure was abstracted. For **categorical measures**, we calculated the risk difference between the intervention of interest and the control intervention across various outcomes. For**continuous endpoints**, we calculated standardized mean difference by dividing the mean score difference of the intervention and comparison groups in each study by the pooled standard deviation estimate for the two groups across various outcomes

** Three studies reported results in more than one type of measure

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Important risk of bias according to EPOC checklist
[2] Indirectness of evidence
[3] Heterogeneity
[4] Imprecision of the observed effect
[5] Publication bias

BACKGROUND

Description of the condition

Shared decision making (SDM) is defined as a process by which a healthcare choice is made by the patient (or significant others, or both) together with one or more healthcare professionals (Charles 1997; Légaré 2011; Towle 1999) and is said to be the crux of patient-centred care (Weston 2001). Briefly, SDM rests upon knowing and understanding the best available evidence on the risks and benefits across all available options while ensuring that the patient's values are taken into account (Charles 1997; Elwyn 1999; Towle 1999). Although SDM represents a complex set of behaviours that must be achieved by both members of the patient-healthcare professional dyad (LeBlanc 2009), it is possible to specify behaviours that both parties must adopt for SDM to occur in clinical practice (Frosch 2009; Légaré 2007a). A systematic review of SDM as a concept identified 161 definitions and summarized the key elements in one integrative model of SDM in medical encounters (Makoul 2006). This model identifies nine essential elements that can be translated into various SDM-related specific behaviours for healthcare professionals during consultations with patients:

- define and explain the healthcare problem,
- present options,
- discuss pros and cons (benefits, risks, costs),
- clarify patient values and preferences,
- discuss patient ability and self-efficacy,
- present what is known and make recommendations,
- check and clarify the patient's understanding,
- make or explicitly defer a decision,
- arrange follow up.

The notion that the healthcare professional is the only party requiring access to evidence is no longer credible. Instead, SDM assumes that both healthcare professional(s) and patient require access to information about the evidence informing a decision, while understanding and respecting both the patient's values and the healthcare professional's recommendations.

Description of the intervention

A variety of interventions have been designed to change healthcare professionals' behaviour. Based on the Effective Practice and Organisation of Care (EPOC) taxonomy of interventions (EPOC 2008), these may include but are not limited to the distribution of printed educational materials, educational meetings, audit and feedback, reminders, educational outreach visits and patient-mediated interventions (that is any intervention aimed at changing the performance of healthcare professionals through interactions with patients, or information provided by or to patients). Additionally, in the context of SDM it is possible to identify three overarching categories of implementation intervention: 1) interventions targeting patients, 2) interventions targeting healthcare professionals, and 3) interventions targeting both.

How the intervention might work

Theoretical and empirical evidence about behaviour change in healthcare professionals (Godin 2008) and complex behaviour change (Michie 2009) allows us to make certain hypotheses regarding the mechanisms by which interventions might promote SDM. For example, the distribution of printed educational materials may improve professionals' attitudes towards adopting SDM-related behaviours by reinforcing the underlying salient beliefs associated with their intention to adopt SDM (Giguère 2012). The training of professionals in SDM through educational meetings may increase professionals' perceptions of self-efficacy, one of the key determinants of behaviour (Godin 2008). Patient-mediated interventions such as decision aids have been shown to improve patient knowledge (Stacey 2011), and this may provide patients with more resources with which to engage in the decision-making process. In turn, the engagement of patients in the decision making process may change the habits of healthcare professionals by enhancing their knowledge of emerging evidence within their area of expertise and by increasing their use of this evidence (Brouwers 2010).

Why it is important to do this review

Policy makers perceive SDM as desirable (Shafir 2012) because: a) patient involvement is accepted as a right (Straub 2008); b) it may reduce the overuse of options not clearly associated with benefits for all; c) it may enhance the use of options clearly associated with benefits for the vast majority of the concerned population; d) it may reduce unwarranted healthcare practice variations (Mulley 2012; Wennberg 2004); and e) it may foster the sustainability of the healthcare system by increasing patient ownership of their own healthcare (Coulter 2006). Nonetheless, SDM has not yet been widely implemented in clinical practice. A systematic review of 33 studies using the Observing Patient Involvement in Decision Making instrument (OPTION) showed low levels of patient-involving behaviours (Couët 2013).

OBJECTIVES

The objective of this review was to determine the effectiveness of interventions to improve healthcare professionals' adoption of SDM.

To address this objective, we compared each of the three categories of targeted intervention (targeting patients, targeting healthcare professionals, and targeting both) to the same category of targeted intervention, to each of the other categories of targeted intervention, and to usual care. Thus there were nine comparison categories.

Group 1. Interventions targeting patients compared to usual care.

Group 2. Interventions targeting patients compared to other interventions targeting patients.

Group 3. Interventions targeting healthcare professionals compared to usual care.

Group 4. Interventions targeting healthcare professionals compared to interventions targeting patients.

Group 5. Interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals.

Group 6. Interventions targeting both patients and healthcare professionals compared to usual care.

Group 7. Interventions targeting both patients and healthcare professionals compared to interventions targeting patients alone.

Group 8. Interventions targeting both patients and healthcare professionals compared to interventions targeting healthcare professionals alone.

Group 9. Interventions targeting both patients and healthcare professionals compared to other interventions targeting both patients and healthcare professionals.

METHODS

Criteria for considering studies for this review

Types of studies

This review considered randomised controlled trials (RCTs) and non-randomised controlled trials (NRCTs), controlled before and after studies (CBAs) and interrupted time series (ITS) analyses (EPOC 2008). To be included as a CBA, we required the study to have a minimum of two intervention sites and two control sites. For ITS studies, there needed to be a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. We considered publications in English and French only for eligible studies that needed data extraction.

Types of participants

In this review, there were two main types of participants. The first type were healthcare professionals, including professionals in training who were responsible for patient care (residents, fellows, and other pre-licensure healthcare professionals). We defined professionals as having licensure or, in the case of professionals in training, basic pre-licensure education (for example residents who had a medical degree). The second type were patients, including healthcare consumers and standardized patients. Standardized patients were only deemed to be acceptable participants if the outcome was observer-reported.

Types of interventions

We included in this review studies that evaluated an intervention designed to increase healthcare professionals' adoption of SDM. We organized interventions into categories using the EPOC taxonomy of interventions (EPOC 2008). Patient decision aids were considered a patient-mediated intervention since one of their purposes is to foster patients' participation in decisions during the clinical encounter (Stacey 2011).

We considered studies that evaluated patient-mediated interventions (for example patients' use of patient decision aids in preparation for their consultation or during their consultation with a healthcare professional) only if these studies directly assessed the healthcare professional-related outcome of interest, that is the professional's adoption of SDM (see Types of outcome measures).

In keeping with the EPOC taxonomy of interventions, we sorted interventions into three categories: interventions targeting patients (for example patient-mediated interventions), interventions targeting healthcare professionals (for example distribution of printed educational material, an educational meeting, audit and feedback, reminders and educational outreach visits) and interventions targeting both patients and healthcare professionals (for example a patient-mediated intervention combined with an intervention targeting healthcare professionals). Usual care was the fourth category. This gave us nine comparison categories in total (see Objectives).

Types of outcome measures

In this updated review, we considered not only observer-based findings but also findings by the patients themselves, presenting a more complete portrait of the impact of interventions on adoption of SDM. We specifically avoided inclusion of healthcare professionals' self-reported SDM behaviours given that they tend to over-rate their personal behaviours.

Thus the primary outcomes evaluated by this review were observer-based outcome measures (OBOM) or patient-reported outcome measures (PROM) of healthcare professionals' adoption of SDM.

For each eligible study that included the primary outcome of interest, whether OBOM or PROM, we also extracted secondary outcomes. These were measures of patient health outcomes (for example results of a blood test, health-related quality of life) and other measures reported by healthcare professionals or patients (for example knowledge, attitudes, or satisfaction).

We also extracted potential harms of interventions: a) measures of patient anxiety (from patient health outcomes); b) longer duration of consultations; and c) costs.

Search methods for identification of studies

Electronic searches

An information specialist (S Ratté) developed the search strategies in consultation with the authors.

The SDM component of the search strategy was based on the search strategy developed for a previous systematic review on barriers and facilitators for implementing SDM in clinical practice as perceived by healthcare professionals (Légaré 2008a). Given that the implementation of SDM in clinical practice is a relatively new area of research, we favoured a broad search strategy with high sensitivity as opposed to a very specific search. Searches were conducted at the beginning of August 2012; exact search dates for each database are included in Appendix 1 to Appendix 11.

All databases were searched from their inception to March 2009 for the first review. This update searched for additional literature from 15 March 2009 to August 2012. In addition to our database searches in August 2012, we contacted experts in the field and conducted brief searches in PubMed. By doing so, we identified a number of studies published later than August 2012. We included articles published in English and French only.

The following electronic databases were searched for primary studies:

- Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library* (www.thecochranelibrary.com) (August 2012);
- Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register;
- MEDLINE via Pubmed (1950 to August Week 1, August 2012) using OvidSP;
- EMBASE (1980 to Week 29 2012) via OvidSP;

- CINAHL (Cumulative Index to Nursing and Allied Health Literature) (1981 to August 2012) via EBSCOhost;
- NHS Economic Evaluation Database, Centre for Reviews and Dissemination (CRD);
- Health Technology Assessment Database, CRD;
- PsycINFO (1806 to Week 1 August2012).

Our database searches, in all the databases above, were limited by publication year and month (March 2009 to August 2012). For PsycINFO, we were unable to place strict date limitations and manually excluded citations retrieved outside this date range.

Searching other resources

Trial registries

ClinicalTrials.gov, US National Institutes of Health (NIH) at http://clinicaltrials.gov/ (Week 2 January 2013).

Others

We also:

- handsearched proceeding so the a) International Conference on Shared Decision Making (years 2003, 2005, 2007, 2009, 2011) and b) the annual meetings of the Society for Medical Decision Making (years 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011). Although we intended to search the European Association for Communication in Healthcare (EACH), we were unable to obtain detailed information either online or as a paper copy;
- reviewed reference lists of all included studies, relevant systematic reviews and primary studies;
- contacted authors of relevant studies or reviews to clarify reported published information and to seek unpublished data. Through this process we identified a number of papers published after August 2012;
- included results from searches conducted for a review focused on patient-reported outcomes (Légaré 2012a).

Data collection and analysis

Selection of studies

At least two review authors (MJC, MS, PZ, ST) independently screened each title and abstract to find studies that met the inclusion criteria. We retrieved full text copies of all studies that might be relevant or for which the inclusion criteria were not clear in the title or abstract. In this update, when more than one publication described the same study but each presented new and complementary data we included them all. Any disagreements on the selection were resolved by discussion among the review authors (FL, DS).

Data extraction and management

To extract data, we designed a form derived from the EPOC Review Group data collection checklist (EPOC 2008). At least two review authors (MJC, MS, PZ, ST) independently extracted data from eligible studies. We reached consensus about discrepancies, and any disagreement was adjudicated by FL and DS. We entered data into Review Manager software (RevMan 5) and checked for accuracy. When information regarding any of the above was unclear, we attempted to contact the authors of the original reports to provide further details.

In addition to EPOC's standardized data collection checklist, we extracted the following characteristics of the settings and interventions.

- Level of care: primary or specialized care (as defined by the type of provider).
- Setting of care: ambulatory or non-ambulatory care (i.e. hospitalised patients in acute-care or long-term care facilities).
- Conceptual or theoretical underpinnings of the intervention (i.e. authors stated in their paper that the intervention was based on a theory or at least referred to a theory).
- Barriers assessment (i.e. authors stated in their paper that a barriers assessment was conducted and the intervention was designed to overcome identified barriers).
- Number of components included in the intervention based on the EPOC taxonomy (when a barriers assessment was mentioned, such as the one above, it was considered a component of the intervention).

For ongoing studies, when available we described the primary outcome, the research question(s), the methods and the outcome (see Ongoing studies).

Assessment of risk of bias in included studies

At least two review authors (MJC, MS, PZ, ST) independently assessed the risk of bias in each included study using the criteria outlined in the EPOC Review Group data collection checklist for studies with a separate control group (EPOC 2008) and the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) for ITS designs. We resolved any disagreement by discussion with FL. We assessed each quality criterion as 'Done', 'Not done', or 'Unclear', as recommended by the EPOC Review Group. Then we transformed these three scores into 'Low risk', 'High risk', and 'Unclear' when we entered the data into RevMan 5. The seven standard criteria as suggested for all RCTs and CBA studies are listed below.

1) Concealment of allocation (protection against selection bias).

2) Follow-up of professionals (protection against exclusion bias).

3) Follow-up of patients or episodes of care.

4) Blinded assessment of primary outcome(s) (protection against detection bias).

5) Baseline measurement.

6) Reliable primary outcome measure(s).

7) Protection against contamination.

For PROM measures, the criterion 'reliable primary outcome' was not applicable because of the nature of the outcome.

Measures of treatment effect

We structured data analysis using statistical methods developed for EPOC by Grimshaw and colleagues (Grimshaw 2004). For each study, we reported results for categorical and continuous primary outcomes separately and in natural units. For categorical measures, we calculated the difference in risk between the intervention of interest and the control intervention. We calculated standardized

mean difference for continuous measures by dividing the mean score difference of the intervention and comparison groups in each study by the pooled estimate standard deviation for the two groups. When possible, for categorical and continuous outcomes we constructed 95% confidence intervals (CIs) to compare groups before and after the intervention, according to the recommendations in RevMan 5. The absence of a '0' value in the CI indicated that the baselines differed or that the intervention had a statistically significant positive effect compared to the control intervention or to usual care. When the baseline was different in the two groups, we used the size of the difference and its associated standard error to compare them. If information was not available for the standard error, we extracted a qualitative quote from the primary study on the effectiveness of the intervention and on confounding factors, if available. When no baseline was reported, we considered groups to be similar prior to the intervention. For the analysis, the studies were divided into nine categories of intervention, which were applied to both PROM and OBOM outcomes (that is nine categories for each). Where studies reported more than one primary outcome in the same category, the median measure was abstracted. For each category of intervention and outcome for which a significant effect on our main outcome of interest (healthcare professionals' adoption of SDM) was observed, we reported the median of the standardized mean difference (or risk difference) and a range. We considered a standardized mean difference of 0.2 as small, 0.5 as medium, and 0.8 as large (Cohen 1988). For studies in which the quantitative data were absent or insufficient to make the calculation, and if no replies were obtained from the authors, we reproduced the qualitative data as presented in the article. A meta-analysis would have been performed if the nature of the primary outcome of the various comparisons had been similar.

Summary of findings table

The quality of evidence was evaluated according to GRADE for the 18 categories of intervention and outcome. For each category, conclusions were categorized into four ratings: high quality (further research is very unlikely to change our confidence in the estimate of effect), moderate quality (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate), low quality (further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate), and very low quality (we are very uncertain about the estimate). This rating was downgraded if it met one of the five following criteria.

1) Important risk of bias according to the EPOC checklist: quality of evidence downgraded if the EPOC 'unclear risk' or 'high risk' risk of bias criteria were applicable.

2) Indirectness of evidence: quality of evidence was downgraded if it met one of four further criteria, i) a difference between the population of interest and participants in the studies (applicability); ii) a difference between the intervention of interest and interventions in the studies (applicability); iii) the use of surrogate endpoints to measure SDM (PROM and OBOM are each prone to particular biases and have their own strengths and weaknesses, we can thus rate PROM and OBOM as being of even quality in the context of a process experienced by the patient); and iv) no head-to-head comparisons were made or comparisons between two or more interventions of interest (e.g. multifaceted intervention compared to another multifaceted intervention).

3) Inconsistency: quality of evidence was downgraded according to the heterogeneity index (I^2 > 30%). This criterion was evaluated separately for categorical and continuous measures. It was not appropriate for qualitative statements.

4) Imprecision of the observed effect: quality of evidence was downgraded if the sample size in a study was insufficient or if there was a qualitative statement.

5) Publication bias: publication bias was tested using a funnel plot.

Quality of evidence was upgraded in three cases: 1) demonstration of a strong association in a well-executed observational study; 2) all plausible biases from observational or randomised studies may have been working to underestimate an apparent intervention effect; and 3) there was evidence of a gradient.

Unit of analysis issues

We included cluster-randomised trials in the analyses along with individually randomised trials. Comparisons that randomise or allocate clusters (groups of healthcare professionals or organizations) but do not account for clustering during the analysis have potential unit of analysis errors that can produce artificially significant P values and overly narrow CIs (Ukoumunne 1999). Therefore, when possible, we contacted primary authors for missing information and attempted to re-analyse studies with potential unit of analysis errors. When missing information was unavailable from the study authors, we only reported the point estimate.

Assessment of heterogeneity

To explore heterogeneity, we designed tables that compared the studies' standardized mean differences and their risk differences. We considered the following variables as potential sources of heterogeneity to explain variations in the results of the included studies: type of intervention; characteristics of the intervention (for example duration); clinical setting (primary care versus specialized care); type of healthcare professional (physicians versus other healthcare professionals); level of training of healthcare professionals (for example healthcare professionals in training versus those in practice); and type of outcome (continuous or categorical).

RESULTS

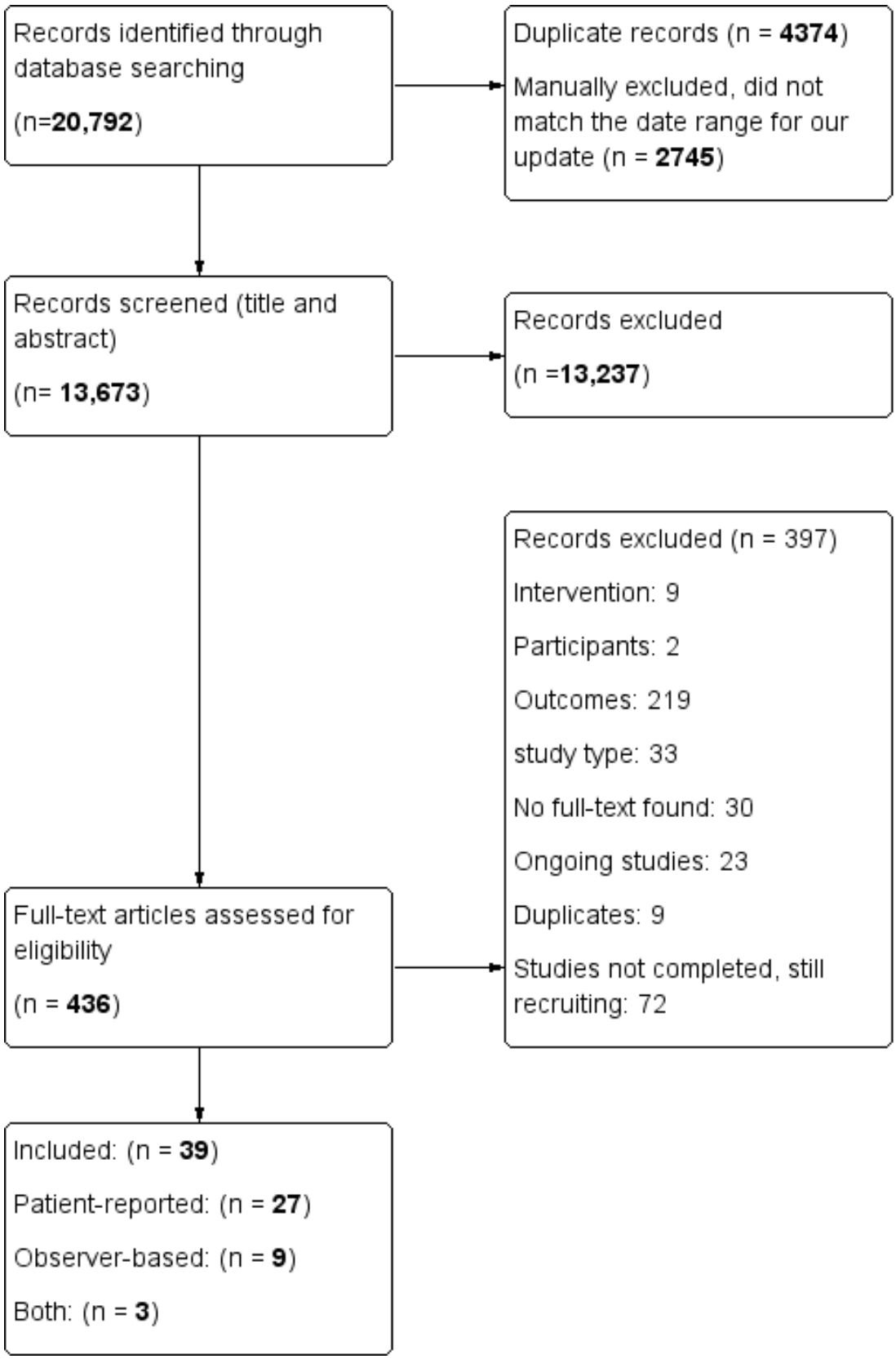
Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

For this update, we found 11,757 potentially relevant citations; for previous versions of this review, we screened 9035 citations (Légaré 2012a). This provided a total of 20,792 potentially relevant citations that we considered, of which 7119 were excluded prior to review of the full publications (4374 were duplicates and 2745 did not match the date range for our update). Of the remaining citations, we retrieved 436 full publications for a more detailed screening. From these, we excluded another 397 citations based on the identified inclusion criteria. This resulted in 39 studies. For more details, see Figure 1.

Figure 1. Flow diagram of Cochrane update on interventions for improving the adoption of shared decision making by healthcare professionals (up to 31 December 2012).



Included studies

We included 39 studies in this review. This current version updates our 2010 version (Légaré 2010), which included five OBOM studies and another systematic review of 21 PROM studies (Légaré 2012). Two studies (Butow 2004; Elwyn 2004) were in both reviews. Three studies were excluded: one was excluded because it reported "preferred role during the consultation" (that is the role the patient would like to play) and not 'assumed role' (the role actually played, the outcome relevant to our review) (Brown 2004). Two more were excluded because they reported the more vaguely-worded "active patient" but not 'assumed role' (Kopke 2009; Whelan 2003).

This updated search added 18 new studies to the 21 original studies that were included, for a total of 39 studies (Bernhard 2011; Cooper 2011; Deen 2012; Deinzer 2009; Fossli 2011; Hess 2012; Landrey 2012; Légaré 2012; Leighl 2011; Montori 2011; Mullan 2009; Murray 2010; Myers 2011; Raynes-Greenow 2010; Roter 2012; Schroy 2011; Shepherd 2011; van Peperstraten 2010).

We identified a further 20 RCTs as ongoing studies (see Characteristics of ongoing studies).

All studies in this review were RCTs except for one, which was a non-randomised controlled trial (NRCT) (Deinzer 2009). Among the RCTs, seven were cluster-randomised trials (Elwyn 2004; Hamann 2007; Haskard 2008; Légaré 2012; Loh 2007; O'Cathain 2002; Wetzels 2005).

Characteristics of settings and participants

Interventions targeting patients (18 studies)

Of the 18 studies of interventions targeting patients, eight were conducted in the United States (Deen 2012; Dolan 2002; Krist 2007; Landrey 2012; Montori 2011; Nannenga 2009; Schroy 2011; Street 1995), three in Canada (Davison 1997; Deschamps 2004; Lalonde 2006), two in Germany (Kasper 2008; Vodermaier 2009), two in the Netherlands (Stiggelbout 2008; van Peperstraten 2010), two in Australia (Butow 2004; Raynes-Greenow 2010) and one in the United Kingdom (Murray 2001). With regard to care settings, eight out of 18 trials were conducted in primary care (Deschamps 2004; Dolan 2002; Krist 2007; Lalonde 2006; Landrey 2012; Montori 2011; Murray 2001; Schroy 2011) and nine in specialized care (Butow 2004; Davison 1997; Kasper 2008; Nannenga 2009; Raynes-Greenow 2010; Stiggelbout 2008; Street 1995; van Peperstraten 2010; Vodermaier 2009). One study was carried out both in primary and specialized care (Deen 2012). All studies were conducted and recruited patients in an ambulatory setting except one, which was in non-ambulatory care (Vodermaier 2009).

Although there was a total of 236 reported participating healthcare professionals, this number under-represented the total number of professionals as eight studies did not report the total number of healthcare professionals involved in the study (Deen 2012; Deschamps 2004; Kasper 2008; Lalonde 2006; Murray 2001; Raynes-Greenow 2010; van Peperstraten 2010; Vodermaier 2009). The minimum number of healthcare professionals reported was two (Davison 1997) and the maximum number was 60 (Montori 2011).

All studies reported the number of patients involved in the study. A total of 4055 patients were enrolled in the interventions, with a minimum of 26 (Lalonde 2006) and a maximum of 666 (Schroy 2011). The most common clinical condition was cancer (seven studies) (Butow 2004; Davison 1997; Dolan 2002; Krist 2007; Schroy 2011; Street 1995; Vodermaier 2009).

Interventions targeting healthcare professionals (eight studies)

Of the eight studies of interventions targeting healthcare professionals, two were conducted in Canada (Légaré 2012; Stacey 2006), two in the United Kingdom (Elwyn 2004; O'Cathain 2002), one in Australia (Shepherd 2011), one in Germany (Krones 2008 (ARRIBA-Herz)) and one in Norway (Fossli 2011). One study was conducted with international collaboration, specifically Australia, New Zealand, Switzerland, Germany and Austria (Bernhard 2011). Seven studies were conducted in primary care (Elwyn 2004; Fossli 2011; Krones 2008 (ARRIBA-Herz); Légaré 2012; O'Cathain 2002; Shepherd 2011; Stacey 2006) and one in specialized care (Bernhard 2011). All eight trials recruited patients in ambulatory care settings.

Although a total of 593 participating healthcare professionals were reported, this number under-represented the total number of professionals as one study did not report the total number of healthcare professionals involved in the study (O'Cathain 2002). The minimum number of healthcare professionals reported was 21 (Elwyn 2004) and the maximum number was 270 (Légaré 2012).

Two studies (Shepherd 2011; Stacey 2006) used simulated patients facing different clinical situations: depression (Shepherd 2011), gall bladder disorders, attention deficit hyperactivity disorder, amniocentesis, and allergy (Stacey 2006). Among the six studies without standardized patients, one did not report the number of patients in the study (Fossli 2011) and five studies (Bernhard 2011; Elwyn 2004; Krones 2008 (ARRIBA-Herz); Légaré 2012; O'Cathain 2002) had a total of 13,707 patients enrolled (minimum 694 (Bernhard 2011) and maximum 10,070 (O'Cathain 2002) patients per study). The five studies that reported numbers of patients involved diverse clinical conditions: breast cancer (Bernhard 2011), cardiovascular disease (Krones 2008 (ARRIBA-Herz)), acute respiratory infection (Légaré 2012), maternity care (O'Cathain 2002), and multi-clinical conditions of non-valvular atrial fibrillation or prostatism or menorrhagia or menopausal symptoms (Elwyn 2004). Most interventions enrolled both male and female patients, except for two studies (Bernhard 2011; O'Cathain 2002) which involved females only.

Interventions targeting both patients and healthcare professionals (13 studies)

Of the 13 studies of interventions targeting both patients and healthcare professionals, six were conducted in the United States (Cooper 2011; Haskard 2008; Hess 2012; Mullan 2009; Myers 2011; Roter 2012), four in Germany (Bieber 2006; Deinzer 2009; Hamann 2007; Loh 2007), one in the Netherlands (Wetzels 2005) and one in Canada (Murray 2010). One study was conducted with international collaboration, specifically Australia and Canada (Leighl 2011). Care settings were divided between primary care (seven studies) (Cooper 2011; Haskard 2008; Loh 2007; Mullan 2009; Myers 2011; Roter 2012; Wetzels 2005) and specialized care (six studies) (Bieber 2006; Deinzer 2009; Hamann 2007; Hess 2012; Leighl 2011; Murray 2010). Ten trials were conducted in ambulatory care settings (Bieber 2006; Cooper 2011; Haskard 2008; Hess 2012; Leighl 2011; Loh 2007; Mullan 2009; Myers 2011; Roter 2012; Wetzels 2005), two in non-ambulatory care settings (Deinzer 2009; Hamann 2007) and one was set in both ambulatory and non-ambulatory care settings

(Murray 2010). A total of 571 healthcare professionals took part in these studies, ranging from 10 (Bieber 2006) to 156 (Haskard 2008) per study.

One study (Murray 2010) used five simulated patients facing care related to end of life treatment. Among the 12 studies without standardized patients, a total of 5474 patients were enrolled, with a minimum of 85 (Mullan 2009) and a maximum of 2196 (Haskard 2008). The most common clinical condition was hypertension (two studies) (Cooper 2011; Deinzer 2009), and multi-clinical conditions (two studies) (Haskard 2008; Wetzels 2005). Most interventions enrolled both male and female patients, except for one study (Myers 2011) which involved males only.

In summary, of the 39 studies included in the review, the three most represented countries were the United States (14 studies), Germany (seven studies) and Canada (six studies). Only two of the 39 studies were conducted with international collaborations: Canada and Australia; and Australia; New Zealand, Switzerland, Germany and Austria. The setting was primary care in 22 studies, with only one in both primary and specialized care. More than half (53.8%) of the healthcare professionals involved in the studies were licensed and the three most frequent clinical conditions studied were cancer (nine studies), cardiovascular disease (eight studies) and multiple conditions (four studies).

Characteristics of interventions and comparisons

Characteristics of interventions

For details, see Characteristics of included studies.

Several studies had more than two arms (Cooper 2011; Deen 2012; Haskard 2008; Krist 2007; Raynes-Greenow 2010; Schroy 2011). One study presented a RCT with two-by-two factorial design (Cooper 2011) and four arms: 1) a patient-mediated intervention and an educational meeting; 2) an educational meeting; 3) a patient-mediated intervention; and 4) control (patients and providers receiving minimal intervention). One study presented an RCT with four arms (Deen 2012): 1) a decision aid and patient activation; 2) a decision aid; 3) patient activation; and 4) control (doctor's visit). One study presented a cluster-RCT (Haskard 2008) with four arms. The first arm (training of healthcare professional and patient) consisted of a multifacted intervention (an educational meeting, distribution of educational materials, and a patient-mediated intervention). The second arm (training of healthcare professional only) consisted of a multifaceted intervention (an educational meeting and the distribution of educational materials). The third arm (patient training only) consisted of a single intervention (patient-mediated intervention). The fourth arm (control group) consisted of usual care. One study presented an RCT (Krist 2007) with three arms: 1) mailed paper version of a decision aid; 2) Internet-based decision aid; and 3) control. One study presented an RCT (Raynes-Greenow 2010) with three arms: 1) a decision aid (booklet and audio); 2) a decision aid (booklet); and 3) a pamphlet. One study presented an RCT (Schroy 2011) with three arms: 1) a decision aid and decision guidance; 2) a decision aid only; and 3) control decision aid. Thus there was an overlap of studies between comparison types (objective).

Interventions targeting patients

Eight studies compared interventions targeting patients with usual care (Cooper 2011; Deen 2012; Haskard 2008; Krist 2007; Landrey 2012; Murray 2001; van Peperstraten 2010; Vodermaier 2009). Of these, three studies compared single interventions to usual care (Landrey 2012; Murray 2001; Vodermaier 2009), one compared multifaceted interventions to usual care (van Peperstraten 2010), and four studies (Cooper 2011; Deen 2012; Haskard 2008; Krist 2007) compared patient-mediated interventions to usual care (RCTs with several arms).

Fourteen studies presented comparisons of interventions targeting the patient with other interventions targeting the patient (Butow 2004; Davison 1997; Deen 2012; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Lalonde 2006; Montori 2011; Nannenga 2009; Raynes-Greenow 2010; Schroy 2011; Stiggelbout 2008; Street 1995). Of these, eight studies compared a single intervention to another single intervention (Butow 2004; Davison 1997; Dolan 2002; Kasper 2008; Montori 2011; Nannenga 2009; Stiggelbout 2008; Street 1995), one study compared a multifaceted intervention to a single intervention (Deschamps 2004), one study compared a multifaceted intervention to another multifaceted intervention (Lalonde 2006), and four studies had arms comparing a patient-mediated intervention to another patient-mediated intervention (Deen 2012; Krist 2007; Raynes-Greenow 2010; Schroy 2011).

Interventions targeting healthcare professionals

Seven studies compared interventions targeting the healthcare professional with usual care (Bernhard 2011; Cooper 2011; Fossli 2011; Légaré 2012; O'Cathain 2002; Shepherd 2011; Stacey 2006). Of these, two studies presented interventions containing educational meetings, audit and feedback, and distribution of educational materials (Bernhard 2011; Fossli 2011); two studies presented interventions using educational meetings and distribution of educational materials (Légaré 2012; O'Cathain 2002); and one presented the distribution of educational materials with educational meetings, audit and feedback, and barriers assessment, as part of a multifaceted intervention (Stacey 2006). We also found one study that compared a single intervention (educational outreach visit) to usual care (Shepherd 2011), and one study had an arm that compared an educational meeting to usual care (Cooper 2011).

One study compared an intervention targeting the healthcare professional with one targeting the patient (Cooper 2011). This study presented an arm comparing a educational meeting with a patient-mediated intervention.

Two studies compared interventions targeting the healthcare professional with other interventions targeting the healthcare professional (Elwyn 2004; Krones 2008 (ARRIBA-Herz)). Of these, one study compared a multifaceted intervention (educational meeting and audit and feedback focusing on SDM skills) to another multifaceted intervention (educational meetings and audit and feedback focusing on risk communication skills) (Elwyn 2004), and one study compared a multifaceted intervention (educational meeting, audit and feedback, distribution of educational material, and an educational outreach component) to a single intervention (educational meeting) (Krones 2008 (ARRIBA-Herz)).

Interventions targeting both patients and healthcare professionals

Eight studies compared an intervention targeting patients and healthcare professionals with usual care (Cooper 2011; Hamann 2007; Haskard 2008; Hess 2012; Leighl 2011; Loh 2007; Murray 2010;

Wetzels 2005). Of these, four studies presented interventions that used educational meetings and patient-mediated interventions (Hamann 2007; Hess 2012; Leighl 2011; Loh 2007); one study presented an intervention that used educational meetings, distribution of educational materials, audit and feedback, barriers assessment, and educational outreach visits (Murray 2010); and one study presented a patient-mediated intervention using educational outreach visits (Wetzels 2005). One study presented an arm with an intervention that used a combination of a patient-mediated intervention, distribution of educational material and educational meetings (Haskard 2008); and one study presented a patient-mediated intervention and an educational meeting (Cooper 2011).

Four studies compared interventions targeting both patients and healthcare professionals with interventions targeting patients alone (Bieber 2006; Cooper 2011; Deinzer 2009; Mullan 2009). Of these, three studies compared educational meetings and patient-mediated interventions with patient-mediated interventions alone (Bieber 2006; Deinzer 2009; Mullan 2009), and one study presented an arm comparing an educational meeting and patient-mediated intervention with a patient-mediated intervention alone (Cooper 2011).

Two studies compared interventions targeting both patients and healthcare professionals with interventions targeting healthcare professionals alone (Cooper 2011; Roter 2012). Of these, one study compared patient-mediated interventions and the distribution of educational materials with the distribution of educational materials alone (Roter 2012), and one study presented an arm comparing educational meetings and patient-mediated interventions with educational meetings alone (Cooper 2011).

One study compared an intervention targeting both patients and healthcare professionals with another intervention targeting both patients and healthcare professionals (Myers 2011). This study compared a multifaceted intervention including a patient-mediated intervention and reminders with another multifaceted intervention also including a patient-mediated intervention and reminders.

Conceptual framework and barriers assessment

Interventions targeting patients (18 studies)

Among the studies of interventions targeting patients, six studies explicitly referred to a conceptual framework or a theory to justify their intervention (Butow 2004; Davison 1997; Raynes-Greenow 2010; Schroy 2011; Stiggelbout 2008; van Peperstraten 2010). Three studies (Raynes-Greenow 2010; Schroy 2011; van Peperstraten 2010) referred to the Ottawa Decision Support Framework, one (Davison 1997) referred to the Empowerment Model by Conger and Kanungo, one (Stiggelbout 2008) to the Markov Model, and one (Butow 2004) did not provide detailed information.

One of the studies of interventions targeting patients reported performance of a barriers assessment (van Peperstraten 2010).

Interventions targeting healthcare professionals (eight studies)

Among the studies of interventions targeting healthcare professionals, four studies explicitly referred to a conceptual framework or a theory to justify their intervention (Elwyn 2004; Fossli 2011; Légaré 2012; Stacey 2006). One study (Stacey 2006) referred to the Ottawa Decision Support Framework, one (Elwyn 2004) referred to a model of interpersonal interaction, one (Fossli 2011) referred to the Four Habit Model, and one study (Légaré 2012) referred to the Theory of Planned Behaviour.

Of the eight studies of interventions targeting healthcare professionals, one (Stacey 2006) reported the performance of a barriers assessment and based its interventions on identified barriers.

Interventions targeting both patient and healthcare professionals (13 studies)

Five of the studies of interventions targeting both patients and healthcare professionals (Haskard 2008; Loh 2007; Murray 2010; Roter 2012; Wetzels 2005) referred to a conceptual framework or a theory to justify their interventions. One study (Murray 2010) referred to the Ottawa Decision Support Framework, one (Haskard 2008) referred to the 4E Model (Engage, Empathize, Educate and Enlist), one study (Roter 2012) referred to the LEAPS (Listen, Educate, Assess, Partner and Support) framework, one (Wetzels 2005) to the SWOT analysis (Strengths, Weaknesses, Opportunities and Threats), and one (Loh 2007) did not provide detailed information.

Of these studies, one (Murray 2010) reported the performance of a barriers assessment and based its interventions on identified barriers.

In summary, 15 studies out of the 39 included in this review used a conceptual framework. The Ottawa Decision Support Framework was the most cited framework. Lastly, only three based their interventions on barriers assessments.

Characteristics of outcomes

Characteristics of primary outcomes

Patient-reported outcome measures (PROM)

Among the 16 PROM studies, 14 unique scales or subscales were used to measure the adoption of SDM by healthcare professionals from a patient perspective. Patient-reported outcomes were predominantly represented by the 'perceived level of control in decision making' or 'assumed role during the consultation' (adaptation of the Control Preference Scale) in 15 studies (Butow 2004; Davison 1997; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Landrey 2012; Légaré 2012; Leighl 2011; Murray 2001; O'Cathain 2002; Raynes-Greenow 2010; Stiggelbout 2008; Street 1995; Vodermaier 2009). Other tools used were: COMRADE (Deinzer 2009; Elwyn 2004; Hamann 2007; Wetzels 2005), and the Man-Son-Hing Instrument or the Patient Participation Satisfaction scale (PPS) (Krones 2008 (ARRIBA-Herz); Loh 2007; Vodermaier 2009). There were also 11 unique scales or subscales used in the studies analysed. For more details, see Characteristics of included studies.

Observer-based outcome measures (OBOM)

Among the three OBOM studies, nine unique scales or subscales were used to measure the adoption of SDM by healthcare professionals from an observer-based perspective. The observer-based outcomes were predominantly represented by the OPTION scale in six studies (Elwyn 2004; Hess 2012; Montori 2011; Mullan 2009; Nannenga 2009; Shepherd 2011), and the Decision Support Analysis Tool (DSAT) in two studies (Murray 2010; Stacey 2006).

There were also seven unique scales or subscales used in the studies analysed. For more details, see Characteristics of included studies.

It was noteworthy that the primary outcome of only five out of the 39 studies included in this review was the same as the primary outcome of this review, that is a measure of healthcare professionals' adoption of SDM (Dolan 2002; Elwyn 2004; Krist 2007; O'Cathain 2002; Wetzels 2005).

Characteristics of secondary outcomes

Patient health measures

Eighteen studies (Bernhard 2011; Bieber 2006; Butow 2004; Cooper 2011; Davison 1997; Deinzer 2009; Elwyn 2004; Hamann 2007; Hess 2012; Krones 2008 (ARRIBA-Herz); Légaré 2012; Leighl 2011; Loh 2007; Murray 2001; Mullan 2009; Raynes-Greenow 2010; Stiggelbout 2008; van Peperstraten 2010) reported 51 patient health measures.

Duration of consultation

Thirteen studies (Butow 2004; Elwyn 2004; Fossli 2011; Krist 2007; Loh 2007; Montori 2011; Murray 2001; Murray 2010; Nannenga 2009; Shepherd 2011; Stacey 2006; Vodermaier 2009; Wetzels 2005) reported duration of consultation.

Other measurements reported by healthcare professionals

In 21 studies (Bernhard 2011; Bieber 2006; Butow 2004; Elwyn 2004; Hamann 2007; Haskard 2008; Hess 2012; Krist 2007; Krones 2008 (ARRIBA-Herz); Légaré 2012; Leighl 2011; Loh 2007; Mullan 2009; Murray 2001; Murray 2010; Roter 2012; Stacey 2006; Stiggelbout 2008; Street 1995; van Peperstraten 2010; Vodermaier 2009) 45 other measurements were reported by healthcare professionals.

Other measurements reported by patients

In 32 studies (Bieber 2006; Butow 2004; Deen 2012; Deinzer 2009; Deschamps 2004; Dolan 2002; Elwyn 2004; Fossli 2011; Hamann 2007; Haskard 2008; Hess 2012; Kasper 2008; Krist 2007; Krones 2008 (ARRIBA-Herz); Lalonde 2006; Landrey 2012; Légaré 2012; Leighl 2011; Loh 2007; Montori 2011; Mullan 2009; Murray 2001; Myers 2011; O'Cathain 2002; Raynes-Greenow 2010; Roter 2012; Schroy 2011; Stiggelbout 2008; Street 1995; van Peperstraten 2010; Vodermaier 2009; Wetzels 2005) 140 other measurements were reported by patients.

Risk of bias in included studies

Interventions targeting patients compared with usual care

Among the seven PROM studies (Cooper 2011; Deen 2012; Krist 2007; Landrey 2012; Murray 2001; van Peperstraten 2010; Vodermaier 2009), all had at least one unclear risk out of the seven risk of bias criteria. Four (Deen 2012; Krist 2007; Murray 2001; van Peperstraten 2010) studies had one high-risk bias and three (Cooper 2011; Landrey 2012; Vodermaier 2009) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of the evidence, in three studies information reported about participants was inadequate (Deen 2012; Murray 2001; Vodermaier 2009) and in one study the participants were couples (van Peperstraten 2010) and therefore not comparable to the other study populations. The interventions varied from one study to another. In one study (Cooper 2011) comparisons were indirect. In the four studies using continuous measures of SDM (Cooper 2011; Deen 2012; van Peperstraten 2010; Vodermaier 2009) the results reported were inconsistent. In the four studies using categorical measures of SDM (Krist 2007; Landrey 2012; Murray 2001; Vodermaier 2009) results reported were inconsistent.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

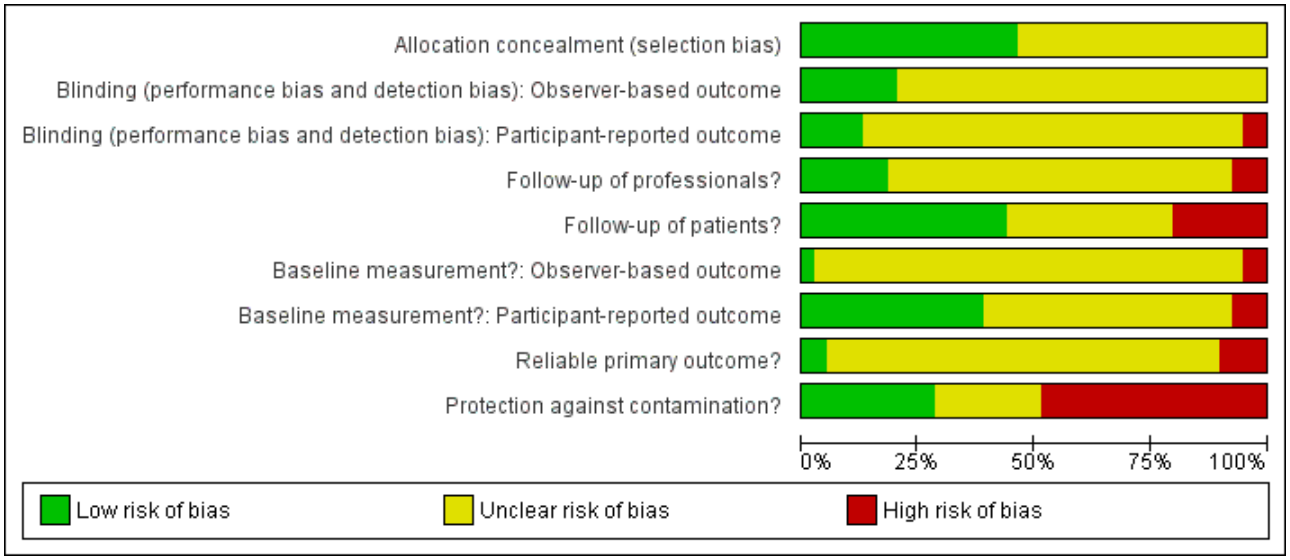


Figure 3. Risk of bias summary for each included study.

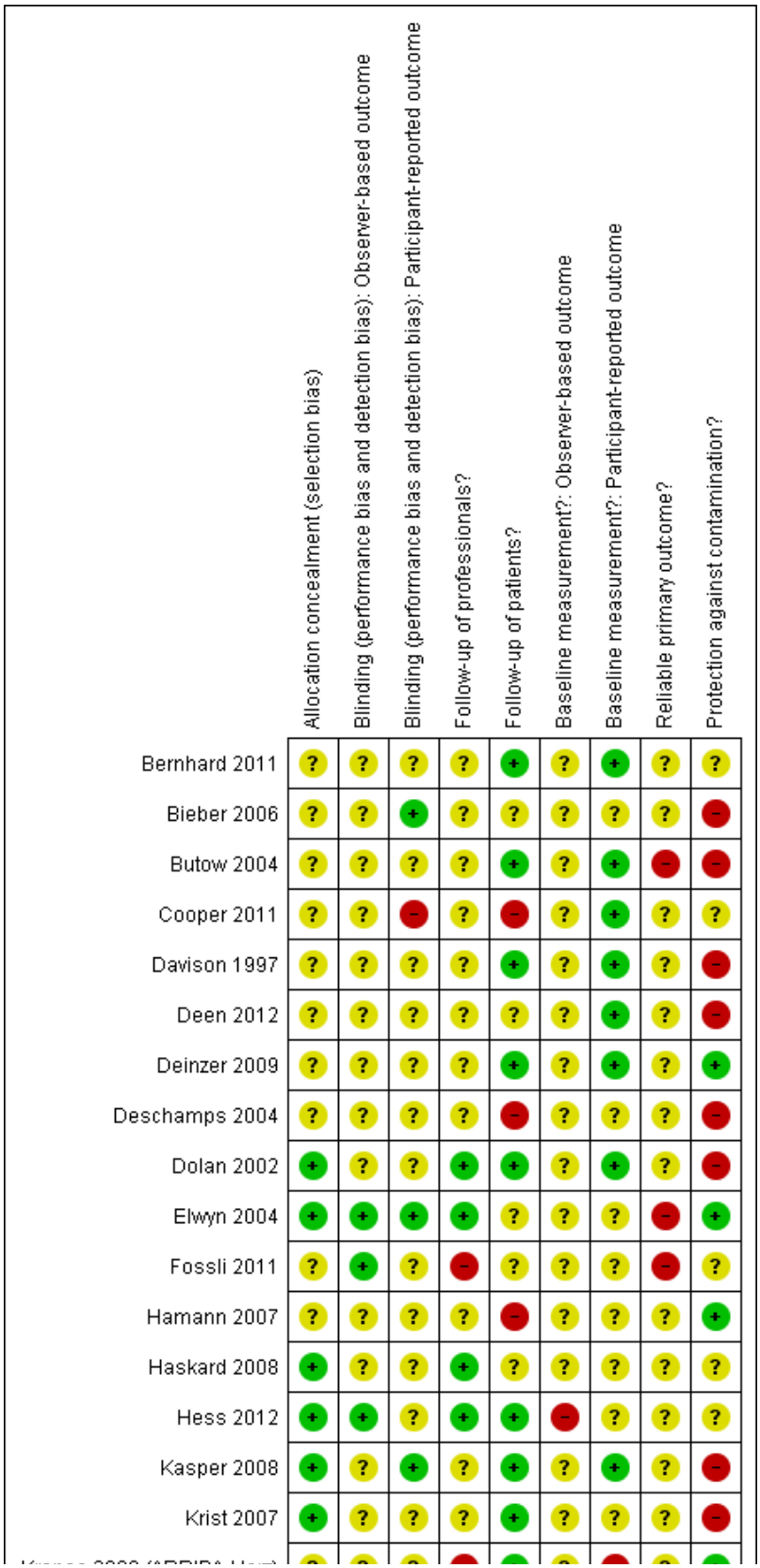
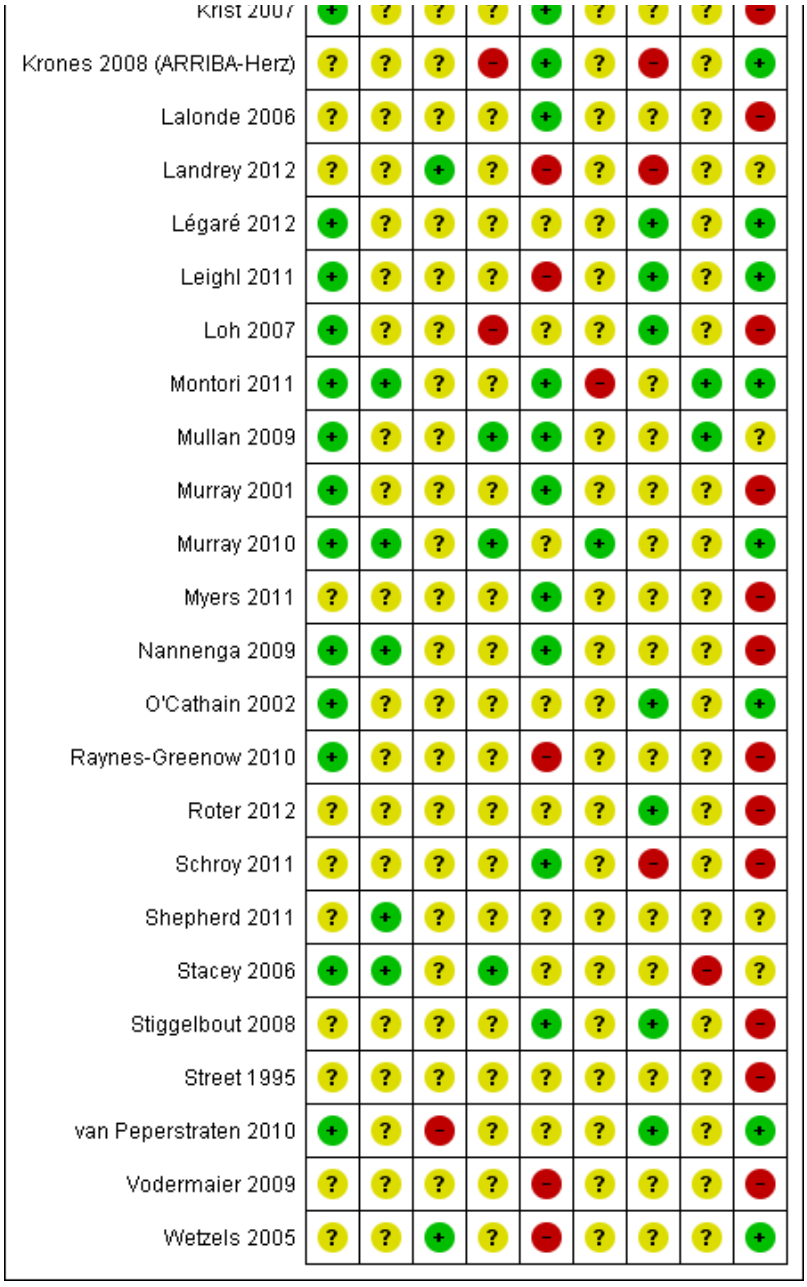


Figure 3. (Continued)



There was one OBOM study (Haskard 2008) which had at least one unclear risk out of the seven risk of bias criteria, and no high-risk bias (see Figure 2 and Figure 3). Regarding indirectness of the evidence, the only problematic criterion was intervention variability. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the heterogeneity across studies and the fact that all studies had potential bias from inadequate protection against contamination.

Interventions targeting patients compared with other interventions targeting patients

Among the 12 PROM studies (Butow 2004; Davison 1997; Deen 2012; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Lalonde 2006; Raynes-Greenow 2010; Schroy 2011; Stiggelbout 2008; Street 1995), 10 (Butow 2004; Davison 1997; Deen 2012; Deschamps 2004; Krist 2007; Lalonde 2006; Schroy 2011; Stiggelbout 2008; Street 1995) had at least one unclear risk out of the seven risk of bias criteria. Eight studies (Davison 1997; Deen 2012; Dolan 2002; Kasper 2008; Krist 2007; Lalonde 2006; Stiggelbout 2008; Street 1995) had one high-risk bias and four (Butow 2004; Deschamps 2004; Raynes-Greenow 2010; Schroy 2011) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of the evidence, in four studies there was inadequate information

about participants (Deen 2012; Kasper 2008; Lalonde 2006; Raynes-Greenow 2010). The interventions varied from one study to another. In two studies (Deschamps 2004; Lalonde 2006) comparisons reported were indirect. Two studies (Deen 2012; Schroy 2011) used continuous measures of SDM and their results were inconsistent. Eight studies (Butow 2004; Davison 1997; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Raynes-Greenow 2010; Stiggelbout 2008) used categorical measures of SDM and their results were consistent. Three studies reported qualitative statements (Butow 2004; Lalonde 2006; Street 1995) and were imprecise as to the observed effect.

Of the two OBOM studies (Montori 2011; Nannenga 2009), one (Nannenga 2009) had at least one unclear risk out of the seven risk of bias criteria. Both studies had one high-risk bias (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, the only problematic criterion was that the intervention varied from other studies. The two studies used continuous measures of SDM and the results reported were consistent. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the heterogeneity across the types of patient-mediated interventions and the fact that all studies had potential bias from inadequate protection against contamination.

Interventions targeting healthcare professionals compared with usual care

Among the four PROM studies (Bernhard 2011; Cooper 2011; Légaré 2012; O'Cathain 2002) all reported at least one unclear risk out of the seven risk of bias criteria. One study (Cooper 2011) reported two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, all studies reported on similar populations, but the intervention varied from one study to another. In one study (Cooper 2011) the comparisons were indirect. One study (Cooper 2011) used a continuous measure of SDM. Two studies (Légaré 2012; O'Cathain 2002) used categorical measures of SDM and the results were inconsistent. One study reported qualitative statements (Bernhard 2011) and was imprecise as to the observed effect.

Among the three OBOM studies (Fossli 2011; Shepherd 2011; Stacey 2006) all had at least one unclear risk out of the seven risk of bias criteria. One study had one high-risk bias (Stacey 2006) and one study had two high-risk biases (Fossli 2011) (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, two studies (Shepherd 2011; Stacey 2006) used standardized patients and in one study (Fossli 2011) there was inadequate information about the participants. The interventions varied from one study to another. There were no indirect comparisons in these studies. The three studies used continuous measures, their results were inconsistent, and they were imprecise as to the observed effect because of small sample size. There was publication bias in these studies.

Interpretation of results for this comparison needed to consider that half of the studies were small and there was heterogeneity across the types of population included.

Interventions targeting healthcare professionals compared with another interventions targeting patients

One study used PROM (Cooper 2011). This study had at least one unclear risk out of the seven risk of bias criteria and two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, the quality of evidence was downgraded because: 1) the intervention varied from one study to another, and 2) the comparisons were indirect.

Interpretation of results for this comparison needed to recognize that findings were based on only one highly biased study.

Interventions targeting healthcare professionals compared with other interventions targeting healthcare professionals

In both PROM studies (Elwyn 2004; Krones 2008 (ARRIBA-Herz)) there was at least one unclear risk out of the seven risk of bias criteria. One study (Krones 2008 (ARRIBA-Herz)) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, both studies reported on similar populations. The intervention varied between studies. There were indirect comparisons in one study (Elwyn 2004). Both studies used continuous measures and results were inconsistent.

In the one OBOM study (Elwyn 2004) there was least one unclear risk out of the seven risk of bias criteria and no high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, the quality of evidence was downgraded because: 1) the intervention varied from one study to another, and 2) the comparisons were indirect. This study used continuous measures of SDM and results were imprecise as to the observed effect because of the small sample size. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the significant findings from one highly biased study due to problems with follow-up of professionals and baseline measurement.

Interventions targeting both patients and healthcare professionals compared with usual care

All five PROM studies (Cooper 2011; Hamann 2007; Leighl 2011; Loh 2007; Wetzels 2005) had at least one unclear risk out of the seven risk of bias criteria. Three studies (Hamann 2007; Leighl 2011; Wetzels 2005) had one high-risk bias, and two studies (Cooper 2011; Loh 2007) had two high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, in two studies there was inadequate information about participants (Hamann 2007; Wetzels 2005). The intervention varied from one study to another. Comparisons in one study (Cooper 2011) were indirect. Three studies (Cooper 2011; Hamann 2007; Wetzels 2005) used continuous measures of SDM and their results were consistent. Two studies reported qualitative statements (Leighl 2011; Loh 2007) and were imprecise as to the observed effect.

All three OBOM studies (Haskard 2008; Hess 2012; Murray 2010) had at least one unclear risk out of the seven risk of bias criteria. One study (Hess 2012) had one high-risk bias (see Figure 2 and Figure 3). Regarding criteria for evaluating the indirectness of evidence, the intervention varied from one study to another. There was publication bias in the two OBOM studies with continuous outcomes (Haskard 2008; Hess 2012). One study (Murray 2010)

reported qualitative statements and was imprecise as to the observed effect.

This comparison group had the most homogenous studies. However, interpretation of results needed to consider the small number of studies and the presence of some methodological bias.

Interventions targeting both patients and healthcare professionals compared with interventions targeting patients

All four PROM studies (Bieber 2006; Cooper 2011; Deinzer 2009; Mullan 2009) had at least one unclear risk out of the seven risk of bias criteria. One study (Bieber 2006) had one high-risk bias and one had two (Cooper 2011) (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, all studies reported on similar populations. The intervention varied from one study to another. Comparisons in all studies were indirect. Three studies (Bieber 2006; Cooper 2011; Mullan 2009) used continuous measures of SDM and their results were inconsistent. One study (Deinzer 2009) reported qualitative statements and was imprecise as to the observed effect.

The one OBOM study (Mullan 2009) had at least one unclear risk out of the seven risk of bias criteria and no high-risk biases (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, two criteria were problematic: 1) the interventions varied, and 2) comparisons were indirect. This study used continuous measures of SDM and had a small sample size. There was publication bias in the OBOM studies with continuous outcomes.

Interpretation of results for this comparison needed to consider the heterogeneity across studies and the fact that most studies had multiple arms.

Interventions targeting both patients and healthcare professionals compared with interventions targeting only healthcare professionals

Both studies using patient-reported outcome measures (Cooper 2011; Roter 2012) reported at least one unclear risk out of the seven risk of bias criteria. There was one high-risk bias in one study (Roter 2012) and two in the other (Cooper 2011) (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, only two criteria were problematic: the interventions varied, and comparisons were indirect. One study (Cooper 2011) reported continuous measures of SDM. One study (Roter 2012) reported qualitative statements and was imprecise as to the observed effect.

Interpretation of results for this comparison needed to consider that findings were based on only two highly biased studies.

Interventions targeting both patients and healthcare professionals compared with other interventions targeting both patients and healthcare professionals

One OBOM study (Myers 2011) had at least one unclear risk out of the seven risk of bias criteria and one high-risk bias (see Figure 2 and Figure 3). Regarding evaluation of the indirectness of evidence, two criteria were problematic: 1) the interventions varied, and 2) comparisons were indirect.

None of the included studies were exempt from bias and there was a publication bias for OBOM and PROM studies with continuous data; there appeared to be a lack of published studies with negative results on a continuous score. No publication bias was found in PROM studies with categorical measures (only one OBOM study used categorical measures). For more details, see Figure 4; Figure 5 and Figure 6. As the funnel plot showed there were few negative OBOM studies, therefore positive OBOM studies could have been over-represented in our review.

Figure 4. Patient-reported outcome (categorical measure).

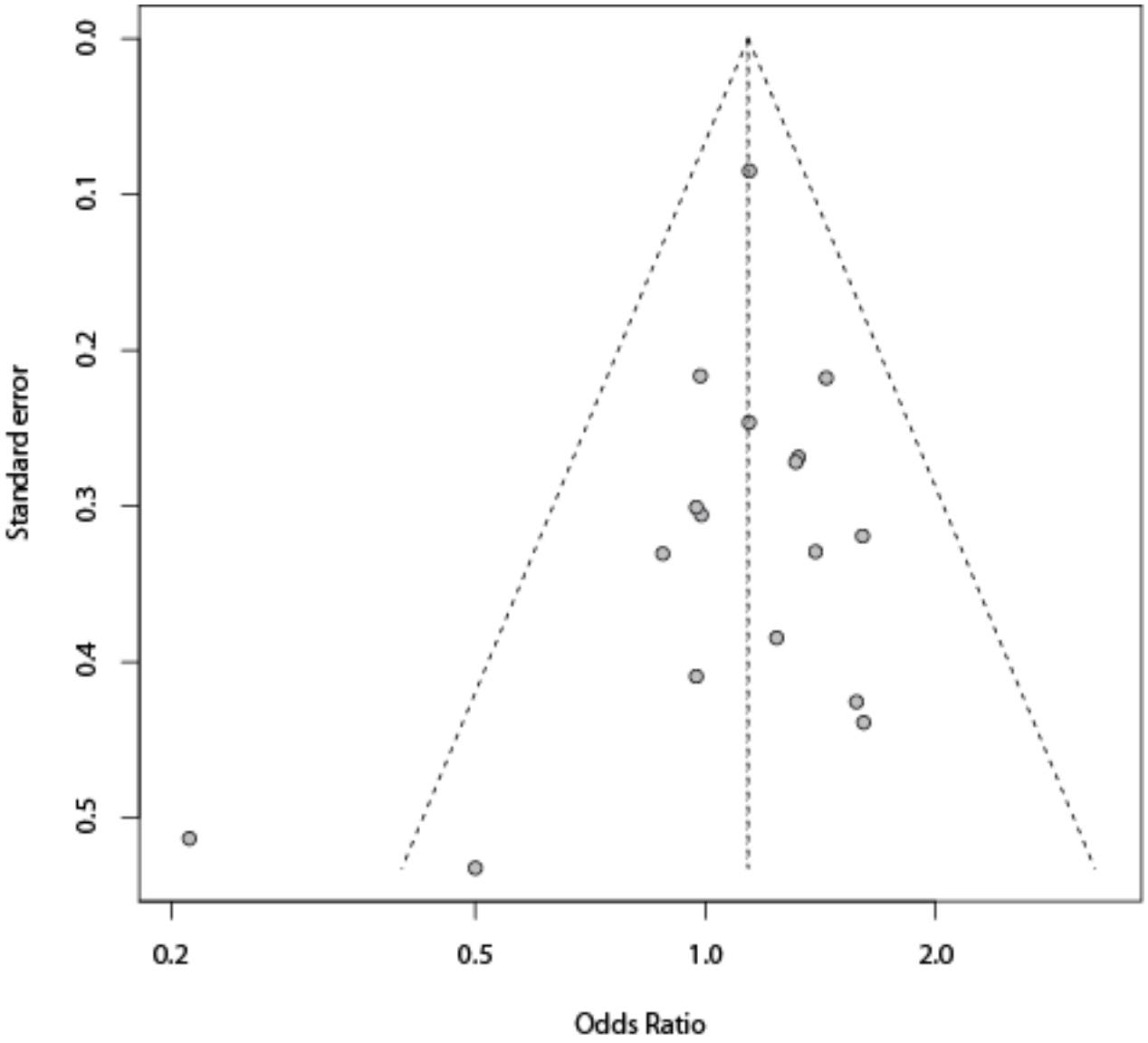


Figure 5. Observer-based outcome (continuous measure).

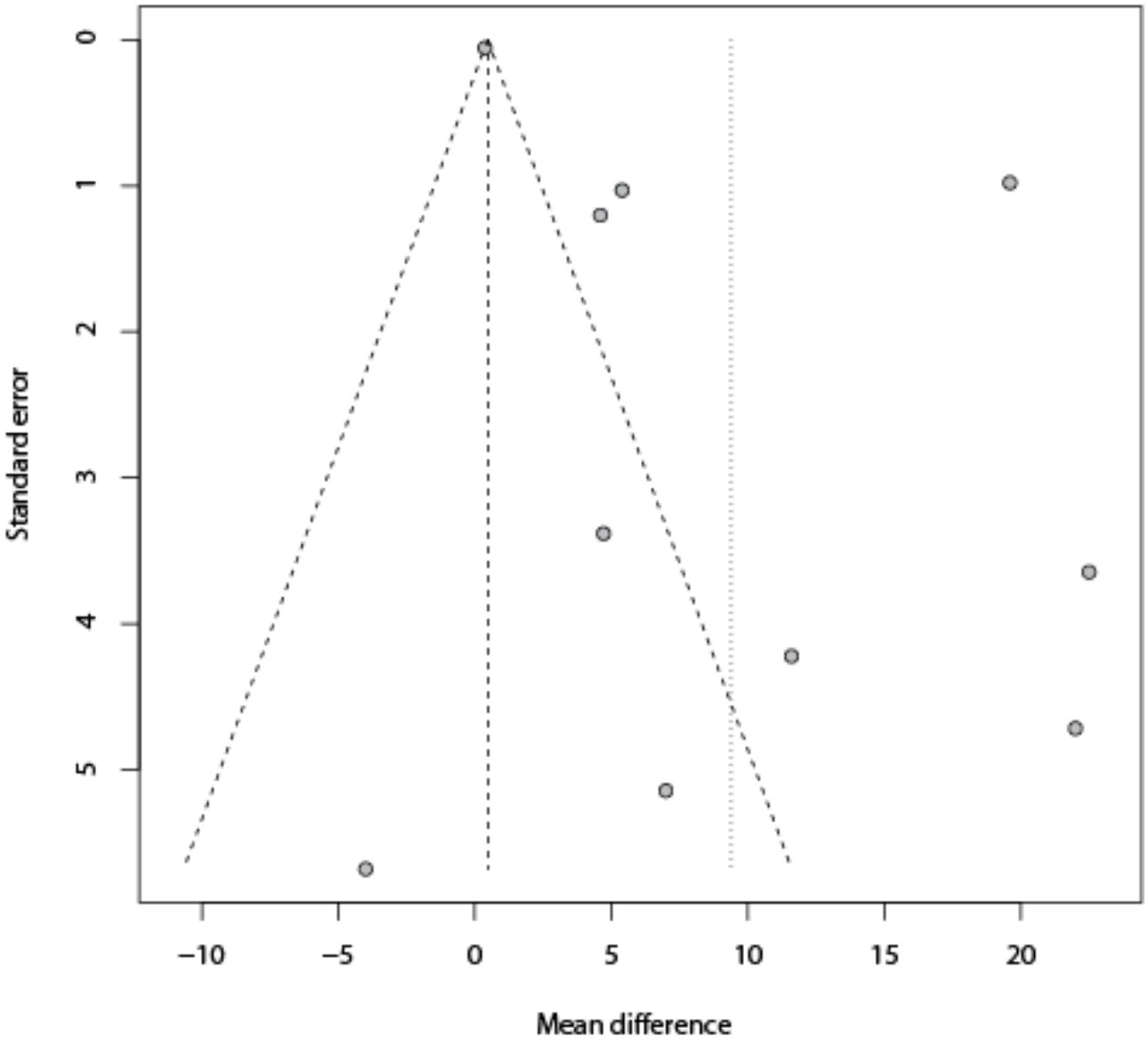
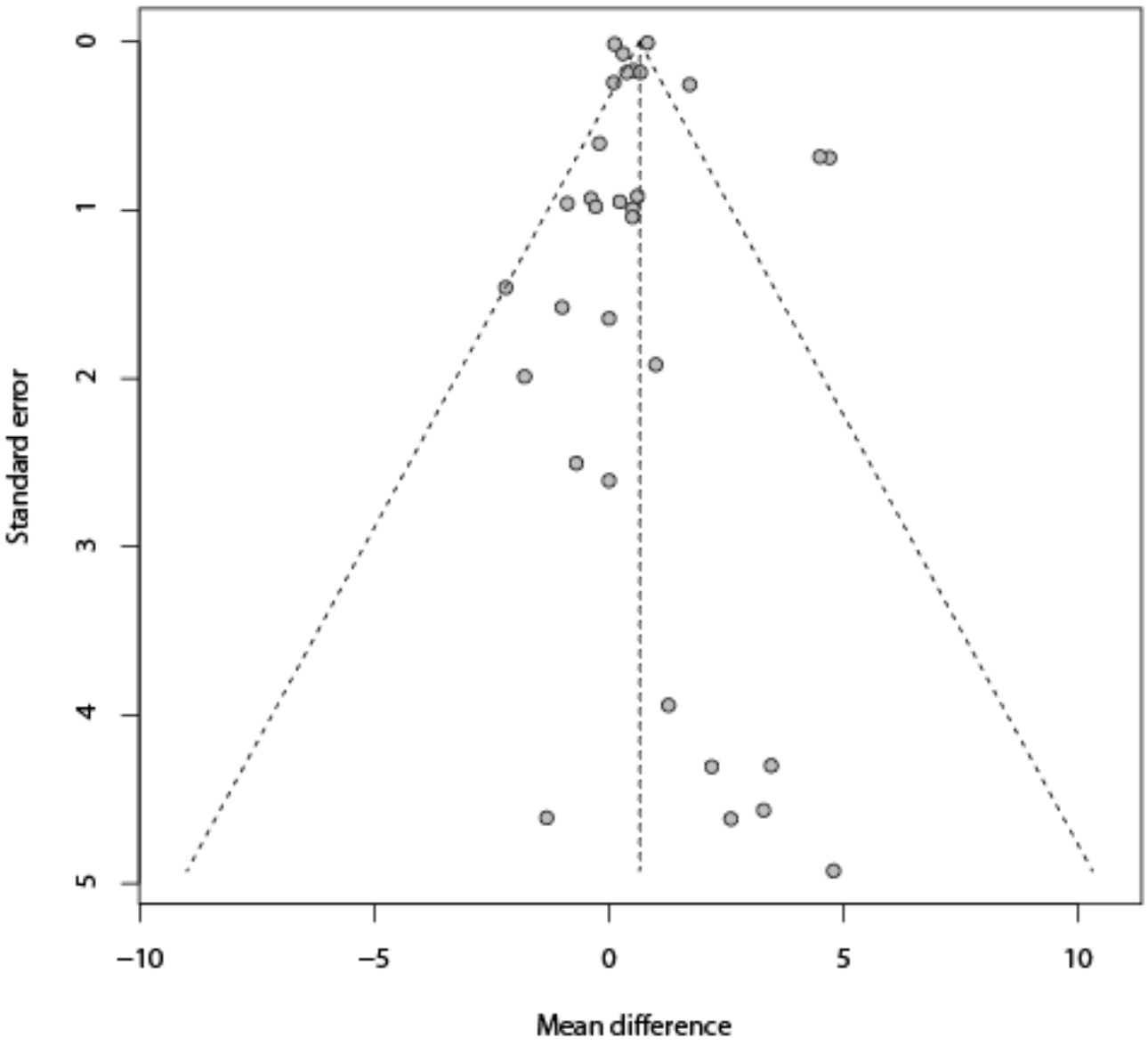


Figure 6. Patient-reported outcome measure (continuous measure).



Interpretation of results for this comparison needed to consider that findings were based on only one highly biased study.

Effects of interventions

See: **Summary of findings for the main comparison**

Primary outcome

Interventions targeting patients compared with usual care

For more details, see Table 1.

Data from six continuous PROMs in four RCTs were evaluated (Cooper 2011; Deen 2012; van Peperstraten 2010; Vodermaier 2009). Data from three studies (Cooper 2011; Deen 2012; van Peperstraten 2010) were available for re-analysis. The median of the standardized mean difference was 0.21 (range 0.04 to 0.50) indicating a small improvement for the group that received the intervention targeting patients.

Data from five categorical PROMs in four RCTs were evaluated (Krist 2007; Landrey 2012; Murray 2001; Vodermaier 2009). We calculated a 0.02 reduction in the median of the risk difference for these outcomes (range -0.28 to -0.01) indicating no evidence of a difference for the group that received the intervention targeting patients.

Data from three continuous OBOMs in one RCT were evaluated (Haskard 2008). A unit of analysis error was observed in this study, and so we could not estimate the statistical significance of the effects reported.

Interventions targeting patients compared with other interventions targeting patients

For more details, see Table 2.

Data from six continuous PROM in two RCTs were evaluated (Deen 2012; Schroy 2011). The median standardized mean difference was 0.29 (-0.05 to 0.63), indicating a small improvement for the group that received a multifaceted patient-mediated intervention (Schroy 2011) compared to the group that received only educational material (Schroy 2011).

Data from 11 categorical PROMs in eight RCTs were evaluated (Butow 2004; Davison 1997; Deschamps 2004; Dolan 2002; Kasper 2008; Krist 2007; Raynes-Greenow 2010; Stiggelbout 2008). We calculated a 0.04 improvement in the median of the risk difference for these outcomes (range -0.21 to 0.12) indicating no evidence of a difference between the two interventions targeting patients.

Three outcomes from three studies (Butow 2004; Lalonde 2006; Street 1995) could not be included in this analysis because of incomplete data sets. None of the authors of the three studies reported any improvement after exposure of study participants to the intervention targeting patients.

Data from two continuous OBOMs in two RCTs were evaluated (Montori 2011; Nannenga 2009). The median of the standardized mean difference was 1.13 (range 1.04 to 1.21) indicating a large improvement for the group that received a patient decision aid (Montori 2011) compared to the group that received a booklet (Montori 2011).

Interventions targeting healthcare professionals compared with usual care

For more details, see Table 3.

Data from one continuous PROM in one RCT were evaluated (Cooper 2011). The standardized mean difference was 0.11.

Data from three categorical PROMs in two RCTs were evaluated (Légaré 2012; O'Cathain 2002). The median of the risk difference was 0.05 (range 0.00 to 0.09) indicating a small improvement for the group that received the healthcare professional targeted intervention.

One outcome from one study (Bernhard 2011) could not be included in this analysis because of incomplete data sets. Study authors reported no improvement after exposure of study participants to the intervention targeting healthcare professionals.

Data from four continuous OBOMs in three RCTs were evaluated (Fossli 2011; Shepherd 2011; Stacey 2006). The median of the standardized mean difference was 1.08 (range 0.38 to 2.07) indicating a significant improvement for the group that received the intervention targeting healthcare professionals.

Interventions targeting healthcare professionals compared with interventions targeting patients

For more details, see Table 4.

Data from one continuous PROM in one RCT were evaluated comparing an intervention targeting healthcare professionals with an intervention targeting patients (Cooper 2011). The standardized mean difference was -0.12.

Interventions targeting healthcare professionals compared with other interventions targeting healthcare professionals

For more details, see Table 5.

Seven continuous PROMs in two RCTs were evaluated (Elwyn 2004; Krones 2008 (ARRIBA-Herz)). The median of the standardized mean difference was 0.20 (range -0.09 to 0.48) indicating some improvement in the group that received a multifaceted intervention (that is an educational meeting, audit and feedback, distribution of educational materials, and educational outreach visit) (Krones 2008 (ARRIBA-Herz)) compared to the group that received a single intervention (for example an educational meeting on an alternative topic) (Krones 2008 (ARRIBA-Herz)).

Data from one continuous OBOM in one RCT were evaluated (Elwyn 2004). The standardized mean difference for this study was -0.30.

Interventions targeting both patients and healthcare professionals compared with usual care

For more details, see Table 6.

Data from three continuous PROMs in three RCTs were evaluated (Cooper 2011; Hamann 2007; Wetzels 2005). Data from two studies (Cooper 2011; Hamann 2007) were available for re-analysis. The median of the standardized mean difference was 0.16 (range 0.16 to 0.16) indicating no evidence of a difference for the group that received the intervention targeting patients and healthcare professionals.

Two outcomes from two studies (Leighl 2011; Loh 2007) could not be included in this analysis because of incomplete data sets. Authors of one of these studies reported that outcomes improved after exposure of study participants to interventions targeting both patients and healthcare professionals (Loh 2007).

Data from four continuous OBOMs in two RCTs were evaluated (Haskard 2008; Hess 2012). A unit of analysis error was observed in one study (Haskard 2008) and so we could not estimate the statistical significance of the effects reported. The standardized mean difference for the other study was 2.83, indicating significant improvement for the group that received the intervention targeting both patients and healthcare professionals.

One outcome from one study (Murray 2010) could not be included in this analysis because of incomplete data sets. Study authors reported significant improvement after exposure of study participants to an intervention targeting both patients and healthcare professionals.

Interventions targeting both patients and healthcare professionals compared with interventions targeting patients

For more details, see Table 7.

Data from five continuous PROMs were evaluated in three RCTs (Bieber 2006; Cooper 2011; Mullan 2009). The median of the standardized mean difference was 0.09 (range -0.06 to 0.73) indicating no evidence of a difference for the group that received the intervention targeting patients and healthcare professionals.

Data from two outcomes from one study (Deinzer 2009) could not be included in this analysis because of incomplete data sets. Study authors reported significant improvement for one outcome after exposure of study participants to an intervention targeting both patients and healthcare professionals.

Data from one continuous OBOM in one RCT were evaluated (Mullan 2009). The standardized mean difference was 1.42, indicating significant improvement for the group that received the intervention targeting both patients and healthcare professionals.

Interventions targeting both patients and healthcare professionals compared with interventions targeting healthcare professionals only

For more details, see Table 8.

Data from one continuous PROM in one RCT were evaluated (Cooper 2011). The standardized mean difference for this study was 0.06 indicating no evidence of a difference between groups.

One outcome from one study (Roter 2012) could not be included in this analysis because of incomplete data sets. The authors reported that outcomes improved after exposure of study participants to interventions targeting both patients and healthcare professionals.

Interventions targeting both patients and healthcare professionals compared with other interventions targeting both patients and healthcare professionals

For more details, see Table 9.

Data from one categorical OBOM in one RCT were evaluated (Myers 2011). The risk difference for this study was -0.04, indicating no evidence of a difference between the two interventions targeting both patients and healthcare professionals.

Heterogeneity

While the goal of this review was not to conduct a meta-analysis, we did briefly explore causes of heterogeneity. Given that we observed heterogeneity in comparison groups with enough studies, the positive effect found in some studies could not be explained by study characteristics only.

Secondary outcomes

Additional data were available in 'Additional tables': Table 10, Table 11, Table 12 and Table 13.

There was no significant effect detected for most secondary outcomes. No evidence of harms to patients was found following these interventions. We have present outcomes that were statistically significant; however, given that the majority of the outcomes had no effect, caution was needed in determining if the measure was relevant.

Patient health measures

Two studies reported an effect related to patient health (Elwyn 2004; van Peperstraten 2010). The Elwyn 2004 study reported two continuous measures of patient health with a small effect size. The authors nevertheless felt it was not clinically significant. A statistically significant standardized effect size of 0.25 (95% CI 0.02 to 0.49) was reported for one measure of anxiety (lower anxiety) when healthcare professionals received an SDM intervention compared to when they received a risk communication intervention. A statistically significant standardized effect size of 0.24 (95% CI 0.00 to 0.47) was also reported for one measure of mental health status when healthcare professionals received a risk communication intervention compared to when they received an SDM intervention. The van Peperstraten 2010 study reported one categorical measure of patient health with a risk difference of 0.09 (95% CI 0.02 to 0.16) for subclinical depression.

Duration of consultation

An effect related to the duration of the consultation was observed in two studies (Montori 2011; Murray 2010).

Other measurements reported by the healthcare professionals

An effect related to measures reported by the healthcare professionals was observed in five studies (Elwyn 2004; Murray 2010; Roter 2012; Stacey 2006; van Peperstraten 2010) with eight measures. Two studies (Murray 2010; Stacey 2006) showed that the knowledge of the healthcare professional was significantly higher in the intervention group than in the control group. One study (Elwyn 2004) using three measures reported that, according to the healthcare professionals, patients in the intervention group had greater agreement with their provider, satisfaction with the decision making and overall consultation, and satisfaction with the information reported. One study (Roter 2012) using two measures reported better treatment adherence and interpersonal rapport in the intervention group. Economic evaluation was only performed in one of the studies included in this review (van Peperstraten 2010); the patient-mediated intervention effectively reduced the cost of clinical in vitro fertilization by increasing single (versus multiple) embryo transfers.

Other measurements reported by the patients

Details of these results are presented in Table 13.

DISCUSSION

Summary of main results

This updated search added 34 new studies to the five studies included in the original Cochrane review for a total of 39 studies. It should be noted that 1400 professionals were enrolled in the 39 studies, with a minimum enrolment of two (Davison 1997) and a maximum of 270 (Légaré 2012), and there were 23,236 patients overall.

The countries most represented in this review were the United States, Germany and Canada. Only two of the 39 included studies were conducted with international collaborations (Bernhard 2011; Leighl 2011). Primary care was the setting of the majority of included studies and only one study was conducted in both primary and specialized care (Deen 2012). It is noteworthy that the primary outcome of only five out of the 39 studies was the same as the

primary outcome of this review, that is a measure of healthcare professionals' adoption of SDM (Dolan 2002; Elwyn 2004; Krist 2007; O'Cathain 2002; Wetzels 2005).

For categorical measures of SDM, we observed no effect.

For continuous measures of SDM, we observed three main types of results: 1) slight significant effect, 2) dose-response pattern with no conclusive effect, and 3) non-significant effect. More specifically, for studies using continuous PROMs we observed a slight significant effect in three categories of comparison: 1) interventions targeting patients compared to usual care, 2) interventions targeting patients compared to other interventions targeting patients, and 3) interventions targeting healthcare professionals compared to other interventions targeting healthcare professionals. For studies using continuous OBOMs we observed a slight significant effect in two categories of comparisons: 1) interventions targeting patients compared to other interventions targeting patients, and 2) interventions targeting healthcare professionals compared to usual care.

We observed a non-significant effect for studies using continuous PROMs in three categories of comparison: 1) interventions targeting both patients and healthcare professionals compared to usual care, 2) interventions targeting both patients and healthcare professionals compared to interventions targeting patients alone, and 3) interventions targeting both patients and healthcare professionals compared to interventions targeting healthcare professionals alone. There was no study reporting a continuous measure of SDM for the last category of comparison, interventions targeting both patients and healthcare professionals compared to interventions targeting both patients and healthcare professionals.

There was no significant effect detected for most of the secondary outcomes either, even for outcomes that could be impacted by adoption of SDM: duration of consultation, patient's health, and cost of the intervention.

Overall, our main results lead us to make the following observations.

First, while one precise intervention cannot be recommended over another, this review suggests that SDM interventions that actively target patients, health professionals, or both, are better than no intervention at all. Also, these results suggest that interventions targeting health professionals may achieve more than interventions targeting patients when each of these single-target interventions are compared to usual care. In addition, they indicate that among interventions targeting patients some types perform better than others (for example a patient decision aid compared to a booklet (Montori 2011)). Although limited by the number of studies included in each category of comparison, our update does tell us something about whom the intervention should target. Targeting both members of the decision-making dyad (patient and healthcare professional) may be more likely to be effective than those targeting solely the healthcare professional or solely the patient. SDM represents a complex set of behaviours in which both members of the patient-healthcare professional dyad, and preferably the whole patient healthcare team, must engage (LeBlanc 2009). Future studies may consider both participants simultaneously to account for the impact of interaction, reciprocity and interdependence on the process (Guerrier 2013).

Second, among the 39 included studies only three targeted more than one type of healthcare professional, but all were positive. Although this appears promising, the lack of studies addressing the interprofessional approach is clearly a major limitation to understanding the implementation of SDM in clinical practice. Many healthcare systems are moving towards an interprofessional healthcare team-based approach to patient care that will require this approach to decision making (Légaré 2008b). An interprofessional approach to SDM is an emerging field of research (Légaré 2011) and the reporting of an interprofessional approach to SDM is not yet standardized. In this review, authors only needed to report that the intervention involved more than one type of professional to be identified as taking an interprofessional approach to SDM. Therefore, more studies are needed to inform policy makers about the content, definition and effectiveness of an interprofessional approach to SDM.

Third, although the study of the implementation of SDM in healthcare professionals' practice is growing exponentially, we still need more international collaboration. Studies by international collaborations are starting to be published but these international collaborations do not involve low-income countries, which are still under-represented in the list of countries in which SDM is on the policy makers' agenda (Härter 2011). One international collaboration involves Australia and Canada, for example; another involves Austria, Australia, Canada, Germany, New Zealand and Switzerland. Multi-country approaches permit the sharing of expertise and experiences regarding interventions in a range of settings. It would be important to expand this valuable knowledge base by including middle- and low-income countries (International Shared Decision Making 2013). Specialized care clinical settings were also to some extent under-represented in the studies included in this updated review, with only one study targeting both primary and specialized care. However, only four studies reflected the clinical heterogeneity that is the norm in primary care by focusing on a set of diverse clinical conditions (Elwyn 2004; Haskard 2008; Stacey 2006; Wetzels 2005), indicating that research is still slow in taking this basic characteristic of primary care into account. Most studies included in this updated review focused on licensed healthcare professionals, demonstrating the need for further implementation studies involving healthcare professionals in training as well (Stacey 2009). In terms of the clinical conditions targeted in the included studies, cancer and cardiovascular diseases were the most common. Implementation studies in SDM are thus addressing the diseases that healthcare professionals are most likely to encounter in their practice; these diseases have also been identified as the two most important causes of the global burden of disease (Institute for Helath Metrics and Evaluation 2013). However, more implementation studies in the area of multi-morbidity are needed (Smith 2012).

Fourth, three of the secondary outcomes were worthy of note, but the results of the secondary outcomes must be interpreted with caution because most of the included studies did not show that the intervention had a statistically significant effect on healthcare professionals' adoption of SDM. First, the impact of SDM on length of consultations is still unclear. Second, in this review, 58 patient health measures were used to describe the impact of interventions on patient health outcomes, and all but two of these measurements (measures of anxiety and measure of mental health status) were non-significant. Lastly, an economic evaluation was undertaken in only one of the 39 studies included in this review, although this was

effective and resulted in a reduction of the cost of the intervention (van Peperstraten 2010). It should be noted that no evidence of harms to patients was found following these interventions.

Quality of the evidence

Overall, when reviewing studies assessing the impact of any interventions to improve the adoption of SDM by healthcare professionals, we observed that the evidence was of low quality. First, there is still no consensus on which type of measure (OBOM or PROM) is most accurate. However, there were differences between studies based on the type of measure they used. Each kind of study used different scales to capture SDM. In OBOM studies, the most commonly used instrument was OPTION, and in PROM studies the 'perceived level of control in decision making' scale (adapted from the Control Preference Scale) was most common. As for studies not using either of these two scales there were as many instruments as studies. These findings confirm that there is still no standardized instrument for assessing the adoption of SDM by healthcare professionals. However, we observed that studies that had coded SDM behaviours into categories that matched the eight essential elements of Makoul's definition of SDM (Makoul 2006) had the most significant results, and most of these were OBOM studies. This line of inquiry needs to be pursued with a systematic analysis. Finally, it is important to highlight that in only five out of the 39 studies included in this review was the primary outcome of the study the same as the primary outcome of this review (Dolan 2002; Elwyn 2004; Krist 2007; O'Cathain 2002; Wetzels 2005), that is the adoption of SDM by healthcare professionals. This could explain the lack of positive effect in the majority of the studies. As the implementation of SDM in clinical practice was not their primary outcome of interest, they may not have been sufficiently powered to accurately assess its adoption by healthcare professionals.

Second, it is important to note that in line with the EPOC taxonomy of interventions we refer to patient-mediated interventions as single entities and we have not disentangled the effectiveness of various elements of multifaceted patient-mediated interventions. However, this information is contained in the tables. Moreover, we included a number of EPOC intervention types in the same intervention category. It would be important to consider the distinctions between EPOC intervention types in a further update that includes more studies.

In conclusion, due to the heterogeneity of interventions that were used, primary outcomes assessed, and the risks of bias that were observed, we cannot draw a robust conclusion regarding the objectives of our review, that is about the most effective types of intervention for increasing the adoption of SDM by healthcare professionals. The message of the study is nevertheless that SDM interventions that actively target patients, health professionals, or both, are better than no intervention at all. Also, it appears more promising to use interventions that target both the patient and the health professional together than those that target either the patient or the health professional alone. The overall quality of the evidence for the outcomes, assessed with the GRADE tool, ranged from low to very low.

Potential biases in the review process

We observed a potential publication bias in studies reporting a continuous OBOM measure of SDM. There appeared to be a lack of negative, continuous OBOM studies, implying that positive continuous OBOM studies might be over-represented.

The adoption of SDM by healthcare professionals translates into the performance of a number of SDM-related behaviours by both the patient and the healthcare professional (Frosch 2009; Légaré 2007a). We acknowledge that the assessment of this complex behaviour in healthcare professionals, and even more so in dyads of patients and healthcare professionals, is challenging and may suffer from many measurement biases (Butow 2009).

Overall, we were unable to extract much information regarding the general context of the included studies. We relied on published and publicly available material and contacted authors of included studies to obtain more information when needed. However, we were not able to always get an answer from them.

Agreements and disagreements with other studies or reviews

The Dwamema update (Dwamena 2012) of a Cochrane systematic review (Lewin 2001) on the effects of interventions targeting healthcare professionals that aim to promote patient-centered care approaches in clinical consultations concluded that some interventions, such as training activities, are effective across studies in transferring patient-centered skills to providers. The new finding of the Dwamema review was that short-term training (less than 10 hours) is as successful as longer training for promoting patient-centered care within clinical consultations. All the studies included in Dwamema's review that identified shared decision making as an aim of patient-centered care (Bieber 2008; Krones 2008 (ARRIBA-Herz); Loh 2007; Longo 2006) were also included in the present review, some as primary studies (Krones 2008 (ARRIBA-Herz); Loh 2007) and others as complementary studies (Bieber 2008; Longo 2006).

Our review sought studies on all the types of intervention suggested by the EPOC taxonomy, including patient-mediated interventions, while the Dwamema review focused solely on interventions targeting healthcare professionals in training. We believe that together the reviews add to the knowledge base and can inform policy makers on important implementation strategies regarding SDM in healthcare professionals' practices.

We also identified a recently published Cochrane review on the effects of interventions to promote SDM with children aged four to 18 years who are suffering from cancer (Coyne 2011). This review did not find any eligible studies.

Finally, the idea that effective interventions for changing clinical practice must target patients as well as healthcare professionals is gaining interest outside the SDM community. A recent systematic review on factors that differentiate between effective and ineffective computerized clinical decision support systems in improving the process of care or improving patient outcomes indicated that the likelihood of success was greater with systems that provided advice to patients and practitioners concurrently (Roshanov 2013).

AUTHORS' CONCLUSIONS

Implications for practice

The results of this Cochrane review do not allow us to draw firm conclusions regarding the types of intervention that are the most effective for increasing healthcare professionals' adoption of SDM across multiple studies. It is uncertain whether interventions aiming to improve adoption of SDM lead to better uptake given the low quality of the evidence. However, SDM interventions that actively target patients, health professionals, or both, are better than no intervention at all. Also, interventions targeting patients and healthcare professional together may be more promising than those targeting only one or the other. However, there were not enough studies (only two) to confirm this.

Implications for research

Several gaps in knowledge exist regarding the effectiveness of interventions focused on improving healthcare professionals' adoption of SDM.

- Future studies should be designed to minimize bias and should have enough power to estimate the effects of active interventions on healthcare professionals' adoption of SDM (primary outcome).
- Further research is needed to develop better patient-derived measures of SDM.
- Further research is required to assess the same intervention across multiple studies and also across diverse jurisdictions (i.e. international collaborations).
- Future research should assess the effect of interventions that target both the patient and the healthcare professional to confirm this result (only two studies at present).
- Further research is required to determine more clearly the effectiveness and the cost of interventions to improve healthcare professionals' adoption of SDM.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bernhard 2011

Methods	**Study design**: Clinician RCT **Unit of allocation**: Clinician **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized care; Ambulatory care; Australia, New Zealand, Switzerland, Germany, and Austria **Health professionals**: 62; Various type of physician (Medical, surgical, radiation and gynaecological oncologists) ; Fully trained **Patients**: 694; Breast cancer; Female **Recruitment information** "Medical, surgical, radiation and gynaecological oncologists, working in major cancer centres or clinics (including private oncologists) , ... were eligible. The following patient criteria were additionally required: ... capable of participating." Page 2
Interventions	**1. Multifaceted intervention:** Educational meeting, audit and feedback, distribution of educational materials (interactive face-to face workshop and two follow-up telephone calls) "The training consisted of a 7 hours interactive face to-face workshop with one to two follow-up telephone calls over 2 months. The elements of this training were evidence-based .... The training focused on four key concepts: ... The workshops were held at the participating centres and conducted in the local language by one to two clinical psychologists ... The teaching materials were in English .... Before the workshop, participants were expected to have read the strategies document." Page 2

Bernhard 2011 *(Continued)*

	2. Usual care (control): No training workshop "Following baseline assessment and before the scheduled training workshop, they were randomly assigned to ... or control (no training workshop) group" Page 2
Outcomes	Patient involvement preference and actual involvement; Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** Number of approached patients (eligible): SGA (Swiss/German/Austrian): 429; ANZ (Australian/New Zealand): 340 Number of patients per physician: SGA (Swiss/German/Austrian): 41; ANZ (Australian/New Zealand): 21

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Method of randomisation not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	Low risk	See flow-chart, Page 4
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"Within two weeks of their initial consultation discussing treatment options, patients gave informed consent and completed a baseline questionnaire gathering demographics; preferences for information (degree of detail required on a Likert scale from 'prefer few details' to 'prefer as many details ... " Page 2
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Unclear risk	Not specified in paper

Bieber 2006

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient

Bieber 2006 *(Continued)*

	Unit of analysis: Patient **Power calculation**: Not clear
Participants	**Care setting**: Specialized care and ambulatory care (Rheumatologic Outpatient Clinic of the University of Heidelberg); Germany **Health professionals**: 10; internal medicine; fully trained **Patients**: 149; fibromyalgia syndrome; male and female **Recruitment data**: "All patients applying for a first consultation in the outpatient clinic with the main complaint of musculoskeletal pain were asked to participate in the study. When they gave informed consent they were randomised either to the SDM group or the information group. After confirmation of the diagnosis they were included in the study" Page 358
Interventions	**1. Multifaceted intervention**: Educational meeting with physician (18 hours); patient-mediated intervention (computer-based visualized information tool). The computer-based tool provided information on fibromyalgia syndrome, combining textual information with diagrams and short video sequences. The educational meeting involved training physicians to improve patient-centered communication and interaction skills **2. Single intervention (control):** Patient-mediated intervention (computer-based visualized information tool) The tool was the same as the multifaceted intervention
Outcomes	Doctor-patient interaction, from the patient perspective, using the QQPPI (Questionnaire on the Quality of Physician-Patient Interaction) (continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Unit of allocation is not described explicitly in the paper. Patients were randomised but the method was unspecified
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"Patients were informed on the intervention but they were blinded to the fact in which group they were being treated" Page 359
Follow-up of professionals?	Unclear risk	NA Patient unit of allocation
Follow-up of patients?	Unclear risk	For the scored measured, there were no reported number on those who participated in the trial

Bieber 2006 *(Continued)*

Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Baseline measurements for the FAPI are not reported, nor were they measured.
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	It was the patients and not the professionals who were randomised

Butow 2004

Methods	**Study design**: Patient-RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not clear
Participants	**Setting of care**: specialized care; ambulatory care (University of Sydney teaching hospital); Australia **Healthcare professionals**: 4; medical oncologists (2) and radiation oncologists (2); fully trained **Patients**: 164; cancer; male or female **Recruitment data**: "Consecutive patients with heterogeneous cancers attending an initial consultation with either of two medical or two radiation oncologists at a University of Sydney teaching hospital outpatient clinic were invited to participate." Page 4402 "A research nurse telephoned eligible patients to inform them of the study and invite their participation. Patients were informed that they would be offered a copy of the audiotape after their consultation. The research nurse assigned an identification to consenting patients, determined random assignment, and sent the appropriate package with a consent form at least 48 hours before the first consultation. Physicians were blinded to which package the patient received." Page 4403
Interventions	**1. Single intervention:** patient-mediated intervention (consultation preparation package: booklet "How treatment decisions are made" + brochure "Your right and responsibilities" + question prompt sheet) Patients received an information package at least 48 hours before their first oncology appointment. The information package included a question prompt sheet, booklets on clinical decision making and patient rights, and an introduction to the clinic **2. Single intervention (control):** patient-mediated intervention (booklet "NSW Cancer council booklet on living with cancer) Patients received the control booklet at least 48 hours before their first oncology appointment. This booklet contained only the introduction to the clinic
Outcomes	"Physician encouragement of patient participation in the consultation and decision making process" subscale of the behaviours coding system (categorical); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision making process

Butow 2004 *(Continued)*

	"Perceived level of control in the decision making process"; SDM is assessed as the joint process between healthcare professionals and patients to make decisions
Notes	Additional information: **Number of approached patients (eligible)**: 246 **Number of patients per physician**: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Allocation concealment is not described explicitly in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in the paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA - Patient-reported outcome, professionals were not followed up
Follow-up of patients?	Low risk	There were 164 participating patients "A total of 160 audible consultation audiotapes were available for verbatim transcription and coding" Page 4404
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Low risk	No differences in preference before the consultation, page 4406
Reliable primary outcome? All outcomes	High risk	"Each coder coded 10% of the others' consultations and recorded 10% of their own. Inter- and intra-rater reliability as measured by the statistic were good (0.69 and 0.67, respectively)." Page 4404
Protection against contamination?	High risk	One of the outcomes is patient reported and the intervention is patient allocated. Consequently patients could discuss the intervention amongst themselves

Cooper 2011

Methods	**Study design**: RCT (factorial design) **Unit of allocation**: Physician and patient **Unit of analysis**: Physician and patient **Power calculation**: Unclear

Cooper 2011 *(Continued)*

Participants	**Care setting**: Primary care, Ambulatory care (especially low SES service), USA **Health professionals**: 41, physicians fully trained **Patients**: 279, hypertensive; 184 female **Recruitment information** **"**Physicians recruited for the Patient–Physician Partnership Study were general internists and family physicians who saw patients 02at least 20 hours per week at one of the participating study sites." Page 1298
Interventions	**Four arms:** **1. Patient-mediated intervention**, educational meeting (Physician communication skills training and patient coaching by community health workers) **2. Educational meeting:** Physician communication skills training **3**. **Patient-mediated intervention**: patient coaching by community health workers **4**. **Patient and physician minimal intervention:** (control) "The physician communication skills program was designed to provide physicians with personalized feedback based on their videotaped performance with a simulated patient scheduled for an office appointment. ... Intervention group physicians reviewed the videotape of their personal interviews with the simulated patient and completed exercises on the CD-ROM or in the workbook." Page 1298 "Control group physicians participated in the simulated visit but did not receive any feedback until the end of the study" Page 1298
Outcomes	Participatory Decision making (PDM); Patient involvement in care
Notes	**Additional information:** **Number of approached patients (eligible):** 980 **Number of patients per physician**: 50

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	"The Patient–Physician Partnership Study was a randomised controlled trial, with a two-by-two factorial design. Physicians and patients were randomised with equal probability to minimal or intensive interventions"
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	"Due to the nature of the interventions, complete masking of participants, investigators, and CHWs was not possible" Page 1299
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	High risk	Table 4: Process measures at baseline and change at 12 month follow-up by intervention group

Cooper 2011 *(Continued)*

Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	Table 4: Process measures at baseline and change at 12 month follow-up by intervention group
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Unclear risk	Not specified in paper

Davison 1997

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not clear
Participants	**Care setting**: Specialized care and ambulatory care (Winnipeg Community Clinic); Canada **Health professionals**: 2; urologist; fully trained **Patients**: 60; prostate cancer; men **Recruitment data**: "A consecutive sample of 60 men newly diagnosed with prostate cancer was recruited from one Winnipeg community clinic" Page 189
Interventions	**1. Single intervention**; patient-mediated intervention (individual empowerment sessions) This session helped them to think on how to discuss with the doctor what treatment is best for them and what questions to ask the physician **2**. **Single intervention** (control); patient-mediated intervention (information package) A list of questions, also found in the empowerment session
Outcomes	Perceived level of control in the decision-making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 60 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Randomisation method was not specified in the text

Davison 1997 *(Continued)*

Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Patient-mediated intervention and patient reported the outcome, so the patient was not really blind
Follow-up of professionals?	Unclear risk	NA patients unit of allocation
Follow-up of patients?	Low risk	"All men who were approached by the investigator agreed to participate in the study, but one 80 year old man refused to complete the second set of questionnaires." Page 189
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"At the pre-test, no significant differences were found between the role preference of the two groups ($Chi^2 = 4.365$, $P = 0.113$)" Page 194
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	The patients in the study reported outcome

Deen 2012

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary care; specialized care and ambulatory care (health center); USA **Health professionals**: Not mentioned in paper **Patients**: 279; no one particular type of clinical condition; 103 males and 176 females **Recruitment information:** **"**Patients aged 18 and older attending the William F. Ryan Health Center in New York City were approached ... Patients included those with scheduled appointments as well as walk-in, and those seeing their continuity provider as well as those seeing a covering primary care clinician" Page 2
Interventions	**Four arms:** 1. **Patient-mediated intervention** (Decision aid (DA) and Patient Activation (PA)) 2. **Patient-mediated intervention** (PA) 3. **Patient-mediated intervention** (DA)

Deen 2012 *(Continued)*

	4. **Control** (doctor visit) "Individuals agreeing to participate provided informed consent and were then randomly assigned to one of 4 groups: no intervention (control = data collection and doctor visit), pre-visit exposure to a PAI, pre-visit exposure to the DA, and pre-visit exposure to both DA and the intervention (DA + PAI). The DA selected for this project, ..., to impart general information to patients about their role in gaining information and care within a medical setting." Page 2
Outcomes	Patient Activation Measure (PAM); the fostering by healthcare professional of active participating of patients in the decision-making process
Notes	**Additional information:** **Number of approached patients (eligible):** 945 **Number of patients per physician**: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Not reported in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA healthcare professionals are not described in paper
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"Pre and post-visit data were collected in the CHC waiting room prior to and following a physician visit." Page 2
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	It was the patients and not the professionals who were randomised

Deinzer 2009

Methods	**study design**: Controlled clinical trial

Deinzer 2009 *(Continued)*

	Unit of allocation: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized palliative care, non-ambulatory care, Germany **Healthcare professionals**: >15 (total only reported in intervention group); physicians: fully trained **Patients**: 86, hypertensive, male and female **Recruitment data**: "Forty patients were recruited by the 15 study physicians who were trained in special communication skills for SDM. Forty-six patients were recruited and allocated to the hypertension education program." Page 267
Interventions	**1. Multifaceted intervention**: educational meetings (training for physicians), patient-mediated intervention (patient education program) Training for physicians with 4 special consultations “The SDM interventions were performed ... by physicians who had undergone special communication Training ... “ Page 267 “Subjects in both the SDM and control groups took part in the patient education program which consisted of modules on the main topics of hypertension ...” Page 267 **2. Single intervention**: Patient-mediated intervention (patient education program) “Subjects in both the SDM and control groups took part in the patient education program which consisted of modules on the main topics of hypertension ...” Page 267 "Physicians of control patients were just informed about patient empowerment" Page 267
Outcomes	COMRADE (continuous, score); SDM is assessed as the joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Method not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Observer-based outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper

Deinzer 2009 *(Continued)*

Follow-up of professionals?	Unclear risk	NA, unit of allocation is the patient
Follow-up of patients?	Low risk	Done, 97% of the patients were present at follow up (86 recruited, 84 analysed)
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"The degree of SDM was significantly higher in the SDM group at baseline and after 1 year visits." Page 268
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"Physicians of control patients did not take part in such a special communication program thereby avoiding any contamination with the SDM group" Page 267

Deschamps 2004

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary and ambulatory care (a family medicine clinic); Canada **Health professionals**: unknown number; general practitioners; unclear level of training **Patients**: 128; hormone replacement therapy; female **Recruitment data**: "Women aged 48 to 52 years of age were invited to participate." Page 22
Interventions	**1. Multifaceted intervention**: patient-mediated intervention (pharmacist consultation, patient-specific information and a 40-minute consultation with pharmacist) and other (a letter to the patient's physicians) The letter to the physician highlights the decision made during the pharmacist consultation **2. Single intervention** (control): patient-mediated intervention (decision aid: "Making choices: hormones after menopause") The decision aid package was created by the Ottawa Health Decision Centre; it describes both the risks and the benefit of the therapy or therapies
Outcomes	Perceived level of control in the decision making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): not reported

Deschamps 2004 *(Continued)*

Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	The method of randomisation was not specified in the paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Patient-mediated intervention and patient reported the outcome
Follow-up of professionals?	Unclear risk	NA patient unit of allocation
Follow-up of patients?	High risk	Only 87 of the original 128 participated in the intervention, page 23
Baseline measurement? Observer-based outcome	Unclear risk	NA patient randomised controlled trial
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Dolan 2002

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not clear
Participants	**Care setting**: primary and ambulatory care (two practices in Rochester New York); USA **Health professionals**: 6, general internist; 5 fully trained and 1 in training **Patients**: 96; colorectal cancer screening patients; male and female **Recruitment data**: "Most patients were recruited from a suburban practice ... They were told that all participants would receive a $25 stipend upon completion of the study." Page 126

Dolan 2002 *(Continued)*

Interventions	**1. Single intervention**: patient-mediated intervention (preliminary phase + detailed analysis of the decision using the analytic hierarchy process (decision aid) The preliminary phase describes colorectal cancer, the study, administers a demographic survey, ask about family and personal history, established past screening and patients' preference and a knowledge test. (Pages 126 to 127) **2. Single intervention** (control): patient-mediated intervention (preliminary phase and educational phase) "The educational phase consisted of a short description of colorectal cancer and the 5 screening programs for average risk patients" Page 127
Outcomes	Perceived level of control in the decision making process (categorical); Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 178 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"All randomisation schedules were created using a computer random number generator before the onset of patient enrolment." Page 126
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA patient-mediated intervention and patient-reported outcome
Follow-up of professionals?	Low risk	NA patient unit of allocation
Follow-up of patients?	Low risk	"...of the 97 patients who entered the study, 1 patient from the experimental group dropped out ... [and] another from the control group ..." Page 130
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"There were no significant differences between study groups in pre-intervention views about how screening decisions should be made (chi square = 4.54 df=2 P = 0.10) or in patients' perception about how decisions should be made (Chi^2 = 2.1 df = 2 P = 0.34)" Page 132
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Elwyn 2004

Methods	**Study design**: Cluster-RCT **Unit of allocation**: Provider (one per practice) **Unit of analysis**: Provider **Power calculation**: Done
Participants	**Care setting**: Primary care; ambulatory care (usual practice and protected research clinics; urban and rural in Gwent, South Wales); UK **Healthcare professionals**: 21; general practitioners; fully trained **Patients**: 747 included in COMRADE, 352 in OPTION; non-valvular atrial fibrillation or prostatism or menorrhagia or menopausal symptoms; male or female **Recruitment data**: "Patients were approached by the practices for consent to participate in the study if they were known to have one of the four following conditions: non-valvular atrial fibrillation; prostatism; menorrhagia; or menopausal symptoms." Page 339 "These patients were identified from Read Codes on electronic practice databases by staff from the practices using a standard protocol, assisted by a research officer (CA)." Page 339
Interventions	**1. Multifaceted intervention**: educational meeting (SDM skills) and audit and feedback; 5 hours Practitioners attended two workshops. During the first workshop, the background literature on SDM was outlined and participants were asked to debate its relevance to clinical practice. The skills of SDM were described and demonstrated using simulated consultations. This provided opportunities for all the participants to comment on the method, using an observational competence checklist. Simulated patients were also encouraged to comment. Participants were asked to consult with the simulated patients using pre-prepared scenarios involving the study conditions. At the second workshop, participants were asked to consider the competences in more depth. By the end of the workshop, all participants had conducted and received feedback from at least one consultation with a simulated patient. **2. Multifaceted intervention** (control): educational meeting (risk communication skills) with audit and feedback; 5 hours A risk communication aid was presented for the four study conditions. The risk data were based on systematic reviews and presented as the best evidence available at the time of the trial. The participants were provided with treatment outcome information for the study conditions. Participants were asked to use them in simulated patient consultations. The consultations were conducted in pairs, where colleagues alternated between clinician and observer roles. This was repeated until each participant had received feedback after conducting two or three consultations using the risk communication aids across a range of conditions. A plenary group discussion, which included the patient simulators, allowed the group to share learning points and consider the application of the materials in clinical practice.
Outcomes	OPTION (continuous); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process COMRADE (continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 2585

Elwyn 2004 *(Continued)*

	Number of patients per physician:12 or 24 patients per physician according the phase (baseline, first and second intervention)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"All randomizations were undertaken by random number generation, and allocations by the trial statistician (KH) were concealed from those implementing the interventions or assessments." Page 339
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"All consultation recordings were intended to be rated by two raters and ratings were undertaken blind to study group allocation of clinicians or patients." Page 340
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"Both clinicians and patients were informed that the trial was investigating 'communication skills' but were otherwise 'blinded' to the decision-making or risk communication focus of the interventions." Page 339
Follow-up of professionals?	Low risk	"One doctor dropped out after the baseline phase." Page 341
Follow-up of patients?	Unclear risk	"197 patients consulted with 20 practitioners: 182 recording achieved" "95 patients consulted with 20 practitioners: 84 recordings achieved"
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	High risk	"Consistent inter-rater differences for OPTION scores were identified." Page 343
Protection against contamination?	Low risk	Unit of allocation is the provider. "Only one practitioner per practice would be recruited." Page 338

Fossli 2011

Methods	**Study design**: Clinician RCT, cross-over **Unit of allocation**: Clinician **Unit of analysis**: Clinician **Power calculation**: Done
Participants	**Setting of care**: Primary care, ambulatory care; Norway **Healthcare professionals**: 72; Various type of physician (residents, consultants, medical surgeons, neurologist, podiatrists, gynaecologist), fully trained and residents **Patients**: Not reported **Recruitment data**:

Fossli 2011 *(Continued)*

	"This led us to the design of an RCT with cross-over design. The participating doctors were randomised into two groups which both received the intervention, but at different points in time." Page 2
Interventions	**1. Multifaceted intervention**: educational meeting, distribution of educational materials, Audit and feedback after role-play "Doctors participated in the 20 hours (a 45 min) course over two consecutive days. …The course consisted of a 50/50 mix of theory and 45 min group sessions (3–7 participants and two teachers per group) including role-plays, with plenary debriefs after each group." Page 2 "Our course was based on the same content as the 5-day course Communication Skills Intensive offered by Kaiser Permanente" Page 2 "At the conclusion of the course, all participants received a one-sheet overview of the Four Habits to carry in their pockets as reminder in everyday work" Page 3 **2. Usual care (Control)**
Outcomes	Four Habits Coding Scheme (continuous, score); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: not reported, planned for eight video consultations per physicians

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Not clear, did not specify method used
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"Raters were blinded to all information about the doctors and the encounters, including whether the video was made before or after the intervention." Page 3
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	High risk	72 doctors were included, 51 were included in the final analysis: follow up was 70%
Follow-up of patients?	Unclear risk	NA clinicians are the unit of allocation
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	High risk	Inter-rater correlation is, for the most part less than 0.80, according to Kupart et al 2008

Fossli 2011 *(Continued)*

Protection against contamination?	Unclear risk	Not specified in paper

Hamann 2007

Methods	**Study design**: Cluster-RCT **Unit of allocation**: Group of providers for wards **Unit of analysis**: Patient **Power calculation**: Not clear
Participants	**Care setting**: Specialized and non-ambulatory care (12 acute psychiatric wards of two state hospitals); Germany **Health professionals**: unknown number; Specialists (psychiatrists) **Patients**: 107; schizophrenic; male and female **Recruitment data**: "Briefly stated, inpatients (male/female, aged 18-65 years, no exclusion criteria) with a diagnosis of schizophrenia ... were randomly included in a decision aid program or received usual care (randomizations of the wards)." Page 993
Interventions	**1. Multifaceted intervention**: patient-mediated intervention (decision aid) + educational meeting with nurses, aided by various charts, lasting 30-60 minutes A nurse assisted the patient work through the decision aid. Patients met with their physician 24 hours after having consulted the decision aid **2.Usual care** (Control)
Outcomes	COMRADE (continuous); Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Method of randomisation is not specified. Page 993
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in the paper

Hamann 2007 *(Continued)*

Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	High risk	Wards are the unit of allocation and 2."... at 6 months, follow-up data on 86 patients (80%) were available; and at 18 months, follow-up on 71 patients (66%) were available" Page 994
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	Wards were randomised, patients remained in their respective wards

Haskard 2008

Methods	**Study design**: Cluster-RCT **Unit of allocation**: Provider **Unit of analysis**: Provider **Power calculation**: Not done
Participants	**Care setting**: primary care; ambulatory care (a west coast university medical centre, a Department of Veterans Affairs clinic and a staff model HMO); USA **Healthcare professionals**: 156; from three primary care specialties, Various type of physician (obstetrics/gynaecology, family medicine, internal medicine); fully trained (87) and in training (69) **Patients**: 2196; various clinical conditions; male or female **Recruitment data**: "Enrollment and informed consent to participate took place in the waiting or examining rooms as patients waited for their primary care medical appointments. Patients scheduled to see a study physician during a specific session were approached by research staff." Page 514
Interventions	1. **Multifaceted intervention** (physician and patient trained arm): educational meeting + distribution of educational materials + patient-mediated intervention; 20 hours and 20 minutes Physician received a 3X6 hours interactive workshop over a period of 3 months. The first workshop focused on core communication skills in healthcare (engaging; empathising; educating patients of diagnosis, prognosis, and treatment; and enlisting patients in mutually agreed upon treatment plans). The second workshop focused on patient adherence, enhancing patients' health lifestyles, reducing health risk behaviours, and building confidence and conviction in patients to make healthy behaviour changes. The third workshop focused on sources and nature of interpersonal difficulties between clinicians and patients, recognizing and assessing tension in relationships, acknowledging problems, discovering meaning, showing compassion, setting boundaries, and helping patients find additional support. Each workshop was followed by the utilization and distribution of educational materials about the main topic covered during the workshop.

Haskard 2008 *(Continued)*

	Patient received a 20-minute waiting room pre-visit intervention. This intervention involved listening to audio CD with accompanying patient guide book focusing on planning and organizing concerns and questions for physician and encouragement to discuss treatment choices, negotiate best plan, repeat their understanding of the plan, follow up of care with their physician, asking questions about medications, tests, procedures, and referrals. 2. **Multifaceted intervention (physician only trained arm)**: educational meeting + distribution of educational materials; 20 hours See the above description for the physician intervention 3. **Single intervention (patient only trained arm)**: patient-mediated intervention; 20 minutes See the above description for the patient intervention 4. **No intervention (control)**
Outcomes	Physician-patient global rating (continuous). SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision making process
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: up to 24 patients per physician

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"... physicians were randomised to one of four conditions using a computer-generated random order" Page 515
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in the paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Low risk	Data from 127/156 randomised professionals were analysed at the three points in time. Page 515
Follow-up of patients?	Unclear risk	NA, the unit of randomisation was the provider
Baseline measurement? Observer-based outcome	Unclear risk	Baseline measurements were not reported
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper
Protection against contamination?	Unclear risk	Unit of allocation is the provider and not separated by practice. Page 515

Hess 2012

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Tertiary care; Ambulatory care, USA **Health professionals**: 102; Physicians, residents; fully trained and in training **Patients**: 204; chest pain ; **male and female**: 120 females, 84 males **Recruitment information:** **"**Eligible patients included adults aged 17 years who presented to the ED with primary symptoms of nontraumatic chest pain and who were being considered for admission to the ED observation unit for monitoring and cardiac stress testing within 24 hours." Page 252
Interventions	**1. Multifaceted intervention:** patient-mediated intervention (one brief demonstration of the use of the decision aid) and educational meeting (one hour training session) "Participating clinicians were oriented during a 1-hour training session given by the lead investigator (E.P.H.) as well as a brief (3 min) demonstration from the study coordinator on how to use the decision aid before meeting the first enrolled patient and as needed." Page 252 **2. No intervention, standard care (control)**
Outcomes	Observing Patient Involvement (OPTION) scores; The fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information:** Number of approached patients (eligible)**:** 310 Number of patients per physician: 208 patients for 51 clinicians

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment (selection bias)	Low risk	"Patients were randomised to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion ... Two investigators who were blinded to allocation assessed outcomes in all enrolled patients." Page 253
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"Third investigator (H.H.T.), who was also blinded to allocation, reviewed all potentially positive outcomes. ... The principal investigator, blinded to allocation and to patient outcome, reviewed and approved all post randomisation exclusions as prespecified in the study protocol" Page 254
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Low risk	The study is a patient RCT

Hess 2012 *(Continued)*

Follow-up of patients?	Low risk	See flow chart, page 4
Baseline measurement? Observer-based outcome	High risk	Not clear in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper "Two trained raters watched 30 videos independently and in duplicate to assess for interrater reliability 17 of scoring, and the remaining videos were scored by 1 of the trained raters." Page 4
Protection against contamination?	Unclear risk	Not clear in paper

Kasper 2008

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient Power calculation: done
Participants	**Care setting**: specialized care and ambulatory care (Hamburg University Hospital); Germany **Health professionals**: Unknown number; physicians; unclear level of training **Patients**: 297; multiple sclerosis; male and female **Recruitment data**: "We recruited participants between October 2004 and February 2006. MS patients were alerted by advertisement in local newspapers all over Germany, on web sites and in the national self-help group journal. Patients at Hamburg university hospital were also approached personally." Page 1346
Interventions	1.**Single intervention**: patient-mediated intervention (decision aid including a patient information booklet about immunotherapy options and an interactive workshop) The decision aid was formulated after assessing patients' needs and determining its feasibility 2. **Single intervention (control)**; patient-mediated intervention (decision aid consisting of a standard information package) This information can be found on the Internet
Outcomes	Perceived level of control in the decision-making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 304 Number of patients per physician: not reported

Kasper 2008 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"Randomization was carried out by concealed allocation using computer generated random numbers." Page 1346
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"To preserve blinding assessors explicitly asked patients not to refer to details of the information materials. ... However, [the treating physicians] were not informed about their patient's allocation and did not receive the patient information" Page 1347
Follow-up of professionals?	Unclear risk	NA Patients are the unit of allocation
Follow-up of patients?	Low risk	Patient follow-up is 95%, page 1346
Baseline measurement? Observer-based outcome	Unclear risk	NA Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	In the intervention, 18 preferred shared and 122 prefer another style, in the control group 34 prefer shared, 109 prefer another style. This yields a Chi^2- value of 5.96, P > 0.05, page 1349
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Krist 2007

Methods	**Study design**: Patient RCT **Unit of allocation:** Patient **Unit of analysis**: Patient **Power calculation**: Not clear
Participants	**Care setting**: primary care and ambulatory care (1 large family practice centre in suburban northern Virginia); USA **Health professionals**: 29; family physicians; 13 fully trained and 16 in training **Patients**: 497; prostate cancer screening; male **Recruitment data**: "Between June 2002 and June 2004, two weeks before their office visit, male patients aged 50 to 70 years who scheduled a health maintenance examination were contacted by telephone." Page 1346
Interventions	1.**Single intervention**: patient-mediated intervention (mailed paper version of the decision aid)

Krist 2007 *(Continued)*

	The brochure duplicated the content of the website 2. **Single intervention (control):** patient-mediated intervention (Internet-based decision aid) The web-based decision aid was created by the author and reviewed by experts, presents evidence of prostate cancer 3. **No intervention (control)**
Outcomes	Perceived level of control in the decision-making process (categorical). Joint process between health-care professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 1073 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"At the time of enrolment, the allocation was concealed from the coordinator ... the coordinator referred to pre-generated randomisation tables to inform the participant to which arm he was randomised" Page 113-114
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA patient-mediated intervention and an outcome reported by patients
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	Low risk	"Questionnaires were completed by 87% of patients and 91% of physicians overall." Page 114
Baseline measurement? Observer-based outcome	Unclear risk	NA patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Krones 2008 (ARRIBA-Herz)

Methods	**Study design**: Clinician (RCT)

Krones 2008 (ARRIBA-Herz) *(Continued)*

	Unit of allocation: Clinician **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary care; ambulatory care (CME groups in Hessen); Germany **Health professionals**: 91; family doctors; fully trained **Patients**: 1132; cardiovascular; male and female (Krones 2008) **Recruitment information:** "Thirty CME groups comprised of 162 family doctors who were eligible and agreed to participate. ... After the completion of educational sessions, we asked participating physicians to recruit a maximum of 15 [patients]..." Page 324
Interventions	1. **Multifaceted intervention**: educational meeting, audit and feedback, distribution of educational materials, educational outreach visit Educational meeting two 2 hr sessions (risk of CVD, ethics of SDM, practical communication strategies), audit and feedback (after role-play feedback was given by their peers), distribution of educational materials (ARRIBA-Heart counselling sheet), educational outreach (CME members were invited to moderate the sessions) "In the sessions they discussed epidemiological background of global cardiovascular disease risk calculation and ethics of SDM. ... emphasis on practical communication strategies ... Use of script-like decision aid was practiced through role play, participants received feedback from their peers ...." Page 324 The participating family doctors were taught how to moderate a session 2. **Single intervention** (control): Placebo educational meeting "Family doctors in the control arm were offered seminars on defined alternative topics that would not interfere with CVD prevention." Page 324
Outcomes	Patient Participation scale, SDM-Q; Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** Number of approached patients (eligible): NA Number of patients per physician: at least one patient per physician (Hirsch 2010)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Method of randomisation not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias)	Unclear risk	" ... patients were unaware of their physician's group allocation" Page 219 (Krones 2008)

Krones 2008 (ARRIBA-Herz) *(Continued)*

Participant-reported outcome		
Follow-up of professionals?	High risk	160 physician were allocated to the intervention, 81 physicians present at follow up and all CMEs were present at follow up (the unit of allocation) Page 325 (Hirsch 2010)
Follow-up of patients?	Low risk	81% of the recruited patients were present at follow up, page.325 (Hirsch 2010)
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	High risk	"Patients' participation preference in decision making also differed significantly in the 2 study arms, which might represent a selection bias in the intervention group or an intervention effect" Page 222 (Krones 2008)
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	The intervention was stratified in accordance to CME groups

Lalonde 2006

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Care setting**: primary care and ambulatory care (10 community pharmacies in Montréal); Canada **Health professionals**: Unknown number; pharmacist; unclear level of training **Patients**: 26; cardiovascular problems; male and female **Recruitment data**: " A pilot study was conducted in a convenience sample of community pharmacies in Montréal .... Pharmacist received a total of Canadian $45 per patient recruited in partial compensation for their time. Pharmacist identified eligible patients and invited them to participate in the study. " Page 52
Interventions	1. **Multifaceted intervention**: distribution of educational materials (decision aid + personal risk profile) + patient-mediated intervention (decision aid) The decision aid is made of a booklet providing general information on the illness, the risk factors and lifestyle change and treatment option. "A four-step decision making strategy is suggested (Page 52)". It also included a personal worksheet which summarizes their risk and allows them to create an action plan 2. **Multifacted intervention (control)**; distribution of educational materials (decision aid + personal risk assessment) + patient-mediated intervention (personal risk profile) The risk profile identifies the patient risk factors and estimates a 10-year CVD risk, changing as the patient changes their risk factors. It also includes a four-page information handout

Lalonde 2006 *(Continued)*

Outcomes	Decision satisfaction inventory (continuous). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 42 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	"Randomisation was stratified by community pharmacy" Page 52. Method not detailed
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, the patient is the unit of allocation
Follow-up of patients?	Low risk	In all, 88% of the patients were included in the follow-up (described on page 54)
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Landrey 2012

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not clear
Participants	**Care setting**: Primary care and ambulatory care, USA **Health professionals**: 44, physicians; fully trained

Landrey 2012 *(Continued)*

	Patients: 303; prostate cancer screening; male Males with no history of prostate cancer **Recruitment data**: "The study was conducted in 2 general internal medicine practices affiliated with the University of Colorado Hospital. Eligible men were between 50 and 74 years old and were scheduled to have an annual health maintenance exam between October 2009 and August 2010. Men were excluded if they had a PSA test within the past 12 months, a history of prostate cancer, or any other diagnosis of cancer, terminal illness or dementia." Page 2
Interventions	1. **Single intervention (mailed flyer),** patient-mediated intervention "One week prior to their upcoming annual health maintenance visits, eligible patients were randomised to receive a mailed flyer (intervention group) or no flyer (usual care group)." Page 2 2. **No intervention (control)**
Outcomes	Control Preference Scale (CPS). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 752 Number of patients per physician: 303 patients for 44 providers

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	"Two research assistants blinded to group assignment collected chart outcome information by reviewing clinic notes following patient appointment" Page 2
Follow-up of professionals?	Unclear risk	NA - Patient-reported outcome and the unit of allocation is the patient
Follow-up of patients?	High risk	See flow-chart of the study, page 4
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	High risk	There was no baseline, a follow-up telephone survey consisting of 13 items was conducted within 2 weeks of the clinic visit
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome

Landrey 2012 *(Continued)*

Protection against contamination?	Unclear risk	Not specified in paper

Leighl 2011

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized care, Ambulatory care; Australia, Canada **Health professionals**: 13 oncologists; fully trained **Patients**: 207, advanced colorectal cancer; **male and female**: 120 males, 87 females **Recruitment information** **"**Outpatients who attended cancer clinics at participating centers were eligible to participate if they had a diagnosis of incurable metastatic colorectal cancer and ... Patients were excluded if they had previously received chemotherapy for metastatic colorectal cancer .... Oncologists also provided consent to participate." Page 2079
Interventions	**1. Multifaceted intervention:** Patient-mediated intervention (decision aid), physician training (educational meeting) Decision aid: booklet with accompanying narration on an audiotape or CD "The DA used in this study was developed as a booklet with accompanying narration on an audiotape or compact disc for patients to take home ... Oncologists were trained to use the DA during the consultation and instructed to have patients return after the initial consultation for a final treatment decision as part of the study" Page 2079 **2. No intervention, (control):** Standard consultation
Outcomes	Modified Control Preferences Scale. Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** Number of approached patients (eligible)**:** 229 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"Eligible consenting patients ... were randomly assigned to a standard medical oncology consultation or to a consultation in which the DA was reviewed and a take home patient version was provided. Randomization lists, stratified by the consulting oncologist, were computer-generated, and the code was concealed in a sealed envelope until the time of random assignment." Page 2078

Leighl 2011 *(Continued)*

Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the patient
Follow-up of patients?	High risk	Figure 1: consort diagram. Q1-Q, questionnaire 1-4. Page 2079
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	See table 1, page 2078
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"Those receiving the DA were counselled not to share it with others in the waiting room to avoid contamination of the standard arm. To further minimize contamination between the arms, five consultations were audiotaped before study commencement as a baseline for comparison with consultations in the standard arm." Page 2078

Loh 2007

Methods	**Study design**: Cluster RCT **Unit of allocation**: Provider **Unit of analysis**: Patient **Power calculation:** Not done
Participants	**Care setting**: primary care and ambulatory care (Department of Primary Care at University Hospital of Freiburg); Germany **Health professionals**: 30; primary care physicians; fully trained **Patients**: 405; depressive disorders; male and female **Recruitment data**: "All accredited general practitioners in Freiburg and all general practitioners that are associated as teaching practices with the Department of Primary Care at the University Hospital of Freiburg were defined as the sampling frame and were sent a letter of invitation to participate in the study." Page 326
Interventions	1. **Multifaceted intervention**: educational meeting with physicians and patient-mediated intervention (decision aid as well as a patient information leaflet); 20 hours(educational meeting) Physician followed modules (lectures, round discussions, facilitation practice, role-play, videos, standardized case vignettes and case studies) for guidelines concerning depression care, including how to

Loh 2007 *(Continued)*

	how to include patients in the decision. The SDM portion was based on the works of Towle and Godlphin, as well as those of Elwyn and colleagues. Page 326 The physicians were given the decision aid and patient information leaflet to be used during the consultation. The patient's leaflet was based on the Clinical Practice Guideline on Depression in Primary Care of the Agency for Health Care and Policy 2. **No intervention** (control)
Outcomes	Man-Son-HIng Instrument (continuous). joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"...were randomly assigned by drawing blinded lots under supervisions of the principal investigator ..." Page 326
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	High risk	In all, 76% of the physicians were included in the follow up. Page 327
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	Table 2 shows not statistically significant differences between groups (P = 0.999). Page 329
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Légaré 2012

Methods	**Study design**: Cluster RCT **Unit of allocation**: Family practice teaching units

Légaré 2012 *(Continued)*

	Unit of analysis: Family physicians and patients **Power calculation**: Done
Participants	**Care setting**: Primary care (family practise), Ambulatory care Canada **Health professionals**: 270 family physician; teachers and residents; Fully trained and in training **Patients**: 712; acute respiratory infections; male and female **Recruitment information** "We finally included patients (adults and children who were accompanied by a parent or legal guardian) with a diagnosis of acute respiratory infection (e.g., bronchitis, otitis media, pharyngitis or rhinosinusitis) and for which the use of antibiotics was subsequently considered either by the patient or physician during the visit" Page E728
Interventions	**1. Multifaceted intervention:** educational meeting, distribution of educational materials (online tutorial and workshop) "DECISION+2 consisted of a 2-hour online tutorial followed by a 2-hour on-site interactive workshop" **2. Usual care (control):** "Physicians in the control group were asked to provide usual care" Page E728
Outcomes	Control Preference Scale (CPS). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"A biostatistician used Internet-based software to simultaneously randomise all 12 family practice teaching units to either the intervention group (DECISION +2) or control group" Page E728
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	Not clear in the paper
Follow-up of patients?	Unclear risk	NA, the unit of allocation is the cluster
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Légaré 2012 *(Continued)*

Baseline measurement? Participant-reported outcome	Low risk	"Family physicians' intentions to engage in shared decision-making ... were recorded at baseline and again at the end of the study" Page E729
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"To avoid contamination bias, access to the online tutorial was denied to participants in the control group during the trial" Page E728

Montori 2011

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Physicians and patients **Power calculation**: Done
Participants	**Care setting**: Primary care, Ambulatory care, USA **Health professionals**: 60; primary care physicians; Fully trained **Patients**: 100 osteopenia/osteoporosis; 100% of female **Recruitment information** **"**Eligible patients were postmenopausal women, age 50 years and more with bone mineral density levels consistent with a diagnosis of low bone mass (osteopenia) or osteoporosis, ... and had a follow-up appointment with that clinician, and who were available for a phone follow-up 6 months after randomisation." Page 550
Interventions	**1. Single intervention:** patient-mediated intervention; decision aid Osteoporosis Choice decision aid "The Osteoporosis Choice decision aid provides the patient's individualized 10-year risk estimate risk of having a major osteoporotic fracture ... .The decision aid also showed the absolute risk reduction in fracture risk with alendronate, ... In addition, the decision aid described the potential downsides of taking bisphosphonates. The decision aid also prompted further discussion with the question What would you like to do?" Page 550 **2. Other single intervention (control):** Usual care and booklet "In addition to usual care ... , patients randomised to the control group received the National Osteoporosis Foundation booklet, "Boning Up On Osteoporosis: A Guide To Prevention and Treatment." Page 550
Outcomes	OPTION to quantify the extent to which clinicians are able to involve patients in the decision-making process
Notes	**Additional information:** Number of approached patients (eligible): 14,060

Montori 2011 *(Continued)*

	Number of patients per physician: 13 clinicians enrolled more than one patient; five clinicians enrolled more than two

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"A computer-generated allocation sequence randomised patients 1:1 in a concealed fashion (using a secure study website) to control (usual care booklet) or intervention (Osteoporosis Choice decision aid)" Page 551
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"After randomisation, data collectors and data analysts were blind to allocation" Page 551
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the patient
Follow-up of patients?	Low risk	"All patients were followed for 6 months after the visit date, except for 7 who were lost to follow-up (decision aid, n5; control, n2)." Page 552
Baseline measurement? Observer-based outcome	High risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Low risk	"Interobserver agreement for the OPTION scale score was 0.97." Page 553
Protection against contamination?	Low risk	"Because few physicians had more than 1 patient in the study, we explored possible clinician contamination descriptively" Page 551

Mullan 2009

Methods	**Study design**: Clinician RCT **Unit of allocation**: Clinicians **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Setting of care**: Primary care, Ambulatory care, USA **Healthcare professionals**: 40; Various healthcare professional and interprofessional (physicians, physicians assistant, nurse practitioners managing diabetes); Fully trained and residents **Patients**: 85; diabetes type 2; males and females **Recruitment data**:

Mullan 2009 *(Continued)*

	"Enrollment began in November 2006 and finished a year later.Weenrolled 50 clinicians from the 11 locations participating in the trial: 40 clinicians had at least 1 eligible patient and were randomised, 21 to deliver the decision aid to 48 patients and 19 to provide only usual care to 37 patients." Page 1563
Interventions	1. **Multifaceted intervention**: Patient-mediated intervention (decision aid used during the clinical encounter); and educational training (how to use decision aid) "[The Diabetes Medication choice decision aid tool] is designed to enable clinicians to discuss with patients the potential advantages and disadvantages of adding an [antihyperglycemics pharmaceutical] agent." Page 1562 « Ideally, the clinician presents all 6 cards [describing the possible side effect of the medication] to the patient and asks which of the cards the patient would like to discuss first. After reviewing and discussing the cards that the patient and the clinician choose [what] to discuss", Page 1562 "The patient receives a copy of the cards in the form of a take-home pamphlet." Page 1562 "Clinicians randomised to the intervention arm received a brief demonstration from the study coordinator on how to use the decision aid prior to meeting the first enrolled patient." Page 1562 2. **Single intervention (control)**: Patient-mediated intervention (decision aid) "... 12-page general pamphlet on oral antihyperglycemics medication to take home." Page 1562
Outcomes	OPTION (continuous, score) and validated pictorial instrument ; SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information**: Number of approached patients (eligible): 1341 Number of patients per physician: at least one, page 1563

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	“We randomised clinicians … using a computer-generated allocation sequence, unavailable to personnel enrolling patients or clinicians, randomised clinicians to intervention (decision aid) or usual care and was accessed by the study coordinators via telephone.” Page 1562
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Low risk	No clinicians were lost to follow-up, page 1563
Follow-up of patients?	Low risk	No patiens were lost due to follow-up, page 1563
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement?	Unclear risk	Not specified in paper

Mullan 2009 *(Continued)*

Participant-reported outcome		
Reliable primary outcome? All outcomes	Low risk	"Two raters watched each video in duplicate and independently until they achieved near perfect agreement (intraclass correlation for total OPTION score of 0.99), rating the remaining videos separately." Page 1563
Protection against contamination?	Unclear risk	Not specified in paper

Murray 2001

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Care setting**: Primary care and ambulatory care (33 practices in two urban areas (Oxford and London), one suburban area (Harrow),and one in a semi-rural area (Thames and the Chilterns); United Kingdom **Health professionals**: unknown number; general practitioners; Level of training unclear **Patients**: 112; benign prostatic hypertrophy; male **Recruitment data**: "We asked participating doctors to recruit men with benign prostatic hypertrophy opportunistically ...and to refer patients to the study as soon they were confident about the diagnosis." Page 1
Interventions	1.**Single-intervention**: patient-mediated intervention (decision aid); 60 minutes Information of the decision aid HealthDialog interactive videodisc on options, outcomes, clinical problem, outcome probability, and other's opinion 2.**Usual care (control)**
Outcomes	Percived level of control in decision making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 159 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"The randomisation schedule, stratified according to recruitment centre, was generated by computer" Page 3
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome

Murray 2001 *(Continued)*

Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA patient unit of allocation
Follow-up of patients?	Low risk	In all, 91% patients were included in the follow up. Page 4
Baseline measurement? Observer-based outcome	Unclear risk	NA, the study has a patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported the outcome

Murray 2010

Methods	**Study design**: Clinician RCT **Unit of allocation**: Clinician **Unit of analysis**: Clinician **Power calculation**: Done
Participants	**Setting of care**: Specialized palliative care, Non-ambulatory care, Canada **Healthcare professionals**: 88; Various healthcare professional (nurses, pharmacists, non-nurse case managers, social works); Fully trained **Patients**: 5; simulated patients **Recruitment data**: "Participants were recruited from seven community-based organizations and three hospital-based institutions in three Ontario health networks. Flyers and announcements about the study were posted in staff locations at participating organizations." Page 114
Interventions	1. **Multifaceted intervention**: including educational meetings, audit and feedback, distribution of education materials; educational outreach; barriers assessment. Interventions were chosen to target identified barriers to providing decision support for place of end-of-life care and were based on their proven effectiveness in improving practitioners' decision support knowledge and skills "Three components were delivered over six weeks. The first was an online, self-directed, module-based tutorial. ... The second component was a three-hour skills building workshop … Participants were given feedback on their decision support skills during their baseline standardized calls. Next, participants viewed and rated the quality of decision support ... then they practised providing decision support us-

Murray 2010 *(Continued)*

	ing the [Place-of-care patient decision aid] during role-playing sessions. ... Based on evidence from social marketing, education outreach was chosen as the third component." Page 114 2. **Usual care** (control)
Outcomes	DSAT10 (continuous, score); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information**: Number of approached patients (eligible): not applicable, the patients are simulated Number of patients per physician: 1

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	“Allocation was conducted through a computer-generated random numbers table provided centrally by a statistician external to the study.” Page 114
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	“DSAT10 scoring was done by one of two raters who were blinded to group assignment” Page 115
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Obsever-based outcome
Follow-up of professionals?	Low risk	In total 88 consented, 78 were included in the analysis, yielding a 88% follow-up
Follow-up of patients?	Unclear risk	NA, the clinicians are the unit of allocation
Baseline measurement? Observer-based outcome	Low risk	"Baseline scores for non-retained calls were non significantly different from baseline scores for complete cases (P = 0.866). The baseline score change from baseline ..." Page 116
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper
Protection against contamination?	Low risk	Yes, separated geographically

Myers 2011

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient

Myers 2011 *(Continued)*

	Power calculation: Unclear
Participants	**Setting of care**: Primary care, Ambulatory care, USA **Healthcare professionals**: 22 physicians; Fully trained (board certified practitioners) **Patients**: 313; eligible for prostate cancer screening; males **Recruitment data**: "An electronic appointment scheduling system and medical records were used to identify potentially eligible men with a scheduled visit for non-acute care. These men were mailed a study invitation letter, along with instructions for opting out of the study. A study research assistant then attempted to call patients who did not opt out in order to verify eligibility, obtain verbal consent, and administer a baseline survey" Page 241
Interventions	Interventions 1.**Multifaceted intervention**: Including patient-mediated interventions (pamphlet and counselling) and reminders (prompting) "... mailed a12-page information brochure on prostate cancer and screening to all participants." Page 241 "The nurse educators met EI Group men at the office visit, reviewed the content of the mailed booklet, and conducted a structured decision counselling session about prostate cancer. [The nurses] elicited factors that were likely to influence the participant's screening decision, align with their relative influence and strength. Then nurse educator then used a hand-held computer with a pre-programmed algorithm to compute each participants's decision preference score ..." Page 241 "... the nurse educator also placed a generic note on each EI group participant's medical chart to prompt the physician to discuss prostate cancer screening." Page 241 2. **Multifaceted intervention**: Including patient-mediated interventions and reminders (prompting) (control) The brochure and the prompt were the same as those in the intervention group
Outcomes	Informed decision-making scale; SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information**: Number of approached patients (eligible): 1245 Number of patients per physician: median number of patients per physician is 8

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	"Using a system of sealed envelopes, the nurse educator then determined the participant's study group assignment to either [groups]" Page 241
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias)	Unclear risk	NA - Observer-based outcome

Myers 2011 *(Continued)*

Participant-reported outcome		
Follow-up of professionals?	Unclear risk	NA Patients were the unit of allocation
Follow-up of patients?	Low risk	For the entire study, there was an over 90% follow-up, however, only 50% audio-recorded encounters; 84% of the audio recording encounters were analysed. Page 242
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in paper
Protection against contamination?	High risk	Certain patients in either the groups received their unassigned intervention. Page 242

Nannenga 2009

Methods	**Study design**: Provider-RCT (factorial 2x2 RCT) **Unit of allocation**: Provider and patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Setting of care**: Specialised care; Ambulatory care (clinic for diabetes at Mayo Clinic in Rochester, MN); USA **Healthcare professionals**: 16; endocrinologists; Fully trained **Patients**: 98; ypype 2 diabetes; male or female **Recruitment data**: "Providers and patients were naive to this study objective and randomised by concealed central allocation to a two by two clustered factorial design to intervention from their clinician during the visit or from the researcher prior to the visit, thus creating four groups." Page 39
Interventions	1. **Single intervention:** decision aid administered by provider during visit Statin Choice decision aid is a one-page document tailored to the individual patient including the patients name, cardiovascular risk factors and estimated cardiovascular risk. Benefits and downsides were presented 2. **Single intervention**: patient-mediated intervention (decision aid administered by researcher prior to visit) See the above description of the decision aid 3. **Single intervention (control)**: pamphlet administered by provider during visit

Nannenga 2009 *(Continued)*

	The standard Mayo patient education pamphlet outlined guidelines for reducing hyperlipidaemia, cholesterol, and triglycerides without consideration of patient-specific cardiovascular risk. It defined lipid disorders and provided primarily dietary guidelines for control of cholesterol along with general statements encouraging exercise and smoking cessation 4. **Single intervention (control)**: patient-mediated intervention (pamphlet administered by researcher prior to visit) See the above description of the pamphlet
Outcomes	OPTION (continuous); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information**: Number of approached patients (eligible): 260 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"...randomisation by concealed central allocation..." Page 39-40
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"Using the videotaped encounters, reviewers blinded to questionnaire result quantified encounter duration and used the OPTION scale to quantify the extent to which clinicians invited patient participation in decision making" Page 41
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	NA, the unit of allocation was the patient
Follow-up of patients?	Low risk	See, figure 1. "All patients received the allocated intervention, with one patient in the decision aid group (researcher arm) failing to complete any of the survey items" Page 40
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not specified in the paper
Protection against contamination?	High risk	Unit of allocation is the patient

O'Cathain 2002

Methods	**Study design**: Cluster-RCT **Unit of allocation**: Group of providers **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary care and Ambulatory care (maternity units); UK **Health professionals**: unknown number; physicians in maternity care and midwives; unclear level of training **Patients**: 10,070; maternity care; female **Recruitment data**: "Women were identified through hospital computer systems and the records of midwives and clerks in hospital and community antenatal clinic" in the first sample; in the second sample "Women were identified through child health computer records and hospital and home delivery registers". Questionaires were sent to all identified individuals. Page 2
Interventions	1. **Multifaceted-intervention**: education meeting with staff + distribution of educational materials ; 2 hours (educational meeting) The educational materials consisted of pairs of "Informed Choice" leaflets (given at different periods during gestation) which provided information concerning the benefits and risks of available options concerning labour, and a detailed professional leaflet. The staff in the units receiving the units were trained 2. **Usual care** (control)
Outcomes	Percived level of control in decision-making process (categorical); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 10,070 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"Members of pairs were randomly assigned by tossing a coin to receive the set of leaflets (five intervention units) or to the continue with usual care (five control units)"
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	Not specified in paper

O'Cathain 2002 *(Continued)*

Follow-up of patients?	Unclear risk	NA providers are the unit of allocation and the patients before the intervention are not the same as the patients after intervention
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	The difference was non significant between groups at P = 0.05 Sample 1:1.13 (0.47 to 2.74); Sample 2: 0.99 (0.68 to 1.44)
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	Unit of randomisation was the maternity units

Raynes-Greenow 2010

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized care (2 obstetric hospital, Sydney); Ambulatory care; Australia **Health professionals**: Unknown; Unclear level of training **Patients**: 596; primiparous women in their final trimester planning a vaginal birth of a single infant; female **Recruitment:** "Primiparous women, in their final trimester, who were planning a vaginal birth of a single infant, were eligible for the study. Primiparous women were selected because previous pregnancy has a strong impact on decision making and analgesia use in labour" Page 2
Interventions	1.**Single intervention**: Patient-mediated intervention (decision aid: booklet and audio guide) 2. **Single intervention** : Patient-mediated intervention (decision aid: booklet) The booklet was 55 pages and the audioguide 40 minutes. "Information was presented in a style that was sparse" Page 2 The content included both pharmacological and non-pharmacological analgesics 3. **Single intervention** (comparison group): patient-mediated (pamphlet) Same booklet as intervention group, Page 2
Outcomes	Perceived level of control in decision-making process (continuous)
Notes	**Additional information**: Number of approached patients (eligible): 1065

Raynes-Greenow 2010 *(Continued)*

Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"Treatment allocation was randomly generated by computer using random variable black sizes." Page 3
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	The intervention is patient-mediated intervention and the outcome is reported by the patient
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	High risk	In all, 76% patients were present at follow-up. Page 6
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Roter 2012

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Physicians and patients **Power calculation**: Unclear
Participants	**Care setting**: Primary care, Ambulatory care; USA **Health professionals**: 29 family physicians fully-trained and in training **Patients**: 197; type of clinical condition not mentioned; 50 females and 80 males **Recruitment information:** "enrolment averaged 4 patients per day. Patient enrolment was estimated to range between 80% and 90% of patients approached but only one site formally collected statistics on refusals ... " Page 407

Roter 2012 *(Continued)*

Interventions	**1. Multifaceted intervention:** patient-mediated intervention (decision aid); distribution of educational materials Separate interactive video glossaries demonstrating communication skills organized by the LEAPS heuristic "The interventions were comprised of separate interactive video glossaries demonstrating communication skills organized by the LEAPS heuristic. The patient glossary included the performance of 228 10-s video clips demonstrating the 18 targeted patient communication skills in various ways ... " Page 407 **2. Single intervention (control):** distribution of educational materials "Since control group patients would have benefited from seeing web exposed physicians as well as intervention group patients." Page 412
Outcomes	Separate interactive video glossaries demonstrating communication skills to patients and to clinicians
Notes	**Additional information:** Number of approached patients (eligible): not reported Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	"Some practices assigned patients to study groups on alternating days and others used a random numbering system." Page 407
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the patient
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	"Communication behaviours were assessed at baseline and after a follow-up visit through an 18-item self-report questionnaire"
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	The patient reported the outcome

Schroy 2011

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary care (Boston Medical Care centre, South Boston Community Health Centre); Ambulatory care; USA **Health professionals**: 50; Various healthcare professional with interprofessional (board-certified general internist, nurse practitioners); Fully trained **Patients**: 666; colorectal cancer screening; female and male **Recruitment**: "The vast majority of patients were recruited using an investigator-initiated "opt-out" approach in which patients due for screening were identified from monthly audits ... Two other strategies , including an investigator-initiated "opt-in" letter approach and a provider-mediated, "out-in" letter approach ..." Page 5
Interventions	1. **Single (first intervention group)**: patient-mediated intervention(DVD audio-visual touch screen decision aid explaining screening importance, epidemiology of disease, recommended methods and their comparison, and decision guidance: Your Disease risk assessment tool with feedback) 2. **Single intervention (second intervention group)**: patient-mediated intervention (DVD audio-visual touch screen decision aid explaining screening importance, epidemiology of disease, recommended methods and their comparison, and decision guidance) 3. **Single intervention (control)**: educational materials (a modified “9 ways to stay healthy and prevent disease")
Outcomes	12-item satisfaction with the decision-making process scale (categorical)
Notes	**Additional information:** Number of approached patients (eligible): 9869 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not clear in the paper
Follow-up of professionals?	Unclear risk	NA, the patients are the unit of allocation

Schroy 2011 *(Continued)*

Follow-up of patients?	Low risk	In all, 100% of the patiens were included at follow-up. Page 5
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	High risk	"Patient satisfaction with the decision-making process was assessed on the posttest using the validated 12-item Satisfaction with the Decision-Making Process Scale (Appendix 2)" Page 6
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported the outcome

Shepherd 2011

Methods	**Study design**: RCT (cross-over trial) **Unit of allocation**: The order of the standardized patients visits **Unit of analysis**: Physicians and patients **Power calculation**: Done
Participants	**Care setting**: Primary care, Ambulatory care, Australia **Health professionals**: 36; family physicians; Fully trained **Patients**: 2, depression ; patients are simulated, male or female not reported **Recruitment information** Two standardized simulated patients were used "Practicing family physicians in Sydney, Australia were identified through the Medical Directory of Australia and Divisions of General Practice (local organizations representing family physicians). Recruitment was by invitations sent directly to recipients from researchers, or through an indirect Division of General Practice mail-out (number and identities of recipients unknown to researchers)." Page 380
Interventions	**1. Single intervention:** Educational outreach visit Healthcare professional visited by an unannounced and standardized patient who asked three questions **2. Usual care** (control): No intervention (the control standardized patient did not ask the three questions)
Outcomes	Assessing Communication about Evidence and Patient Preferences (ACEPP); Observing Patient Involvement (OPTION) scores; The fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information:** Number of approached patients (eligible): NA, simulated patients were used in the study Number of patients per physician: NA, simulated patients were used in the study

Shepherd 2011 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	"The order of the standardized patient visits (intervention vs. control) was allocated randomly" Page 380
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"The transcribed consultations were analysed using ACEPP and OPTION by two trained coders who were not investigators on the study and blinded to the study purpose – specifically that this was an intervention study, nor any information about the intervention." Page 381
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	Unclear risk	NA, the patients are simulated
Baseline measurement? Observer-based outcome	Unclear risk	Not specified in paper
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	Unclear risk	Not clear in the paper
Protection against contamination?	Unclear risk	Not clear in paper

Stacey 2006

Methods	**Study design**: Provider-RCT **Unit of allocation**: Provider **Unit of analysis**: Provider **Power calculation**: Done
Participants	**Setting of care**: Primary care; Ambulatory care (province-wide health call centre in British Columbia); Canada **Healthcare professionals:** 41; nurse; Fully trained **Patients**: Simulated patients; decisions about amniocentesis, treatment for attention deficit disorder and herniated disk, decisions about allergy injections, and treatment for gall bladder attacks and borderline hypercholesterolaemia **Recruitment data**:

Stacey 2006 *(Continued)*

	"Allocation was concealed until after the nurses completed their baseline simulated call. Once informed written consent was obtained, each nurse received one call from a simulated patient." Page 411
Interventions	1. **Multifaceted intervention:** distribution of educational materials, educational meeting, as well as audit and feedback; barriers assessment; 6 hours. The intervention involved a structured coaching protocol, a 3-h online tutorial and a 3-h skill-building workshop that included performance feedback from baseline calls with simulated patients. The coaching protocol was introduced in the tutorial, used in the workshop and available exclusively to trained nurses for use with routine calls 2. **Usual care** (control)
Outcomes	Decision Support Analysis Tool (continuous); SDM is assessed as the fostering by healthcare professionals of active participation of patients in the decision-making process
Notes	**Additional information:** Number of approached patients (eligible): not reported (simulated patients) Number of patients per physician: not reported (simulated patients)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"The allocation schedule was computer-generated centrally by a statistician. Allocation was concealed until after the nurses completed their baseline simulated call." Page 411
Blinding (performance bias and detection bias) Observer-based outcome	Low risk	"In the present study, two of five raters trained in the use of the DSAT and blinded to group assignment, assessed the recorded calls independently." Page 412
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Follow-up of professionals?	Low risk	Of 41 randomised nurses, 2 dropped out and 1 baseline call was not recorded due to technical errors. There was a 93% follow up rate. Page 411
Follow-up of patients?	Unclear risk	NA OBOM outcome, the patients are simulated
Baseline measurement? Observer-based outcome	Unclear risk	Baseline measures were not reported
Baseline measurement? Participant-reported outcome	Unclear risk	NA - Observer-based outcome
Reliable primary outcome? All outcomes	High risk	"The inter-rater reliability for the quality of decision support scores was moderate (ICC = 0.66; 95% CI = 0.51–0.77)." Page 413
Protection against contamination?	Unclear risk	Unit of allocation is the provider within a province wide call centre. Page 411

Stiggelbout 2008

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Care setting**: Specialized care and ambulatory care (outpatient clinic of 2 teaching hospitals in the West of the country); Netherlands **Health professionals**: 15; vascular surgeon; fully trained and in training **Patients**: 113; abdominal aortic aneurysm; male and female **Recruitment data**: "Patients with an asymptomatic abdominal aneurysm of the aorta ... who either visited the outpatient clinic for the 1st time or where shown to have an expanding aneurysm at follow-up were recruited from the outpatient clinic of two teaching hospitals ..." Page 752
Interventions	1. **Single-intervention**: patient-mediated intervention (individualized brochure) This brochure contained an output providing information on three strategies concerning the management of the patient, ranked in accordance to the patients' risk 2. **Single-intervention (control)**: patient-mediated intervention (general brochure)
Outcomes	Patients' decisional role subscale (continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): 136 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	Low risk	In all, 88% of the patients are present in the follow-up
Baseline measurement?	Unclear risk	NA - Patient-reported outcome

Stiggelbout 2008 *(Continued)*

Observer-based outcome

Baseline measurement? Participant-reported outcome	Low risk	"... whereas the IB group had preferred a (non significant) more active decision-making role before hand (mean 2.9, SD 1.3 versus mean 2.5, SD 0.9, P = 0.15)." Page 757
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Street 1995

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Care setting**: Specialized care and ambulatory care (Scott and White clinic and Hospital (Texas)); USA Health professionals: 10; Various type of physician (4 medical oncologist, 2 radiation oncologist, 4 surgeons); Fully trained **Patients**; 60; breast cancer; female **Recruitment data**: "After orientating the patient to upcoming appointments, the nurse overviewed this project, solicited the patients' participation, and obtained informed consent." Page 2277
Interventions	1. **Single-intervention**: patient-mediated intervention (Interactive multimedia program (decision aid));15-20 minutes. The program "Options for treating breast cancer" is an interactive program using a touch-screen monitor containing audio-visual elements. It provides an introductions, elaborate the problem, treatment options and provides testimonies of other women's experiences. Page 2277 2. **Single-intervention** (control): patient-mediated intervention (brochure (decision aid)) This is an eight page brochure entitled "Care of patients with early breast cancer". It contains comments by other women, elaborates the problem and presents treatment options. The medical information is the same in both the multimedia format and the brochure format. Page 2278
Outcomes	Perceived decision control (continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information**: Number of approached patients (eligible): not reported Number of patients per physician: not reported
Risk of bias	

Street 1995 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	Not specified in paper
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in the paper
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

van Peperstraten 2010

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient (Client couple) **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Specialized care (fertilization clinics); Ambulatory care; Netherlands **Health professionals**: NA; nurses and staff at the fertilization clinics; Fully trained **Patients**: 308, need in vitro fertilization; Females and males (Client couple) **Recruitment information** "The criteria for inclusion were couples on the waiting list for a first in vitro fertilisation cycle ever or a first cycle after previous successful in vitro fertilisation, with the women younger than 40." Page 2
Interventions	**1. Single intervention,** patient-mediated intervention (decision aid, support call), reimbursement of fees; barriers assessment. Decision Aid and reimbursement; discussion; telephone call discussion

van Peperstraten 2010 *(Continued)*

	"The multifaceted strategy aimed to empower couples ... The strategy consisted of a decision aid, support of a nurse specialising in vitro fertilisation, and the offer of reimbursement by way of an extra treatment cycle." Page 1 **2. No intervention, usual care** (control) No intervention (usual discussion) "The control group received standard care for in vitro fertilisation." Page 1
Outcomes	Decision Evaluation Scale (informed choice). Joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** Number of approached patients (eligible): 344 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	"Randomisation took place centrally using a computer generated randomisation list. Participants were randomised in blocks of four couples. A secretary outside our department was the only person with access to the randomisation list. She randomised the couples on the day consent was received and informed the couple that same day." Page 2
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	High risk	"Because of the nature of the intervention it was not possible to blind the participants or in vitro fertilisation doctors to the allocation." Page 2
Follow-up of professionals?	Unclear risk	NA, the unit of allocation is the client couple
Follow-up of patients?	Unclear risk	Not specified in paper
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Low risk	See Table 3: Decision-making outcomes at baseline and after exposure to multifaceted intervention but before start of in vitro fertilization (IVF), Page 5
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	"The elements of the strategy were sent by post, because use of the Internet or email could have made elements of the intervention available to the control group." Page 2

Vodermaier 2009

Methods	**Study design**: Patient RCT **Unit of allocation**: Patient **Unit of analysis**: Patient **Power calculation**: Not done
Participants	**Care setting**: Specialized care and non-ambulatory care (gynaecological department of the University of Munich-Grosshadern; Germany **Health professionals**: Unknown number; physicians; Unclear level of training **Patients**: 152; breast cancer; Female **Recruitment data**: "We recruited patients with a strong suspicion of having breast cancer from the gynaecological department of the University of Munich-Grosshadern." Page 591
Interventions	1. **Single-intervention**: Patient-mediated intervention (decision aid) The decision aid took the form of three decision boards (corresponding to tumour size) relating to chemotherapy information with hormone-responsive breast cancer, for preoperative chemotherapy. They are presented in 20 minute sessions going over the options so that the patient understands and can discuss them; they also present how the patient can participate in the decision making. They receive a brochure summarizing the boards content 2.**Usual care** (control)
Outcomes	1. Perceived level of control in the decision-making process (categorical); joint process between healthcare professionals and patients to make decisions 2. Man-Son-Hing Instrument (continuous)
Notes	**Additional information:** Number of approached patients (eligible): 246 Number of patients per physician: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	"Random assignment was performed by means of numbered cards in envelopes for the intervention and the control group ..." Page 591
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Unclear risk	Not specified in paper if the patients were blinded
Follow-up of professionals?	Unclear risk	NA patients are the unit of allocation

Vodermaier 2009 *(Continued)*

Follow-up of patients?	High risk	This study only had 73% patient follow-up rate. Page 593
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	High risk	Patients reported outcome

Wetzels 2005

Methods	**Study design**: Cluster RCT **Unit of allocation**: A group of providers (a practice) **Unit of analysis**: Patient **Power calculation**: Done
Participants	**Care setting**: Primary care and Ambulatory care (20 practices in south-eastern Netherlands); Netherlands **Health professionals**: 25; General practitioners, unclear level of training **Patients**: 1246; Various clinical conditions; male and female **Recruitment data**: "Recruitment of GPs occurred in May and June 2002 by mail." Page 287
Interventions	1. **Multifaceted intervention**: educational outreach visit , patient-mediated intervention; 30 minutes (educational outreach visit). All patients received a consultation leaflets by mail. The leaflet provided a motivational text, including a series of questions, encouraging patient involvement. The general practitioners received a 30-minute visit, in which they were motivated to involve the patient and to use the brochure 2. **No intervention (control)**
Outcomes	COMRADE (4 items, continuous); joint process between healthcare professionals and patients to make decisions
Notes	**Additional information:** Number of approached patients (eligible): 1246 Number of patients per physician: approximately 30

Risk of bias

Bias	Authors' judgement	Support for judgement

Wetzels 2005 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	"To secure blinding of allocation, practices were numbered in the order of their arrival in our mail. All participating GPs in a particular practice were randomised to the same intervention. An independent person, who was blinded for the practices as these were numbered, performed the allocation" Page 287
Blinding (performance bias and detection bias) Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Blinding (performance bias and detection bias) Participant-reported outcome	Low risk	All GPs in one practice were assigned to an intervention by a person blinded to the study. Page 287
Follow-up of professionals?	Unclear risk	Not specified in paper
Follow-up of patients?	High risk	See figure 1, page 288
Baseline measurement? Observer-based outcome	Unclear risk	NA - Patient-reported outcome
Baseline measurement? Participant-reported outcome	Unclear risk	Not specified in paper
Reliable primary outcome? All outcomes	Unclear risk	NA - Patient-reported outcome
Protection against contamination?	Low risk	The intervention was allocated according to practices

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Alexander 2006	The design of the study was not appropriate
Allen 2009	The study type was not appropriate. This is a one group pre/posttest quasi-experimental design
Brown 2004	The outcome was inappropriate, only preference was stated
Davison 2007	The intervention was after the consultation
Golnik 2012	The design of the study was not appropriate. Inappropriate number of control site, less than four
Green 2011	The outcome was not appropriate
Hack 2007	The intervention was after the consultation
Hanson 2011	The outcomes were not appropriate
Hermansen Kobulnicky 2002	Relevant data was not presented and is clearly unobtainable

Study	Reason for exclusion
Hirsch 2010	The study in this paper is already included (ARRIBA-Herz 2008)
Kopke 2009	The outcomes were not appropriate, only the active patient was reported and not the shared decision
Langewitz 1998	The outcome related to SDM is limited to a single item from observer-based multiple instrument
Leader 2012	The outcomes of the study were not appropriate
Man-Son-Hing 1999	The outcomes of the study were not appropriate
Maslin 1998	Relevant data was not presented and is clearly unobtainable
McCormack 2011	The design of the study was not appropriate. Inappropriate number of control site, less than 4
Ockhuysen-Vermey 2008	The outcomes of the study were not appropriate
Roelands 2004	The outcomes of the study were not appropriate
Schwalm 2012	The outcomes of the study were not appropriate
Simon 2012	The participants in the study were not appropriate. The healthcare professional was virtual, so it was difficult to measure shared decision making
Smith 2010a	The outcomes of the study were not appropriate, we could not be sure if the preference for involvement in the screening decision was assumed or preferred
Spertus 2012	The design of the study was not appropriate. This is a pre-post cross-sectional study
van Tol-Geerdink 2008	The design of the study was not appropriate
Whelan 2003	The outcomes of the study were not appropriate, only the active patient was reported and not the shared decision

Characteristics of ongoing studies *[ordered by study ID]*

Berg ongoing

Trial name or title	Can health coaching help patients with spinal stenosis make an informed treatment choice? (DEC)
Methods	Patient RCT
Participants	Patients with lumbar spinal stenosis (SS)
Interventions	Decision aid
Outcomes	Patient demographics (e.g., age, gender, and education); Understanding of SS treatment options based on a 3-time multiple choice test; decisional conflict scale (DCS); and coaching status
Starting date	
Contact information	Susan Z Berg Susan.Z.Berg@hitchcock.org

Berg ongoing *(Continued)*

	Center for Shared Decision Making Dartmouth-Hitchcock Medical Center Lebanon, NH 03756 Phone: (603) 650-5578/Fax: (603) 653-0668
Notes	

Brinkman ongoing

Trial name or title	Pilot Testing of Decision Aids to Improve Decision Making in ADHD Care
Methods	Pre/post open trial
Participants	Pediatricians
Interventions	Intervention to facilitate shared decision making
Outcomes	Primary outcomes included the amount of shared decision-making, parent knowledge of treatment options, parent decisional conflict, and visit duration Secondary outcomes included chart audit of attention-deficit hyperactivity disorder care in 3 months following treatment initiation and physician satisfaction with the intervention
Starting date	
Contact information	Brinkman, William (Bill) Bill.Brinkman@cchmc.org Division of General & Community Pediatrics James M. Anderson Center for Health Systems Excellence Cincinnati Children's Hospital Medical Center
Notes	

Davis ongoing

Trial name or title	Integrating Decision Aids and Enhancing Shared Decision Making in Rural Non-Academic Primary Care: The Essential Role of Practice Facilitation
Methods	Mixed method: qualitative and quantitative
Participants	Clinical staff; patients
Interventions	DA implementation project in four member clinics of the Oregon Rural Practice-based Research Network (ORPRN)
Outcomes	To identify "Best Practices"for integrating DAs in small, rural non-academic primary care clinics
Starting date	

Davis ongoing *(Continued)*

Contact information	Melinda Davis, PhD, CCRP email: davismel@ohsu.edu Research Scientist, Oregon Rural Practice-based Research Network (ORPRN) Research Assistant Professor, Department of Family Medicine Oregon Health & Science University (OHSU), Mail Code L222 3181 SW Sam Jackson Pk Rd Portland, OR 97239 phone: (503) 494-4365
Notes	

Fullwood 2013

Trial name or title	Evaluation of the WISE approach in primary care: improving outcomes in chronic conditions through effective self-management - a two-arm practice-level cluster randomised controlled trial (WISE RCT)
Methods	Two-arm practice-level cluster randomised controlled trial
Participants	Patients with Chronic obstructive pulmonary disease (COPD), diabetes or irritable bowel syndrome (IBS)
Interventions	The intervention is designed to encourage practices to adopt a structured and patient-centred approach in their routine management of long-term conditions, providing the practice with skills, resources and motivation to make changes to service delivery in line with the principles of the WISE approach. The planned approach to training combines evidence-based approaches to changing professional behaviour with approaches to 'normalise' those behaviours in current practice The training will seek to impart three core skills to primary care staff: 1. Assessment of the individual patient's needs in terms of their self-management capabilities and current illness trajectory 2. Shared decision making about the appropriate type of support based on that assessment (types include support from primary care, written information sources, generic support groups or condition specific education) 3. Facilitating patient access to support. This may involve signposting patients to various resources which relate to the assessment and shared decision making processes. The training will encompass ways health professionals can negotiate with and guide patients into more appropriate utilization of health service resources. In the case of IBS, this may also involve referral to psychological treatment services (CBT and hypnotherapy) for eligible patients (so called 'stepped up care') Training of practice staff takes place over two 3 hour sessions - the effects of the training will be determined through recording patient-level outcomes The control group will receive no training Follow-up for both arms will be at 6 months and 12 months post-intervention
Outcomes	1. Shared decision making 2. Self-efficacy

Fullwood 2013 *(Continued)*

	3. Empowerment 4. Health behaviour 5. Positive attitudes 6. Management options 7. Condition-specific quality of life 8. Health-related quality of life 9. Service utilization Measured at baseline, 6 months and 12 months
Starting date	20/05/2009
Contact information	Prof David Thompson Department of Gastroenterology Clinical Sciences Building Hope Hospital Stott Lane david.thompson@manchester.ac.uk
Notes	

Goss ongoing

Trial name or title	The involvement of breast cancer patients in the informative and decisional processes during oncological consultations. The study protocol of a clinical multi-centre randomised controlled trial
Methods	Not reported in abstract
Participants	Patients with breast cancer at an early stage
Interventions	The intervention consists in the presentation of a list of relevant illness-related questions
Outcomes	The main outcome measures are: a) the number of questions asked by patients during the consultation, b) the involvement of the patient, c) patient's perceived achievement of her informative needs
Starting date	
Contact information	Claudia Goss claudia.goss@univr.it
Notes	

Köpke ongoing

Trial name or title	Patient education program on diagnosis, prognosis and early therapy for persons with early multiple sclerosis - outline and first results of a multi-centre randomised controlled trial (ISRCTN12440282)
Methods	RCT
Participants	Patients
Interventions	A patient education program to facilitate informed choice in persons with early MS (multiple sclerosis): a comprehensive 60 page information brochure and a 4-hour interactive educational program based on the current evidence about significance of prognostic factors, accuracy of diagnostic procedures and efficacy of drug therapies
Outcomes	“informed choice”after 6 months; decision autonomy, anxiety and depression and risk knowledge
Starting date	
Contact information	Sascha Köpke Nursing Research Group Institute for Social Medicine University of Lübeck Ratzeburger Allee 160 D-23538 Lübeck Germany Tel.: +49 451 500-5467 Mob.: +49 176 20270493 Fax: +49 451 500-5964 Email: sascha.koepke@uksh.de
Notes	

NCT00949611

Trial name or title	Wiser Choices in Osteoporosis Choice II: A Decision Aid for Patients and Clinicians
Methods	RCT
Participants	Patients with osteoporosis or osteopenia or fragility fractures
Interventions	FRAX (Fracture Risk Assessment Tool) and a Decision Aid FRAX estimated fracture risk
Outcomes	Primary outcomes: Medication start/stop, knowledge, and patient involvement
Starting date	Mai 2009
Contact information	Victor Montori

NCT00949611 *(Continued)*

	Montori.Victor@mayo.edu Annie LeBlanc Mayo Clinic | 200 First Street SW | Rochester MN | 55905 Tel.507.293.0175 Fax.507.538.0850 LeBlanc.Annie@mayo.edu
Notes	

NCT00955188

Trial name or title	Computer-Based Tailored or Standard Information for Colorectal Cancer Screening
Methods	Observational model: case-only
Participants	Patients with colorectal cancer
Interventions	Computer-assisted intervention; educational intervention; medical chart review
Outcomes	Secondary outcomes: Elements of informed decision making; Knowledge about screening options ; Decisional conflict and satisfaction; Intention to get screened
Starting date	August 2004
Contact information	Sarah T Hawley Associate Professor Division of General Medicine, University of Michigan Ann Arbor VA Medical Center sarahawl@med.umich.edu
Notes	

NCT01484665

Trial name or title	Evaluating the Effect of a Decision Aid on Shared Decision Making for Prostate Cancer Screening
Methods	Intervention model: single group assignment
Participants	Patients with prostate cancer
Interventions	PROCASE Decision-Aid
Outcomes	Primary outcome: Provider satisfaction with implementation of the shared decision making process; Secondary outcomes: Patient satisfaction with shared decision making and reach of the intervention
Starting date	December 2011

NCT01484665 *(Continued)*

Contact information	Christopher A Warlick Department of Urologic Surgery University of Minnesota MMC 394 420 Delaware St. S.E. Minneapolis, MN 55455 Ph: 612-625-7486 Fax: 612-626-0428 email: cwarlick@umn.edu
Notes	

NCT01492257

Trial name or title	Shared Decision Making in Patients With Osteoarthritis of the Hip and Knee (SDM)
Methods	RCT
Participants	Patients with hip osteoarthritis and/or knee osteoarthritis
Interventions	Shared decision making intervention: Digital video discs and booklets produced by the Foundation for Informed Medical Decision Making and Health Dialog; a question-prompting phone call with a trained health coach; audio-recordings of the patient-surgeon consultation; and a copy of the surgeon's dictated note
Outcomes	Primary outcome: Stage of decision making
Starting date	July 2011
Contact information	Kevin J Bozic William R. Murray Professor and Vice Chair UCSF Department of Orthopaedic Surgery kevin.bozic@ucsf.edu
Notes	

NCT01606930

Trial name or title	A Pilot Study to Improve Patient-Doctor Communication
Methods	RCT
Participants	Patients with common chronic illnesses: hyperlipidemia, chronic obstructive pulmonary disease, asthma, congestive heart failure, chronic pain, ischemic heart disease, osteoarthritis, depression, back pain, chronic headaches, or diabetes

NCT01606930 *(Continued)*

Interventions	Patient Activation Tool: The instrument is completed before the scheduled appointment and is designed to prompt patients to reflect on their specific goals for the medical encounter, prioritise those goals, and to "Prime" them to engage in a discussion centered on their concerns and expectations. In addition, participants will be encouraged to bring this form into their physician visit and use it to engage their clinician in a discussion about their health needs
Outcomes	Primary outcome: Degree of shared medical decision-making assessed from transcribed audio-tapes of the doctor-patient encounter using Roter Interaction Analysis System (RIAS)
Starting date	November 2010
Contact information	Patrick G O'Malley MD, MPH Division Director, General Internal Medicine Professor of Medicine and Biomedical Informatics Uniformed Services University, Bethesda, MD patrick.omalley@usuhs.edu
Notes	

Omer ongoing

Trial name or title	Personalized decision support for breast cancer prevention
Methods	Patient RCT
Participants	Women aged 40-65 years with no history of breast cancer
Interventions	Decision aid: a web-based tool that provides automated risk assessment and personalized decision support designed for collaborative use between patients and clinicians
Outcomes	Visit duration; patient acceptability and clinician satisfaction
Starting date	
Contact information	Elissa Ozanne elissa.ozanne@ucsfmedctr.org
Notes	

Quinn ongoing

Trial name or title	Factors in informed decision making in hepatitis C testing (DEC)
Methods	Study design not reported in the abstract
Participants	Patients
Interventions	Baseline survey, session with a health educator to review a study-specific booklet and underwent decision counselling

Quinn ongoing *(Continued)*

Outcomes	Patient's preferences for or against testing
Starting date	
Contact information	Amy Leader Amy.Leader@jefferson.edu
Notes	

Ruud ongoing

Trial name or title	Conducting a multi-site cluster-randomised practical trial of decision aids: lessons learned
Methods	RCT
Participants	Patients
Interventions	Diabetes medication decision aids
Outcomes	Estimate of the impact of patient decision aids versus usual care on measures of patient involvement in decision making and diabetes control
Starting date	
Contact information	Kari Ruud Knowledge & Evaluation Research Unit Phone: 507-266-9822 ruud.kari@mayo.edu Mayo Clinic, 200 First Street S.W. , Rochester, MN 55905
Notes	

Sanders ongoing

Trial name or title	Training general practitioners in enforcing patients' own expectations in order to maximize health benefits: observed effects on communication in consultations
Methods	RCT in general practice
Participants	GPs and patients
Interventions	A training course to use SDM and positive reinforcement (PR) in a situation of clinical equipoise (non-chronic low back pain) consisting of two training session of 2½ hours and feedback on video-taped consultations
Outcomes	Trained behaviours were systematically observed using an adopted OPTION-scale added with global measurement for patient participation
Starting date	

Sanders ongoing *(Continued)*

Contact information	Ariette Sanders ev van Lennep A.R.J.Sanders-vanLennep@umcutrecht.nl
Notes	

Schrijvers ongoing

Trial name or title	Implementation and evaluation of a web-based decision aid in the decision making process of newly diagnosed patients with localized prostate cancer
Methods	Not reported in the abstract
Participants	Newly diagnosed patients with localized prostate cancer, their partners and health care professionals
Interventions	Web-based decision aid: information on the prostate, prostate cancer, the various treatment options and the probability of side effects
Outcomes	Quantity and quality of the information; the impact of the decision aid on the consultation, on the shared decision making process and on the treatment choice
Starting date	
Contact information	Jessie Schrijvers Jessie.Schrijvers@med.kuleuven.be
Notes	

Shah ongoing

Trial name or title	Use of a Decision Aid for Patients Hospitalized with Acute Myocardial Infarction (AMI). A randomised controlled trial
Methods	RCT
Participants	Patients
Interventions	The AMI Choice Decision Aid
Outcomes	Knowledge transfer, decisional conflict, patient involvement in the decision-making process (OPTION scale), adherence to medications at 6 months, readmissions, and death
Starting date	
Contact information	Nilay Shah shah.nilay@mayo.edu
Notes	

Thompson ongoing

Trial name or title	Cluster-randomised trial of a suite of decision aids for women in pregnancy
Methods	
Participants	
Interventions	Decision aids for pregnancy and birth
Outcomes	Identify effective methods of promoting shared decision making between maternity care consumers and their care providers
Starting date	
Contact information	Rachel L Thompson Rachel.L.Thompson@dartmouth.edu
Notes	

Tinsel ongoing

Trial name or title	Association between patient rated amount of participation in Decision-Making and clinical outcome in patients with hypertension in General Practice
Methods	Cluster-RCT (the present study by analyse baseline data of a RCT, WHO Clinical Trials Registry DRKS00000125)
Participants	Patients and GPs
Interventions	Not reported in abstract
Outcomes	Primary outcomes were optimisation of blood pressure level and enhancement of patients' participation
Starting date	
Contact information	Iris Tinsel UNIVERSITAETSKLINIKUM FREIBURGLehrbereich AllgemeinmedizinSchwerpunkt Forschung Elsässerstr. 2m 79110 Freiburg Tel +49 761 270-77920 / Fax -77900 iris.tinsel@uniklinik-freiburg.de
Notes	

Wills ongoing

Trial name or title	Validation of the Shared Decision Making Questionnaire-9 (SDM-Q-9) in a Stratified Age-Proportionate U.S. Sample

Wills ongoing *(Continued)*

Methods	A stratified (race, ethnicity, gender) randomly-selected age-proportionate national sample of adults aged 21-70 years was recruited from the National Institutes of Health ResearchMatch research volunteer registry
Participants	Adults aged 21-70 years
Interventions	No intervention
Outcomes	The SDM-Q-9, other decision-making measures (Satisfaction With Decision scale,the Decisional Conflict Scale), sociodemographic and health conditions questionnaires
Starting date	
Contact information	Celia E Wills, PhD, RN The Ohio State University College of Nursing 384 Newton Hall 1585 Neil Avenue Columbus, OH 43210 (614) 292-4524 or (800) 678-6348 wills.120@osu.edu
Notes	

ADDITIONAL TABLES

Table 1. Effect of interventions: Intervention targeting patients compared to usual care

Observer-based outcome measure - Continous Data

Study	Intervention	Control	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Haskard 2008	Patient mediated intervention (n=67)	Usual Care (n=80)	Physician informative and participatory	NA	-0,04 (0,36)	NA	0,09 (0,38)	Unit of error analysis	
Haskard 2008	Patient mediated intervention (n=67)	Usual Care (n=80)	Patient active	NA	0,00 (0,30)	NA	0,05 (0,35)	Unit of error analysis	
Haskard 2008	Patient mediated intervention (n=67)	Usual Care (n=80)	Physician-patient interaction	NA	-0,01 (0,43)	NA	0,03 (0,46)	Unit of error analysis	

Observer-based outcome measure - Categorical Data

Study	Intervention	Control	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Observer-based outcome measure - Qualitative statement

Study	Intervention	Control	Outcome	Qualitative quote
No study				

Patient reported outcome measure - Continous Data

Study	Intervention	Control	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Deen 2012	Patient mediated intervention (Decision aid) (n=69)	Usual Care (n=69)	Patient Activation Measure (PAM)	41,78 (5,42)	43,68 (5,28)	42,21 (5,22)	44,06 (5,66)	-0,07 (-0,40 to 0,26)	0,04 (-0,07 to 0,09)

Table 1. Effect of interventions: Intervention targeting patients compared to usual care *(Continued)*

Deen 2012	Patient mediated intervention (Patient Activation) (n=73)	Usual Care (n=69)	Patient Activation Measure (PAM)	42,31 (6,35)	44,57 (6,16)	42,21 (5,22)	44,06 (5,66)	0,09 (-0,24 to 0,41)
Deen 2012	Patient mediated intervention (Decision aid + Patient Activation) (n=68)	Usual Care (n=69)	Patient Activation Measure (PAM)	41,67 (5,68)	44,29 (5,47)	42,21 (5,22)	44,06 (5,66)	0,04 (-0,29 to 0,38)
van Peperstraten 2010	Patient mediated intervention (n=124)	Usual Care (n=128)	Decision Evaluation scale	NA	4,1 (0,56)	NA	3,8 (0,57)	0,50 (0,25 to 0,75)
Vodermaier 2009	Patient mediated intervention	Usual Care	Man-Son-Hing Instrument	No data				
Cooper 2011	Patient mediated intervention (n=40)	Usual Care (n=43)	Participatory Decision making (PDM)	70,94 (24,67)	74,17 (23,25)	74,61 (21,59)	69,38 (21,50)	0,21 (-0,22 to 0,64)
Patient reported outcome measure - Categorical Data								
Study	**Intervention**	**Control**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
Krist 2007	Patient mediated intervention (Decision aid brochure) (n=174)	Usual Care (n=63)	Modified Control Preference Scale	NA	63/174	NA	23/63	0,00 (-0,14 to 0,14)	-0,01 (-0,01 to 0,00)
Krist 2007	Patient mediated intervention (Decision aid web) (n=198)	Usual Care (n=63)	Modified Control Preference Scale	NA	71/198	NA	23/63	-0,01 (-0,14 to 0,13)	
Landrey 2012	Patient mediated intervention (n=74)	Usual Care (n=78)	Modified Control Preference Scale	NA	29/74	NA	33/78	-0,03 (-0,19 to 0,12)	-0,03
Murray 2001	Patient mediated intervention (n=57)	Usual Care (n=48)	Modified Control Preference Scale	NA	34/57	NA	42/48	-0,28 (-0,44 to -0,12)	-0,28

Table 1. Effect of interventions: Intervention targeting patients compared to usual care *(Continued)*

Voder-maier 2009	Patient mediated intervention (n=53)	Usu-al Care (n=54)	Modified Control Pref-erence Scale	NA	35/53	NA	36/54	-0,01 (-0,19 to 0,17)	-0,01

Patient reported outcome measure - Qualitative statement

Study	Intervention	Control	Outcome	Qualitative quote
No study				

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Montori 2011	Patient mediated interven-tion (n=52)	Patient mediated in-tervention (n=48)	OPTION	NA	49,80 (21,40)	NA	27,30 (14,70)	1,21 (0,78 to 1,64)	1,21
Nannenga 2009	Patient mediated interven-tion (n=48)	Patient mediated in-tervention (n=43)	OPTION	NA	7,13 (6,63)	NA	1,74 (2.53)	1,04 (0,60 to 1,48)	1,04

Observer-based outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Patient reported outcome measure - Continous Data

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients *(Continued)*

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Deen 2012	Patient mediated intervention (Decision aid) (n=69)	Patient mediated intervention (Patient Activation) (n=73)	Patient Activation Measure (PAM)	41,78 (5,42)	43,68 (5,28)	42,31 (6,35)	44,57 (6,16)	-0,15 (-0,48 to 0,18)	-0,05 (-0,15 to 0,11)
Deen 2012	Patient mediated intervention (Decision aid + Patient Activation) (n=68)	Patient mediated intervention (Patient Activation) (n=73)	Patient Activation Measure (PAM)	41,67 (5,68)	44,29 (5,47)	42,31 (6,35)	44,57 (6,16)	-0,05 (-0,38 to 0,28)	
Deen 2012	Patient mediated intervention (Decision aid + Patient Activation) (n=68)	Patient mediated intervention (Decision aid) (n=69)	Patient Activation Measure (PAM)	41,67 (5,68)	44,29 (5,47)	41,78 (5,42)	43,68 (5,28)	0,11 (-0,22 to 0,45)	
Schroy 2011	Patient mediated intervention (Decision aid) (n=205)	Patient mediated intervention (Educational material) (n=217)	Satisfaction with the decision making process	NA	50,70 (6,20)	NA	46,00 (7,90)	0,66 (0,46 to 0,85)	0,63 (-0,03 to 0,66)
Schroy 2011	Patient mediated intervention (Decision aid + YDR) (n=214)	Patient mediated intervention (Educational material) (n=217)	Satisfaction with the decision making process	NA	50,50 (6,20)	NA	46,00 (7,90)	0,63 (0,44 to 0,83)	
Schroy 2011	Patient mediated intervention (Decision aid + YDR) (n=214)	Patient mediated intervention (Decision aid) (n=205)	Satisfaction with the decision making process	NA	50,50 (6,20)	NA	50,70 (6,20)	-0,03 (-0,22 to 0,16)	

Patient reported outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
Butow 2004	Patient mediated intervention (n=69)	Patient mediated intervention (n=62)	Modified Control Preference Scale	NA	22/69	NA	17/62	0,04 (-0,11	0,04

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients *(Continued)*

								to 0,20)	
Davison 1997	Patient mediated intervention (n=30)	Patient mediated intervention (n=30)	Modified Control Preference Scale	NA	10/30	NA	15/30	-0,17 (-0,41 to 0,08)	-0,17
Deschamps 2004	Patient mediated intervention (n=42)	Patient mediated intervention (n=48)	Modified Control Preference Scale	NA	24/42	NA	22/48	0,11 (-0,09 to 0,32)	0,11
Dolan 2002	Patient mediated intervention (n=43)	Patient mediated intervention (n=43)	Modified Control Preference Scale	NA	27/43	NA	22/43	0,12 (-0,09 to 0,32)	0,12
Kasper 2008	Patient mediated intervention (n=136)	Patient mediated intervention (n=142)	Modified Control Preference Scale	NA	55/136	NA	53/142	0,03 (-0,20 to 0,27)	0,03
Krist 2007	Patient mediated intervention (Decision aid web) (n=198)	Patient mediated intervention (Decision aid brochure) (n=174)	Modified Control Preference Scale	NA	71/198	NA	63/174	0,00 (-0,10 to 0,09)	0
Raynes-Greenow 2010	Patient mediated intervention (Decision Aid (Audio)) (n=176)	Pamphlet (n=175)	Modified CPS - First Follow-up	NA	39/176	NA	31/175	0,04 (-0,04 to 0,13)	0,04 (0,04 to 0,07)
Raynes-Greenow 2010	Patient mediated intervention (Decision aid) (n=168)	Pamphlet (n=175)	Modified CPS - First Follow-up	NA	37/168	NA	31/175	0,04 (-0,04 to 0,13)	
Raynes-Greenow 2010	Patient mediated intervention (Decision Aid (Audio)) (n=141)	Pamphlet (n=136)	Modified CPS - Second Follow-up	NA	26/141	NA	19/136	0,04 (-0,04 to 0,13)	

Table 2. Effect of interventions: Intervention targeting patients compared to another intervention targeting patients *(Continued)*

Raynes-Greenow 2010	Patient mediated intervention (Decision aid) (n=150)	Pamphlet (n=136)	Modified CPS - Second Follow-up	NA	31/150	NA	19/136	0,07 (-0,02 to 0,13)	
Stiggelbout 2008	Patient mediated intervention (n=31)	Patient mediated intervention (n=33)	Modified Control Preference Scale	NA	16/31	NA	24/33	-0,21 (-0,44 to 0.02)	-0,21

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
Lalonde 2006	Patient mediated intervention	Patient mediated intervention	Decision satisfaction inventory	No statistically significant differences in patient satisfaction with the decision-making process were detected between the study groups. Page 55
Street 1995	Patient mediated intervention	Patient mediated intervention	Perceived Decision Control Instrument	The experimental manipulation (computer program versus brochure) had very little effect on the dependent variables. Page 2280
Butow 2004	Patient mediated intervention	Patient mediated intervention	Physician behaviours facilitating patient involvement	On average, oncologists demonstrated about 7.5 of the 12 behaviours, with no significant differences between the groups (cancer consiltation preparation package (CCPP) versus control booklet). Page 4406

Table 3. Effect of interventions: Intervention targeting healthcare professionals compared to usual care

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Fossli 2011	Educational meeting, audit and feedback, distribution of educational material (n=26)	Usual Care (n=25)	Fours Habits Coding Scheme (4HCS)	59,66 (8,78)	63,57 (11,96)	60,87 (11,08)	58,85 (12,19)	0,38 (-0,17 to 0,94)	0,38
Shepherd 2011	Educational outreach visit (n=18)	Usual Care (n=18)	Assessing Communication about Evi-	NA	21,30 (3,58)	NA	16,70 (3,63)	0,90 (0,21 to 1,58)	1,08 (0,90 to 1,25)

Table 3. Effect of interventions: Intervention targeting healthcare professionals compared to usual care *(Continued)*

			dence and Patient Preferences (ACEPP)						
Shepherd 2011	Educational outreach visit (n=18)	Usual Care (n=18)	OPTION	NA	36,60 (12,62)	NA	25,00 (12,72)	1,25 (0,53 to 1,97)	
Stacey 2006	Distribution of educational materials, educational meeting, audit and feedback and barriers assessment (n=18)	Usual Care (n=20)	Decision Support Analysis Tool (DSAT)	0,53 (0,18)	0,81 (0,17)	0,43 (0,17)	0,44 (0,18)	2,07 (1,26 to 2,87)	2,07
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Cooper 2011	Educational meeting (n=51)	Usual Care (n=43)	Participatory Decision making (PDM)	68,46 (22,81)	71,57 (19,94)	74,61 (21,59)	69,38 (21,50)	0,11 (-0,30 to 0,51)	0,11
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**

Table 3. Effect of interventions: Intervention targeting healthcare professionals compared to usual care *(Continued)*

Légaré 2012	Educational meeting and distribution of educational material (n=176)	Usual Care	Modified Control Preference Scale (n=177)	71/182	79/176	59/171	64/177	0,09 (-0,01 to 0,19)	0,09
O'Cathain 2002	Educational meeting and distribution of educational material (Pre: n=1526; Post: n=1531)	Usual Care	Modified Control Preference Scale (antenatal sample) (Pre: n=1219; Post: n=1206)	345/1526	263/1531	287/1219	235/1206	-0,02 (-0,05 to 0,01)	0,00 (-0,02 to 0,02)
O'Cathain 2002	Educational meeting and distribution of educational material (Pre: n=1490; Post: n=1515)	Usual Care	Modified Control Preference Scale (postnatal sample) (Pre: n=1666; Post: n=1698)	369/1490	354/1515	426/1666	358/1698	0,02 (-0,01 to 0,05)	

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
Bernhard 2011	Educational meeting, audit and feedback, distribution of educational material	Usual Care	Patient involvement preference and actual involvement	There was considerable variation in patient outcomes between the SGA and ANZ cohorts and no substantial training effect. Page 6

Table 4. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting patients

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
No study									

Observer-based outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Table 4. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting patients *(Continued)*

Observer-based outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Patient reported outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Cooper 2011	Educational meeting	Patient mediated intervention (n=51)	Participatory Decision making (PDM) (n=40)	68,46 (22,81)	71,57 (19,94)	70,94 (24,67)	74,17 (23,25)	-0,12 (-0,53 to 0,29)	-0,12

Patient reported outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Elwyn 2004	Educational Meeting and Audit and feedback (n=9)	Educational Meeting and Audit and feedback (n=11)	OPTION	27,00 (14,00)	39,00 (11,80)	32,00 (13,80)	43,00 (13,60)	-0,30 (-1,19 to 0,59)	-0,3

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals *(Continued)*

Observer-based outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Observer-based outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Patient reported outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=79; Post: n=139)	Educational Meeting and Audit and feedback (Pre: n=108; Post: n=188)	COMRADE (communication) - Time 1	63,50 (18,60)	67,30 (14,10)	66,30 (13,50)	68,30 (14,10)	-0,07 (-0,29 to 0,15)	-0,09 (-0,18 to 0,05)
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=69; Post: n=121)	Educational Meeting and Audit and feedback (Pre: n=94; Post: n=169)	COMRADE (communication) - Time 2	62,10 (18,10)	62,40 (17,00)	63,30 (16,20)	64,20 (16,30)	-0,11 (-0,34 to 0,13)	
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=79; Post: n=139)	Educational Meeting and Audit and feedback (Pre: n=108; Post: n=188)	COMRADE (confidence) - Time 1	72,00 (9,90)	74,20 (9,40)	72,00 (9,80)	73,70 (9,20)	0,05 (-0,17 to 0,27)	
Elwyn 2004	Educational Meeting and Audit and feedback (Pre: n=69; Post: n=121)	Educational Meeting and Audit and feedback (Pre: n=94; Post: n=169)	COMRADE (confidence) - Time 2	70,00 (10,80)	70,00 (13,10)	71,80 (9,30)	72,20 (11,00)	-0,18 (-0,42 to 0,05)	
Krones 2008	Educational meeting, audit and feedback, educational material	Educational Meeting (n=550)	PPS (Man Son-	NA	1,36 (0,25)	NA	1,24 (0,25)	0,48 (0,36 to 0,60)	0,48 (0,40 to 6,11)

Table 5. Effect of interventions: Intervention targeting healthcare professionals compared to another intervention targeting healthcare professionals *(Continued)*

	and educational outreach visit (n=582)		Hing) : I made the decision jointly (Score inversé pour respecter le sens de l'échelle)						
Krones 2008	Educational meeting, audit and feedback, educational material and educational outreach visit (n=550)	Educational Meeting (n=582)	Shared Decision Making Q (SDM-Q)	NA	9,18 (4,08)	NA	7,46 (4,5)	0,40 (0,28 to 0,52)	
Krones 2008	Educational meeting, audit and feedback, educational material and educational outreach visit (n=539)	Educational Meeting (n=513)	PPS (Man-Son-Hing)	NA	7,69 (0,16)	NA	6,87 (0,1)	6,11 (5.82 to 6.40)	

Patient reported outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care

Observer-based outcome measure - Continous Data

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care *(Continued)*

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Haskard 2008	Patient mediated intervention + Distribution of educational material + education meeting (n=61)	Usual Care	Physician informative and participatory (n=66)	NA	0,02 (0,39)	NA	-0,10 (0,41)	Unit of error analysis	
Haskard 2008	Patient mediated intervention + Distribution of educational material + education meeting (n=61)	Usual Care	Patient active (n=66)	NA	-0,02 (0,32)	NA	-0,08 (0,37)	Unit of error analysis	
Haskard 2008	Patient mediated intervention + Distribution of educational material + education meeting (n=61)	Usual Care	Physician-patient interaction (n=66)	NA	-0,03 (0,46)	NA	-0,06 (0,50)	Unit of error analysis	
Hess 2012	Patient mediated intervention + educational meeting (n=100)	Usual Care	OPTION (n=100)	NA	26,60 (8,10)	NA	7,00 (5,50)	2,83 (2,44 to 3,22)	2,83
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
Murray 2010	Educational meeting, audit and feedback, distribution of educational materials, educational outreach, barriers assement	Usual Care	Decision Support Analysis Tool (DSAT)	"The mean score change from baseline in the intervention group 3.75 (95% CI 2.46 to 5.03) was significantly greater than the mean score change in the control group -0.667 (95% CI -1.57 to 0.24) using the two sided t-test (P < 0.0001)" Page 116					
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**

Table 6. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to usual care *(Continued)*

Cooper 2011	Patient mediated intervention + Educational meeting (n=58)	Usual Care	Participatory Decision making (PDM) (n=43)	66,67 (23,98)	72,84 (21,19)	74,61 (21,59)	69,38 (21,50)	0,16 (-0,23 to 0,56)	0,16
Hamman 2007	Patient mediated intervention + Educational meeting (n=33)	Usual Care	Combined Outcome Measure for Risk Communication and Treatment (COMRADE) (n=49)	NA	76,8 (20,9)	NA	73,5 (19,3)	0,16 (-0,28 to 0,61)	0,16
Wetzels 2005	Patient mediated Intervention + educational outreach visit (n=121)	Usual Care	Combined Outcome Measure for Risk Communication and Treatment (COMRADE) - 4 items (n=142)	1,82 (NA)	1,83 (NA)	1,89 (NA)	1,80 (NA)	Unable to calculate. No differences between groups were detected.	NA

Patient reported outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
Leighl 2011	Patient mediated intervention and educational meeting	Usual Care	Modified CPS	There was no difference after the intervention: the mean score of the item on the CPS scale in the intervention group was: 2.86 (0.92), it was 2.87 (1.04) in the control group. See Figure 4, page 2082. Data are from the authors.
Loh 2007	Patient mediated intervention and educational meeting	Usual Care	PPS (Man-Son-Hing)	In the intervention group, significantly higher patient participation from pre- to post-intervention was found for … the Man-Son-Hing patient participation scale, P = 0.10. Page 329

Table 7. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting patients

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Mullan 2009	Patient mediated intervention + Education meeting (n=21)	Patient mediated intervention (n=19)	OPTION	NA	49,70 (17,74)	NA	27,70 (11,75)	1,42 (0,72 to 2,12)	1,42

Observer-based outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
No study									

Observer-based outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Patient reported outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
Bieber 2006	Patient mediated intervention and educational meeting (n=34)	Patient mediated intervention	Questionnaire on the Quality of Physician-Patient Interaction (QQPPI) (first consultation) (n=33)	NA	4,11 (0,7)	NA	3,59 (0,7)	0,73 (0,24 to 1,23)	0,73 (0,50 to 0,88)
Bieber 2006	Patient mediated intervention and educational meeting (n=34)	Patient mediated intervention	Questionnaire on the Quality of Physician-Patient Interaction (QQPPI) (3 months) (n=33)	NA	4,05 (0,7)	NA	3,67 (0,8)	0,50 (0,01 to 0,99)	

Table 7. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting patients *(Continued)*

Bieber 2006	Patient mediated intervention and educational meeting (n=34)	Patient mediated intervention	Questionnaire on the Quality of Physician-Patient Interaction (QQPPI) (6 months) (n=33)	NA	3,8 (0,8)	NA	3,13 (0,7)	0,88 (0,38 to 1,38)	
Cooper 2011	Patient mediated intervention + Educational meeting (n=58)	Patient mediated intervention	Participatory Decision making (PDM) (n=40)	66,67 (23,98)	72,84 (21,19)	70,94 (24,67)	74,17 (23,25)	-0,06 (-0,46 to 0,34)	-0,06
Mullan 2009	Patient mediated intervention + Educational meeting (n=47)	Patient mediated intervention	Validated pictorial instrument (n=36)	NA	4,8 (1,1)	NA	4,7 (1,1)	0,09 (-0,34 to 0,52)	0,09
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
Deinzer 2009	Patient mediated intervention + Educational meeting	Patient mediated intervention	Combined Outcome Measure for Risk Communication and Treatment (COMRADE)	The degree of SDM was significantly higher in the SDM group at basline and after 1-year visits. Both groups showed an increase in SDM (both P = 0.001). Page 268					
Deinzer 2009	Patient mediated intervention + Educational meeting	Patient mediated intervention	Autonomy Preference Index (API)	The preference for SDM as assessed by the API (Figure 2) showed no differences between the SDM and control group at baseline (P = 0.60) and did not change after 1 year (P = 0.83). Page 268					

Table 8. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting healthcare professionals

Observer-based outcome measure - Continous Data									

Table 8. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting healthcare professionals *(Continued)*

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
No study									
Observer-based outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Observer-based outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
No study									
Patient reported outcome measure - Continous Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre mean (SD)**	**Post mean (SD)**	**Pre mean (SD)**	**Post mean (SD)**	**SMD**	**Median (Range) by Study**
Cooper 2011	Patient mediated intervention + Educational meeting (n=58)	Educational meeting (n=51)	Participatory Decision making (PDM)	66,67 (23,98)	72,84 (21,19)	68,46 (22,81)	71,57 (19,94)	0,06 (-0,32 to 0,44)	0,06
Patient reported outcome measure - Categorical Data									
Study	**Intervention**	**Intervention**	**Outcome**	**Pre n/N**	**Post n/N**	**Pre n/N**	**Post n/N**	**RD**	**Median (Range) by Study**
No study									
Patient reported outcome measure - Qualitative statement									
Study	**Intervention**	**Intervention**	**Outcome**	**Qualitative quote**					
Roter 2012	Patient mediated intervention and distribution of	Distribution of educational materials	LEAPS	The study interventions led to significant and parallel increases in both patient and physician reported use of patient-centered communication skills, and an increase in patient satisfaction with communica-					

Table 8. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to another intervention targeting healthcare professionals *(Continued)*

	educational materials	tion-related visit goals. For patients, the intervention was associated with a positive change in reported skills in five of the six communication areas. Page 412

Table 9. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to intervention targeting both patients and healthcare professionals

Observer-based outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
No study									

Observer-based outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study
Myers 2011	Patient mediated intervention + reminders (n=74)	Patient mediated intervention + reminders (n=60)	Informed decision making scale (IDM)	NA	3/74	NA	5/60	-0,04 (-0,13 to 0,04)	-0,04

Observer-based outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Patient reported outcome measure - Continous Data

Study	Intervention	Intervention	Outcome	Pre mean (SD)	Post mean (SD)	Pre mean (SD)	Post mean (SD)	SMD	Median (Range) by Study
No study									

Patient reported outcome measure - Categorical Data

Study	Intervention	Intervention	Outcome	Pre n/N	Post n/N	Pre n/N	Post n/N	RD	Median (Range) by Study

Table 9. Effect of interventions: Intervention targeting both patients and healthcare professionals compared to intervention targeting both patients and healthcare professionals *(Continued)*

No study

Patient reported outcome measure - Qualitative statement

Study	Intervention	Intervention	Outcome	Qualitative quote
No study				

Table 10. Secondary outcome: patient health measures (Positive studies are in italics)

Study	Instrument	Intervention			Control			Std. effect size (CI 95%)
		N	Pre	Post	N	Pre	Post	
Continuous data: mean (SD)								
Elwyn 2004	Anxiety (short form of Spielberger) Time 1	Pre: 79 Post: 138	11.33 (3.74)	10.00 (3.55)	Pre: 107 Post: 187	11.62 (3.67)	9.86 (3.78)	Pre: -0.08 (-0.37 to 0.21) Post: 0.04 (-0.18 to 0.26)
Elwyn 2004	*Anxiety (short form of Spielberger) Time 2*	*Pre: 73* *Post: 117*	*9.94 (3.42)*	*11.25 (4.28)*	*Pre: 92* *Post: 164*	*10.36 (3.59)*	*10.23 (3.79)*	*Pre: -0.12 (-0.43 to 0.19)* *Post: 0.25 (0.02 to 0.49)*
Elwyn 2004	Anxiety (short form of Spielberger) Time 3	Pre: 61 Post: 101	10.15 (3.24)	10.51 (3.93)	Pre: 75 Post: 136	10.87 (3.55)	9.99 (3.23)	Pre: -0.21 (-0.55 to 0.13) Post: 0.15 (-0.11 to 0.40)
Elwyn 2004	*Health status (SF-1220) mental subscale Time 1*	*Pre: 101* *Post: 171*	*48.65 (10.26)*	*50.41 (10.90)*	*Pre: 68* *Post: 124*	*50.31 (9.66)*	*47.77 (11.21)*	*Pre: -0.16 (-0.47 to 0.14)* *Post: 0.24 (0.00 to 0.47)*
Elwyn 2004	Health status (SF-1220) mental subscale Time 2	Pre: 79 Post: 149	49.11 (11.14)	51.16 (10.41)	Pre: 68 Post: 108	50.16 (10.73)	49.23 (11.98)	Pre: -0.09 (-0.42 to 0.23)

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) *(Continued)*

								Post: 0.17 (-0.07 to 0.42)
Elwyn 2004	Health status (SF-1220) physical subscale Time 1	Pre: 101 Post: 171	41.16 (13.05)	42.47 (11.76)	Pre: 68 Post:124	43.01 (12.48)	41.90 (13.08)	Pre: -0.14 (-0.45 to 0.16) Post: 0.05 (-0.18 to 0.27)
Elwyn 2004	Health status (SF-1220) physical subscale Time 2	Pre: 79 Post: 149	39.71 (12.35)	40.81 (12.14)	Pre: 68 Post: 108	43.34 (11.46)	40.91 (11.81)	Pre: -0.30 (-0.63 to 0.02) Post: -0.01 (-0.26 to 0.24)
Hamann 2007	Clinical global impression scale	35	NA	4.0 (1.5)	40	NA	4.1 (1.4)	-0.07 (-0.52 to 0.38)
Hamann 2007	Global assessment of function scale	30	NA	54.7 (16.5)	37	NA	51.0 (18.5)	0.21 (-0.27 to 0.69)
Légaré 2012	Quality of life physical scale	181	49.30 (8.80)	49.40 (7.50)	178	47.70 (8.90)	48.20 (7.80)	0.16 (-0.05 to 0.36)
Van Peperstraten 2010	Level of anxiety	Pre:150 Post: 127	35.60 (10.60)	36.40 (10.20)	Pre: 154 Post: 135	34.60 (9.50)	34.70 (8.20)	0.18 (-0.06 to 0.43)
Categorical data (n/N)								
Hamann 2007	Patient hospitalised within 6 mo after discharge	36	NA	8/36	37	NA	8/37	0.01 (-0.18 to 0.20)
Hamann 2007	Patient hospitalised within 18 mo after discharge	38	NA	20/38	41	NA	19/41	0.06 (-0.16 to 0.28)
Hamann 2007	Patient with drug switches (main antipsychotic) within 6 mo after discharge	36	NA	12/36	40	NA	16/40	-0.07 (-0.28 to 0.15)
Hess 2012	Admitted to hospital	101	NA	6	103	NA	6	0 (-0.06 to 0.07)
Hess 2012	Repeat emergency department visit	101	NA	3	103	NA	0	0.03 (-0.01 to 0.07)

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) *(Continued)*

Hess 2012	Rehospitalization	101	NA	2	103	NA	0	0.02 (-0.01 to 0.05)
Hess 2012	Acute myocardial infarction	101	NA	1	103	NA	0	0.01 (-0.02 to 0.04)
Légaré 2012	Proportion of use of antibiotics	Pre: 182 Post: 180	75	49	Pre :171 Post:178	67	93	-0.25 (-0.35 to -0.15)
Van Peperstraten 2010	*Subclinical depression*	*Pre:147* *Post: 126*	*16*	*16*	*Pre: 151* *Post: 136*	*13*	*5*	*0.09 (0.02 to 0.16)*
Qualitative data								
Butow 2004	Spielberger State Trait Anxiety Scale	"In both groups, anxiety decreased by 3 points after the consultation, and there was no significant difference between the groups immediately after the consultation and one month later." Page 4407						
Butow 2004	Beck Depression Inventory (short form)	"No significant differences between groups were observed in raw or change scores on depression immediately after the consultation or one month later." Page 4407						
Mullan 2009	Adherence	" ... adherence to diabetes medications were near perfect in both groups and significantly better in the control group." Page 1565						
Mullan 2009	HbA	"The decision aid did not affect glycemic control or patient-reported health status at six months" Page 1565						
Krones 2008 (ARRI-BA-Herz)	Framingham Scoring system	Non significant (P = 0.31)						
Bernhard 2011	Anxiety (State Trait Anxiety Inventory)	"Anxiety slightly decreased over time for all cohorts. Patients in the SGA (Figure 4a) and ANZ (Figure 4b) cohorts reported comparable anxiety levels at each time point. The quality of life indicators showed similar findings (data not shown)." Page 6						
Bernhard 2011	Quality of life	"Anxiety slightly decreased over time for all cohorts. Patients in the SGA (Figure 4a) and ANZ (Figure 4b) cohorts reported comparable anxiety levels at each time point. The quality of life indicators showed similar findings (data not shown)." Page 6						
Bieber 2006	Center for epidemiological studies depression scale - CES-D	Non significant: P = 0.26 (table 4). Page 363						
Bieber 2006	Visual analogue scale for pain intensity	Non significant: P = 0.45 (table 4). Page 363						

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) *(Continued)*

Bieber 2006	Health status and physical function SF-36	Non significant: P = 0.89 (table 4). Page 363
Bieber 2006	Hannover Functional Questionnaire FFbH	Non significant: P = 0.81 (table 4). Page 363
Cooper 2011	Blood Pressure control	"Improvements in patient adherence and BP control did not differ across groups for the overall patient sample" p1; "In the overall sample, changes in systolic and diastolic BP at 12 months did not differ for any of the intervention groups when compared to the patient+physician minimal intervention group" p1300; "Changes in patient-reported adherence to medications at 12 months did not differ for any of the intervention groups compared to the patient+physician minimal intervention group."Page 1300
Davison 1997	Spielberger State Trait Anxiety Scale	"There was no evidence trait scores were different among groups, among measurement times, or between groups and measurement times" Page 195
Davison 1997	Center for epidemiological studies depression scale - CES-D	"No significant differences in mean depression scores were found among the groups, among measurement times, or between groups and measurement times" Page 196
Deinzer 2009	Self measurement of systolic and diastolic blood pressure	"Thus in both groups BP decreased but there were no significant differences between the 2 groups (systolic P = 0.24 and diastolic P = 0.16 respectively)." Page 268
Hamann 2007	Severity of illness (PANSS)	NA "... there were no differences between ... PANSS score at discharge" Page 994
Hamann 2007	Plasma level of antipsychotic	Not reported
Hamann 2007	Medication at discharge	Not reported
Hess 2012	Major adverse cardiac event	"Excluding the index presentation, there were no deaths or major adverse cardiac events within 30 days" Page 256
Leighl 2011	Functional Assessment of Cancer Therapy–General (FACT-G)	Patients completed the physical, emotional, and functional subscales of the Functional Assessment of Cancer Therapy - General (FACT-G) and had similar scores in both arms comparable with those of other patients with advanced cancer. Page 2080
Loh 2007	Brief PHQ-D - Depression severity	Non significant (P = 0.236)

Table 10. Secondary outcome: patient health measures (Positive studies are in italics) *(Continued)*

Murray 2001	Health status and physical function SF-36	" ... no difference in score was observed between the two groups" Page 5
Murray 2001	Health states and valuation of health states EQ-SD	" ... no difference in score was observed between the two groups" Page 5
Murray 2001	Spielberger state of trait anxiety inventory short form	"The Spielberger scores were similar in the final assessment in the two groups" Page 5
Murray 2001	Prostatic symptoms (American Urological Association symptom scale)	"The amount of change was not significantly different in the two groups" Page 5
Raynes-Greenow 2010	Mode of delivery	There were no differences between labour and birth outcomes between the groups P = 0.97 (table 4). See page 10
Raynes-Greenow 2010	Labour Type	There were no differences between labour and birth outcomes between the groups P = 0.97 (table 4). See page 10
Raynes-Greenow 2010	Analgesia used	There were no significant differences between groups in regards to analgesia use (P = 0.18-0.84). See page 7
Raynes-Greenow 2010	Apgar score	P = 0.12 (1 minute) and P = 0.68 (5 minutes) (table 4). See page 10
Stiggelbout 2008	Quality of life (HADS)	"Patients' quality of life was stable over time, in both groups. No effects were observed in the repeated measures for the anxiety and depression scales of the HADS, nor on the quality of life scales" Page 757
Stiggelbout 2008	100 mm visual analogue	"Patients' quality of life was stable over time, in both groups. No effects were observed in the repeated measures for the anxiety and depression scales of the HADS, nor on the quality of life scales" (100 mm visual analogue scale) Page 757

Table 11. Secondary outcome: duration of consultation (Positive studies are in italics)

Study	Instrument	Intervention	Control	Std. effect size (CI 95%)

Table 11. Secondary outcome: duration of consultation (Positive studies are in italics) *(Continued)*

		N	Pre	Post	N	Pre	Post	
Continuous data: mean (SD)								
Stacey 2006	Call length	Pre: 18 Post: 18	17.80 (4.50)	18.50 (6.30)	Pre: 20 Post: 20	16.70 (7.70)	16.70 (6.50)	Pre: 0.17 (-0.47 to 0.81) Post: 0.27 (-0.36 to 0.91)
Qualitative data								
Butow 2004	Consultation length	"Consultation length was similar between groups - on average, 36 minutes per consultation." Page 4407						
Elwyn 2004	Consultation length	"There was no difference in the mean consultation lengths at baseline, phase 1 and phase 2 (overall consultation mean duration was 12.5 minutes)" Page 342						
Fossli 2011	Consultation length	"There was a non significant difference between both groups (RD: -1:03 CI -6:13;4:07) P = 0.69" Page 4						
Krist 2007	Consultation length	"These [discussion times] patient-physician differences did not differ significantly across the control, brochure, and Web groups." Page 116						
Loh 2007	Consultation length	Non significant differences between the groups (Table 2) Page 329						
Montori 2011	*Consultation length*	*"The median (range)duration of osteoporosis discussions was 12.4 minutes (2.3-27.4) in the decision aid arm compared with 9.4 minutes (2.1-58) in the usual care arm (P .045)" Page 552-553*						
Murray 2001	Consultation length	Not reported						
Murray 2010	Consultation length	*"At baseline there was no significant difference. However, in the post-calls, the mean call duration was longer in the intervention group at 13,47 minutes (95% confidence interval 11.8;14.21), than in the control group at 10.29 minutes (95% CI 8.79 to 11.79 P = 0.004)" Page 117*						
Nannenga 2009	Consultation time	"We found no significant difference in face-to-face consultation duration with the staff endocrinologist (mean difference 3.8 min longer with the decision aid, 95% CI - 2.9 to 10.5)." Page 42						

Table 11. Secondary outcome: duration of consultation (Positive studies are in italics) *(Continued)*

Shepherd 2011	Consultation length	"These effects occurred without any significant difference in consultation length, mean consultation lengths were 26 minutes for control and intervention visits." Page 381
Vodermaier 2009	Consultation time	"No time differences emerged in the length of the treatment decision consultation with the physicians on patient self-reports. The mean time for the treatment decision making appointment was about 15 minutes" Page 593
Wetzel 2005	Consultation time	No differences between intervention and control groups were detected, consultations was between 12.2 and 13 minutes for all groups (Table 4) Page 292

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics)

Study	Instrument	Intervention			Control			Std. effect size (CI 95%)
		N	Pre	Post	N	Pre	Post	
Continuous data: mean (SD)								
Haskard 2008	Physician satisfaction questionnaire	61	NA	74.82 (5.47)	66	NA	74.60 (6.47)	Unit of error analysis
Haskard 2008	Satisfaction with the management and functioning of their office practice	61	NA	3.20 (0.65)	66	NA	3.08 (0.58)	Unit of error analysis
Haskard 2008	Overall quality of life	63	NA	3.00 (0.83)	63	NA	2.82 (0.73)	Unit of error analysis
Haskard 2008	Stress	61	NA	2.68 (0.69)	66	NA	2.78 (0.60)	Unit of error analysis
Mullan 2009	Acceptability amount of information	21	NA	6.59 (0.91)	19	NA	6.37 (1.14)	0.20 (-0.41 to 0.83)
Mullan 2009	Acceptability clarity of information	21	NA	6.20 (0.96)	19	NA	6.20 (0.80)	0.00 (-0.62 to 0.62)

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) *(Continued)*

Mullan 2009	Helpfulness of the information	21	NA	6.15 (0.94)	19	NA	5.74 (1.04)	0.41 (-0.22 to 1.03)
Mullan 2009	Would recommend to others	21	NA	6.16 (1.51)	19	NA	5.89 (1.82)	0.16 (-0.46 to 0.78)
Mullan 2009	Would want to use for other decisions	21	NA	6.04 (1.55)	19	NA	5.69 (1.75)	0.21 (-0.44 to 0.84)
Murray 2010	*Knowledge*	*35*	*NA*	*69.30 (2.98)*	*35*	*NA*	*60.50 (2.27)*	*3.28 (2.55 to 4.02)*
Krones 2008 (ARRI-BA-Herz)	Patient participation scale, physician rating	19	NA	1.66 (0.45)	26	NA	1.65 (0.48)	0.02 (-0.57 to 0.61)
Bieber 2006 (first consultation)	Difficult doctor patient questionnaire	34	NA	29.40 (5.80)	33	NA	33.50 (10.00)	-0.50 (-0.98 to -0.02)
Bieber 2006 (month follow up)	Difficult doctor patient questionnaire	34	NA	28.90 (6.70)	33	NA	32.20 (6.50)	-0.49 (-0.98 to -0.01)
Légaré 2012	Physician quality of decision	Pre: 172 Post: 166	8.20 (1.10)	8.20 (1.30)	Pre: 162 Post: 170	8.20 (1.40)	8.40 (1.00)	-0.17 (-0.39 to 0.04)
Légaré 2012	Physician intention to follow CPG	Pre: 151 Post: 132	1.60 (0.80)	1.70 (0.90)	Pre: 108 Post: 98	1.60 (0.90)	1.80 (0.70)	-0.12 (-0.38 to 0.14)
Loh 2007	Physician's assessment of treatment adherence	96	4.20 (1.10)	4.30 (1.10)	191	4.30 (0.90)	4.80 (0.60)	Intracluster correlation error
Categorical data: (n/N)								
Légaré 2012	Physician Decisional Conflict (Proportion who had a value of 2.5 or more)	Pre: 178 Post: 175	8	8	Pre: 166 Post: 176	5	2	0.03 (-0.00 to 0.07)

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) *(Continued)*

Murray 2001	Perceived role in decision making: shared role	48	NA	25/48	49	NA	32/49	-0.13 (-0.33 to 0.06)
Vodermaier 2009	Chose Breast-conserving therapy	39	NA	37/39	41	NA	36/41	0.07 (-0.05 to 0.19)
Vodermaier 2009	Chose Chemotherapy	35	NA	11/35	39	NA	11/39	0.03 (-0.18 to 0.24)
Vodermaier 2009	Chose pre-operative chemotherapy	16	NA	10/16	15	NA	7/15	0.16 (-0.19 to 0.50)
Qualitative data								
Butow 2004	Physician satisfaction with the decision making process	"Physicians were also equally satisfied with decision making whether or not their patients had received the CCPP or the control booklet" Page 4407						
Elwyn 2004	*Clinician perception of the level of clinician agreement*	*"Clinicians showed significant differences between the RC and SDM arms (see Table S3). Doctors receiving the risk communication tools and training first perceived significantly higher doctor–patient agreement on treatment (P 0.001), patient satisfaction with information (P = 0.01), doctor satisfaction with decision (P = 0.01) and general overall satisfaction (P = 0.001) with the consultation than those who were exposed to SDM training. The latter group of doctors showed lower scores after the interventions. The differences were largely maintained in the second intervention phase, i.e. even when provided with the risk communication training and tools, the group of doctors who had received SDM training first still reported lower levels of satisfaction, agreement, etc. In contrast, doctors who had received risk communication training first maintained their higher levels of satisfactions and agreement, even when later given the SDM training which appeared less beneficial (to doctors) in the first phase." Page 343*						
Elwyn 2004	*Clinician satisfaction with the decision and overall consultation*	*"Clinicians showed significant differences between the RC and SDM arms (see Table S3). Doctors receiving the risk communication tools and training first perceived significantly higher doctor–patient agreement on treatment (P 0.001), patient satisfaction with information (P 0.01), doctor satisfaction with decision (P 0.01) and general overall satisfaction (P 0.001) with the consultation than those who were exposed to SDM training. The latter group of doctors showed lower scores after the interventions. The differences were largely maintained in the second intervention phase, i.e. even when provided with the risk communication training and tools, the group of doctors who had received SDM training first still reported lower levels of satisfaction, agreement, etc. In contrast, doctors who had received risk communication training first maintained their higher levels of satisfactions and agreement, even when later given the SDM training which appeared less beneficial (to doctors) in the first phase." Page 343*						
Elwyn 2004	*Patient satisfaction with information provided (as described by clinicians)*	*"Doctors receiving risk communication tool and training first perceived significantly higher doctor-patient agreement on treatment (P < 0.001), patient satisfaction with information (P < 0.01), doctor satisfaction with decision (P < 0.01) and general overall satisfaction (P < 0.001)" Page 343*						

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) *(Continued)*

Mullan 2009	Decision aid acceptability	Not reported
Murray 2010	Acceptability of the instrument	"In all, 37 members of the intervention group (97%) commented on the acceptability of the skills building workshop. … The 31 (81%) agreed that the PtDA would be acceptable to patients, while 24 (63%) agreed that it would be acceptable to practitioners." Page 117
Murray 2010	Utility of the intervention PtDA	"All 36 who participated in the educational outreach call indicated an interested in using the POC PtDa and express frustration that it was not available for use in their clinical practice setting." Page 117
Murray 2010	Intention to engage	"All participants, regardless of group assignment, saw patient decision support as helpful to patients (n = 32 [100 percent] interventions; n = 38 [98 percent] control) While 27 members of the intervention group (87%) and 34 members of the control group (84%) indicated a positive intention to engage in decision support, 16 members of the intervention group (50%) strongly agreed that they could provide decision support compared to 11 members of the control group (28%)" Page 117
Stacey 2006	*Nurses' knowledge*	*"The nurses in the intervention group (n = 19) had a mean knowledge score of 74% and the mean score in the control group (n = 20) was 60%. The difference between the groups was significant (P = 0.007)." Page 413*
Stacey 2006	Nurses' perception of factors influencing use of the coaching protocol	"Most of the 19 nurses in the intervention group agreed that the protocol was compatible with their practice (n = 15), provided a logical approach (n = 17), was easy to try (n = 15) and helped with exploring the benefits and harms of the options available to callers (n = 16). Another advantage of using the protocol, as reported by one nurse, was that it ... increases focus on caller's needs rather than just giving information." Page 413
Bernhard 2011	Maslach Burnout Inventory	"When doctors' stress and burnout factors were accounted for in the mixed effects models for decisional conflict, the ESs became slightly larger in the SGA cohort but remained low. There was no influence by these factors on the ESs in the ANZ cohort (data not shown)." Page 5
Hamann 2007	Doctor patient relationship	"Doctor-patient relationship (WAI) and PANSS scores did not prove to be independent significant prognostic factors" Page 996
Hamann 2007	Physicians satisfaction with treatment results	Not reported
Hess 2012	Clinician satisfaction with and acceptability of the DA	"Of the 51 clinicians who used the decision aid, 50 (98%) considered it helpful, and 32 (63%) indicated their desire to use the decision aid again if given the opportunity. Most clinicians indicated a desire to use a decision aid for other clinical management decisions" Page 255
Krist 2007	Physician perception of the decision making process	"Physicians tended to reports that they had greater control over the decision than did the patients, as measured by the CPS" Page 116

Table 12. Secondary outcome: other measurement reported by the healthcare professional (Positive studies are in italics) *(Continued)*

Krist 2007	Number of test ordered	Not reported
Leighl 2011	Physician satisfaction with decision-making score	"Australian medical oncologists were surveyed regarding their satisfaction with the decision-making process after each consultation;scores were generally high and similar in both arms" Page 2080
Murray 2001	Evaluation of the intervention	"General practitioners were positive about the decision aid; of 50 follow up consultation with patients in the intervention group they said that the decision aid had helped in 46, made no difference in three, and hindered one." Page 5
Roter 2012	Time management	The area in which there was no significant difference in reported skill use was in relation to time management. p.412 Treatment adherence (P = 0.03); Interpersonal rapport (P = 0.004) Table 7, page 412
Roter 2012	*Treatment adherence*	*The area in which there was no significant difference in reported skill use was in relation to time management. page 412* *Treatment adherence (P = 0.03); Interpersonal rapport (P = 0.004) Table 7, page 412*
Roter 2012	*Interpersonal rapport*	*The area in which there was no significant difference in reported skill use was in relation to time management. page 412* *Treatment adherence (P = 0.03); Interpersonal rapport (P = 0.004) Table 7, page 412*
Stiggelbout 2008	Surgeon's perceptions	"No differences were seen between the arms of the trial in the surgeons' reply to the question whether and how they presented probabilities; nor to the question on the risk that were discussed, the total number of risks that were discussed, or the understanding of the information by the patients; nor to the question whether much discussion had taken place during the consultation." Page 757
Street 1995	Physician facilitation	Not reported
Van Peperstraten 2010	*Cost evaluation of the empowerment strategy*	*"The mean total savings in the intervention group were calculated to be €169.75 per couple included from the waiting list for in vitro fertilisation" Page 5*

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics)

Study	Instrument	Intervention			Control			Std. effect size (CI 95%)
		N	Pre	Post	N	Pre	Post	
Continuous data: mean (SD)								

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Bieber 2006	Satisfaction with decision scale	34	NA	4.11 (0.40)	33	NA	4.02 (0.60)	0.17 (-0.30 to 0.65)
Bieber 2006	Satisfaction with decision scale	34	NA	4.10 (0.60)	33	NA	4.07 (0.60)	0.05 (-0.43 to 0.53)
Bieber 2006	Desicional conflict scale	34	NA	12.90 (4.20)	33	NA	12.40 (3.70)	0.12 (-0.35 to 0.60)
Bieber 2006	Desicional conflict scale	34	NA	12.80 (3.00)	33	NA	12.50 (3.40)	0.09 (-0.39 to 0.57)
Deen 2012	Decision self-efficacy (DSE)	17	73.52 (19.13)	79.55 (12.79)	15	76.97 (17.95)	77.42 (19.29)	0.13 (-0.57 to 0.82)
Deen 2012	Decision self-efficacy (DSE)	21	71.54 (25.57)	79.55 (12.79)	15	76.97(17.96)	77.42 (19.30)	0.13 (-0.53 to 0.80)
Deen 2012	Decision self-efficacy (DSE)	17	77.27 (16.13)	83.82 (15.56)	15	76.97(17.97)	77.42 (19.31)	0.36 (-0.34 to 1.06)
Dolan 2002	Decisional conflict scale	45	NA	1.83 (0.52)	43	NA	2.03 (0.81)	-0.30 (-0.71 to 0.27)
Haskard 2009	Patient perceived decision-making	61	NA	2.94 (0.43)	66	NA	2.85 (0.46)	Unit of error Analysis
Haskard 2009	Patient choice	61	NA	4.15 (0.55)	66	NA	3.96 (0.68)	Unit of error Analysis
Krones 2008 (ARRIBA-Herz)	Decisional regret	372	NA	14.69 (NA)	372	NA	18.08 (NA)	Unable to calculate
Krones 2008 (ARRIBA-Herz)	Knowledge	535	NA	2.03 (NA)	576	NA	1.92 (NA)	Unable to calculate
Lalonde 2006	Decisional conflict scale	26	2.49 (0.53)	2.36 (0.30)	24	2.50 (0.39)	2.33 (0.30)	Pre: -0.02 (-0.58 to 0.53) Post: 0.0.10 (-0.46 to 0.65)
Landrey 2012	Knowledge of prostate cancer screening	71	NA	3.50 (1.50)	77	NA	3.30 (1.40)	0.14 (-0.19 to 0.46)
Légaré 2012	Patients' quality of decision	Pre: 158 Post: 162	8.70 (1.50)	8.50 (1.60)	Pre: 151 Post: 159	8.70 (1.50)	8.50 (1.50)	0 (-0.22 to 0.22)
Légaré 2012	Intention to engage in shared decision-making	Pre: 165	1.90 (1.20)	2.10 (1.10)	Pre: 164	2.00 (1.20)	1.90 (1.20)	0.17 (-0.04 to 0.39)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

		Post: 163			Post: 165			
Légaré 2012	*Regret over decision*	*Pre: 165* *Post: 162*	*10.50 (15.40)*	*12.40 (19.10)*	*Pre: 164* *Post: 164*	*10.80 (20.80)*	*7.60 (13.70)*	*0.29 (0.07 to 0.51)*
Loh 2007	*Doctor facilitation (PICS-DF)*	*191*	*15.40 (3.50)*	*17.40 (3.10)*	*96*	*14.70 (3.70)*	*14.50 (3.30)*	*Pre: 0.20 (-0.05 to 0.44)* *Post: 0.91 (0.66 to 1.17)*
Loh 2007	Information seeking (PICS-IS)	191	12.30 (2.70)	12.30 (3.40)	96	11.30 (2.90)	10.30 (2.90)	Pre: 0.36 (0.11 to 0.61) Post: 0.61 (0.36 to 0.87)
Loh 2007	Treament adherence	191	4.30 (0.80)	4.30 (0.90)	96	3.90 (0.80)	3.90 (1.00)	Pre: 0.50 (0.25 to 0.75) Post: 0.43 (0.18 to 0.67)
Loh 2007	*Patients satisfaction (ZUF8)*	*191*	*NA*	*29.80 (2.70)*	*96*	*NA*	*27.00 (3.60)*	*0.92 (0.66 to 1.18)*
Mullan 2009	Acceptability clarity of information	NA	NA	6.20 (0.96)	NA	NA	6.20 (0.80)	-0.01 (-0.38 to 0.36)
Mullan 2009	*Acceptability helpfulness of the information*	*NA*	*NA*	*6.15 (0.94)*	*NA*	*NA*	*5.74 (1.04)*	*0.38 (0.04 to 0.72)*
Mullan 2009	Acceptability; would recommend to others	NA	NA	6.16 (1.51)	NA	NA	5.89 (1.82)	0.38 (-0.28 to 1.05)
Mullan 2009	Acceptability; would want to use for other decisions	NA	NA	6.04 (1.55)	NA	NA	5.69 (1.75)	0.34 (-0.39 to 1.08)
Mullan 2009	Decisional conflict scale	NA	NA	14.10 (17.89)	NA	NA	14.95 (12.68)	-0.89 (-5.37 to 3.59)
Mullan 2009	Informed subscale of DCS (knowledge)	NA	NA	13.65 (19.84)	NA	NA	15.28 (15.49)	-2.49 (-7.21 to 2.23)
Mullan 2009	Trust in Physician scale	NA	NA	94.69 (7.14)	NA	NA	93.06 (9.58)	2.06 (-1.78 to 5.89)
Mullan 2009	Acceptable amount of information	NA	NA	6.59 (0.91)	NA	NA	6.37 (1.14)	0.2 (-0.41 to 0.83)
Murray 2001	Decisional conflict score	57	NA	2.30 (0.40)	48	NA	2.60 (0.50)	-0.66 (-1.06 to -0.27)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Murray 2001	Prosectomy rates and referrals	57	NA	0.11 (0.31)	48	NA	0.02 (0.14)	0.36 (-0.03 to 0.75)
Myers 2010	Knowledge change	142	NA	0.80 (1.90)	144	NA	1.50 (2.10)	-0.35 (-0.58 to -0.11)
Myers 2010	Decisional conflict	142	NA	0.32 (0.49)	144	NA	0.29 (0.34)	0.07 (-0.16 to 0.30)
Raynes-Greenow 2010	Decisional conflict at primary follow up	395	31.40 (12.80)	23.90 (10.60)	201	31.20 (13.40)	24.90 (12.90)	Pre: 0.02 (-0.15 to 0.19) Post: -0.09 (-0.25 to 0.08)
Raynes-Greenow 2010	Decisional conflict at second follow up	395	31.40 (12.80)	19.90 (12.30)	201	31.20 (13.40)	20.20 (14.10)	Pre: 0.01 (-0.15 to 0.18) Post: -0.02 (-0.19 to 0.15)
Raynes-Greenow 2010	Anxiety first follow up	395	33.90 (10.10)	33.30 (9.30)	201	34.30 (11.80)	34.30 (11.00)	Pre:-0.04 (-0.21 to 0.13) Post: -0.10 (-0.27 to 0.07)
Raynes-Greenow 2010	Anxiety second follow up	395	33.90 (10.10)	29.40 (8.50)	201	34.30 (11.00)	29.00 (9.50)	Pre: -0.04 (-0.21 to 0.13) Post: 0.04 (-0.12 to 0.21)
Raynes-Greenow 2010	Satisfaction with decision making first follow up	395	NA	81.50 (10.30)	201	NA	80.70 (11.70)	0.07 (-0.10 to 0.24)
Raynes-Greenow 2010	Satisfaction with decision making second follow up	395	NA	84.40 (12.90)	201	NA	82.80 (16.10)	0.11 (-0.06 to 0.28)
Raynes-Greenow 2010	*Knowledge of analgesia first follow up*	*395*	*53.40 (21.90)*	*65.10 (29.50)*	*201*	*54.40 (20.90)*	*56.50 (27.40)*	*Pre: 0.05 (-0.22 to 0.12)* *Post: 0.30 (0.13 to 0.47)*
Stiggelbout 2008	*Active participation of the patient*	*31*	*NA*	*1.40 (0.90)*	*33*	*NA*	*1.00 (0.20)*	*0.61 (0.11 to 1.18)*
Van Peperstraten 2010	*Knowledge experienced*	*Pre: 150* *Post: 127*	*5.70 (2.50)*	*7.70 (0.60)*	*Pre: 154* *Post: 135*	*5.80 (2.50)*	*7.20 (1.20)*	*0.52 (0.27 to 0.77)*
Van Peperstraten 2010	*Knowledge actual*	*127*	*NA*	*6.20 (2.85)*	*135*	*NA*	*4.30 (1.76)*	*0.74 (0.49 to 0.99)*

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Vodermaier 2009	Decisional conflict scale	53	NA	1.82 (0.59)	54	NA	1.99 (0.62)	-0.28 (-0.66 to 0.10)
Vodermaier 2009	Perceived involvement in care doctor facilitation (1-4)	53	NA	2.65 (0.66)	54	NA	2.72 (0.67)	-0.10 (-0.48 to 0.27)
Vodermaier 2009	Perceived involvement in care patient information	53	NA	3.04 (0.74)	54	NA	3.09 (0.73)	-0.10 (-0.40 to 0.36)
Vodermaier 2009	ZUF-8	53	NA	29.08 (2.99)	54	NA	28.67 (2.86)	0.14 (-0.24 to 0.52)
Categorical data (n/N)								
Dolan 2002	Annual fecal occult blood test	45	NA	11/23	43	NA	6/17	0.12 (-0.18 to 0.43)
Dolan 2002	No test (wait and see)	45	NA	8/8	43	NA	15/16	0.06 (-0.14 to 0.26)
Dolan 2002	Annual fecal occult blood test and flexible sigmoidoscopy every five years	45	NA	2/6	43	NA	7/8	
Dolan 2002	Flexible sigmoidoscopy every five years	45	NA	4/6	43	NA	1/2	0.17 (-0.15 to 0.48)
Dolan 2002	Double contrast barium enema every five years	45	NA	0/1	43	NA	0/0	NA
Dolan 2002	Colonoscopy every ten years	45	NA	1/1	43	NA	0/0	NA
Hess 2012	The proportion of patients who decided to undergo observation, unit admission, and cardiac stress testing	100	NA	58	100	NA	77	-0.19 (-0.32 to -0.41)
Krist 2007	PSA test ordered	196	NA	163/196	75	NA	64/75	-0.02 (-0.1 to -0.07)
Krist 2007	PSA test ordered	226	NA	194/226	75	NA	64/75	0.01 (-0.09 to 0.10)
O'Cathain 2002	More anxious (antenatal)	Pre: 600 Post: 803	69/600	96/803	Pre: 595 Post: 724	77/595	87/724	Pre: -0.01 (-0.05 to 0.02) Post: 0 (-0.03 to 0.03)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

O'Cathain 2002	More anxious (postnatal)	Pre: 879 Post: 846	99/879	86/846	Pre: 772 Post: 630	89/772	64/630	Pre: -0 (-0.03 to 0.03) Post: 0 (-0.03 to 0.03)
O'Cathain 2002	Drank less (antenatal)	Pre: 599 Post: 796	474/599	623/796	Pre: 595 Post: 696	443/592	551/696	Pre: 0.04 (0.00 to 0.10) Post:-0.10 (-0.03 to 0.03)
O'Cathain 2002	Planned hospitals birth (antenatal)	Pre: 619 Post: 826	608/619	799/826	Pre: 620 Post: 743	604/620	725/743	Pre: 0.01 (0.01 to 0.02) Post:-0.01 (-0.02 to 0.01)
O'Cathain 2002	Had screening test (antenatal)	Pre: 619 Post: 824	518/619	653/824	Pre: 619 Post:827	619/619	826/827	Pre: -0.16 (-0.19 to 0.13) Post: -0.21 (-0.23 to -0.18)
O'Cathain 2002	Partner/family present during labour (postnatal)	Pre: 922 Post: 886	867/922	836/886	Pre: 819 Post: 661	777/819	619/661	Pre: -0.01 (-0.03 to 0.01) Post: 0.01 (-0.02 to 0.03)
O'Cathain 2002	Stayed in bed during labour (postnatal)	Pre: 888 Post: 847	420/888	428/847	Pre: 796 Post: 635	409/796	319/635	Pre: -0.04 (-0.09 to 0.01) Post: 0 (-0.05 to 0.05)
O'Cathain 2002	Continuous monitory (postnatal)	Pre: 922 Post: 886	451/922	397/886	Pre: 819 Post: 661	387/819	319/661	Pre: 0.02 (-0.03 to 0.06) Post: -0.03 (-0.08 to 0.02)
O'Cathain 2002	Had epidural (postnatal)	Pre: 922 Post: 886	216/922	223/886	Pre: 819 Post: 661	177/819	160/661	Pre: 0.02 (-0.02 to 0.06) Post: 0.01 (-0.03 to 0.05)
O'Cathain 2002	Breast fed (postnatal)	Pre: 921 Post: 883	518/921	511/883	Pre: 818 Post: 660	482/818	389/660	Pre: -0.03 (-0.07 to 0.02) Post: -0.01 (-0.06 to 0.04)
O'Cathain 2002	Satisfied with amount of information	Pre: 891 Post: 855	619/891	635/855	Pre: 780 Post: 637	536/780	458/637	Pre: 0.01 (-0.04 to 0.05) Post: 0.02 (-0.02 to 0.069)
O'Cathain 2002	Satisfied with way choices were made	Pre: 886 Post: 855	683/886	656/855	Pre: 780 Post: 633	600/780	502/633	Pre: 0 (-0.04 to 0.04) Post: -0.03 (-0.07 to 0.02)

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

O'Cathain 2002	Enough discussion	Pre: 883 Post: 847	570/883	548/847	Pre: 774 Post: 636	481/774	414/636	Pre: 0.02 (-0.02 to 0.07) Post: -0 (-0.05 to 0.04)
Raynes-Greenow 2010	*Enough information to make decision*	*395*	*NA*	*352/395*	*201*	*NA*	*160*	*0.10 (0.03 to 0.16)*
Raynes-Greenow 2010	Analgesia used:support	395	NA	258	201	NA	120	0.06 (-0.03 to 0.14)
Raynes-Greenow 2010	Analgesia used: bath use	395	NA	143	201	NA	65	0.04 (-0.04 to 0.12)
Raynes-Greenow 2010	Analgesia used: epidural used	395	NA	133	201	NA	66	0.01 (-0.07 to 0.09)
Van Peperstraten 2010	*Fully empowered couples, decision empowerment*	*Pre: 150* *Post: 127*	*116*	*116*	*Pre: 154* *Post: 99*	*112*	*99*	*0.18 (0.09 to 0.27)*
Qualitative data								
Butow 2004	Satisfaction with the consultation and decision	"No significant differences were found between the groups in satisfaction with either the consultation or treatment decision" Page 4407						
Butow 2004	Satisfaction with the booklet	"No significant differences were found between groups in terms of reported anxiety provoked, perceived utility, or ease of understanding of materials. … There was significant reported usefulness of the CCPP and control booklet for the family (P = 0.004)." Page 4405						
Butow 2004	Information subscale of the Krantz Health Opinion Survey	"No significant results were obtained" Page 4407						
Deinzer 2009	*Hypertension Questionnaire*	*"Only in the SDM group was there an increase in knowledge after 1 year (P = 0.006). After 1 year both groups showed similar levels of knowledge" Page 269*						
Deinzer 2009	Short Form 36 Item Health Survey (SF-36)	"There were no differences between the 2 groups concerning health-related quality of life measured with the 8 scales of SF-36" Page 269						

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Deinzer 2009	*Difficult Doctor Patient Relationship Questionnaire (DDPRQ)*	*"Doctor-patient relationship … was better in the SDM group than the control at the beginning … and after 1 year (p.0016). In the control group … an improvement occurred … (P = 0.045) that did not occur in the SDM group (P = 0.16)" Page 269*
Deinzer 2009	Autonomy Preference Index	"Preference for SDM as assessed by the API showed no differences between the SDM and control group at baseline (P = 0.60) and did not change after 1 year (P = 0.83)" Page 268
Deschamps 2004	Decision conflict score and the informed subscale items	The differences between groups were non-significant (Table 2), page 25
Deschamps 2004	Satisfaction with preparation for decision making	The differences between groups were non-significant (Table 3), page 25
Deschamps 2004	Satisfaction with decision	"Women in the pharmacist and decision-aid groups had mean SWD scores of 4.3 and 4.4 respectively (scale range: 1 to 5) with no significant differences being reported between groups. Page 26
Deschamps 2004	Adherence to HRT	"There was no statistically significant difference in adherence between the study groups" Page 26
Elwyn 2004	Intention to adhere to chosen treatment	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes ... However, significant effects of the research clinic (i.e. mainly the provision of more time)did lead to improvement (0.7 increase, 95% CI 0.04 to 1.36, P < 0.05)" Page 351
Elwyn 2004	Patient's satisfaction with information provided	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Elwyn 2004	Enablement	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Elwyn 2004	Satisfaction with decision made	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Elwyn 2004	Patient's perceived support in decision	"No significant effects of the risk communication or SDM intervention were seen on the whole range of patient-based outcomes" Page 351
Fossli 2009	Patient global satisfaction	Non significant P = 0.38
Hamann 2007	Autonomy preference index (API)	Differences between groups not reported
Hamann 2007	Patient's satisfaction with overall care	Differences between groups not reported

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Hamann 2007	The medication adherence rating scale	Differences between groups not reported
Hamann 2007	Patient knowledge of disease and treatment (7-item multiple choice)	Differences between groups not reported
Hamann 2007	Compliance with drug regime	Overall compliance was "good" for 42 (49%) of the patients at 6 months and 40 (59%) at 18 months
Hess 2012	*Knowledge*	*Knowledge (P < 0.0001) Table 2. Page 6*
Hess 2012	DCS	DCS (MD=-13.6 (-19.1 to -8.1)) Table 2. Page 6
Hess 2012	Trust in physician	Trust in physician (MD=4.1 (-1.4 to 9.6)), Table 2. Page 6
Hess 2012	*Patient satisfaction with the decision-making process*	*Patients who used the decision aid reported greater satisfaction with the decision-making process (strongly agree, 61% versus 40%; absolute difference, 21%; 95% CI 7% to 33%). Page 5*
Kasper 2008	Treatment decision	"Pearson's chi square P-value for this table is not significant for patients already on immunotherapy at baseline and patients not yet on immunotherapy at baseline, compared to patients in the CG." Page 1350
Kasper 2008	Patients evaluation of the decision	"Six months after randomization, the two groups did not show any significant differences in their evaluation of their decisions" Page 1350
Kasper 2008	Measure of the decision making process	"Both groups progressed significantly in making their decision. However they did not show differences in the course of progress over the three measurement points" Page 1349
Krist 2007	*Prostate cancer screening knowledge*	*"… the percentage of correct answers on the knowledge scale was 54% in the control group (P < 0.001) vs 69% in the brochure group (P < 0.001)" Page 115*
Krist 2007	Decisional conflict score	"DCS scores among all 3 groups were equally low and did not differ significantly … " Page 115
Krist 2007	Patients and physicians topics covered in the discussion	"The decision aids did not appear to alter … the number of prostate cancer screening topics that patients or physicians recalled addressing" Page 115
Lalonde 2006	Risk perception	"No statistically significant improvements were observed after the intervention" p55 No mention of between-group differences
Lalonde 2006	Knowledge of hypertension	"However, knowledge of the estimated benefits of treatment tended to improve after the intervention (29% versus 58%; P = 0.06)" No mention of differences between group" Page 55

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Landrey 2012	Flyer acceptability	"Among patients who reported receiving the flyer, 86.4% felt the content was clearly presented, 86.4% felt it contained about the right amount of information, 45.5% felt the information was completely balanced, and 43.2% viewed it as biased against PSA testing; 88.6% would recommend it to others." Page 5
Leighl 2011	Decisional conflict score	Decision satisfaction and decisional conflict scores were similar in both arms. Page 2080
Leighl 2011	Patient satisfaction with decision	Decision satisfaction and decisional conflict scores were similar in both arms. Page 2080
Leighl 2011	Patient satisfaction with consultation	"Patients in both arms were highly satisfied with the consultation" Page 2080
Montori 2011	Knowledge: DA specific	Knowledge DA specific (P = 0.001) Table 2, page 553
Montori 2011	Knowledge: Not in the DA	Knowledge not in the DA (P = 0.35) Table 2, page 553
Montori 2011	Decisional conflict scale	Decisional conflict scale (P = 0.72) Table 2, page 553
Montori 2011	Trust	Trust (P = 0.46) Table 2, page 553
Murray 2001	Acceptability of decision aid	"Patients reacted positively to the decision aid" Page 5
Murray 2001	Satisfaction	Not reported
Murray 2001	Choice of treatment	The choice in treatment did not vary significantly from one group to another. For more details, see page 5.
Myers 2010	Screening use	"Screening use was lower in EI Group than in SI Group (63% versus 71%), but this difference was not statistically significant (odds ratio= 0.67; 95% confidence interval, CI: 0.41-1.08; P = 0.102)" Page 4
Raynes-Greenow 2010	Stages of decision making	"Even distribution among stages.... A small proportion of women in both groups were not considering their choices …, or had made up their mind and were 'unlikely to change mind' … A large proportion of women … were amenable to change or were in active deliberation stages ... the largest proportion ... were women who 'had made some choices but were willing to reconsider" Page 6
Raynes-Greenow 2010	Choice predisposition towards analgesia	"Overall, higher proportions of women in both groups intended to use non-pharmacological methods for labour pain relief rather than pharmacological methods." Page 6

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Raynes-Greenow 2010	Adherence and acceptability	"Most women had read all of the intervention (decision aid 98% compared to pamphlet group 95%, chi-square = 2.782, df=1, P = 0.061), and equally both groups would recommend the intervention they received to a pregnant friend (decision aid group 94% compared to pamphlet group 93%, chi-square, df=1, P = 0.57)" Page 7
Raynes-Greenow 2010	Source of information	"Both groups equally relied on family and friends, books and antenatal classes" Page 7
Raynes-Greenow 2010	Labour, Mode of delivery, Birth Weight, Apgar score	All information can be found in Table 4, page 10. There were no significant differences between groups
Roter 2012	Patient satisfaction:identification of problems and concerns	Patient satisfaction: identification of problems and concerns (P = 0.25) Table 6, page 411
Roter 2012	*Patient satisfaction:information exchange*	*Patient satisfaction: information exchange (P = 0.01) Table 6, page 411*
Roter 2012	*Patient satisfaction:shared decision-making*	*Patient satisfaction: shared decision-making (P = 0.03) Table 6, page 411*
Schroy 2011	*Screening intentions*	*"Differences in intention to schedule or complete a screening test for the 2 intervention groups versus control corresponded to moderate effect sizes ranging between 0.36 and 0.44. Scores were comparable for the 2 intervention groups." Page 9*
Stiggelbout 2008	*Understanding*	*"The only difference that was seen for the items related to understanding was a difference in favour of the IB group in the stated understanding of the issues that were important in the treatment decision: 84% (n = 32) of the IB group felt that due to the brochure they had better understanding, v. 62% (n = 21) of the GB group (chi-square test P = 0.004)" Page 756*
Stiggelbout 2008	*Consultation with the surgeon*	*"A main difference between the 2 groups was seen in satisfaction with the duration of the consultation … (chi-square test P = 0.04). … For patients' impression whether the surgeon perceived them more as a medical problem that as a person with a problem, an interaction effect was observed F (1.68)=4.31, P = 0.04." Page 757*
Street 1995	Patient knowledge	"The effect for method of communication approached significance (F = 3.30, P = 0.07) as patients in the computer group tended to learn more (mean, 75.5%; SD 13.64%) than did patients in the brochure group (mean, 71.4%; SD, 15.7%)" Page 2279
Street 1995	Patient optimism	"Optimism scores were not affected by … the educational intervention (F = 0.95, P = 0.93)" Page 2279
Street 1995	Patients' behavioural measures	Differences between groups not reported
Street 1995	Perceived involvement in decision making	Differences between groups not reported

Table 13. Secondary outcomes: other measures reported by patients (Positive studies are in italics) *(Continued)*

Wetzels 2005	Point in time of decision making	The points in time of decision making were not statistically significant (p-value = 0.93) Table 4, page 595
Wetzels 2005	*Patient enablement index*	*Significant effect size difference: -0.232 (-0.444; -0.021) P = 0.03, table 3, page 292*
Wetzels 2005	Satisfaction with their care-EU-ROPEP	Non significant; effect size difference -0.056 (-0.302; 0.192) P = 0.66, table 3, page 292
Wetzels 2005	Use of leaflet	"Sub-analyses showed that the scores for these 47 patients did not differ significantly on the outcomes measures from those of the control group or the intervention group non-users" Page 290
Wetzels 2005	Discussion of one of the eight known underreported health problems	None of the discussion topics were shown to be statistically significant. Table 4, page 292

APPENDICES

Appendix 1. PubMed strategy

[#]	[Search strategies in Pubmed (2 august 2012)]	[Results]
#1	shared decision*[tiab] or sharing decision*[tiab] or informed decision*[tiab] or informed choice*[tiab] or decision aid*[tiab] or ((share*[ti] or sharing*[ti] or informed*[ti]) and (decision*[ti] or deciding*[ti] or choice*[ti]))	2118
#2	decision making[mh:noexp] or decision support techniques[mh:noexp] or decision support systems, clinical[mh] or choice behaviour[mh:noexp] or decision making*[tiab] or decision support*[tiab] or choice behaviour*[tiab] or ((decision*[ti] or choice*[ti]) and (making*[ti] or support*[ti] or behaviour*[ti]))	28,283
#3	patient participation[mh] or patient participation*[tiab] or consumer participation*[tiab] or patient involvement*[tiab] or consumer involvement*[tiab] or ((patient*[ti] or consumer*[ti]) and (involvement*[ti] or involving*[ti] or participation*[ti] or participating*[ti]))	3734
#4	professional-patient relations[mh] or ((nurses[mh] or physicians[mh] or nurse*[ti] or physician*[ti] or clinician*[ti] or doctor*[ti] or general practitioner*[ti] or gps[ti] or health care professional*[ti] or healthcare professional*[ti] or health care provider*[ti] or healthcare provider*[ti] or resident*[ti]) and (patients[mh] or patient*[ti] or consumer*[ti] or people*[ti]))	16,592
#5	clinical trial[pt:noexp] or randomized controlled trial[pt] or controlled clinical trial[pt] or evaluation studies[pt] or comparative study[pt] or intervention studies[mh] or Evaluation Studies as Topic[mh:noexp] or program evaluation[mh:noexp] or random allocation[mh] or random*[tiab] or double blind*[tiab] or controlled trial*[tiab] or clinical trial*[tiab] or pretest*[tiab] or pre test*[tiab] or posttest*[tiab] or post test*[tiab] or prepost*[tiab] or pre post*[tiab] or controlled before*[tiab] or "before and after"[tiab] or interrupted time*[tiab] or time serie*[tiab] or intervention*[tiab]	463,581
#6	(#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5	**1235**

Appendix 2. EMBASE strategy

[#]	[Search strategies in Embase (2 august 2012)]	[Results]
#1	'Shared Decision':TI,AB OR 'Sharing Decision':TI,AB OR 'Informed Decision':TI,AB OR 'Informed Choice':TI,AB OR 'Decision Aid':TI,AB OR ((Share*:TI OR Sharing*:TI OR Informed*:TI) AND (Decision*:TI OR Deciding*:TI OR Choice*:TI))	1496
#2	'Clinical Decision Making'/EXP OR 'Decision Making'/EXP OR 'Decision Support System'/EXP OR 'Ethical Decision Making'/EXP OR 'Family Decision Making'/EXP OR 'Medical Decision Making'/EXP OR 'Patient Decision Making'/EXP OR 'Decision Making':TI,AB OR 'Decision Support':TI,AB OR 'Choice Behaviour':TI,AB OR ((Decision*:TI OR Choice*:TI) AND (Making*:TI OR Support*:TI OR Behaviour*:TI))	41,774
#3	Patient Participation'/EXP OR 'Patient Participation':TI,AB OR 'Consumer Participation':TI,AB OR 'Patient Involvement':TI,AB OR 'Consumer Involvement':TI,AB OR	3790

(Continued)		
	((Patient*:TI OR Consumer*:TI) AND (Involvement*:TI OR Involving*:TI OR Participation*:TI OR Participating*:TI))	
#4	Doctor Patient Relation'/EXP OR 'Nurse Patient Relationship'/EXP OR (('Nurse'/EXP OR 'Physician'/EXP OR Nurse*:TI OR Physician*:TI OR Clinician*:TI OR Doctor*:TI OR 'General Practitioners':TI OR GPs:TI OR 'Health Care Professionals':TI OR 'Healthcare Professionals':TI OR 'Health Care Providers':TI OR 'Healthcare Providers':TI OR Resident*:TI) AND ('Patient'/EXP OR Patient*:TI OR Consumer*:TI OR People*:TI))	65,970
#5	clinical trial'/exp OR 'randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'controlled trial'/exp OR 'pretest posttest control group design'/exp OR 'comparative study'/exp OR 'evaluation research'/exp OR 'intervention study'/exp OR 'randomization'/exp OR random*:ti,ab OR 'double blind':ti,ab OR 'controlled trial':ti,ab OR 'clinical trial':ti,ab OR pretest*:ti,ab OR 'pre test':ti,ab OR 'pre tests':ti,ab OR posttest*:ti,ab OR 'post test':ti,ab OR 'post tests':ti,ab OR prepost*:ti,ab OR 'pre post':ti,ab OR 'controlled before':ti,ab OR 'before and after':ti,ab OR 'interruped time':ti,ab OR 'time serie':ti,ab OR 'time series':ti,ab OR intervention*:ti,ab	1,113,563
#6	(#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5	**2044**

Appendix 3. CINAHL strategy

[#]	[Search strategies in Embase (2 august 2012)]	[Results]
#1	AB Shared Decision* OR TI Shared Decision* OR AB Sharing Decision* OR TI Sharing Decision* OR AB Informed Decision* OR TI Informed Decision* OR AB Informed Choice* OR TI Informed Choice* OR AB Decision Aid* OR TI Decision Aid* OR ((TI Share* OR TI Sharing OR TI Informed*) AND (TI Decision* OR TI Deciding* OR TI Choice*))	2075
#2	MH "Decision Making+" OR MW Decision Support OR AB Decision Making* OR TI Decision Making* OR AB Decision Support* OR TI Decision Support* OR AB Choice Behaviour* OR TI Choice Behaviour* OR ((TI Decision* OR TI Choice*) AND (TI Making* OR TI Support* OR TI Behaviour*))	22,891
#3	MH Consumer Participation OR AB Patient Participation* OR TI Patient Participation* OR AB Consumer Participation* OR TI Consumer Participation* OR AB Patient Involvement* OR TI Patient Involvement* OR AB Consumer Involvement* OR TI Consumer Involvement* OR ((TI Patient* OR TI Consumer*) AND (TI Participating* OR TI Participation* OR TI Involving* OR TI Involvement*))	5167
# 4	MH Professional Patient Relations OR MH Nurse Patient Relations OR MH Physician Patient Relations OR ((MH Nurses+ OR MH Physicians+ OR TI Nurse* OR TI Physician* OR TI Clinician* OR TI Doctor* OR TI General Practitioner* OR TI GPs OR TI Health Care Professional* OR TI Healthcare Professional* OR TI Health Care Provider* OR TI Healthcare Provider* OR TI Resident*) AND (MH Patients+ OR TI Patient* OR TI Consumer* OR TI People*))	9932
#5	MH Experimental Studies+ OR MH Quasi-Experimental Studies OR MH Comparative Studies OR MH Evaluation Research OR AB Random* OR TI Random* OR AB Double Blind* OR TI Double Blind* OR AB Controlled Trial* OR TI Controlled Trial* OR AB Clinical Trial* OR TI Clinical Trial* OR AB Pretest* OR TI Prestest* OR AB Pre Test* OR TI Pre Test* OR AB Posttest* OR TI Posttest* OR AB Post Test* OR TI Post Test* OR AB Prepost* OR TI Prepost* OR AB Pre Post* OR TI Pre Post* OR AB Controlled Before* OR TI Controlled Before* OR AB "Before and After*" OR TI "Before and After*" OR AB	129,817

(Continued)

	Interruped Time* OR TI Interrupted Time* OR AB Time Serie* OR TI Time Serie* OR AB Intervention* OR TI Intervention*	
#6	(#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)) AND #5	**2082**

Appendix 4. PsycINFO strategy

[#]	[Search strategies in psycINFO (17 august 2012)]	[Results]
#1	ab=(("Shared Decision") OR ("Sharing Decision") OR ("Informed Decision") OR ("Informed Choice") OR ("Decision Aid")) OR ti=((Share* OR Sharing* OR Informed*) AND (Decision* OR Deciding* OR Choice*))	776
#2	it="Decision Making" OR it="Choice Behavior" OR it="Group Decision Making" OR it="Choice Shift" OR it="Management Decision Making" Or it="Decision Support" OR ab=(("Decision Making") OR ("Decision Support") OR ("Choice Behaviour")) OR it=((Decision* OR Choice*) AND (Making* OR Support* OR Behaviour))	17,413
#3	it="Client Participation" OR ab=(("Consumer Participation") OR ("Consumer Involvement") OR ("Patient Participation") OR ("Patient Involvement")) OR it=((Patient* OR Consumer*) AND (Participating* OR Participation* OR Involving* OR Involvement*))	583
#4	it="Therapeutic Processes" OR (it="Nurses" OR it="Psychiatric Nurses" OR it="Public Health Service Nurses" OR it="School Nurses" OR it="Physicians" OR it"Family Physicians" OR it="General Practitioners" OR it="Gynecologists" OR it="Internists" OR it="Neurologists" OR it="Obstetricians" OR it="Pathologists" OR it="Pediatricians" OR it="Psychiatrists" OR it="surgeons" OR ti=(Nurse* OR Physician* OR Clinician* OR Doctor* OR ("General Practitioner") OR GPs OR ("Health Care Professional") OR ("Healthcare Professional") OR ("Health Care Provider*") OR ("Healthcare Provider")) AND (it="Patients" OR it="Geriatric Patients" OR it="Hospitalized Patients" OR it="Medical Patients" OR it="Outpatients" OR it="Psychiatric Patients" OR it="Surgical Patients" OR it"Terminally ill Patients") OR ti=(Patient* OR Consumer* OR People*))	5124
#5	#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)	**3787**

Appendix 5. The Cochrane Library (CDSR, CENTRAL, DARE, Technology Assessment and Economic Evaluation) strategy

[#]	[Search strategies in COCHRANE Library (CDSR, CENTRAL, DARE, Technology Assessment and Economic Evaluation) search strategy (17 august 2012)]	[Results]
#1	"Shared Decision*" OR "Sharing Decision*" OR "Informed Decision*" OR "Informed Choice*" OR "Decision Aid*" OR ((Share* OR Sharing* OR Informed*):ti AND (Decision* OR Deciding* OR Choice*):ti)	288
#2	"Decision Making*" OR "Decision Support*" OR "Choice Behaviour" OR ((Decision* OR Choice*):ti AND (Making* OR Support* OR Behaviour*):ti)	1990

(Continued)

#3	"Patient Participation*" OR "Consumer Participation*" OR "Patient Involvement*" OR "Consumer Involvement*" OR ((Patient* OR Consumer*):ti AND (Involvement* OR Involving* OR Participation* OR Participating*):ti)	555
#4	"Professional-Patient Relation*" OR "Nurse-Patient Relation*" OR "Physician-Patient Relation*" OR ((Nurse* OR Physician* OR Clinician* OR Doctor* OR "General Practitioner*" OR GPs OR "Health Care Professional*" OR "Healthcare Professional*" OR "Health Care Provider*" OR "Healthcare Provider*" OR Resident*):ti AND (Patient* OR Consumer* OR People*):ti)	237
#5	#1 OR (#2 AND #3) OR (#2 AND #4) OR (#3 AND #4)	**398**

Appendix 6. EPOC Register strategy

[#]	[Search strategies in EPOC Register (18 June 2012)]	[Results]
1	{decision making} OR {shared decision*} OR {sharing decision*} OR {collaborat* decision*} OR {informed decision*}	159
2	{decision*} AND {shar*}	161
3	{decision*} AND {collaborat*}	161
4	{decision*} AND {informed}	162
5	{decision making} OR {shared decision*} OR {sharing decision*} OR {collaborat* decision*} OR {informed decision*}	169
6	patient* decision*	169
7	{collaborat*} AND {decision*}	183
8	{share*\} AND {decision*}	194
9	{collaborat*} AND {care}	400
10	{informed} AND {decision*}	410
11	{informed} AND {care}	457
12	{2.0}OR {2009} OR {2010} OR {2011} OR {2012} OR {inc} OR {misc}	**154**

(share* or collaborative or informed) and (care or decision*)

Appendix 7. ClinicalTrials.gov, US National Institutes of Health (NIH)

[#]	[Search strategies in ClinicalTrials.gov (2013-01-15)]	[Results]
#1	"informed choice"	45

(Continued)

#2	"decision making"	342
#3	"decision support"	372
#4	"informed decision"	90
#5	"decision aid"	377
#6	"sharing decision"	65
#7	"shared decision"	172
	Total	**1463**

Appendix 8. International Shared Decision Making Conference (ISDM)

[Search in ISDM proceeding]	[Results]
References	**255**

Appendix 9. Society for Medical Decision Making (SMDM)

[Search in SMDM proceeding]	[Results]
References	**338**

Appendix 10. Previous review on patient-reported outcome measure of SDM

[Previous review (Légaré 2012a)]	[Results]
References	**9035**

Appendix 11. Reference from expert

[Reference sent by expert]	[Results]
Reference	**1**

WHAT'S NEW

Date	Event	Description
12 September 2014	New citation required but conclusions have not changed	New search, 18 additional studies added to the review
12 September 2014	New search has been performed	New search has been performed

HISTORY

Protocol first published: Issue 3, 2007
Review first published: Issue 5, 2010

Date	Event	Description
30 November 2011	Amended	
29 September 2011	New search has been performed	Updated observer-reported outcomes to 2010
29 September 2011	Amended	Included patient-reported outcomes to 2010

CONTRIBUTIONS OF AUTHORS

2010 review (Légaré 2010)

SR developed the search strategy.

FL, SR, DS, JK, IDG, MS, LP and KG identified eligible studies for this review.

FL, SR, MS, LP and ST helped with data abstraction.

FL, SR, DS and ST assisted with data analysis.

FL, SR, MS and ST developed the draft of the review.

FL, SR, DS, JK, IDG, MS and ST reviewed and participated in the writing of the final review.

2010 to 2012 update (current review)

FL, DS, ST and MJC identified eligible studies for the update of this review.

FL, ST and MJC helped with data abstraction.

FL, DS, ST and MJC assisted with data analysis.

FL, ST and MJC developed the draft of the review.

AL, DS, ST, MJC, JK, IDG, AL, MCP, RT, GE and NDB reviewed and participated in the writing of the final review.

DECLARATIONS OF INTEREST

This review includes studies that were published by some of its authors (DS, FL, GE, IDG, NDB).

MCP is on the medication adherence advisory board for Merck.

No other conflicts of interest are known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Tier 2 Canada Research Chair in Implementation of Shared Decision Making in Primary Care, Université Laval, Québec, Canada.
- Consortium de recherche sur les services de génétique de laboratoire (CanGènetest), Québec, Canada.
- Centre de recherche du Centre Hospitalier Universitaire de Québec, Québec, Canada.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Since publishing the protocol and the 2010 version of this review (Légaré 2010), we organized the types of intervention defined by the EPOC taxonomy into three categories: interventions targeting patients (for example patient-mediated interventions), interventions targeting healthcare professionals (distribution of printed educational material, educational meetings, audit and feedback, reminders and educational outreach visits), and interventions targeting both patients and healthcare professionals (that is a patient-mediated intervention combined with one that targets the healthcare professional). These three categories correspond to the specific objectives of the review. Also, we split the outcomes into observer-based outcomes and patient-reported outcomes because measures for observer-based outcomes are more objective than patient-reported outcomes. Finally, we used GRADE tools to summarize our findings (see Summary of findings for the main comparison). Since publishing the protocol, two authors were removed (S Ratté and Karine Gravel) and six new authors were added (MJC, AL, MCP, RT, GE and NDB).

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Making; *Decision Support Techniques; *Patient Participation; Health Personnel [*education]; Patient Education as Topic [methods]; Randomized Controlled Trials as Topic

MeSH check words

Humans

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Review

Choosing treatment and screening options congruent with values: Do decision aids help? Sub-analysis of a systematic review

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ABSTRACT

Objective: To understand how well patients make value congruent decisions with and without patient decision aids (PtDAs) for screening and treatment options, and identify issues with its measurement and evaluation.
Methods: A sub-analysis of trials included in the 2014 Cochrane Review of Decision Aids. Eligible trials measured value congruence with chosen option. Two reviewers independently screened 115 trials.
Results: Among 18 included trials, 8 (44%) measured value congruence using the Multidimensional Measure of Informed Choice (MMIC), 7 (39%) used heterogeneous methods, and 3 (17%) used unclear methods. Pooled results of trials that used heterogeneous measures were statistically non-significant ($n = 3$). Results from trials that used the MMIC suggest patients are 48% more likely to make value congruent decisions when exposed to a PtDA for a screening decision (RR 1.48, 95% CI 1.01 to 2.16, $n = 8$).
Conclusion: Patients struggle to make value congruent decisions, but PtDAs may help. While the absolute improvement is relatively small it may be underestimated due to sample size issues, definitions, and heterogeneity of measures.
Practice Implications: Current approaches are inadequate to support patients making decisions that are consistent with their values. There is some evidence that PtDAs support patients with achieving values congruent decisions for screening choices.

Contents

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1. Introduction

There is increasing attention on patient-centered care, care defined as being "respectful of and responsive to individual patient preferences, needs, and values," which ensures "that patient values guide all clinical decisions" [1]. Policy shifts toward patient-centered care focus on providing patients with greater choice, recognizing their roles as consumers of health care who know best their own preferences and values. In decision-making, values refers to the patient's "informed attitudes about the relative desirability/undesirability of a health care option's unique characteristics, which include that option's protocol, possible benefits, and potential harms" [2].

However merely informing patients of their options, providing evidence on risks and benefits, and empowering them to be involved in the decision-making process does not necessarily lead to patient centered care [3]. In behavioral economics, there is increasing recognition that consumers can be poor decision makers, making irrational choices in spite of having good knowledge and understanding of their personal values [4,5]. This understanding has led to a greater focus on decision quality—the extent to which people are informed and receive options that reflect their goals and treatment preferences [6]. Apart from being important on ethical and patient-centered grounds [7,8], high quality decision-making is being recognized as an important intermediary for improving clinical outcomes [9].

In health care, there has been rapid growth in the development of tools to support decision-making, such as patient decision aids (PtDAs). They provide evidence on risks and benefits of options, help patients clarify what matters most to them, and empower patients to engage in making choices [10]. PtDAs are tools that support preference-sensitive health care decisions where there is no "best" option and the decision depends on what attributes of the choice matter most to the patient. Ideally, the PtDA is embedded in a process of shared decision-making, where the patient and practitioner discuss the benefits and harms of each option, the patient has time to reflect and clarify his or her preferences and desired involvement in making the decision, and together they make or defer a decision and discuss follow-up [11]. Despite a rapid growth in the development of PtDAs, there is limited evidence supporting their effectiveness in achieving decisions that reflect patients' values.

A Cochrane Systematic Review recently summarized the evidence on value congruence for 115 randomized controlled trials (RCTs) of PtDAs for screening and treatment choices [10]. Twenty trials (17%) reported a measure of value congruence and authors reported a pooled relative risk of value congruent decision-making for the 13 trials that provided quantitative results. Exposure to a PtDA increased value congruence in comparison to usual care (RR 1.51, 95% CI 1.17 to 1.97, $p = 0.0017$, $n = 13$) [10]. The authors concluded that patients who used PtDAs "were more likely to reach decisions that were consistent with their values" [10]. However, there are limitations to the Cochrane review analysis of value congruence and the positive results should be interpreted cautiously. The authors found considerable heterogeneity in the measurement of value congruence and classified the pooled results as low quality evidence due to lack of precision, consistency, and directness among the 13 trials [10,12]. Further, the review did not discuss the quality of methods used or propose how future studies might measure value congruence to overcome these limitations. For these reasons a deeper analysis of studies included in the Cochrane review is needed.

This review focuses on value congruence, a key component of decision quality [6]. A quality decision is (a) informed by knowledge of the options and (b) "value congruent," defined as the match between the chosen option and the patient's values. A patient may make an informed decision that is based on good knowledge of their options, however if the chosen option does not then match their values, it would not be a quality decision. A key element of shared decision making is that practitioners understand what matters to patients in order to support them in choosing screening or treatment options that match their values. While this may be difficult to achieve in routine practice, the consequences of not aligning health care decisions with patients' values can be significant. For instance, in a cross-sectional survey, practitioners believed that 71% of patients with breast cancer rated keeping their breast as a top priority, but the figure reported by patients was only 7% [13]. Using previously described organizing frameworks [14,15] we further investigated the results of studies included in the Cochrane review to understand how well patients made value congruent treatment decisions with and without PtDAs for screening and treatment choices. We sought to identify issues with its measurement and evaluation, and to propose how future studies might approach measurement.

2. Methods

2.1. Study Design

This systematic review was conducted as a sub-analysis of RCTs included in the 2014 Cochrane Review, Decision Aids for People Facing Health Treatment or Screening Decisions [10]. We chose to analyze this dataset due to the review's conclusion that PtDAs enhance value congruent decision-making. Conducting a sub-analysis of RCTs allowed us to explore measurement of value congruence more rigorously than if we were to pool results from various observational study designs. Inclusion of observational studies would have increased risk of bias due to heterogeneity between studies and the lack of controls or comparison groups. A detailed description of search strategy methods is available in the methodology section of the 2014 Cochrane review [10], but briefly citations were searched from the start of each database and grey literature to June 2012 (MEDLINE, CENTRAL, EMBASE, PsycINFO) and to September 2008 for CINAHL.

The review identified 115 RCTs of PtDAs of which 20 included value congruence outcomes (see Fig. 1). For this sub-analysis review, two reviewers (SM, NB) screened all included trials by first

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examining the table of characteristics of trials included in the full Cochrane review, and then reviewing information on risk of bias in included studies. All trials that measured "values congruence with chosen option" as an outcome were eligible for full text review. To be included in the final full text review, trials had to report a relationship or measure of congruence between patients' values and choices, based on (a) a value clarification method that reported "the extent to which the positive and negative characteristics of different health care options are personally important to the patient" [2], and (b) the patients' intended or actual choices. We excluded studies that used a measure of "feeling clear" about one's values alone (e.g. the values subscale of the Decisional Conflict Scale (DCS) [16]), as this measures one's perception of clear values and does not qualify as a true value clarification method. No trials were excluded based on risk of bias.

2.2. Data extraction

The full texts of eligible publications were read independently by the two reviewers and data were extracted using a standardized form. Data extracted included: the type of decision support intervention, the choice of treatment or screening, the method used to measure patients' preferences/values, the method used to measure patients' choices, the type of choice recorded, the method for defining value congruence, and the value congruence outcome. Discrepancies were resolved through discussion, through re-examination of the trial publications, and if necessary further discussion with a third author (DS). Data were entered into an Excel database for synthesis.

2.3. Defining values and choice

Value congruence is a calculation of the match between the chosen option or "choice" (dependent variable) and the patient's "values" (independent variable). Following Sepucha and Ozanne's [14] terminology, "choice" was defined as the selected option, either intended or actual, for screening or treatment decisions.

"Values" were defined as "patients' preferences for health outcomes or attributes" of the screening or treatment options [14]. Included trials used the terms values, attitudes, and preferences synonymously. "Value clarification methods" reported "the extent to which the positive and negative characteristics of different health care options are personally important to the patient" [2]. Value clarification is a necessary step in making a preference-sensitive decision as the patient's "preferred choice depends on the individual patient's informed attitudes toward each option's positive and negative characteristics—including the probabilities associated with those characteristics" [2].

2.4. Classification scheme

We used a classification scheme to illustrate how trials included in the Cochrane review used different combinations of variables to calculate value congruence (see Fig. 2). Specifically, we adapted a framework developed by Sepucha and Ozanne [14,15] that presents ten different models of defining preferences and choices to calculate value congruence. In their classification scheme, Sepucha and Ozanne identified three methods for defining "values" and three methods for defining "choice." Adaptations included minor changes to the language of variables to reflect our usage of the key concepts. For instance we replaced Sepucha and

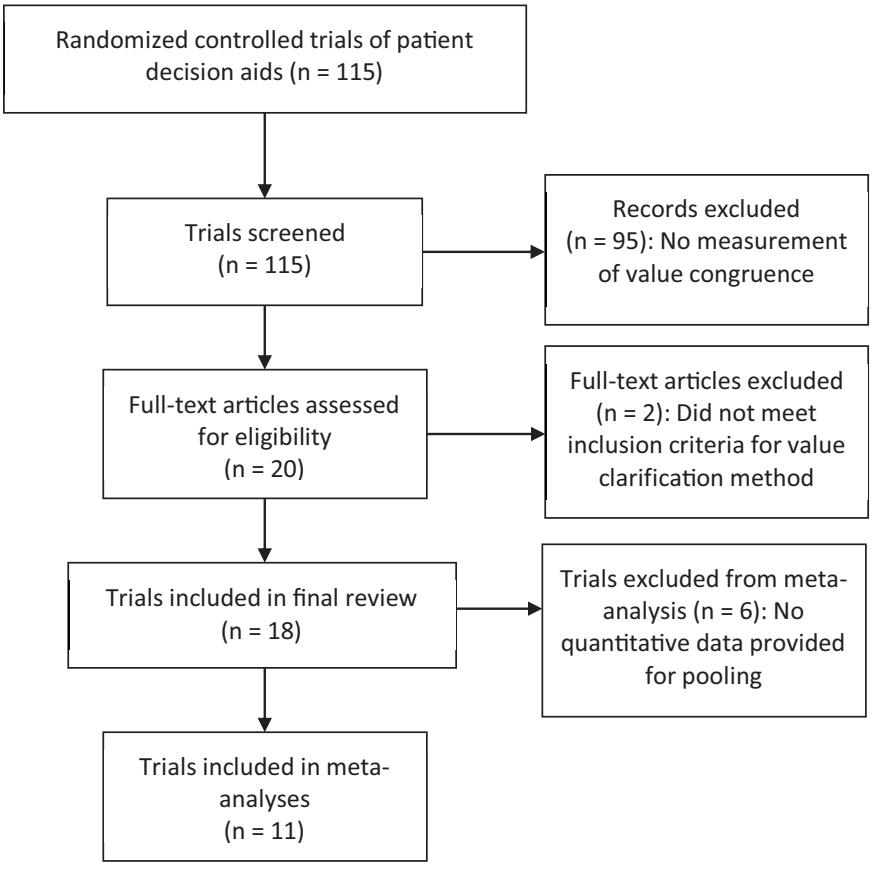

Fig. 1. PRISMA/QUORUM diagram.

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Ozanne's original usage of "preferred treatment" with "preferred option" to reflect the inclusion of both screening and treatment choices.

In Fig. 2, the top row of the classification scheme includes three ways of defining "values": (a) patients' preferred choice calculated, for instance via a model or summary score; (b) patients' preferences or attitudes toward health outcomes and/or attributes; and (c) patients' preferred choice directly assessed. In the bottom row, there are three approaches to defining "choices": (a) the option received by the patient; (b) the patient's preferred option calculated; and (c) the patient's preferred option directly assessed. Roman numerals are used to differentiate the various models for calculating value congruence. For example, in Model IX value congruence is calculated as patients' preferences or attitudes toward health outcomes and/or attributes (values) and preferred option directly assessed (choice).

2.5. Data synthesis

Data synthesis was guided by the research question, *How well do patients make value congruent screening or treatment decisions with and without PtDAs?*Results were reported descriptively. The primary outcome for this sub-analysis focused on value congruence with chosen option, one element for the 'attributes of the choice' primary outcome in the Cochrane review.

2.6. Data analysis

Results were pooled where quantitative results were available for: (a) trials that used heterogeneous statistical methods to calculate value congruence, and (b) trials that calculated value congruence using the Multidimensional Measure of Informed Choice. Review Manager 5.2.6 software (RevMan 2013) was used to estimate a weighted treatment effect (with 95% confidence intervals). Pooled relative risks (RR) were calculated and all data were analyzed with a random-effects model because of the diverse nature of the studies being combined.

3. Results

3.1. Characteristics of the studies

Eighteen trials met inclusion criteria for measurement of value congruence. Trials considered a range of screening or treatment decisions including: bariatric surgery [17]; hormone replacement therapy [18–20]; natural health products for menopause symptoms [21]; prenatal testing [22,23]; coronary angiography [24]; uterine fibroid treatment [25]; referral for lung transplantation [26]; and genetic testing or screening for breast [27,28], breast and ovarian [29,30], prostate [31], colorectal [32,33], and bowel [34] cancers (See Table 1). Comparison (i.e. usual care) groups consisted of information-only interventions (i.e. brochure, education session), no information, or simple PtDAs that did not include explicit values clarification methods.

3.1.1. Value clarification method

To clarify values, 6 of the 18 trials (33%) used the attitude rating scale from the Multidimensional Measure of Informed Choice [22,28–30,33,34]. In the original MMIC attitude scale, based on measures taken from the Theory of Planned Behaviour, Marteau and colleagues asked participants to respond to the statement "*For me, having the screening test for Down's syndrome when I am 15 weeks pregnant will be . . .* " [35]. In the 18 trials, participants were asked to respond to different statements related to having the specific screening decision. Participants were asked to indicate on seven-item scales their level of agreement with the following four responses to the statement: Beneficial or Harmful, Important or Unimportant, Bad thing or Good thing, and Pleasant or Unpleasant.

Another 8 trials (44%) clarified values by using a numerical rating scale that asked patients to rate the value or importance they placed on key attributes of the screening or treatment options [7,19,23–25,27,31,32]. For instance, Lerman et al. provided women with a series of benefits, limitations, and risks of BRCA1 testing and asked them to rate the level of importance of each of the attributes on 3-point scales (1 = not at all important, 2 = somewhat important, or 3 = very important) [27]. Two of these 8 trials used the MMIC to

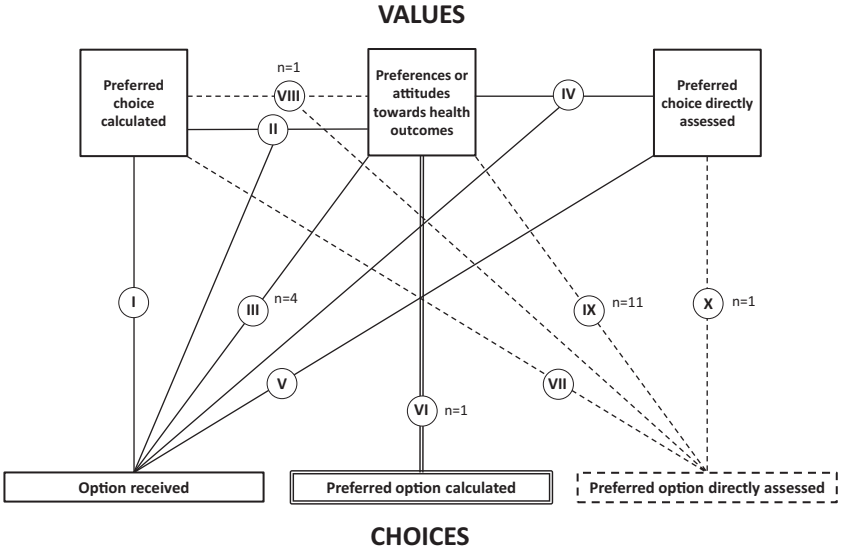

Fig. 2. Classification of models for defining and calculating values and choices, adapted from Sepucha and Ozanne [12]. *Note:* Roman numerals indicate the name of the model. The following definitions are derived from Sepucha and Ozanne [12]. "Preferred choice calculated" includes choices calculated via a decision analytic model or summary score. "Preferences or attitudes towards health outcomes" are patients' attitudes toward specific health outcomes and/or attributes (i.e. through qualitative interviews or use of a categorical scale). "Preferred choice directly assessed" and "Preferred option directly assessed" refer to asking patients their preference directly (i.e. through a one item question regarding which treatment or screening option they prefer). "Option received" refers to the actual treatment or screening option the patient received. "Preferred option calculated" includes choices calculated using a model or summary score.

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measure value congruence but used different methods other than the MMIC attitude rating scale to clarify values. Specifically, Bjorklund et al. substituted the MMIC's original attitude rating scale for a 6 item values questionnaire, using 6-point Likert scales [23], while Wakefield asked participants to list their pros and cons of undergoing genetic testing and to rate each on a 5 star scale on a blank worksheet [32].

Of the remaining 4 trials (22%), one employed a rating exercise where patients shaded boxes to indicate the importance of each risk and benefit associated with possible options [20], and another calculated utilities using a visual analog scale with a range of 100 points [18]. Two trials used questionnaires with unclear value clarification methods [21,26].

3.1.2. Choice measure

Of 18 trials, 13 (72%) measured choice by recording the participant's screening or treatment preference or intention post intervention. Three trials (15%) classified choice as the option that patients actually received [23,24,34]. One trial defined choice as a combination of actual and planned uptake of screening at 6 months post-intervention [33]. One trial calculated patients' preferences for surgery using a logistic model and stated preferences [17].

Table 1
Characteristics of eligible articles ($n = 18$).

Author, Year	Intervention	Screening/treatment	Value clarification method	Choice measure	Value congruence measure	Model
Arterburn, 2011 [17]	Decision aid vs usual care using pamphlets	Bariatric surgery	8 values items in 4-point Likert scales	Predicted surgery preference and stated preference.	Percent match between predicted and stated preferences	VI
Bjorklund, 2012 [23]	Decision aid vs usual care using pamphlet	Down syndrome screening	6 values items in 6-point Likert scales	Actual uptake of screening	MMIC	III
Dodin, 2001 [19]	Detailed decision aid vs simple decision aid	Menopausal hormone replacement therapy	Unspecified number of values items in 10-point scales	Treatment decision	Congruence between values and treatment decision	IX
Frosch, 2008 [31]	Decision aid vs decision aid + chronic disease trajectory vs chronic disease trajectory vs usual care using Internet information	Prostate cancer screening	1 value item in a 5-point scale	Treatment preference	Congruence between values and treatment preferences	IX
Holmes-Rovner, 1999 [18]	Detailed decision aid vs simple decision aid	Estrogen or progesterone/ estrogen replacement therapy (ERT/PERT)	Expected utility	Treatment preference (3-point scale)	Correlation between expected utility (EU) and likelihood of taking hormones	VIII
Légaré, 2008 [21]	Decision aid vs usual care using brochure	Natural health products for managing menopausal symptoms	5 values items in 10-point rating scales	Treatment intention at baseline and after intervention (15-point scale)	Regression analysis	IX
Lerman, 1997 [27]	Decision aid vs waiting list control	BRCA1 gene testing	14 items in 5-point Likert scales	Testing intention at baseline and after intervention	Hierarchical regression	X
Mathieu, 2010 [28]	Decision aid vs usual care using delayed intervention	Mammography screening	MMIC attitude scale	Intention to screen (5 point Likert scale)	MMIC	IX
Nagle, 2008 [22]	Decision aid vs pamphlet	Prenatal genetic testing	MMIC attitude scale	Intention to screen	MMIC	IX
O'Connor, 1999 [20]	Detailed decision aid vs simple decision aid n	Long term hormone therapy	Unspecified number of values items in 10-point rating scales	Treatment preference	Discriminant function analysis	IX
Schwalm, 2012 [24]	Decision aid vs usual care	Coronary angiography	6 values items in 5-point Likert scales	Treatment received	Unclear	III
Smith, 2010 [34]	Detailed decision aid vs simple decision aid vs usual care using booklet	Bowel cancer screening	MMIC attitude scale (adapted)	Actual treatment received	MMIC (comparing decision aid groups with booklet)	III
Solberg, 2010 [25]	Detailed decision aid vs simple decision	Uterine fibroid treatment	7 outcome preference items in 10-point scales	Treatment choice (4 options)	ANOVA	IX
Steckelberg, 2011 [33]	Decision aid vs usual care using pamphlet	Colorectal cancer screening	MMIC attitude scale	Combination of actual and planned uptake of screening after 6 months	MMIC	III
Vandemheen, 2009 [26]	Decision aid vs blank pages	Referral for lung transplantation for patients with cystic fibrosis	4 values items in 5-point scales	Treatment intention at baseline and after intervention	Regression analysis	IX
Wakefield, 2008 [32]	Detailed decision aid vs simple decision aid	Genetic testing for colorectal cancer	Blank personal values worksheet using 5-star rating scale	Participant's decision (intention to screen)	MMIC	IX
Wakefield, 2008 [29][a]	Detailed decision aid with vs simple decision aid	Genetic testing for breast and ovarian cancer	MMIC attitude scale	Participant's decision (intention to screen)	MMIC	IX
Wakefield, 2008 [30][a]	Detailed decision aid vs simple decision aid	Genetic testing for breast and ovarian cancer	MMIC attitude scale	Participant's decision (intention to screen)	MMIC	IX

[a] These are two different trials. Wakefield 2008a ($n = 145$) assessed the impact of the decision aid administered after the clinical encounter while Wakefield 2008b ($n = 148$) assessed the impact of the decision aid administered during the clinical encounter.

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3.1.3. Value congruence definition

Twelve trials (67%) measured "preferences and attitudes toward health outcomes" (independent variable) and directly assessed participants' preferred option (dependent variable), or Model IX in Sepucha and Ozanne's classification scheme (see Fig. 2). Four trials employed Model III, "preferences and attitudes toward health outcomes" and "option received."

3.1.4. Value congruence measure

To measure value congruence, 8 trials (44%) used the MMIC [35,36]. The MMIC measures the congruence between patient knowledge (8-item scale), attitudes (4-item scale), and uptake (actual option received) [36]. The knowledge scale assesses whether the patient is informed of his/her options. Participants make an "informed choice" if their scores on the knowledge and attitude tests are above the midpoint [36]. Only 3 of these 8 trials used actual option received in their MMIC calculation [23,33,34], which is the recommended approach [35,36].

In seven trials (39%), statistical measures used included correlation [18], discriminant function analysis [20], regression analyses [21,26,27], ANOVA [25],or a simple percent match [17]. Three trials did not provide clear descriptions of the statistical methods used to measure the congruence between values and option preferences [19,24,31].

3.1.5. Value congruence outcome

Eleven trials (61%) reported the number of patients that made value congruent decisions. Six trials reported the difference between PtDA and control at the group level, but did not report the number of patients with value congruent decisions in each group (see Table 2a) [17,21,25–27,31]. One trial provided data on within-group correlations for value congruent decision-making, but in a format that made it not possible to determine the number of patients per se [18].

3.2. Value congruence results without PtDAs

In the control arms of the 11 trials that provided quantitative results, the mean rate of value congruent decision-making for participants who did not use a PtDA ($n = 1844$) was 38.2% (range: 12.2–67%). Of those trials, only 3 calculated value congruence using a method other than the MMIC. Among the participants in those trials who did not use a PtDA ($n = 223$), the mean rate of value congruent decision-making was 35.7% (range: 14.3–67%) (see Table 2b). The remaining 8 trials used the MMIC and found the mean rate of value congruent decision-making was 39.2% (range: 12.2–64.9%) among participants who did not use a PtDA ($n = 1621$) (see Table 2c).

Table 2b
Numeric results of value congruence in usual care (no decision aid) and intervention (decision aid) groups using heterogeneous measures.

Author, Year	Value congruence		Results RR [95% CI]
	Comparison group % ($n = 223$)	Intervention group % ($n = 229$)	
Dodin, 2001	14.3 (7/49)	23.1 (12/52)	1.62 [0.69, 3.77]
O'Connor, 1999	67.0 (67/100)	65.3 (66/101)	0.98 [0.80, 1.19]
Schwalm, 2012	25.7 (19/74)	47.4 (36/76)	1.84 [1.17, 2.91]
			RR: 1.35 [0.80, 2.30]

3.3. Value congruence results with PtDAs

In the intervention arms of the 11 trials that provided quantitative results, the mean rate of value congruent decision-making for participants who used a PtDA ($n = 1967$) was 49.5% (range: 23.1–76%). In the 3 trials that measured value congruence using a method other than the MMIC the mean rate of among participants who used a PtDA ($n = 229$) was 45.3% (range: 23.1–65.3%) (see Table 2b). In the 8 trials that used the MMIC, the mean rate of value congruent decision-making was 51.1% (range: 27.3–76%) among participants who used a PtDA ($n = 1738$) (see Table 2c).

Only 4 trials (22%) found a statistically significant difference in value congruent decision-making between groups [22,24,33,34]. For these trials, the mean rate of value congruent decision-making was 28.9% and 50.3% in usual care and PtDA groups, respectively. The remaining 7 trials that provided quantitative results reported non-significant findings. Three of these trials had fewer than 100 participants in each arm and may have been underpowered to detect Type II errors.

All trials that used the MMIC, the homogenous measure of value congruence, happened to be for PtDAs that explored screening options, while all that used heterogeneous measures were for treatment options. For the 3 trials that measured value congruence using a method other than the MMIC, the pooled relative risk of making a value congruent decision if exposed to a PtDA for treatment options was 1.35 (95% CI 0.80 to 2.30, $p = 0.26$; see Fig. 3a). For the 8 trials that used the MMIC, the pooled relative risk

Table 2a
Descriptive results of value congruence in usual care (no decision aid) and intervention (decision aid) groups using heterogeneous measures.

Author, Year	Value congruent		Results
	Comparison group	Intervention group	
Arterburn, 2011	–	–	Statistically significant improvement in both groups post-intervention ($p = 0.009$)
Frosch, 2008	–	–	No statistically significant difference
Holmes-Rovner, 1999	Group A: no correlation; Group B: statistically significant correlation for PERT (0.36)	Group C: statistically significant correlation for ERT (0.37)	
Légaré, 2008	No difference at baseline. Increased congruence after intervention ($p = 0.0009$) observed in both groups (no difference). Only F-values reported. No frequencies provided.	No statistically significant difference	
Lerman, 1997	No significant associations between intention to test and values. Between group differences not reported.	No statistically significant difference	
Solberg, 2010	–	–	No difference. $p < 0.01$
Vandemheen, 2009	–	–	No statistically significant difference

PERT: progesterone or estrogen replacement therapy.
ERT: estrogen replacement therapy.

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Table 2c
Numeric results of value congruence in usual care (no decision aid) and intervention (decision aid) groups using the Multidimensional Measure of Informed Choice (MMIC).

Author, Year	Value congruence		Results RR [95% CI]
	Comparison group % (n = 1621)	Intervention group % (n = 1738)	
Bjorklund, 2012	62.4 (123/197)	71.5 (128/179)	1.15 [0.99, 1.32]
Mathieu, 2010	63.6 (70/110)	71.4 (65/91)	1.12 [0.93, 1.36]
Nagle, 2008	64.9 (111/171)	76.0 (127/167)	1.17 [1.02, 1.35]
Smith, 2010	12.2 (21/172)	33.9 (121/357)	2.78 [1.81, 4.25]
Steckelberg, 2011	12.8 (101/792)	43.9 (345/785)	3.45 [2.83, 4.20]
Wakefield, 2008	23.0 (14/61)	33.3 (16/48)	1.45 [0.79, 2.67]
Wakefield, 2008a	39.7 (25/63)	51.8 (29/56)	1.31 [0.88, 1.94]
Wakefield, 2008b	34.6 (19/55)	27.3 (15/55)	0.79 [0.45, 1.39]
			RR: 1.48 [1.01, 2.16]

for making a value congruent decision with a PtDA for screening options was 1.48 (95% CI 1.01 to 2.16, p = 0.04; see Fig. 3b).

4. Discussion and conclusion

4.1. Discussion

We reviewed RCTs that measured the influence of PtDAs on value congruence—a key element of decision quality. Our findings suggest that without the use of a PtDA, patients struggle to make value congruent decisions. This is not surprising given the complexity associated with many health care treatment and screening decisions, and evidence of poor decision-making in similarly complex areas such as finance and healthy eating [37]. With multiple sources of evidence on benefits and harms often requiring difficult trade-offs the rationale for PtDAs is clear. This sub-analysis found that in the 11 trials providing quantitative results, patients who used a PtDA were more likely to make value congruent choices in comparison to those who did not use a PtDA (49.5% vs 38.2%). Pooled results of trials that used heterogeneous measures were statistically non-significant; however results from trials that used the MMIC suggest that patients are 48% more likely to make a value congruent decision when exposed to a PtDA for a screening decision. These findings are similar to the 52% observed improvement reported in the Cochrane review analysis of value congruence (pooled RR 1.51, 95% CI 1.17 to 1.97, p = 0.0017, n = 13) [10].

One interpretation of these results is that while PtDAs can help patients make value congruent decisions the absolute improvement is relatively small as over half of patients did not make choices consistent with their values. An alternative interpretation is that these findings demonstrate the methodological challenges in measuring value congruence appropriately. We describe how existing value congruence measures are heterogeneous and, in some cases, based on composite measures that potentially underestimate the effect of PtDAs on value congruent decision-making. Nevertheless, there appears to be room for improvement of PtDAs to help patients make value congruent choices, and in our ability to develop accurate ways of measuring this important outcome.

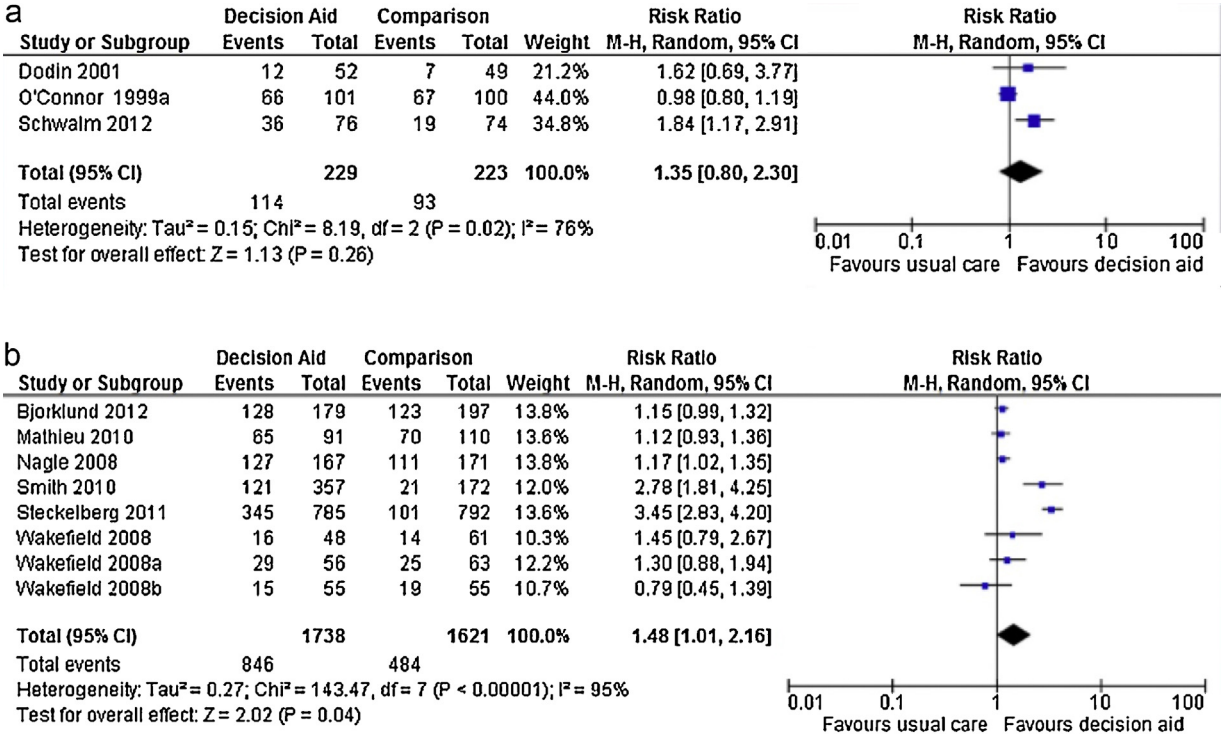

Fig. 3. (a) Meta-analysis of value congruence in usual care (no decision aid) and intervention (decision aid) groups using heterogeneous measures. (b) Meta-analysis results of value congruence in usual care (no decision aid) and intervention (decision aid) groups using the Multidimensional Measure of Informed Choice (MMIC).

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This review, which provides closer inspection of the value congruence measures used in trials included in the Cochrane review, finds that while PtDAs may provide an increase in value congruence, the effect is small and based on very heterogeneous outcomes. The limited effect observed may be due to sample size and/or heterogeneity of measures. While the Cochrane review included over 115 RCTs evaluating PtDAs, this sub-analysis indicates that only 18 trials (15.7%) measured value congruence. Most trials in the Cochrane review assessed other outcomes, such as knowledge (66.1%) or decisional conflict (50.4%) [10]. While these are important decision quality and process outcomes, respectively, value congruence is one of the key indicators of a quality decision and an important component of patient-centered care. That it has been vastly understudied among trials of PtDAs is concerning.

Limitations to current measures may explain the low rates of value congruent decisions identified in the review. In addition to the Cochrane review, Sepucha and Ozanne included observational studies that measured value congruence in their systematic review of 49 studies (1967–2007) that measured value congruence [14]. In their review, 71% of studies were observational, 14 (29%) were RCTs, and only 12 (24%) included a PtDA. In the 2015 update of this review Winn, Sepucha and Ozanne included 61 articles (1967–2012) of which a greater number were RCTs (34%) and included a PtDA (43%). They concluded that variability of measurement of value congruence "makes it difficult to draw conclusions about the quality of care across studies and a lack of standardization may also discourage future researchers from using it as primary outcome for their studies" [15]. Similarly, we found that included RCTs used a range of methods for measuring value congruence, including calculated percent match, correlation, discriminant function analysis, regression analyses, ANOVA, and the MMIC.

We also observed wide variation in the definitions for "values" that were used in calculating value congruence. For example, some economists would challenge that rating tasks do not necessarily represent values unless the notion of a trade-off is included, reflecting the compensatory strategies required for making decisions [38]. Patient values can also be unstable and a choice made using a PtDA may change over time as new information emerges, patients experience some of the outcomes, clinical circumstances change, or as the patient receives recommendations from a practitioner, family members, and other trusted individuals. It is noteworthy that the studies in this sub-analysis provided little information on the psychometric properties of value clarification methods used. This is likely because, with the exception of the MMIC attitude scale, most value clarification methods were developed specifically for each PtDA.

With regard to how trials recorded "choice," most defined this as the option that patients preferred or intended to get, while few trials recorded the option that patients actually received. Both outcomes are important to capture since a patient's preferred or intended option provides information on whether a PtDA helps the patient to make a choice consistent with her values. Additionally, recording the option the patient actually receives helps to determine whether the care provided was consistent with patient values, and thus patient-centered. Previous research has found that despite preparing patients for shared decision making by using PtDAs, unless the practitioner is also prepared for shared decision-making, the end result may not represent patient preferences [39]. As a consequence, even the outcomes that are used to define value congruence have significant shortcomings, further limiting the quality of the evidence base.

Of particular concern is the validity of the MMIC for assessing value congruence, the method used by half of the trials in this review. All trials that used the MMIC, the "homogenous" measure of value congruence, were for PtDAs that explored screening options, while all that used heterogeneous measures were for treatment options. We predict that this pattern was because the MMIC is designed specifically for screening decisions [36]. However, the MMIC does not measure the match between a patient's values and his or her screening decision; rather it subjectively measures whether or not patients make an "informed choice," defined as "one that is based on relevant knowledge, consistent with the decision-maker's values and behaviorally implemented" [35]. Further, the MMIC was not used with fidelity in two trials. We excluded them from this sub-analysis as they used the values subscale of the Decisional Conflict Scale (DCS) rather than the MMIC attitudes scale [40,41]. The International Patient Decision Aid Standards Collaboration has expressed concerns about the MMIC, arguing that it may reaffirm, "in a composite measure, that PtDAs improve knowledge and reduce decisional conflict" [6]. We would agree that the DCS values subscale measures the patient's perception of clear values and does not measure actual strength of values for outcomes of options.

Regardless of the values measure used to calculate an MMIC score, we would argue that neither the attitudes scale nor the values subscale of the DCS fully captures patients' values and that the MMIC in its current form should not be a preferred approach for calculating value congruence. The construct of feeling informed, which is a perception of having knowledge, is not the same as actually being informed, as in scoring well on a knowledge test. Both decisional conflict and being informed are important constructs in decision-making. However, in the context of making a value congruent decision, these constructs could be viewed as process measures or prerequisites for the patient before making a choice, as that choice should match one's informed, clear values. Despite this, one strength of the MMIC is its underlying theory. The MMIC is built on the premise that a quality decision is based on both patient knowledge and values. We would argue that it is imperative that patients are first appropriately informed with knowledge of the risks and benefits of their options, otherwise their choice may match their values but be based on incomplete or inaccurate information. This review has highlighted the limitations of the MMIC as a measure of value congruent decision-making. In future iterations of the Cochrane review, we would recommend that value congruence outcomes be reported by type of method used.

There are several limitations to this review. Quantitative findings should be interpreted with caution due to the small sample size and significant heterogeneity in trials' measurement of value congruence, values, and choices. Further, the Cochrane review follows strict inclusion and exclusion criteria. Thus other trials may have measured value congruence but were excluded from the sample at some stage of the review.

There is a clear need for a standardized approach for measuring value congruence. Sepucha and Ozanne suggest that in selecting which measure to use, researchers should consider first whether they are interested in understanding value congruence at an individual or population level. "For studies that are interested in making high level comparisons about the level of concordance among hospitals, groups, settings or diseases," they propose examining "the association between preferred treatment directly assessed and treatment received" [14]. Researchers that explore how values clarification methods help guide clinical decision-making for individual patients "may also elicit patients' preferences for specific attributes or outcomes, and examine concordance between specific outcomes" [14]. While these recommendations assist in identifying which model to use, no studies have provided guidance on which value congruence method is most valid. As a first step, we suggest that further research should explore a number of questions.

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First, what is the relationship between different measures of value congruence? The range of value congruent decision-making across studies suggests that measures used to calculate value congruence might be unreliable and inconsistent. We suggest the creation of criteria for comparing value congruence approaches, following Llewellyn-Thomas and Crump's recommendation for comparing values clarification methods [2]. Second, does value congruent decision-making vary by context, condition and type of decision? This research might elucidate which features of decision-making patients struggle with the most, and where PtDAs are most required. Third, we suggest authors report value congruence separately for patients deemed to be informed vs uninformed, as well as for patients who feel clear vs not clear about their values, therefore reporting explicitly on those who make quality decisions. This could be achieved in part by adapting the MMIC to measure patient preferences using a values clarification method that requires the patient to make trade-offs (i.e. weigh scale exercise) [38]. Next, we recommend that researchers use a robust definition of values, such as "the patient's "informed attitudes about the relative desirability/undesirability of a health care option's unique characteristics, which include that option's protocol, possible benefits, and potential harms" [2], as proposed by Llewellyn-Thomas and Crump and report on the psychometric properties of the values clarification method used, if any. We also encourage future studies to define choice as the option that matches the patient's clear, informed values, either by calculating or directly assessing it. While it is important to evaluate the match between the options patients prefer and receive, we would argue that it is more accurate to classify this as a form of adherence to one's chosen option. Lastly, future research should consider whether certain patient characteristics are associated with quality decision-making. Research should investigate how culture, numeracy, and literacy amongst other outcomes are associated with degrees of value congruence. This might help developers make PtDAs that are targeted to individuals' decision-making needs.

4.2. Conclusions

To provide patient-centered care, patients need better support to make informed value-based decisions. Findings from this review indicate that there is limited evidence that patients make decisions that are consistent with their values, and that while PtDAs help, there is room for improvement. Trials have not measured value congruence in a systematic fashion and have not used approaches for clarifying patient values that encourage patients to make trade-offs between option attributes. Research should prioritize methods to improve value clarification in current PtDAs, and evaluate them using meaningful measures of value congruence.

4.3. Practice recommendations

To help patients make quality screening and treatment decisions, practitioners must do more than inform patients of their options and provide evidence on risks and benefits. Practitioners must also help patients clarify their values, feel clear about which values matter most to them, and support them to make choices that match those preferences. The results of this review suggest that PtDAs may support shared decision-making. To facilitate implementation of PtDAs in routine care, we recommend that developers ensure that the tool or the findings from using the tool be discussed during the clinical encounter. When PtDAs are used in preparation for the consultation, one approach is to include a summary report at the conclusion of the PtDA that the patient can print out or email to their practitioner for discussion in their next visit. Such "patient preference reports" have been developed for PtDAs for treatment of osteoarthritis. They summarize the patient's clinical and decisional needs based on the patient's responses in the PtDA [42]. Reading this report together can help the patient and practitioner focus on issues of concern to the patient and reach a decision that matches the patient's informed preferences.

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SPECIAL ISSUE

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Decisional needs assessment of patients with complex care needs in primary care

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Abstract

Rationale: Patients with complex care needs who frequently use health services often face challenges in managing their health and with integrated care, leading to frequent decision making. These complex care needs require a good understanding of health issues and their impact on daily life. As the decisional needs of this particular clientele have yet to be described in scientific literature, they warrant further study.

Objectives: To assess the decision-making needs of patients with complex care needs (PCCN) who frequently use health care services.

Methods: We performed a multicenter cross-sectional qualitative descriptive study in four institutions of the health and social services network of Quebec (Canada). We enrolled a convenience sample of PCCNs who frequently use health care services, health care providers, case managers, and decision-makers. We conducted interviews and focus groups and investigated decisional needs according to the Ottawa decision support framework: roles played and desired in the decision-making process, facilitators, and barriers. We conducted qualitative data collection and qualitative deductive/inductive thematic analysis within and across participating groups.

Results: In total, 16 patients, 38 clinicians, six case managers, and 14 decision-makers participated in the study. The decisional needs of this clientele are numerous, varied and different from those of the general population. We identified 26 decisional needs grouped under five themes. The most frequent decisions related to visiting the emergency department, moving to a nursing home, and adhering to a plan or treatment. In addition, we identified new themes such as patients' fear and mistrust of health professionals, differences of opinion between health professionals and health professionals' preconceived opinions of patients.

Conclusion: We observed a wide range of types of decisions that patients face and differences in decision-making needs across participating groups. Our results should inform future research on the development of a patient decision aid tool.

KEYWORDS

decision aids, patient partner, primary health care, shared decision making, vulnerable population and chronic disease

1 | INTRODUCTION

Shared decision-making (SDM) is an interpersonal, interdependent process in which the health care provider and the patient relate to, and influence, each other as they collaborate in making decisions about the patient's health care. SDM is patient-centered and relies on medical evidence, providers' clinical expertise, and the unique attributes of the patient and his or her family.[1] It allows patients to improve their knowledge of available options, clarify what matters most to them so their choices are evidence-informed and congruent with their values.[2] However, SDM is yet to be the norm in health care and the most vulnerable Canadians are not benefiting from SDM.[3]

Effective SDM implementation strategies include patient (Pt) decision aids (DA).[4] PtDA are evidence-based tools designed to help patients make specific and deliberate choices among health care options.[5] They aim to foster an understanding of the evidence, identify patients' values, undue pressure from others, and clarify the roles the patients want to play in decision-making.[6,7] PtDA complement clinicians' counseling rather than replace it. A systematic review of 105 PtDA trials showed that when patients use DA, they improve their knowledge of the options, feel more informed, and clear about what is most important to them. Above all, they contribute to reducing overutilization of options that have no added value and may increase the uptake of options that have high value.[5]

Patients with complex care needs who frequently use health care services[1] are vulnerable patients. They seek care in emergency departments, are often hospitalized, and consult their health care professionals more frequently or inappropriately.[8] For some of these patients, the simultaneous presence of psychological or social issues with other physical ailments contributes to complex situations that interfere with usual care and leads to unmet health and social needs.[9] These patients often attempt, unsuccessfully, to meet their health and social services needs by using multiple types of care and services, resulting in significant costs to the health care system[10] without improving their health.

These patients face difficult decisions all along their health care pathways and transitions. Case management programs are potentially effective to support patients in managing their condition[11] and support them in decision-making processes. In order to help the patient make this kind of decision, a PtDA can be developed based on the decisional needs of patients and used by health care professionals to present the options for or against case management at the different stages of the decision-making process. However, we know little of patients' decisional needs. A need refers to a gap between what is and what should be. A decisional need assessment should be conducted when we need to estimate the needs of a group and what has to be improved to support patients during share decision-making process.[12] Needs assessment can target several objectives, among others, to distinguish between decisions for which support is essential and those for which support in the decision-making process can be improved, without being essential. Thus, we sought to assess the decision-making needs of patients with complex care needs that frequently use health care services and explore prerequisites and barriers of this process according to the stakeholders.

2 | METHODS

2.1 | Study design and setting

We performed a cross-sectional multicenter qualitative descriptive study[13] in four establishments of the health and social services network of the Province of Quebec, Canada. We used the GRIPP2 guideline,[14] which was the first international evidence-based consensus informed guidance to report on patient and public involvement, to provide the most quality, transparency, and consistency as possible.

2.2 | Patient-oriented research

We carried out this study according to the principles of patient-oriented research (POR) as suggested by Canada's Strategy for POR.[15] POR refers to a process that engages patients as partners in a research project to improve health outcomes through evidence-informed care.[15] According to the continuum of involvement of patients suggested by Pomey et al,[41] Patient Partners (PP) were considered as co-researchers in this study. The PPs collaborated in all stages of the project to ensure that the project remained close to patient needs and made sense for the targeted population. They contributed to the writing of the research question, and revised the protocol, the interview guides, and

[1]Throughout the text, we will use the term patient to refer to patients with complex care needs who frequently use healthcare services.

the data-coding grid used to analyze the interviews. They also conducted interviews with patients, participated in one focus group with clinicians, in meetings with the research team and in the data interpretation and dissemination. We reported the complete POR strategies and our learning in a previously published paper.[16]

2.3 | Ethical considerations

Ethics approval was obtained from the ethics' committee of the *Centre intégré Universitaire de Santé et de Services Sociaux du Saguenay–Lac-Saint-Jean*.

2.4 | Sampling and recruitment

We selected various types of stakeholders and enrolled a purposeful sample[13,17] of patients, health care providers, case managers, and decision-makers involved in the continuum of health care or services. For health care providers, case managers, and decision-makers, we recruited participants from three case management programs and one institution with a special interest in this clientele and that oriented primary care services to answer those patients' needs through an interprofessional team in a family health clinic. For each organization with a case management program, we recruited one case manager. For the organization without a case management program, we solicited each health care professional involved in care for this clientele. To recruit patients, health professionals supported researchers in identifying potential patients from their caseload that fulfilled the following inclusion criteria: (a) aged 18 and over, (b) diagnosed with at least one chronic condition, and (c) identified as a frequent user of health care services by a program or health care providers. As each organization possesses its own criteria to define a frequent user according to their capacity of care, we do not have a specific threshold to include patients.

2.5 | Data collection

We collected data between March and December 2017. The data collection was informed by the Ottawa Decision Support Framework (ODSF)[7] workbook that proposes formal approaches and steps for decisional needs assessment ranging from defining the objective to the presentation of key findings, including data collection.[12] They strongly suggest including several stakeholders in addition to the target group, which is patients with complex care needs. We built interview guides based on the ones proposed in this workbook and adapted them for each type of stakeholder. The principal investigator (M.E.P.), the research coordinator (I.G.), and 3 PP conducted 36 semi-structured interviews with clinicians and case managers (nurses, social workers, general practitioners, and psychologists), patients, decision-makers (mostly nurses and general practitioner), and a caregiver that were audio-recorded and transcribed verbatim.

The principal investigator (M.E.P.) and the research coordinator (I.G.) also conducted seven focus groups. For each of the focus groups, while either M.E.P. or I.G. was acting as an animator, the other acted as an observer and took notes on group dynamics, the discussion process, and participants' behavior. According to the ODSF's workbook,[7] we asked participants to describe: (a) types of decision they made, (b) their actual and desired role in the decision-making process, and (c) factors that positively and negatively influence decisions. Participants also completed a sociodemographic questionnaire. PPs were present, as observers, for some interviews with patients and focus groups with clinicians depending on their availability.

2.6 | Data analysis

We performed a qualitative deductive/inductive thematic analysis.[13,18] We analyzed interviews with patients, case managers, decision-makers, and focus groups with health care providers, according to the ODSF.[7] We used NVivo 11 Software to manage the qualitative data. To describe our sample, we used Microsoft Excel to report sociodemographic data.

We clustered qualitative data into categories and each decision according to each group of participants. Data are then presented in the following sections: Characteristics of participants and stings, types of decisions, the actual and desired role of the stakeholders in the decision-making process and key elements of the decision-making process. During the data analysis process, the research coordinator (I.G.) coded emerging themes to enrich the data analysis grid. To ensure reproducibility of analysis and results, the principal investigator (M.E.P.) independently coded 30% of the interviews and focus groups. PPs also coded one interview and discussed the main results of the interviews with the principal investigator and research coordinator. Team members reached consensus through discussion when facing disagreement. All team members, including the PPs, approved the final version of the themes.

3 | RESULTS

3.1 | Characteristics of participants and settings

In total, 16 patients (response rate [RR]: 89%), 38 clinicians (RR: 70%), six case managers (RR: 100%), and 14 decision-makers (RR: 88%) participated in the study. Table 1 describes patient characteristics and Table 2 presents the characteristics of the settings under study.

3.2 | Types of decisions

Based on the clustering, we identified 26 decision points across the four groups of participants and grouped these under five main themes: (a) use of services and choice of providers, (b) management of patients' physical and social environment, (c) level of care and end of life, (d) management of the health care condition, and (e) acceptance of the health care condition. Table 3 presents the five themes, their

TABLE 1 Patient characteristics

	Setting 1 (n = 7)	Setting 2 (n = 3)	Setting 3 (n = 3)	Setting 4 (n = 3)	Total (n = 16)
Number of ED visits[a] (mean/SD)	5 (3.5)	8.3 (4.7)	15 (8.9)	1.5 (0.7)	7.4 (6.3)
Number of hospitalizations[a] (mean/SD)	1.4 (1.3)	4.3 (4)	16.5 (12)	2 (1)	4.1 (6.3)
Age (mean/SD)	59.5 (17.7)	53.3 (17.6)	51.7 (19.6)	77.3 (17.5)	59.9 (18.5)
Male (Nb/%)	1 (14.3)	1 (33.3)	3 (100)	0	5 (31.3)
Marital status (Nb/%)					
Married	2 (28.6)	1 (33.3)	0	0	3 (18.8)
Divorced	0	2 (66.7)	2 (66.7)	2 (66.7)	6 (38)
Widowed	2 (28.6)	0	0	1 (33.3)	3 (18.8)
Unmarried	3 (42.9)	0	1 (33.3)	0	4 (25)
Occupation (Nb/%)					
Work	1 (14.3)	0	1 (33.3)	0	2 (13)
Student	1 (14.3)	0	0	0	1 (6.3)
Retired	2 (28.6)	1 (33.3)	1 (33.3)	2 (66.7)	6 (38)
Health issues prevent work	3 (42.9)	2 (66.7)	1 (33.3)	1 (33.3)	7 (43.8)
Medical condition (Nb/%)					
Asthma or chronic obstructive pulmonary disease	2 (28.6)	2 (66.7)	1 (33.3)	0	5 (31.3)
Diabetes	3 (42.9)	1 (33.3)	1 (33.3)	1 (33.3)	6 (38)
Epilepsy	2 (28.6)	0	0	0	2 (13)
Hypertension	2 (28.6)	1 (33.3)	0	1 (33.3)	4 (25)
Heart failure or atherosclerotic heart disease	3 (42.9)	0	0	2 (66.7)	5 (31.3)
Chronic pain	2 (28.6)	1 (33.3)	0	0	3 (18.8)
Cancer	2 (28.6)	0	0	0	2 (13)
Graft	1 (14.3)	0	0	0	1 (6.3)
Psychiatric diagnosis	3 (42.9)	0	0	0	3 (18.8)
Substance abuse	1 (14.3)	0	3 (100)	0	4 (25)
Education (Nb/%)	n = 7	n = 3	n = 3	n = 2	n = 15[b]
Elementary school completed	2 (28.6)	1 (33.3)	2 (66.7)	0	5 (33.3)
High school completed	0	1 (33.3)	0	0	1 (6.7)
Professional studies completed	4 (57.1)	0	0	0	4 (26.7)
College completed	0	1 (33.3)	0	0	1 (6.7)
University completed	1 (14.3)	0	1 (33.3)	2 (100)	4 (26.7)
Income CAN$ (Nb/%)	n = 7	n = 3	n = 1	n = 1	n = 12[c]
Less than $10 000	2 (28.6)	0	0	0	2 (16.7)
From $10 000 to $19 999	4 (57.1)	2 (66.7)	1 (100)	1 (100)	8 (66.7)
From $20 000 to $29 999	0	1 (33.3)	0	0	1 (8.3)
From $30 000 to $39 999	0	0	0	0	
From $40 000 to $49 999	1 (14.9)	0	0	0	1 (8.3)

[a]Visits and hospitalizations occurred between January 1st, 2016 and December 31st, 2016.
[b]One missing element for this category for setting 4.
[c]Four missing elements for this category for settings 3 and 4.

specific related decision, and their frequency of mention. Table 4 shows the frequency of each type of decision and the number of times that stakeholders identified it as being difficult or frequent.

The most frequent decision point for patients included in our study is to visit the emergency department or not. For clinicians, the most frequent decision point is about change in the living environment, adherence to a treatment plan and lifestyle change. Most of the participants identified two difficult decisions: *Should I establish the terms of an intervention plan/treatment or let health care professionals do it?* and *Should I take medication or establish the terms of taking medication or*

TABLE 2 Characteristics of the settings

	Program/intervention description	Participants	Clinicians' profession
Setting 1	• Patient identification • Patient evaluation • Individualized Services Plan (ISP) • Monthly follow-ups • Coordination of services • Support for self-management • Main point of contact	Patients (n = 7) Case managers (n = 3) Clinicians (n = 21) Decision makers (n = 6)	Nurse (n = 10) Social worker (n = 6) Respiratory Therapist (n = 2) Occupational therapist (n = 1) Doctor (n = 2)
Setting 2	• Patient identification • Home assessment of patients • Interdisciplinary/Individualized • Services Plan (IIP/ISP) • Monthly telephone follow-ups • Coordination of services • Support for self-management • Main point of contact	Patients (n = 3) Case manager (n = 1) Clinicians (n = 4) Decision makers (n = 3)	Specialized nurse practitioner (n = 1) Nurse (n = 1) Psychologist (n = 1) Psycho-educator (n = 1)
Setting 3	• Identification of patients during emergency visits • Patient evaluation • Interdisciplinary/Individualized Services Plan (IIP/ISP) • Monthly follow-ups • Coordination of services • Support for self-management	Patients (n = 3) Case manager (n = 1) Clinicians (n = 8) Decision makers (n = 3)	Nurse (n = 2) Social worker (n = 4) Occupational therapist (n = 1) Family doctor (n = 1)
Setting 4	• Patient identification during medical appointments • Follow-up if requested by the patient • Coordination of services if requested by the patient	Patients (n = 3) Clinical nurse (n = 1) Clinicians (n = 5) Decision-makers (n = 3)	Nurse (n = 3) Psychologist (n = 1) Doctor (n = 1)

not? Results also suggested that the participants mostly identified decisions related to the daily management of health conditions.

3.3 | The actual and desired roles of the stakeholders in the decision-making process

According to the clinicians included in this study, patients are mostly passive in the SDM process as mentioned by one of them: "The role they actually play is still more of a passive role" (Decision maker 1). According to health care providers, patients with an active role show good self-management skills, communicate their opinions, values, goals, and show initiative by being resourceful. Based on the analysis of the stakeholders' comments, patients could play a different role depending on the decision and the health care provider they visit. Health professionals included in this study agreed about the desired role for the patient: they want patients to play an active role in SDM and some of them are playing it. For example, one patient told us: "I'm the boss. […] If someone is making decision in my place, I'm not happy with that" (Patient 12). On the other hand, some patients are passive in their care as one of the stakeholders told us: "Patients really like it when we do things for them, when we take charge of their care, which is not the expected role." (Decision maker 2).

One other issue that emerged from this study is that informal caregivers (family or other) support patients during their decision process, but they sometimes decide for the patient. For example, caregivers bring the patient to the hospital or call the health care professionals on their own initiative to ask questions. One example of this was reported by one health care professional: "What I see in elderly patients is that we have interprofessional meetings to present the case, but the patient is never there, we will present to the family" (Clinician 1). It is, therefore, important that caregivers play a supportive role with patients because they trust them, and patients ask them for help. Stakeholders highlighted the fact that caregivers must play the role the patient wants them to play and not the role that caregivers want to play. Clinician 1 also mentioned that family members must modulate their involvement depending on patient needs and preferences and be more transparent and this is supported by one of the patients who told us: "She's (his sister) an advisor, she needs to understand that I have other advisors (Patient 12)."

In collaboration with the patient, case managers seem to play a central role in the SDM process. They interact with patients to clarify

TABLE 3 Types of decisions identified by all types of stakeholders

Themes	Types of decisions and related options	Clinicians	Decision-makers	Case managers	Patients	Total
Services utilization and provider choice	1. Do I need to go to the emergency department or not?	7	3	3	20	33
	"[…] at the level of physical illnesses and all that, there is the whole notion too, well when is he going to the emergency, or when is it appropriate to go to the emergency room? when am I going, when am I not going to, and then it is actually at the level of, well, chronic disease trajectories, I do not know if there is any help to decision" (Case manager 4)					
What are my options in terms of services and providers?	2. Do I need to consult a provider or a service for my current need or not?	0	2	1	4	7
	"Do I go to see my family doctor to talk to her, see what she thinks about it? Am I trying to take Benadryl before, because she told me that by trying the Reactine before, it could help but I'm allergic to Reactine, that's why I decided to take Benadryl before, and then try it again, just to see" (Patient 5)					
	3. Do I need to change the provider or to obtain a second opinion or not?	0	0	2	0	2
	"Then, you know, we see it, regarding stages of grief, at the beginning, it's no, no, no I (the patient)do not want to know, then the time after, well, perhaps, it becomes a little ambivalent, I will go get another opinion to Charles-LeMoyne, eventually they end up back to the plan, must see the benefits" (Decision maker 10)					
	4. Which provider or service is the best suited for my problem or condition?	5	6	2	0	13
	"Do they go to the emergency room, do they go to the family doctor, if they have one, first of all? They come to the CLSC, for most people, is not so simple to understand the health system, so, these patients with complex needs, it's even harder for them" (Decision maker 7)					
	5. Do I have to ask for emergency assistance or not?	0	0	0	1	1
	"Of course it becomes difficult, you have to make choices. I remember another moment that happened recently, I had so much knee pain that I was not even able to pick up the phone at the edge of my bed, I would have called the ambulance if I could touch the phone, it was too serious, I had too much pain. Finally, my boyfriend arrived, he put ice on my knee, he took care of me but I do not see how, even the paramedics, they could have taken me out of the house, I do not know" (Patient 5)					
Global management of the physical and social environment	6. Do I have to move to a nursing home or stay in my current home?	22	0	3	9	34
	"For accommodation services, us, for the elderly is something, it's the big decision we have to make, decide to leave your home, it is not easy to leave your house that it's been 50 years that you stay in it, or to say, now I'm going to live in a nursing home, I'm leaving" (Clinician 1)					
What are my options in terms of living environment and social issues?	7. Should I stop working or continue to work?	1	1	0	5	7
	"I had a burnout (without nervous depression), well, when I came back, I was exhausted and my system was barely working, and I was looking forward to going back to work, in my mind, I was happy, I loved my job, but my brain was not working anymore, it was like, there was concrete in my brain, and then, the director said – you have a nervous breakdown, and this is when I stopped, I said - ok, I'm not able, I'm not even able to write a letter, it was long, it was painful" (Patient 6)					
	8. Should I get rid of my things or keep them?	0	0	0	4	4
	"Maybe I will have to sell my trailer, because I cannot anymore, it's 28 feet I think, then, I do not know what we're going to decide because money became a problem, it's big decisions to make, I'm not happy with that" (Patient 7)					
	9. Am I able to maintain activities of daily and home living or not?	0	0	0	3	3
	"But decision-making is to take a shower or not, can I or not, these kinds of decisions, I have some on a daily basis" (Patient 5)					
		0	1	0	0	1

(Continues)

TABLE 3 (Continued)

Themes	Types of decisions and related options	Clinicians	Decision-makers	Case managers	Patients	Total
	10. Should I choose or maintain a social activity or not?					
	"I was always very energetic, very involved. I belonged to an organization called "Femmes du monde" and I've been on their board for years and years and I had to miss a board meeting this week because I was in the hospital and I think I'm going to have to stop going there. (…) So, that, by the time it's 8 or 9 o'clock at night, I'm not ready … I'm not talking about having a bad thing, I just don't have the ability or the energy or the interest in going anywhere" (Patient 8)					
	11. Should I keep driving my car or not?	0	0	0	3	3
	"I must say that since I became sick, I used to have…, we had a car and I drove it around, so, now I'm having to … not that I don't realize that this had to happen – but I now have to take a cab. And … um … you know, made decisions" (Patient 9)					
	12. Should I return to my country of origin or stay in Quebec?	0	0	0	2	2
	"Well, I mean, it was a decision … would I stay in Canada or go back to Scotland? I mean, I came in 57. I worked in New Brunswick and then, um, Manitoba, and I came here in 63. So, I've been here since and I did homecare" (Patient 9)					
Level of care and end of life	13. Should I be resuscitated or not?	1	0	1	8	10
What are my options in terms of levels of care?	*"Well, I even met her at home to explain to her, she wanted to sign the non-resuscitation form, so I visit her at her home, then we looked at the documentation together, I explained things to her and then she made the decision to sign the form, if she ever had to go to the emergency room, if the paramedics took her to the hospital, her document was in her room, signed by her doctor, by herself, so as not be resuscitated"* (Case manager 3)					
	14. Should I receive doctor-assisted dying or not?	0	0	0	5	5
	"My own feeling about it – death doesn't scare me. It really doesn't. I wish I had, you know, this law that they just passed in Québec, which is not the law they said they were going to pass – so, unless you can show that you are going to be dying soon anyway, they don't allow us assisted dying. And I wish that I had my hands on something so that I can choose the time of my own death. I don't have that" (Patient 8)					
	15. Should I make funeral and inheritance arrangements or not?	0	0	0	3	3
	"But I'm just thinking that I really should go over it and make sure that one nephew wants that painting there. And a great-niece would like that one. So, I must get it all organized. And I've arranged that when I die that I want to be cremated and my ashes are going to be sent over to Scotland" (Patient 9)					
Management of the health condition	16. Should I permanently end my treatment or pursue it?	0	0	1	1	2
What are my options for managing my health?	*"I saw him again for a few months, because he gave me infiltration in the knee, and then, after that, I decided to stop the infiltration in the knee"* (Patient 7)					
	17. Should I adhere to a plan/treatment or not?	15	10	3	2	30
	"Yeah. and I didn't have treatment and, so I couldn't … the treatment that I was given – because I didn't have money to buy … I didn't have the funds to buy a machine" (Patient 11)					
	18. Should I adopt new lifestyle habits and behaviors or maintain the status quo?	12	5	5	10	32
Management of the health condition	*"So I stopped eating crusts and pies and things like that, I can't, unless it is a pizza with a thin crust, or things like that, so that's fine with me I think it helps me to be healthy, finally, by obligation for my damaged stomach"* (Patient 6)					
	19. Should my health condition be handled by	1	0	0	0	1

(Continues)

TABLE 3 (Continued)

Themes	Types of decisions and related options	Clinicians	Decision-makers	Case managers	Patients	Total
	the health system or not?					
	"For example, a person who wants to be supported, who seeks care, while we know that his decision will make him regress, well we know that's what he wants, his decision is to stay, but we go a little against his wish there. It's actually kind of therapeutic" (Clinician 4)					
What are my options for managing my health?	20. Should I establish the terms of an intervention plan/treatment or let health care professionals, do it?	2	2	4	26	34
	"My decision, when I went to the last therapy, I warned everyone that I would not go back to therapy, except when you can't continue anymore, you open your arms and say come and get me (…), they tell us, - you want to stop rambling, but they will bring you back in your childhood to search for something, first I do not even remember, and then, what applies to someone does not necessarily apply to me, in any case, for me the therapy houses, it's over, for sure" (Patient 12)					
	21. Should I take medication or establish the terms for taking medication or not?	4	1	2	20	27
	"Oh, she wanted to cut my pills, I said - no (laughs), I prefer to have control of my antidepressant and I decreased the dose very, very, very slowly, I know myself, I feel it, and then it is very nice, she let me do it, and finally, I decreased it by myself on, on 8 months I think, as soon as I felt good, I decreased it, a little bit, I continued until I completely stop it" (Patient 6)					
Management of the health condition	22. Should I accept treatment or not?	1	1	0	1	3
	"Well, it is to expose the risks of each of the decisions that can be made, the consequences of following a treatment or not, it is really to show the patient the best way for him. But in the end, it is him who makes the decision, me I have a support role and I have to be opened up. I do not impose the patient a decision, I expose him all the possible solutions, what can be done, after that, we go with the decision" (Case manager 5)					
What are my options for managing my health?	23. Should I accept a proposed service (other than health services) from a community organization or not?	1	1	2	0	4
	"The decision is to accept a home visit by a social worker to assess needs at home, visits of an occupational therapist to adapt the living environment, it helps to identify these needs, we exposed them to the patient and then he agrees or not to be supported by the health professional" (Clinician 6)					
	24. What elements of my condition should I prioritize?	1	0	0	0	1
	"Well, what he has to do is that he must know what the patient's needs are, what he wants, what he wants to work on, where he is in his decision making, really respect his need, respect his pace also in there, to make yourself available" (Decision maker 6)					
	25. Do I have to make the decision for the patient or let him decide (for a provider or a caregiver)?	1	0	0	0	1
	"Well, yes, I think we are several professionals in the health system that take care of patients from the head to the toes, so we disempower the patients, whether they are big users or patients on intensive care units. We are moving away a lot from our primary role as a service organization, often, in fact, we decrease the autonomy of the patient, we show that if patients come to the hospital, everything is going to settle, we have to change the culture, then it is as much at the medical level as at the professional level" (Decision maker 2)					
Acceptance of the health condition	26. Do I acknowledge my condition and accept to be involved in its management?	4	3	3	8	18
What attitude I must have when coping with my health condition?	*"I think that before making a decision, they must accept, must recognize that they have problems, that is, not always the case, especially when we touch mental health. To be able to accept"* (Decision maker 9)					

TABLE 4 Types of decisions identified as difficult or frequent by all types of stakeholders

Themes	Types of decisions and related options	Difficult decisions	Frequent decisions	Total
Services utilization and provider choice *What are my options in terms of services and providers?*	1. Do I need to go to the emergency department or not?	9	17	26
	2. Do I need to consult a provider or a service for my current need or not?	1	0	1
	3. Do I need to change the provider or to obtain a second opinion or not?	0	0	0
	4. Which provider or service is the best suited for my problem or condition?	0	8	8
	5. Do I have to ask for emergency assistance or not?	1	0	1
Global management of the physical and social environment *What are my options in terms of living environment and social issues?*	6. Do I have to move to a nursing home or stay in my current home?	8	11	19
	7. Should I stop working or continue to work?	2	2	4
	8. Should I get rid of my things or keep them?	4	0	4
	9. Am I able to maintain activities of daily and home living or not?	0	0	0
	10. Should I choose or maintain a social activity or not?	0	1	1
	11. Should I keep driving my car or not?	0	0	0
	12. Should I return to my country of origin or stay in Quebec?	0	0	0
Level of care and end of life *What are my options in terms of levels of care?*	13. Should I be resuscitated or not?	6	0	6
	14. Should I receive doctor-assisted dying or not?	3	0	3
	15. Should I make funeral and inheritance arrangements or not?	0	0	0
Management of the health condition *What are my options for managing my health?*	16. Should I permanently end my treatment or pursue it?	2	0	2
	17. Should I adhere to a plan/treatment or pursue it?	1	12	13
	18. Should I adopt new lifestyle habits and behavior or maintain the status quo?	9	12	21
	19. Should my health condition be handled by the health system or not?	0	0	0
	20. Should I establish the terms of an intervention plan/treatment or let health care professionals, do it?	13	6	19
	21. Should I take a medication or establish the terms for taking medication or not?	12	3	15
	22. Should I accept treatment or not?	0	0	0
	23. Should I accept a proposed service (other than health service) from a community organization or not?	0	4	4
	24. What elements of my condition should I prioritize?	0	0	0
	25. As a caregiver/provider, should I make the decision for the patient or let him decide?	0	1	1
Acceptance of the health condition *What attitude I must have when coping with my health condition?*	26. Do I acknowledge my condition and accept to be involved in its management?	10	1	11

their needs, their desires, and their preferences. Most of the time, they initiate the SDM process by recognizing that a decision must be made and provide guidance. One of the case managers explained how he sees his role: "The role is to provide health care services to frequent users of services, to manage these services, to organise follow-ups for this clientele who always show up at the emergency room, this is really it, this is like being a conductor; it's really about representing the client" (Case Manager 1). Nevertheless, to improve their role, case managers need more time as expressed by one of them: "If I had more time, we would meet all the time for all our patients" (Clinician 2).

In several cases, stakeholders highlighted that health care providers communicate with patients to support them in their decisions. They are more involved in single SDM processes related to decisions that fall within their scope of practice, than in ones that involve an interprofessional team. They inform patients and present the different options offered. Some of the health care professionals would like to

be better equipped for presenting options and integrating interprofessional perspective into the SDM process. One of them explained how those elements should be part of training: "[…] if we had more resources then we had a little bit of training, continuing education that would teach us a little bit how to manage more complex situations or about difficult decisions to make with the patients, probably it would be something useful" (Clinician 3). Decision-makers also raised this issue as mentioned here: "First and foremost universities should train doctors in this perspective…our future professionals should enter with a minimum of training on the collaborative approach […]" (Decision maker 3).

Decision-makers involved in this study occasionally support patients in their care and decision-making process. For example, when patients need specific information that only decision-makers can provide or when health professionals feel they need some support. They can support and encourage patients and health care professionals: "I play an administrative role. I have to stick to administration, except that since I currently don't have anyone who can support my clinical teams, in cases with frequent users of services or in very complex cases, then god only knows that they (health care professionals) have some… it's terrible, some will have the reflex, those who knew me in my old life, will call me *- I want to talk to you about a situation, what do we do? What do I do? I don't know what to do […] What do I answer a patient who tells me this or that*? I give advice to some of them but only a few." (Decision maker 4).

3.4 | Key elements of the decision-making process

This section presents themes and subthemes according to the determining factors of the decision. The identified themes refer to the ODSF[7] except for a new one that emerged from the data: organizational characteristics. All stakeholders made comments that fall under this theme, particularly clinicians and decision-makers.

3.4.1 | Perception of decisions

This element refers to patients' knowledge of their health care condition, patient expectations regarding the possible outcomes of each option, patient values (desirability of the options), patient decisional conflicts (uncertainty about which action plan to follow), decision-making stages, and patients' predisposition for one option or another.[7] These factors, as experienced by the patient, can promote decision making as well as hinder it, as expressed by two patients who addressed this notion: "I'm mentally ready and I look forward to it" (Patient 1). "The other day, my psychiatrist told me […] it would be good for you to find some things like that, to try to break down the isolation […] maybe some yoga, something like that […]. There was tai chi; this is something I think I would like, we can unwind, because sometimes we just get frustrated, we just say, it seems I've been more irritable in the last week… I have more trouble controlling myself. It seems like everybody gets on my nerves, then everyone is like, you know, it looks like there's a period like that" (Patient 2).

In addition, two new barriers emerged from our data. The first barrier refers to the moment when the patient is unwilling, or is unable, to adhere to the recommendations, as mentioned by this decision-maker: "I can clearly explain the values for glycemia [to the patient] but if he is not ready to change and he continues to drink two liters of soft drinks each day, his glycemia will never be between four and six" (Decision maker 5). In some cases, the priorities identified differ from those of the providers, as expressed by one decision-maker: "Because, it can be very confronting when the needs of the patient are not given the same priority by the provider, so how are we supposed to proceed in this case? […] We need to provide the right tools to the professionals" (Decision maker 6). The second barrier refers to the difference of opinion between the health care professional and the patient and the patient's fear or mistrust of health care professionals or the health care system. One case manager explains this: "[…] sometimes they refuse because he had bad experiences in his country, the social worker meant something bad, or the culture or I don't know what, seeing a psychologist means that you're sick in the head" (Case manager 2).

3.4.2 | Perception of others

This paragraph refers to the fear of patients to be judged by others, including family members and health care professionals. The perception of others could enhance patient decision making by providing support and advice and can be considered as a barrier to their decision-making process.[7] Indeed, both health care professionals and family members can interfere with patients' decisions or put pressure on them. One clinician expressed this: "Sometimes, it's not always a choice; when you come to the hospital, it's often imposed, I mean, we talk about choice and all, but, if you don't have any injury or pain, you go home, even if you want to stay, so we don't consult them all the time" (Clinician 4). Patients could make a decision in order to avoid displeasing a caregiver for example.

Two subthemes emerged from the Perception of others: the stigma experienced by some patients and their unwillingness to collaborate with health care professionals. Many patients seem to experience stigma from their loved ones, health care professionals, and the overall population, as expressed by one patient: "You know, when you live with pain… then try to make the person understand, but the person, they judge you, they say - well, make an effort… I answer - yes I make daily efforts" (Patient 2). In addition, some patients do not want to collaborate with certain professionals because they do not trust them or they disagree with a proposed treatment. One clinician illustrate this disagreement: "We can explain, what the patient must do but he answers, – *"no, I don't need it, I don't need it (the patient)"*, we are like threatening a little, even if we bring it up in a more delicate way" (Clinician 5).

3.4.3 | Resources needed

According to the analysis of the results, resources needed for decision-making processes fall into two categories: personal and

external resources. Personal resources refer to the experiences, self-confidence, motivation, and ability of patients.[7] External resources refer to the moral, informational, and financial support offered to patients and to the social or community network on which they rely. These factors can be positive vectors for decision-making. If the patient has had previous positive experiences, has self-confidence, is motivated, can be supported by a network, and has enough financial and material resources, he will be better able to make decisions. On the other hand, if one of these elements is missing, decision making may be difficult as mentioned by one patient who talks about the difficulty of getting around to see her friends: "Because I have some nice friends, but they don't have any transport. I mean, I could go but I'd have to pay for the taxi" (Patient 9).

3.4.4 | Patient characteristics

It refers to age, sex, family situation, education, occupation, culture, residence, medical diagnosis and prognosis, and health care condition.[7] Each of these factors can play a role in decision-making. Two were discussed by stakeholders, specifically by clinicians and decision-makers: the complexity of patients' conditions and patient involvement in their health care.

Regarding patient complexity, most of the stakeholders mentioned difficulties related to physical and psychiatric comorbidity, polypharmacy, and the fact that some patients are homeless, as reported by one patient: "With the panoply of antibiotics I take, I said - do you have other antibiotic reserves for me? They said - Maam, don't worry, that's always there but in your case, sometimes it's a little difficult to make a decision." (Patient 3). They also mentioned that some patients do not fit into the programs offered by the health care system because of their various diagnoses.

Regarding patient engagement in their health care, many health care professionals interviewed point out patients' lack of empowerment, as expressed by one clinician: "[…] there aren't 50 solutions, I mean, if you want to heal, well you come back then - I want to heal but I don't want to help myself, it's not magic." (Clinician 4). On the other hand, some professionals are more conciliatory and admit that this step is difficult to achieve, as explained by one decision-maker: "Sometimes, they tend to disempower themselves and then trust the nurse or the doctor will fix everything, but you know, they have a role to play, that part may not be so obvious to them. Either because of lack of knowledge or because they are not at that point, but I think, it can be a difficult decision to make" (Decision maker 7).

3.4.5 | Professional characteristics

Health care professionals' characteristics refer to their age, gender, education, specialization, culture, practice, experience, and counseling style.[7] Again, these characteristics can constitute both facilitating factors and barriers to decision making. The process will be facilitated if the health care professional establishes a trusting relationship with the patient, adopts an approach based on their needs, works in collaboration with other providers, and demonstrates openness to involving the patient in decision-making. One decision-maker reports: "The best services offer, well it would be first and foremost that universities train doctors in this perspective, and that our future professionals enter with a minimum of training on the collaborative approach" (Decision maker 1).

A new subtheme emerged from our analysis: the preconceived opinions of some health care professionals. Some of them had preconceived opinions, made diagnoses quickly based on their experience with this clientele, or made negative remarks about patients, as mentioned by one patient: "He did not want me to have the operation, he said that I had too many mental health problems, automatically, he made a diagnosis, […] you don't have the mind to make decisions yourself" (Patient 4). Some health care professionals believe this clientele is difficult to treat and represents a professional risk, as expressed by one decision-maker: "[…] sometimes it's very hard as a health care professional do not want to cure people or help people. So, if we see the possible health risks or the consequences of the decision, sometimes it's harder for us to accept and support that patient" (Decision maker 8).

3.4.6 | Organizational characteristics

It refers to social norms and values, organizational rules and routines, institutional norms and organizational structures of the health care system.[7] A clear trend seemed to emerge as all stakeholders criticized the organization of the health care system. Concerning social norms and values, several stakeholders consider that health care professionals do not value this clientele, as expressed by one case manager: "[…] you know it means the trash of society, do you understand, they are the trash of society because nobody wants these cases in their workload, because it impedes mass production, it is a lot of work; at the end of the day, we do not make a lot of progress, we make a little, so it's depreciated" (Case manager 2).

Several stakeholders criticized the institutional norms of the health care network. Some of them reported the rigidity of the admission criteria for programs offered to patients and the absence of a clear definition of this clientele. They also criticized the screening and referral process for this clientele and the fact that it is rarely a priority, as explained by one case manager: "We have an orphan clientele, who does not have a family physician, and by not having a family physician, cannot be referred to a specialist, because no one will read the consultations or the recommendations" (Case manager 3).

Finally, the recent reorganization of the health care system has led to significant changes in institutional norms and organizational structures. We noted that several stakeholders exposed the development of a vision focused on the monetary aspect of the health system, which results in an obligation to perform interventions with patients in must less time, a bigger workload, and a lack of family doctors. Others condemn the rigidity, the slowness and the administrative burden of the health care system and the constraints related to confidentiality. This case manager reports on this administrative burden when he says: "But you know, the further we go in time, the more papers

we have to complete…, we do a lot of paperwork, notes in files and lots of other things" (Case manager 3). Several stakeholders mentioned that the current organization of the health care system is not adapted to this clientele and many patients are unfamiliar with the way it works because of its complexity. One decision-maker explains this: "I would tell you that one of the main reasons people are going to the emergency room right now, in my cohort, is due to a lack of knowledge about services" (Decision maker 9).

4 | DISCUSSION

This original qualitative research study is the first to assess the decisional needs of primary care patients with complex care needs. We identified 26 types of decisions specific to this clientele and clustered them under five major questions: *What are my options in terms of services and providers? What are my options in terms of living environment and social issues? What are my options in terms of levels of care? What are my options for managing my health? and What attitude should I have when coping with my health condition?* The most frequently mentioned specific decisions by participants were: *Do I need to go to the emergency department or not? Do I need to move to a nursing home or stay in my current home? Should I establish the terms of an intervention plan/treatment or let health care professionals do it?*, and *Should I adopt new lifestyle habits and behaviors or maintain the status quo?*

This study shows that patients in our sample frequently make decisions that differ from the overall population. A first study on the decision making needs of Canadians conducted in 2003 by O'Connor et al[19] identified that Canadians have different health-related decisional needs about surgery, medical treatments, birth control, the institutionalization of a family member, pregnancy and childbirth, lifestyle changes, and diagnostic testing. These types of decisions are made periodically, that is, everybody faces such decisions at specific moments in their life, but they usually make one decision at a time.

In contrast, a good illustration of the life experience reported by participating patients is the high frequency of the decision whether to go to the emergency room or not. The difficulty experienced by people in deciding whether or not to consult in the emergency department, and this as a last resort, has never been identified in the general population, O'Connor.[19] Many patients told us that the most difficult decisions to make are related to the management of their health condition, because the burden is present daily, compared to the decision to visit the emergency room, which is more frequent, but not on a daily base. Patients are aware that their choices, such as whether to start a treatment plan or not and whether to take medication, can affect their condition for days to months. This makes the decision even more difficult to make and influences patients' commitment to managing their condition. These results are consistent with the literature, which emphasizes that patients with multiple chronic diseases face a heavier burden than the general population.[20] Clinicians also believe that the complexity associated with this burden makes it difficult to manage the patients' condition because it requires higher levels of care and services (ie, higher intensity of care in terms of financial and professional resources) compared to the general population.[21,22]

Another factor that has an impact on the burden of disease is the number of decisions to be made, several times per week or month. According to the burden related to the decision-making process, our results highlight that patients' commitment to their health care condition is an important element that facilitates SDM and self-management. This element can both promote and hinder patients' health and decision-making process. To our knowledge, there is no other study that documented the multitude of decisions made by patients with complex care needs in primary care and frequent users of health and social care services. Thorne and colleagues investigated everyday self-care decision making among persons with chronic illness, but who are not specifically frequent users.[23] Numerous studies have shown that patient engagement in case management programs fosters successful interventions and can greatly improve patients' health status.[11,24-26] On the other hand, this remains hard for a lot of patients since half of the patients involved in our study identified the decision "Do I acknowledge my condition and accept to be involved in its management?" as a difficult decision. Case management interventions enable patients to play a more active role in their care, and at the same time, reduce overutilization of health care services.[24,26] In addition, establishing a trusting relationship between the case management team and the patient is a key factor in improving patients' self-management and medical condition.[11]

Clinicians lack understanding of the decision-making needs faced by primary care patients with complex care needs, which increases the imbalance between their needs and the services currently offered by interprofessional teams. This is an important issue to address because it is now known that Canadians experience a low degree of SDM,[3] and that most patients do not have the opportunity to talk about their preferences in terms of care and treatment. Patients could greatly benefit from the SDM approach,[27,28] but it is often unknown to health care professionals and requires to be well informed about the "real-life" of living with a complex health condition.[23] The SDM approach is underutilized among vulnerable clienteles[3,29]; health professionals presume that they wish to be less active in decision making about their health care.[30] The huge number of decisions faced by patients in our study supports that patients would benefit from a Patient Decision Aid (PtDA) to discuss engaging or not in a decision making case management program. Such a PtDA could help inform patients about their health burden and provide options for effective health management. In addition, it would also contribute to identifying their values and preferences for health care services and would be a useful tool for health care professionals.

As with other types of patients,[31-33] it seems that no decision aid supporting the decision to participate or not in a case management program for effective decision support exists for this clientele.[34] Several studies have shown that better coordination of care, under the responsibility of a case manager, within an interprofessional team[35,36] and greater involvement of patients in decisions concerning their health[37] are effective interventions. These interventions reduce the burden of care, reduce the use of health care services, and improve patient outcomes.[38]

5 | IMPLICATIONS FOR FUTURE RESEARCH

Based on these results and the scientific literature, we will develop a PtDA to support patients in their decision to engage or not in a case management program. The ODSF[7] and the International Patient Decision Aid Standards[39] will be used to create this PtDA. This approach will meet most of the issues raised by the stakeholders in this research project and they will undoubtedly help with the implementation of a decision aid, specifically addressing the needs and concerns of this clientele.

6 | STRENGTHS AND LIMITATIONS

The context of the study, which is case management programs and frequent users of health services, is specific and, therefore, our results may only potentially be transferable to similar contexts. Patients with complex care needs in primary care are usually (but not necessarily) frequent users of health and social care services, and they may not be enrolled in specific programs, or they may be enrolled in at least three other types of programs: information-sharing program (eg, patient navigator), integrated care (case manager embedded in a multidisciplinary team), or a home health care program. It is important to qualify our comments in relation to the frequency of the decisions we report in the study. This frequency corresponds to the number of times a participant mentioned the decision during interviews and focus groups and does not necessarily reflect the number of times they actually made the decision. We must keep in mind that there is a difference between what participants say and what they do on a daily basis. In addition, we are very aware that there are almost twice as many clinicians as patients involved in our study. As clinicians gather nurses, general practitioners, social workers, case managers, team leaders, and so forth, combined with the fact that we wanted a good representativeness of each type of health care professionals, this must explain this lack of proportion. However, we balanced this proportion by conducting individual interviews with patients to give them more time to address their needs and concerns about the topic. We also reached saturation of data for both clinicians and patients allowing us to think that no group was under-represented in the results. Finally, the triangulation of the sources showed consistency between all stakeholders. This study is reported in accordance with the COnsolidated criteria for the REporting Qualitative research checklist.[40] We adopted a POR process and involved the Patient Partner throughout all steps. We also used multiple sources of data including different types of stakeholders that ensure a comprehensive portrait of stakeholders' viewpoints on patients' decisional needs. In addition, our qualitative research design and data analysis included collecting, coding, and validating data with several researchers. We achieved saturation at the third setting under study and validated results with PP to be sure that they were relevant and patient-oriented.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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ORIGINAL RESEARCH ARTICLE

High Users of Healthcare Services: Development and Alpha Testing of a Patient Decision Aid for Case Management

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Abstract

Background Some patients with complex healthcare needs become high users of healthcare services. Case management allows these patients and their interprofessional team to work together to evaluate their needs, priorities and available resources. High-user patients must make an informed decision when choosing whether to engage in case management and currently there is no tool to support them.

Objective The objective of this study was to develop and conduct a pilot alpha testing of a patient decision aid that supports high-user patients with complex needs and the teams who guide those patients in shared decision making when engaging in case management.

Methods We chose a user-centered design to co-develop a patient decision aid with stakeholders informed by the Ottawa Research Institute and International Patient Decision Aid Standards frameworks. Perceptions and preferences for the patient decision aid's content and format were assessed with patients and clinicians and were iteratively collected through interviews and focus groups. We developed a prototype and assessed its acceptability by using a think-aloud method and a questionnaire with three patient-partners, six clinicians and seven high-user patients with complex needs.

Results The three rounds of evaluation to assess the decision aid's acceptability highlighted comments related to simplicity, readability and visual aspect. A section presenting clinical vignettes including story telling was identified as the most helpful.

Conclusions We created and evaluated a patient decision aid. Considering the positive comments, we believe that this aid has the potential to help high-user patients with complex care needs make better choices concerning case management.

Plain Language Summary

Some patients are living with physical and mental health problems. They also may have handicaps and unsuitable backgrounds. This may lead them to use health services more often. Case management is a service offered by a team of health professionals. They help patients to decide what is important to them based on their values and preferences. Currently, no tools exist for that service. We built and assessed a tool to support patients in their decisions. With this tool, they think about engaging in case management or continuing with usual care. They can also postpone their decision to a later time. This tool will present data based on scientific studies about case management. It will help patients to clarify their values and preferences to make the best decision for them. This tool was built with a team of researchers, healthcare professionals, managers and patient-partners. It was built according to several guidelines. We met participants and they answered questions that

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helped us to build our tool. We also ensured the tool was acceptable to them. The most frequent comments were to make it simpler and to use simple vocabulary. The look was also important for the participants. The latter found that the section where patients could write their own story was useful. Patients also found that reading stories about other patients like them was helpful. Our tool will help patients with complex care needs make better choices concerning their health based on their values and scientific data.

Key Points for Decision Makers

Complex interventions such as case management need to be better described so that they can be improved by researchers and better translated to patients.

Current guidelines for the creation of a patient decision aid are not optimal for complex interventions that depend on multiple elements.

The co-creation of a patient decision aid must involve several stakeholders such as patient-partners, decision-makers and clinicians.

1 Introduction

"Patients with complex care needs" is a term used to describe a subpopulation of patients with multimorbidity, psychiatric comorbidities and/or psychosocial factors with or without functional limitations [1, 2]. Their level of independence and functionality may bring a part of this population to use healthcare services more frequently (high users) and involve more complexity than the general population [1, 3–6]. A recent systematic review on high users showed that they are generally older and experience multiple chronic conditions [7]. They often have circulatory diseases and mental and behavioural disorders [7]. For the remainder of the article, we use the term "patients" and it will refer to patients with complex care needs and who are high users of healthcare services. In the Province of Quebec (Canada), the majority of those patients are elderly women who present with coronary heart diseases or diabetes mellitus [8]. Some of them are persistent high users and others are occasional users [8]. More than 80% of these patients have chronic conditions such as asthma, chronic obstructive pulmonary disease, diabetes, hypertension and atherosclerosis [9, 10]. In Canada, which has a publicly funded health system [11], those patients are responsible for 50% of the expenditures [12]. Clinicians must better address patients' needs to improve patient-related outcomes by using patient-centred care that is adapted for patients with complex conditions [13].

Case management (CM) may help support those specific patients and their clinicians [14]. Case management programmes involve both an interprofessional team (nurses, physician, social workers) and the patient to work together to evaluate needs, priorities and available resources [15–18]. Case managers plan, facilitate and coordinate patient-centred healthcare to provide patients with the right service at the right time [18, 19]. Moreover, they also provide education, self-management support and offer a personalised service allowing direct communication. Case management can reduce emergency department visits, improve patients' quality of life and increase clinicians' satisfaction [6, 20]. However, it requires a high level of engagement from both patients and clinicians to produce positive outcomes [19].

To decrease patients' decisional conflict, the use of shared decision making is known to have a positive impact on both the patient and healthcare providers [21]. The purpose of shared decision making is to help patients understand the evidence-based healthcare involved in their care before making any decision and to help practitioners explore and consider patient values related to the decision. It helps patients clarify their values and identify the influence of external societal pressures, allowing them to regain control over their health and to be comfortable with their decisions. From this process, patients can have clear and realistic expectations about their care, and they become more aware of the conflicting aspects of the decision [22–25]. Shared decision making is also known to improve patients' affective, behavioural and health outcomes [26]. In such a model, patients and clinicians relate to, and influence, each other as they collaborate in making the right decision corresponding to patients' values and needs.

Although some tools have been developed for shared decision making for specific populations, currently, there is no patient decision aid (PtDA) promoting an interprofessional approach supporting these patients in their decision-making process to engage in CM. This study aims to develop and evaluate a PtDA to help patients in engaging in CM, which presents the following options: (1) to engage in CM; (2) to not engage in CM; or (3) to postpone their decision and to assess its acceptability.

2 Methods

We obtained approval to conduct this study from the Ethics Committee of the Centre Intégré Universitaire de Santé et de Services Sociaux du Saguenay-Lac-Saint-Jean.

2.1 Theoretical Frameworks and Conceptual Models

We used the Ottawa Decision Support Framework [24], a highly relevant, evidence-based theoretical model including input from several domains that facilitates the development of interventions for healthcare providers involving shared decision making [27]. It allows professionals to improve the quality of decision processes through the evaluation of what could influence decision making. The interprofessional shared decision-making conceptual model [28] also guided the creation of our primary care PtDA allowing all stakeholders [29] to share their knowledge. This model allows the adaptation of the aid in response to the actual needs of current health and social services networks and therefore uses an integrative and coherent approach. As suggested by Coulter et al. [30], we also based our work on the user-centred design [31] conceptual model, which is a proven framework for the development of products and services. The user-centred design model is an iterative method allowing optimisation of the user experience and maximisation of usability and understandability [32]. Finally, we also used the criteria of the International Patient Decision Aid Standard [33] to produce a good-quality and effective PtDA. Figure 1 illustrates the methodology used and the four design steps needed prior to the prototype drafting.

2.2 Development of the Decision Aid

2.2.1 Designs 1 and 2: Scoping and Patients' and Clinicians' Views on Decisional Needs

Our team performed the scoping of more than 70 patients and clinicians' views on decisional needs between 2016 and 2018. This study took a pragmatic approach [34, 35] and the complete results are published elsewhere [29]. Briefly, results revealed that patients frequently face difficult

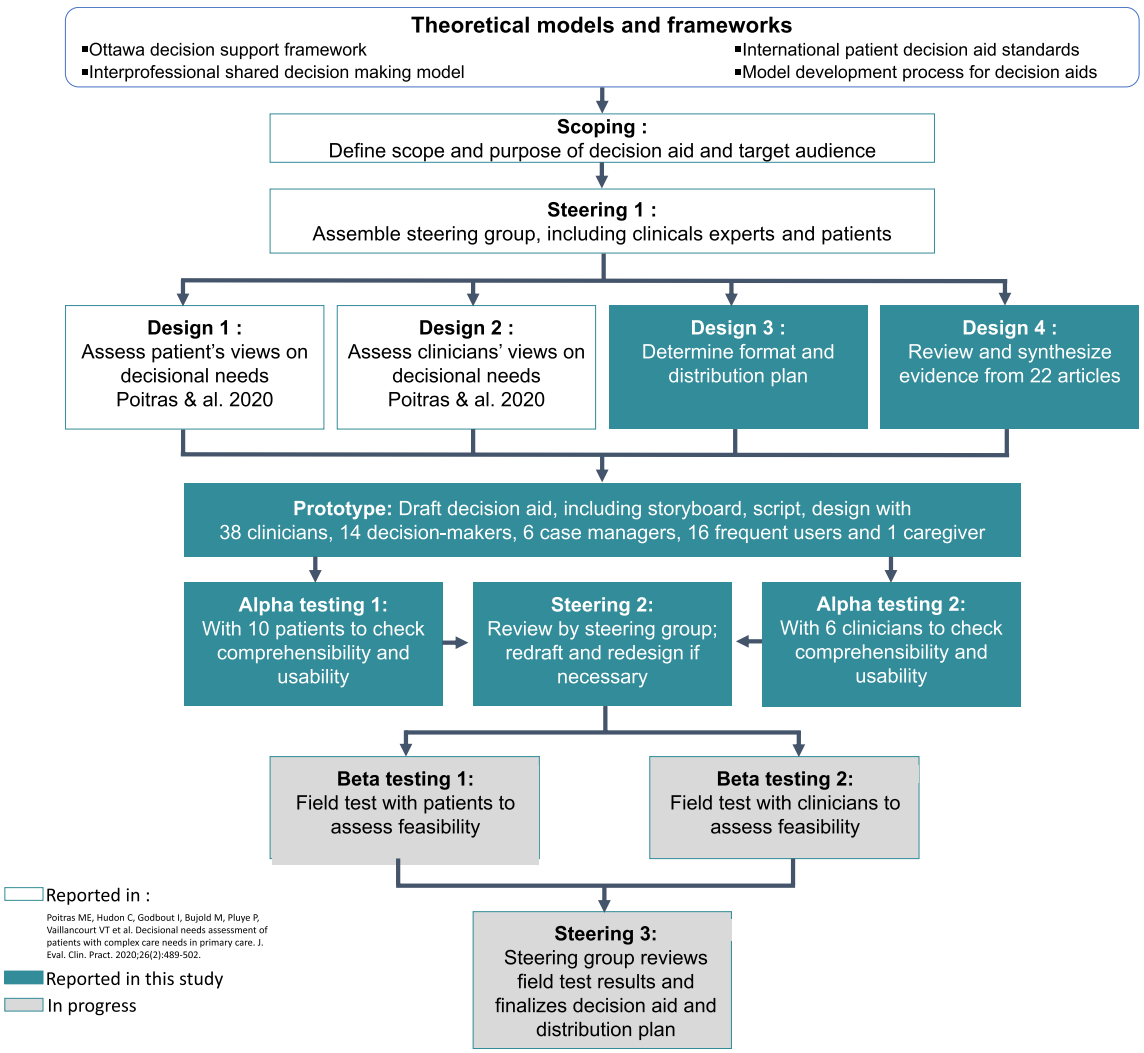

Fig. 1 Schematic of the systematic development process for our patient decision aid, adapted from Coulter et al. [30]

dilemmas regarding their choices, or even priorities, in terms of health management [29]. We also found that, according to patients and clinicians, the decision about engaging in CM (or not) was crucial to reach patient health-related outcomes. Patients and clinicians revealed that a decision aid could better support shared decision-making processes to engage (or not) in CM. More specifically, patients revealed that this decision aid could inform them about the harms and benefits of each option. Clinicians described that a decision aid could help them be more comfortable when they presented options and scientific evidence. Clinicians perceived that a decision aid could support patients in reiterating their choice to remain engaged in a CM program. Indeed, clinicians observed that the patients' engagement decreases over time. Including several stakeholders from multiple backgrounds allowed us to obtain a wider spectrum of comments representing different perspectives on the decision aid.

2.2.2 Design 3: Content, Design and Distribution Plan

This part of the user-centred design was embedded in the study aiming to assess decisional needs. While assessing the clinicians and patients' views on decisional needs (design steps 1 and 2), we also asked them about their preferences regarding content, visual aspect and format of the PtDA (Electronic Supplementary Material [ESM]). Focus groups and individual interviews were recorded and transcribed. Analysis was performed in an iterative manner. We performed a qualitative hybrid thematic analysis (deductive/inductive) assisted by NVivo 11 Software to identify relevant content and format for the PtDA. We also identified facilitators and barriers of the use of the PtDA to build an efficient distribution plan in further steps. This type of analysis allows the combination of themes derived from philosophical frameworks (deductive) and those emerging from participants' discussions (inductive). The coding scheme was supported by the user experience honeycomb that allows exploration of several facets of experience such as usability, accessibility, credibility and usefulness.

2.2.3 Design 4: Review and Synthesise Evidence

Informed by the results of a systematic review on the characteristics of CM in primary care for frequent users of healthcare by Hudon and colleagues [19], we aimed to include data on the frequency of hospitalisation, length of hospitalisation, emergency visits and the cost of hospitalisation. Briefly, this systematic review, guided by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guidelines, identified 22 eligible publications. Because of the low number and high heterogeneity of the studies, the pooling of the studies and meta-analysis was feasible for the cost of hospitalisation only (no difference was observed, data not shown). More details about the methods used for this systematic review can be found in the published paper [19].

Taking this into account and to better translate evidence to patients, our team chose to support our decision aid with the literature synthesis of articles (without a meta-analysis) included in Hudon and colleagues' systematic review [19], which considers the influence of contexts and interactional elements on patient outcomes (harms and benefits).

2.2.4 Prototype

Deductive analysis complemented by inductive analysis allowed the identification of new themes emerging from interviews. Data were triangulated among sources and discussed according to the conceptual frameworks used to support the development process in a shared decision context. With the comments of stakeholders and data generated from the literature synthesis, we created a prototype of a PtDA.

2.3 Alpha Testing

Coulter and colleagues [30] recommend conducting alpha testing with both patients and clinicians. We therefore included three patient-partners and six case managers in the design step based on their availability and interest. We also recruited seven patients, through regional case managers, who evaluated the aid and allowed us to reach data saturation. Individual interviews using think-aloud methods [37] were conducted using the user experience honeycomb [38]. As we used a user-centred design, which is iterative, the number of evaluation rounds needed is not predefined and is rather defined by the needs expressed by the stakeholders. In our case, three rounds were required to reach acceptability.

After the interview, participants were invited to complete an adaptation of the Decision Self Efficacy Scale Questionnaire developed by O'Connor [39] and Lalonde (ESM) to measure the acceptability of our PtDA, both quantitatively and qualitatively. Briefly, this survey contains nine questions to assess the content and presentation of the PtDA, two questions graded from 1 to 10 to measure the general appreciation of content and visual aspect and finally, three open-ended questions to identify aspects that were appreciated, disliked and may need improvement. Quantitative data were analysed with Excel software and qualitative data with content analysis. After each round, the research team adapted the PtDA according to participants' feedback and a final version of the prototype was available for alpha testing.

3 Results

3.1 Determination of Content and Design

We found that a meta-analysis was not the appropriate method to document the effectiveness and outcomes of a complex intervention such as CM, even less so when patients are also presenting complex conditions. In the context of the literature synthesis for the construction of the PtDA, the meta-analysis was possible only for the cost of hospitalisation and there was no difference between control and intervention groups (data not shown). According to patient-partners and clinicians, this outcome was not relevant for shared decision making in a Canadian context of care because patients do not have to pay for their hospitalisation as it is publicly funded. We therefore did not include this result in our PtDA. The previous work performed by Hudon et al. [19] allowed us to identify and include in our PtDA the following categories of patient-related outcomes: healthcare condition; quality of life, use of healthcare services, relationship between patients and healthcare professionals, and accessibility to information and healthcare services.

All stakeholders agreed on the relevance of a PtDA to help patients assess their preferences and make a decision on their engagement in CM. All participants wanted an aid that is accessible, simple and easy to use to avoid burdening their tasks. We did not reach a consensus on the format because some participants, regardless of their occupation, preferred a paper format and others a digital format. For clinicians and decision makers who preferred the digital format, many of them mentioned that it would be preferable to connect the PtDA to current electronic medical software. Clinicians would like to have a section where the patient could write down his or her needs. Decision makers mentioned that patients would appreciate videos on the PtDA.

Clinicians expressed some concerns about the confidentiality aspect as a limit to PtDA use. Some of them reported the fact that using a tool in a paper format could allow anyone to have access to personal data recorded on the tool. Thus, it would make anyone able to read a patient's confidential data or medical records as it is easier for a paper format tool to be inadvertently left on the corner of a table, for example, for anyone to see. That would obviously not be the case if using an electronic version on a computer. Additionally, in their view, their current workload (reports and forms to fill out), could reduce the tool's usefulness. To optimise the usability of the PtDA, they told us that it must be simple, easily available (visibility), adaptable (patients, relatives, caregivers) and accessible among clinicians.

3.2 Prototype

With the feedback from stakeholders, the research team created a prototype of the decision aid in French. The prototype contained the following six sections: (1) definition of CM and roles of case managers; (2) benefits and harms of CM for patients and for healthcare organisations compared to usual care and some statistics about pre- and post-intervention outcomes based on scientific evidence; (3) clinical vignettes on real cases that can help patients understand how CM can help them in managing their health; (4) a series of questions to help patients identify their personal values and the importance they place on the advantages and disadvantages of CM; (5) a series of questions assessing patient healthcare situations and personal objectives; and (6) the SURE test to evaluate patients' decisional conflicts and their comfort with their decisions [40].

3.3 Alpha Testing (Acceptability)

To investigate PtDA acceptability according to patient-partners, patients and clinicians, we performed a small-scale in-depth exploration. Three back-and-forth rounds were required to improve the PtDA and reach acceptability (Figs. 1–4 of the ESM). Globally, all stakeholders found the aid very relevant and patient centred. Recurring comments related to the quantity and the complexity of the information presented recommended decreasing the amount of information to keep the PtDA as simple as possible and to use simpler vocabulary (lay language). Everyone appreciated the section presenting clinical vignettes and proposed to improve these by adding barriers and facilitators of the decision-making process. Stakeholders also helped the research team developing an aid that presents options in a balanced manner and that is not skewed towards on one of the options.

Specifically, clinicians suggested including factors influencing the success of CM to inform patients that impacts of CM vary. They also recommended showing benefits and disadvantages of the decision options (engage in CM, continue with usual care or postpone the decision), and not only the advantages and disadvantages of CM. Clinicians also said that the aid was helpful to understand the way patients think and it was useful to measure the gap between clinician and patient perspectives. They also mentioned that they could use the PtDA to promote health services. In this sense, they recommended providing the aid in a kit from which they could select sections they needed according to clinical settings and patients.

Patient-partners provided relevant recommendations such as making the facts and examples more concrete, removing vocabulary that patients might perceive as derogatory and addressing the message directly to them (message expressed in the second person). They also

proposed to add a small section describing who were the potential users of the PtDA.

They appreciated the clinical vignettes and reported that it was eloquent and that they could identify with the fictive high-user patients. They suggest adding a blank clinical vignette in which patients could write about their own stories, values and health conditiosn. They also stated that it was rewarding for them to know that CM exists and that they could benefit from it. Half of them expressed the need for some information about community organisations and available services.

According to these results and suggestions provided by alpha testing, we modified and improved the prototype and produced a ten-page final version (ESM). This version was simplified and refined. It contains enough clear information to better guide patients in their decision-making process (Fig. 2).

4 Discussion

We developed and evaluated a PtDA, based on the Ottawa Decision Support Framework, to help patients with complex care needs who are frequent users of healthcare services in engaging in CM. This PtDA included three options: engaging in CM, maintaining usual care or postponing their decision. First, we found that systematic reviews and a meta-analysis were not appropriate for complex interventions with patients living with complex conditions. Overall, we found that all stakeholders agreed on the relevance of a PtDA. However, they did not reach a consensus on the format: paper vs digital. In addition, between the initial version of the PtDA and the version produced by three iterative cycles, the most significant changes were the number of pages, the vocabulary used and a substantial reduction in written content. These results led us to make the following observations.

First, we found that a meta-analysis was not the best method to report the effectiveness of complex interventions

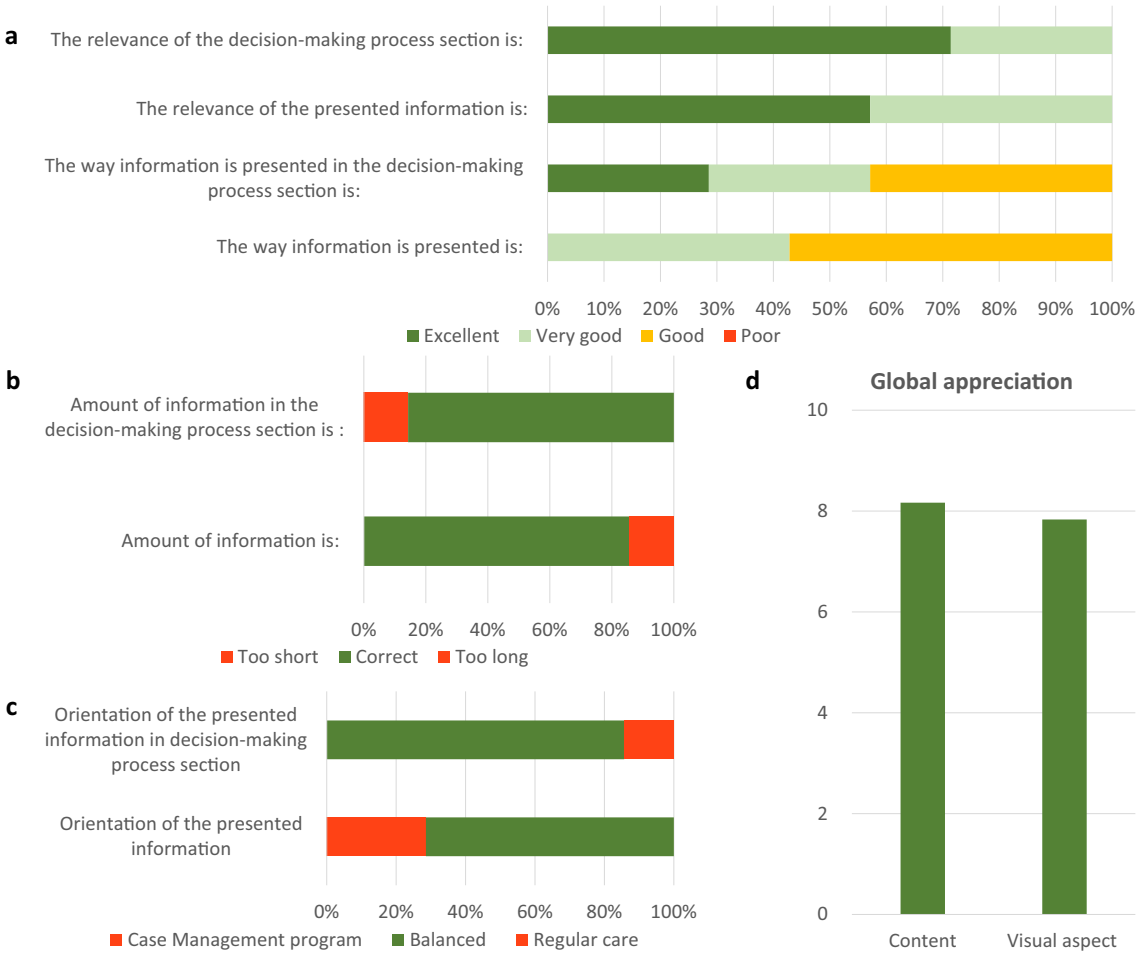

Fig. 2 Excerpt of the answers to the acceptability questionnaire for the final patient decision aid prototype. **a** Relevance and presentation of sections and information, **b** amount of information presented, **c** orientation of the aid and **d** overall assessment

with patients living with complex conditions. Indeed, a meta-analysis tends to find modest effects of behavioural change interventions [41], even less in regard to complex interventions and context [42]. In addition to the heterogeneity of interventions included in the same review, results depend on several elements such as patient and clinician behaviours and the level of involvement in the process. For these reasons, some authors conduct a realist synthesis [36] to better understand contexts and mechanisms of complex interventions conducting to positive patient reported experience measures rather than their measurable impacts. Integrating both qualitative and quantitative data [43] allows more explicit details on the importance of context and patient engagement to reach positive health-related outcomes.

Moreover, in the context of a CM program for high users of healthcare services, a meta-analysis has some limitations for patient-related outcomes because they did not inform about the intervention's process or the patient engagement level in his/her own self-management process [36, 44]. In other words, the measured outcomes sometimes do not reflect what the patient is really experiencing. A higher complexity of intervention brings higher heterogeneity and it became difficult to present evidence-based outcomes to the patients. Another factor that makes the data synthesis difficult is the inability to pool the studies together. This may be explained by the fact that multiple different time points can be used and that no clear descriptions of the intervention are presented in most of the published articles [45]. None of the frameworks or guidelines available really mention how to report intervention characteristics [41], which are most of the time multi-component and depend on the behaviours of the people involved. Currently, the development of PtDAs is informed by theoretical models and intuitive methods rather than systematic methods [46, 47], which lead to poor reproducibility. Nevertheless, current frameworks provide important key steps to fulfil in the development process of a PtDA specific for complex interventions. As the current available guidelines and frameworks are not sufficient to guide the co-creation of PtDA used in complex interventions, additional work is still needed to document this process.

Second, we found that all stakeholders agreed on the relevance of a PtDA but did not reach a consensus on the format: paper vs digital. Patients would prefer to have a paper format because it is more accessible and simpler, which is consistent with the literature [48, 49]. This can also be explained by the fact that most of our patients had a lower socioeconomic status and that this may increase the preference for paper PtDA format [49]. Clinicians preferred digital PtDA, which can be explained by the fact that they can add their own notes in the file, save it for later consultations and track the changes in the patient's decision-making process. Those observations are consistent with the literature [49]. As the format does not influence the knowledge acquisition and reduction in decisional conflict [50], the next important step is to target the audience's preference regarding the PtDA format to maximise its utilisation.

Finally, between the initial version of the PtDA and the version produced by three iterative cycles, the most significant changes were the number of pages, the vocabulary used and the substantial reduction in written content. As shown in our evaluation process, the inclusion of several stakeholders in the development of PtDA, as suggested by guidelines [30], is essential to capture all different perspectives. This is consistent with previous studies showing that clinicians and patients have different points of view regarding health issues and content of PtDA [51, 52]. Their perspectives, when brought together, allowed the creation of a patient-centred tool that can be used by patients and clinicians. However, as reported by Ankolekar and colleagues [51], involving a large number of stakeholders in a co-creation process can increase developmental time and cost. It took 3 years for a part-time coordinator to recruit participants, conduct interviews, and process and analyse the data generated by more than 70 participants. Consequently, researchers must plan enough human resources for the development of a PtDA. In our study, the major concern expressed by the patient-partners and the clinicians in each evaluation round of the alpha testing was the complexity of vocabulary used and the amount of information in the PtDA. As recommended by the Ottawa Hospital Research Institute, language used in the tool must be readable at a grade 8 level [27] and this is what we have tried to achieve with the feedback from our stakeholders. For the next steps prior to implementation, case managers will be validating (beta testing) our aid in primary care settings to evaluate its effects on the knowledge of the patients, their decision comfort and decision durability, for which we expect improvements.

4.1 Strengths and Limitations

The user-centred design is a strength of our study compared with other studies reviewed, as only about half of those involved patients in the development of their decision aids [30]. It is essential in the co-creation of a PtDA to incorporate patient perspectives and expertise and to use a user-centred design. For example, the inclusion of clinical vignettes was made following a suggestion from a patient-partner and this section was one of the most appreciated by all stakeholders. Another supporting example is that the need to include information on community organisations and available services emerged from several patients' feedback. Co-creation with an interprofessional team is also a strength of our study as this promoted efficiency and positive outcomes for the patients [19]. We included five types of clinicians and some decision makers. This allowed us

to merge the expertise of several individuals and create an aid that can be used by a wide variety of professionals.

Our co-creation process involved various participants, leading to a large spectrum of points of view. This made the integration of all those opinions challenging. The research team had to come to a decision on some elements, such as the PtDA's format, as the stakeholders reached no consensus. Even though small-scale in-depth exploration is recommended for alpha testing by the Ottawa Decision Support Framework [27], the inclusion of only 16 stakeholders in the PtDA's evaluation may represent a limitation. We also had to deal with the limited availability of the clinicians and some difficulty while working with patients, as they constitute a population with specific needs. However, we did reach data saturation.

5 Conclusions

We developed and assessed alpha testing of a PtDA to support patients with complex care needs and who are high users of healthcare services. This patient-oriented tool should contribute to improve shared decision making with patients and allow them to make their decision while considering all advantages and disadvantages of their options in terms of engaging in CM or continuing with usual care. At the end of the process, patients will make their decision according to their personal objectives and values. We now need to evaluate the aid in the field with patients and clinicians with beta testing and develop an implementation strategy. Further research is needed to support the process of creating decision aids in the context of complex interventions that require the integration of contextual data to inform us of the effectiveness of those interventions and its impact on patient-related outcomes.

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Declarations

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Conflicts of Interest/Competing Interests Marie-Eve Poitra, France Légaré, Vanessa T. Vaillancourt, Isabelle Godbout, Annie Poirier, Karina Prévost, Claude Spence, Maud-Christine Chouinard, Hervé Tchala Vignon Zomahoun, Lobna Khadhraoui, José Massougbodji, Mathieu Bujold, Pierre Pluye and Catherine Hudon have no conflicts of interest that are directly relevant to the content of this article.

Ethics Approval Ethics approval was obtained from the Ethics Committee of the Centre Intégré Universitaire de Santé et de Services Sociaux du Saguenay-Lac-Saint-Jean.

Availability of Data and Material The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Consent to participate All participants gave their informed consent to participate in the study.

Consent to publish All authors gave their consent to publish and approved the final version of the article.

Code Availability Not applicable.

Authors' Contributions MEP is the principal investigator of the study. She conceived the idea for the paper and led the writing. VTV and FL were major contributors to the drafting of the paper. CH is the principal author of the systematic review used to create the decision aid. FL, IG, MB, CP, AP, MCC, BD, PP, KP and CH were involved in the design, data collection and conduct of the study. HZTV, JM and LK were involved in the data extraction and analysis.

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Measurement of shared decision making – a review of instruments

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Summary

The last years have seen a clear move towards shared decision making (SDM) and increased patient involvement in many countries. However, as the field of SDM research is still relatively young, new instruments for the measurement of (shared) decision making (process, outcome and surrounding elements) are constantly being developed. Thus, the aims of this structured review were to give an update on current developments regarding the measurement in the field of SDM, as well as to give a short overview of published and unpublished instruments. We conducted an electronic literature search in PubMed and the Web of Science database, performed hand searches of relevant journals and contacted key authors in the field. We found eight scales that have been subjected to further psychometric testing, eleven new and psychometrically tested instruments and nine developments that are still in the publishing process. The results show that there is a trend towards measuring SDM processes from a dyadic approach (assessing both the patient's and the clinician's perspective). More and more scales have been developed and tested in languages other than English, which indicates the growing research efforts in various countries. While reliability of most scales is good, they differ in their extent of validation. Further psychometric testing is needed, as well as the development of a theoretical measurement framework in order to improve consistency of measured constructs across research groups.

Key words: shared decision making, measurement, psychometrics, reliability, validity, review
(As supplied by publisher)

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Messung der Partizipativen Entscheidungsfindung – Übersicht über die Messinstrumente

Zusammenfassung

In den letzten Jahren hat der Ansatz der Partizipativen Entscheidungsfindung (PEF) in vielen Ländern zunehmend an Bedeutung gewonnen. Da es sich um ein relativ junges Forschungsgebiet handelt, werden beständig neue Messinstrumente zur Erfassung von PEF (Entscheidungsprozess, Ergebnis und damit einhergehende Konstrukte) entwickelt. Das Ziel dieser Studie war es, eine strukturierte Übersicht über neue Entwicklungen im Bereich der Messung von PEF zu erstellen, einen Überblick über bekannte Skalen zu geben und einen Ausblick auf neue Entwicklungen zu gewähren. Es wurde eine elektronische Literaturrecherche sowie eine Handsuche durchgeführt. Zudem wurden internationale Experten aus dem Forschungsbereich befragt. Gefunden wurden acht bekannte Instrumente, die weiteren psychometrischen Überprüfungen unterzogen wurden, sowie elf neue Skalen und neun unpublizierte Beiträge zu Messinstrumenten. Die Ergebnisse zeigen eine Entwicklung hin zu vermehrter „dyadischer Messung" (Erfassung der Sichtweisen von Arzt und Patient) des PEF-Prozesses. Die internationale Relevanz von PEF wird an der vermehrten Entwicklung nicht-englischer Skalen erkennbar. Bei mehrheitlich guter Reliabilität unterscheiden sich die Instrumente hinsichtlich der Validierungsbemühungen. Zur psychometrischen Überprüfung der meisten Skalen bedarf es weiterer Studien. Zudem wird die Entwicklung eines theoretischen Rahmenkonzepts für PEF-Messungen gefordert, um die Messung der verschiedenen relevanten Konstrukte zu vereinheitlichen.

Schlüsselwörter: Partizipative Entscheidungsfindung, Messung, Psychometrie, Reliabilität, Validität, Review
(Wie vom Gastherausgeber eingereicht)

Introduction

As this special issue shows, there has been a clear move towards shared decision making (SDM) and increased patient involvement in health care decision making in many countries in the last years, including recent legislative developments promoting SDM on a macro level (e.g. US 2010 Patient Protection and Affordable Care Act; [1]; UK NHS White Paper [2]). SDM is an approach where clinicians and patients communicate together using the best available evidence when faced with the task of making decisions. Patients are supported to deliberate about the possible attributes and consequences of options, to arrive at informed preferences in making a determination about the best action [3].

The number of studies seeking to empirically analyse SDM and its effects has increased since the late 1990 s. However, when it comes to the measurement in the field of SDM, several challenges remain. First, one must differentiate between the measurement of *elements that surround the task of decision making* ("decision antecedents" e.g. role preference), the measurement of the *decision-making process* ("deliberation"/ "pre-decisional process" and "the decision itself"/ "determination", [4]) and the measurement of *decision outcomes* ("post decision phase", e.g. regret). In this context it is important to acknowledge the ongoing debate on how to define and measure "good" decision making [4]. Second, given the range and complexity of evaluating SDM, there are so far no general applicable primary measurement tools or standard outcome measures [5], which results in inconsistent measurement, making the comparability of research results in systematic reviews difficult. Therefore, the standardization of outcome measures for decision making studies is recommended [6,7]. Third, when looking at the measurement of SDM, one has to distinguish between *observation measures* of the competence and performance of the clinician or the patient and tools that measure the *perception of the patient or the clinician* on SDM outcome or performance. Recently, there was a call for more research on measurement from these different viewpoints [6]. Further insight into SDM can be gained by triangulation of these many perspectives (e.g. patient, clinician, observer) [8] and by using a dyadic data analysis approach [9].

Several reviews on measurement instruments for SDM have been published in the last years. While some of those reviews focussed on singular viewpoints on SDM, e.g. *observer's perspective* [10] or *physician's perspective* [11], others included both observational and self-rating tools [12,13]. With the exception of one review from 2010, which is only looking at the *measurement of decision regret* [14], most recent reviews date from 2007. Two additional reviews looked at *measures used in studies of patient decision support* [15] and in *studies of informed decision making about cancer screening* [16], both trying to identify and appraise the respective used primary outcome measures. Regarding the different domains of SDM (decision antecedents, decision process, decision outcomes), some reviews focus on one [10,14] or two [11] of the domains, while others include instruments that measure all domains [12,13].

As the field of research on SDM is still relatively young, new instruments for the measurement of (shared) decision making (process, outcome and surrounding elements) are constantly being developed. Thus, the main aim of this structured review was to give an update on current developments regarding the measurement of SDM, using the review of Simon and colleagues [13], which was included in the first special issue for the International Shared Decision-Making Conference 2007 in Freiburg, as a starting point. Furthermore, we aimed at giving a short overview over known instruments as well as an outlook on unpublished instruments.

Methods

Search strategy

We conducted an electronic literature search of the PubMed database, covering the years 2005 until January 2011. The search was done by a combination of Medical Subject Headings (MeSH) and free text terms. Full details on the search strategies are reported in the appendix. In addition, we searched all publications that cited the instruments included in the review of Simon et al. [13], using the Web of Science database. Furthermore hand-searches were done in the following journals: *Patient Education and Counseling*, *Health Expectations*, *Medical Decision Making* and *Journal of Communication in Health Care*. We also contacted key authors in the field in order to receive information about unpublished scales.

Inclusion and exclusion criteria

All searches were downloaded to a reference management software for initial screening of titles and abstracts by a member of the review team. Duplicates were removed. In a next step the remaining full texts were screened. The following inclusion criteria were applied: 1) language of publication: English, German, French, Dutch or Italian; 2) accessibility of the instrument; 3) data on development and (psychometric) testing are reported (if modified version of a previously tested scale: further psychometric testing is reported); and 4) if multi-dimensional instrument: separate psychometric data for SDM-relevant subscales are reported. The following exclusion criteria were applied: 1) paper does not focus on the psychometric evaluation of a specific measurement instrument (e.g. intervention study, review of instruments, study protocol); 2) measured construct is not an aspect of SDM (see [17]); and 3) instrument is limited to a particular disease and does not appear to be easily adaptable to other diseases.

Data extraction

The following information was extracted from the included full texts: name of instrument, authors, year, construct, viewpoint (e.g. clinician, patient or observer rating), response scale, number of dimensions and items, instrument development process, sample, reliability, validity, language and translations.

Results

Included instruments

The progress through the stages of the review is documented in fig. 1. The main reasons for exclusion of full-texts were that the measured construct was not an aspect of SDM (N = 40) or that the paper did not report on a specific scale (N = 16).

Known instruments

The aim of this paper was to perform a structured review on new developments in the measurement of SDM. Thus, we give only a short overview on existing scales. Tab. 1 shows instruments [18–26] included in Simon's review [13], where no further psychometric testing was found in our search. Tab. 2 displays scales [27–34] included in the review

Table 1. Overview of known instruments.

Instrument, Author (Year)	Construct (and subscales)	Items	Response	Viewpoint
Krantz Health Opinion Survey Krantz et al. (1980)	patient preferences • behavioural involvement • information	15	binary	patient
Patient attitudes and beliefs scale Arora et al. (2005)	attitudes and beliefs regarding participation in decision making • pros for participation • cons against participation	12	5-point scale	patient
Decision Self Efficacy Scale O'Connor (1995)	patients' self-confidence or belief in abilities for decision making	11	5-point scale, 3-point scale	patient
Facilitation of Patient Involvement Scale Martin et al. (2001)	perceived physician encouragement for participation	9	6-point scale	patient
Rochester Participatory Decision Making Scale Shields et al. (2005)	physician behaviour encouraging patient participation	9	3-point scale	observer
Satisfaction with Decision Scale Holmes-Rovner et al. (1996)	satisfaction with a decision	6	5-point scale	patient
Provider Decision Process Assessment Instrument Dolan (1999)	degree of comfort with a treatment decision	12	5-point scale	physician
Decision Attitude Scale Sainfort & Booske (2000)	satisfaction with a decision • satisfaction with choice • usability of information • adequacy of information	9	5-point scale	patient
Decision Regret Scale Bréhaut et al. (2003)	decisional regret	5	5-point scale	patient

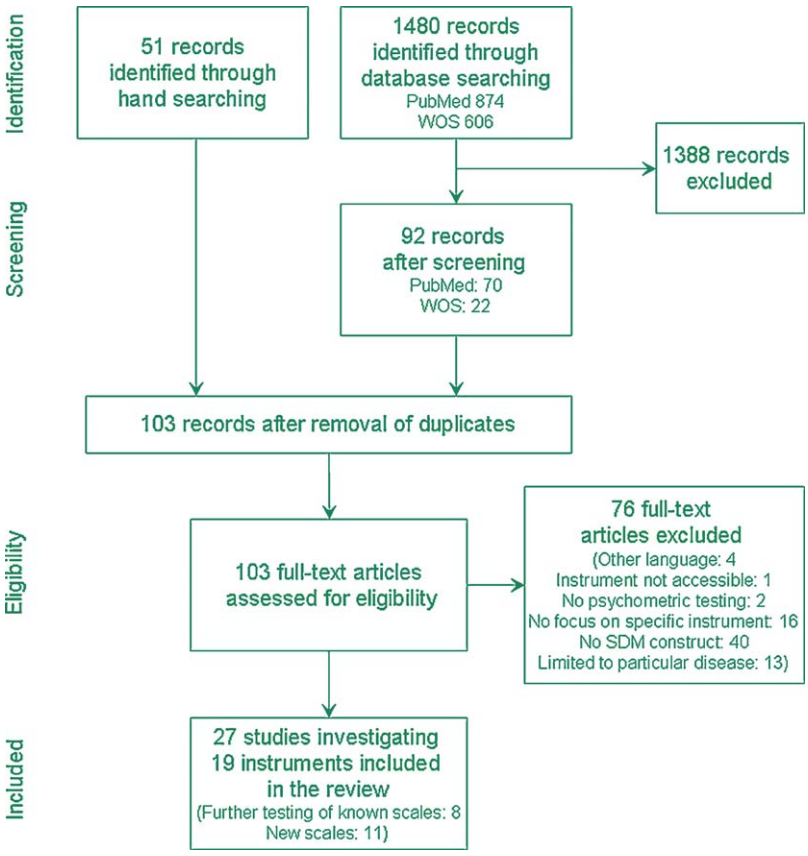

Figure 1 Study flow chart
WOS = Web of Science.

of Simon and colleagues [13] that have been subjected to further psychometric testing [35–49]. For more detailed information on these instruments we refer to the original publications and the mentioned review [13].

New instruments

Eleven instruments were identified that have been developed since the review of Simon et al. [13]. Details on those instruments are displayed in tab. 3. Six of the included scales focus on the *decision making process in a specific medical encounter* and the *behaviour of the physician and/or patient in this encounter* (SDM-Q-9, dyadic OPTION, SDM Scale, DSAT, DSAT-10, DAS-O) [50–56]. Smoliner's scale measures both the experienced *decision-making process* and the *participation preferences* in the context of inpatient nursing [57]. One scale focuses on *decisional conflict* and was adapted from O'Connor's Decisional Conflict Scale [33] for the use in clinical practice (SURE) [58]. Another scale focussing on the post-decisional phase measures *decisional regret of bereaved family members* [59]. Two scales have a broader conceptualisation, one on *communication preferences* in general (KOPRA) [60] and one on *empowerment* (HCEQ) [61], both including a subscale on SDM.

Only one of the included instruments, the dyadic OPTION scale [52,54], assesses an aspect of SDM from the physician's and the patient's perspective ("dyadic approach"). Six instruments focus on the view of the patient (or family member) [51,52,54,57,58,60,61] and four scales can be used by observers (rating/coding system) [50,53,55,56].

There was a great variation in the detail of the reported information regarding the item generation of the included instruments. Some authors explicitly state that the scale development was theory-driven (SDM-Q-9, DSAT, SURE, Smoliner's scale) [50,51,57,58], others refer to prior versions of the instrument (dyadic OPTION, DSAT-10) [52,54,56] or only report that they performed a literature review (SDM scale, KOPRA, family regret scale, HCEQ) [55,59–61]. Pretests are reported in most studies, with the dyadic OPTION scale [52,54] giving the most detailed information.

Sample sizes and populations of the studies vary greatly, ranging from N = 34 (DSAT) [50] to N = 2351 (SDM-Q-9) [51]. Testing of observer rating scales [50,53,55,56] have smaller sample sizes (from N = 34 to N = 76).

Regarding reliability, most studies tested for internal consistency (Cronbach's Alpha) and found values above the broadly consented threshold of .7. Less than optimal internal consistency was found for the SURE scale [58], as well as for some subscales of the SDM scale [55]. No data on reliability is reported for the dyadic OPTION scale [52,54]. All four observer rating scales [50,53,55,56] reported moderate to substantial inter-rater agreement (for thresholds, see Landis & Koch, 1977, [62]).

Table 2. Further psychometric testing of known instruments.

Author (Year)	Aim and study details	Main findings
OPTION Scale (Elwyn et al., 2005: SDM process, 12 items, 5-point scale, observer rating)		
Gagnon et al. (2010)	testing of French version in a sample of 41 family physicians having 128 consultations with women on prenatal screening decisions	.73[a] / inter-rater reliability: .50-.85[c] / one factorial structure / pos. correlation with duration of the consultation
Goss et al. (2007)	testing of Italian version in a sample of 6 GPs having 235 consultations with patients having various health problems	.82[a] / inter-rater reliability: .29 -.73[k] / .46-.82[c] test-retest reliability: .48-.94[k] / .37-.95[c]
Goss et al. (2008)	testing of Italian version in a sample of 16 psychiatrists having 186 consultations with patients having depression or anxiety disorders	pos. correlation with duration of the consultation .85[a] / .43-.86[b] / inter-rater reliability: 22-.81[k] / .95[c]
Decision Evaluation Scales (Stalmeier et al., 2005: evaluation of a decision, 15 items, 3 dimensions (satisfaction-uncertainty, informed choice, decision control), 5-point scale, patient rating)		
Erci & Özdemir (2008)	testing of Turkish version in N = 199 cancer patients	.71-.75[a] / .36-0.71[b] / test-retest reliability .70-.78[c]
Decisional Conflict Scale (O'Connor, 1995: uncertainty in decision making, 16 items, 5 dimensions (uncertainty, informed, values clarity, support, effective decision), 5 point scale, patient rating)		
O'Connor user manual (updated 2010)	testing of low literacy format in N = 63 women considering breast cancer options	.86[a]
Urrutia et al. (2008)	testing of Spanish version in N = 321 first-year nursing students	.50-.80[a] / 4 factors explaining 52% of the variance
Knapp et al. (2009)	testing of the scale in N = 266 parents of children with life-limiting illnesses	.85-.92[a] / CFA: not all indexes were acceptable more trust in physician less decisional conflicts
Preparation for Decision-Making Scale (Graham & O'Connor,1996: usefulness of decision support intervention, 11 items, 5-point scale, patient rating (physician version without psychometric testing))		
Bennett et al. (2010)	testing of revised scale (in response to the IPDAS quality criteria; 10 items, 5-point scale) in N = 400 orthopaedic patients	.92-.96[a] / .75-0.81[b] one-dimensional structure / neg. correlations with subscales of the DCS; discriminates between patients who did and did not find decision aids helpful
Autonomy Preference Index (Ende et al., 1989: role preference, 23 items, 3 dimensions (need for information, preferences for participation in general, and preferences for participation regarding certain diseases), 5-point scale, patient rating)		
Simon et al. (2010)	testing and modification of German version in N = 1592 patients with various conditions	.85-.86[a] / CFA of modified scale: acceptable to good indices of fit
Sung et al. (2010)	testing of adapted version for women with pelvic floor disorders in N = 109	correlates pos. with CPS .8[a] / test-retest reliability ICC .7[d]
Control Preference Scale (Degner et al.,1992: role preference, 5 statements, questionnaire and card-sorting version, patient rating)		
Gattelari et al. (2005)	testing in a sample of N = 514 men (community survey)	poor agreement between CPS and Arora & McHorney's measure
Giordano et al. (2008)	testing of Italian version in N = 140 patients with multiple sclerosis	test-retest reliability: agreement: 90%/ .65[k]
Kremer & Ironson (2008)	testing in a sample of N = 79 HIV patients	agreement (Kendall's tau-b) between self- and researcher-rated decisional roles: .82
Sung et al. (2010)	testing of adapted version for women with pelvic floor disorders in a sample of N = 109	test-restest reliability ICC .5[d], correlates pos. with API
Perceived Involvement in Care Scale (PICS) (Lermann et al.,1990: degree of involvement in decision making, 13 items, 3 dimensions (doctor facilitation, patient-physician information exchange, patient decision making), yes-no scale, patient rating)		
Smith et al. (2006)	modification of PICS (for chronic pain, M-PICS) and testing in N = 87 cancer patients	.79-.89[a] / Spanish version: .76-.86[a] 3 of the 4 dimensions replicated; correlates neg. with pain-related communication barriers, pos. with health care satisfaction
Jacobsen et al. (2009)	translation (Danish) and modification of M-PICS and testing in N = 33 cancer patients	.86-.89[a] correlates pos. with pain relief and neg. with cognitive pain management barriers, anxiety and reported pain levels
Combined Outcome Measure for Risk Communication and Treatment Decision-making Effectiveness (COMRADE) (Edwards et al.,2003: risk communication, confidence in decision, 20 items, 2 dimensions, 5-point scale, patient rating)		
Knapp et al. (2009)	testing of the scale in N = 266 parents of children with life-limiting illnesses	.94-.96[a] / CFA: data failed to replicate 2-factorial structure

[a]Cronbach's α, [b]corrected item-total correlations, [c]intraclass correlation coefficient (ICC), [d] test-retest-reliability, [k] Cohen's Kappa coefficient, CFA: confirmatory factor analysis, neg.: negative(ly), pos.: positive(ly).

Table 3. New instruments.

Instrument, Author (Year)	Description of instrument	Development	Sample	Validity	Reliability	Language/ translations
9-item Shared Decision-Making Questionnaire (SDM-Q-9) Kriston et al. (2010)	• SDM process • 9 items, 6-point scale • patient rating	extensive revision of the existing SDM-Q [74], item generation by experts, based on the SDM model of Elwyn et al. (2000) [75] and theories from psychology [76,77] and decision analysis [78]	N = 2351 German primary care patients	• face validity • EFA: 1-factorial structure	.94[a] .69-.83[b]	German* English
Dyadic OPTION Scale Melbourne et al. (2010; in press)	• SDM process • 12 items, 4-point scale • patient and physician rating	modification of the original OPTION Scale [29], cognitive debriefing interviews	N = 36 simulated consultations between 6 GPs and 6 standardised patients	• correlates pos. with Observer OPTION	no data	English*
Shared Decision-Making Scale Singh et al. (2010)	• SDM process • 20 items, 2-point scale • observer rating	literature review regarding SDM in oncology	N = 63 consultations on adjuvant therapy between oncologists and cancer patients	• 3-factorial structure (after omitting 2 items)	.50-.77[a] 90%[c]	English*
Decision Support Analysis Tool (DSAT) Guimond et al. (2003)	• practitioners' decision support (6 categories) and related communication skills (4 categories) • observer rating	based on the ODSF and Ivey's problem-solving model [79], the categories were established by an expert panel	N = 34 transcripts of counseling sessions of family physicians and their menopausal patients in Canada	• discriminates between patients' exposure to different types of decision support interventions • correlates pos. with satisfaction with the decision, resolution of decisional conflict, satisfaction with the decision-making process	75%-76%[c] .58-.68[k]	English*
Brief Decision Support Analysis Tool (DSAT-10) Stacey et al. (2008)	• practitioners' decision support (5 categories) • observer rating	the original DSAT was simplified for use in clinical practice and education: communication skills section was removed, some items changed, unit of analysis changed	N = 76 audiotaped encounters between nurses and standardized patients (common health decisions)	• no data	.55[k] 74.3%-91.1%[c]	English* French*
Decision Analysis System for Oncology (DAS-O) Brown et al. (2010); Butow et al. (2010)	• SDM process, including the discussion of clinical trials • 70 items, 5 dimensions (e.g. establishing the physician-patient team), 3-point scale • observer rating	qualitative analysis of oncology consultation, expert workshops with patients, clinicians, researchers, linguists, etc.	N = 70 audiotaped encounters between breast cancer patients and their oncologists in Australia and New Zealand	• correlates pos. with the OPTION scale and with the Decision Support Analysis Tool	inter-rater: 49-.64[k] intra-rater: 49-.76[k]	English*

Table 3 (*Continued*).

Instrument, Author (Year)	Description of instrument	Development	Sample	Validity	Reliability	Language/ translations
SURE Légaré et al. (2010)	• decisional conflict (screening test for clinical practice) • 4 items, 2-point scale • patient rating	item selection was based on core concepts of the ODSF; field testing of 4-item scale with experts and graduate students	2 samples: 1) N = 123 French-speaking women (prenatal screening) in 4 family medicine groups 2) N = 1474 English-speaking patients facing various treatment decisions	• 1-factorial structure in the English-speaking sample, 2 factors in the French-speaking sample • correlates neg. with the Decisional Conflict Scale • discriminates between patients who had made a choice for a treatment and those who had not	sample 1: .65[a], .33-49[b] sample 2: .54 -.61[a], .07-.59[b]	French* English*
Scale on participation in nursing care decisions Smoliner et al. (2009)	• participation preferences and participation experiences in nursing care • 10 items,2 dimensions, 6-point scale • patient rating	literature review regarding SDM, items generation by experts, based on the SDM model of Charles et al. (1999) [80]	N = 967 patients in surgical and medical wards in Austria	• correlates pos. with satisfaction with the information and the decision making	.84-.86[a] .60-.79[b]	German*
KOPRA questionnaire (communication preferences of patients with chronic illness) Farin et al. (2011)	• communication preferences of chronically ill patients • 32 items, 4 dimensions (e.g. patient participation and patient orientation), 5-point scale • patient rating	literature review, focus groups, cognitive interviews	N = 472 patients with chronic back pain or chronic ischemic heart disease	• CFA: satisfactory model fit	.80-.92[a]	German*
Bereaved family regret scale Shiozaki et al. (2008)	• 7 items, 2 dimensions (intrusive thoughts of regret, decisional regret), 5-point scale • rating by family members	item generation from prior studies, item wording based on comments of clinicians regarding understandability	N = 127 participants (bereaved family members)	• CFA: confirmation of 2-factorial structure • correlates neg. with the care evaluation scale	.79-.85[a] .69-.70[d]	Japanese*
The Health Care Empowerment Questionnaire (HCEQ) Gagnon et al. (2006)	• individual empowerment in relation to personal health care and service, • 10 items, 3 dimensions (e.g. involvement in decisions),4-point scale • patient rating	literature review and generation of corresponding items, pretests with health care experts and patients	N = 873 persons above 75 years of age	• EFA: 3 factors explaining 69% of the variance. CFA: satisfactory fit only	.79-.89[a] .60-.70[d]	English* French*

[a] Cronbach's α, [b]corrected item-total correlations, [c]inter-rater agreement, [d] test-retest-reliability, [k] Cohen's Kappa coefficient, ODSF: Ottawa Decision Support Framework, * original validation, EFA: exploratory factor analysis CFA: confirmatory factor analysis, pos.: positively, neg.: negatively.

With regard to validity, some studies only focussed on factorial validity (KOPRA, SDM-Q-9, HCEQ) [51,60,61], while other (also) analysed criterion or construct validity. Other analysed criterion validity, for example, the dyadic OPTION scale [52,54] correlates positively with Observer OPTION, SURE [58] correlates negatively with the Decisional Conflict Scale and the DAS-O correlates positively with the OPTION scale and the Decision Support Analysis Tool [53,63].
Regarding the languages of the included measures, three have been validated in German [51,57,60], four in English [50,52–55], three in English and French [56,58,61] and one in Japanese [59].

Work in progress

In addition to the above cited instruments that have been developed and tested in the last few years, we want to give an outlook on scales that have been developed, but no psychometric data has been published yet. Thus, this section is an unsystematic overview of instruments based on the information received from key authors in the field.
Wills and colleagues tested the English version of the 9-item Shared Decision Making Questionnaire (SDM-Q-9, see tab. 3, [51]) in a stratified sample of N = 488 respondents in the US. Results show high internal consistency, a unidimensional structure, as well as evidence for convergent and discriminant validity. These results are consistent with the German results [51] and are currently being prepared for publication.
Scholl and colleagues recently adapted the patient-report SDM-Q-9 ([51]) to a physician version (SDM-Q-Doc) in order to allow measurement from both viewpoints (dyadic approach). This scale was tested in medical encounters between 29 physicians and 324 patients in German outpatient care. Results indicate good acceptance by the physicians, high internal consistency, and a good model fit in confirmatory factor analysis [64].
Another unpublished instrument is the DelibeRATE Scale, which has been developed by Elwyn and colleagues, following a conceptual analysis [4]. It consists of nine items and measures readiness to decide (deliberation) from the patient's perspective. It was used in an evaluation of an online patient decision support intervention to support women facing surgery options for early breast cancer (N = 52). Psychometric testing of the scale is pending.
Sepucha, Fowler and colleagues have developed and tested a generic set of involvement items that can be combined into an Involvement Scale. The content of the items was drawn from conceptual framework of SDM, and overlapped with the IPDAS decision-making process criteria, particularly to what extent 1) the patient was given a choice, 2) pros were discussed, 3) cons were discussed, and 4) patient preferences were discussed. The items were first used in the DECISIONS study, a nationwide study of common medical decisions in the United States, to report on the nature of the patient-provider interactions about screening, medication and surgical decisions [65]. Psychometric data on the scale's performance are currently being prepared for publication.
Buchholz and colleagues tested the German version of the Preparation for Decision-Making Scale [31] in a sample of 572 health insurants evaluating a web-based interactive decision aid. Results indicate concurrent validity and reliability of the German version, whereas the confirmatory factor analysis does not support prior findings regarding dimensionality: they found two dimensions, preparation for the medical encounter and preparation for decision making [66].
Furthermore, new results exist for the Decisional Conflict Scale [33]. A first psychometric testing of its German translation in a sample if 1286 primary care patients revealed the five-factorial structure suggested by the original authors as well as high internal consistency [67]. The DCS user manual includes a question format with 16 items and 5 response categories for which psychometric testing is currently tested in a large scale sample in New Hampshire [68]. Another unpublished result concerns the dyadic version of the DCS, which was tested by LeBlanc in a sample of N = 112 consultations of physicians in family medicine and their patients in Canada. The study showed that the DCS has similar factorial structure in both physicians and patients [69].
Lastly, a published protocol [70] for a study funded by the Canadian Institutes of Health Research indicates that the authors will provide further evidence on the validity and reliability of an identified set of existing relationship-centered measures (i.e., dyadic measures). In a longitudinal study in 17 primary care clinics with 264 physicians and 269 patients five components of SDM were measured: i) defining/explaining the problem, presenting options, and discussing benefits and drawbacks (information-giving subscale, Medical Communication Competence Scale (MCCS)); ii) clarifying the patient's values and preferences (values clarification subscale, Decisional Conflict Scale (DCS)); iii) discussing the patient's ability/self-efficacy (self-efficacy scale, Theory of Planned Behaviour); iv) discussing the doctor's knowledge and recommendations (doctor's recommendations subscale, Patient-Physician Discordance Scale); and v) checking/clarifying the patient's understanding (feeling uninformed, DCS and information verifying subscales, MCCS). In both physicians and patients, all measures except the doctor's recommendations subscale showed adequate reliability and factorial validity. The dyadic nature of three measures was confirmed: the values clarification subscale; the self-efficacy scale; and the uncertainty subscale. Of six dyadic measures of SDM, only the values clarification subscale, the self-efficacy scale and the uncertainty scale were reliable and valid.

Discussion

This update gives an overview of previously known and current developments on instruments for the measurement of different aspects of SDM and their psychometric testing. This review shows that patient participation and involvement in medical decision making and its measurement is a growing research area: we found eight instruments that have been subjected to further psychometric testing since the

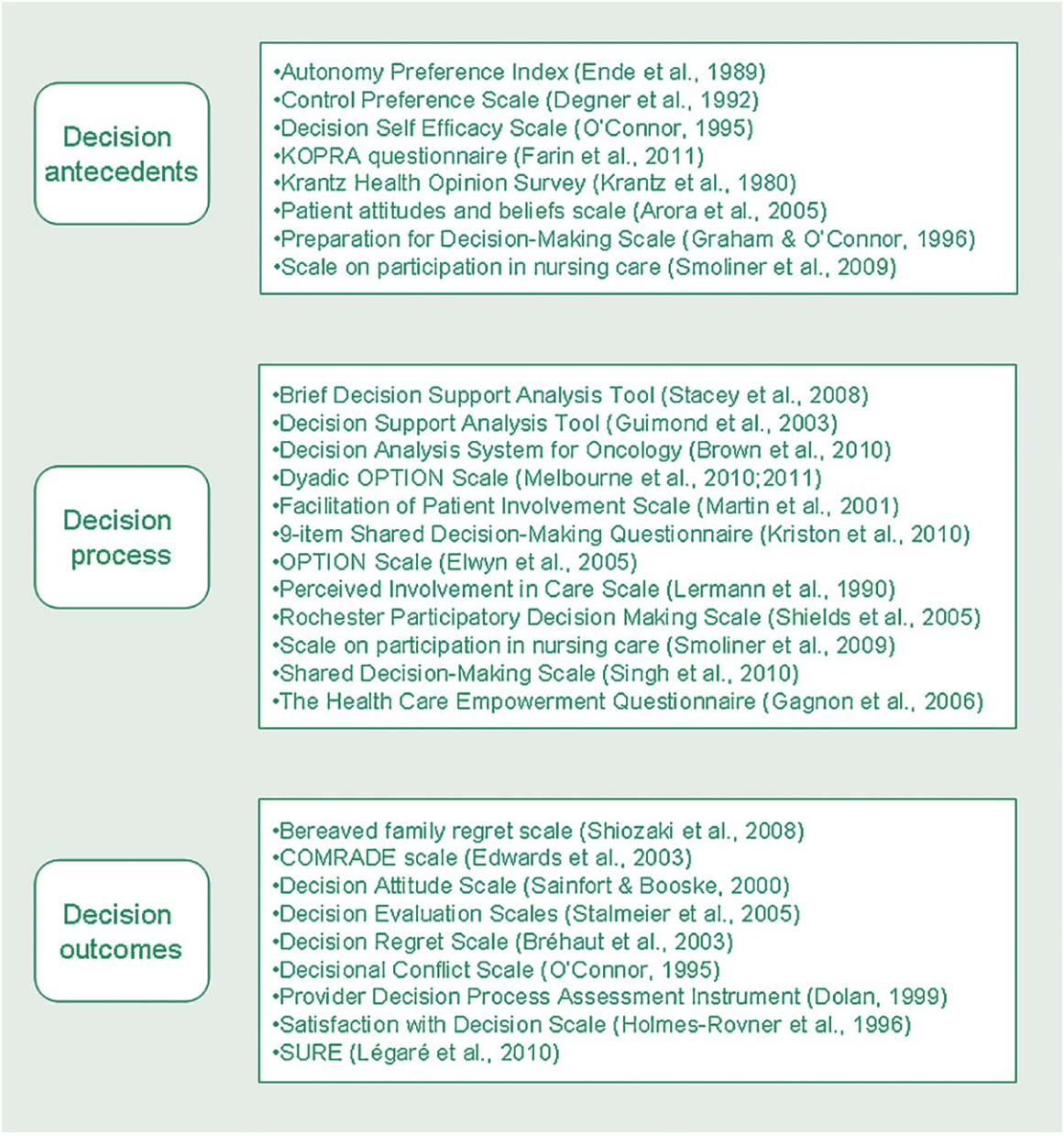

Figure 2 Published instruments mapped on measurement framework.

review of Simon in 2007 [13], eleven new instruments and nine developments that are still in the publishing process. Most instruments are self-report scales that assess the patient's perspective regarding decision making. However, there is a trend towards a dyadic approach (dyadic OPTION Scale [52,54], SDM-Q-9/-Doc, [51,64], dyadic DCS [69]), similar to the results of Légaré and colleagues, who pointed out that the dyadic approach starts to be used more and more [11]. While several observation tools exist that assess the physicians' behaviours and skills [26,29,50,55,56], observation scales focussing on patients' behaviour in the medical encounter are missing. Research on the latter would be a further step into the direction of a dyadic approach. The smaller sample sizes in studies on observation scales [50,55,56] are likely due to the fact that this measurement mode is more time-consuming and complex. Whether this method of measurement provides more objective insight into the consultation deserves further research. When looking at the measured constructs, one can see that most new scales aim at assessing the *decision process* [50–52,55–57,61]. Some instruments focus on *elements that surround the task of decision making* [57–60,71]. This classification remains tentative and reveals the need for a *consistent measurement framework in the field of SDM*. This could include three major categories: tools measuring *decision antecedents* (e.g. role preference), instruments assessing the *decision process* (i.e. observed and perceived deliberation phase), and scales focussing on the *decision outcomes* (i.e. evaluation of the deliberation process, decisional conflict, regret, satisfaction, etc).

In Figure 2 the published instruments included in this review are mapped on this framework. Further work on this is needed.

The number of publications on translated scales [36,37,39–41,46,49] and scales developed in languages other than English [34,42,51,57,59,60] show the growing research efforts in SDM in various countries, a finding that reinforces the importance of the international character of this special issue. Regarding psychometric quality, most of the presented instruments show satisfactory to excellent reliability. However, validity has often not been sufficiently investigated. Many of the measures which do report some form of validation only tested for factorial validity but did not investigate convergent or discriminant aspects of validity. Only a few measures have been directly compared with each other (e.g. positive correlation of dyadic OPTION and observer OPTION [54]; negative correlation of SURE and DCS [58], and positive correlation of DAS-O, OPTION and DSAT [63]). Some of the instruments criticised by Simon [13] have successfully undergone further testing of validity (e.g. API, see tab. 2), while others have no new results regarding validity (e.g. COMRADE, see tab. 2). Very few instruments have been tested with both exploratory and confirmatory factor analyses and item response theory is rarely applied. Generally, the reporting of psychometric properties, especially of different aspects of validity, is carried out heterogeneously. The quality of reporting psychometric evaluations of scales in the field of SDM could be improved and be more consistent by adhering to recommendations like the COSMIN checklist (COnsensus-based Standards for the selection of health status Measurement INstruments,[72]), e.g. by including information on measurement error, content validity, responsiveness and interpretability.

A strength of this review is that it was carried out by researchers from five different countries and with different professional backgrounds, all working in the field of SDM with experience in psychometric development of instruments. Furthermore, this review has a strong focus on new developments, especially by including a chapter on unpublished scales.

The review has several limitations. First, the search process was limited to two databases only. As a consequence we might have missed relevant publications. Second, the selection process was not entirely systematic, as the screening of titles and abstracts, the full text screening and the data extraction was performed by one person only.

This review can be used to assist researchers and clinicians in choosing the optimal instrument for their specific aims. However, it is important to note that whenever a scale is used in a new setting, a different patient group or a different country psychometric properties should be re-established [73]. Thus, when researchers plan to use a scale in a different context than the one in which it was originally tested, a pilot study on the scale's psychometric properties should be done before using it in a large evaluation trial. Otherwise, results can be biased. Especially scales tested with standardized patients only [52,54,56] should be re-analysed in a sample of genuine patients. Furthermore, this article shows the increasing interest in the dyadic approach towards measuring SDM. It allows the comparison of the views of both the patient and the clinician on the SDM process in future research. Perhaps demonstrating concordance among patients' and providers' view of the decision process would provide strong evidence that SDM had occurred.

Finally, this review shows that although there has been a growing focus on measurement issues, only a few are widely used and there is a need for further methodological development. Besides research on validity, more testing with both exploratory and confirmatory factor analyses and further revision of existing instruments, scales should also be tested for responsiveness, especially before being used in intervention studies. Another important aspect of future work is to focus on discriminant validity in order to assess if a scale can distinguish between a shared process and unilateral one (either lead by clinician or patient). Besides further psychometric testing, the development of a theoretical measurement framework should be put on the research agenda, in order to improve consistency of measured constructs across research groups. A long-term objective could be the standardization of outcome measures, in order to allow cross-study comparisons [6].

Conflict of interest

Dr. Sepucha receives research and salary support from the Foundation for Informed Medical Decision Making, a not-for-profit organization that develops patient decision aids. France Légaré is Canada Research Chair in Implementation of Shared Decision Making in Primary Care. The other authors do not declare any conflict of interest.

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Appendix1. PubMed search strategy

- Limits Activated: Publication Date from 2005/01/01 to 2011/01/05
- ((“Decision Making”[Majr:noexp]) OR (decision making[Title/Abstract]) OR (“Patient Participation”[Majr]) OR (shared decision-making[Title/Abstract]) OR (shared decision making[Title/Abstract]) OR (patient participation[Title/Abstract]) OR (patient involvement[Title/Abstract])) AND ((reliability[Title/Abstract]) OR (psychometric*[Title/Abstract]) OR (“Psychometrics”[Majr]) OR (“Questionnaires”[Majr:noexp]) OR (“Factor Analysis, Statistical”[Majr]) OR (factor analysis[Title/Abstract]) OR (factorial[Title/Abstract]))

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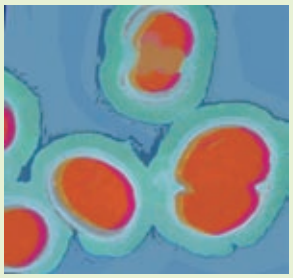

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Running the gauntlet to improve patient care

Several topics turn the spotlight on areas that are less than glamorous and are perhaps all too often passed over, even as their impact on individual lives and society increases

This supplement is the result of a gauntlet thrown down, and picked up, during a dinner in London just over a year ago. The gauntlet thrower was Don Berwick, president of the Institute for Healthcare Improvement in Boston. What, he asked, was the BMJ Publishing Group really for? What were we trying to achieve? In reply, I and our chief executive, Stella Dutton, were quick to quote the *BMJ*'s mission, which ends with the crucial words "to improve outcomes for patients." Fine, said Don, but how about being more specific: which outcomes, what patients, by how much?

We took his suggestion seriously. Why not target a few important healthcare problems, taking a quality improvement approach and focusing on the evidence on how to make a difference in these areas? But how to choose which issues to tackle among the many millions of pressing healthcare challenges facing the world? We turned in the first instance to *BMJ* readers. In May 2007 we asked you to tell us what information was most needed to improve the quality of care of patients in clinical practice. From your many rapid responses we harvested more than 200 ideas. After categorising these and matching them against the priorities of national and international bodies, we created a shortlist of 12. With the help of an expert panel (see http://makingadifference.bmj.com) we cut these down to six.

Inevitably the choice of topics is subjective rather than scientific, but the six we have ended up with are interesting. Several turn the spotlight on areas that are less than glamorous and are perhaps all too often passed over, even as their impact on individual lives and society increases. Two topics deal with problems of old age: multiple illness and adverse drug reactions. Two deal with palliation: of chronic pain and in dying from non-malignant disease. The remaining topics deal with two very different but serious and growing public health challenges: drug resistant infections in the developing world and excessive drinking in young women. You will no doubt find important gaps in what we have chosen. But if this initiative proves useful we can expand it further.

On each of the six topics we've invited leading commentators to write the pairs of articles that make up this supplement. One article in each pair aims to describe the importance of the problem in terms of its health and societal impact. The other looks at the available evidence on quality improvement initiatives to tackle the problem. Perhaps inevitably, several of the quality improvement articles conclude that the evidence is inadequate and more research is needed, but the authors do lay out what they think are the priorities for future research. One key priority is to develop new and better research methodologies for evaluating quality improvement initiatives.

We need to choose one or two of these topics to focus on over the next year, on which we will create and compile content across the BMJ Group's portfolio of products: the *BMJ*, BMJ Journals, *Clinical Evidence*, Best Treatments, and BMJ Learning. How will we know whether we have made a difference? We probably won't in any scientific sense. But we will be looking for ways to evaluate the effect of the initiative. On this, as well as on the topics themselves, we would welcome your thoughts.

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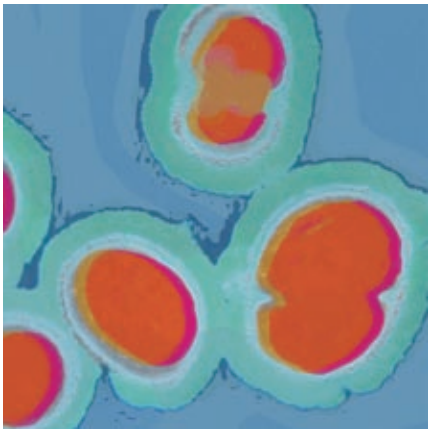

Drug resistant infections in poor countries

Resistance to drugs in many common childhood infections is a growing problem in the developing world, says **Zulfiqar Bhutta**. Effective programmes to combat resistance are within reach in developing countries, argue **Ralph Gonzales and colleagues**, but we must move swiftly

A major burden on children

Around the world an estimated 10 million children under the age of 5 years die each year, the vast majority (90%) in a mere 42 countries. Of the major causes of death among children, infections such as newborn sepsis, diarrhoeal disorders, pneumonia, meningitis, and malaria are major killers. While much is known about the role that poor availability of interventions has in childhood morbidity and mortality in developing countries, much less is known about the contribution of antimicrobial resistance—but it is likely that the contribution of resistant infections is significant. In a prospective study of 1828 children with signs of systemic infections in Tanzania, the mortality from Gram negative bloodstream infection (44% of the deaths) was more than double that from malaria (20%) and Gram positive bloodstream infections (17%), and antimicrobial resistance was found to be a significant risk factor for mortality. A literature review has underscored the importance of hospital acquired resistant bacterial infections among newborn infants in developing countries.

The emergence of antimicrobial resistance is recognised as a major contributor to excess morbidity and healthcare costs in developed countries. In poorer countries, limited laboratory facilities and the lack of robust, population based surveillance systems has meant that information on the effect of antimicrobial resistance on health outcomes is restricted to a small number of infections. Emerging drug resistance in malaria, recognised for many years, has now resulted in many traditional drugs such as chloroquine becoming completely ineffective. An evaluation of trends in malaria treatment in sub-Saharan Africa has shown that continuing use of ineffective chloroquine treatment has contributed to excess malaria mortality. The case fatality rate for malaria fell as an increasing proportion of children received an effective treatment regimen: adjusted malaria case fatality rates were 5.1% in 1992 and 3.3% in 1994, and the corresponding percentages of children who received effective therapy were 85% in 1992 and 97% in 1993-4.

The increasing resistance of *Streptococcus pneumoniae* and *Haemophilus influenzae* to drugs has an effect on pneumonia mortality that is less well recognised, largely because of the difficulty in isolating the organisms from the bloodstream. In a prospective study of children in 5000 Bangladeshi urban households who had invasive pneumococcal disease, the

A shrinking window of opportunity

Certain principles of effective quality improvement interventions are universal. Relevant stakeholders must believe that it is worth while to remedy the deficiency in quality, that the benefits of change outweigh the costs, and that change is possible. The threat of antibiotic resistance and its coevolution with particular patterns of antibiotic use are also universal.

Unfortunately, the public health agendas of few countries have prioritised the problem of antibiotic resistance. This is especially true in less developed countries, where antibiotics are often overused and misused by formal and informal healthcare providers and by patients, who are often able to obtain antibiotics without a prescription. Few policy makers, few members of the general public, and unfortunately too few medical schools and health professionals recognise the urgency and implications of the problem. Instead, pharmaceutical policies often focus on scaling up and ensuring access to drugs, including broad spectrum antibiotics, without considering rational use.

What will really help to create change and foster effective quality interventions to tackle resistant infections in developing countries? Strategies in such countries require changes at the levels of policy, the institution (including healthcare providers), and the individual. Quality improvement strategies to improve the behaviour of providers and patients do exist in developing countries, but their success depends on government and stakeholder support.

To increase government and stakeholder involvement and accountability, it is important to establish national programmes that publically report rates of antibiotic use and resistance. Although the World Health Organization (WHO), the Pan American Health Organization, and others have promulgated useful recommendations for hospitals and communities around the world to combat antimicrobial resistance, few developing countries have been able to implement these recommendations fully. When resources are limited, assuring access to drugs tends to overshadow the quality of their utilisation. The international community should partner with developing countries to perform the initial cycles of measurement and to design systems to link the data with information to the public on the effect of the problem on population health, personal health, and the economy. Such measurement should occur across several countries in close proximity to harness "peer pressure" and foster better practices.

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incidence of the disease was 447 episodes per 100 000 child years, and the rates of resistance to penicillin, co-trimoxazole, chloramphenicol, and ciprofloxacin were, respectively, 3%, 82%, 15%, and 24%.

Such evidence of the failure of co-trimoxazole has led to the recommendation to use amoxicillin to treat pneumonia in primary care settings, but as yet few health systems in the poorest countries have the extra funds needed to implement these recommendations widely. This is akin to the need for combination therapy for effective malaria treatment and to second line treatment for drug resistant tuberculosis in children, both looming realities in public health systems in sub-Saharan Africa. In South and South East Asia a major burden of childhood bacteraemic infections is related to typhoid fever, as well as the infections listed above. Over the last two decades the prevalence of multidrug resistant typhoid has steadily increased in Asia, and with the widespread use of generic ciprofloxacin and cephalosporins resistance to these second line antibiotics has steadily grown. Increasing antimicrobial resistance results in a much higher economic burden on the health systems of poor countries, because of the higher likelihood of treatment failure and of complications associated with such infections.

Antimicrobial resistance results in a much higher economic burden on the health systems of poor countries

Several factors are associated with the rise of resistance to common infections in developing countries, including the global spread of drug resistant clones as travel becomes easier and local antimicrobial pressure on common organisms. This second factor may be related to inappropriate prescribing of antibiotics, the unregulated availability over the counter of these drugs, and (for reasons of affordability) inappropriate dosages and duration of treatment.

Increasing public awareness, improving standards of care, and the appropriate regulation of the use of such antimicrobials are all important steps. A recent evaluation of the effect of the Swedish national programme for the surveillance of antibiotic use and resistance and the implementation of rational antibiotic use showed that antibiotic use among outpatients fell from 15.7 defined daily doses per 1000 people in 1995 to 12.6 per 1000 in 2004. The largest reduction (by 52%) was noted in children, with no measurable negative consequences on admission rates for common upper respiratory infections. However, examples of successful application of such interventions in developing countries are few.

What are the main challenges with regard to antimicrobial resistance in common childhood infections in developing countries? We need better information systems defining the magnitude of the problem and training programmes to optimise treatment with antibiotics. As we need to balance antibiotic "access" as well as "excess," measures to regulate antibiotic availability must be accompanied by strengthening workforce capacity and drug supplies in dysfunctional health systems. The crisis of increasing antimicrobial resistance to serious and common childhood bacterial infections is a reality in developing countries, and solutions are urgently needed.

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Performance measurement and accountability are potent inducers of behavioural and systemic change in organisations. For example, accreditation agencies and funders now require hospitals in the United States to publically report performance and outcome measures, a policy that has triggered an explosion of quality improvement activity in US hospitals. An excellent template for the annual measurement and comparison between countries of consumption of antimicrobials and resistance rates has been developed by the GRACE project in Europe (www.grace-lrti.org/portal/en-GB). Similar utilisation and resistance profiles for developing countries are needed, and efforts are under way to accomplish this in Latin America through a partnership between research institutions, government agencies, and WHO.

Many lessons from quality improvement interventions in health care in wealthier countries can be applied elsewhere. Various frameworks and theories have been found useful for diagnosing contextual factors and developing strategies to change specific policies, organisational practices, and the behaviour of providers and individual consumers. For example, education and decision support, when part of a comprehensive effort, have been useful in HIV prevention, tuberculosis management, and tobacco control, as well as in appropriate antibiotic use. The literature also shows that quality improvement initiatives that lack local champions and stakeholder support will face formidable challenges to success.

Strategies that work in one place must be assessed for their applicability to other settings, and programmes must be tailored to countries' unique circumstances. Formative research into social factors and practices in specific regional and local contexts, such as how the public and professionals make decisions to recommend, procure, and use antibiotics, is indispensable to achieve change. For example, we found that most patients (62%) purchasing antibiotics in Mexican pharmacies without a prescription reported acting on the recommendation of a clinician. Thus, in Mexico, education campaigns to reduce unnecessary antibiotic use must target doctors as well as the public. Nevertheless, educating the public is crucial, as patients often misuse antibiotics regardless of whether they were bought over the counter or were prescribed.

In developing countries, access to antibiotics without a prescription is commonplace. Here the priority should be to change regulatory policies related to antibiotic procurement and to enforce these policies. This includes creating an infrastructure for surveillance, communication, and effective sanctions. For example, in Chile a mass media campaign preceded enforcement of regulatory measures making antibiotics available by prescription only, resulting in a 35% decrease in antibiotic consumption. It may be useful to emphasise the repercussions that are unique to antibiotic use: in contrast to other drugs the consequences of an individual using antibiotics extend to that person's family and community. Finally, we need to use data and the media to challenge the perception that providing access to antibiotics without a prescription somehow helps to compensate for the lower access to doctors in poorer countries.

The window of opportunity for combating antibiotic resistance continues to shrink. Much work remains to be done in most countries, but particularly in developing countries. We believe that effective programmes to tackle resistant infections are tenable and within reach of the constrained resources of developing countries. The major barriers are the political and public will to set up the systems that can bring about change. Partnerships among national and international stakeholders will help.

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Multiple health problems in elderly people

With ever increasing pressure on doctors' time, **Iona Heath** wonders whether primary care really meets the needs of elderly people at all, while **John Wasson** suggests ways for doctors to improve the care of older patients that don't require extra resources or staffing

Never had it so good?

What does it mean to be old? What is the relation between ageing and illness? How does the subjective experience of multiple and compounding illnesses relate to the medical model and the taxonomy of disease? These questions become more pressing as an ever greater proportion of the population survives into extreme old age, and as the postwar baby boomers—those who "never had it so good," as Harold Macmillan put it—begin to draw their pensions.

Globally the proportion of people aged ≥60 years is growing very fast. It is expected that by 2025 a total of about 1.2 billion people will be in this age group. By 2050 this number will have risen to two billion, 80% of them in developing countries. The older population itself is also ageing. Currently 69 million people are aged over 80, and although this age group now accounts for only 1% of the world's population (and 3% in developed countries), it is the fastest growing segment of the population.

The World Health Organization and many national governments are promoting the concept of "active ageing," which portrays ageing as a positive experience and promotes continuing participation in social, economic, cultural, and civic activities. The concept is based on rights rather than on need and seeks to move away from a view of elderly people as frail and dependent. All this is to be applauded, but it may conceal a worrying reluctance to acknowledge the inevitable reality of death and dying. All bodies must die and find ways of doing so.

Age is a fundamental cause of disease, working through a multiplicity of causal pathways to generate multiple risk factors and multiple disease outcomes. All clinicians are familiar with this process, by which treating one disease in a frail, older person often means that symptoms reappear through another pathway. As the treatment of disease slowly becomes more effective, an ever greater proportion of the population survives with multiple compounding chronic diseases. The commonest of these are cardiovascular disease, stroke, diabetes, cancer, chronic obstructive pulmonary disease, musculoskeletal conditions, and mental illness (including dementia), occurring in many different combinations. The orthodox medical view is that these are distinct and definable conditions each of which carries a different prognosis and

Adapting what is known

Multiple health problems are not unique to older persons; they are, however, more prevalent in this group. Furthermore, as a person ages, what was once a reasonable choice in treatment may be less appropriate, even harmful. In making clinical decisions about the health of older patients and in quality improvement for managing care, what are the trade-offs between benefit and risk? What are the opportunities for, and the barriers against, putting such knowledge into practice?

A 78 year old woman with complex health problems visits her doctor. Although in younger patients clinical recommendations may include screening mammography or intensive control of diabetes, this woman may not actually live long enough to benefit from these interventions. The issues that are most important to her may bear little relation to the bioclinical problems her doctor has been trained to diagnose and treat. Collaborative decision making by clinicians and older patients such as this woman is almost always made in a grey zone of unavailable evidence and divergent expectations. Yet tools are becoming available to help weigh the trade-offs between treatment benefits and competing risks. As these tools become more sophisticated and easier to use in the everyday clinical setting, they will help in clarifying the choices that must be made by older patients with multiple health problems.

The environment in which care is offered and decisions made—the system of "usual care"—is often bad for health. Its toxicity may be a consequence of too many health workers providing fragmented care, too many drugs having adverse side effects, or too much intensive treatment leading to dangerous complications. And usual care suffers by being fast paced, reimbursed according to volume, and focused too much on what the matter is with the patient, rather than what matters to the patient. Many alternatives to this usual care are better, but most of these add additional workforce—nurses, case managers, "coaches," and "teams"—in bewildering combinations called disease management, case management, transition management, and geriatric evaluation and management. Other effective alternatives to usual care, such as routine telephone calls to the patient from an identified primary care clinician, need no additional workforce.

That there are so many things wrong with the usual care and so many ways to improve it raises an obvious question: why hasn't qual-

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requires different treatment. However, people who live with multiple diseases, physical and mental, experience them simultaneously and inseparably. The patient with diabetes and depression and congestive cardiac failure does not have these conditions in separate compartments of her life. She has all three inseparably and, if she is also lonely and frightened, all of this is a single condition.

The problem is that in health care the specialist medical view predominates. And, as a direct result, multiple diagnoses lead almost inevitably to polypharmacy as each condition is treated in perverse isolation from the others. Research findings are extrapolated from younger age groups and interpreted overoptimistically in the context of what inevitably are limited life expectancies. As a direct result, older people are taking an ever increasing number of prescribed drugs, but because of diminished physiological reserve they are also more susceptible to adverse drug reactions and interactions. Nevertheless, the all too easy accusation of age discrimination means that the limited time available for older people to derive clinical benefit is not seen as a legitimate reason for "underprescribing."

Systems of "quality improvement" that involve payment for performance, such as the UK Quality and Outcomes Framework (QOF), apply standards with no allowance for age and systematically encourage overtreatment of hypertension and type 2 diabetes, to the detriment of patients. Many preventive treatments in old age may simply change the cause of death and not its date. The energetic treatment of cardiovascular risk factors is effective in reducing cardiovascular mortality but does not prolong life and increases the likelihood of a diagnosis of cancer or dementia.

Old people themselves have different priorities and can find the epidemiological perspectives of healthcare professionals to be intrusive and inappropriate. Most elderly people are very aware of death and know that it must be faced and negotiated: "The big event of old age—the thing which replaces love and creativity as a source of drama—is death" (the author Diana Athill).

Many frail older people have a rapidly diminishing appetite for technological health care and a proportionately increased need for sensitive, gentle, hands-on physical care: a need that is easily compromised by the very real fear of becoming a burden. At present, medicine seems to have limited means of marking this transition, but such means are urgently needed, because the continuing emphasis on individual diseases leads, usually inadvertently, to undertreatment, overtreatment, or mistreatment—and often all three.

Tragically, the global trends of commodification, privatisation, and fragmentation in health care mean that the dimensions of care most needed by frail elderly people become less and less accessible. Yet multiple illnesses can be coherently managed only by a personal generalist physician who is able to provide continuity of care for the patient's whole experience of illness, while at the same time remaining alert to those diagnostic possibilities that are readily remediable. But how, within a market system, can unprofitable need for time intensive and hands-on personal care from a known other ever be given commensurate priority?

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ity improvement already resulted in better usual care for older persons with multiple health problems?

One reason commonly given for the persistence of poor care is that most studies of successful interventions for elderly patients, when compared with usual care, have not provided clear evidence of cost savings. However, saving costs seems a poor reason for not improving care, and indeed many of the attributes of good quality care may not require extra staff or money. In fact, within the range of usual care about a fifth of older patients with multiple health problems are already receiving the high levels of access, continuity, communication, and self management that are associated with successful alternatives.

The fact that these crucial attributes of quality care are already available to some patients raises a second question: can this high quality care be generalised to more patients?

The prevailing culture has to change to enable breathing room from oppressive volumes of consultations and paperwork

An affirmative answer to this question is provided by one innovative US example of a quality improvement project: an online collaboration involving a group of primary care practices across the country (www.idealmedicalpractices.org). In these practices, the percentage of older patients with complex health problems who are attaining attributes of high quality care as listed on the website is more than twice that in non-participating practices, even though they receive no special reimbursement.

The thrust of future research into quality improvement for older patients with multiple health conditions should be directed towards two objectives. The first is research into how to adapt and adopt what is known. The existing literature on quality improvement demonstrates numerous ways to improve health care for these patients through timely assessment of "what matters," easy access to care, continuity of care with an identifiable clinician, and understandable, relevant information and support for condition management and collaborative decision making. Although no particular setting, patient population, or disease mix will be identical to those reported in the published literature, many essential elements are constant. For example, it is not surprising to clinicians that their patients' confidence in self management, financial status, and managing pain and psychosocial problems affects their healthcare outcomes. What is surprising is that clinicians don't systematically evaluate these factors when assessing older patients and placing them into categories for the delivery of planned care. Technologies and methods are already freely available to help busy health professionals capture these valuable opportunities.

The second area is research into how to overcome the most conspicuous barrier to the improvement of care: the current healthcare culture. The current culture induces dysfunctional workforce expectations, unwanted variation in practice patterns, ineffective training venues, counterproductive payment incentives that are often based on inappropriate measures, and excessive technological imperatives. Only in a very few clinical practices are measures of "what matters" to the patient really at the centre of care. At a minimum, the prevailing culture has to change to enable breathing room from oppressive volumes of consultations and paperwork so that the few motivated health professionals implementing patient centred, collaborative care can become the many.

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Excessive drinking in young women

The growing problem of binge drinking among young women is one that must be dealt with at a societal level, says **Ian Gilmore**. Nevertheless, doctors can make a difference at an individual level, and **Brenda Reiss-Brennan and colleagues** describe one US quality improvement intervention in primary care

Not just a "lifestyle disease"

Are we now seeing the undesirable consequences, for instance in drinking and smoking habits, of female emancipation? As women quite rightly seek greater opportunities for equality in the workplace and in other aspects of life, we see signs of them falling prey more and more to so called lifestyle diseases. Young women are all too commonly seen huddling outside enjoying a cigarette; and while lung cancer rates fall overall, they continue to rise in women.

Women are also conspicuously heading for equality in their drinking habits. In the most recent British general household survey, 42% of men and 39% of women aged 16 to 24 years had exceeded safe recommended daily limits in the previous week, with over half of those drinking heavily or "bingeing." The United Kingdom has the heaviest drinking young women in Europe, nearly 40% of whom admit to having drunk six or more units in one session in the previous week.

Does it matter that our young women are having fun? Most get away without harm and will probably settle down. But those who do not escape harm may have their life changed fundamentally under the influence of alcohol. Most first consensual sexual experiences and unwanted pregnancies occur in this way, and the distinction between rape and sex regretted the next day can become blurred when women are drunk. Genitourinary clinics see drink as the biggest factor in unprotected sex and sexually acquired infections. Some young women will be scarred for life through drunken brawls and arguments. In Scotland about 30% of women committing violent crime are drunk.

Of course, the victims of accidents need not be drunk themselves: alcohol is responsible for much third party or collateral damage. In England and Wales, over half of victims of violence perpetrated by a stranger judged the attacker to be under the influence of alcohol. This is particularly an issue in domestic violence, where again at least half of perpetrators are likely to have been drinking. It is remarkable how damage to the health of third parties was such a tipping point for public opinion on the issue of smoking in public places, yet alcohol is hugely more serious in this regard.

Teenage girls and young women are unlikely to be receptive to arguments about serious organ

Reducing harm through quality improvement

The concept of harm reduction has evolved over nearly 90 years from its beginnings in the 1920s, when it applied to drug misuse in adult populations. Applying the concept to adolescent groups at risk is relatively new, requiring that the concept be adapted appropriately.

Adolescent harm reduction spans a wider array of harmful behaviours than are discussed in the literature: substance misuse, multiple sexual partners, violence and weapon carrying, non-use of helmets when cycling, skating, or snowboarding, riding with a driver who has been drinking, and suicide plans. But the main contributor to death from injuries in people in the United States under the age of 21 is underage drinking.

Young women are "outdrinking" their male counterparts of the same age and are more likely to experience adverse health consequences. Such behaviour may undermine neurological brain development, predispose to adult dependency, and increase mortality. The strong association between drinking and having multiple sexual partners "underscores the need to educate young people about the effects of alcohol on partner choice and the risk of infection with sexually transmitted diseases," as one study put it.

Harm from drinking often involves others; among young women this other will often be an unborn child. Fetal alcohol syndrome is the leading cause of brain damage in children in the United States. Young girls are now drinking and smoking like boys and are more likely to be depressed and to attempt suicide. In primary care the complexity of these risky behaviours among young people often goes undetected, owing to lack of time, of access to effective treatment, and of coordinated and adequately funded resources in the community to reduce harm.

A growing number of patients with serious mental illness and substance misuse report being treated in primary care or emergency rooms. Despite the availability of evidence based treatment for these disorders, many patients and families do not receive effective treatment in real world settings. One strategy to help remove such barriers is to re-engineer the processes of care delivery, using an evidence base of changes that lead to improvements in the quality and efficiency of care.

Our organisation, the non-profit Intermountain Healthcare (http://intermountainhealth-

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damage in years to come, and so it is important to highlight dangers that are more immediately relevant to them. It is now apparent that fetal alcohol syndrome, where babies are born with severe brain damage and a typical physical appearance, is but one end of a spectrum (fetal alcohol spectrum disorders); and less obvious behavioural disorders such as attention deficit hyperactivity disorder may result from exposure to alcohol in the womb. Unfortunately exposure in early pregnancy is likely to be important, and so far no safe threshold has been identified. Thus the only safe advice is for women to avoid alcohol if they seek to become pregnant—tough advice where every celebration now seems to have alcohol at its core.

Alcohol misuse remains the most important cause of death from chronic liver disease (cirrhosis), the prevalence of which has grown startlingly in women, particularly in the 35-44 year age group (sevenfold in the last three decades) but also in even younger women. This reflects the early age when heavy drinking starts. Particularly striking is the emergence of the syndrome of alcoholic hepatitis (not always associated with histological cirrhosis), where the patient is febrile, deeply jaundiced, and often has ascites and other features of decompensation of liver function. Histologically this can be indistinguishable from non-alcoholic fatty liver disease, and it has been suggested that alcoholic hepatitis may be a "double hit" of alcohol on top of a fatty liver, often associated with obesity, which would explain the rapid increase in the disease. Certainly the burden of harm is seen disproportionately in the most disadvantaged in society, a striking example of health inequality that remains unexplained.

Alcohol is our favourite drug, and it is distressing to see young women pressured into misusing it

What can be done to turn this tide of alcohol related health harm in young women? We know that telling them to behave better will not work. England's national alcohol harm reduction strategy of 2004 relied heavily on voluntary partnerships with producers and retailers of drink, linked to public education and information. Sadly, these initiatives have palpably failed. This should not surprise us too much, because the best predictor of alcohol related health damage is per capita consumption, and it can hardly be in the industry's interests to have falling sales. Hence we need to fall back on the tools that have an international evidence base: mainly price and availability. Alcoholic beverages have never been as cheap in real terms as they currently are—particularly those sold in off-licences and supermarkets—nor as available.

Although approaches to increase price and reduce availability smack of the "nanny state," it is simplistic to dismiss alcohol dependence and physical damage as lifestyle diseases, somehow down to the individual's free choice and nothing to do with the state. Cheap drink is available and heavily promoted. Alcohol is our favourite drug, and it is distressing to see young women pressured into misusing it.

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care.org/xp/public/about-intermountain/), became increasingly concerned that primary care resources were not being used effectively to treat patients with mental health conditions. Its medical leaders were influential in establishing the mental health integration (MHI) quality improvement programme. Over the last decade Intermountain has implemented MHI throughout 68 primary care clinics to identify patients with mental health or substance use disorders and to treat them and refer them to additional services. MHI makes available a clinical team and offers financial support to the primary care doctor.

Sustained results show that MHI leads to improved functional status in patients and improved satisfaction and confidence among physicians in managing mental health problems as part of routine care at a neutral cost.

The primary care environment presents opportunities and challenges for reducing harm in young female drinkers. Alcohol dependence and underage drinking are complex family health problems and are intensely personal and isolating issues for girls and young women. It is an opportune consultation in which teenagers' health risks are uncovered and wellness can be promoted. Although guidelines are available, the routine screening of young women for harmful behaviours varies widely among primary care doctors.

The MHI assessment begins with a common screening toolset administered by the family doctor, who determines, with the patient and family, the severity of the mental health concerns. It includes comprehensive, self reported measures of family history and relational support, environmental stressors, use of substances, depression, anxiety, and bipolar and attention deficit disorders.

The results determine whether the doctor continues routine treatment or triages the patient to the MHI psychologist, psychiatrist, or psychiatric nurse practitioner for prompt consultation. The team includes a nurse care manager, who provides support and feedback to the doctor, the patient, and the family. The care manager also provides education and information and links the patient to community resources, if this will benefit the patient.

The team members use harm reduction strategies to improve education and to provide treatment for alcohol misuse. They also facilitate the involvement of families and community resources in social support and reinforcement of abstinence. Strategies that are tailored to the preferences of patients and communities are more likely to result in positive behaviour change.

Intermountain's MHI database identified 123 263 patients across all age groups, 45% of whom were women (55 568). The data show that 25 945 girls and women aged <39 were being treated for substance misuse and that 9107 had comorbidity of depression and substance misuse. Of those with a diagnosis of substance misuse, 420 (1.6%) were 18 years old or younger.

Adopting a harm reduction approach to help young female drinkers and their families will require quality improvement interventions that provide institutional support for the primary care doctor to deliver care that is matched to the family's and community's social, financial, and cultural healthcare preferences for wellness. Higher levels of social capital exert strong protective effects against alcohol misuse and harm.

Intermountain's MHI programme is one example of a quality improvement intervention that tackles social capital needs and such barriers as failed access and limited, fragmented treatment choices, which many families face when trying to find help.

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Management of chronic pain

The burden of chronic pain for those who have it and their families is substantial, says **Henry McQuay**, and these patients deserve better. **Dawn Stacey and colleagues** describe an example of quality improvement in practice for one group of people with chronic pain, those with osteoarthritis

Help and hope at the bottom of the pile

Chronic pain is common—but it isn't sexy. People who through no fault of their own have their lives demolished by pain deserve our help. The Pain in Europe survey found that 19% of almost 50 000 people questioned in a poll had chronic pain, defined as pain of at least moderate severity occurring almost every day for at least six months. One in five of these people had pain for more than 20 years, and most had pain for more than five years.

The main causes are back pain and arthritis, and the incidence of chronic pain increases with age. Our populations are ageing. In the United States the number of people aged 65 years or older will have almost doubled by 2025 to 63 million, from 37 million in 2006, and there will be a third of a million Americans over the age of 100 years by 2020.

Chronic pain has a substantial impact on quality of life. A Dutch study that analysed eight large datasets by quality of life factors ranked different medical problems. Musculoskeletal conditions (including arthritis and back pain) had the most severe effect on quality of life. This impact of everyday pain on quality of life is something that has yet to be fully appreciated by those who organise our health services and allocate resources.

Most normal or nociceptive pain can be managed with conventional painkillers, from paracetamol through to morphine, with the more powerful painkiller added for more severe pain. Most pains wax and wane, and flexible prescribing takes time to explain. Problematic pains include severe pain on movement with little pain at rest, leaving patients oversedated with painkillers when they are not moving. Problematic side effects of the drugs include drowsiness and constipation, a major burden for elderly people.

Perhaps the most testing pains are those that result from nerve damage, the neuropathic pains. Peripheral nerve damage from surgery, trauma, back pain, and the classic post-herpetic neuralgia, painful diabetic neuropathy, and trigeminal neuralgia often respond poorly to conventional painkillers and need the unconventional drug classes, the antidepressants and the antiepileptics. Titrating these drugs to maximise pain relief and minimise side effects is fiddly but necessary.

Improving shared decision making in osteoarthritis

Common treatments for osteoarthritis include physiotherapy, bracing, pharmacotherapy, and joint replacement surgery. When treatments are proposed that increase the risk of harm (such as non-steroidal anti-inflammatory drugs, opioids, or surgery), patients' values concerning potential benefits and harms need to be considered. However, clinicians find it difficult to judge patients' values, which are also often based on unrealistic expectations. Therefore tools that improve the shared decision making process are important.

Shared decision making is a process in which the patient and clinician together reach an informed decision about the plan of care on the basis of the patient's clinical needs, priorities, and values. The clinician's expertise lies in diagnosing and identifying treatment options according to clinical priorities; the patient's role is to identify and communicate their informed values and personal priorities, as shaped by their social circumstances.

Patient decision aids are tools that prepare patients for consultations by explaining options, quantifying risks and benefits, helping patients to clarify their values, and providing structured guidance in deliberation and communication. A review of 10 systematic reviews of patient decision aids found that they improved patients' participation, increased their knowledge of treatment options, realigned their expectations, and improved the match between their values and subsequent treatment decisions. The aids also reduced the overuse of elective surgery (for herniated disc, for example) without apparent adverse effects on health outcomes. Another study showed the potential for patient decision aids to reduce inequalities among ethnic groups. The Cochrane inventory of patient decision aids (www.ohri.ca/decisionaid) uses international standards to rate their quality. Decision aids for osteoarthritis treatment are available online, in brochures, and on DVD.

In 2006, patient decision aids were accessed more than eight million times, mostly through the internet. Ideally, these tools should be linked to clinical care processes, but practitioners report several barriers to implementation: inappropriate content for their patients; forgetting to offer them; inadequate time; content that was too complex or too simple; and cost. Practitioners are more likely to use patient decision aids if they have a positive effect on patients' outcomes

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Most chronic pain is managed with drugs in primary care. Obstinate pains—pains that resist drug control at acceptable levels of side effects—may need other treatment options, from injections through to a multidisciplinary pain management programme. The necessary skill mix includes nursing, psychology, drug expertise, and injection options and physiotherapy.

The imperative to provide this tier of expertise is humanitarian and economic. Patients with chronic pain who are managed poorly will bounce around the healthcare system, becoming more and more exasperated and consuming considerable resources. Well managed pain contains this excess use of resources, saving an estimated £1500 (€1900; $3000) per patient per year. Set against the background of the large economic burden of chronic pain, the cost of this tier of expertise is marginal.

Chronic disease comes low on the political priority list, and chronic pain just gets forgotten. The burden for the sufferers, their families, and society is substantial

An estimate of the financial burden of musculoskeletal illness in the United States argued for $50bn, and the indirect costs of back pain in the United Kingdom are estimated at £11bn. Certainly, chronic pain increased costs for payers by more than double, in comparison with matched controls without pain ($C4200 (£2070; €2600; $4100) versus $C1800 a year), an excellent Canadian database survey found. There are also financial implications for the person with the pain, reduced household income being the most obvious example.

No one thing will improve this situation. We need more and better basic research, the most tangible products of which are likely to come from the major drug companies. But there have been pitiably few new painkillers in the past 30 years.

Clinical research and practice are now much more likely to make a difference, helping to make existing evidence sensible and understandable so that people can use it. The evidence base in pain enables us to assess the relative effectiveness of treatments, for instance in nociceptive and neuropathic pain and indeed in migraine. This evidence does not dictate what analgesic to use for a particular patient but does help us to make choices about treatments on the basis of their effectiveness, propensity for harm, and cost.

Then there's the provision of care. Chronic disease comes low on the political priority list, and chronic pain just gets forgotten. The burden for the sufferers, their families, and society is substantial and merits better treatment.

The mark of a gracious society is how it treats those with least voice. That chronic pain puts people at the bottom of the pile is precisely why we should be agitating on their behalf for a fairer share of the medical resource cake.

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or on the clinical interaction. Orthopaedic surgeons rated the content of patient decision aids for osteoarthritis treatments as good to excellent and were motivated to use them to improve patients' understanding but had concerns about interrupting the flow of clinic work.

Patient decision aids have been implemented successfully in specialist clinics in the United Kingdom and Canada and in specialist and primary care clinics in the United States. Patients with osteoarthritis, for example, use decision aids together with balanced, evidence based information on the treatment options and the likelihood of the benefits and harms of those treatments. The decision aids help patients clarify their values concerning benefits and harms by describing what it is like to experience them. Patients then complete a personal decision form, which elicits their knowledge, values, preferred option, and any unresolved "decisional needs" (for example, uncertainty about their preference, gaps in their knowledge of the options, lack of clarity of their values concerning benefits and harms, and support needs). This information is summarised on a "patient preference report," which is sent to the clinician to "close the loop" on decision making with the patient.

In Canada, patients on the waiting list for a surgical consultation are screened for eligibility by trained general practitioners or physiotherapists before they receive a decision aid and personal decision form. The Canadian patient preference report (see http://makingadifference.bmj.com) lists clinical priorities as determined by self reported pain and functional limitations, the trained screener's assessment of surgical priority, and the patient's preferences and decisional needs. The report is paper based, but one author (NC) has developed a similar computerised report as part of the US Veterans Administration's electronic patient health records.

Using the patient preference report together with patient decision aids has the potential to improve the clinical encounter and to provide the incentive that practitioners need to overcome their resistance to using the aids. For example, when patients arrive at a surgeon's consultation with their preference report, the surgeon can focus on issues of concern to the patient, such as fears of side effects of surgery. Thus the surgeon's time will be used more efficiently, and the care provided is more patient centred, so patients and practitioners are both more likely to be satisfied with the process.

Outcomes such as pain reduction and improved function cannot be the sole quality indicators in treatments that involve trade-offs between potential benefits and harms. In such treatment decisions, the quality of decision making should be defined by how well the chosen treatment option matches the features that matter most to the informed patient. Patient preference reports document decision quality as an indicator of the shared decision making process. In addition to monitoring postoperative complications such as infections, these reports can be used by quality improvement teams to monitor the extent to which high quality decisions are achieved and decisional needs met.

Patient decision aids prepare patients for making shared decisions concerning treatment. Patient preference reports that summarise patients' clinical and decisional needs improve communication. With standardised measures and documentation of decisions, healthcare organisations can monitor and include decision quality as another indicator of the quality of their programmes.

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An example of a patient preference report is at http://makingadifference.bmj.com

Adverse drug reactions in elderly people

Doctors should pay greater attention to managing the risk-benefit relationship to improve care of patients over 65, urge **Jerry Avorn** and **William Shrank**. The challenge of safer prescribing, says **Anne Spinewine**, lies in shared decision making

A substantial cause of preventable illness

Patients over 65 years old bear the greatest burden of illness and thus are the greatest beneficiaries of drugs to prevent, ameliorate, or treat conditions. One of the most rapidly growing segments of the population, they consume an ever increasing proportion of all prescribed drugs.

For decades elderly people were excluded from randomised trials of many preventive drugs, reinforcing scepticism over whether they would benefit from treatment of conditions such as hypercholesterolaemia and hypertension. But elderly patients may benefit from such treatments at least as much as their younger counterparts. In fact, because of the higher prevalence of preventable disease in older patients, they often derive greater benefits from such prescribing than younger patients.

For this reason, much primary care has shifted from the treatment of acute illness to the management—often pharmacological—of "risk states" in elderly people, including hypertension, hypercholesterolaemia, and osteoporosis, as well as diseases such as atrial fibrillation, heart failure, and diabetes. Solid evidence from clinical trials indicates that appropriate prescribing can substantially reduce the burden of preventable morbidity in these conditions. Although such concerns are traditionally seen as a problem of the industrialised world, they are rapidly becoming a major issue facing developing countries as well.

But this benefit comes at a price: the high prevalence of adverse drug reactions in older patients. The problem has several sources. One is the altered pharmacokinetic status of elderly people; they are less able to metabolise and excrete many common drugs, even in the absence of liver or kidney diseases. They may also have altered pharmacodynamic responses, with some receptor systems (such as those for opiates and benzodiazepines) having greater sensitivity with advancing age, and others (such as those for insulin) showing reduced sensitivity. Unfortunately, the under-representation of older patients (especially frail ones) in clinical trials makes it even harder for the prescribing doctor to prevent untoward drug reactions in older patients.

When an elderly person experiences an adverse drug reaction, it may be mistakenly attributed by the patient or doctor to a new disease or (even worse) the ageing process itself. Examples include the parkinsonian side effects of many antipsychotic drugs and the fatigue, confusion,

The challenge of safer prescribing

Quality improvement for the care of older people has become a priority in many countries. Elderly people consume a large proportion of health care, including drugs, and evidence shows that prescribing to this group is often inappropriate. Inappropriate prescribing occurs in all care settings and at the transition between settings. Negative consequences include adverse drug events, higher costs for the patient and society, and impaired quality of life.

Specific approaches tailored to the needs of frail elderly people are needed. A recent review of ways to optimise prescribing to older people found that geriatric medicine services (involving a multidisciplinary team that includes a geriatrician and other healthcare providers with specialised geriatrics training), involvement of pharmacists in care, and computerised decision support can all improve the quality of prescribing to this group in different settings.

Quality improvement strategies are more likely to be effective when there is direct interaction with the prescriber and when the strategies are provided at the time of prescribing. In nursing homes, involvement of nurses in strategies is another important factor. The effect of educational interventions is mixed, although the lack of training of doctors in geriatrics is often cited as a cause of inappropriate prescribing.

However, widespread diffusion of effective approaches has not yet occurred. As in many other fields, translating research into practice is a delicate task. In the domain of quality improvement for safer prescribing to older people, this is further complicated by a lack of strong data showing the impact of effective approaches on important health outcomes. Also, the question of who should meet the cost of such approaches is a matter for debate. And we lack data on the cost effectiveness of strategies. With regard to computerised decision support systems, we first need systems that have been tailored to elderly patients before they can be implemented more widely.

It is important to take environmental barriers into account. Some barriers can be specific to the setting of care or even to the country of practice. For example, improving the quality of prescribing of neuroleptics in nursing homes is less likely to occur without an increase in staffing and resources. Direct contact with prescribers

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or depression-like symptoms that can result from excessive use of heavily marketed psychoactive drugs. Elderly people are at special risk of such misattributions because of the pervasive cultural assumption that growing older brings with it a collection of inherent and inevitable disabilities. The problem is compounded by the slender preparation that most students receive in geriatrics and in clinical pharmacology. There is ample evidence of the clinical burden of iatrogenic illness in the elderly. Studies of US patients aged over 65 indicate that each year more than 180 000 life threatening or fatal adverse drug effects occur in the outpatient setting, of which over half may be preventable. Another study attributed 6.5% of all hospitalisations in the general population to adverse drug events, a rate that is likely to be higher in elderly people.

Despite these gloomy realities, the most notable aspect of drug induced illness in elderly people is the most encouraging. Once recognised, a side effect of a drug is probably the single most reversible affliction in all of geriatric medicine. Usually, care of elderly people requires the management of conditions with a downward course. But discovering that a symptom is caused by a drug presents an uncommon opportunity to effect a total "cure" by stopping the offending prescription or lowering the dose. In our own practices we have often seen patients on a seemingly inexorable trajectory towards institutional care whose functional capacity was restored by thoughtful reassessment of their drug regimens. This has led to the useful if overstated recommendation that "any new symptom in an older patient should be considered a possible drug side effect until proved otherwise."

As well as being alert to the possibility of new iatrogenic problems, it is also prudent to reassess a patient's entire drug regimen at least twice a year, including categories often overlooked by patients and doctors: drugs bought over the counter and "nutraceuticals" such as herbal remedies or dietary supplements. Although these products are often devoid of therapeutic benefit, they can impose important toxicities, and their interactions with prescribed drugs are poorly understood. With growing use of the electronic medical record, we can expect that drug regimen review will increasingly be prompted by the computer in the course of routine care. In one computerised system for entering prescription orders, the system automatically checks all prescribed drugs and dosages against the age of the patient and recommends a lower dose or different drug if necessary.

Non-compliance with prescribed drug regimens can produce a different kind of drug related morbidity. In this "silent epidemic," as much as half of prescribed drugs are simply not taken. Considerable morbidity results from this other kind of drug related illness in elderly people, in which potentially useful treatments are not taken or (because of misplaced therapeutic nihilism) not prescribed in the first place.

Broader systems based and educational approaches are emerging to guide the evidence based use of drugs in older patients so as to reduce their burden of iatrogenic illness while ensuring that needed drugs are prescribed properly. Better attention to managing this benefit-risk relationship will play an increasingly important role in maintaining and improving the health of an ageing population.

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(such as with a clinical pharmacist) is not always feasible in nursing homes, and this can decrease the efficacy of the intervention. In some countries pharmacists do not have access to patients' records. Consequently, a quality improvement strategy that is effective in one care setting cannot be directly transposed to another without adaptation. The same applies to transposition between countries, because of differences in practice environments and culture.

Big improvements in communication at the interface between primary and secondary care are urgently needed too. Many adverse drug events result from problems with communication relating to management of drugs during the transition between care settings. National online databases of drugs dispensed to patients (as in Denmark), to which all doctors and pharmacists have access, should help to tackle such problems. The same should apply to patient records. Such a challenge should be taken up at the national level, although of course steps must be taken to protect patients' privacy. Better communication among prescribers to track changes in treatment and to record the reasons for those changes will also help to avoid the fragmentation of care. This aspect should be included in measures of quality performance.

Big improvements in communication at the interface between primary and secondary care are urgently needed

Quality improvement strategies for safer prescribing in older people must include shared decision making. The beliefs and preferences of older patients concerning treatment affect adherence and, in turn, the safe use of drugs. Several recent studies have shown the importance of considering patients' wishes, but many questions remain unanswered.

The high prevalence of people with dementia and the need to involve carers in decisions complicate further the task of shared decision making. Furthermore, many prescribers are not familiar with the principles of shared decision making or are reluctant to engage in it because of the extra time needed. Therefore a huge amount of work needs to be done here, from research to implementation. Education and training programmes for prescribers should include sessions on communicating with patients and on involving them in decisions. Health authorities should also consider including this dimension of care in quality performance measures.

What are the most urgent of the unanswered research questions? We need more clinical trials that enrol frail elderly patients, to enhance our knowledge of the benefits and risks of treatments in this group. With regard to quality improvement strategies, we need to evaluate the effect of multifaceted approaches on important health outcomes and costs. This is a challenging task that will certainly require multicentre trials with large samples.

It is important that quality improvement approaches are multidisciplinary in nature, use computerised decision support systems that are specific to this age group, and take the patient's view into account.

Meanwhile, national health systems should provide incentives for prescribers to regularly review treatments, develop information systems to facilitate seamless care, and encourage the implementation of multidisciplinary approaches including geriatric medicine services. Quality improvement strategies need to be customised to account for differences in patients, prescribers, and environmental factors.

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Palliative care beyond cancer

Scott Murray and **Aziz Sheikh** say that the lessons learnt from palliative care for cancer need to be applied to other fatal conditions. Healthcare delivery that is tailored to the varying needs of patients with these diseases will be crucial in making a difference, says **Joanne Lynn**

Care for all at the end of life

We must apply the lessons learnt from cancer (often slowly and painfully) to the growing number of people now dying from non-malignant illnesses. New theoretical insights into the trajectories of decline in a range of long term conditions—together with technical developments that aid the delivery of care in people's own homes and the timeless clinical qualities of listening, compassion, empathy, and inspiring hope—mean that we now have the means to make a real difference to the lives of so many people in the throes of their final illness and to the lives of their loved ones. Getting end of life care "right" lies at the heart of what it means to be a civilised society, and thus prioritising this area needs no apologies.

In 2005 cancer was responsible for a relatively small percentage of deaths worldwide (13%), while other long term conditions caused 47%. By 2030 the annual number of deaths around the world is expected to rise from 58 million to 74 million, with conditions related to organ failure and physical and cognitive frailty responsible for most of this increase. Yet despite these rapid demographic changes, palliative care services typically still cater only for people with cancer. For example, hospices in economically developed countries currently provide 90% of their care to patients with cancer. Moreover, people dying from cancer usually have needs lasting for weeks or months, whereas those dying from organ failure or old age often have unmet needs that extend over many months or years. It is little wonder, then, that people dying of the "wrong" condition and their carers, whether family, social, or professional, are increasingly frustrated by the major obstacles to accessing appropriate care.

The drive to extend palliative care beyond cancer has so far been hampered by a combination of factors: prognostic uncertainty; funding difficulties (in the United Kingdom influential cancer charities support many hospices and outreach programmes); lack of palliative care clinicians with expertise in non-malignant diseases; and a hitherto relatively weak evidence base in relation to appropriate models of care. Although the empirical evidence base remains weak, we do now have a good theoretical understanding of when and how to intervene in a range of conditions.

Prognostic uncertainty can and does hinder clinicians in thinking and planning ahead. Most

Reliable comfort and meaningfulness

To live well in the time left to them, patients with fatal chronic conditions need confidence that their healthcare system ensures excellent medical diagnosis and treatment, prevention of overwhelming symptoms, continuity and comprehensiveness of care, advance care planning, patient centred decisions, ands support for carers. Hospices and palliative care have improved these dimensions of quality for people dying from cancer. Applying those insights to other fatal chronic conditions could greatly improve the last part of life, although the endeavour entails substantial challenges.

End of life care for elderly people will have to last for a long time: being disabled enough to need daily help now continues for an average of more than two years before death. Patients with non-malignant, long term illness are older and frailer than patients with cancer (as are their carers). Transfers between hospitals, nursing homes, and home care often engender delirium, depression, falls, treatment errors, and pressure ulcers, in addition to the common hospice problems of pain and loss. Entities that are often unfamiliar to hospices—such as social insurance programmes for poor people and disability transportation—will need to be partners in care.

How can we ensure reliable services for all in the last phase of life? Systematic quality improvement and policy reforms will offer reliable and efficient strategies if they focus on the three common patient trajectories: short decline typical of cancers; intermittent exacerbations and sudden death typical of organ system failures; and the slow dwindling course typical of frailty.

For gains to be achieved and sustained, quality improvement requires clear goals, appropriate teams, ways to monitor progress, sequential testing of improvements, and the institutionalisation of improved processes. Local quality improvement has a track record of success in correcting some shortcomings of ordinary care. These include improving pain prevention and treatment (such as by routinely responding at a patient's home within a time period determined by the patient or a family member), developing and implementing advance care plans (deciding whether to attempt resuscitation, for example), and preventing and healing pressure ulcers (one quality improvement programme reduced the incidence of full thickness lesions by 69%). Quality improvement projects can reduce overtreatment near the end of life, improve prognostication and counselling by providing automatic

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patients with heart failure die when they are still expected to live for more than six months, and accurate prognostication is also virtually impossible in people with chronic obstructive pulmonary disease (COPD). Although this uncertainty is frustrating for doctors, its very presence can be a basis for initiating end of life discussions.

Recent work is helpful in identifying critical events and stages when a palliative approach may be introduced. People with progressive chronic illnesses follow three characteristic trajectories (see figure on http://makingadifference.bmj.com): a cancer trajectory, with steady progression and usually a clear terminal phase; an organ failure trajectory, with gradual decline punctuated by episodes of acute deterioration and eventually a seemingly unexpected death; and a trajectory of prolonged gradual decline (typical of physical or cognitive frailty).

Hospices provide excellent and accessible care to people with cancer but are not configured to address the needs of patients who don't have cancer. So what can we do? A typical critical juncture in an organ failure trajectory, such as hospitalisation for acute heart failure or an exacerbation of COPD, should trigger a holistic assessment and care plan for the next stage of the illness. Practical models of care are now being formulated and tested to fit the other two trajectories. Some Scottish general practitioners are, for instance, documenting a care plan for every patient admitted to hospital with COPD. Clinicians are thus alerted to "change gear" from routine chronic disease management to a more personalised palliative care approach, while continuing active treatment. These trajectories thus help us consider what should be done to promote quality of life rather than focus on what can be done, which may lead to futile treatment. A strategic policy overview of these trajectories may also help services to consider all people with serious chronic illnesses equitably, rather than cancer "top slicing" care.

Palliative care for everyone underscores the need for anticipatory personalised care for all people with life threatening illnesses. Technical developments such as video conferencing and remote monitoring devices may help in realising this aspiration, but far more important are the medical vocation's essential clinical skills—active listening, respecting autonomy, and empathic care—none of which depends on first world infrastructures. These can be implemented anywhere in the world, as long as health services respect the importance of clinicians and patients having time together, ideally in the context of a relationship that allows for personal continuity of care.

Facilitating a good death should be recognised as a core clinical proficiency, as basic as diagnosis and treatment. Death should be managed properly, integrating technical expertise with a humanistic and ethical orientation. We also need research into how best to identify, assess, and plan the care of all patients who are sick enough to die, and we need education that keeps alive our humanity and sense of vocation. This is an enormous challenge in politicised, market driven healthcare models but one that will make an important difference to those most in need.

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A figure showing the three main trajectories of decline at the end of life is at http://makingadifference.bmj.com

feedback to clinicians, and implement shared accountability and effective drug reconciliation throughout changes of care settings.

Sustainable excellence requires supportive social policies. Practitioners working in trustworthy arrangements for delivering care must make a living. But powerful economic interests and social forces now encourage the overselling to patients and families of treatments with little chance of success. Citizens and clinicians must encourage political leaders to champion more appropriate policies, such as allocating healthcare payments to reward continuity and comprehensive primary care and ensuring an adequate income in retirement for family members who are carers.

Such reforms will be more efficient when they set out to match eligibility and service patterns to the three dominant patterns in the last phase of life. If palliative and hospice care are available only to those who die in a predictable way in a short time, most people will never qualify, because their timing of death will stay uncertain until very close to the end of life. A short period of hospice care does meet the needs of many cancer patients, but people with heart and lung failure are better served by having a much longer period of support for self care and rapid response to help people at home in times of crises. In contrast, people with dementia or who are frail are often best served by having many years of support to carers in the family. Delivery systems that are tailored to the usual needs of these groups would enable clinicians to customise care plans to the preferences of individual patients and their families.

Local quality improvement has a track record of success in correcting some shortcomings of ordinary care

The combination of specific innovations from quality improvement, encouragement in the form of payment and regulatory policy, and services tailored to particular groups of patients is a powerful package for reform. In various forms, such a strategy is being pursued in many places: the United Kingdom, Saskatchewan in Canada, and Sweden, and in the United States by Kaiser Permanente, the Veterans Affairs Health System, and Medicare's Quality Improvement Organizations in each state.

Every clinical team can use quality improvement to adapt its own care system to the needs of patients with fatal illnesses. For example, doctors can shoulder the burden of helping patients and families come to a realistic view of the outlook and to collaborate in making plans. Claiming to be sustaining hope, doctors often offer improbable treatment plans, falsely implying that all will be well if the patient and family go along with them. Instead, an honest appraisal of the situation, the likely course of the illness, and the treatment alternatives would allow the patient, family, and clinicians to negotiate the priorities among various goals, the preferred strategy, and a timeframe for reconsideration.

The ageing of populations will greatly increase the number of sick and dying older people, while smaller families and reduced retirement security will shrink the number of available carers in the family. The coming crisis is obvious. Policy makers and practitioners must learn to support family carers, and local quality improvement and innovation in governmental policy are the right prescriptions.

The dying patient's clinical care team must provide highly skilled diagnosis and treatment. Doctors must be able to promise to prevent pain and dyspnoea near death, for example. Specialist palliative care is well established in many countries, but palliative care skills among those professionals who serve most patients—long term care nurses, home care teams, generalist physicians, and specialist physicians—lag far behind.

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Integrating Patient Decision Support in an Undergraduate Nursing Curriculum: An Implementation Project

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Integrating Patient Decision Support in an Undergraduate Nursing Curriculum: An Implementation Project*

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Abstract

A 4-year curriculum project (2004-2008) to integrate patient decision support into an existing curriculum was guided by the Knowledge-to-Action process model. The purpose of this project was to integrate a patient decision support theoretical framework and associated evidence-based resources throughout a four-year baccalaureate nursing curriculum. Interventions designed to adapt knowledge to local context and overcome barriers to knowledge use included faculty workshop to increase awareness, instructional resources designed for courses and core content, curricular blueprint of key threads to be included within courses, shared resources on the school of nursing internal website, and development of decision support resources in French. Curricular change and sustained use of knowledge was evidenced by repeated use of guest lecturers, assignments, and problem-based scenarios in courses, and students' evaluations on the tutorial and assignments.

KEYWORDS: nursing curriculum, patient decision support, faculty development, shared decision making, decision coaching, implementation

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Nursing faculty members are involved in continuous curricular review and renewal to ensure that their program prepares graduates to meet the challenges of clinical practice. An emerging body of evidence is the availability of effective tools to facilitate patients' involvement in health decisions and the need for nurses to better support patients facing decisions that require weighing of benefits and harms across options (e.g. mode of birth delivery, breast cancer surgery, location of care at end of life). Current decision support in clinical practice is inadequate and nurses have identified the need for better training in how to address patients' decision support needs (O'Connor, Hogg, et al., 2006; Murray, Wilson, Stacey, & O'Connor, in press; Stacey, Graham, O'Connor, & Pomey, 2005; Wirrmann & Askham, 2006). The purpose of this curriculum project was to improve the knowledge and skills of faculty and undergraduate nursing students in patient decision support. The university's Research Ethics Board provided ethics approval. Faculty members had free choice to determine their level of participation in the project (e.g. attend workshops, provide feedback, and/or integrate learning activities in their courses).

The *Knowledge to Action Process* conceptual framework (Graham et al., 2006) was used to guide the process of introducing this evidence-based practice innovation to faculty and students. This framework is intended to guide the implementation of evidence in clinical practice and was determined to be relevant to the process for integrating evidence in curriculum. At the core of the framework is *knowledge creation* process. The circular *action cycle* begins with the recognition of a problem followed by identification, review, and selection of knowledge relevant to the problem. The knowledge is then adapted to the local context. Barriers to knowledge use are assessed and interventions are introduced to overcome known barriers. In the next phases, knowledge use is monitored, outcomes are evaluated, and strategies for sustained knowledge use are identified. The curricular innovation will be described in more detail according to each of the components of the *Knowledge to Action Process*.

Knowledge Creation

According to the *Knowledge to Action Process*, (Graham et al., 2006), *knowledge creation* can be conceptualized as an inverted pyramid of knowledge leading to more tailored knowledge that is based on individual studies, then synthesized with systematic reviews or practice guidelines, and finally transferred into tools or products that are relevant for use in clinical practice. In patient decision support, there is a large body of knowledge based on the *Ottawa Decision Support Framework* (O'Connor, Tugwell, et al., 1998) and related tools such as the Decisional Conflict Scale, (O'Connor, 1995), patient decision aids

(Coulter & Ellins, 2007), and interventions for integrating decision support in practice (Stacey, O'Connor, Graham, & Pomey, 2006).

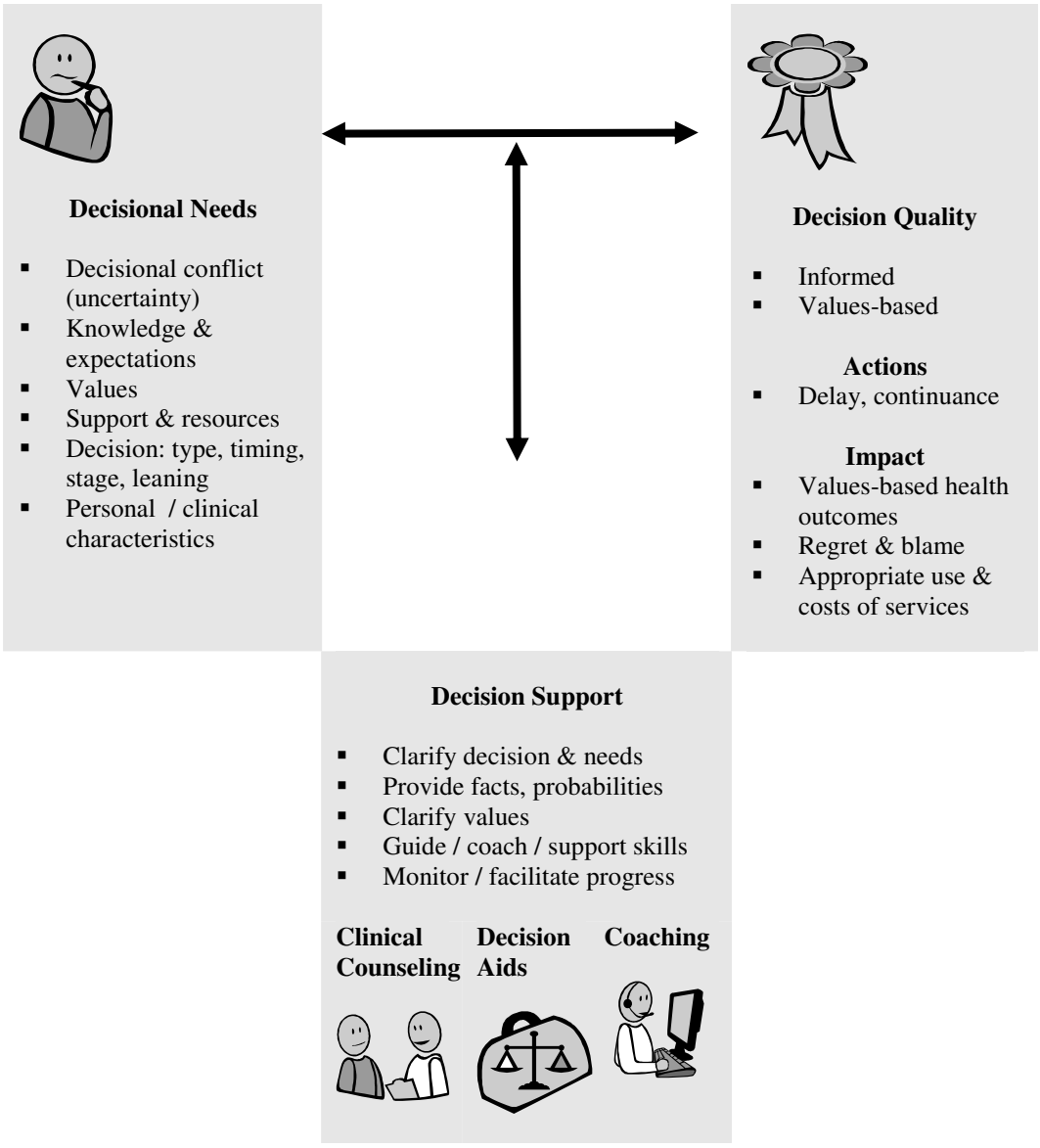

Figure. Ottawa Decision Support Framework.

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The *Ottawa Decision Support Framework* (Figure) is based on a nursing construct of decisional conflict (NANDA International, 2005) as well as theories from psychology, social psychology, economics, and social support (O'Connor, Tugwell, et al., 1998). Asserted in this framework is that the quality of decision-making can be adversely affected by decisional needs such as: decisional conflict (personal uncertainty about the best course of action); inadequate knowledge and unrealistic expectations; unclear values; inadequate support or resources; complex decision type; urgent timing; unreceptive stage of decision making; polarized leaning toward an option; and participants' characteristics (e.g. patients' cognitive limitations, poverty, limited education, or physical incapacitation). People whose decisional needs are unresolved after counseling are more likely to delay decisions, feel regret, express dissatisfaction, and blame the practitioner for poor outcomes (Gattellari & Ward, 2005; O'Connor, Sun, et al., 2005). However, decision support which is tailored to unresolved decisional needs can improve decision quality so that it is informed and based on personal values. Decision support involves: a) clarifying the decision and the person's needs; b) providing facts and probabilities; c) clarifying values; d) guiding/coaching/supporting in deliberation and communication; and e) monitoring/facilitating progress. Delivery of decision support depends on the context, but some combination of clinical counseling, decision tools, or coaching may be used. This framework has been used in multiple studies: to identify patients' decisional needs; to guide the development of patient decision aids and decision coaching tools; and to enhance health professionals' knowledge and skills in decision support (Legare, O'Connor, et al., 2006; O'Connor, Drake, et al., 1999; Stacey, O'Connor, et al., 2006).

Patient decision aids are used to translate evidence into patient-friendly tools that provide information on the benefits and harms of options, help clarify values for outcomes, and provide guidance in the decision making steps (O'Connor, Bennett, et al., 2007). A meta-systematic review of decision aid trials found that compared to usual care, patients exposed to decision aids had improved knowledge, more realistic expectations, decisions congruent with patients' values, and participated in decision making (Coulter & Ellins, 2007). When nurses involved in decision coaching used a decision aid to help patients clarify their values, it was more cost-effective (Kennedy et al., 2002).

Although patient involvement in health decisions is essential for patient centered care, patients frequently have unresolved decisional needs and current nursing practice is inadequate (Institute of Medicine, 2001; O'Connor, Bennett, et al., 2007; Registered Nurses' Association of Ontario [RNAO], 2006). In studies, it was revealed that nurses focus primarily on information provision, without addressing other needs such as unclear patients' values, inadequate support and

skills in decision making (Stacey, Graham, et al., 2005; Stacey, Chambers, Jacobsen, & Dunn, 2008). Despite the availability of patient decision aids, these resources have not been widely implemented in clinical practice or curriculum (Legare, Ratte, Gravel, & Graham, 2008).

Problem Identification

At this university, there was a lack of awareness and use of patient decision support resources by nursing students, and a lack of knowledge of decision support by faculty members. These observations were confirmed in an audit of the types of resources in course outlines for the 4-year undergraduate nursing program 2005-2006. Of 34 English program course outlines, only one course on nursing theories, included patient decision support references. This audit was limited by examining only easily accessible printed course outlines, because of the difficulties in accessing class materials posted on individual course websites.

In 2005 to 2007, a needs assessment was conducted with faculty members to determine the degree of decision support taught within their course(s), discuss the merits of including decision support, and explore factors influencing use of decision support, including need for instructional resources. Nineteen faculty members participated in an informal interview. Findings indicated that current teaching activities related to patient decision support were limited to a single 3-hour lecture in the nursing theories course offered in third year. Most faculty members were supportive of incorporating decision support within their course(s).

Adapt Knowledge to Local Context

The next step in the *action cycle* involved drafting a master plan for the integration of decision support as a thread throughout the 4-year nursing curriculum. The master plan aimed to have a stepwise approach to developing nursing students' decision support knowledge and skills (Table 1). To obtain internal support for the project in 2004, the plan was shared with the Director of the School of Nursing, and the Assistant Director of the Undergraduate Nursing program (the key decision-makers). A project advisory team was established that comprised faculty members and a graduate student that all had a strong interest in evidence-based nursing practice (the early adopters).

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Table 1.

Step-wise Building of Nursing Students' Decision Support Competencies

Year (clinical focus)	Overall objectives	Classroom lecture topics	Problem-based scenarios	Written assignments
I (health promotion with individuals)	To introduce patient decision making & influence of values on clinical decisions	Understand the influence of values on nursing practice* Support clients to be effective consumers & decision makers for lifestyle choices*	Students explored a personal decision that they were currently facing	1.1a Exploring the influence of patients & nurses values on health decisions
II (child-bearing & older families)	To identify the nurse's role in supporting families making decisions using patient decision support tools	Health decision making & the family for triage and values-sensitive decisions (English & French)*	2.1c-Circumcision; infant feeding 2.2c-Postpartum depression	2.1a Use of patient decision aids: maternity focus (English & French)* 2.1b Use of patient decision aids: birth control or tube feeding (English)
III (community health, acute care with adults & children, mental health)	To explore the ODSF & its relevance for clinical practice	ODSF as a mid-range nursing theory* Breast cancer patient decision making within 3-hr cancer nursing lecture*	3.1c-Lung cancer end of life care* 3.2c-Adolescent suicide*	3.1a Autotutorial with knowledge test* 3.2a Applying the ODSF*
IV (complex care, consolidating knowledge & skills)	To build & appraise decision coaching skills for supporting patients facing decisions in a complex care environment	Decision support skill building workshop* Address oncology patient information & decision support needs*	4.1c- Stroke rehabilitation	4.1a Critical appraisal of Patient Decision Coaching

Note. Lectures, problem-based cases, & assignments are publicly available.
* indicates those used with student. ODSF = Ottawa Decision Support Framework.

The proposed master plan was subsequently adapted to this school of nursing by tailoring the proposed levels for building decision support knowledge and skills to match the clinical focus within each of the years of the nursing program. For example, the initial objective in the master plan was to introduce patient decision support and the influence of values on clinical decisions. In the introductory nursing courses, the focus was limited to individual decision making without consideration of other family members, and decisions used were relevant to health promotion.

Assess Barriers to Knowledge Use

The faculty needs assessment, identified several barriers to integrating patient decision support (Table 2). These included: lack of faculty members' awareness of decision support resources and evidence to support their use; feeling of time pressure to teach previously established content; limited resources in French; and lack of instructional tools tailored to specific courses (e.g. presentations, problem-based case scenarios for small group seminars, exam questions, assignments related to decision support).

Select, Tailor, and Implement Interventions

Faculty development activities were designed to address the identified barriers and to facilitate implementation of patient decision support knowledge into the undergraduate curriculum (Table 2). For example in 2004, six full-time and part-time faculty members teaching in Year I attended a 90-minute workshop on patient decision support. The goal of the workshop was to increase faculty awareness of decision support resources for use in Year I courses and seminars. At a faculty-wide curriculum day in 2005, 56 faculty members received a 2-page newsletter profiling the various types of decision support resources, including a website of patient decision support resources and the Healthwise Handbook. The Handbook is a self-care manual for patients making basic decisions about home treatment, when to call a doctor, and lifestyle choices to improve health.

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Table 2

Interventions for Barriers to Integrating Decision Support in Curriculum

Barrier	Data source	Interventions to overcome barriers
Lack of awareness of decision support	Faculty interviews	▪ provided faculty education workshops ▪ created 2-page newsletter of decision support resources
Limited resources in French	Faculty interviews	▪ identified French resources ▪ translated class lectures in French ▪ planned to seek funding to translate the tutorial
Felt time pressure to teach core content	Faculty interviews	▪ integrated core content (e.g. oncology) as content to discuss decision support
Lack of instructional resources for courses	Faculty interviews	▪ developed problem based scenarios, lectures, and assignments for specific courses
Lack of common location to share curriculum resources	Research team	▪ added decision support instructional resources to www.ohri.ca/decisionaid ▪ placed decision support instructional resources on school of nursing website
Academic freedom in course design	Faculty interviews	▪ planned to draft a curricular blueprint that identifies key threads and concepts for specific courses

Faculty members who were open to incorporating patient decision support within their course(s) identified the needed instructional resources (Table 1). These resources were based on the original curricular plan for building of knowledge across the curriculum. For example, presentations were developed about decision support and tailored to the specific course with related exam questions. As well, problem-based case scenarios and new learning assignments

were created. To ensure realistic and accurate scenarios, the problem-based case scenarios and assignments were also reviewed by clinical experts that included advanced practice nurses and physicians.

In Year I, two presentations were provided: the influence of patients' and nurses' values on decision making and the processes used by patients to make health decisions (Table 1). The learning activities in Year II further developed their understanding by having students explore the use of decision support tools to facilitate decision making within families. Case studies in Year II seminars were designed to facilitate discussion of decisions, values, and resources to support patients' participation in decision making.

To assess student learning of the new curricular concepts, assignments were created and tailored to the level of the learner. For example, in a Year II course focused on the care of child bearing and older families, the learning assessment activity included a 4-page assignment where students were instructed to critically examine a patient decision aid (Table 3). The assignment objectives, guidelines, and marking criteria remained consistent for several years (2005 to 2008). To discourage plagiarism, the clinical scenario changed each year (e.g., decisions related to amniocentesis, vaginal birth after cesarean, infant feeding, circumcision, and tube feeding in a frail senior). One month prior to the assignment submission deadline, students received a class lecture on decision support for families. In 2006, students chose either the clinical scenario on birth control (n=67) or tube feeding (n=47), and the mean grade was 72% (range 42 to 95%). Students scoring greater than 85% were invited to present their assignment to the entire class. The faculty member, who did not self-identify as an expert in decision support, said "*I feel that this was the best learning strategy of the term*".

All faculty members and students in the English and French streams of Years I and II in the nursing program received a copy of the Healthwise Handbook and access to the related online information, including patient decision aids. This information source was selected because it includes decision support resources and is used by members of health plans in the United States, and by residents living within several Canadian provinces. Faculty and students in Year I were encouraged to use the patient decision support resources for personal health issues. Students in Year II were also encouraged to use these resources as part of the course assignment described above.

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Table 3

Assignment to Explore Resources for Providing Decision Support

Objectives	▪ describe the concept of decisional conflict ▪ discuss the nurses' role in helping clients make informed, values-based decisions ▪ describe the role of other health team members ▪ write an academic paper with interventions justified by literature
Scenario	Ms. D is a 32-year-old woman who gave birth to a healthy daughter yesterday and is breastfeeding. In a routine postpartum assessment, she expresses uncertainty about what birth control method to use. Although she has a history of infertility problems, after the birth of her first daughter 18 months ago (conceived using fertility drugs) she became pregnant. Now, she and her husband do not plan to have more children and are concerned about subsequent pregnancies. Ms. D would prefer not to take daily pills for birth control but she is unsure about the success with other birth control methods, including sterilization.
Assignment Structure / Grading Scheme	1. Introduction (20%): describe decisional conflict in this family 2. Literature (25%): describe risks and benefits of options supported by evidence from at least 3 references 3. Clinical Interventions (25%): select and describe a patient decision aid that could be used with this family; justify the choice of this patient decision aid; describe the role of nursing in coaching clients to make informed, values-based decisions; describe the role of other healthcare providers in decision making 4. Conclusion (20%): describe key highlights of the paper 5. Format (10%): 5-pages typed; references to scholarly literature

In 2006, the *Ottawa Decision Support Framework* lecture provided in the Year III nursing theories class was changed from an in-class learning activity to an online self-directed tutorial. The rationale for this change was to expose students to a publicly available resource for which they could have ongoing access (in the program and after graduation). To assess student learning from the tutorial, the final test in the tutorial accounted for 5% to 15% of their final course grade as determined by the faculty member. The three cohorts of students had median scores of 83% (N=78), 90% (N=110), and 92% (N=92) on the final tutorial test (range 29.2-100%). Overall, the students were highly satisfied with the tutorial as a method of learning. For example, one student said *"I think it was great, easy to understand and provided only relevant information."* In response to the questions provided as a review at the end of each section another student said *"I found it especially helpful that when a question was answered incorrectly, there was a rationale provided as to why it was incorrect."* Students suggested that the tutorial could be strengthened by having more case studies *"to improve guidance and understanding of how to work through the ODST* (Ottawa Decision Support Tutorial)*"*, *"things in point form"* and *"more focus on mental health"*.

Problem-based case scenarios were created based on the standardized format proposed by Rideout (2001), with the aim to further develop nursing students' critical thinking and application of decision support knowledge and skills. Some scenarios included decision support as central to the problem (e.g. prostate cancer decision to stop treatment with family pressure to continue treatment); while others included decision support more peripheral to the problem (e.g. anti-depressant medication decision for suicidal adolescent) (see Table 1). For example, the case focused on an adolescent girl who had undertaken several suicide attempts and was expressing uncertainty in trying a new anti-depressant due to previous side effects with other anti-depressants. Students are expected to identify the decisional conflict and contributing factors, and subsequently explore treatment options for depression, available decision tools, and evidence-based references to support or refute these options. All problem-based learning cases consisted of a case scenario, pertinent chart data and a tutor guide including references. Students verbalized that the cases were "*realistic*" and *"relevant to their clinical practicum experiences"*.

Monitor Knowledge Use

According to the *Knowledge to Action Process*, after the initial implementation of the intervention, monitoring use involves assessing changes in levels of knowledge, understanding, attitudes, and behaviours (Graham et al., 2006). In this project, there was faculty support for the integration of decision

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support throughout the undergraduate curriculum, as evidenced by the eight initial guest speaker invitations for courses (6 English, 2 French) and use of problem-based scenarios and assignments (Table 1). Lectures were given by one faculty member and/or graduate student. Moreover, there was repeated use of learning activities and assignments over multiple academic years, even when faculty members responsible for courses changed between 2005 and 2008. Although the original plan was to concentrate on the junior years of the program in English only, there were requests for presentations and access to the assignments as other faculty informally became aware of the curriculum project.

Knowledge use among students was observed in the course assignments described above. More recently, part-time faculty members involved in supervising students in their clinical placements have requested an educational session on patient decision support so they can better support their students using this knowledge within their clinical placements. Student's knowledge of the *Ottawa Decision Support Framework* and related resources, critical thinking and application of decision support resources was measured within the online tutorial, small group seminars, examination questions, and written learning assignments.

Evaluate Outcomes and Sustained Knowledge Use

The next two phases of the *Knowledge to Action Process* target: a) evaluating the impact of knowledge use on health outcomes, practitioners, and health systems; and b) re-assessing the barriers and facilitators for ongoing sustainable knowledge use (Graham et al., 2006). For this project, more formal evaluation is required to evaluate the impact of integrating decision support in the nursing curriculum on outcomes at the level of the faculty member, student, and patient. More specifically, a study should be designed to measure the impact of integrating decision support on faculty teaching outcomes and on whether students providing decision support improves patients' involvement in discussing decisions with their physicians and surgeons.

During the curriculum implementation process, there were several barriers identified by the faculty that had the potential to interfere with sustained use of decision support within the curriculum. These barriers included, lack of resources available in French, faculty autonomy in course design, lack of a system to share curriculum resources with current and new faculty (Table 2). To address the lack of instructional resources available in French, French language resources were located that included decision aids (*La vasectomie: est-ce le bon choix pour moi?; Faire des choix: l'installation d'une sonde d'alimentation a long terme chez les*

patients âgés), or English versions translated (e.g. class presentations). Currently, funding is being sought to translate the decision support tutorial into French.

Some faculty members expressed concern about being required to teach decision support, versus academic freedom to choose what is taught in their assigned course. As a result, the sustained use of the decision support instructional activities over time will be strongly influenced by which faculty members are assigned to specific courses. One initiative to overcome this issue is to seek faculty agreement for a curricular blueprint that identifies key curricular threads and concepts to be integrated into specific courses.

Another barrier was a lack of an organized system to be able to share decision support resources among faculty and students. Access to individual courses is limited to students registered for the course, or to others given special permission. To address this barrier, the curriculum resources (e.g. problem-based scenarios, assignments) and the tutorial were made publicly available on a research website at www.ohri.ca/decisionaid. These available assignments and problem-based scenarios can be easily adapted to other health decisions and clinical situations. Given the change of faculty course assignments from year to year, it has also been necessary to make contact with the newly assigned faculty to inform them of the range of decision support instructional activities available and/or previously used.

In response to ongoing requests for faculty support, they are routinely referred to the publicly available resources, offered individual discussion on use of resources within their course(s) including guest lectures, and/or if appropriate invited to workshops. For example, in spring 2008, there was a half-day workshop for faculty members on integrating threads such as decision support within the curriculum. A recent request for a workshop by the large academic teaching hospital directly associated with the university was stimulated by students' discussions about patient decision support with nursing staff in clinical areas.

DISCUSSION

This is the first known curriculum project to focus on implementing evidence-based patient decision support within an existing nursing curriculum. Overall, most faculty members in the School of Nursing were very positive and supportive of working with the project team to develop resources for use within their courses, to incorporate guest presentations relevant to their courses, and to evaluate student learning using focused exam questions and assignments. However, some remaining barriers are likely to interfere with longer-term

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sustainable integration of decision support in the curriculum. Furthermore, there is a need for ongoing monitoring of barriers and for research to evaluate the impact of these curricular initiatives on patient care.

Findings from this curriculum project are similar to other studies that focused on integrating new curriculum content and/or implementation of decision support with health care professionals' practices. The barriers identified are consistent with others who have reported that curriculum change is frequently met with resistance by faculty who may be reluctant to embrace change (Iwasiw, Goldenberg, & Andrusyszyn, 2005), or cite academic freedom as the rationale for maintaining the status quo (Larson, 1997). In another study to determine applicability of the *Ottawa Decision Support Framework* for use in primary care, clinical practices reported similar barriers by 118 health care professionals (mostly physicians) such as being unfamiliar with the topic, lack of time, perception of topic not being relevant, need for practical tools, forgetting, and challenge to autonomy to make practice decisions (Legare, O'Connor, et al., 2006). Studies involving over 100 call centre health professionals (mostly nurses) identified that the most common barriers to providing decision support were lack of time, lack of knowledge and skills, and lack of clear organizational mandate (Stacey, O'Connor, et al., 2006; Stacey, Chambers, et al., 2008). Although lack of time is commonly identified, the length of time for nurses to provide decision support is not necessarily longer than when nurses provide information only (Stacey, Pomey, O'Connor, & Graham, 2006).

The *Knowledge to Action Process* (Graham et al., 2006) was a useful conceptual framework to guide faculty development and the integration of new knowledge into an existing undergraduate curriculum. The majority of studies in which knowledge translation was investigated, have focused on health care professionals in the practice context (Grol, Wensing & Eccles, 2005). It is equally important that the faculty teaching in both classroom and clinical courses incorporate evidence-based decision support into their courses. Despite extensive literature on the importance of developing a process-focused curriculum, many faculty members continue to develop their courses using a content-based approach (Rideout, 2001). Integrating evidence-based patient decision support needs to be viewed as a process of supporting patients that is applicable across numerous health conditions, social situations, and clinical practice environments.

Although the decision support implementation project was not evaluated extensively, students' evaluations revealed that they had learned key concepts relevant to patient decision support. Students' scores of 83% or higher on the final tutorial test was either similar or better than health care professionals in practice.

For example, nurses scored 60% control group versus 74% post tutorial and health professionals in a cancer call centre had 61% pre and 84% post tutorial (Stacey, Pomey, et al., 2006; Stacey, Chambers, et al., 2008). Requests for repeat lectures and more workshops were additional indicators of success.

CONCLUSION

To better meet the needs of patients and to achieve patient-centered care, nurses should enhance their decision support knowledge and skills. One approach is to embed evidence-based approaches for nurses to provide decision support within nursing curricula. A stepped approach to developing decision support competencies being used at a school of nursing, involves increasing students' awareness of decision making needs of patients and resources to support patients, and immersing students in learning activities to increase their knowledge, skills, and competencies in providing decision support. Learning activities such as problem-based clinical case scenarios, online self-paced tutorial, and assignments are publicly available for use in healthcare professional curriculum.

Subsequent research is needed to measure the effect of curricular changes on patient outcomes and the effect on the patient-practitioner decision making. Conceptual models inclusive of the nurses' role in providing decision support within the broader interprofessional health care team could further enhance teaching to nursing students. A new interprofessional approach to shared decision making conceptual model for use in clinical practice, education and research is being validated (Legare, Stacey, et al., 2008). Finally, the *Knowledge to Action Process* conceptual model was helpful in guiding the integration of patient decision support in curriculum and could be considered for other curriculum change initiatives requiring the integration of scientific knowledge.

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Decision aids for people facing health treatment or screening decisions (Review)

Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L

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[Intervention Review]

Decision aids for people facing health treatment or screening decisions

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ABSTRACT

Background

Decision aids are interventions that support patients by making their decisions explicit, providing information about options and associated benefits/harms, and helping clarify congruence between decisions and personal values.

Objectives

To assess the effects of decision aids in people facing treatment or screening decisions.

Search methods

Updated search (2012 to April 2015) in CENTRAL; MEDLINE; Embase; PsycINFO; and grey literature; includes CINAHL to September 2008.

Selection criteria

We included published randomized controlled trials comparing decision aids to usual care and/or alternative interventions. For this update, we excluded studies comparing detailed versus simple decision aids.

Data collection and analysis

Two reviewers independently screened citations for inclusion, extracted data, and assessed risk of bias. Primary outcomes, based on the International Patient Decision Aid Standards (IPDAS), were attributes related to the choice made and the decision-making process.

Secondary outcomes were behavioural, health, and health system effects.

We pooled results using mean differences (MDs) and risk ratios (RRs), applying a random-effects model. We conducted a subgroup analysis of studies that used the patient decision aid to prepare for the consultation and of those that used it in the consultation. We used GRADE to assess the strength of the evidence.

Main results

We included 105 studies involving 31,043 participants. This update added 18 studies and removed 28 previously included studies comparing detailed versus simple decision aids. During the 'Risk of bias' assessment, we rated two items (selective reporting and blinding of participants/personnel) as mostly unclear due to inadequate reporting. Twelve of 105 studies were at high risk of bias.

With regard to the attributes of the choice made, decision aids increased participants' knowledge (MD 13.27/100; 95% confidence interval (CI) 11.32 to 15.23; 52 studies; N = 13,316; high-quality evidence), accuracy of risk perceptions (RR 2.10; 95% CI 1.66 to 2.66; 17 studies; N = 5096; moderate-quality evidence), and congruency between informed values and care choices (RR 2.06; 95% CI 1.46 to 2.91; 10 studies; N = 4626; low-quality evidence) compared to usual care.

Regarding attributes related to the decision-making process and compared to usual care, decision aids decreased decisional conflict related to feeling uninformed (MD −9.28/100; 95% CI −12.20 to −6.36; 27 studies; N = 5707; high-quality evidence), indecision about personal values (MD −8.81/100; 95% CI −11.99 to −5.63; 23 studies; N = 5068; high-quality evidence), and the proportion of people who were passive in decision making (RR 0.68; 95% CI 0.55 to 0.83; 16 studies; N = 3180; moderate-quality evidence).

Decision aids reduced the proportion of undecided participants and appeared to have a positive effect on patient-clinician communication. Moreover, those exposed to a decision aid were either equally or more satisfied with their decision, the decision-making process, and/or the preparation for decision making compared to usual care.

Decision aids also reduced the number of people choosing major elective invasive surgery in favour of more conservative options (RR 0.86; 95% CI 0.75 to 1.00; 18 studies; N = 3844), but this reduction reached statistical significance only after removing the study on prophylactic mastectomy for breast cancer gene carriers (RR 0.84; 95% CI 0.73 to 0.97; 17 studies; N = 3108). Compared to usual care, decision aids reduced the number of people choosing prostate-specific antigen screening (RR 0.88; 95% CI 0.80 to 0.98; 10 studies; N = 3996) and increased those choosing to start new medications for diabetes (RR 1.65; 95% CI 1.06 to 2.56; 4 studies; N = 447). For other testing and screening choices, mostly there were no differences between decision aids and usual care.

The median effect of decision aids on length of consultation was 2.6 minutes longer (24 versus 21; 7.5% increase). The costs of the decision aid group were lower in two studies and similar to usual care in four studies. People receiving decision aids do not appear to differ from those receiving usual care in terms of anxiety, general health outcomes, and condition-specific health outcomes. Studies did not report adverse events associated with the use of decision aids.

In subgroup analysis, we compared results for decision aids used in preparation for the consultation versus during the consultation, finding similar improvements in pooled analysis for knowledge and accurate risk perception. For other outcomes, we could not conduct formal subgroup analyses because there were too few studies in each subgroup.

Authors' conclusions

Compared to usual care across a wide variety of decision contexts, people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably have a more active role in decision making and more accurate risk perceptions. There is growing evidence that decision aids may improve values-congruent choices. There are no adverse effects on health outcomes or satisfaction. New for this updated is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation. Further research is needed on the effects on adherence with the chosen option, cost-effectiveness, and use with lower literacy populations.

PLAIN LANGUAGE SUMMARY

Decision aids to help people who are facing health treatment or screening decisions

Review question

We reviewed the effects of decision aids on people facing health treatment or screening decisions. In this update, we added 18 new studies for a total of 105.

Background

Making a decision about the best treatment or screening option can be hard. People can use decision aids when there is more than one option and neither is clearly better, or when options have benefits and harms that people value differently. Decision aids may be pamphlets, videos, or web-based tools. They state the decision, describe the options, and help people think about the options from a personal view (e.g. how important are possible benefits and harms).

Study characteristics

For research published up to April 2015, there were 105 studies involving 31,043 people. The decision aids focused on 50 different decisions. The common decisions were about: surgery, screening (e.g. prostate cancer, colon cancer, prenatal), genetic testing, and medication treatments (e.g. diabetes, atrial fibrillation).The decision aids were compared to usual care that may have included general information or

no intervention. In the 105 studies, 89 evaluated a patient decision aid used by people in preparation for the visit with the clinician, and 16 evaluated its use during the visit with the clinician.

Key results with quality of the evidence

When people use decision aids, they improve their knowledge of the options (high-quality evidence) and feel better informed and more clear about what matters most to them (high-quality evidence). They probably have more accurate expectations of benefits and harms of options (moderate-quality evidence) and probably participate more in decision making (moderate-quality evidence). People who use decision aids may achieve decisions that are consistent with their informed values (evidence is not as strong; more research could change results). People and their clinicians were more likely to talk about the decision when using a decision aid. Decision aids have a variable effect on the option chosen, depending on the choice being considered. Decision aids do not worsen health outcomes, and people using them are not less satisfied. More research is needed to assess if people continue with the option they chose and also to assess what impact decision aids have on healthcare systems.

SUMMARY OF FINDINGS

Summary of findings for the main comparison.

Patient decision aids compared with usual care for adults considering treatment or screening decisions

Patient or population: adults considering treatment or screening decisions

Settings: all settings

Intervention: patient decision aid

Comparison: usual care

Outcomes	Illustrative comparative benefits* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed benefit	Corresponding benefit				
	Usual care	Patient decision aid				
Knowledge - all studies Standardized on score from 0 (no knowledge) to 100 (perfect knowledge), soon after exposure to the decision aid	The mean knowledge score was 56.9% across control groups, ranging from 27.0% to 85.2%	The mean knowledge score in the intervention groups was 13.27 higher (11.32 to 15.23 higher)	—	13,316 (52 studies)	⊕⊕⊕⊕ **High** [a,b]	Higher scores indicate better knowledge. 46 out of 52 studies showed a statistically significant improvement in knowledge
Accurate risk perceptions - all studies Assessed soon after exposure to the decision aid	**269 per 1000** [c]	**565 per 1000** (447 to 716 per 1000)	**RR 2.10** (1.66 to 2.66)	5096 (17 studies)	⊕⊕⊕⊖ **Moderate** [a,d]	—
Congruence between the chosen option and informed values - all studies Assessed soon after exposure to the decision aid	**289 per 1000** [c]	**595 per 1000** (422 to 841 per 1000)	**RR 2.06** (1.46 to 2.91)	4626 (10 studies)	⊕⊕⊖⊖ **Low** [a,d,e,f]	—
Decisional conflict: uninformed subscale - all studies	The mean for outcome 'feeling uninformed'	The mean feeling uninformed in the intervention groups was	—	5707 (27 studies)	⊕⊕⊕⊕ **High** [a,b]	Lower scores indicate feeling more informed

Standardized on score from 0 (not uninformed) to 100 (uninformed) Assessed soon after exposure to the decision aid	ranged across control groups from 11.1 to 61.1. Scores ≤ 25 associated with following through on decisions. Scores > 38 associated with delay in decision making	9.28 lower (12.20 to 6.36 lower)				
Decisional conflict: unclear about personal values subscale - all studies Standardized on score from 0 (not unclear) to 100 (unclear) Assessed soon after exposure to the decision aid	The mean for outcome 'feeling unclear about personal values' ranged across control groups from 15.5 to 53.2. Scores ≤ 25 associated with follow-through with decisions. Scores > 38 associated with delay in decision making	The mean feeling unclear values in the intervention groups was 8.81 lower (11.99 to 5.63 lower)	—	5068 (23 studies)	⊕⊕⊕⊕ **High** [a,b]	Lower scores indicate feeling clearer about values
Participation in decision making: clinician-controlled decision making - all studies Assessed soon after consultation with clinician	**228 per 1000** [c]	**155 per 1000 (125 to 189 per 1000)**	**RR 0.68** (0.55 to 0.83)	3180 (16 studies)	⊕⊕⊕⊖ **Moderate** [a,e]	Patient decision aids aim to increase patient involvement in making decisions; lower proportion of clinician-controlled decision making is better
Adverse events	There were no adverse effects on health outcomes or satisfaction, and no other adverse effects reported.					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR**: risk ratio

GRADE Working Group grades of evidence
High quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: we are very uncertain about the estimate.

[a]The vast majority of studies measuring this outcome were not at high risk of bias.
[b]The GRADE ratings for these outcomes were not downgraded for heterogeneity given the generally consistent direction of effects across studies for the decision aid compared to usual care groups.
[c]The data source for the assumed risk was the mean control event rate.
[d]The GRADE rating was downgraded given the lack of precision.
[e]The GRADE rating was downgraded given the lack of consistency.
[f]The GRADE rating was downgraded given the lack of directness. As well, the outcome was measured using various approaches with no gold standard approach.

BACKGROUND

Many health treatment and screening decisions have no single 'best' choice. These types of decisions are considered 'preference-sensitive' because there is insufficient evidence about outcomes or there is a need to trade off known benefits and harms. *Clinical Evidence* analyzed 3000 treatments, classifying 50% as having insufficient evidence, 24% as likely to be beneficial, 7% as requiring trade-offs between benefits and harms, 5% as unlikely to be beneficial, 3% as likely to be ineffective or harmful, and only 11% as being clearly beneficial (Clinical Evidence 2013). Not only does one have to take into account the strength of the evidence, but even for the 11% of treatments that show beneficial effects for populations, physicians need to translate the probabilistic nature of the evidence for individual patients to help them reach a decision based on informed values. Patient decision aids are an intervention that can be used to present such evidence (Brouwers 2010). This review is an update of the review last published in 2014 of the comparisons between patient decision aids and usual care (Stacey 2014b). To provide a more focused review, we removed 28 studies that compared detailed versus simple decision aids.

Description of the intervention

According to the International Patient Decision Aids Standards (IPDAS) Collaboration (Elwyn 2006; IPDAS 2005a; Joseph-Williams 2013), decision aids are evidence-based tools designed to help patients make specific and deliberated choices among healthcare options. Patient decision aids supplement (rather than replace) clinicians' counselling about options. The specific aims of decision aids and the type of decision support they provide may vary slightly, but in general they:

1. explicitly state the decision that needs to be considered;
2. provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties;
3. help patients to recognize the values-sensitive nature of the decision and to clarify, either implicitly or explicitly, the value they place on the benefits and harms. (To accomplish this, patient decision aids may describe the options in enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects, or they may guide clients to consider which benefits and harms are most important to them.)

Decision aids differ from usual health education materials. Decision aids make the decision being considered explicit, providing a detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making. In contrast, health education materials help people to understand their diagnosis, treatment, and management in general terms, but given their broader perspective, these materials are not focused on decision points and thus do not necessarily help them to participate in decision making. Many decision aids are based on a conceptual model or theoretical framework (Durand 2008; Mulley 1995; O'Connor 1998b; Rothert 1987).

In response to concerns about variability in the quality of patient decision aids, the IPDAS Collaboration reached agreement on criteria for judging their quality (Elwyn 2006). More than 100 researchers, clinicians, patients, and policymakers from 14 countries participated. Participants addressed three domains of quality: clinical content, development process, and evaluation of a patient decision aid's effectiveness. A series of background papers informing the original IPDAS criteria were updated in 2013 (IPDAS 2013). Subsequently, an international team of researchers reached consensus on a shorter set of qualifying and certifying criteria (Joseph-Williams 2013). Informed by IPDAS, the Washington State Health Authority launched the first programme for certifying patient decision aids in 2016 (Washington State 2016).

How the intervention might work

Decision aids can be used before, during, or after a clinical encounter to enable patients to become active, informed participants. Providing the patient decision aid in preparation for the consultation allows people more time to digest the information and be ready to discuss the decision, but this may not be feasible in some health decisions (e.g. antibiotics for upper respiratory infections). Decision aids can also facilitate shared decision making. Shared decision making is defined as a process through which clinicians and patients make healthcare choices together (Charles 1997; Makoul 2006), representing the crux of people-centred care (Weston 2001). However, the way the clinician provides information may strongly affect people's preferences (Hibbard 1997), prompting the need for standardized information such as patient decision aids. Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences (Hibbard 2013; Kiesler 2006). In summary, patient decision aids may help clinicians and patients come to quality decisions, grounded in patients' values and taking into account the potential trade-offs in benefits and risks of different options.

Why it is important to do this review

Given the broad range of stakeholders interested in patient decision aids and the rapidly expanding field of research, there was a need to update this review to identify studies on new decisions or conducted in new countries and to strengthen the synthesized evidence supporting use of patient decision aids for outcomes that do not yet have high-quality evidence. In fact, the 2014 publication was the most cited Cochrane Review in 2015 based on 1888 reviews published in 2013 and 2014. With growing development of patient decision aids for use in the consultation, we wanted to conduct a subgroup analysis of patient decision aids used in preparation for versus within the consultation.

Results from previous reviews were used to inform clinical practice guidelines such as Patient Experience in Adult NHS Services (NCGC/NICE 2012) and Decision Support for Adults Living with Chronic Kidney Disease (RNAO 2009). Subgroup analyses of included studies have focused on anxiety (Bekker 2003), adherence (Trenaman 2016), values congruence (Munro 2016), participant trial identity (Brown 2015), and heterogeneity (Gentles 2013).

Other systematic reviews have been conducted on the use of patient decision aids as one type of intervention to facilitate shared decision making in clinical practice (Coyne 2013; Duncan 2010; Elwyn 2013; Legare 2010; Legare 2014).

OBJECTIVES

To assess the effects of decision aids in people facing treatment or screening decisions.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published studies that used a randomized controlled trial (RCT) design evaluating patient decision aids.

Types of participants

We included studies involving adults aged 18 years or older who were making decisions about screening or treatment options for themselves, a child, or an incapacitated significant other. We excluded studies in which participants were making hypothetical choices.

Types of interventions

We included studies that evaluated a patient decision aid as part of the intervention. Decision aids were defined as interventions designed to help people make specific and deliberated choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) information on the options and outcomes relevant to a person's health status as well as implicit methods to clarify values. The aid also may have included: information on the disease/condition; costs associated with options; probabilities of outcomes tailored to personal health risk factors; an explicit values clarification exercise; information on others' opinions; a personalized recommendation on the basis of clinical characteristics and expressed preferences; and guidance or coaching in the steps of making and communicating decisions with others.

We excluded studies if interventions focused on: decisions about lifestyle changes, clinical trial entry, or general advance directives (e.g. do not resuscitate); education programmes not geared to a specific decision; and interventions designed to promote adherence or elicit informed consent regarding a recommended option. We also excluded studies when the relevant decision aid(s) were not available to us and not adequately described in the article(s), because we could not determine the aids' characteristics and whether or not they met the minimum criteria to qualify as patient decision aids.

Types of comparisons

We included studies that compared patients exposed to a patient decision aid to patients in comparison groups that were exposed to usual care, general information, clinical practice guideline, placebo intervention, or no intervention. For the purposes of this review, we refer to all such control comparisons as 'usual care'.

We excluded studies that compared two different types of patient decision aids.

Types of outcome measures

To ascertain whether the decision aids achieved their objectives, we examined a broad range of outcomes. Although the decision aids focused on diverse clinical decisions, many had similar objectives such as improving knowledge scores, the accuracy of risk perceptions, and participation in decision making. Many of these evaluation criteria mapped onto the International Patient Decision Aids Standards (IPDAS) criteria for evaluating the effectiveness of decision aids (Elwyn 2006; IPDAS 2005b; Sepucha 2013). The IPDAS criteria were attributes related to the choice (e.g. match between the chosen option and the features that matter most to the informed patient) and to the decision-making process (e.g. helps patients to recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the features that matter most; discuss values with their clinician; and become involved in their preferred ways). A complete list of outcomes, specified in advance of the review, included primary and secondary outcomes.

Primary outcomes

Evaluation criteria that map onto the IPDAS criteria

- Attributes of the choice made: does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient (demonstrated by outcomes such as knowledge, accurate risk perceptions, values-choice congruence)?
- Attributes of the decision-making process: does the patient decision aid help patients to recognize that a decision needs to be made, feel informed about the options and their features, be clear about the option features that matter most, discuss values with their clinician, and become involved in decision making?

Other decision-making process variables

- Decisional conflict
- Patient-clinician communication
- Participation in decision making
- Proportion undecided
- Satisfaction with the choice, with the process of decision making, and with the preparation for decision making

Secondary outcomes

Behaviour

- Choice (the actual choice implemented; if not reported, the participants' preferred option was used as a surrogate measure)
- Adherence to chosen option

Health outcomes

- Health status and quality of life (generic and condition-specific)
- Anxiety, depression, emotional distress, regret, confidence

Healthcare system

- Costs, cost-effectiveness
- Consultation length
- Litigation rates

Search methods for identification of studies

Our search strategy for the review included:

1. searching electronic medical and social science databases; and
2. searching other resources.

Electronic searches

For this update, we used the same search strategy that was revised by the Trials Search Coordinator at the Cochrane Consumers and Communication Group in the last update (Stacey 2014b).

Therefore, the cumulative search of electronic databases is as follows.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 6) in the Cochrane Library (searched to 24 April 2015).
- MEDLINE Ovid (1966 to 24 April 2015).
- Embase Ovid (1980 to 24 April 2015).
- PsycINFO Ovid (1806 to 24 April 2015).
- CINAHL Ovid (1982 to September 2008), then in Ebsco (to 24 April 2015).

We present the search strategies in Appendix 1 and Appendix 2.

Searching other resources

On 18 December 2015 we also searched trial registries (World Health Organization, ClinicalTrials.gov), the Internet using Google and Google Scholar, and the Decision Aid Library Inventory (decisionaid.ohri.ca). Finally, reference lists of all newly included trials were searched.

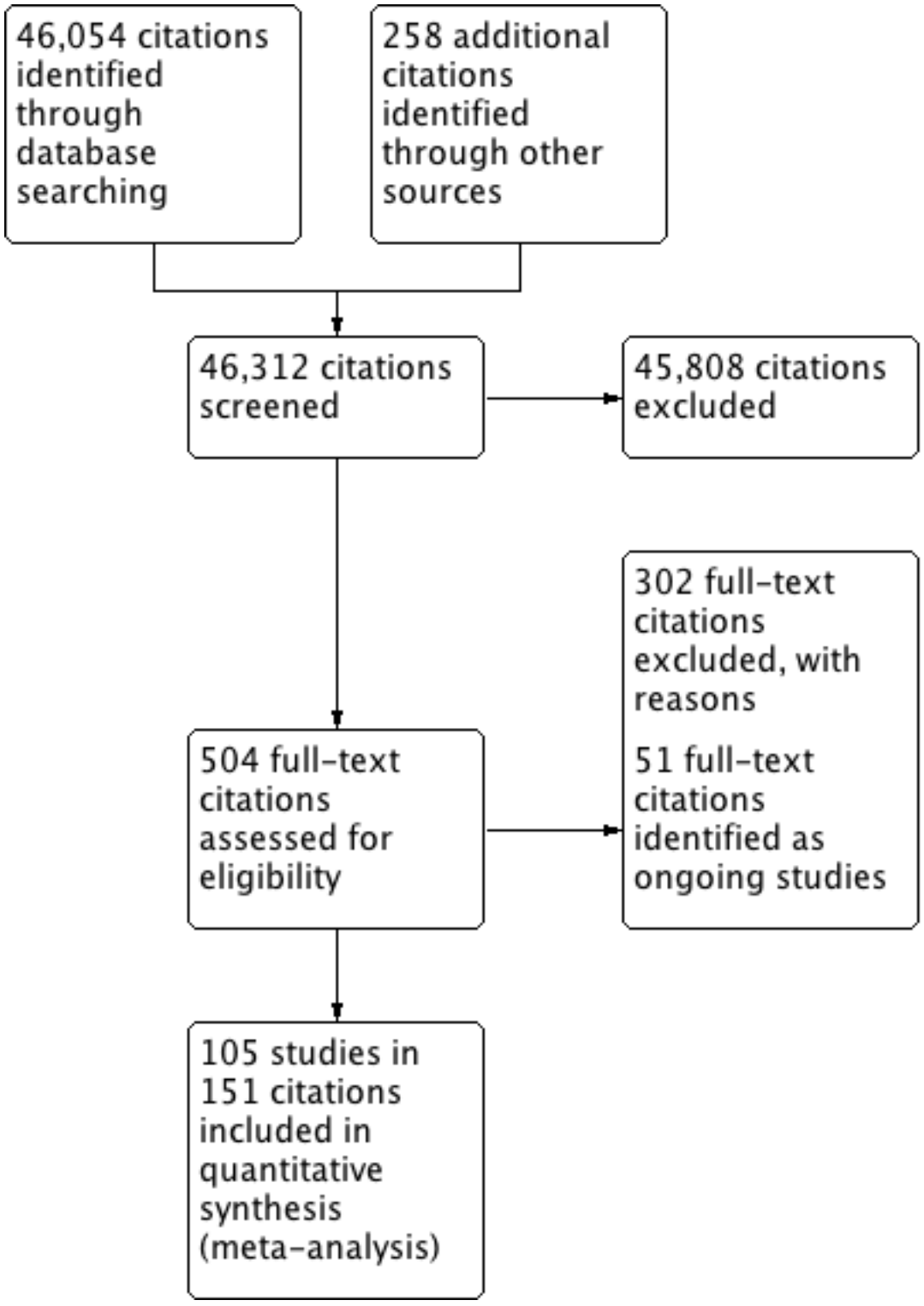
Data collection and analysis

For this current update, we focused only on new publications that had appeared since the previous publication (Stacey 2014b), and we limited the inclusion to patient decision aids versus usual care. As such, we removed studies from the previous reviews that compared detailed versus simple patient decision aids to provide a more focused review.

Selection of studies

Pairs of eight review authors (CB, DS, RT, MB, MHR, KE, NC, DR) screened all identified citations. We retrieved the full text of any papers identified as potentially relevant by at least one author, listing all papers excluded from the review at this stage, with reasons, in the 'Characteristics of excluded studies' table. We also provided citation details and any available information about ongoing studies, and we collated and reported details of additional publications, so that each study (rather than each report) was the unit of interest. We report the screening and selection process in Figure 1.

Figure 1. Study flow diagram.



Data extraction and management

Two research assistants extracted data independently (KL, IS). We compared findings and resolved inconsistencies through discussion with the principal investigator (DS) and, when necessary, with a co-author (CB). No review authors extracted data for their own studies in this update nor in any other versions of this review.

One review author entered all extracted data into Review Manager 5 (RevMan 5), and a second one worked independently to check for accuracy against the data extraction sheets (RevMan 2014).

Assessment of risk of bias in included studies

Two research assistants independently appraised studies using the Cochrane 'Risk of bias' tool (current update: KL, IS) (Higgins 2011, Chapter 8). We judged each item as conferring high, low, or unclear risk of bias as set out in the criteria provided by Higgins 2011, and we provided a quote from the study report and a justification for our judgement for each item in the 'Risk of bias' table. For the item on 'other' potential sources of bias, the assessment included: whether the same clinician provided consultation to both the intervention and usual care groups with measures taken postconsultation, whether clustering was accounted for in the analysis; and potential sources of bias reported by the authors in the study limitations.

We resolved inconsistencies by discussion with the principal investigator (DS) and, when necessary, with a co-author (CB). No review authors appraised risk of bias for their own studies in this update nor in any other versions of this review.

Studies were deemed to be at the highest risk of bias if they were scored as at high risk on any of the items of the risk of bias tool (Higgins 2011).

Measures of treatment effect

For dichotomous outcomes, we analyzed data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we analyzed data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI.

First, we described study characteristics individually. The a priori comparison was usual care versus decision aids. For studies in which there were more than one intervention group, we extracted data from the groups that provided the strongest contrast between the intervention and control groups. We pooled results across studies in cases where investigators used similar outcome measures and the effects were expected to be independent of the type of decision studied. For example, we expected decision aids to improve knowledge and create accurate percetions of options, benefits, and harms; to reduce decisional conflict; and to enhance active participation in decision making. Therefore, we pooled data from included RCTs for these outcomes if trials used comparable measures. To facilitate pooling of data for some outcomes (e.g. knowledge, decisional conflict), we standardized the scores to range from 0 to 100 points. When analysing the effects of decision aids on choices, we pooled outcomes on more homogeneous subgroups of decisions (choice of major surgery versus conservative options; screening test or not, etc.).

Unit of analysis issues

We checked for unit-of-analysis errors. Where we found errors and sufficient information was available, we re-analyzed the data using the appropriate unit of analysis by taking account of the intracluster correlation (ICC). We obtained estimates of the ICC by contacting authors of included studies, or we imputed them using estimates from external sources. For two studies (Kupke 2013; Lewis 2010), it was not possible to obtain sufficient information to re-analyze the data, and we reported these studies as being at high risk for 'other' bias based on these unit-of-analysis errors. We made no adjustments to the data based on these two studies that were included in meta-analysis for knowledge only.

Dealing with missing data

We contacted authors to obtain missing data. Where possible, we conducted analysis on an intention-to-treat basis; otherwise, we analyzed data as reported. We reported on the levels of loss to follow-up and assessed this as a source of potential bias.

Assessment of heterogeneity

For this update and in previous versions of the review, we grouped studies together across populations and settings. The aim was to enable an assessment of the effectiveness of decision aids across conditions, rather than to focus on disease-specific contexts. Given that decision aids are a well-defined and clearly delineated type of intervention, we decided that this approach was defensible. On the basis of grouping studies across populations and decision aid elements, we anticipated that there would be a substantial degree of heterogeneity in our pooled effect estimates. However, we decided that we would consider the direction of effects and variability in these rather than variability in the size of effects, as the major basis for our interpretation of heterogeneity. This meant that for those pooled effect estimates where the direction of effect was consistent across studies, we did not downgrade for inconsistency, despite some variability in the size of effects across individual studies. We did downgrade for inconsistency for one outcome: congruence between the chosen option and informed values. This was because there is no accepted gold standard measure for assessing this outcome, and we considered that variability in measurement by the included studies added further uncertainty about the effects of decision aids for this outcome.

Where heterogeneity was present in pooled effect estimates, we explored possible reasons for variability by conducting subgroup analysis in the 2009 update (O'Connor 2009b). The post hoc analysis included the IPDAS effectiveness criteria to explore heterogeneity according to the following factors: the type of decision (treatment versus screening), the type of media of the decision aid (video/computer versus audio booklet/pamphlet), and the possibility of a ceiling effect based on usual-care scores (resulting in the removal of studies with lower scores for knowledge and accurate risk perception and higher scores for decisional conflict using the subscales measuring levels of informedness and clarity of values). We analyzed the effect of removing the biggest outlier(s) (defined by visual inspection of forest plots). Given that the post hoc analysis did not alter the findings from the 2009 update, we did not re-conduct the post hoc analysis for the IPDAS effectiveness criteria.

Assessment of reporting biases

We used funnel plots to assess publication bias.

Data synthesis

We used RevMan 5 software to estimate a weighted intervention effect with 95% confidence intervals (RevMan 2014). For continuous measures, we used mean differences (MD); for dichotomous outcomes, we calculated pooled relative risks (RR). We analyzed all data with a random-effects model because of the diverse nature of the studies being combined and then anticipated variability in the populations and interventions of the included studies. We summarized all of the results for the primary outcomes and rated

the strength of evidence using GRADE (Andrews 2013), presenting these in a 'Summary of findings' table (Higgins 2011).

Subgroup analysis and investigation of heterogeneity

For this update, we conducted a subgroup analysis to compare the effects of the intervention when used in preparation for the consultation with the effects of those used during the consultation to usual care.

Sensitivity analysis

We performed post hoc sensitivity analyses to examine the effect of excluding studies of lower methodological quality. The analysis excluded studies that were at high risk of bias for any of the categories in the 'Risk of bias' assessment (Higgins 2011).

'Summary of findings' table

We prepared a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We presented the results of meta-analysis for the major comparison of the review for each of the key outcomes. We provided a source and rationale for each assumed risk cited in the table and used the GRADE criteria to rank the quality of the evidence for each outcome on each of the following domains: risk of bias, inconsistency, imprecision, indirectness, and publication bias. Two authors independently assessed the quality of the evidence using the GRADEprofiler (GRADEpro) software (GRADEpro GDT).

RESULTS

Description of studies

The current version of our review updates our 2014 version, Stacey 2014b, with 18 new studies (Bozic 2013; Brazell 2014; Chabrera 2015; Fraenkel 2012; Knops 2014; Köpke 2014; Kuppermann 2014; Lam 2013; LeBlanc 2015; Legare 2012; Lepore 2012; Mathers 2012; Mott 2014; Sawka 2012; Shourie 2013; Stacey 2014a; Taylor 2006; Williams 2013). For this update, we excluded 28 previously included studies due to the comparisons being limited to detailed versus simple patient decision aids (Deschamps 2004; Deyo 2000; Dodin 2001; Goel 2001; Green 2004; Hunter 2005; Kuppermann 2009; Labrecque 2010; Lalonde 2006; Legare 2003; Leung 2004; Myers 2005a; Myers 2011; O'Connor 1998a; O'Connor 1999a; Raynes-Greenow 2010; Rostom 2002; Rothert 1997; Schapira 2000; Schapira 2007; Solberg 2010; Street 1995; Tiller 2006; Van Roosmalen 2004; Volk 2008; Wakefield 2008a; Wakefield 2008b; Wakefield 2008c).

Results of the search

In total, we identified 46,054 citations from the electronic database searches and 258 citations from other sources. Of these, we assessed 504 citations for eligibility using the full text (see Figure 1).

Included studies

The remaining 151 citations provided data on 105 studies that met our inclusion criteria, 18 of which are new for this update. The 105 RCTs, involving 31,043 participants, presented results from 10 countries: Australia (10 studies), Canada (15 studies), China (1 study), Finland (2 studies), Germany (6 studies), Netherlands (2 studies), Spain (1 study), Sweden (1 study), the UK (16 studies), the USA (50 studies), and Australia plus Canada (1 study). We present study details below and in the Characteristics of included studies table.

Unit of randomization

Ninety studies randomized individual patients, and 15 randomized clusters. For cluster trials, Allen 2010 randomized 12 company worksites; Fraenkel 2012, 2 groups of primary care physicians; Hamann 2006, 12 inpatient psychiatric units; Kupke 2013, 49 dental students; Legare 2011, 4 family medicine group practices; Legare 2012, 12 family medicine group practices; Lewis 2010, 32 family medicine group practices; Loh 2007, 30 general practitioners; Mathers 2012, 49 general medicine practices; McAlister 2005, 102 primary care practices; Mullan 2009, 40 clinicians; Nagle 2008, 60 general practitioners; Shourie 2013, 50 general medicine practices; Weymiller 2007, 21 endocrinologists; and Whelan 2004, 27 surgeons.

For 10 studies (Allen 2010; Legare 2011; Legare 2012; Loh 2007; Mathers 2012; Mullan 2009; Nagle 2008; Shourie 2013; Weymiller 2007; Whelan 2004), the cluster effect was taken into account in the published outcome data, and the meta-analysis used published results. Although Hamann 2006 did not account for the cluster effect in the published outcome data, the way this study was reported did not allow us to include it in the meta-analysis, so we did not re-analyze the data and report the study separately. For McAlister 2005, meta-analysis was done applying the design effect (based on the published intracluster correlation coefficient (ICC)). For Fraenkel 2012, the authors stated that adding a random effect for physician clusters did not contribute to better-fitting regression models, and we removed it from the analysis. The analysis by Kupke 2013 and Lewis 2010 did not account for clustering.

Decision aids and comparisons

The 105 included studies evaluated decision aids that focused on 50 different decisions (Table 1). The most common decisions were about prostate cancer screening (14 studies), colon cancer screening (10 studies), medication for diabetes (4 studies), breast cancer genetic testing (4 studies), prenatal screening (4 studies), medication for atrial fibrillation (4 studies), and surgery (mastectomy for breast cancer, 4 studies; hysterectomy, 3 studies; prostate cancer treatment, 4 studies). New decision topics added in this update included surgery for prolapsed pelvic organs (1 study) and asymptomatic aortic abdominal aneurysm (1 study); restoration for tooth decay (1 study); measles, mumps, and rubella vaccine for infants (1 study); treatment of post-traumatic stress disorder (1 study); and radioactive iodine treatment for thyroid cancer (1 study).

The decision aids used different formats and were compared to a variety of control interventions (e.g. usual care, general information, no intervention, guideline, placebo intervention). We noted the nature of usual care when reported (see Characteristics of included studies table). For this review, we have grouped control interventions and refer to them as 'usual care'.

According to the definition of a patient decision aid, all of the studies evaluated patient decision aids that included information about the options and outcomes and provided at least implicit clarification of values. Most patient decision aids included information on the clinical problem (90.5%) as well as outcome probabilities (89.5%). Fewer patient decision aids provided guidance in the steps of decision making (65.7%), explicit

methods to clarify values (57.1%), and/or examples of others' experiences (41.0%) (see table Characteristics of included studies).

Excluded studies

We excluded 302 studies upon close perusal of the relevant papers (see Characteristics of excluded studies). The reasons for exclusion were: the study was not a randomized controlled trial; the decision was hypothetical, with participants not actually at a point of decision making; the intervention was not focused on making a choice; the intervention offered no decision support in the form of a decision aid or did not provide enough information about the decision aid; no comparison outcome data were provided; the study did not evaluate the decision aid; the study was a protocol; the decision aid was about clinical trial entry, lifestyle choice, or advanced care planning; the study involved testing the presentation of the decision aid, but with no difference in the content of the decision aid between study groups; or the study compared a detailed versus simple decision aid.

We also identified 61 ongoing RCTs through trial registration databases, personal contact, and published protocols in the electronic database searches (see references to Ongoing studies and table Characteristics of ongoing studies).

Risk of bias in included studies

Details on the ratings and rationale for risk of bias are in the Characteristics of included studies table and displayed in Figure 2 and Figure 3.

Figure 2. Risk of bias summary as percentages across all included studies.

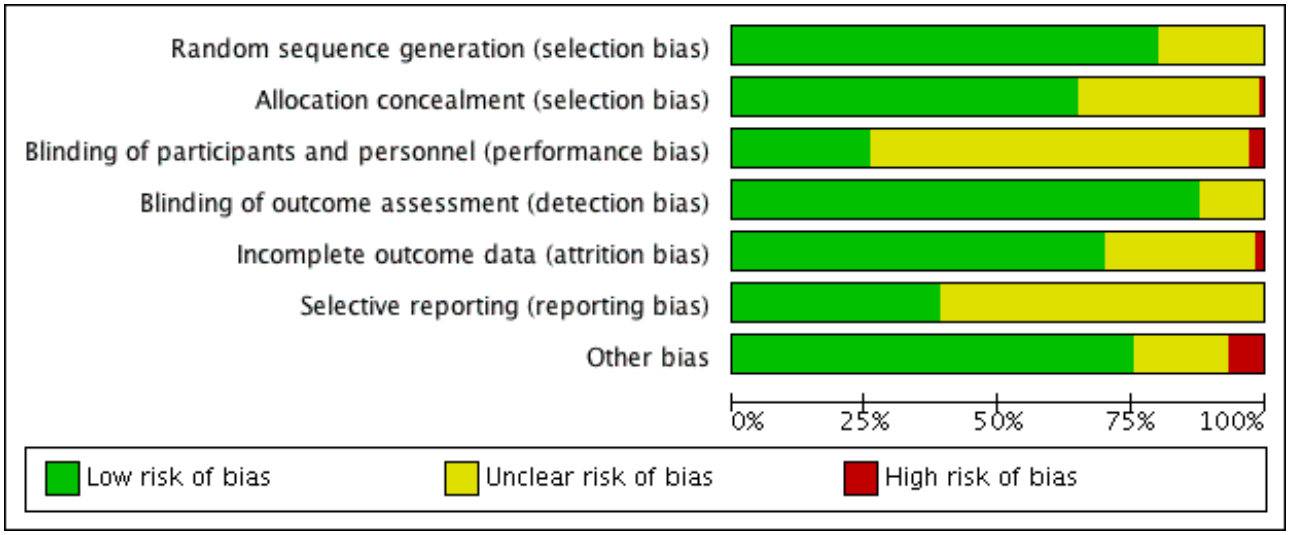


Figure 3. Risk of bias summary for each included study.

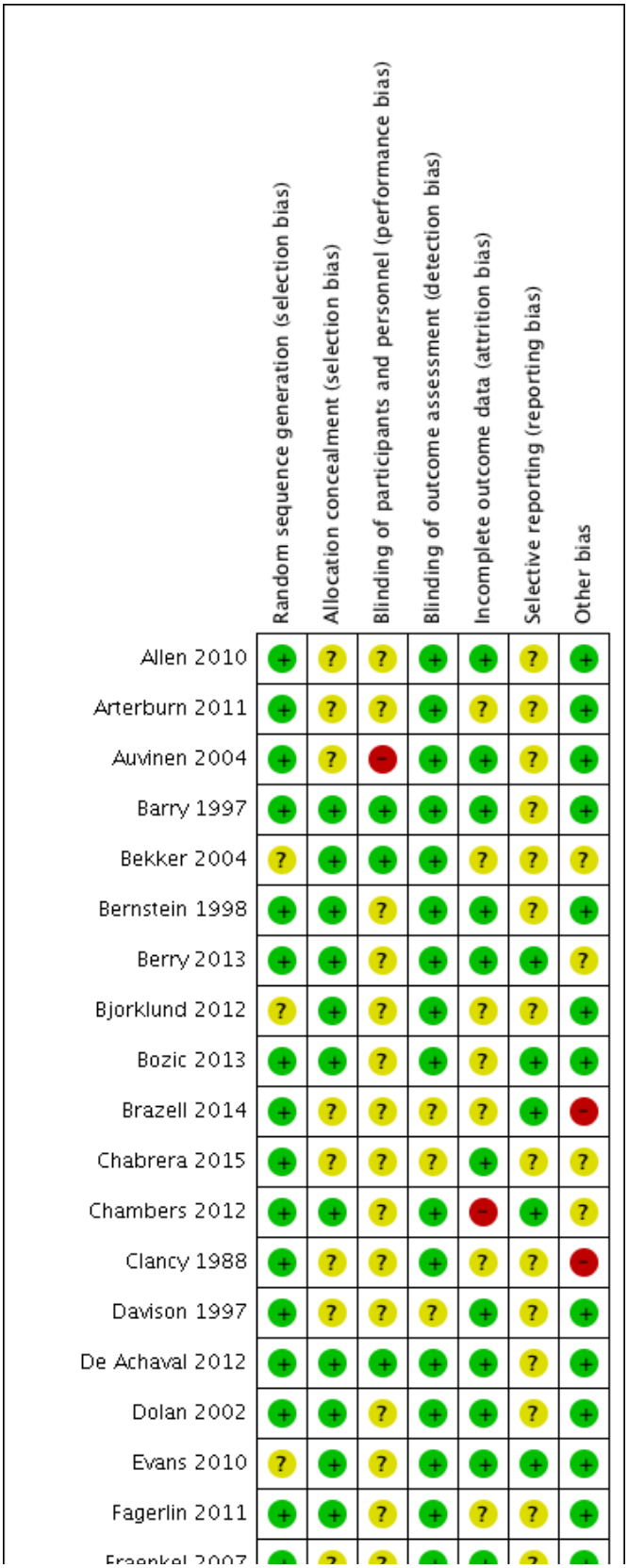
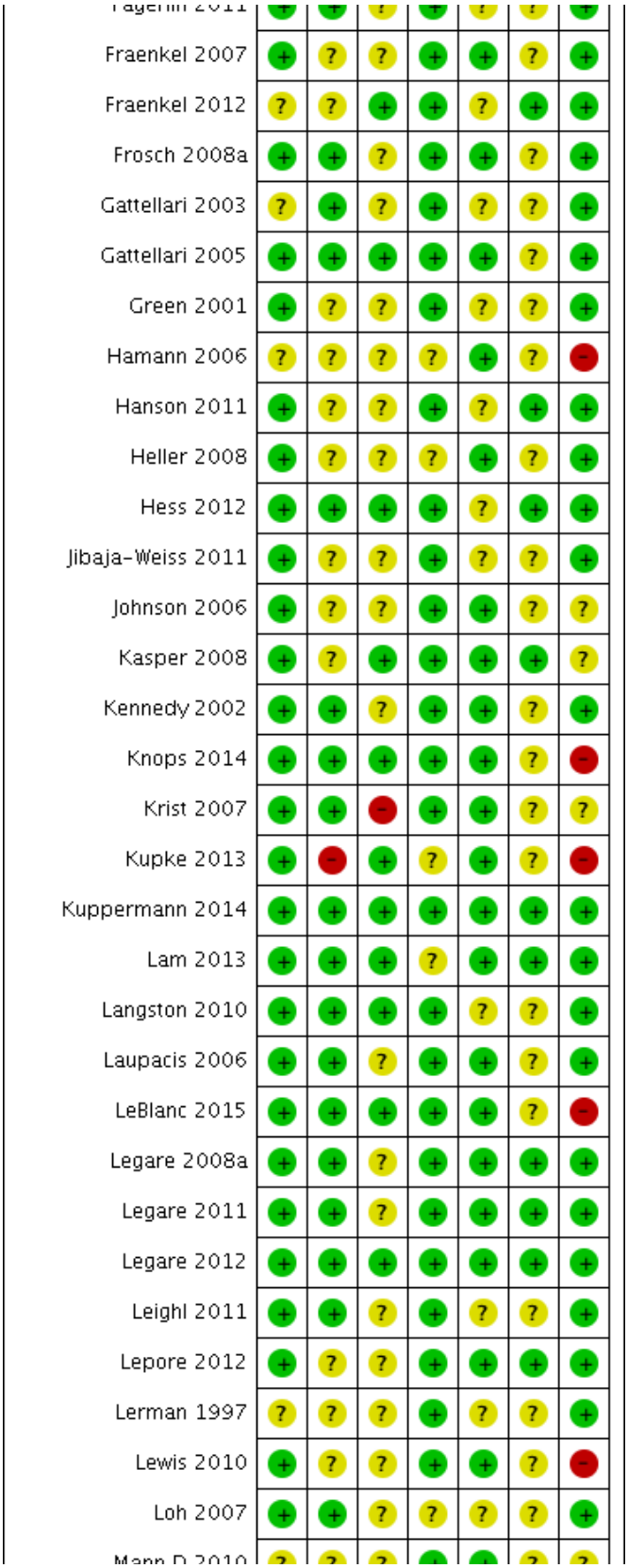


Figure 3. (Continued)



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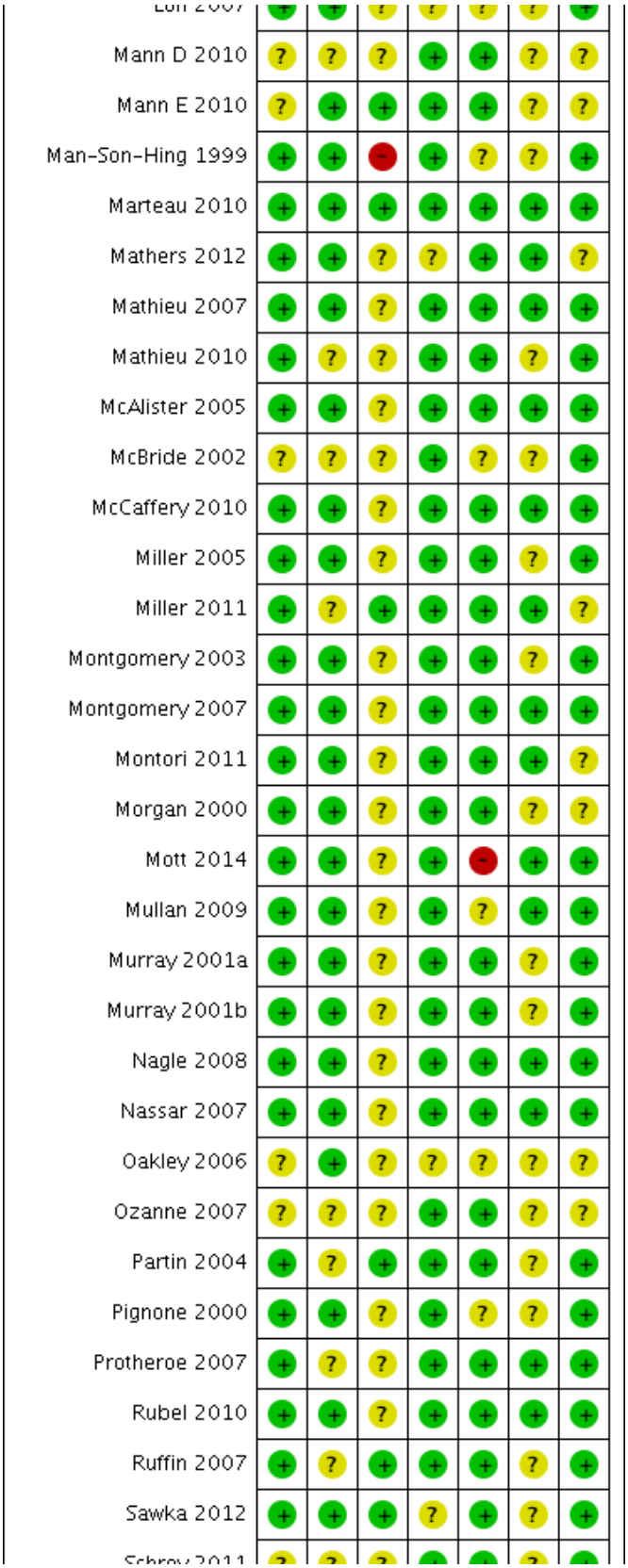

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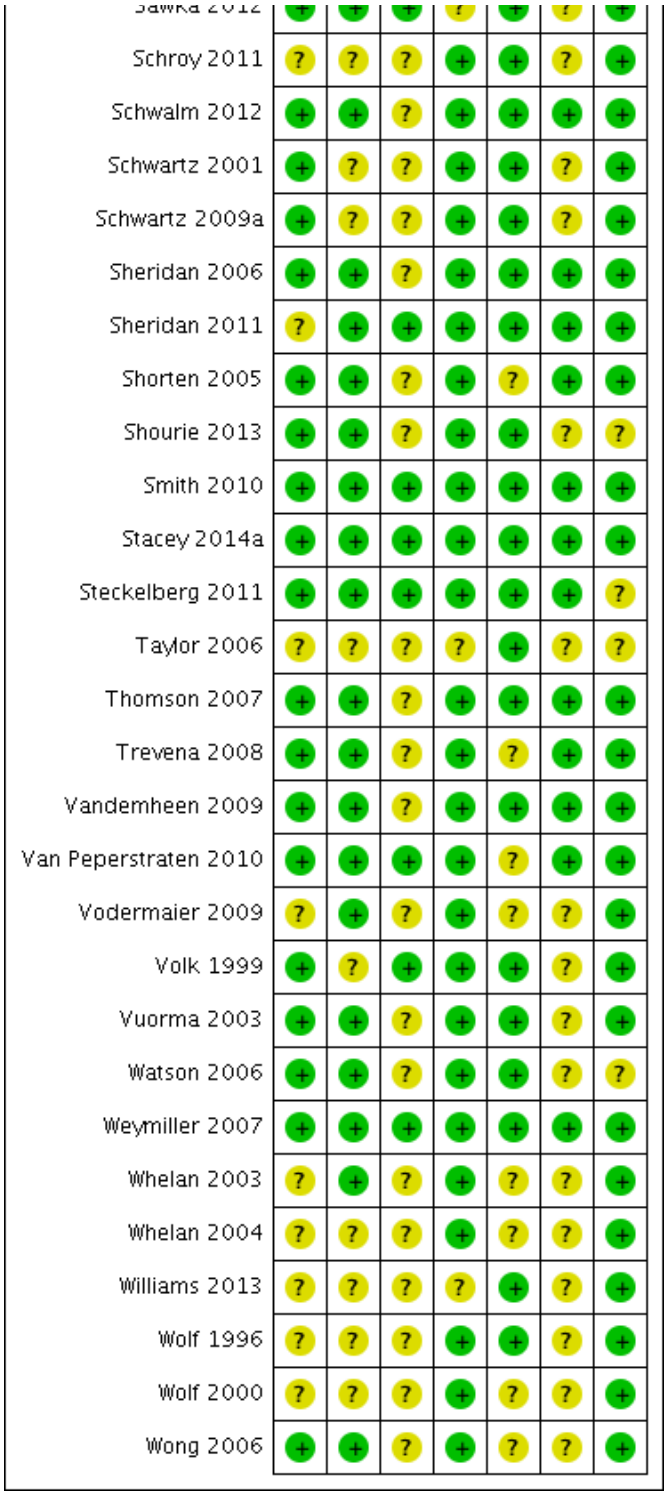


Allocation

When assessing risk of selection bias, we rated all 105 studies as being at low or unclear risk of bias. Allocation concealment methods prompted a rating of low or unclear risk of bias in 104 studies and high risk of bias in 1 study (Kupke 2013).

Blinding

We judged 102 studies to be at low or unclear risk of performance and detection bias for the blinding of participants and personnel, while 3 (2.9%) studies were at high risk of bias. High risk of bias was due to lack of blinding of physicians to the status of patients randomized to the patient decision aid and alternative interventions (Auvinen 2004; Krist 2007; Man-Son-Hing 1999).

We rated the blinding of outcome assessment as leading to low or unclear risk of bias in all 105 studies.

Incomplete outcome data

For 103 studies, aspects related to incomplete outcome data conferred low or unclear risk of bias. In two (1.9%) studies (Chambers 2012; Mott 2014), there was high risk of bias due to high attrition rates.

Selective reporting

We rated all 105 studies as being at either low risk of bias because the protocol was registered publicly or at unclear risk of bias because we could not assess the extent or the impact of any reporting bias.

Other potential sources of bias

Of 105 studies, we rated 98 as being at low or unclear risk of other potential sources of bias. The other seven (6.7%) discussed other potential risks of bias (Brazell 2014; Clancy 1988; Hamann 2006; Knops 2014; Kupke 2013; LeBlanc 2015; Lewis 2010). We rated Brazell 2014 and LeBlanc 2015 as being at high risk of bias given that the same physicians provided consultation to both intervention and control groups, and measures were taken after physician consultation. Clancy 1988 describes a potential for selection bias because non-randomized medical residents were added to the decision aid group, and there was a low response rate among those offered decision aid. We rated Knops 2014 as being at high risk of bias given that a large number of potential participants did not participate in the study. Hamann 2006, Kupke 2013, and Lewis 2010 did not account for clustering in their analyses.

Effects of interventions

See: **Summary of findings for the main comparison**

In addition to Summary of findings for the main comparison, see the Data and analyses figures for pooled data and Additional tables for outcome data that we did not pool. This section presents the attributes of the choice made, the attributes of the decision process, and secondary outcomes.

Primary outcomes

Attributes of the choice made: does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient?

The randomized controlled trials used three measures that correspond to this outcome: knowledge scores, accuracy of risk perceptions, and congruence between the chosen option and the patient's values.

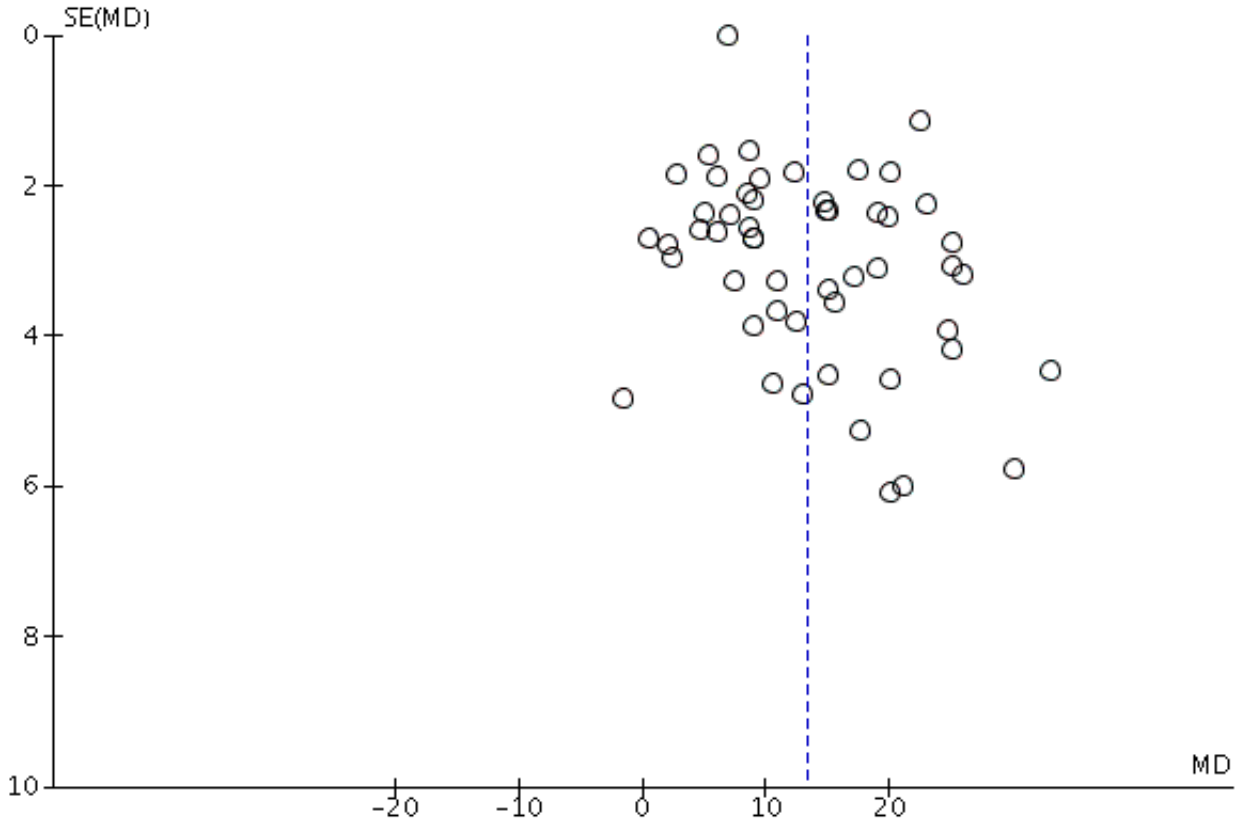
Knowledge

Seventy-one of the 105 studies (67.6%) assessed the effects of decision aids on knowledge. The studies' knowledge tests were based on information contained in the decision aid. The proportion of accurate responses was transformed to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses).

There is high-quality evidence that patient decision aids were more effective than usual care (52 studies) on knowledge scores (MD 13.27, 95% CI 11.32 to 15.23; Analysis 1.1). In absolute terms the group receiving usual care had, on average, 57 of 100 answers correct. Those in the decision aid group scored better, with 70 of 100 answers correct on average (from 68 to 72 correct).

Nineteen additional studies presented knowledge scores that could not be included in the pooled outcome (see Table 2). Most of these other studies reported statistically-significantly higher knowledge scores for those exposed to the decision aid compared to usual care. The funnel plot for knowledge as an outcome in studies comparing decision aid to usual care shows that these studies are at low risk for publication bias (Figure 4).

Figure 4. Funnel plot of comparison: 1 Knowledge, outcome: 1.1 Knowledge - all studies.



Accurate risk perceptions (i.e. perceived probabilities of outcomes)

Of 105 studies, 25 (23.8%) examined the effects of patient decision aids on the accuracy of patients' perceived probabilities of outcomes (see Analysis 2.1; Table 3). We classified the accuracy of perceived outcome probabilities according to the percentage of individuals whose judgments corresponded to the scientific evidence about the chances of an outcome for similar people. For studies that elicited risk perceptions using multiple items, we averaged the proportion of accurate risk perceptions.

There is moderate-quality evidence that patient decision aids were more effective than usual care for transmitting accurate risk perceptions (risk ratio (RR) 2.10, 95% CI 1.66 to 2.66, 17 studies; Analysis 2.1). This means that for every 1000 people receiving usual care, 269 were likely to accurately interpret risk, whereas far more people (565 people per 1000; from 447 to 716) accurately interpreted risk after using a decision aid.

Eight studies reported results that were not amenable to pooling (see Table 3). Fraenkel 2012; Hanson 2011; Kuppermann 2014; Mathieu 2010; and Smith 2010 reported a statistically significant improvement in accurate perceptions of outcomes for the decision aid group compared to usual care, and Miller 2005 reported no effect on risk perception. In another study, Weymiller 2007 reported participants allocated to the decision aid had a significantly more accurate perception of their estimated cardiovascular risk without statin therapy compared to the usual care group; this effect was greater when the clinician used the decision aid during the consultation rather than when the researcher used the decision aid in preparation for the consultation ($P_{interaction}$= 0.03). For the final study by Mann E 2010, three of eight knowledge test items measured accurate risk perceptions, but results were presented for total knowledge and not individual items.The funnel plot for accurate risk perception as an outcome in studies comparing decision aid to usual care shows low risk for publication bias.

Congruence between chosen option and values

Of 105 studies, 16 (15.3%) measured congruence between the chosen options and the patients' values. Six measured values-choice congruence without considering knowledge (Arterburn 2011; Berry 2013; Frosch 2008a; Legare 2008a; Lerman 1997; Vandemheen 2009). Of 10 studies that measured informed values-choice congruence, eight used the Multi-Dimensional Measure of Informed Choice (Bjorklund 2012; Fagerlin 2011; Mathieu 2007; Mathieu 2010; Nagle 2008; Smith 2010; Steckelberg 2011; Trevena 2008), which assesses the extent to which the choice is based on relevant knowledge, is consistent with a person's values/attitudes, and is behaviourally implemented (Michie 2002). These studies operationalized the measure in terms of knowledge scores higher than the mid-point of the scale, attitude scale scores higher than the mid-point, and choice being congruent with attitude.Two other studies measured informed values-based choice: Schwalm 2012 assessed the extent to which the choice was based on knowledge score ≥ 60% and a score for three values-importance ratings that matched the choice; and Stacey 2014a assessed the extent to which the choice was based on knowledge score ≥ 66% and measured values-choice congruence using a logistic regression model. For the 10 studies that measured informed values-choice congruence, two

used preferred choice (Mathieu 2010; Trevena 2008), and the other eight used actual choice.

There is low quality evidence that patient decision aids were more effective than usual care for selecting an option that was congruent with their informed values (RR 2.06, 95% CI 1.46 to 2.91, 10 studies; Analysis 3.1). Of the 10 studies, 8 individually showed statistically higher congruence scores for the patient decision aid compared to usual care, and 2 showed no difference (Bjorklund 2012; Mathieu 2010). Repeating this analysis using the studies that measured actual choice and not preferred choice revealed a pooled RR of 2.13 (95% CI 1.44 to 3.14; 8 studies). A sub-analysis of studies using the Multi-Dimensional Measure of Informed Choice revealed a pooled RR of 2.08 (95% CI 1.40 to 3.08, 8 studies; Analysis 3.3).

There was no difference between patient decision aid and usual care for the six studies that measured values-choice congruence without considering knowledge scores (Arterburn 2011; Berry 2013; Frosch 2008a; Legare 2008a; Lerman 1997; Vandemheen 2009; see Table 4). We did not pool these studies because of how they reported results. Arterburn 2011 reported that, compared to the control group, those exposed to the decision aid experienced a more rapid early improvement of value-choice concordance immediately after exposure. Legare 2008a reported that women's valuing of the non-chemical aspect of natural health products was positively associated with their choice of natural health products in managing menopausal symptoms (P = 0.006). The other four studies reported no differences between groups. However, Frosch 2008a observed that men exposed to the decision aid who chose not to have a prostate-specific antigen (PSA) test rated their concern about prostate cancer lower than men who requested a PSA test, while men assigned to the usual care group provided similar ratings of concern regardless of their PSA choice.

Attributes of the decision process: does the decision aid help patients to recognize that a decision needs to be made, know the options and their features, understand that values affect the decision, be clear about the features that matter most to them, discuss values with their clinician, and become involved in their preferred ways?

In relation to the International Patient Decision Aids Standards (IPDAS) decision process criteria, no studies evaluated the extent to which patient decision aids helped participants to recognize that a decision needed to be made or understand that values affect the decision. Some studies measured participants' self-reports about feeling informed and clear about personal values. The measures used to evaluate these criteria were two subscales of the previously validated Decisional Conflict Scale (DCS) (O'Connor 1995).

Decisional conflict

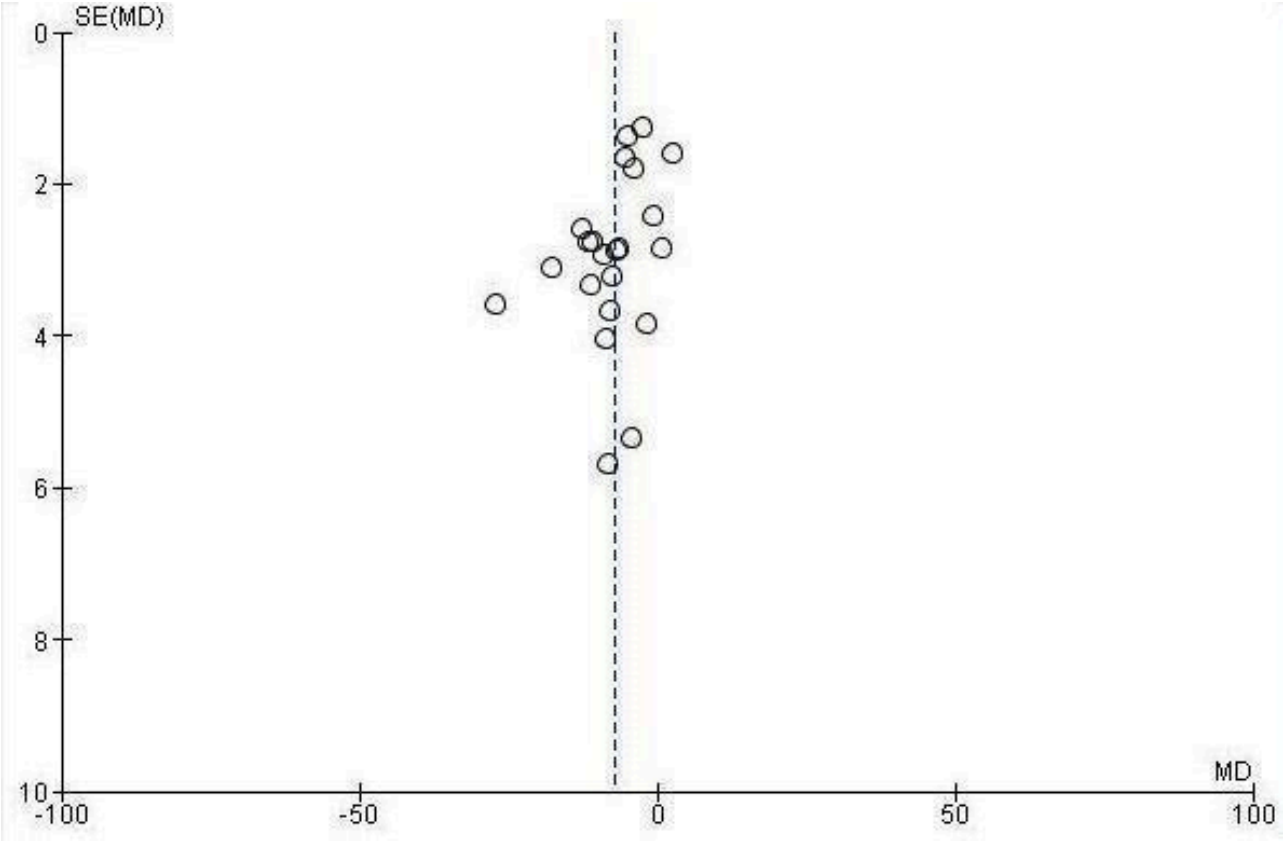
Of 105 studies, 63 (60.0%) evaluated decisional conflict using the DCS (O'Connor 1995). The DCS is reliable, discriminates between those who make or delay decisions, is sensitive to change, and discriminates between different decision support interventions (Morgan 2000; O'Connor 1995; O'Connor 1998b). The scale measures the constructs of overall decisional conflict and the particular factors contributing to uncertainty (e.g. feeling uncertain, uninformed, unclear about values, and unsupported in decision making). A final subscale measures perceived effective decision making. The scores were standardized to range from 0 (no decisional conflict) to 100 points (extreme decisional conflict). Scores of 25 or lower are associated with follow-through with decisions, whereas scores that exceed 38 are associated with delay in decision making (O'Connor 1998b). When decision aids are compared to usual care, a negative score indicates a reduction in decisional conflict, favouring the decision aid.

Analysis 4.1.1 summarizes the decisional conflict results for the 42 studies that compared decision aids to usual care. We report on 21 studies that were not amenable to pooling in Table 5 (original DCS), Table 6 (low literacy version), and Table 7 (SURE test version).

The mean difference (MD) for total DCS scores was −7.22 points out of 100, favouring the patient decision aid over usual care groups (95% CI −9.12 to −5.31; see Analysis 4.1.1). Sixteen studies that could not be pooled (Table 5) reported mixed results on the original DCS. Of four studies that used the low literacy version (Fraenkel 2012; Smith 2010; Taylor 2006; Williams 2013), all reported statistically significant improvement (i.e. reduced) in total (or subscale) decisional conflict scores in the decision aid group, compared to usual care (Table 6). Stacey 2014a reported no difference between groups using the SURE test version.

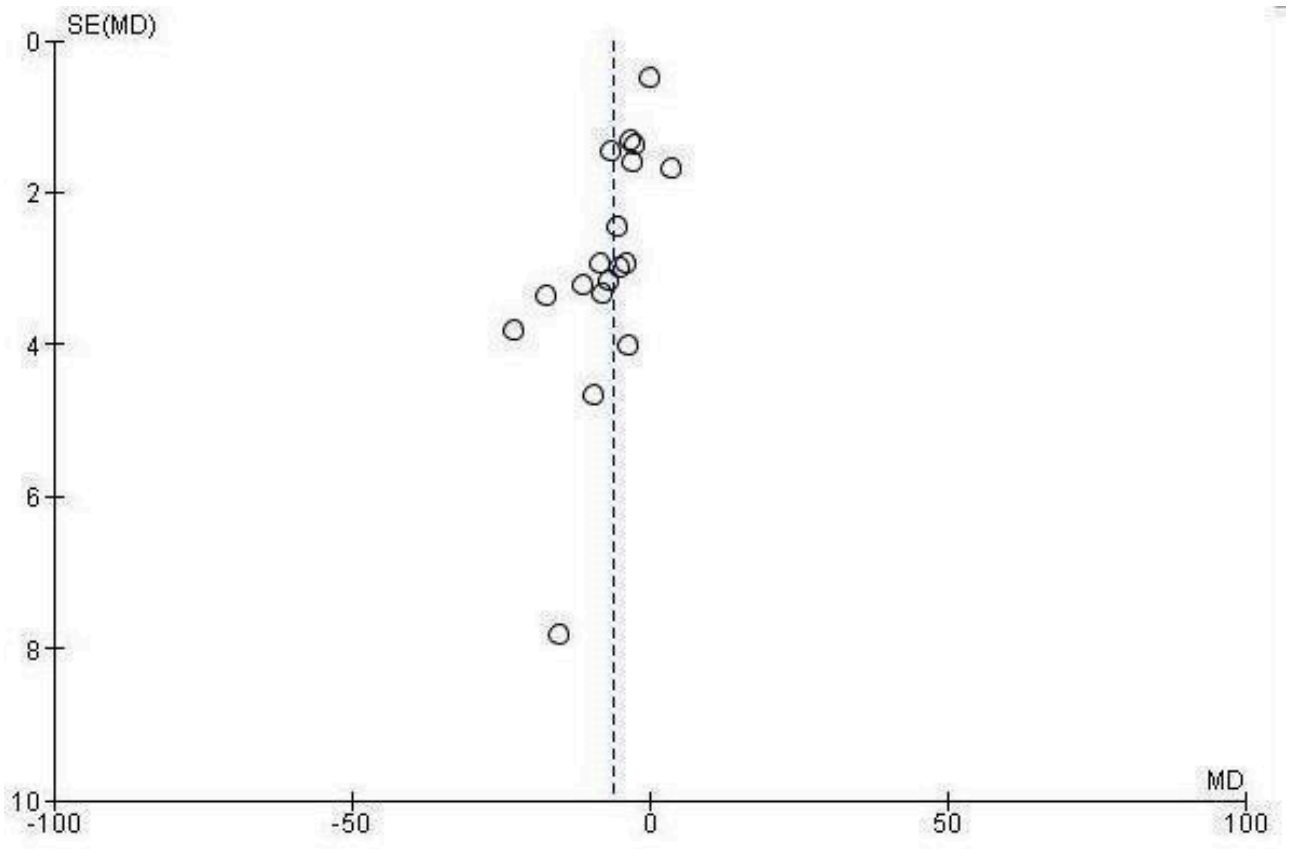
The 'feeling uninformed' subscale of the DCS measures self-reported comfort with knowledge, not actual knowledge. We elected to consider this as a process measure and to reserve the gold standard of objective knowledge tests for assessing decision quality. There was high-quality evidence that patient decision aids were more effective than usual care in reducing patients' 'feeling uninformed' about options, benefits, and harms (MD −9.28, 95% CI −12.20 to −6.36; 27 studies; Analysis 4.1.2). The funnel plot for 'feeling uninformed' as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 5).

Figure 5. Funnel plot of comparison: 4.1 Decisional conflict: DA vs usual care - all studies, outcome: 4.1.2 Uninformed subscale



There was high-quality evidence that patient decision aids were more effective than usual care for reducing patients' 'feeling unclear about values' subscale of the DCS (MD −8.81; 95% CI −11.99 to −5.63; 23 studies; Analysis 4.1.3). The funnel plot for using 'feeling unclear about values' as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 6).

Figure 6. Funnel plot of comparison: 4.1 Decisional conflict: DA vs usual care - all studies, outcome: 4.1.3 Unclear subscale



Patient-clinician communication

Of 105 studies, 10 (9.5%) measured the effect of decision aids on patient-clinician communication. Of these 10 studies, 5 evaluated a patient decision aid used primarily within the consultation with the clinician, and 5 evaluated a patient decision aid used in preparation for the consultation.

Five studies compared the effect of usual care versus a decision aid used within the clinical encounter (or, in Weymiller 2007, half the decision aid participants were exposed just prior to the encounter), evaluating the extent of shared decision making communication by analyzing the audio recordings using the OPTION scale (Hess 2012; LeBlanc 2015; Montori 2011; Mullan 2009; Weymiller 2007). The OPTION scale measures the extent to which healthcare providers use behaviours that involve patients in decision making (Elwyn 2005). All five studies reported statistically higher mean OPTION scores in the patient decision aid group compared to usual care (see Table 8).

Four of five studies reported that compared to those in the usual care group, significantly higher proportions of participants exposed to the patient decision aid in preparation for the consultation reported that they discussed the decision with their clinician (Fraenkel 2012; Hanson 2011; Lepore 2012; Sheridan 2011; see Table 8). The fifth study showed no between-group difference in discussion of cardiovascular disease with the clinician (Sheridan 2006; see Table 8).

Participation in decision making

Of 105 studies, 24 (22.9%) measured the effect of decision aids on patients' perceived participation in decision making (Analysis 5.1; Table 9). Davison 1997 used the Control Preferences Scale (Degner 1992). This scale uses five response statements to measure the role in decision making: two represent an active or patient-controlled role; one a shared or collaborative role; and two response statements represent a passive or clinician-controlled role. Most other studies used comparable response statements that could be classified within each of the three groupings of the Control Preferences Scale, except for Hamann 2006, which used the COMRADE instrument to measure patient perception of involvement, and two others that used other measures of perceived involvement (Hanson 2011; Loh 2007; see Table 9).

Using the groupings of the Control Preferences Scale, 16 of 24 studies reported on clinician-controlled decision making. Consistent with the hypothesis that patient decision aids increase patient participation in decision making, there was moderate-quality evidence that patient decision aids were more effective than usual care for reducing clinician-controlled decision making (RR 0.68; 95% CI 0.55 to 0.83; Analysis 5.1.1). In this field, there is no consensus on the hypothesized effects of decision aids on measures of patient-controlled decision making or shared decision making. Of 24 studies, 15 reported on participants assuming an active (patient-controlled) role in decision making and were pooled for analysis. Compared to usual care, decision aid use increased patient-controlled decision making (RR 1.28, 95% CI 1.05 to 1.55;

Analysis 5.1.2). The 15 studies that reported on a shared decision-making role showed no difference between decision aid and usual care (RR 0.95; 95% CI 0.83 to 1.10; Analysis 5.1.3).

Of eight studies that could not be pooled, Allen 2010, Leighl 2011, Rubel 2010, and Van Peperstraten 2010 reported no between-group differences in these roles (Table 9). Three studies reported that a statistically significant proportion of patients exposed to the decision aid either participated (Sheridan 2011) – or at least felt involved – in decision making (Hamann 2006; Loh 2007). However, Hamann 2006 did not analyze results accounting for the use of design clusters. Hanson 2011 reported that a higher proportion described feeling involved (83% vs. 77%), but the difference between groups was not statistically significant.

Proportion undecided

Of 105 studies, 24 (22.9%) measured the proportion of participants remaining undecided: of these, 22 studies could be pooled. A significantly lower proportion of people remained undecided after exposure to a decision aid (RR 0.64; 95% CI 0.52 to 0.79; Analysis 6.1).

Kasper 2008 measured progress in decision making using a single item ranging from '0 = completely undecided' to '100 = made my decision'. Given the difference in the measure Kasper used, these results were not included in the meta-analysis. In this study, both the patients exposed to a decision aid and the usual care group progressed in their decision making, with no difference between the groups (Table 10). Sawka 2012 reported that 10.8% in the patient decision aid group versus 21.6% in the usual care group reported not knowing if they preferred taking adjuvant radioactive iodine.

Satisfaction

Nineteen included studies (18.1%) measured satisfaction as it relates to the choice and the preparation for and the process of decision making. When possible, we standardized the scores to a 0 to 100 point scale, with higher scores reflecting greater satisfaction.

Nineteen studies (18.1%) measured satisfaction with the choice. Of these 19 studies, 4 reported that people exposed to the decision aid had higher satisfaction with their choice compared to usual care, and the other 15 reported no statistically significant differences (Chabrera 2015; Heller 2008; Laupacis 2006; Montgomery 2007; see Analysis 7.1 and Table 11). For results that used a similar measure (Analysis 7.1), there was high satisfaction for all participants, with a median score of 82.5% for the decision aid and 80.0% for the usual care groups.

Of 105 total studies, 11 (10.5%) measured satisfaction with the decision, 11 (10.5%) measured satisfaction with the decision-making process (see Analysis 7.6; plus Hess 2012 and Vodermaier 2009 in Table 12), 4 measured satisfaction with information provided (LeBlanc 2015; Laupacis 2006; Montori 2011; Oakley 2006), 3 measured satisfaction with the clinician (Laupacis 2006; Miller 2005; Vodermaier 2009), and 1 measured satisfaction with participating in decision making (Kennedy 2002). There were mixed results, but no studies reported that those exposed to patient decision aids were significantly less satisfied compared to usual care. For results that used a similar measure of satisfaction with the decision-making process (Analysis 7.4), there was high satisfaction for all participants, with median scores of 83.8% for the decision aid and 77.8% for the usual care groups. Although there were no differences between participant groups in satisfaction with the information in the Montori 2011, clinicians using the decision aid had higher satisfaction.

Three studies (2.9%) measured satisfaction with preparation for decision making using the Preparation for Decision Making Scale (Bennett 2010) (Table 13). Compared to usual care, two studies reported significant improvements in people's satisfaction with their preparation for making decisions: in Fraenkel 2007 after using decision aids about management of knee osteoarthritis, and in Vandemheen 2009 regarding referral to a lung transplant centre. The third study found no statistically significant difference on this subscale's four items (Stacey 2014a).

Secondary outcomes

Behaviour

Choice

Choice was defined as the actual choice implemented. However, when studies did not report the actual choice, we used the patients' preferred option as a surrogate measure. Actual choices or preferences were reported as the percentage of individuals actually implementing or stating a preference for the most intensive or most invasive option.

In summary, patient decision aids decreased the number of patients choosing elective surgical procedures (excluding prophylactic mastectomy) and PSA testing in multiple studies. Single studies showed that decision aids increased the number of people choosing hepatitis B vaccination, psycho-educational therapies for mental health conditions, and medication for cardiovascular disease prevention. In contrast, decision aids decreased the rate of cardiac stress testing, the number of embryos being transplanted, and the rate of antibiotic use for upper respiratory infections. The effect on patients' choice in other situations was more variable. There were mixed results for the choice of colon cancer screening, genetic testing, prenatal testing, anti-thrombosis therapy, breast screening, and diabetes medications. There was no difference between groups for choices about natural health products, hypertension therapy, breast cancer chemotherapy, schizophraenia medication, immunotherapy for multiple sclerosis, vaccines (for flu or measles, mumps, rubella), diabetes screening, birth control, osteoporosis treatment, chemotherapy for advanced cancer, chemopreventive medications, use of blood transfusions, childbirth procedures, treatment of prolapsed pelvic organs, or radioactive iodine treatment for thyroid cancer.

Choice for major elective surgery

Eighteen studies (17.1%) focused on choices regarding major elective surgery (Analysis 8.1).

Using intention-to-treat analysis, there was a non-significant reduction in the number of patients choosing major elective surgery in the group receiving the decision aid compared to usual care (RR 0.86; 95% CI 0.75 to 1.00, 18 studies; Analysis 8.1.2). Schwartz 2009a reported a statistically significant uptake of prophylactic mastectomy for women who are BRCA1/2 gene carriers (114%). And after removing this study from the pooled results, there was a statistically significant reduction in the number

of patients choosing major elective surgery (RR 0.84 95% CI 0.73 to 0.97; 17 studies; Analysis 8.1.3).

Four other studies showed statistically significant reductions in surgery rates: −29% for cardiac revascularization and bariatric surgery (Arterburn 2011; Morgan 2000), −33% for orchiectomy (Auvinen 2004), and −74% for mastectomy (Whelan 2004). The other 15 studies showed no difference between the decision aid or usual care groups.

Choice for other elective surgery

Two studies evaluated the effect of decision aids versus usual care on other elective surgical decisions. Decision aids did not significantly influence surgical abortion rates in Wong 2006 or feeding tube insertions in Hanson 2011 (Table 14).

Choice for prostate-specific antigen screening

The effects of decision aids on prostate-specific antigen (PSA) screening decisions were variable in 13 studies (12.4%) that compared decision aids to usual care. The pooled RR for 10 studies was 0.88 (95% CI 0.80 to 0.98; Analysis 8.2.1); Frosch 2008a, Lepore 2012, and Williams 2013 could not be included in the pooled data (Table 14). Frosch reported a reduction in screening rates and the other two reported no difference.

Choice for colon cancer screening

Of 10 studies (9.5%) on colon cancer screening, 3 reported statistically significant differences in choices, and 7 showed no difference. Two studies reported that compared to usual care, the decision aid significantly increased the screening rates by 64% and 70% (Pignone 2000; Ruffin 2007). The other study reported a statistically significant reduction of 21% for screening (Smith 2010). There was an increase in screening rates in five studies, by 6% to 39%, but the difference was not statistically significant (Lewis 2010; Miller 2011; Schroy 2011; Steckelberg 2011; Wolf 2000). In two studies (Dolan 2002; Trevena 2008), there was a 73% and 4% decrease in screening rates that was not statistically significant. The pooled RR was 1.12 (95% CI 0.95 to 1.31, 10 studies; Analysis 8.2.2).

Choice for cancer genetic screening

Four studies reported preferences or uptake rates for breast cancer genetic screening (3.8%). The decision aid did not significantly affect preferences for breast cancer genetic screening when compared to usual care. The pooled RR was 0.99 (95% CI 0.71 to 1.38, 3 studies; Analysis 8.2.3). One study reported an increase in screening rates by 14% (Lerman 1997), a second study reported an increase of 18% (Green 2001), and a third study reported a decrease of 29% (Schwartz 2001). Miller 2005 reported that women exposed to the decision aid who were at higher risk of breast cancer increased their intention to obtain genetic testing, while those at average risk decreased their intention (Table 14).

Choice for breast screening

There were lower mammography screening rates among women aged 38 to 45 years of age (Mathieu 2010), but no between-group difference in women aged 70 or older who were exposed to a decision aid versus usual care (Mathieu 2007; Table 14).

Choice for prenatal screening

In all four studies focusing on decisions around prenatal screening, prenatal testing rates were not affected by a decision aid compared to usual care (Bekker 2004; Bjorklund 2012; Kuppermann 2014; Nagle 2008). Meta-analysis included two studies, showing no effect (RR 0.99, 95% CI 0.91 to 1.09, 2 studies; Bjorklund 2012; Kuppermann 2014; Analysis 8.2.4).

Choice for stress test for chest pain

Compared to usual care, adults presenting with chest pain in the emergency department who received the decision aid had significantly lower rates of stress testing (58% versus 77%) (Hess 2012; Table 14).

Choice for screening for diabetes

Compared to usual care, there was no difference in diabetes screening rates in Marteau 2010 or preferences for screening in Mann E 2010 in adults exposed to a decision aid (Table 14).

Choice to take antibiotics for upper respiratory infection

Compared to usual care, using a decision aid in the consultation decreased prescriptions for antibiotics for upper respiratory infections in Legare 2012, although this difference was not statistically significant in Legare 2011 (Table 14).

Choice for atrial fibrillation treatment

Three studies evaluated the effect of a decision aid on the use of anti-thrombotic therapy for atrial fibrillation versus usual care (Table 14). One study demonstrated a non-significant reduction in warfarin use of 25% (Man-Son-Hing 1999). The second study evaluated the proportions of patients choosing the option that was appropriate relative to their level of risk, and found no significant difference between the groups (McAlister 2005). Thomson 2007 reported that patients in the usual care group (guided by practice recommendations) were much more likely to start warfarin (15/16; 93.8%) compared to the decision aid group (4/16; 25%; RR 0.27; 95% CI: 011 to 0.63).

Choice to take breast cancer prevention medication

There was no difference in medication use among women at risk of breast cancer who were exposed to the decision aid versus usual care (Fagerlin 2011; Table 14).

Choice for cardiovascular disease prevention

There was an increase in patient preferences for any effective cardiovascular disease risk-reducing strategy (including medication) when using a decision aid versus usual care (63% versus 42%) (Sheridan 2011; Table 14).

Choice for chemotherapy for cancer

There was no statistically significant difference in the rates of chemotherapy for adults with advanced colorectal cancer (77% versus 71%) (Leighl 2011; Table 14). Whelan 2003 also found no significant effect on preferences for adjuvant chemotherapy versus no chemotherapy for early stage breast cancer.

Choice for diabetes treatment with new medications

Four studies evaluated patient decision aids compared to usual care on decisions about starting new medications for diabetes (Mann D 2010; Mathers 2012; Mullan 2009; Weymiller 2007). Although there was no statistically significant difference between groups for individual studies, pooled results indicated a significant

increase in starting new medications (RR 1.65, 95% CI 1.06 to 2.56; Analysis 8.3).

Choice to take hypertension medication

Montgomery 2003 found no significant effect for decision aids over usual care on the initiation of medication for hypertension (Table 14).

Choice for menopausal symptom treatment

In a study comparing a decision aid to usual care (Murray 2001b), there was a non-significant decrease of 8% in hormone therapy (Table 14). Preferences for natural health products in women experiencing menopausal symptoms were no different for women exposed to the decision aid compared to women exposed to the usual education materials (Legare 2008a).

Choice for multiple sclerosis immunotherapy

Kasper 2008 reported no difference in the uptake of immunotherapy in people with multiple sclerosis who were exposed to a decision aid compared to usual care based on practice guidelines (Table 14).

Choice to take osteoporosis treatment

There was no difference in prescriptions for bisphosphonates for osteoporosis treatment (LeBlanc 2015; Table 14). Montori 2011 found no significant effect of decision aids over usual care on the uptake of medication for osteoporosis treatment.

Mental health

Hamann 2006 found no difference in prescription rates for antipsychotic medications but reported a statistically significant increase in the uptake in psycho-education (P = 0.003) in people with schizophraenia exposed to the decision aid compared to usual care (Table 14). Mott 2014 reported that a higher proportion of participants in the decision aid group with post-traumatic stress disorder completed psychotherapy sessions (4 of 9) compared to usual care (1 of 11).

Obstetrical choices

Childbirth procedures

Three studies focused on childbirth issues, using a decision aid compared to usual care. There was no difference in preference for vaginal birth in Shorten 2005 or actual vaginal mode of delivery in Montgomery 2007 following a previous cesarean section. Another study found no difference in actual choice to undergo external cephalic version for women with breech presentation (Nassar 2007).

Birth control approaches

There was no difference in the birth control methods chosen for those in the decision aid versus usual care groups (Langston 2010).

Embryo transplantation

Compared to usual care, those in the decision aid group were significantly more likely to choose a single embryo transplant (43% versus 32%) (Van Peperstraten 2010).

Vaccines

Compared to usual care, there was a non-significant increase in intentions to get the flu vaccine in those exposed to the decision aid (46% versus 27%) (Chambers 2012), a statistically significant increase in uptake of hepatitis B vaccination with decision aids (Clancy 1988), and no difference in uptake of measles, mumps, rubella vaccine in infants (Shourie 2013).

Other choices

Blood transfusions

There was no difference in the uptake of preoperative autologous blood donation when a decision aid was compared to usual care (Laupacis 2006).

Lung transplant referral

There was no difference in referral rates for consideration of lung transplant in people with advanced cystic fibrosis exposed to a decision aid versus usual care (Vandemheen 2009).

Pelvic organ prolapse treatment

There was no difference in treatment rates for prolapsed pelvic organs (Brazell 2014).

Thyroid cancer radioactive iodine treatment

There was no difference in the rates of adjuvant radioactive iodine treatment for thyroid cancer (Sawka 2012).

Adherence (continuance/compliance) with chosen option

Of 105 studies, 16 (15.2%) measured adherence using various approaches (Table 15).

Based on the measurement framework by Trenaman 2016, we grouped adherence according to adherence to the baseline choice and adherence to the treatment. Six studies measured only adherence to the baseline choice (Langston 2010; Legare 2012; Lepore 2012; Man-Son-Hing 1999; Mathers 2012; Trevena 2008), 6 studies measured only adherence to treatment (Loh 2007; Mann D 2010; Mott 2014; Mullan 2009; Oakley 2006; Sheridan 2011), and 4 studies measured both (LeBlanc 2015; Montgomery 2003; Montori 2011; Weymiller 2007).

For the 10 studies that measured adherence to choice, two studies reported that patients exposed to decision aids had higher adherence compared to usual care (Mathers 2012; Montori 2011), and 8 reported no difference between groups. For example, Mathers 2012 asked participants, 6 months after their decision, whether or not they had changed their initial choice about starting insulin for type II diabetes (decision aid 68.1% versus 56.3% usual care; P = 0.041). Montori used pharmacy records to determine if participants who chose bisphosphonates actually took their medication on more than 80% of the days for which it was prescribed (100% decision aid versus 74% usual care; P = 0.009).

For the 10 studies that measured adherence to treatment, 2 studies reported that patients exposed to decision aids had higher adherence compared to usual care (Mott 2014; Sheridan 2011), 1 study reported that patients exposed to decision aids had lower adherence (Mullan 2009), and 7 reported no difference. Mott reported the percentage of participants at four months who engaged in nine or more psychotherapy sessions (4 of 4 decision aid group participants versus 1 of 5 usual care). Sheridan measured the

percentage of participants who, 3 months after initiating therapy, were continuing (59% decision aid versus 34% usual care; P < 0.01). Mullan used pharmacy records to determine the days covered by medication use (97.5% decision aid versus 100% usual care).

Health outcomes

General health outcomes

Eleven studies (10.5%) compared a decision aid to usual care in terms of general health outcomes (Table 16). Ten of these used either the previously validated Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) or the 12-item Short-Form Health Survey (SF-12) (Stewart 1992), while Vuorma 2003 used the RAND-36 (Hays 1993). As shown in Table 16, there were no significant differences for mental health function or social function in any of the seven studies. In one study (Barry 1997), general health and physical function outcome scores were significantly better in the decision aid group compared to usual care for men considering treatments for benign prostatic disease. Of the two studies evaluating the effect of a decision aid for women considering treatment for abnormal uterine bleeding, Kennedy 2002 found a statistically significant improvement in role physical function, and Vuorma 2003 found a statistically significant improvement in emotional role functioning for women.

In two studies measuring health utilities using the Euroqol EQ-5D (Murray 2001a; Murray 2001b), there was no difference between the decision aid and usual care groups. There was also no between-group difference in the LeBlanc 2015 study, which used the Euroqol 5D health thermometer.

Condition-specific health outcomes

Seven studies (6.7%) used various measures to assess condition-specific health outcomes (Table 17). Outcomes included urinary symptoms (Barry 1997; Murray 2001a), angina (Bernstein 1998), functional assessment of cancer therapy (Leighl 2011), menopausal symptoms (Murray 2001b), and menstrual symptoms (Protheroe 2007; Vuorma 2003). Five studies found no significant effects on condition-specific health outcomes (Bernstein 1998; Leighl 2011; Murray 2001a; Murray 2001b; Vuorma 2003). Protheroe 2007 reported significantly higher menorrhagia-related quality of life scores in women exposed to the decision aid compared to usual care. Barry 1997 showed an improvement in urinary symptoms in favour of the decision aid group, but it was not statistically significant.

Other health outcomes

Seven studies (6.7%) reported on other health outcomes (Table 18), including death (Auvinen 2004; Knops 2014), glycated haemoglobin (Mathers 2012), angina (Morgan 2000), stroke (Thomson 2007), successful pregnancy (Van Peperstraten 2010), and pain (Vuorma 2003). There were no statistically significant differences between groups.

Preference-linked health outcomes

None of the 105 studies measured preference-linked health outcomes – that is, whether the patients experienced the outcomes they preferred and avoided the outcomes they wanted to avoid.

Anxiety

Of 105 studies, 31 (29.5%) measured anxiety, with 24 using the previously validated State Trait Anxiety Inventory (Spielberger 1970), 2 using the anxiety subscale of the Hospital Anxiety and Depression Scale (Knops 2014; Lam 2013), 2 using questions about worry (Fraenkel 2012; Smith 2010), 2 measuring intrusive thoughts (Lewis 2010; McCaffery 2010), and 1 using a single question on a seven-point Likert scale (Johnson 2006; see Table 19). Of 18 studies that used the State Trait Anxiety inventory within 1 month postintervention, 2 (11.1%) reported that the decision aid group had significantly lower anxiety scores for people considering birthing options after a previous caesarean (Montgomery 2007) and for women considering options for the treatment of menorrhagia (Protheroe 2007). None of the studies demonstrated significant differences in effects on people's state anxiety at one month (2 studies), three months (6 studies), six months (4 studies), or one year (2 studies). There was no significant difference between groups for the other instruments that measured anxiety.

Depression

Of 105 studies, 6 (5.7%) measured the effect of decision aids on depression using various instruments (Table 20). None of the studies reported a statistically significant difference between groups for decisions about cancer treatment (Davison 1997; Whelan 2004), depression (Loh 2007), prenatal genetic testing (Nagle 2008), or for women considering the number of embryos to transplant (Van Peperstraten 2010). At 10 months' postintervention, there were lower levels of depression in women deciding about breast cancer surgery who were exposed to the patient decision aid versus the usual care, but no differences at 1 week, 1 month, or 4 months postintervention (Lam 2013).

Regret

Of 105 studies, 7 (6.7%) measured the effect of decision aids on decision regret, using the five-item Decisional Regret scale (Brehaut 2003; see Table 21). At 4 and 10 months postintervention, women with breast cancer who were considering surgery and used a decision aid reported lower regret scores compared to women receiving usual care (Lam 2013). There was no statistically significant between-group difference in the other six studies.

Confidence

Of 105 studies, 8 (7.8%) measured the effect of decision aids on confidence levels (see Table 22). Four of these studies used the Decisional Self-efficacy Scale (Allen 2010; Arterburn 2011; Fraenkel 2007; Smith 2010). Four studies reported a statistically significant improvement in confidence or self-efficacy with decision making in the decision aid compared to the usual care groups (Chambers 2012; Fraenkel 2007; Gattellari 2003; McBride 2002), and the other studies reported no difference between groups.

Healthcare system effects

Cost and resource use

Of eight studies (7.6%) examining cost and resource use, one conducted a cost-effectiveness analysis (Kennedy 2002), five evaluated the effect of decision aids compared to usual care on total costs (Montgomery 2007; Murray 2001a; Murray 2001b; Van Peperstraten 2010; Vuorma 2003), and two measured resource use (Legare 2012; Thomson 2007) (see Table 23).

The cost-effectiveness analysis (Kennedy 2002) was conducted from the healthcare system perspective, using USD values from 1999 to 2000 and calculating costs over two years. The decision aid with nurse coaching demonstrated the lowest mean cost (USD 1566) compared to decision aid alone (USD 2026) or usual care (USD 2751).

Of the five studies that evaluated total costs, two reported no statistically significant difference in the patient decision aid compared to usual care (Montgomery 2007; Vuorma 2003). Two studies reported higher costs for the patient decision aid group when including the cost of the interactive video disc equipment (USD 216 at 1999 prices) and no statistically significant difference between groups when removing this cost (Murray 2001a; Murray 2001b). The fifth study reported that the mean total savings in the decision aid group versus usual care was EUR 169.75 per couple (Van Peperstraten 2010).

For healthcare resource use in upper respiratory infection, Legare 2012 reported no difference in the rates of repeat consultations for the same reason, and Thomson 2007 reported no difference in the rates of general clinician consultations in the three months following the intervention. Both studies used the patient decision aid in the consultation.

Consultation length

Of 105 studies, 10 (9.5%) evaluated the effect of a decision aid compared to usual care on consultation length (see Table 23). The median consultation length was 24 minutes (range 3.8 to 68.3) for patient decision aid compared to 21 minutes (range 4.2 to 65.7) for usual care. The difference was 2.6 minutes longer (7.5% increase) than usual care consultations (range 0.4 minutes shorter to 23 minutes longer). The length of consultation was significantly longer for the patient decision aid group in two studies (Bekker 2004; Thomson 2007), and eight studies reported no difference. Bekker 2004 reported that consultations about prenatal diagnostic testing were 5.9 minutes longer, and Thomson 2007 reported consultations about treatment for atrial fibrillation were 23 minutes longer when using a computerized decision aid with standard gamble method within the consultation.

Litigation rates

None of the 105 studies examined the effect of decision aids on litigation.

Adverse events

There were no adverse effects on health outcomes or satisfaction, and no other adverse events reported.

Subgroup analysis - in preparation for versus during the consultation

Of 105 studies, 89 (84.8%) primarily evaluated the patient decision aid when used by the patient in preparation for the consultation, and 16 (15.2%) primarily evaluated the patient decision aid when used within the consultation. The patient decision aids used during the consultation focused on prenatal screening (Bekker 2004); cardiac stress testing (Hess 2012); dental surgery (Johnson 2006); restoration of tooth decay (Kupke 2013); antibiotics for upper respiratory infection (Legare 2011; Legare 2012); medication use for depression (Loh 2007), diabetes (Mann D 2010; Mullan 2009; Weymiller 2007), osteoporosis (LeBlanc 2015; Montori 2011), prevention of breast cancer (Ozanne 2007), and atrial fibrillation (Thomson 2007); surgery for breast cancer (Whelan 2004); and chemotherapy for breast cancer (Whelan 2003).

Knowledge

When considered separately by subgroups, there was no difference between knowledge scores for those exposed to the decision aid in preparation for the consultation compared to those used in the consultation itself (Analysis 1.2: MD 13.77% versus 10.57%, test for subgroup difference P = 0.31, I^2: 3%). Weymiller 2007 reported a higher mean difference when the decision aid was administered during the consultation but not if it was administered by research staff in preparation for the consultation. For the studies evaluating decision aids used in the consultation not included in the pooled outcome, two showed a statistically significant improvement in knowledge (LeBlanc 2015; Ozanne 2007), and two showed no difference (Mann D 2010; Thomson 2007).

Accurate risk perceptions

When analyzing pre-consultation and in-consultation decision aids further, accurate risk perceptions were not different between studies that used the decision aid in preparation for the consultation and those where the intervention occurred during the consultation (Analysis 2.2: RR 2.25 versus RR 1.79, test for subgroup differences: P = 0.33, I^2: 0%). The only study evaluating a decision aid within the consultation that was not included in the meta-analysis, Weymiller 2007, reported a higher proportion with accurate risk perception when the decision aid was administered during the consultation, but found no difference between groups when administered by research staff in preparation for the consultation.

Decisional conflict uninformed subscale

Too few studies measured the uninformed subscale in those exposed to decision aid within the consultation to be able to compare with those who used decision aids in preparation for the consultation. Weymiller 2007 reported that participants felt less uninformed when the decision aid was administered during the consultation, but not if it was administered by research staff in preparation for the consultation.

Decisional conflict unclear values subscale

Too few studies measured the unclear values subscale in those exposed to decision aid within the consultation to be able to compare with those who used decision aids in preparation for the consultation. Weymiller 2007 reported that participants felt less unclear about values when the decision aid was administered during the consultation, but not if it was administered by research staff in preparation for the consultation.

Patient-clinician communication

Due to variation in the reporting of data for this outcome, we were unable to investigate the effect of intervention timing on the variation in the effect on communication. Five studies evaluated a patient decision aid primarily used within the consultation with the clinician, and five evaluated a patient decision aid used in preparation for the consultation (see Table 8). All five studies that used the decision aid during consultations reported statistically higher mean OPTION scores in the patient decision aid group compared to usual care (Hess 2012; LeBlanc 2015; Montori 2011;

Mullan 2009; Weymiller 2007). Four of five studies assessing the effects of pre-consultation decision aid delivery (Fraenkel 2012; Hanson 2011; Lepore 2012; Sheridan 2011) reported that, compared to those in the usual care group, significantly higher proportions of participants exposed to the patient decision aid in preparation for the consultation reported that they discussed the decision with their clinician, and the fifth study showed no between-group difference (Sheridan 2006).

Participation in decision making

There were too few studies on decision aids used during the consultation to interpret findings from the subgroup analysis (Analysis 5.2; Analysis 5.3).

Length of the consultation

Due to variation in the reporting of data for this outcome, we were unable to investigate the effects of intervention timing on the length of consultation. Of seven studies that evaluated decision aids used within the consultation (Bekker 2004; LeBlanc 2015; Loh 2007; Ozanne 2007; Thomson 2007; Weymiller 2007; Whelan 2003), two reported that the length of the consultation was significantly longer for the patient decision aid group (Bekker 2004; Thomson 2007). There was no difference for the other studies. The three studies that evaluated decision aids used in preparation for the consultation reported no between group difference in the length of the consultation (Bozic 2013; Krist 2007; Vodermaier 2009).

Other outcomes

For values-choice congruence and proportion undecided, none of the studies of patient decision aids used during the consultation measured these outcomes. For satisfaction, there were a range of different approaches to measuring this outcome with mixed results and too few studies to make any descriptive comparisons. For choice, there were too few studies to conduct a subgroup analysis of pooled comparisons.

Post hoc analysis

Effects of study quality

To examine the potential bias arising from including studies of low methodological quality, we excluded 12 studies with a high risk of bias for any of the seven risk of bias criteria from the analysis (Auvinen 2004; Brazell 2014; Chambers 2012; Clancy 1988; Hamann 2006; Knops 2014; Krist 2007; Kupke 2013; LeBlanc 2015; Lewis 2010; Man-Son-Hing 1999; Mott 2014; see Figure 3). Overall, the results remained the same (Table 24; Analysis 1.3; Analysis 2.3; Analysis 3.5; Analysis 4.4).

Heterogeneity

When comparing patient decision aids to usual care, there was statistically significant heterogeneity in five of six of the IPDAS effectiveness criteria: knowledge scores, accurate risk perceptions, congruence between values and choice; feeling uninformed, and feeling unclear regarding personal values. There was no statistically significant heterogeneity for participation in decision making. It should be noted that the heterogeneity of the effect was not manifested in its direction but only in its size. For the 2009 update (O'Connor 2009b), we explored the potential factors contributing to heterogeneity (Table 25). Overall, regardless of the subgroup analyses conducted, scores for outcomes were similar to the overall effect, as indicated by overlapping confidence intervals.

DISCUSSION

Summary of main results

In this updated review, we added 18 new studies for a total of 105 studies comparing patient decision aids to usual care. This update also removed 28 studies that compared detailed versus simple patient decision aids that were included in the previous update. Based on the GRADE assessment (Summary of findings for the main comparison), there is high-quality evidence that compared to usual care, decision aids improve people's knowledge regarding options and reduce the decisional conflict stemming from feeling uninformed and unclear about their personal values. There is moderate-quality evidence that decision aids stimulate people to take a more active role in decision making and increase the accuracy of their risk perceptions. There is lower-quality evidence that decision aids improve congruence between the chosen option and personal values. This outcome is measured using a variety of different approaches, and the evidence could be strengthened by more standardized measurement. Moreover, decision aids decreased the proportion of people remaining undecided.

Although not a primary outcome of the review, the effect of decision aids on patients' choosing particular options continues to be variable. The numbers of patients choosing to have major elective surgery continues to decrease in favour of more conservative options, except when the baseline rates are low (e.g. surgery for benign prostate hyperplasia, prophylactic mastectomy for women who are carriers of the BRCA gene). The numbers of men choosing prostate-specific antigen (PSA) testing were fewer after exposure to decision aids.

Decision aids do no better than usual care in terms of their effects on people's satisfaction with decision making or health outcomes such as general quality of life or condition-specific quality of life. However, no studies measured preference-linked health outcomes, nor were adverse events reported. There was also no difference in anxiety. For length of consultation, eight studies found no difference, while two studies found a median increase of 2.6 minutes (7.5%) in the decision aid group compared to usual care consultations.There continue to be too few studies to determine the effects of decision aids on costs/resource use (Trenaman 2014). Although there may be additional costs involved in delivering decision aids, an independent review of decision aid studies with economic outcomes concluded that "this was likely to be small relative to the benefit to patients in terms of improved decision quality when effective decision aids are used" (NCGC/NICE 2012). Given the variability in measurement strategies, it difficult to determine the effect of patient decision aids on adherence to the chosen option or treatment.

New for this update, we analyzed the pooled data for decision aids used in preparation for the consultation separately from decision aids used in the consultation, and we found that there were similar improvements in knowledge, accurate risk perceptions, and patient-clinician communication.

Overall completeness and applicability of evidence

Main effects of decision aids

The largest and most consistent benefits of decision aids, relative to usual care, are better knowledge of options and outcomes, and more accurate perceptions of outcome probabilities. These

observations are clinically important because the usual care groups' scores for knowledge and perception of outcome probabilities were lower than the intervention groups'; both knowledge and perception of outcome probabilities are important for ensuring informed decision making. These effects suggest that current 'usual care' may not be good enough when informing people about these complex, values-sensitive decisions. People need to comprehend the options and outcome probabilities in order to consider and communicate to their clinicians the personal value they place on the benefits versus the harms. Likewise, pooling results from additional studies in this update shows a significant increase in informed values-based choice when decision aids were compared to usual care, and the results appear to be similar across subgroup analyses of studies that used the same composite measure.

Decision aids also help people feel more comfortable with their choices than usual care. This is revealed by the reduced scores for overall decisional conflict and for the decisional conflict subscales. People who use decision aids generally feel more informed about options and clearer regarding their personal values.

Compared to usual care strategies, decision aids improve individuals' perception of involvement in decision making. This observation suggests that the International Patient Decision Aids Standards criterion of helping patients participate 'in ways that they prefer' needs to be assessed after a patient has adequate information about what involvement means using interventions such as patient decision aids. People may have a mistaken preference for passivity because they believe that the best choice relies on the expertise of the clinician (which option is medically reasonable?) rather than understand the importance of their own preferences for outcomes of options (which outcomes matter most to me?).

Evidence continues to build that decision aids have a positive effect on the patient-clinician consultation (in 9 of the 10 studies that assessed this effect). Of the studies that measured patient-clinician communication, five involved using decision aids within the consultation and five in preparation for the consultation. At the same time, evidence on length of consultation indicates either no difference (8 studies) or slightly longer (2 studies) consultations in the decision aid group compared to usual care consultations.

However, few studies have reported on the impact of the context in which the patient decision aids are used. A previous subgroup analysis of 29 studies evaluating patient decision aids for treatment decisions reported greater improvement in knowledge scores (P = 0.03) when the patient decision aid was evaluated within the clinical pathway of care, compared to when patients volunteered to participate in the study independent of their clinician (Brown 2015).

Variable effects of decision aids

There may be several reasons for the variable effect of decision aids on the outcome of choices. First, most studies were under-powered to detect important differences in the outcome of choices. Second, not enough is known about baseline rates for optimal use of specific options. Third, in the studies reporting the outcome 'choices' at baseline and postdecision aid, some options may have been under-used and others over-used, relative to the choices individuals would make if they were more fully informed. Under these circumstances, one could expect to observe directional effects on choices once people become better informed and more involved in decision making.

Relatively under-used options at baseline were prostate surgery for benign prostatic hyperplasia and prophylactic mastectomy for breast cancer gene carriers. In this prostate-related example, there was a shortage of urologists and low referral rates for benign prostatic hyperplasia, whereas the breast-related example reflects the growing number of women who test gene positive and become aware of their options for preventing breast cancer. Hence, under-use of an option may be corrected with exposure to a decision aid.

In the other surgical decision aid studies, there were higher numbers of people choosing surgery in the control group (e.g. cardiac revascularization, back surgery, hysterectomy, orchiectomy, mastectomy). The procedure may have been chosen due to people's inflated perceptions of the probabilities of benefits, lack of appreciation of the probabilities of harms, and lack of awareness of alternatives (Hoffman 2015). Exposure to the decision aid reduced the number of people choosing elective surgery in favour of more conservative alternatives.

Limited effects of decision aids

The limited effects of decision aids on reported satisfaction with the decision-making process and with the actual choice made may indicate that decision aids have a limited effect on satisfaction. The null effects may also be due to measurement insensitivity. This is especially likely when satisfaction with usual care is already quite high (e.g. ceiling effects) and when choices are inherently difficult to make because of competing benefits and harms. Furthermore, once the decision is made, people may find it psychologically more comforting to say that they are satisfied rather than entertain doubts about what they have chosen (Gruppen 1994).

There is a need to establish the 'essential ingredients' in decision aids and to identify the people who are most likely to benefit from them. As the body of available research grows, it will become easier and more important to assess the usefulness of different components of decision support for different clinical contexts, decision problems, and groups of people. For example, an analysis of decision aids used in higher versus lower socioeconomic groups indicated greater improvements for those of lower socioeconomic status (Durand 2014). Recently, the IPDAS Collaboration completed a set of evidence reviews underlying the IPDAS checklist (IPDAS 2013), proposing criteria for defining the intervention as a patient decision aid and minimal certifying criteria (Joseph-Williams 2013). These are being used to inform the certification of patient decision aids in the USA, England, and Norway.

It is not surprising that decision aids had limited effects on health outcomes. One reason for using a decision aid is that there is often no option with a clear health outcome advantage. For example, when men with localized prostate cancer consider active treatment options, their health outcomes can be different, depending on whether they choose surgery with higher risks of impotence or radiation therapy with higher risks of longer term bowel irritation. Therefore, if health outcomes are used in future investigations of decision aids in situations in which there is clearly no health outcome advantage, the key question to pose is: do patients experience the health outcomes they prefer and avoid the outcomes to which they are averse?

More recently, decision aids are being used in situations in which there may be a longer-term health advantage, for example, in preventive decisions about the management of type II diabetes and/or hypertension, when the longer-term health outcome may be to avoid stroke (Mann D 2010; Mathers 2012; Montgomery 2003; Mullan 2009; Weymiller 2007). Interestingly, the pooled results showed a statistically significant increase in medication initiation when participants were exposed to the decision aid compared to usual care.

Unknown effects of decision aids

The effect of patient decision aids on adherence to the chosen option is an area of uncertainty. The adherence results are difficult to interpret due to incomplete data, primarily self-reported data, varying length of follow-ups, and small sample sizes. Moreover, studies reporting this outcome such as Man-Son-Hing 1999 had very little variation in choice (over 90% of long-term aspirin users decided to stay on aspirin). When examining adherence, it would be important to do so in the early phase, when presumably the issue is actually decisional in nature (e.g. filling the prescription, picking up the prescription, refilling the prescription) rather than involving the management of side effects and in a manner that separates those choosing to change versus those remaining with the status quo.

Despite the positive effects of decision aids on patient-clinician communication, some authors are concerned about the potential negative influence that decision aids may have on the relational aspects of the decision-making process; this concern highlights the need for further evaluation when decision aids are implemented as part of the routine process of care (Charles 2010; LeBlanc 2010).

In the context of decision aid use, cost-effectiveness and health utilities are other secondary outcome measures about which little is known and further evaluation is required (Trenaman 2014). We also need to establish ways of measuring preference-linked health outcomes to better determine the effect on quality of life. It is unlikely that we will observe the effect of decision aids on litigation rates in studies of decision aids, given the time delay to litigation and the rarity of this type of event. There do not appear to be any adverse events from using decision aids, but this could be more clearly examined in future studies. In fact, a mock trial that used a patient decision aid for prostate-specific antigen testing found that the majority of jurors (94%) would indicate that the standard of care had been met (Barry 2008). A recent systematic review concluded that there was insufficient evidence to determine if patient decision aids could reduce medical malpractice litigation (Durand 2014).

Quality of the evidence

Risk of bias ratings reveal between-study variability. We rated few studies as being at low risk of bias for blinding of participants and personnel and most studies as being at unclear risk of bias. Likewise, the majority of studies were rated as being at unclear risk of bias for selective reporting. When we conducted a post hoc analysis that involved removing studies at high risk of bias from the meta-analysis, there was no effect on the results. The conclusions of this review are limited by inadequate power to detect important between-subgroup differences in effectiveness and by the wide variability in the decision contexts, the elements within the patient decision aids, the type of comparison delivered (collectively referred to as usual care here), the targeted outcomes, and the evaluation procedures. The small number of studies for most outcomes did not allow for analysis of publication bias due to failure to publish negative studies. Moreover, most studies were at unclear risk of selective outcome reporting, indicating that there may have been bias arising from a failure to report all negative findings.

We rated the six primary outcomes in the 'Summary of findings' table using GRADE and assessed outcomes as high quality (knowledge, feeling uninformed, feeling unclear values), moderate quality (accurate risk perception, clinician-controlled role in decision making), and low quality (values-choice congruence). For values-choice congruence, the GRADE rating was downgraded for lack of consistency, directness, and precision. More specifically, congruence was measured using various approaches, as there is no gold standard measurement approach (Munro 2016). Several of the outcomes demonstrated statistically significant levels of heterogeneity. For the outcome of knowledge, for example, heterogeneity would be expected, given that the knowledge tests themselves were not standardized. However, we did not downgrade the ratings for knowledge, feeling uninformed, and feeling unclear values based on heterogeneity given the consistent direction of findings across studies. Moreover, the heterogeneity found in the various outcomes reflects differences across clinically diverse studies; therefore, the pooled effect size and confidence intervals should be interpreted as a range across conditions, which may not be applicable to a specific condition.

Potential biases in the review process

The strength of this systematic review is that patient decision aids improve several key primary outcomes across a wide variety of populations and decision contexts. The potential biases in the review process are due to limitations associated with having inadequate power to detect potentially important differences in effectiveness between subgroups, to differentiate between the most effective elements within the patient decision aid, and to investigate any differences associated with the type of comparison interventions used in studies. Several of the outcomes demonstrated statistically significant heterogeneity. This reflects differences across clinically diverse studies; therefore, the pooled effect size and confidence intervals should be interpreted as a range across conditions, which may not be applicable to a specific condition. In the Gentles 2013 subgroup analysis exploring three potential sources of heterogeneity (e.g. type of control intervention, decision aid IPDAS quality score, participants' baseline accurate risk perception), participants' baseline accurate risk perception was an important variable for explaining heterogeneity. Authors reported that when participants' baseline scores for accurate risk perception were lower, decision aids led to great improvement. Furthermore, we limited the extracted study data to only two comparison groups (e.g. most intensive intervention including a patient decision aid and usual care); therefore, we did not investigate the possibility of intermediate effects with less intensive decision aid interventions.

Agreements and disagreements with other studies or reviews

Our results confirm many of the observations reported in the previous versions of our review and in a comparative effectiveness review that focused on studies evaluating oncology-specific patient decision aids (Trikalinos 2014). We published the first systematic review of 17 randomized trials of decision aids in 1999 (O'Connor

1999b; O'Connor 2001), followed by updates in 2003 with a total of 35 studies (O'Connor 2003), in 2009 with a total of 55 studies (O'Connor 2009b), in 2011 with a total of 86 studies (Stacey 2011), and 2014 with a total of 115 studies (Stacey 2014b).

AUTHORS' CONCLUSIONS

Implications for practice

The positive effects of decision aids on improving people's knowledge of risks and benefits, feeling informed, and feeling clear about their values across a wide variety of decision contexts provides sufficient evidence for using them in clinical practice. They probably also facilitate accurate risk perception and active participation in decision making. However, several conditions may be necessary for successful implementation, including: good quality decision aids that meet the needs of the population; clinicians who are willing to use decision aids in their practice; effective systems for delivering decision support; and clinicians and healthcare consumers who are skilled in shared decision making. Although there have been some strides in achieving these conditions (Elwyn 2013; O'Connor 2007), the use of patient decision aids will not occur without adequate attention to implementation barriers to implementation and careful design of effective strategies for introducing and maintaining their use in routine clinical practice (Elwyn 2013; Gravel 2006; Legare 2008b; Legare 2010 ; Legare 2014).

New in this update was a subgroup analysis of the findings based on timing of decision aid used either before or during a consultation. Although knowledge scores and accurate risk perceptions were significantly higher in the decision aid group compared to the usual care, there was no difference in these outcomes when comparing decision aids used in preparation for versus during the consultation.

Implications for research

Studies are needed to deepen our understanding of interactions between patient decision aid use and the patterns of patient-clinician communication; format issues such as the web-based delivery of patient decision aids; and downstream effects on cost, resource use, and adherence. Although this update shows new studies conducted in Spain and China, most studies have taken place in North America, the UK, Europe, and Australia. There were far fewer studies of patient decision aids used within the consultation than those delivered pre-consultation, and this is an area of further research given the important issue of implementation.

With the addition of more studies in the systematic review, it may be possible to tease out the reasons for heterogeneity of results, including variability in: study quality; comparison intervention; elements within patient decision aids; decision type; setting where it was used; and format of decision aid (e.g. video, Internet, booklet). Research should also explore the degree of detail in patient decision aids that is required for positive effects according to the IPDAS criteria. In particular, evaluation is needed to compare the effect of those decision aids that meet the minimal IPDAS criteria for certification versus those that meet the full roster of IPDAS quality criteria (Joseph-Williams 2013).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Allen 2010

Methods	Cluster-randomized to decision aid vs usual care
Participants	398 + 414 men considering prostate cancer screening in the USA
Interventions	DA: computer tailored programme on clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision; interactive computer programme: inherently guided the patient through the decision aid and decision making process), tailored printout given to patients to promote discussion with others (practitioner, significant others) Comparator: no intervention
Outcomes	Primary outcomes: decisional status, knowledge, decision self-efficacy, decisional consistency Secondary outcomes: desire for involvement in decision making, decisional conflict, preferred options Outcomes assessed pre- and postintervention
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Sites were blocked on size and percent of male employees and randomly assigned by computer-generated random numbers to condition within blocks" (p 2173, Setting)
Allocation concealment (selection bias)	Unclear risk	The study does not address this criterion.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study does not address this criterion.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes measured were not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data and low rate of attrition that was consistent between groups
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Intervention delivery: mention of money incentive to complete paperwork, but was judged to have no effect on outcomes measured (p 2175)

Arterburn 2011

Methods	Randomized to decision aid vs usual care
Participants	75 + 77 participants considering bariatric surgery in the USA
Interventions	DA: booklet + video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to discuss with clinician) Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: knowledge, values, values concordance Secondary outcomes: treatment preference, decisional conflict, decisional self-efficacy, proportion undecided Primary outcomes assessed at baseline, postintervention and 3 months follow-up; secondary outcomes assessed at baseline and postintervention
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[U]sed computer-assisted, block randomisation process to ensure balanced allocation of participants" (p 1670, Participants and randomization)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment and no mention of impact on study
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[S]tudy was not blinded" (p 1670, Participants and randomization); no mention of impact on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Measures: mentioned 4 choices for treatment preference (surgery, drug therapy, diet and/or exercise programme and unsure) but only reported on surgery and unsure options (p 1671); minimal attrition that was consistent between groups
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol or trial registration; all pre-specified outcomes included
Other bias	Low risk	The study appears to be free of other sources of bias

Auvinen 2004

Methods	Randomized to decision aid vs usual care
Participants	103 + 100 men newly diagnosed with prostate cancer in Finland
Interventions	DA: pamphlet patient decision aid created for study on options' outcomes, outcome probability, guidance

Auvinen 2004 *(Continued)*

	Comparator: usual care by clinical guideline
Outcomes	Primary outcome: uptake of options Secondary outcome: participation in decision making Other outcomes (from Huang 2014): death (5 years), disease-free survival (10-years), biochemical failure (serum PSA elevation) (5 years), biochemical failure-free survival (5 years), disease progression (5 years), disease progression-free survival (5 years) (data from 104 + 106 men)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Auvinen 2001, p 2: "randomized centrally, using software based on a random number generator"; no blocking used Auvinen 2004, (primary study), p 1: "randomized using a computer algorithm based on random numbers"
Allocation concealment (selection bias)	Unclear risk	Auvinen 2001,p 2, Patients and Methods: randomized centrally at the Finnish Cancer Registry Auvinen 2004, (primary study), p 1: randomized centrally Comment: central allocation confers low risk
Blinding of participants and personnel (performance bias) All outcomes	High risk	Auvinen 2001, p 3: "recognized carry-over effect because same physician in charge for intervention and control groups, diminish contrast between groups, as these physicians were more motivated to inform patients than those physicians not participating" Auvinen 2004 (primary study): no blinding but primary outcome is choice of treatment for prostate, objectively recorded. But unsure how physicians may have influenced decisions
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but primary outcome is choice of treatment for prostate, objectively recorded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Auvinen 2001, p 3: flow-chart "Imbalance in the numbers of patients between the arms within two hospitals. Not expected to affect the results in any way"; "some participants refused to give informed consent, health deterioration, not seen by urologist" (p 4) Auvinen 2004 (primary study), p 2: flow diagram and results; low attrition and consistent between groups
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry. Auvinen 2001, p 2: "The study protocol was approved by an ethical committee in each participating hospital" Auvinen 2004 (primary study), p 1: "The study protocol was approved by the institutional review board at each participating hospital"
Other bias	Low risk	Appears to be free of other potential biases

Barry 1997

Methods	Randomized to decision aid vs usual care
Participants	104 + 123 patients considering benign prostatic hyperplasia treatment in the USA
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinion Comparator: usual care using general information on the clinical problem
Outcomes	Primary outcome: knowledge Secondary outcomes: uptake of option, satisfaction with DM process, satisfaction with decision, interest in DM, general health outcomes, condition specific health outcomes
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Stratified by study site in concealed blocks of 10" (p 2)
Allocation concealment (selection bias)	Low risk	Study coordinator opening serially numbered, opaque, sealed envelopes (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding but phase 1 eliminated risk of contamination
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but phase 1 eliminated risk of outcome assessor interfering with decision
Incomplete outcome data (attrition bias) All outcomes	Low risk	Patient accrual and follow-up reported; post-randomization withdrawals could have biased the results (more in intervention group) - however they reported no evidence of a differential effect of the study group (p 3)
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry
Other bias	Low risk	Appears to be free of other potential biases

Bekker 2004

Methods	Randomized to detailed vs routine consultation
Participants	59 + 58 pregnant women who have received a maternal serum screening positive test result for Down syndrome in the UK
Interventions	DA (in consult): decision analysis plus routine consultation on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching Comparator: routine consultation on options' outcomes, outcome probability

Bekker 2004 *(Continued)*

Outcomes	Primary outcome: anxiety Secondary outcomes: uptake of option, knowledge, decisional conflict, informed decision making, satisfaction with consultation, consultation length
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Bekker 2003, p 2 - section 2.3 Sample and Procedure: "randomly allocated... using previously numbered... envelopes" Bekker 2004 (primary study), p 3: "Participants were randomly allocated by previously numbered envelopes"; does not mention how sequence was generated
Allocation concealment (selection bias)	Low risk	Bekker 2003, p 2 - section 2.3 Sample and Procedure: "Using previously numbered, sealed, opaque envelopes" Bekker 2004 (primary study), p 3: previously numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants blinded, personnel not blinded. Same personnel did control & intervention. Tape recorded sessions to ensure no bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Bekker 2003 flow diagram indicates postrandomization attrition with more attrition in decision aid group; no discussion on implications of attrition Bekker 2004 (primary study), p 4: results/flow diagram; baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	Bekker 2003: the coding frame was developed from literature. Does not mention protocol Bekker 2004 (primary study): no information provided about central trials registry
Other bias	Unclear risk	Bekker 2003: does not directly address baseline characteristics of participants Bekker 2004 (primary study): appears to be free of other potential biases

Bernstein 1998

Methods	Randomized to decision aid vs usual care
Participants	65 + 53 patients with coronary artery disease considering revascularization surgery in the USA
Interventions	DA: Health Dialog video on options' outcomes, clinical problem, outcome probability, others' opinion Comparator: usual care (no information provided)

Bernstein 1998 *(Continued)*

Outcomes	Primary outcome: satisfaction with decision and decision making process Secondary outcomes: uptake of option, knowledge, satisfaction with care, general health outcomes, condition specific health outcomes
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was stratified by study site in blocks of 10" (p 3)
Allocation concealment (selection bias)	Low risk	"[R]andomization performed by a study coordinator opening opaque, sealed envelopes at study headquarters" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Neither subjects nor study staff were blinded to treatment assignment - could lead to different satisfaction ratings based on knowing the treatment received
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3); low attrition of eligible participants randomized and consistent between group
Selective reporting (reporting bias)	Unclear risk	No information provided indicating trial was included in central trials registry
Other bias	Low risk	Appears to be free of other potential biases

Berry 2013

Methods	Randomized to decision aid vs usual care
Participants	266 + 228 men considering prostate cancer treatment in the USA
Interventions	DA: interactive web based video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to ask doctor and automated summary) Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcome: preferred/actual treatment choice (pre- and post-DA), proportion undecided Other outcomes (Bosco 2012): choice concordance (6 months post-DA). (Data from 239 + 209 men)
Notes	—

Risk of bias

Berry 2013 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Methods section- second paragraph, p 3: "Participants were randomized automatically by the P3P application to study groups (1:1 using a simple randomization scheme with no blocking)"
Allocation concealment (selection bias)	Low risk	Methods section, p 3: "Participants were randomized automatically by the P3P application to study groups"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded and study does not address the effect on the results
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear whether outcome assessors are blinded, but outcomes are not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis and low dropout (p 4)
Selective reporting (reporting bias)	Low risk	Protocol made available
Other bias	Unclear risk	Was a multicentre trial which could have lead to contamination, protocol violation and biased questionnaire completion

Bjorklund 2012

Methods	Randomized to decision aid vs usual care
Participants	236 + 247 women less than 11 weeks pregnant considering Down syndrome screening in Sweden
Interventions	DA: linear video on options' outcomes, clinical problem, outcome probabilities, others' opinion, and guidance (step-by-step process for making the decision) Comparator: usual care using pamphlet
Outcomes	Primary outcomes: knowledge (post-DA), attitude (post-DA), uptake of combined ultrasound and biochemical screening (post-DA) Secondary outcomes: values congruent with chosen option (post-DA)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The midwife allocated the participants randomly by sealed envelopes" (p 391) but does not state the actual sequence generation method
Allocation concealment (selection bias)	Low risk	Used sealed envelopes, "prepared, sequentially coded and distributed to the maternity units by the research group" (p 391)

Bjorklund 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"It was not possible to blind neither [sic] the midwives nor the participants due to the characteristics of the intervention" (p 395). The study does not address the effects of this on the results
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of why some participants' data were excluded in Tables 2, 3 and 4
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	Low risk	Appears to be free of other sources of bias

Bozic 2013

Methods	Randomized to decision aid vs usual care
Participants	95 + 103 participants with hip and/or knee osteoarthritis considering hip/knee surgery
Interventions	DA: DVD and booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, and guidance/coaching with health coach Comparator: usual care using pamphlet
Outcomes	Primary outcomes: informed decision/knowledge (pre, immediately post, and 6 weeks follow-up) Secondary outcomes: preferred treatment choice (pre and immediately post), patient and provider satisfaction (immediately post), length of consultation time
Notes	Trial registration: NCT01492257

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization was blocked with use of random permuted blocks in groups of four, six, or eight to help ensure that the groups were balanced" (p 1634)
Allocation concealment (selection bias)	Low risk	"Patients were randomized to either the intervention group or the control group with use of the sealed envelop method" (p 1634)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[S]urgeons were not blinded to the intervention" (p 1635). Knowing the allocation of participants, surgeons' favourable scoring could be due to greater investment in decision-making. Insufficient information to make a judgment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes are objectively measured and not subject to interpretation.

Bozic 2013 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	62% (123/198) retention rate therefore high attrition rate - however the attrition was balanced between groups
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Appears to be free of other sources of bias

Brazell 2014

Methods	Randomized to DA + standard counselling vs usual care + standard counselling
Participants	53 + 51 women presenting for the management and treatment of pelvic organ prolapse
Interventions	DA: paper-based or web-based DA on clinical problem, options' outcomes, outcome probabilities, patient stories and standard counselling Comparator: standard counselling alone
Outcomes	Primary outcomes: decisional conflict (immediately postconsultation) Secondary outcomes: choice (3 months after making decision), decisional regret (3 months after making decision)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized 1:1 using a random numbers table in blocks of 6" (p 231)
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided to make judgment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High attrition but balanced between groups: "39 randomized subjects were either missed by the research assistant at their new patient visit and thus did not receive a DCS questionnaire to complete or they canceled their appointments and did not reschedule a new one" (p 233). There was a 48% (50/104) attrition rate for Decisional Regret measures.
Selective reporting (reporting bias)	Low risk	Trial registered

Brazell 2014 *(Continued)*

Other bias	High risk	Risk of contamination due to same physicians in both groups. Also, outcomes measured after the PtDA and physician consult

Chabrera 2015

Methods	Randomized to DA vs usual care
Participants	73 + 74 men recently diagnosed with prostate cancer considering treatment options
Interventions	DA: 2-part decision support booklet with clinical problem, options' outcomes, outcome probabilities, patient stories, explicit values clarification, and guidance Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict, satisfaction with decision-making process Secondary outcome: coping Outcomes assessed at 3 months postintervention
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[S]tudy participants were randomized into 1 of 2 arms using a computer-generated random list with unequal blocks" (p E44)
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided to make judgment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Balanced attrition in both groups
Selective reporting (reporting bias)	Unclear risk	No protocol provided; trial not registered
Other bias	Unclear risk	Prostate cancer in Catalonia is common; however, only 147 were recruited for this trial (p E44)

Chambers 2012

Methods	Randomized to DA vs usual care

Chambers 2012 *(Continued)*

Participants	74 + 77 healthcare workers who did not receive the influenza vaccine considering receiving the vaccine in Canada
Interventions	DA: web-based DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance Comparator: usual care using pamphlet
Outcomes	Primary outcomes: confidence in decision (post-DA) Secondary outcomes: impact on immunization intent (post-DA), proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization list was generated using the randomization function in Excel 2002 (version 10.6856.6856 SP3)" (p 199)
Allocation concealment (selection bias)	Low risk	"The list was imported from Excel into a Microsoft SQL Server database. The online application would sequentially assign a random identification number and their decision aid status (seeing the decision aid or not) from the randomization list when users logged into the survey." (p 199)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported whether or not they were blinded during the course of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Questionnaire scores are objective and not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	High risk	65% completion rate in intervention arm and 77% completion rate in control arm: attrition could be different where the respondents and non-respondents are different
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Unclear risk	Figure 1 numbers for exclusion are not logical

Clancy 1988

Methods	Randomized to decision aid vs usual care
Participants	753 + 263 health physicians considering Hep B vaccine in the USA
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification (personal decision analysis), guidance/coaching Comparator: usual care (no information provided)
Outcomes	Uptake of option

Clancy 1988 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers table; all incoming residents were assigned to Group 2 (non-randomized residents identified as subgroup) (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding of participants or personnel. Did not report on how this may affect their findings
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but decisions for screening were retrieved from health records (objective data)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow chart not included. Insufficient information to make a judgment
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	High risk	Potential selection bias - non-randomized residents were added to group 2 and therefore potential unbalanced distribution (p 287) Low response rate among those offered decision analysis

Davison 1997

Methods	Randomized to decision aid + audio-taped consultation vs usual care
Participants	30 + 30 men with prostate cancer considering treatment in Canada
Interventions	DA: written + audiotape consultation of options' outcomes, clinical problem, outcome probability, others' opinion Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: role in decision making Secondary outcomes: anxiety, depression
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Davison 1997 *(Continued)*

Random sequence generation (selection bias)	Low risk	"The group to which subjects were assigned was predetermined by a block randomization procedure. This ensured there were an equal number of subjects in both groups for each physician." (p 5, Data collection)
Allocation concealment (selection bias)	Unclear risk	Not mentioned; group assignment predetermined by block randomization procedure (p 5)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; study does not report on how the results could be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding and whether outcomes could be affected by unblinded assessor
Incomplete outcome data (attrition bias) All outcomes	Low risk	No flow diagram; p 12 explains why certain men did not listen to audiotape. All men approached by study investigator agreed to participate; only 1 man refused to complete the second set of questionnaires.
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other sources of bias; similar baseline characteristics

De Achaval 2012

Methods	Randomized to detailed vs simple vs usual care
Participants	70 + 70 + 71 patients diagnosed with knee osteoarthritis considering treatment in the USA
Interventions	Complex DA: video booklet + interactive joint analysis on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (list of questions) Comparator DA: video booklet on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance (list of questions) Comparator: usual care receiving generic booklet
Outcomes	Decisional conflict (baseline and postintervention)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated list with uneven blocks (p 231)
Allocation concealment (selection bias)	Low risk	Numbered, sealed and opaque envelopes (p 231)
Blinding of participants and personnel (performance bias)	Low risk	Likely not blinded, but low threat of bias in study (p 231)

De Achaval 2012 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants were not blinded but outcome was objectively measured (p 231)
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 dropouts; missing data effect size unlikely to have significant impact on study outcome
Selective reporting (reporting bias)	Unclear risk	Protocol not available
Other bias	Low risk	Appears to be free of other sources of bias

Dolan 2002

Methods	Randomized to decision aid vs usual care
Participants	50 + 47 average risk for colorectal cancer considering screening in the USA
Interventions	DA: computer with analytic hierarchy process on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance/coaching Comparator: usual care with information on options, clinical problem
Outcomes	Primary outcomes: uptake of option, decisional conflict Secondary outcomes: role in decision making
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomization schedules were created using a computer random number generator" (p 2, Study interventions)
Allocation concealment (selection bias)	Low risk	Computer-based (p 2, Study interventions)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding of participants. All patient interviews in both the experimental and control groups were done by the same investigator, unclear on how this could contribute to risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram - low attrition
Selective reporting (reporting bias)	Unclear risk	Nothing specifically mentioned re study protocol

Dolan 2002 *(Continued)*

Other bias	Low risk	Appears to be free of other sources of bias

Evans 2010

Methods	Randomized to online decision aid vs paper decision aid vs questionnaire vs usual care
Participants	129 + 126 + 127 + 132 men considering PSA screening in Wales
Interventions	DA: online programme on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer programme; summary) Comparator: paper version of online DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer programme; summary) Comparator: received a questionnaire Comparator: received nothing
Outcomes	Primary outcomes: knowledge (post-DA) Secondary outcomes: attitude (post-DA), intention to undergo PSA testing (post-DA), anxiety (post-DA), uptake of PSA test (post-DA), total decisional conflict
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"[A] random sample of 100 men was selected from the list." "The process ensured individual level randomization" (p 4, Recruitment process)
Allocation concealment (selection bias)	Low risk	"[A]ffirmative consent forms from each practice were transferred to the research officer who allocated each participant with a number provided remotely by the trial statistician to ensure concealment" (p 4, Recruitment process)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study does not address this outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram indicating high attrition consistently across groups
Selective reporting (reporting bias)	Low risk	Registered as a trial
Other bias	Low risk	The study appears free of other sources of bias

Fagerlin 2011

Methods	Decision aid vs delayed intervention vs control
Participants	382 + 159 + 100 women with an elevated 5-year risk of breast cancer considering breast cancer prevention medication in the USA
Interventions	DA: tailored DA on options' outcomes, clinical problem, outcome probabilities, and explicit values clarification Comparator 1: given DA after 3-month follow-up Comparator 2: given DA after all outcome measures were taken
Outcomes	Decisional conflict (post-DA), behavioural intent (post-DA), actual behaviour (post-DA), proportion undecided, perception of benefits (post-DA), perception of risk (post-DA) Other outcomes: • Banegas 2013: decisional conflict (post-DA) (data from 690 + 160 + 162 women), proportion undecided (3 months) • Korfage 2013: knowledge (immediately post and 3 months post-DA), attitudes (immediately post and 3 months post-DA), behavioural intent (post-DA), actual behaviour (3 months post-DA), informed decision defined as "participants with sufficient knowledge about chemoprevention behavior, whose attitudes were concordant with their intentions or decisions to engage in chemoprevention behavior" (data from 383 + 102 + 100 women).
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence generation was provided by the author
Allocation concealment (selection bias)	Low risk	Central and web-based allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding - using an online decision aid would have avoided control participants accessing the decision aid
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not report exclusions; inadequate reporting on participant flow through the study to determine risk for attrition bias or incomplete outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	Low risk	Appears to be free of other sources of bias

Fraenkel 2007

Methods	Randomized to decision aid vs usual care
Participants	47 + 40 patients with knee pain considering treatment options in the USA
Interventions	DA: interactive computer tool options' outcomes, outcome probability, explicit values clarification Comparator: usual care using the Arthritis Foundation information pamphlet
Outcomes	Decisional self-efficacy, preparation for decision making
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization sequence (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided; computer generated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding but study does not report if it had an impact on the outcomes measured
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low risk of attrition bias - outcome data for all 40 controls and 44 of 47 intervention (p 3, Results)
Selective reporting (reporting bias)	Unclear risk	No information provided; no indication of trial was registered centrally
Other bias	Low risk	Appears to be free of other potential biases

Fraenkel 2012

Methods	Cluster-randomized control trial of clinics to decision aid versus usual care
Participants	69 + 66 patients with nonvalvular atrial fibrillation considering anticoagulation with aspirin or warfarin
Interventions	DA: computer-based tool on options' outcomes, clinical problem, options' probabilities, guidance, explicit values clarification Comparator: control arm (no further information provided)
Outcomes	Primary outcomes: feeling informed and having clear values (baseline, immediately post) Secondary outcomes: knowledge (baseline, immediately post), accuracy of risk (baseline, immediately post), anxiety (baseline, immediately post), worry (baseline, immediately post), rationale for preferred treatment (during the encounter - DA group only), discussion of related outcomes (during the

Fraenkel 2012 *(Continued)*

	encounter as captured on audiotape), change in treatment plan (post intervention), anxiety, accurate risk expectations (stroke, bleeding)
Notes	Trial registration NCT00829478

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Inadequate information on random sequence generation
Allocation concealment (selection bias)	Unclear risk	inadequate information on allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"To avoid contamination, participants were randomized at the level of the firm so that all participants in one firm received the intervention, and all participants in the second firm were included in the control arm" (p 1435)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"An interviewer blinded to the participant's group assignment reassessed the primary and secondary outcomes after participant's primary care visit" (p 1436)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not appear to be incomplete outcome data; flow diagram does not report participation beyond randomization
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Does not appear to be any other potential sources of bias

Frosch 2008a

Methods	Randomized to decision aid vs. decision aid + chronic disease trajectory vs chronic disease trajectory vs usual care (Internet information)
Participants	155 + 152 + 153 + 151 men considering prostate cancer screening
Interventions	DA: information on options' outcomes, clinical problem, outcome probabilities, others' opinions Comparator 1: information on options' outcomes, clinical problem, outcome probabilities, others' opinions, explicit values clarification (utilities for outcomes associated with prostate cancer) Comparator 2: explicit values clarification (utilities for outcomes associated with prostate cancer) Comparator 3: usual care using public information on prostate cancer screening on American Cancer Society and Centers for Disease Control and Prevention websites 2005-2006
Outcomes	Primary outcomes: knowledge, actual option, decisional conflict Secondary outcomes: concern about prostate cancer, treatment preference if prostate cancer diagnosed
Notes	—

Frosch 2008a *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer algorithm randomly assigned participants to the 4 study groups
Allocation concealment (selection bias)	Low risk	Revealed after signed consent and completed baseline measures
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Accessed a secure Internet site that hosted all study materials; participants had unlimited access to assigned intervention, unclear blinding of personnel
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were measured via questionnaires and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis; imputed missing data for participants who did not complete follow-up assessments; minimal attrition
Selective reporting (reporting bias)	Unclear risk	No indication of published protocol
Other bias	Low risk	Appears to be free of other potential biases

Gattellari 2003

Methods	Randomized to decision aid vs usual care
Participants	126 + 122 men considering PSA testing in Australia
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification Comparator: usual care using brief information on screening test and chances of false-positive results
Outcomes	Preferred option, knowledge, decisional conflict, accurate risk perceptions, perceived ability to make an informed choice
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Pre-randomized code - no further information (p 1)
Allocation concealment (selection bias)	Low risk	Pre-randomized code unobtrusively marked on envelopes (p 1)
Blinding of participants and personnel (performance bias)	Unclear risk	Consenting men were blinded to allocation, but unclear if personnel were blinded

Gattellari 2003 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Pre-test characteristics included. Flow chart not included and reasons for attrition not mentioned; some attrition but balanced between groups
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

Gattellari 2005

Methods	Randomized to decision aid booklet vs decision aid video vs usual care
Participants	140 + 141 + 140 men considering PSA testing in Australia
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification Comparator 1: video on clinical problem, outcome probability, others' opinion Comparator 2: usual care using brief information on screening test and chances of false-positive results
Outcomes	Preferred option, knowledge, decisional conflict, perceived ability to make an informed choice
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Unique identification codes assigned to participants according to date and time enrolled into the interventional component of the study. Block randomization of identification codes then performed via computer software (p 2 - 2.3.1)
Allocation concealment (selection bias)	Low risk	"Allocation concealment was ensured as the interviewers, responsible for enrolling participants onto the trial, were blinded to the randomized study design while one of the authors (MG) was responsible for randomisation. Hence, it was not possible for either participants or interviewers to be aware of the randomisation sequence." (p 2 - 2.3.1)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and interviewers were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	At post-test, it was not possible to blind the interviewers but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias)	Low risk	Minimal attrition that is consistent across groups (figure 1)

Gattellari 2005 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Unclear risk	"[S]uccess of study protocol" limitation to protocol: men not confronted with actual decision to undergo PSA screening; no indication that trial registered in central trials registry (p 13, paragraph 5)
Other bias	Low risk	"[H]igh follow-up rate and allocation concealment; study not subjected to selection bias" (p 13, paragraph 5). Appears to be free of other sources of bias

Green 2001

Methods	Randomized to decision aid + counselling vs counselling alone vs usual care
Participants	29 + 14 women with a first degree relative with breast cancer interested in learning about genetic testing in the USA
Interventions	DA: CD-ROM plus counselling on options' outcomes, clinical problem, others' opinions, guidance/coaching Comparator: counselling Comparator: usual care
Outcomes	Primary outcome: preferred options Secondary outcome: knowledge
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[B]lock randomization schedule to one of three groups in a 2:2:1 ratio" (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[G]enetic counsellor blinded to randomization until just prior to the session" (p 2), unclear if participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Values do not always add up to the number of participants due to missing data"; reasons not mentioned (p 4). "Participants' baseline knowledge was reflected in the control group's answers"; participants balanced in study groups
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other sources of bias

Hamann 2006

Methods	Cluster-randomized trial of decision aid vs usual care
Participants	54 + 59 patients with schizophraenia considering treatment options (cluster-RCT with 12 wards paired and randomized) in Germany
Interventions	DA: 16-page booklet on options' outcomes, outcome probabilities, explicit values clarification, coaching/guidance Comparator: usual care
Outcomes	Knowledge, participation in decision making (COMRADE - doctor gave me a chance to decided which treatment I thought was best for me), uptake of psycho-education, rehospitalization, adherence, satisfaction with care, severity of illness (baseline only), attitudes about drug use, decision making preference
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[O]ne member of each pair being randomly assigned to the control or to the interventional condition" (p 266). Sequence generation method was not stated
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for attrition mentioned
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	High risk	Clustering was not accounted for in the analysis

Hanson 2011

Methods	Randomized to decision aid vs usual care
Participants	127 + 129 patients diagnosed with advanced dementia and eating problems considering long-term feeding tube placement in the USA
Interventions	DA: booklet or audio recording on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (steps in decision making, worksheet, summary)

Hanson 2011 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (3 months post-DA) Secondary outcomes: surrogate knowledge, risk perceptions, frequency of communication with providers (3 months post-DA), feeding treatment use (3, 6 and 9 months post-DA), participation in decision making, satisfaction with the decision, decisional regret
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerized random number generation (p 2010, Randomization)
Allocation concealment (selection bias)	Unclear risk	No description of method used to conceal allocation (p 2010, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Cluster randomization prevented double blinding and may have introduced bias due to site effects" (p 2014, Discussion); study authors unsure of effect on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[B]ecause of cluster randomization, data collectors were not blinded to group assignment" (p 2010, Randomization); authors believe has little impact on study
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intervention group missing data for 1 participant, reason for omission not reported (table 1) No explanation for number of participants in each group (n = 127) given numbers vary from those in 'recruitment and retention' figure (table 4)
Selective reporting (reporting bias)	Low risk	Registered with clinicaltrials.gov, protocol on website
Other bias	Low risk	Appears to be free of other potential biases

Heller 2008

Methods	Randomized to decision aid vs usual care
Participants	66 + 67 breast cancer patients eligible for breast reconstruction in the USA
Interventions	DA: interactive software programme on options' outcomes, others' opinions Comparator: standard patient education
Outcomes	Knowledge, anxiety, satisfaction with treatment choice, satisfaction with decision-making ability
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement

Heller 2008 *(Continued)*

Random sequence generation (selection bias)	Low risk	"upon study entry, the participants were randomized (computer generated) to one of two groups" (p 2)
Allocation concealment (selection bias)	Unclear risk	Not enough information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline anxiety and knowledge included in graphs. Participant numbers between study groups balanced (p 3). Reasons for incomplete questionnaires and study withdrawals mentioned.
Selective reporting (reporting bias)	Unclear risk	No information provided re protocol
Other bias	Low risk	Appears to be free of other potential biases

Hess 2012

Methods	Randomized to decision aid vs usual care
Participants	103 + 105 patients in the the emergency department with primary symptoms of nontraumatic chest pain and were being considered of admission to the emergency department observation unit for monitoring and cardiac stress testing within 24 hours
Interventions	DA (in consultation): 1-page printout on options' outcomes, clinical problem, and outcome probabilities Comparator: usual care
Outcomes	Primary outcomes: knowledge Secondary outcomes: risk perceptions, decisional conflict, actual choice, satisfaction with decision making process, patient-practitioner communication
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion" (p 253)
Allocation concealment (selection bias)	Low risk	"Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion" (p 253)

Hess 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel were blinded, but unclear if patients were blinded (p 253, Outcome measures). However, the primary outcome is unlikely to be biased.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Investigators assessing outcomes were blinded (p 253, Outcome measures).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some of the numbers of patients reported in the results did not match the flow chart
Selective reporting (reporting bias)	Low risk	Protocol is available
Other bias	Low risk	Appears to be free of other biases

Jibaja-Weiss 2011

Methods	Randomized to decision aid vs usual care
Participants	51 + 49 women diagnosed with breast cancer considering surgical treatment in the USA
Interventions	DA: computer programme on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision) Comparator: usual care + breast cancer treatment educational materials normally provided to patients
Outcomes	Surgical treatment preference (post-DA), breast cancer knowledge (pre, post-DA, post-DA and consult), satisfaction with surgical decision (post-DA), satisfaction with decision-making process (post-DA), decisional conflict (pre, post-DA, post-DA and consult), proportion undecided
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients at each hospital were randomized using permuted blocks" (p 42, Methods section)
Allocation concealment (selection bias)	Unclear risk	Not addressed in the study
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not addressed in the study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Jibaja-Weiss 2011 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There is no way to know if the plots include all of the participants' data since they do not specify what was the number of patients used to obtain these mean scores
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Appears to be free of other potential biases

Johnson 2006

Methods	Randomized to decision aid vs usual care
Participants	32 + 35 patients considering endodontic treatment options in the USA
Interventions	DA (in consultation): decision board on options' outcomes, clinical problem, outcome probability, guidance Comparator: usual care
Outcomes	Primary outcomes: knowledge, satisfaction with decision making process, anxiety
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[F]our computerized random generation lists to assign to one of two groups" (p 3)
Allocation concealment (selection bias)	Unclear risk	Not for residents: computer-generated randomization lists (1 for each resident) were prepared by the PI (p 3-4); therefore residents would have had pre-generated lists; Unclear for patients: "allocation was concealed from patients" (p 3) but does not explain how
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not mentioned. Allocation was concealed from patients only (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 6); all 40 patients agreed to participate in the study, but only 32 questionnaires were useable several residents did not understand need for entering data on the envelope and placing matched questionnaire in it (p 5)
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry

Johnson 2006 *(Continued)*

Other bias	Unclear risk	"[B]aseline data obtained because possible that clinicians training in the EndoDB would alter usual care discussions" (p 5). Mentions taking baseline characteristics, but not included in article

Kasper 2008

Methods	Randomized to decision aid vs usual care
Participants	150 + 147 multiple sclerosis patients considering immunotherapy in Germany
Interventions	DA: booklet and worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification (based on IPDAS) Comparator: information material on immunotherapy (80 pages)
Outcomes	Primary outcomes: role in decision making Secondary outcomes: choice, feeling undecided, helpfulness with making a decision, attitudes toward immunotherapy, expectations of side effects realized at 6 months
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[A]llocation using computer generated random numbers" (p 5)
Allocation concealment (selection bias)	Unclear risk	Randomization was carried out by concealed allocation, but method of concealment was not described (p 2, Assignment)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were not told whether the information they received was standard information or the newly developed DA (p 3, Masking)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were not told whether the information they received was standard information or the newly developed DA (p 3, Masking)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of participants (p 2, Fig 1); baseline data/characteristics included
Selective reporting (reporting bias)	Low risk	"The protocol of this study has been published with the trial registration at http://controlled-trials.com/ ISRCTN25267500" (p 2)
Other bias	Unclear risk	Difference in preferred interaction style between groups at baseline (P value 0.04) (p 5)

Kennedy 2002

Methods	Randomized to decision aid + coaching vs decision aid only vs usual care
Participants	215 + 206 + 204 women considering treatment for menorrhagia in the UK
Interventions	DA: video + booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance/coaching Coaching: ~ 20 minute coaching with explicit values clarification by a registered nurse prior to seeing physician Comparator: usual care
Outcomes	Primary outcomes: general quality of life Secondary outcomes: uptake of option, satisfaction, menorrhagia severity, cost-effectiveness
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequence was generated by computer and stratified by consultant and the age at which the woman left full-time education (p 3)
Allocation concealment (selection bias)	Low risk	"Secure randomization ensured by using a central telephone randomization system" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Possibility of contamination bias; clinicians could have applied the experience gained from consultations with the interventions groups in their consultations with the control group (p 6)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear if blinding used but most outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Table 1 and Figure 1 flow diagram (p 4-5)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free from other risks of bias

Knops 2014

Methods	Randomized to decision aid vs usual care
Participants	91 + 87 patients with asymptomatic abdominal aortic aneurysm considering elective surgery vs watchful waiting
Interventions	DA: interactive CD-ROM on options' outcomes, clinical problem, outcome probabilities, explicit values clarification Comparator: usual care with regular information

Knops 2014 *(Continued)*

Outcomes	Primary outcomes: decisional conflict (baseline, 1, 4, and 10 months) Secondary outcomes: patient knowledge (baseline and 1 month), anxiety (baseline, 1, 4, and 10 months), satisfaction with conversation with the surgeon (baseline and 1 month), final treatment choice (10 months), aneurysm rupture (10 months), possible date of surgery (10 months), postoperative morbidity and mortality (10 months), physical quality of life (baseline, 1, 4, and 10 months)
Notes	Trial registration: NTR1524

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer-generated randomisation ALEA v.2.2, NKI-AVL, the Netherlands) was performed by the investigators" (p 2)
Allocation concealment (selection bias)	Low risk	"Computer-generated randomisation ALEA v.2.2, NKI-AVL, the Netherlands) was performed by the investigators" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients and investigators could not be blinded after group assignment, a factor which is inherent to the decision aid and the design of the study. Surgeons and nurses involved in the outpatient care of the participants were blinded to the patient's allocation group, although patients were not prohibited from sharing their allocation with them." (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome measurement is not likely to be influenced by lack of blinding as all outcomes were measured objectively using validated scales and data retrieved from medial records.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Appears to have similar attrition between groups. The proportion of values missing varied from 2% to 9% per outcome measure. Missing values were completed by multiple imputation analysis. If one of the outcome measures had more than 25% missing values, that outcome measure for that patient was excluded from analysis. Therefore, missing data have been handled appropriately (p 3).
Selective reporting (reporting bias)	Unclear risk	Insufficient information to make judgment
Other bias	High risk	"Considerable number of patients could not be included, were not asked to participation, or declined to participate. Selection bias may have occured in patients that were not included" (p 6) "Both patients and surgeons were aware of the aim and subject of the study and could not be blinded to the allocation. It is possible that surgeons in the contributing centres offered more than average information to their patients" (p 6). Performance bias may have been introduced in terms of altered communication style.

Krist 2007

Methods	Randomized to decision aid booklet vs decision aid web-based vs usual care
Participants	196 + 226 + 75 patients considering prostate cancer screening in the USA
Interventions	DA: 4 page pamphlet with options' outcomes, clinical problem, outcome probability

Krist 2007 *(Continued)*

	Comparator: web-site with same information as paper based DA Comparator: usual care
Outcomes	Primary outcomes: role in decision making Secondary outcomes: knowledge, decisional conflict, time spent discussing screening, choice (PSA test ordered)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]oordinator referred to pre-generated randomisation tables to inform the participant to which arm he was randomised" (p 2)
Allocation concealment (selection bias)	Low risk	At the time of enrolment, the allocation was concealed from the coordinator (p 2)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Physicians were not blinded - could affect decision making process and uptake of screening
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	p 3, Results; p 4, Flow diagram
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	Uneven groups but done intentionally, ration of 1:3:3 but appears to be free of other potential biases

Kupke 2013

Methods	Cluster-randomized trial of 2 groups of dental students to decision board group and non-decision board group. Patients randomized to students in either group.
Participants	57 + 36 patients with defect in posterior tooth (Class II defect) considering 6 treatment options, including no therapy
Interventions	DA (in consultation): options' outcomes, outcome probabilities Comparator: usual care with discussion of the treatment options
Outcomes	Knowledge (costs/self-payment, survival rate, characteristics and treatment time) (postintervention); overall satisfaction with consultation (postintervention)
Notes	Primary outcome not specified

Kupke 2013 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned by a dice (selection of students and patient allocation) (p 20)
Allocation concealment (selection bias)	High risk	"The patients were assigned to the students according to common standards of the university independently and without knowing which group the student belonged to." (p 20)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients were assigned to the students independently and without knowing which group the students belonged to" (p 20)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge if blinding of outcome assessment occurred
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attribution in both groups; "missing answers were treated as incorrect answers, while illegible answers were treated as missing values" (p 22)
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol or trial registration. No way to ensure the outcomes they intended to measure are fully reported
Other bias	High risk	Did not adjust for clustering in analysis

Kuppermann 2014

Methods	Randomized to decision aid vs usual care
Participants	375 + 369 11-week pregnant women who had not yet undergone prenatal screening or diagnostic testing
Interventions	DA: describes clinical condition, options, outcome probabilities, values clarification Comparator: usual care
Outcomes	Primary outcomes: invasive prenatal diagnostic testing (3 to 6 months) Secondary outcomes: testing strategy undergone (3 to 6 months), knowledge (3 to 6 months), accurate risk perception (procedure related miscarriage, DS affected fetus) (3 to 6 months), decisional conflict (3 to 6 months), decisional regret (3 to 6 months)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A computer generated random allocation sequence assigned participants to experimental groups within permuted blocks of random size, with a 1:1 allocation ratio, stratified by age, clinical site, parity, and interviewer" (p 1211)

Kuppermann 2014 *(Continued)*

Allocation concealment (selection bias)	Low risk	"The randomization code was not available to any study-related personnel until data analysis was complete" (p 1211)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Different research associates facilitated baseline and follow-up interviews and medical record review to ensure blinding to the randomization assignment" (p 1211)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Different research associates facilitated baseline and follow-up interviews and medical record review to ensure blinding to the randomization assignment" (p 1211)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition in both groups. "[A]ll reported analyses were based on a modified intention-to-treat sample" (p 1211)
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	Low risk	Appears to be free of other sources of bias

Lam 2013

Methods	Randomized to decision aid or standard information booklet after initial consultation
Participants	138 + 138 women considering breast cancer surgery for early-stage breast cancer
Interventions	DA: take-home booklet on clinical problem, options' outcomes, outcome probabilities, guidance, explicit values clarification Comparator: standard information booklet
Outcomes	Primary outcomes: treatment decision making difficulties and decisional conflict scale at 1 week post consultation, knowledge at 1-week postconsultation, decision regret at 1 month after surgery Secondary outcomes: postoperative psychological distress (anxiety and depression) at 1, 4, and 10 months after surgery, decision regret at 4 and 10 months after surgery, treatment decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patient assignment to treatment and control arms was performed using a prior computer-generated random-number sequence" (p 2880)
Allocation concealment (selection bias)	Low risk	"A serially labeled, opaque, sealed-envelope method was used for block randomization" (p 2880)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Two research staff members - one responsible for preintervention assessment and block allocation and the other for postintervention assessments - ensured that the researcher performing follow-up assessments was blinded regarding women's allocation status." "Blinding surgeons to allocation status proved impractical." (p 2880)

Lam 2013 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	1 research staff member was responsible for postintervention assessments to ensure that the researcher performing follow-up assessments was blinded regarding women's allocation status (p 2880).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data; similar attrition in both groups
Selective reporting (reporting bias)	Low risk	Study protocol available online with published study
Other bias	Low risk	Does not appear to be subject to other sources of bias

Langston 2010

Methods	Randomized to decision aid + coaching vs usual care
Participants	114 + 108 women pregnant women in their first trimester considering use of contraceptives in the USA
Interventions	DA: double-sided flip chart on clinical problem, outcome probabilities, guidance (administered by a research assistant), coaching (structured, standardized, non-directive contraceptive counselling) + usual care Comparator: usual care
Outcomes	Primary outcomes: proportion of participants choosing very effective contraceptive method (post-DA and consult) Secondary outcomes: actual choice on day of procedure (post-DA and consult), adherence of very effective and/or effective methods at 3 months and at 6 months (post-DA and consult)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Using a random-number table, we determined the sequence for 1:1 allocation constrained by blocks of 10" (p 363, Methods-study procedures)
Allocation concealment (selection bias)	Low risk	"Randomization assignments were sealed inside numbered, opaque envelopes" (p 363, Methods-study procedures)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"No blinding of participants or coordinators was feasible due to the nature of the intervention. Physician-providers did not know the participant's allocation group, did not discuss the study with patients, and were asked not to change their counselling" (p 363, Methods-study procedures)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	For "method initiation on the day of the procedure" it is only said that the "[p]articipants in the intervention group were not more likely to initiate the requested method immediately compared to those in the usual care group";

Langston 2010 *(Continued)*

		possible that the results contradicted the hypothesis and were excluded for this reason
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol; not enough information to permit judgement
Other bias	Low risk	Appears to be free of other potential biases

Laupacis 2006

Methods	Randomized to decision aid vs usual care
Participants	60 + 60 patients undergoing elective open heart surgery considering pre-operative autologous blood donation in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework) Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: uptake of option, satisfaction with decision making process, satisfaction with decision, accurate risk perceptions
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomization envelopes were prepared centrally by a statistician" (p 2)
Allocation concealment (selection bias)	Low risk	"The envelopes were labeled with identification numbers and contained a card specifying the patient's group assignment. The envelopes were opened by the interviewer after completion of the baseline interview." (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results, p 4; fig 1, flow diagram
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

LeBlanc 2015

Methods	Randomized to decision aid vs individualized score only vs usual care
Participants	32 + 33 + 14 women over 50 years diagnosed with osteopenia or osteoporosis not taking biphosphonates or other prescription medication
Interventions	DA (in consultation): clinical problem, individualized risk of condition, options' outcomes, guidance Comparator 1: individualized risk Comparator 2: usual care
Outcomes	Primary outcomes: knowledge (immediately post), decisional conflict (immediately post), participation in decision-making process (immediately post), decision to start (immediately post), adherence (6 months), acceptability (timing not specified), satisfaction with the decision-making process (not specified), quality of life (not specified), time (review of video consultation) Secondary outcome: decision quality (not reported)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" (p 5)
Allocation concealment (selection bias)	Low risk	"Patients were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" (p 5)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients and clinicians were aware of the overall objective, presented as improvement in communication between patients and clinicians during the clinical encounter, but remained blinded to the specific aims" (p 5)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After randomization, only data analysts remained blind to allocation" (p 5)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis; similar attrition in both groups
Selective reporting (reporting bias)	Unclear risk	Trial registered; Checklists available for CONSORT and protocol. Sample size originally calculated based on adherence but re-calculated for decisional conflict given inability to reach original target
Other bias	High risk	"Possible contamination at the clinician level (i.e. clinician who, having used the decision aid with a prior patient, recreates elements of the decision aid with a subsequent patient allocated to receive FRAX alone or usual care) was monitored by a detailed review of the available video recorded encounters" (p 5)

Legare 2008a

Methods	Randomized to decision aid vs usual care
Participants	45 + 45 women considering use of natural health products for managing menopausal symptoms
Interventions	DA: booklet with worksheet on options' outcomes, clinical problem, explicit values clarification, guidance/coaching (Ottawa Decision Support Framework) Comparator: general information brochure on the clinical problem (did not address risks and benefits)
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge of natural health products in general (not specific option outcomes), preferred choice, values-choice agreement, proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomization scheme was carried out by a biostatistician using computer-generated unequal blocks.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing 1 or the other documents (a PDA in the intervention group and a general information brochure in the control group) were prepared by another individual, external to the study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The investigators were blinded but no mention of blinding of participants
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See Figure 1 for flow diagram, reason for loss to follow-up was described.
Selective reporting (reporting bias)	Low risk	Trial registration identifier is NCT00325923
Other bias	Low risk	No statistically significant difference in women's characteristics between groups (Table 1)

Legare 2011

Methods	Cluster-randomized to decision aid vs usual care
Participants	245 + 214 patients with non-emergent acute respiratory infections considering using antibiotics in Canada
Interventions	DA (in consultation): pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching

Legare 2011 *(Continued)*

	Comparator: delayed intervention
Outcomes	Primary outcomes: • Patient outcomes: actual choice (pre and post-DA), perceived decision quality (pre and post-DA), decisional conflict (pre and post-DA), decision regret (pre and post-DA), general health outcomes • Practitioner outcomes: decision, perceived decision quality, decisional conflict Secondary outcomes: • Patient outcomes: intention to engage in future SDM (pre and post-DA), participation in decision making • Practitioner outcomes: intention to engage in future SDM and comply with clinical practice guidelines
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A biostatistician simultaneously randomised all FMGs and allocated them to groups using Internet-based software" (p 99)
Allocation concealment (selection bias)	Low risk	"Using Internet-based software" (p 99)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding of participants and personnel: only biostatistician was blinded (p 99)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biostatistician who assesses the outcomes is blinded, outcomes were objectively measured (p 99)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appear to be no missing data
Selective reporting (reporting bias)	Low risk	No missing pre-specified outcomes
Other bias	Low risk	Appears to be free of other sources of bias

Legare 2012

Methods	Cluster-randomized controlled trial to decision aid vs usual care
Participants	239+210 adults and children with with a diagnosis of acute respiratory infection (e.g., bronchitis, otitis media, pharyngitis, rhinosinusitis)
Interventions	DA (in consultation): pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching (participating physicians also received training in the form of a 2-hour online tutorial and a 2-hour on-site interactive workshop). Comparator: usual care

Legare 2012 *(Continued)*

Outcomes	Primary outcome: use of antibiotics (immediately post consultation) Secondary outcomes: decisional conflict (immediately post), control preference scale (immediately post), quality of decision (immediately post), adherence to the decision (2 weeks post), repeat consultation (2 weeks post), decisional regret (2 weeks post), quality of life (2 weeks post) and intention to engage in SDM in future consultations regarding antibiotics for acute respiratory infections (2 weeks post)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A biostatistician used internet-based software to simultaneously randomize all 12 family practice teaching units to either the intervention group or control group. The teaching units were stratified according to rural or urban location" (p E728)
Allocation concealment (selection bias)	Low risk	"A biostatistician used internet-based software to simultaneously randomize all 12 family practice teaching units to either the intervention group or control group. The teaching units were stratified according to rural or urban location" (p E728)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients with symptoms suggestive of an acute respiratory infection were initially recruited by a RA in the waiting room before consultation with a physician" (p E728)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The biostatistician was unaware of group allocation, the researchers and research assistants who recruited patients and collected data were not" and "Statistical analysis was performed by a statistician who was unaware of the teaching unit allocations" (p E729)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol registered and published
Other bias	Low risk	"To avoid contamination bias, access to the online tutorial was denied to providers in the control group during the trial" (p E728)

Leighl 2011

Methods	Randomized to DA + usual care vs usual care
Participants	107 + 100 patients diagnosed with metastatic CRC considering advanced chemotherapy in Australia and Canada
Interventions	DA: booklet and audiotape on option' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance (steps in decision making + worksheet) Comparator: usual care
Outcomes	Primary outcomes: knowledge (post-DA), satisfaction with decision (post-DA)

Leighl 2011 *(Continued)*

	Secondary outcomes: anxiety (pre and post-DA), satisfaction with consultation (post-DA), choice leaning (post-DA), decisional conflict (post-DA). achievement of their information preference (post-DA), participation in decision making (post-DA), acceptability (post-DA), quality of life (post-DA)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomized lists (p 2078, Study design)
Allocation concealment (selection bias)	Low risk	Code concealed in sealed envelopes until time of random assignment (p 2078, Study design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients not blinded and subjective outcomes may be affected by them knowing their assignment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcomes are not subjected to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	31% dropout rate, but similar losses across all groups
Selective reporting (reporting bias)	Unclear risk	Protocol not available
Other bias	Low risk	Appears to be free of other sources of bias

Lepore 2012

Methods	Randomized to decision support intervention (decision coaching by telephone + educational pamphlet) vs control
Participants	244 + 246 African American men aged 45-70 in the USA
Interventions	DA: condition-specific educational pamphlet on prostate cancer screening and tailored telephone education on options' outcomes, explicit values clarification, others' opinions, and guidance (decision coaching) Comparator: attention control (education on fruit and vegetable consumption)
Outcomes	Primary outcomes: knowledge (pretest and post-test at 8 months postrandomization), decisional conflict (posttest), physician visit to discuss testing (post-test), adherence as congruence between testing intentions and behaviors (post-test) Secondary outcomes: testing intention (post-test), benefit-to-risk ratio of testing (post-test), PSA screening (post-test), anxiety (pretest and post-test)
Notes	Trial registration NCT01415375

Lepore 2012 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The principal investigator used a computer-generated randomization schedule to randomize the participant." (p 322)
Allocation concealment (selection bias)	Unclear risk	"The principal investigator used a computer-generated randomization schedule to randomize the participant and emailed the randomization assignment to the interventionist." (p 322)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Interventionists were not blind to condition. We can assume that patients were blinded as the study design was a telephone call for both intervention and control groups (p 322)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Data collectors were blind to condition but the interventionists were not" (p 322).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Low risk	Appears to have reported on all pre-specified outcomes (protocol).
Other bias	Low risk	Appears to be free of other potential sources of bias

Lerman 1997

Methods	Randomized to decision aid vs waiting list control
Participants	122 + 114 + 164 women considering BRCA1 gene testing in the USA
Interventions	DA: education and counselling on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching Comparator: no intervention
Outcomes	Primary outcome: preferred option Secondary outcomes: knowledge, accurate risk perceptions, perceived personal risk/benefits/limitations, agreement between values and choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided
Allocation concealment (selection bias)	Unclear risk	No information provided

Lerman 1997 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 440 women, 400 completed 1-month follow-up interviews; no reasons provided; baseline data/characteristics included (p 2)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

Lewis 2010

Methods	Cluster-randomized to decision aid vs usual care
Participants	211 + 232 patients considering colorectal cancer screening in the USA
Interventions	DA: web-based, DVD and VHS videotape formats + stage targeted brochures (and booster kit if patients had not been screened) on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encouraged patients to communicate with their practitioners by asking questions and sharing preferences; summary) Comparator: usual care using Aetna annual reminders to obtain CRC screening
Outcomes	Knowledge of the age at which screening should begin (post-DA), completion of colorectal cancer screening (pre, post-DA), intrusive thoughts (pre, post-DA), interest in CRC screening (pre, post-DA), intent to ask provider about screening (pre, post-DA), readiness to be screened (pre, post-DA), perceived risk of colon cancer (pre, post-DA), general beliefs about colon cancer (pre, post-DA), fears about colorectal cancer screening (pre, post-DA), perceptions about whether participants had enough information (post-DA), whether participants had enough information about specific screening tests (post-DA), willingness to pay for screening tests (post), desire to participate in medical decision (post) **Practice level measures:** assess CRC screening practices (pre, post-DA), referrals (pre, post-DA), quality improvement initiatives
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomisation was done using matched pairs and a blocking procedure." (p 2, Practice recruitment and randomization section)
Allocation concealment (selection bias)	Unclear risk	"Thus, purposive assignment to treatment group was used, resulting in a hybrid randomisation" (p 3, Practice recruitment and randomization section). There is no mention of the effect of this purposive assignment on the study

Lewis 2010 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	As mentioned above, staff used purposive assignment and were therefore not blinded, but there is no mention of the effect on the study.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The study did not address this outcome, but outcomes were objectively measured.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appear to be no missing outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	High risk	Unadjusted cluster analysis

Loh 2007

Methods	Cluster-randomized to decision aid vs usual care
Participants	263 + 142 patients with physician diagnosed depression (cluster RCT with 30 general practitioners randomized) in Germany
Interventions	DA (in consultation): options' outcomes, clinical problem, explicit values clarification, guidance/coaching Comparator: usual care
Outcomes	Participation in decision making, adherence, satisfaction with clinical care, depression severity, consultation length
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[T]wo-thirds of the general practitioners were randomly assigned to the intervention group by drawing blinded lots under the supervision of the principal investigator and two researchers" (p 3)
Allocation concealment (selection bias)	Low risk	Drawing blinded lots (p 3 - 2.1)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding, not enough information provided to assess whether this contributes to bias on outcomes not measured by using a scale (e.g. consultation time was documented in minutes by the physicians following each consultation)

Loh 2007 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Further results resting on the baseline phase of this trial were already presented elsewhere" (p 5, fig); "unequal distribution of physicians was due to possibility of higher dropout rate in intervention group because of additional time and effort" (p 3).
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Appears to be free of other potential biases (p 5-6, details pt and physician baseline characteristics). Statistically significant differences were controlled for in outcome analyses

Man-Son-Hing 1999

Methods	Randomized to decision aid vs usual care
Participants	139 + 148 patients on atrial fibrillation trial considering continuing on aspirin vs change to Warfarin in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) Comparator: usual care
Outcomes	Primary outcomes: uptake of options, adherence Secondary outcomes: help with making a decision, knowledge, accurate risk perceptions, decisional conflict, satisfaction with decision making process, role in decision making
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated scheme (p 2)
Allocation concealment (selection bias)	Low risk	Administered from a central location (p 2)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear blinding however, "contamination, physicians may have provided DA information to patients receiving usual care" (p 7)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	P 4, fig 2 flow chart. Reasons for attrition not mentioned. Baseline data not included.
Selective reporting (reporting bias)	Unclear risk	No information provided

Man-Son-Hing 1999 *(Continued)*

Other bias	Low risk	No other potential risks of bias

Mann D 2010

Methods	Randomized to decision aid vs usual care
Participants	80 + 70 participants diagnosed with diabetes considering the use of statins to reduce coronary risk
Interventions	DA (in consultation): healthcare provider led discussion using developed tool (Statin Choice) on options' outcomes,outcome probabilities, guidance (step-by-step process for making the decision; administered by the physician in the consultation) Comparator: usual primary care visit + pamphlet
Outcomes	Knowledge (postconsult and post-DA), decisional conflict (postconsult and post-DA), risk estimation (postconsult and post-DA), beliefs (postconsult and post-DA), adherence (3 and 6 months postconsult and post-DA)
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Participants were randomized but there is no mention of method used (p 138, Methods section)
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline data was provided
Selective reporting (reporting bias)	Unclear risk	Only reports on improvement (i.e. decisional conflict scale); does not present outcome data to fullest (no numerical data on knowledge results between groups, only describes in words)
Other bias	Unclear risk	"We did not adjust the clustering of effects given that few participants received care by the same clinicians" (p 139, Analysis section). No mention of magnitude in change of data due to this choice

Mann E 2010

Methods	Randomized to decision aid vs usual care
Participants	278 + 139 participants considering diabetes screening in the UK
Interventions	DA: screening invitation on clinical problem, outcome probabilities and explicit values clarification Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcomes: preferred option (post-DA) Secondary outcomes: whether invitation type impacts on intention (post-DA), impact on knowledge (post-DA), impact on attitude (post-DA), risk perception
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Invitation taken from the top of a randomly ordered pile (either standard or one of two versions of an informed decision choice invitation). The materials were ordered in a way that the invitation type was hidden until the recruitment process was completed" (p 2-3, Methods, Participants section). Unclear how invitation type was hidden
Allocation concealment (selection bias)	Low risk	"Invitation taken from the top of a randomly ordered pile; materials were ordered in a way that the invitation type was hidden until the recruitment process was completed" (p 2-3, Methods, Participants section).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Interviewers were not aware of the direction of anticipated effect of materials, and materials were dummy-coded so that no sense of intervention or control would have been communicated to interviewers or participants (p 3, Methods, Participants section).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study did not address this outcome, but outcomes were objectively measured and not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of protocol; insufficient information to permit judgment
Other bias	Unclear risk	"Present sample was … not necessarily representative of the highest risk individuals in this age group"; "£5 incentive might have also added a selection bias"; "Lack of anonymity with verbally delivered questionnaire might encourage socially desirable responding" (p 6, Discussion section)

Marteau 2010

Methods	Randomized to decision aid vs usual care
Participants	633 + 639 patients considering diabetes screening in England

Marteau 2010 *(Continued)*

Interventions	DA: screening invitation on clinical problem, outcome probabilities and explicit values clarification Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcome: attendance for screening (post-DA and consult) Secondary outcomes: intention to make changes to lifestyle (post-DA and consult), satisfaction with decisions made among attenders (post-DA and consult)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[G]enerated simultaneously in a batch by random numbers using Excel spreadsheet software, stratifying by number of participants in household" (p 2, Randomization section)
Allocation concealment (selection bias)	Low risk	"Randomisation … was undertaken by the study statistician from a central site" (p 2, Randomization section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel were blinded and appears that patients were unaware which arm they were in (members of the same household received the same intervention) (p 2, Randomization section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinical and trial staff taking measurements and entering data were unaware of the study arm to which participants had been assigned (p 2, Randomization section)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Published protocol (p 2, Methods)
Other bias	Low risk	Appears free of other potential biases

Mathers 2012

Methods	Cluster-randomized controlled trial of 49 general practices in the UK to decision aid, healthcare professional training workshop and use of PDA in consultation, or usual care.
Participants	95 + 80 participants with type 2 diabetes considering adding or changing to insulin therapy
Interventions	DA: booklet about clinical problem, treatment options, options' outcomes, outcome probabilities, explicit values clarification, structured guidance Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (immediately postintervention), glycaemic control (glycosolated haemoglobin, HbA1c) at 6 months

Mathers 2012 *(Continued)*

	Secondary outcomes: knowledge (immediately post), realistic expectations (immediately post), preference option (immediately post), proportion undecided (immediately post), participation in decision-making (immediately post), regret (6 months), adherence with chosen option (6 months)
Notes	Trial registration: ISRCTN14842077

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"All eligible and willing practices were randomly allocated by a computer" (p 3)
Allocation concealment (selection bias)	Low risk	"A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied" (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied" (p 3)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	Unclear risk	Cannot make a judgment with information provided regarding cessation of recruitment at 175 (yet 320 required to allow detection of 0.5% difference in HbA1c)

Mathieu 2007

Methods	Randomized to decision aid versus usual care
Participants	367 + 367 women aged 70 to 71 years and considering a subsequent screening mammography in Australia
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance with worksheet (Ottawa Decision Support Framework) Comparator: BreastScreen NSW brochure - includes information for women 70 + but no numeric information about the outcomes of screening
Outcomes	Primary outcomes: actual decision, informed choice Secondary outcomes: knowledge (includes 5 questions about risk perceptions), anxiety, decisional conflict, breast cancer worry, preference/intension, attitudes about screening, relationship between objective and perceived risk of breast cancer

Mathieu 2007 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer programme, which assigned allocations in accordance with a simple randomization schedule (p 2, Methods)
Allocation concealment (selection bias)	Low risk	Randomized by interview staff who accessed a previously concealed computer programme (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers [at follow-up] were blinded, outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig 1 flow diagram (p 2)
Selective reporting (reporting bias)	Low risk	"The trial was registered with the Australian Clinical Trials Registry and the Clinical Trials Registration System" (p 5)
Other bias	Low risk	Appears to be free of other potential biases

Mathieu 2010

Methods	Randomized to decision aid vs usual care
Participants	189 + 223 women considering mammography screening
Interventions	DA: Internet programme + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (worksheet with questions relevant to decision making process; one or more questions that asked patients to clarify their preferences; summary) Comparator: delayed intervention
Outcomes	Primary outcomes: knowledge (post-DA), risk perception Secondary outcomes: intention (post-DA), values (post-DA), informed choice (post-DA), proportion undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputer generated simple randomization schedule" (p 66, Randomization and baseline questions section)

Mathieu 2010 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	"[R]andomization was conducted in a concealed manner" (p 66). Method of allocation concealment not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes mentioned in Outcome measures section were reported in the results section (p 68, Table 2; information for intention as well as anxiety and acceptability can be found in text format in the secondary outcomes section on pg.67-68)
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Appears to be free of other potential sources of bias

McAlister 2005

Methods	Cluster-randomized to decision aid vs usual care
Participants	219 + 215 patients considering antithrombotic therapy for nonvalvular atrial fibrillation (cluster-RCT with 102 primary care practices randomized) in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) Comparator: usual care
Outcomes	Primary outcomes: uptake of (appropriate) option Secondary outcomes: knowledge, decisional conflict, accurate risk perceptions
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]luster randomization at level of primary care practice to minimize contamination; randomization was done centrally to preserve allocation concealment using a computer generated sequence" (p 2)
Allocation concealment (selection bias)	Low risk	Randomization was done centrally to preserve allocation concealment (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded, but not sure whether the lack of blinding would affect the outcomes

McAlister 2005 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results and Fig 1 - flow diagram (p 3)
Selective reporting (reporting bias)	Low risk	DAAFI trial protocol, including copies of the various questionnaires we employed, has been published (p 1, Methods)
Other bias	Low risk	Appears to be free of other potential biases

McBride 2002

Methods	Randomized to decision aid vs usual care
Participants	289 + 292 perimenopausal women considering hormone replacement therapy in the USA
Interventions	DA: options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching Comparator: delayed intervention
Outcomes	Primary outcome: accurate risk perceptions Secondary outcomes: satisfaction with decision, confidence with knowledge and making/discussing decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided; Bastian 2002, no information provided - Study design is described elsewhere (p 4)
Allocation concealment (selection bias)	Unclear risk	No information provided; Bastian 2002, no information provided - Study design is described elsewhere (p 4)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Complete data are available for 520 (90%) of the women (p 2). Reasons why not mentioned (Bastian 2002, p 5, Results; p 6, Baseline characteristics/data included)
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry

McBride 2002 *(Continued)*

Other bias	Low risk	Appears to be free of other potential biases; Bastian 2002, p 8 - Eligible participants were willing to consider HRT and this may have favoured recruitment of women with higher SES and those who had prior experience with HRT

McCaffery 2010

Methods	Randomized to decision aid + informed choice vs HPV testing vs repeat smear
Participants	104 + 104 + 106 women screened as HPV indeterminate considering HPV testing in Australia
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (worksheet) Comparator 1: no decision support, received immediate HPV testing Comparator 2: no decision support, received a repeat cervical smear at 6 months
Outcomes	Primary outcomes: quality of life (post-DA) Secondary outcomes: waiting time anxiety (post-DA), , perceived risk (post-DA), perceived seriousness of cancer (post-DA), worriedness (post-DA), intrusive thoughts (post-DA), satisfaction with care (post-DA), anxiety (post-DA), distress and concerns (post-DA), self-esteem (post-DA), effect on sexual behaviour (post-DA), help seeking behaviour (post-DA), knowledge (post-DA)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomised centrally by the research team within each clinic in blocks of three" (p 2, Design)
Allocation concealment (selection bias)	Low risk	"Participants were randomised centrally by the research team within each clinic in blocks of three" (p 2, Design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients and staff were unblinded, but objective outcomes were used
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcomes are on questionnaires; not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Figure 3: sensitivity analysis was done to include most of the patients
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Appears to be free of other sources of bias

Miller 2005

Methods	Randomized to decision aid vs usual care
Participants	279 women considering BRCA1-BRCA2 gene testing in the USA
Interventions	DA: educational intervention on options' outcomes, personal family cancer history; clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching Comparator: provision of general information about cancer risk
Outcomes	Preferred option, knowledge, perceived risk, satisfaction
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomized by the CATI system" (p 4) after self-initiated telephone contact
Allocation concealment (selection bias)	Low risk	"[C]omputerized assisted telephone interview system (CATI)" (p 4)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding was not addressed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons stated for initial drop-out of study participants (p 8). Patients contacted offered reasons for dropping out. Study protocol allowed patients to be reached up to 13 times at follow-up; but still not able to be reached
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Appears to be free of other sources of bias

Miller 2011

Methods	Decision aid vs attention placebo
Participants	132 + 132 participants considering colon cancer screening in the USA
Interventions	DA: computer-based web programme on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encourages patient-practitioner communication, summary) Comparator: computer-based web programme on prescription drug refills and safety
Outcomes	Primary outcomes: receipt of CRC screening (post-DA) Secondary outcomes: ability to state a preference, change in readiness to receive screening (pre and post-DA), CRC test ordering (post-DA), proportion undecided

Miller 2011 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block-randomized, stratified by literacy level (p 609, Methods)
Allocation concealment (selection bias)	Unclear risk	Study does not address this domain
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Health care providers were not notified of patients' enrolment in the study at any time (p 609, Methods) RAs that administered post-DA questionnaire were not blinded but believed to be a low risk of bias (p 613, Discussion)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[C]linical outcome assessors were [blinded]" (p 613, Discussion)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol on ClinicalTrials.gov
Other bias	Unclear risk	USD 10 gift card for participation could affect participant pool

Montgomery 2003

Methods	Randomized to decision aid + decision analysis vs decision analysis vs decision aid vs usual care
Participants	51 + 52 + 55 + 59 newly diagnosed hypertensive patients considering drug therapy for blood pressure in the UK
Interventions	DA: decision analysis plus information video and leaflet on options' outcomes, clinical problem, outcome probability, explicit values clarification Comparator: decision analysis on options' outcomes, outcome probability, explicit values clarification Comparator: video and leaflet on options' outcomes, clinical problem Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: uptake of option, knowledge, anxiety
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Montgomery 2003 *(Continued)*

Random sequence generation (selection bias)	Low risk	Allocation schedule was computer-generated by an individual not involved in the study (p 2)
Allocation concealment (selection bias)	Low risk	"[A]llocation was concealed to the author in advance by the nature of the minimization procedure" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 5)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

Montgomery 2007

Methods	Randomized to decision aid with values clarification vs decision aid without values clarification vs usual care
Participants	245 + 250 + 247 women with previous caesarean section in the UK
Interventions	DA: options' outcomes, clinical problem, outcome probability, explicit values clarification Comparator: options' outcomes, clinical problem, outcome probability Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: choice, anxiety, knowledge, satisfaction with decision
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Blocked by using randomly permuted and selected blocks of sizes 6, 9, 12, and 15 generated by computer (p 2 Methods, Randomization)
Allocation concealment (selection bias)	Low risk	1 member of the study team generated the randomization sequence by computer, and another member of staff with no other involvement in the trial performed the allocation (p 2 Methods, Randomization)

Montgomery 2007 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow of women through the study
Selective reporting (reporting bias)	Low risk	Trials registry ISRCTN84367722
Other bias	Low risk	Recruited more than planned to account for lost data (p 4, Sample size); baseline characteristics were balanced

Montori 2011

Methods	Randomized to decision aid vs usual care + booklet
Participants	52 + 48 women with low bone mass or osteoporosis considering taking bisphosphonates in the USA
Interventions	DA (in consultation): worksheet on options' outcomes, clinical problem, outcome probabilities, guidance (administered by physician) Comparator: usual care + general information booklet on osteoporosis
Outcomes	Patient knowledge (post-DA), satisfaction with knowledge transfer (post-DA), decisional conflict (post-DA), patient-clinician communication (OPTION), trust with physician (during intervention), clinician's perception of decision quality (post-DA), clinician's satisfaction with knowledge transfer (post-DA), uptake (post-DA), adherence (post-DA), fidelity (post-DA), contamination (post-DA), risk perception
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"computer generated allocation" (p 551, Randomization)
Allocation concealment (selection bias)	Low risk	Patients randomized "in a concealed fashion (using a secure study website)" (p 551, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No mention of participants being blinded to their allocation; only mention of data collectors and analysts blinding (p 551, Randomization)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After randomization, data collectors and data analysts were blind to allocation" (p 551, Randomization); Outcomes were not subject to interpretation

Montori 2011 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	"The protocol for this trial has been reported in full" (p 550, Design)
Other bias	Unclear risk	Appears to be free of other potential biases

Morgan 2000

Methods	Randomized to decision aid vs usual care
Participants	120 + 120 patients with ischaemic heart disease considering revascularization surgery in Canada
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinions Comparator: usual care
Outcomes	Primary outcome: satisfaction with the decision making process Secondary outcomes: uptake of option, knowledge
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Morgan 1997, p 29: all randomization enrolment was performed by telephone at which time the participant was assigned Morgan 2000 (primary study), p 2, Methods, Patient Population: "Only the statistician was privy to the two randomisation schedules and blocking factor used"
Allocation concealment (selection bias)	Low risk	Morgan 1997, p 29: only the statistician was privy to the two randomization schedules and blocking factor; Morgan 2000, (primary study), p 2, Methods, Patient Population: "only the statistician was privy to the two randomisation schedules and blocking factor used. All randomization enrolment was performed by telephone"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[D]ue to nature of trial, neither patients or investigators were blinded to the study" - may introduce bias to subjective outcomes such as satisfaction
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Morgan 1997, p 39, Patient accrual and follow-up: baseline characteristics included

Morgan 2000 *(Continued)*

		Morgan 2000 (primary study): 78% completed follow-up (90 of 120 in the intervention; 97 of 120 in the control). reasons for attrition were provided
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Unclear risk	Morgan 1997, p 56: significant number of patients were lost to follow-up (25%); Morgan 2000 (primary study): baseline data imbalance (high school grad, income, no. of diseased arteries). Dropout group reported lower incomes, may have affected results. (discussion par. 6) "Selection bias was minimized by enrolling available consecutive patients"

Mott 2014

Methods	Randomized to shared decision-making process with DA versus usual care
Participants	13 +14 military veterans in USA diagnosed with PTSD and had served in Iraq or Afghanistan
Interventions	DA: booklet on clinical problem, options' outcomes, structured guidance Comparator: usual care
Outcomes	Satisfaction with SDM qualitatively (postintervention), perceived advantages and disadvantages of SDM qualitative (postintervention), treatment preferences (4 months), adherence using treatment engagement (4 months)
Notes	Not reported as registered in trials database; no primary outcome reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Participants were randomized to SDM or UC using a computer-generated randomization sequence" (p 146)
Allocation concealment (selection bias)	Low risk	"[R]andomization envelopes were prepared by the study statistician to ensure that study staff remained masked to randomization sequence" (p 146)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff not blinded but because outcomes were taken from medical records. "At 4-month follow-up, study staff reviewed participants' medical records to extract information on treatment preferences and engagement. Medical-record reviews were conducted by a single rater trained in use of the dataextraction form. A second rater, masked to initial ratings, reextracted data from 20% of patients" (p 146).
Incomplete outcome data (attrition bias) All outcomes	High risk	27 participants were consented and enrolled , yet only 20 (UC = 11; SMD = 9) completed the study (p 146-147). Only 5 participants in the SDM arm completed the exit interview. No mention of missing data.
Selective reporting (reporting bias)	Low risk	No protocol available but all expected outcomes reported on

Mott 2014 *(Continued)*

Other bias	Low risk	Does not appear to be any other sources of bias

Mullan 2009

Methods	Cluster-randomized to decision aid vs usual care
Participants	48 + 37 patients with type 2 diabetes considering treatment options (cluster RCT with 40 clinicians randomized) in the USA
Interventions	DA (in consultation): decision cards with information on options, outcomes, outcome probability, explicit values clarification Compare: 12-page pamphlet on oral antihyperglycaemic medications
Outcomes	Knowledge, decisional conflict, participation in decision making, acceptability of the information, change in medication, adherence, HbA1C levels, trust in physician, OPTION to analyse audio-taped encounters
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Low risk	Central allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients were blinded, the clinicians were not, but each session was recorded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons for attrition not included
Selective reporting (reporting bias)	Low risk	Trial registration no. at clinicaltrials.gov reported
Other bias	Low risk	Appears to be free of other sources of bias

Murray 2001a

Methods	Randomized to decision aid vs usual care
Participants	57 + 55 men considering treatment for benign prostatic hypertrophy in the UK

Murray 2001a *(Continued)*

Interventions	DA: Health Dialog interactive videodisc on options, outcomes, clinical problem, outcome probability, others' opinions Comparator: usual care
Outcomes	Primary outcomes: uptake of option, prostate symptoms, costs, anxiety Secondary outcomes: decisional conflict, role in decision making, general health status, utility
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomisation schedule, stratified according to recruitment centre, was generated by computer" (p 4)
Allocation concealment (selection bias)	Low risk	"Allocation were sealed in opaque numbered envelopes, opened by the study nurse" (p 4)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded but not sure how this would introduce bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 5); baseline data/characteristics included and balanced
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Appears to be free of other sources of bias

Murray 2001b

Methods	Randomized to decision aid vs usual care
Participants	102 + 102 women considering hormone replacement therapy in the UK
Interventions	DA: Health Dialog interactive videodisc on options outcomes, clinical problem, outcome probability, other's opinion Comparator: usual care
Outcomes	Primary outcomes: preferred option Secondary outcomes: help with making a decision, decisional conflict, role in decision making anxiety, menopausal symptoms, costs, utility, general health status
Notes	—

Murray 2001b *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomisation schedule, stratified according to recruitment centre, was generated by computer" (p 3 Methods, Randomization)
Allocation concealment (selection bias)	Low risk	"Allocations were sealed in opaque numbered envelopes, opened by the study nurse after collection of the baseline data" (p 3 Methods, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See page 3 figure for Progress of patients through trial
Selective reporting (reporting bias)	Unclear risk	Protocol is not mentioned
Other bias	Low risk	Similar baseline characteristics, appears to be free of other potential biases. Educational achievement was higher in control group. Quote "Subsequent analysis showed that educational level not related to use of HRT nor was there an interaction between educational attainment and the intervention"

Nagle 2008

Methods	Cluster-randomized to decision aid vs usual care
Participants	167 + 172 women in early pregnancy considering genetic testing (26 + 29 general physicians) (cluster RCT with 60 general practitioners randomized) in Australia
Interventions	DA: 24-page booklet and worksheet on options, benefits and risks, test limitations, outcomes; clinical problem, outcome probability, explicit values clarification, opinions of others', guidance (Ottawa Decision Support Framework) Comparator: standard pamphlet on prenatal testing
Outcomes	Primary outcomes: informed choice, decisional conflict Secondary outcomes: anxiety, depression, attitudes toward pregnancy, acceptability of the intervention, choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Nagle 2008 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated random numbers (p 3)
Allocation concealment (selection bias)	Low risk	Computer-generated random numbers by an independent statistician; allocation concealment was achieved (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Due to the nature of the intervention, it was not possible to blind women, GP's or researchers" (p 3); unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were not blinded but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results, p 4; Fig 1 - flow diagram, p 5
Selective reporting (reporting bias)	Low risk	Trial Registration - The ADEPT trial was registered in the UK with Current Controlled Trials [ISRCTN22532458] and with the Australian Clinical Trials Registry (No: 012606000234516) (p 4)
Other bias	Low risk	Appears to be free of other potential biases (p 8); selection bias but was adjusted for in analysis

Nassar 2007

Methods	Randomized to decision aid vs usual care
Participants	102 + 98 women diagnosed with a breech presentation from 34 weeks gestation considering external cephalic version in Australia
Interventions	DA: 24-page booklet, 30-minute audio-CD and worksheet; clinical problem, outcome probability, explicit values clarification, opinions of others', guidance (Ottawa Decision Support Framework) Comparator: usual care counselling and information on the management of breech presentation
Outcomes	Primary outcomes: knowledge, decisional conflict, anxiety, satisfaction with the decision, Secondary outcomes: preferred role in decision making, preferred choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomly generated using computer and stratified by parity and center using random variable block sizes" (p 2)
Allocation concealment (selection bias)	Low risk	"[P]articipants were randomized by telephoning a remote, central location" (p 2)

Nassar 2007 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Womens were not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up because of onset of labour or incomplete data forms (p 3). Baseline characteristics are included and equal. Minimum of 84 participants in each study group achieved; p 4 - flow diagram
Selective reporting (reporting bias)	Low risk	ISRCTN14570598
Other bias	Low risk	"Maternal characteristics and baseline measures of cognitive and affective outcomes were comparable between groups" (p 3 Results, Table 1) "Blinding clinicians and employment of a research midwife to interact with women" (p 6)

Oakley 2006

Methods	Randomized to decision aid vs usual care
Participants	16 + 17 postmenopausal women with osteoporosis considering treatment options to prevent further bone loss in the UK
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework) Comparator: usual care
Outcomes	Satisfaction with information, decisional conflict (intervention group only), improvement in adherence
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information provided
Allocation concealment (selection bias)	Low risk	Group allocation was done by a third party, unconnected to the study and blinded to the identity of the patients (p 1)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding, some outcomes were assessed by open-ended questions, do not know whether this contributes to risk of bias

Oakley 2006 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Sample characteristics not included; baseline satisfaction score included. "No evaluation was carried out to determine the reasons for non-participation" (p 2)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	No baseline characteristics (p 2). Only 16 patients in intervention group and 17 in control group; small sample size.

Ozanne 2007

Methods	Randomized to decision aid + standard counselling vs usual care (standard counselling)
Participants	15 + 15 women considering breast cancer prevention in the USA
Interventions	DA (in consultation): interactive computer decision aid on options outcomes, outcome probability Comparator: standard counselling
Outcomes	Primary outcomes: consultation length Secondary outcomes: knowledge, decisional conflict, satisfaction with the decision, acceptability of the decision aid, physician satisfaction with the consultation
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Patients were randomized evenly between groups; no information provided about generation (p 149)
Allocation concealment (selection bias)	Unclear risk	No information provided (p 149)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Demographic data included; reasons for attrition mentioned
Selective reporting (reporting bias)	Unclear risk	No reference to study protocol
Other bias	Unclear risk	Small sample size, does not say how many physicians participated in study, mentions that there were observed changes in physician behaviour (based on doing both intervention and control)

Partin 2004

Methods	Randomized to decision aid with others' opinions vs decision aid without others' opinions vs usual care
Participants	384 + 384 + 384 men considering PSA testing in the USA
Interventions	DA: Health Dialog video on options' outcomes, clinical problem, outcome probability, others' opinions Comparator 1: pamphlet on options' outcomes, clinical problem, outcome probability Comparator 2: usual care
Outcomes	Primary outcomes: knowledge Secondary outcomes: preferred option, help with making a decision, decisional conflict
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using a computer-generated algorithm (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"[P]roviders were blinded to the fact that their patients were participating in a trial" "coordinator did not have direct contact with subjects" (p 5)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[F]ollow-up interviewers blinded, statisticians were not". Outcomes were objectively measured and not subjective to to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 2); reasons for attrition mentioned and participants balanced across study groups. Sample characteristics included
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Appears to be free of other potential biases

Pignone 2000

Methods	Randomized to decision aid vs usual care
Participants	125 + 124 adults considering colon cancer screening in the USA
Interventions	DA: video of options' outcomes, clinical problem, others' opinion Comparator: video on car safety
Outcomes	Primary outcome: uptake of options

Pignone 2000 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputerized random number generator" (p 2, Methods, Group assignment)
Allocation concealment (selection bias)	Low risk	"[R]andomization was performed centrally and was not balanced among centers. Assignments were placed in sealed, opaque, sequentially numbered envelopes and were distributed to the three sites" (p 2, Methods, Group assignment)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"The providers and staff were not blinded to intervention status" "3 to 6 months after, different RA blinded to participant intervention examined clinic records" (p 2) Does not mention whether patients were blinded; unclear if lack of blinding contributed to potential risk of bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A different research assistant who was blinded to participants' intervention status examined participants' clinic records in a standardized and validated manner to determine whether colon cancer screening tests were actually completed within 3 months of the index visit.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Because of an administrative error, 18 controls did not complete the second and third questionnaires (p 4).
Selective reporting (reporting bias)	Unclear risk	Protocol was not mentioned
Other bias	Low risk	Baseline characteristics similar, appear to be no other potential sources of biases. Minimized bias from repeated measurements by administering the same questionnaires to the intervention and control participants

Protheroe 2007

Methods	Randomized to decision aid vs usual care
Participants	60 + 56 women considering treatment options for menorrhagia in the UK
Interventions	DA: interactive computerized DA on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance Comparator: information leaflet
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, anxiety, condition specific health outcomes, treatment preference, undecided
Notes	—

Risk of bias

Protheroe 2007 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomization, stratified by practice and minimized according to age (p 2, Methods)
Allocation concealment (selection bias)	Unclear risk	Random allocation was concealed from the individual who was making judgments of eligibility, but the method of concealment was not stated (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig 6 flow diagram (p 5); baseline data/characteristics included and balanced (p 4)
Selective reporting (reporting bias)	Low risk	ISRCTN72253427
Other bias	Low risk	Appears to be free of other potential biases

Rubel 2010

Methods	Randomized to pretest + decision aid + post-test vs decision aid + post-test vs pretest + posttest vs posttest
Participants	50 + 50 + 50 + 50 men considering prostate cancer screening in the USA
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probabilities, others' opinions + pretest and post-test Comparator : booklet on options' outcomes, clinical problem, outcome probabilities, others' opinions + post-test Comparator: pretest + post-test Comparator: post-test
Outcomes	Knowledge (pre, post-DA), decisional anxiety (post-DA), decisional conflict (post-DA), participation in decision making (pre, post-DA), schema for PSA testing (pre, post-DA), perception of quality and interpretation of recommendation (post-DA)
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Electronically generated random number sequence (p 309, Study design section)

Rubel 2010 *(Continued)*

Allocation concealment (selection bias)	Low risk	They were given sealed, sequentially numbered packets (p 309, Study design section)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No mention of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, but the outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol followed CONSORT checklist (p 310, Study design section)
Other bias	Low risk	Appears to be free of other potential biases

Ruffin 2007

Methods	Randomized to decision aid vs usual care
Participants	87 + 87 community dwelling adults not previously screened for CRC in the USA
Interventions	DA: interactive website with information on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion, guidance Comparator: non-interactive website with information on clinical problem
Outcomes	Primary outcome: uptake of option
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A block randomisation process programmed by the study computer support staff and verified by a statistician was used including two strata, race and gender" (p 3)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Both blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The investigators, data collectors, data entry, and data analyst were all blinded to study arm assignment.

Ruffin 2007 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

Sawka 2012

Methods	Randomized to decision aid vs usual care
Participants	37 + 37 individuals with early-stage papillary thyroid cancer
Interventions	DA: web-based decision aid with clinical problem, options' outcomes, outcome probabilities, guidance, printout summary Comparator: usual care (consultation with a specialized head and neck surgeon, and with 1 or more medical specialist).
Outcomes	Primary outcomes: knowledge (baseline and immediately post intervention) Secondary outcomes: decisional conflict, undecided, treatment decision (baseline, immediately post intervention, 6 to12 months), individual primarily responsible for the treatment decision (6 to 12 months)
Notes	Trial registration: NCT01083550

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Central computerized randomization in a 1:1 ratio was performed at a patient level by using variable block sizes of 2 and 4 (allocation designed by a study statistician)" (p 2908)
Allocation concealment (selection bias)	Low risk	"Before the random assignment/testing visit, neither the participant, study staff, investigators, nor treating physicians were aware of the allocation, because it had not yet been assigned" (p 2908)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"There was no blinding of participants, study staff, or treating physicians after random assignment was completed" (p 2908), yet it is unlikely that the outcomes are affected by the lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"There was no blinding of participants, study staff, or treating physicians after random assignment was completed. However, the statistician was blinded to the allocation of groups at the time of data analysis." (p 2908)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There does not appear to be any missing outcome data
Selective reporting (reporting bias)	Unclear risk	Authors state the trial is registered, but no link to trial number

Sawka 2012 *(Continued)*

Other bias	Low risk	Appears to be free of other potential sources of bias

Schroy 2011

Methods	Randomized to detailed vs simple decision aid vs control
Participants	223 + 212 + 231 average-risk patients considering CRC screening in the USA
Interventions	Detailed DA: CRC risk assessment + web-based interactive audio-visual DA on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance Comparator 1: web-based decision aid only Comparator 2: usual care using pamphlet
Outcomes	Knowledge (pre and post-DA), satisfaction with decision making process (pre and post-DA), preferred choice (pre and post-DA)
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No mention of randomization process
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Providers were not blinded, subjective outcomes such as satisfaction with decision-making process could have been affected, unclear if participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors not blinded but outcome measures not believed to be influenced by it
Incomplete outcome data (attrition bias) All outcomes	Low risk	No data appears to be missing
Selective reporting (reporting bias)	Unclear risk	No mention of examination of selective outcome reporting or study protocol
Other bias	Low risk	Appears to be free of other sources of bias

Schwalm 2012

Methods	Randomized to decision aid vs usual care
Participants	76 + 74 patients undergoing coronary angiography

Schwalm 2012 *(Continued)*

Interventions	DA: booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, risk perception, value congruent with chosen option
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerized random number generator (p 261, Study design)
Allocation concealment (selection bias)	Low risk	Sealed envelopes (p 261, Study design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients and physicians were not blinded to the allocation (p 261, Study design)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear if DCS score assessed by unblinded individuals, but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Did not seem to have incomplete data
Selective reporting (reporting bias)	Low risk	Protocol is available
Other bias	Low risk	Appeared to be free of other biases

Schwartz 2001

Methods	Randomized to decision aid vs usual care
Participants	181 + 190 Ashkenazi Jewish women considering genetic testing in the USA
Interventions	DA: 16-page booklet on genetic testing with options' outcomes, clinical problem Comparator: general information on breast cancer, *Understanding Breast Changes: A Health Guide for all Women,* published by the National Cancer Institute
Outcomes	Primary outcome: preferred option Secondary outcomes: knowledge, accurate risk perceptions
Notes	—

Risk of bias

Schwartz 2001 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated (p 3)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	High retention rate, baseline data and reasons for lost to follow-up were provided (p 2, Participants section)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

Schwartz 2009a

Methods	Randomized to decision aid + genetic counselling vs genetic counselling alone
Participants	100 + 114 women considering prophylactic mastectomy for being BRCA1/2 mutation carriers in the USA
Interventions	DA: CD-Rom on options' outcomes, clinical problem, risk communication with individually tailored risk graphs, explicit values clarification, others' opinion; guidance/counselling - genetic counselling as usual care (Ottawa Decision Support Framework) Comparator: genetic counselling on benefits and risks of testing, clinical problem (risk assessment, cancer risks associated with mutations, process of testing and interpretation of results) plus written letter outlining all guidelines and recommendations
Outcomes	Primary outcomes: decisional conflict, satisfaction with decision, actual choice (risk reduction mastectomy) Secondary outcomes: remaining undecided
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized via computer-generated random number in a 1:1 ratio (p 3, Procedure)
Allocation concealment (selection bias)	Unclear risk	No information provided

Schwartz 2009a *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig. 1 - flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other sources of bias (p 8) "when variable for not watching DA cd was considered in multivariate models, the results did not change substantively (data not shown)"

Sheridan 2006

Methods	Randomized to decision aid vs usual care (list of risk factors)
Participants	49 + 38 adults with no history of cardiovascular disease in the USA
Interventions	DA: computerized decision aid on options' outcomes, outcome probabilities Comparator: list of CHD risk factors to present to doctor
Outcomes	Patient-practitioner communication (e.g. discussion with doctor, specific plan to reduce risk discussed with doctor)
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[C]omputerized random number generator" (p 2)
Allocation concealment (selection bias)	Low risk	"[S]ealed in security envelopes" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded but the doctors who saw both groups were not
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcome was patient reported
Incomplete outcome data (attrition bias)	Low risk	Results (p 5); Flow diagram (p 10); Baseline characteristics/data included

Sheridan 2006 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov NCT00315978
Other bias	Low risk	Appears to have no other potential risk of bias

Sheridan 2011

Methods	Randomized to decision aid + tailored messages vs usual care
Participants	81 + 79 patients with moderate or high risk for CHD considering CHD prevention strategies in the USA
Interventions	DA: web-based decision aid on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance Comparator: usual care using computer programme
Outcomes	Preferred choice (post-DA), adherence Other outcomes (Sheridan 2014): patient-provider communication (post-DA), patient participation (post-DA), patients perceptions of discussions and the health care visit (post-DA), preferred choice (baseline and post-DA) (data from 81 +79 patients).
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomised by study staff who accessed an online randomised schedule" (p 2). Sequence generation method not stated
Allocation concealment (selection bias)	Low risk	"Patients were randomised by study staff who accessed an online randomised schedule" (p 2).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Patients blinded and physicians unblinded but objective outcomes are not likely affected by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes deemed objective therefore lack of blinding did not influence assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appears to be no missing data
Selective reporting (reporting bias)	Low risk	Protocol made available
Other bias	Low risk	Appears to be free of other sources of bias

Shorten 2005

Methods	Randomized to decision aid vs usual care
Participants	85 + 84 pregnant women who have experienced previous cesarean section considering birthing options in Australia
Interventions	DA: decision aid booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (Ottawa Decision Support Framework) Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: preferred option, help with making a decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-based randomized generation (p 3, Procedure)
Allocation concealment (selection bias)	Low risk	"[O]paque envelopes containing a random allocation for each participant code number" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants/midwives/doctors were blinded to patients' allocation. However, women who used the decision aid as specified and in a process of consultation with their midwife or doctor would have negated the blinding of their clinicians, and perhaps of the women themselves. For the intervention group, this may have affected the level and type of information exchanged between them and their caregivers.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	16 women were lost to follow-up from the intervention group and 18 from the control group (no reasons listed) (p 4, Results)
Selective reporting (reporting bias)	Low risk	Reference to published protocol
Other bias	Low risk	Appears to be free of other potential biases

Shourie 2013

Methods	Cluster-randomized controlled trial of GP practices to web-based MMR DA + usual care, MMR leaflet + usual care, versus usual care
Participants	50 + 93 + 77 parents' of children facing their first dose MMR vaccination
Interventions	Web-based DA: clinical problem, options' outcomes, explicit values clarification, guidance MMR leaflet: Health Scotland leaflet, 'MMR: your questions answered'

Shourie 2013 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (baseline and 2 weeks postintervention) Secondary outcomes: choice uptake of first dose MMR (when child was 15 months), knowledge (baseline and 2 weeks; results not provided), MMR immunization cognitions (baseline and 2 weeks post; results not provided), immunization trade-off beliefs (baseline and 2 weeks post; results not provided), anxiety (baseline and 2 weeks post; results not provided), use of the intervention (baseline and 2 weeks post)
Notes	Trial registration: UK Clinical Research Network - UKCRN ID 4811

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomisation using a computer-generated random list allocated GP practices on a 1:1:1 basis" (p 3)
Allocation concealment (selection bias)	Low risk	"An independent researcher who had no contact with participants generated the allocation sequence and assigned the GP practices to their allocated arm" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"On receipt of the completed baseline questionnaire and consent form, the appropriate intervention was delivered. At this point the researchers and participants were no longer blind to allocation" (p 3). We don't know if receiving the intervention had an effect on the ultimate decision that was made.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome data assessment does not depend on the assessor. It is an objective questionnaire.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing primary outcome data.
Selective reporting (reporting bias)	Unclear risk	Protocol registered. Primary outcome reported as stated. Secondary outcomes are not reported (p 3).
Other bias	Unclear risk	Difference in allocation to groups (50 + 93 + 77). Unclear what effect this difference had on the results.

Smith 2010

Methods	Randomized to detailed vs simple decision aid vs usual care
Participants	196 + 188 + 188 socioeconomically disadvantaged participants diagnosed with average or slightly above average risk of bowel cancer considering bowel cancer screening in Australia
Interventions	DA: booklet + DVD + worksheet + question prompt list on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making the decision; worksheet; encourages patients to communicate with practitioners by asking questions; summary) Comparator: booklet + DVD + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making the decision; worksheet; encourages patients to communicate with practitioners by asking questions; summary)

Smith 2010 *(Continued)*

	Comparator: usual care using standard information booklet
Outcomes	Primary outcomes: values congruent with chosen option (post-DA), participation in decision making (pre, post-DA) Secondary outcomes: knowledge (pre, post-DA), attitude, actual choice (post-DA), decisional conflict (post-DA), decision satisfaction (post-DA), confidence in decision making (post-DA), general anxiety (post-DA), worry about developing bowel cancer (pre, post-DA), risk perception Other outcomes (Smith 2014): screening participation (357 + 173 participants)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants who verbally consented to take part were then randomised to one of the three groups using random permutated blocks of size 6 and 9 for each sex stratum" (p 3, Participants and recruitment section)
Allocation concealment (selection bias)	Low risk	Central allocation; "interviewers responsible for recruiting participants were not aware of the randomization sequence or allocation and therefore did not know which intervention respondents would receive" (p 3, Participants and recruitment section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"It was not possible for the reviewers to be blinded to the group allocation. However, all questions used standardised wording with pre-coded responses and were asked within a supervised environment, where interviewer performances were regularly monitored to ensure scripts were read as written" (p 3, Outcome measures section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[A]nalyses were by intention to treat and carried out blinded to intervention" (p 5, Statistical analysis section); outcomes measured were not subject to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Explanation for the missing data reported at base of tables
Selective reporting (reporting bias)	Low risk	Study protocol available (ClinicalTrials.gov NCT00765869 and Australian New Zealand Clinical Trials Registry 12608000011381)
Other bias	Low risk	Appears to be free of other potential sources of bias

Stacey 2014a

Methods	Randomized to decision aid vs usual care
Participants	71 + 71 adults diagnosed with knee osteoarthritis considering joint replacement in Canada
Interventions	DA: DVD + booklet + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (1 page summary for the surgeon) Comparator: usual care
Outcomes	Primary outcomes: feasibility (including recruitment, data collection), preliminary effectiveness

Stacey 2014a *(Continued)*

	Secondary outcomes: knowledge (post-DA, pre-surgeon consult), informed values-congruent with chosen option (post-DA, pre-surgeon consult), uptake of chosen option at 1 year; decisional conflict (SURE test), preparation for decision making (4 items), wait times
Notes	Trial registration: NCT00743951

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The allocation schedule was computer-generated centrally by a statistician using a permuted block design with randomly varying block lengths of 4, 6, or 8." (p 3)
Allocation concealment (selection bias)	Low risk	"Allocations were concealed in numbered opaque sealed envelopes" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients were not informed of the intervention characteristics" (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Although the research assistant was not blinded to group allocation, study outcomes for effectiveness were objective and obtained from clinic data (e.g. date of surgery or wait list status)" (p 3).
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol registered on ClinicalTrials.gov
Other bias	Low risk	Appears to be free of other potential sources of bias

Steckelberg 2011

Methods	Randomized to decision aid vs usual care
Participants	785 + 792 patients with no CRC history considering CRC screening in Germany
Interventions	DA: brochure on options' outcomes, clinical problem, and outcome probabilities Comparator: usual care using pamphlet
Outcomes	Primary outcomes: values congruent with chosen option (post-DA) Secondary outcomes: knowledge (post-DA), combination of actual and planned uptake (post-DA), risk perception
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Steckelberg 2011 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer generated sequence (p 2, Randomization and blinding)
Allocation concealment (selection bias)	Low risk	Allocation was concealed. Identity numbers were independent of allocation, and study members did not have access to the data. (p 2, Randomization and blinding)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Trial staff who sent out questionnaires and reminders were not aware of study arm, unclear if participants were blinded (p 2, Randomization and blinding)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Trial staff and statistician who entered data were blinded (p 2, Randomization and blinding)
Incomplete outcome data (attrition bias) All outcomes	Low risk	12% missing one or both questionnaires in intervention group vs 9.2% in control; judged to have low impact on study outcome (p 2)
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Unclear risk	Participants who completed the trial do not add up

Taylor 2006

Methods	Randomized to print DA versus video DA versus wait list control
Participants	98 + 95 + 92 African American men with no history of prostate cancer to consider prostate cancer screening
Interventions	Print DA: clinical problem; outcome probabilities; guidance (list of questions to ask at next appointment); others' opinions Video DA: clinical problem; others' opinions Wait list comparator: no information provided until 1 month postrandomization (baseline assessment for this group coincided with 1-month assessment of print and video arms)
Outcomes	Prostate cancer screening intention (baseline and 1 month; not reported), prostate screening uptake (1 year; not included because wait list received intervention before 1 year) process variables including use and perception of the intervention materials (1 month), prostate cancer knowledge (baseline and 1 month post), decisional conflict (baseline and 1 month post), satisfaction with screening decision (baseline and 1 month post)
Notes	No primary outcome reported; not found in trials registry

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient information related to random sequence generation

Taylor 2006 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Insufficient information to judge allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to judge blinding; however, participants were requested to not share intervention materials with others to prevent contamination between groups (p 2180)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Unclear risk	No protocol registered or published
Other bias	Unclear risk	"All participants were mailed $25 for their participation following completion of the 1-month interview" (p 2181) "Men who reported that they had not yet had a chance to read/watch the materials were given an additional week to do so and called again to complete the follow-up assessment" (p 2181)

Thomson 2007

Methods	Randomized to decision aid vs usual care by clinical guidelines
Participants	69 + 67 patients with atrial fibrillation considering treatment options in the UK
Interventions	DA (in consultation): computerized decision on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance/coaching by physician Comparator: guidelines applied as direct advice
Outcomes	Primary outcome: decisional conflict Secondary outcomes: anxiety, knowledge, resource use, choice, health outcomes (stroke, transient ischaemic attack, bleeding events)
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[E]lectronically-generated random permuted blocks via a web-based randomisation service" (p 2, Recruitment and randomization)
Allocation concealment (selection bias)	Low risk	"[E]lectronically-generated random permuted blocks via a web-based randomisation service" (p 2, Recruitment and randomization)

Thomson 2007 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Physicians were blinded. Unclear if patients are blinded and how that may affect the outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram
Selective reporting (reporting bias)	Low risk	ISRCTN24808514
Other bias	Low risk	Baseline characteristics similar, sample size similar, not stopped early

Trevena 2008

Methods	Randomized to decision aid vs usual care by consumer guidelines
Participants	157 + 157 patients not previously screened for colorectal cancer in Australia
Interventions	DA: age-gender-family history specific DA booklet with information on options, outcome probabilities, explicit values clarification, guidance (personal worksheet with steps in decision making) (Theory of planned behaviour) Comparator: consumer guidelines recommending faecal occult blood testing
Outcomes	Primary outcome: informed choice Secondary outcomes: knowledge, values, screening intention (choice); test uptake, anxiety, acceptability of the intervention, satisfaction with the decision
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Sequential ID numbers were randomly assigned by computer program to DA or Guidelines (G) in blocks of four" (p 3)
Allocation concealment (selection bias)	Low risk	"Allocation was concealed via the password-protected program" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded to the intervention type - not sure about GPs
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were blinded to allocation for all telephone interviews, outcomes were objectively measured

Trevena 2008 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics included (p 3). Fig 2 flow chart (p 5). Reasons for loss to follow-up not mentioned
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov - NCT00148226
Other bias	Low risk	Appears to be free of other potential biases

Van Peperstraten 2010

Methods	Randomized to decision aid vs usual care
Participants	152 + 156 infertile women on wait list for in vitro fertilization in the Netherlands
Interventions	DA: self-administered booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making decision, worksheet with questions relevant to decision-making process; 1 or more questions that asked patients to clarify their preferences; summary to be shared with practitioner), coaching (by trained in vitro fertilization nurse) + standard in vitro fertilization care Comparator: standard in vitro fertilization care, including a session in which the number of embryos transferred was discussed
Outcomes	Primary outcomes: actual choice (postintervention and consult) Secondary outcomes: knowledge (pre, post-DA and consult), empowerment (pre, post-DA and consult), participation in decision making, decisional conflict (post-DA and consult), levels of anxiety (pre, post-DA and consult), depression (pre, post-DA and consult), cost evaluation of empowerment strategy (post-DA and consult), condition-specific health outcomes (pregnancies) (post-DA and consult)
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated list (p 2, Methods section)
Allocation concealment (selection bias)	Low risk	Central allocation (p 2, Methods section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Because of the nature of the intervention it was not possible to blind the participants or in vitro fertilisation doctors to the allocation. Participation in our trial did not change the normal in vitro routine." (p 2, Methods section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes assessed were not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There are categories in each column of table 1 (p 3) where the denominators do not match the number of people in the group and no reason was given to explain why this would be or if this affects the study

Van Peperstraten 2010 *(Continued)*

Selective reporting (reporting bias)	Low risk	Outcomes same as those registered with ClinicalTrials.gov
Other bias	Low risk	The study appear to be free of other sources of bias

Vandemheen 2009

Methods	Randomized to decision aid vs usual care
Participants	70 + 79 patients with cystic fibrosis considering referral for lung transplantation in Canada
Interventions	DA: self-administered booklet with clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework) Comparator: blank pages
Outcomes	Primary outcomes: knowledge, accurate risk perceptions, decisional conflict Secondary outcomes: preparation for decision making, choice, durability of decision, undecided
Notes	—

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[C]omputer-generated random listing of two treatment allocations blocked in blocks of 2 or 4, stratified by site and infection status of Burkholderia cepacia" (p 2)
Allocation concealment (selection bias)	Low risk	Central allocation (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single blinded RCT; patients and researchers were blinded but physicians were not because they were involved with patients before being randomized.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research staff, who were blinded to treatment allocation, telephoned each patient and had them complete a follow-up questionnaire; other outcomes reported are objectively measured
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline characteristics included (Flow diagram, p 2)
Selective reporting (reporting bias)	Low risk	Clinical trial registered with www.clinicaltrials.gov (NCT00345449)
Other bias	Low risk	Appears to be free of other potential biases

Vodermaier 2009

Methods	Randomized to decision aid vs usual care
Participants	74 + 78 women with breast cancer considering treatment options in Germany
Interventions	DA: Decision board administered by research psychologists and booklet on options' outcomes, clinical problem, outcome probability Comparator: booklet on clinical problem
Outcomes	Primary outcome: decisional conflict Secondary outcomes: choice, length of consultation, satisfaction with decision making, participation in decision making
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomisation after the patient gave written informed consent" "Random assignment was performed by means of numbered cards in envelopes" "stratified by age group" (p 2)
Allocation concealment (selection bias)	Low risk	"[N]umbered cards in envelopes" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, p 5; baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

Volk 1999

Methods	Randomized to decision aid vs usual care
Participants	80 + 80 men considering PSA testing in the USA
Interventions	DA: Health Dialog videotape and brochure on options' outcomes, clinical problem, outcome probability, others' opinion Comparator: usual care
Outcomes	Primary outcomes: knowledge, preferred/uptake of option

Volk 1999 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Volk 1999 (primary study), p 3: "[r]andomization by permuted blocks" "Each block included the numbers 1 through 4"; Volk 2003, p 2, Methods: Randomization by permuted blocks was used to balance the number of subjects in each arm of the study.
Allocation concealment (selection bias)	Unclear risk	Volk 1999 (primary study): no information provided Volk 2003, p 2: "[d]etails of the study procedures, subjects, and 2-week follow-up results can be found elsewhere"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were not blinded to the treatment assignment, but the physicians were; therefore outcomes were unlikely to be biased.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers were not blinded but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Volk 1999 (primary study), p 2, Procedures: baseline values included. Volk 2003, p 4 Fig 1 - flow diagram; baseline data not included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Volk 1999 (primary study): appears to be free of other potential biases Volk 2003: appears to be free of other sources of bias

Vuorma 2003

Methods	Randomized to decision aid vs usual care
Participants	184 + 179 women considering treatment for menorrhagia in Finland
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability Comparator: usual care
Outcomes	Primary outcomes: uptake of option Secondary outcomes: knowledge, proportion remaining undecided, anxiety, satisfaction, health outcomes, use and cost of healthcare services
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Vuorma 2003 *(Continued)*

Random sequence generation (selection bias)	Low risk	Vuorma 2003 (primary study), p 2, Randomization: computer-generated; done by a researcher who did not participate in the planning or concealment procedures "[D]one in STAKES, by researcher separately for each hospital in computer-generated varying clusters"(p 2) Vuorma 2004: no information provided
Allocation concealment (selection bias)	Low risk	Vuorma 2003 (primary study), p 2 "sequentially numbered, opaque and sealed envelopes" Vuorma 2004, p 2 "sequentially numbered, opaque, sealed envelopes"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding, unclear if measurements could be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff were not blinded but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Vuorma 2003 (primary study): flow chart balanced. Reasons for non-eligibility. "One women on HRT was randomized by mistake and included in analyses." Baseline characteristics included and balanced across groups (p 4-5) Vuorma 2004, flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	Vuorma 2003 (primary study): no mention of study protocol Vuorma 2004: no information provided
Other bias	Low risk	Vuorma 2003 (primary study), p 7: "increase in knowledge in both study groups, carry-over effect; change in decision-making process of intervention group may have altered physician's negotiation with patients" appears to be free of other potential biases Vuorma 2004, p 5: "comparison of the baseline characteristics presented elsewhere" In the pre-trial group compared with the control group, there was a greater increase in the dimensions of physical role functioning and emotional role functioning of the RAND-36

Watson 2006

Methods	Randomized to decision aid vs usual care
Participants	475 + 522 men considering prostate cancer screening in the UK
Interventions	DA: leaflet on options' outcomes, clinical problem, outcome probability Comparator: usual care
Outcomes	Primary outcomes: knowledge, screening intention, attitudes Secondary outcomes: preferred role in decision making

Watson 2006 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andom numbers generated centrally by Stata v8.2" (p 3)
Allocation concealment (selection bias)	Low risk	"[R]andom numbers generated centrally by Stata v8.2" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 2); reason for exclusion from analysis mentioned. Sample characteristics of risk included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	"Adjustment for multiple testing was not accounted for and hence a degree of caution with interpretation is required, particularly in relation to findings with a P-value close to 0.05" (p 3)

Weymiller 2007

Methods	Cluster-randomized to decision aid vs usual care
Participants	51 + 46 patients with type 2 diabetes in the USA
Interventions	DA (in consultation): 1-page decision aid options' outcomes, clinical problem, tailored outcome probability, guidance/coaching Comparator: booklet on cholesterol management
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: consultation length, acceptability of the intervention, adherence, estimated personal risk, trust, patient participation (OPTION), choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated allocation sequence (p 2)

Weymiller 2007 *(Continued)*

		Nannenga 2009: no information provided
Allocation concealment (selection bias)	Low risk	Computer-generated allocation sequence, unavailable to personnel enrolling patients. "[W]ith concealed allocation" (Abstract); "maintained allocation concealment" (p 5); randomized by concealed central allocation (Nannenga 2009, p 2)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and clinicians blinded to the study objectives, providers and patients were naive to this study objective
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analysts and statisticians blinded to allocation; intervention and outcomes; adequate blinding wherever possible
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3); reasons for attrition mentioned (p 4); baseline characteristics included; flow diagram Nannenga 2009, p 3: reasons for attrition mentioned and study groups balanced; baseline characteristics included
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov identifier: NCT00217061
Other bias	Low risk	Enrollment of patients already receiving statin therapy and limited statin uptake decreased the precision of our results; results should best be interpreted as preliminary and requiring verification Nannenga 2009: appears to be free of other potential biases

Whelan 2003

Methods	Randomized to decision aid vs usual care
Participants	82 + 93 women with node negative breast cancer considering adjuvant chemotherapy in Canada
Interventions	DA: decision board and booklet on options' outcomes, clinical problem, outcome probability, guidance/coaching Comparator: booklet on clinical problem
Outcomes	Primary outcomes: knowledge, satisfaction of participant Secondary outcomes: preferred option, anxiety, accurate risk perceptions, participation in decision making
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided

Whelan 2003 *(Continued)*

Allocation concealment (selection bias)	Low risk	Randomization, which was performed at a central location (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unable to blind participants in our trial for practical reasons, measures were taken to minimize bias in the design of the study and the assessment of outcomes
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram not included. "[O]ne patient excluded from analysis, determined by physician not to be candidate for chemotherapy" (p 4). Baseline data/characteristics included.
Selective reporting (reporting bias)	Unclear risk	Unclear if lack of blinding contributed to potential risk of bias
Other bias	Low risk	Appears to be free of other potential biases

Whelan 2004

Methods	Cluster-randomized to decision aid vs usual care
Participants	94 + 107 women with Stage 1 or 2 breast cancer considering surgery (cluster-RCT with 27 surgeons randomized) in Canada
Interventions	DA: decision board on options' outcomes, outcome probability, guidance/coaching Comparator: usual care
Outcomes	Primary outcomes: preferred option, knowledge, decisional conflict, satisfaction Secondary outcomes: accurate risk perceptions, anxiety
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Does not specify how the sequence was generated; a paired cluster randomization process was used (p 2, Study design and procedures).
Allocation concealment (selection bias)	Unclear risk	Randomly assigned in a concealed fashion, but method of concealment was not stated (p 2, Study design and procedures)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[C]hose cluster randomization method to avoid contamination that might have occurred if surgeons used decision board for some patients and not others" (p 6); unclear if this would introduce bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation

Whelan 2004 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included; reasons given for loss of participants
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Appears to be free of other potential biases

Williams 2013

Methods	Randomized to decision aid at home or in clinic versus usual care at home or in clinic
Participants	134 + 138 + 134 +137 men aged 40-70 years with no history of prostate cancer who had pre-registered for screening
Interventions	DA: content adapted from the Centers for Disease Control and Prevention's PCS educational tool. Includes clinical problem, treatment options, outcome probabilities, explicit values clarification, others' stories, summary worksheet Comparator: information booklet. A 3-page fact sheet requiring 5 minutes to read. Information presented in a Q&A format on who is recommended for testing, how to interpret results, and the limitations of testing
Outcomes	Knowledge, decisional conflict, screening outcomes, satisfaction with decision Outcomes assessed at baseline, 2 months, 13 months, except satisfaction with decision (2 months and 13 months)
Notes	No primary outcome reported; trial registration not provided

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient information to judge random sequence generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information to judge allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to judge blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	There does not appear to be any outcome data missing
Selective reporting (reporting bias)	Unclear risk	No registered or published protocol

Williams 2013 *(Continued)*

Other bias	Low risk	Appears to be free of other potential biases

Wolf 1996

Methods	Randomized to decision aid vs usual care
Participants	103 + 102 men considering PSA testing in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probability, others' opinions Comparator: usual care (single sentence)
Outcomes	Preferred option
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Wolf 1996 (primary study): no information provided Wolf 1998, p 2: "the methodology of the randomized trial has been reported previously"
Allocation concealment (selection bias)	Unclear risk	Wolf 1996 (primary study): no information provided Wolf 1998, p 2: "The methodology of the randomized trial has been reported previously"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Wolf 1996 (primary study), p 2: needed a minimum sample size of 150 participants, and was achieved with total sample size of 205. Reasons for attrition mentioned; baseline characteristics included Wolf 1998: no information provided except that methodology of the randomized trial and the content of the informational intervention reported previously (p 2). Baseline characteristics included; flow of participants not included
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry
Other bias	Low risk	Wolf 1996 (primary study): participant population had lower SES therefore external validity of the findings limited, but overall appears to be free of other potential biases Wolf 1998: appears to be free of other potential biases

Wolf 2000

Methods	Randomized to decision aid vs usual care
Participants	266 + 133 elderly (≥ 65 years) considering CRC screening in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probabilities Comparator: usual care (5 sentences)
Outcomes	Primary outcome: preferred option Secondary outcomes: accurate risk perceptions
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[P]atients were randomised" (p 2); does not indicate how
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data not included (p 2, Results)
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other potential biases

Wong 2006

Methods	Randomized to decision aid vs placebo control leaflet
Participants	162 + 164 women referred for pregnancy termination in the UK
Interventions	DA: decision aid leaflet on options' outcomes, clinical problem, outcome probability, explicit values clarification Comparator: placebo leaflet on contraception use post pregnancy termination
Outcomes	Primary outcomes: uptake of option, knowledge, decisional conflict, anxiety
Notes	—

Wong 2006 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"1:1 ratio, balanced block of 10"; "envelope preparation by drawing slips of paper labelled either control or intervention"; "the slip determined leaflet placed into envelope" (p 2)
Allocation concealment (selection bias)	Low risk	Consecutive numbered, opaque trial envelope (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included (p 3); reasons for attrition and incompletion mentioned.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases

CHD: coronary heart disease; **CRC**: colorectal cancer; **DA**: decision aid; **HPV**: human papilloma virus; **HRT**: hormone replacement therapy; **NSW**: New South Wales; **OA**: osteoarthritis; **PSA**: prostate-specific antigen; **PTSD**: post-traumatic stress disorder; **RCT**: randomized controlled trial; **SES**: socioeconomic status.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abadie 2009	Study did not evaluate the decision aid (evaluated clinician use of the decision aid in one arm of a study only)
Adab 2003	Hypothetical choice, not at a point of decision making
Al Saffar 2008	Study not focused on making a choice; adhering to medications only
Alegría 2014	Not a patient decision aid
Altiner 2007	Not a patient decision aid
Anderson 2011	Not a randomized controlled trial
Arimori 2006	Not a patient decision aid (not including benefits and harms)
Armstrong 2005	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided

Study	Reason for exclusion
Arterburn 2013	Not evaluating a patient decision aid
Au 2011	Not a randomized controlled trial
Bakken 2014	Not a patient decision aid; related to lifestyle choices
Becker 2009	Hypothetical choice; not at the point of decision making
Belkora 2012	Not a patient decision aid
Bellmunt 2010	Not a patient decision aid
Bennett 2011	Compares 3 versions of the same patient decision aid
Bieber 2006	Study did not evaluate the patient decision aid (evaluated shared decision-making process); not a patient decision aid
Branda 2013	2 patient decision aids with findings aggregated
Brenner 2014	Not a patient decision aid
Breslin 2008	Not a randomized controlled trial
Brown 2004	Not focused on making a choice (no specific decision to be made)
Brundage 2001	Not a randomized controlled trial
Burton 2007	Not a patient decision aid (general patient education only)
Buzhardt 2011	Not evaluating patient decision making
Campbell 2014	Not evaluating a patient decision aid
Carling 2008	Hypothetical choice, not at point of decision making
Causarano 2015	Not a patient decision aid
Chadwick 1991	Not a randomized controlled trial
Chan 2011	Not a patient decision aid
Chewning 1999	Not a randomized controlled trial
Chiew 2008	Not a randomized controlled trial
Clouston 2014	Not a patient decision aid
Col 2007	Unable to ascertain characteristics of the patient decision aid. Additional information requested from author but not provided (e.g. values clarification)
Colella 2004	Not a patient decision aid (describes model of care)
Costanza 2011	Not a randomized controlled trial
Coulter 2003	Not a randomized controlled trial (editorial)

Study	Reason for exclusion
Cox 2012	Not a randomized controlled trial
Crang-Svalenius 1996	Not a randomized controlled trial
Davison 1999	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid
Davison 2007	Not a patient decision aid
De Boer 2012	Not a randomized controlled trial
De Haan 2013	Not a randomized controlled trial of a patient decision aid
Deen 2012	Not a patient decision aid
Deinzer 2009	Not a patient decision aid
Denig 2014	not a patient decision aid
Deschamps 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Deyo 2000	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Diefenbach 2012	Not a patient decision aid
Dobke 2008	Not focused on making a choice
Dodin 2001	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Donovan 2012	Does not report results of the randomized controlled trial; descriptive article offering techniques of provision of information.
Driscoll 2008	Not a patient decision aid
Dunn 1998	Quasi-RCT: randomization was by days of the week
Eaton 2011	Not a decision aid (no decision support)
Eden 2009	Hypothetical choice, not at point of decision making
Eden 2014	The educational brochure (control group) provided information about the options, benefits, and harms making it a simple patient decision aid
Eden 2015	Not a treatment or screening decision
Edwards 2012	Hypothetical choice, not a randomized controlled trial
El-Jawahri 2010	End of life decision
Ellison 2008	Not a randomized controlled trial (Quasi-experimental design); unclear whether at point of decision making
Elwyn 2004	No difference in intervention between arms; risk communication did not have values clarification
Emery 2007	Not a patient decision aid

Study	Reason for exclusion
Emmett 2007	Not a randomized controlled trial
Feldman-Stewart 2006	Hypothetical choice, not at point of decision making
Feldman-Stewart 2012	Same patient decision aid with vs without values clarification
Fiks 2013a	Not patient decision making (uptake of vaccine)
Flood 1996	Non-randomized allocation; wait list control
Francis 2009	Not a patient decision aid
Fraval 2015	Not a patient decision aid; general education material to obtain informed consent for surgery
Frosch 2001	Not a randomized controlled trial
Frosch 2003	Same decision aid delivered on the Internet versus on DVD plus booklet
Frosch 2008b	Not a randomized controlled trial
Frosch 2011	Not a patient decision aid
Frost 2009	Qualitative study for an included RCT
Fujiwara 2015	Not a patient decision aid and aims to increase screening rates
Garvelink 2013	Hypothetical decision
Genz 2012	Not a patient decision aid
Giordano 2014	Not a patient decision aid
Goel 2001	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Graham 2000	Not a patient decision aid (general information)
Gray 2009	Hypothetical choice, not at the point of decision making
Green 2001b	Not a patient decision aid (educational intervention)
Green 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Greenfield 1985	Not focused on making a choice (intervention to increase patient involvement in care)
Griffith 2008a	Hypothetical choice, not at the point of decision making
Griffith 2008b	Not a randomized controlled trial
Gruppen 1994	Not a patient decision aid
Gummersbach 2015	Not a patient decision aid and a hypothetical decision
Hacking 2013	Not a patient decision aid
Hall 2007	Not about evaluating a patient decision aid

Study	Reason for exclusion
Hall 2011	Not a patient decision aid
Hamann 2014	not a patient decision aid
Harmsen 2014	Not a patient decision aid
Harwood 2011	Not a randomized controlled trial
Healton 1999	Not a patient decision aid (education to promote compliance)
Henderson 2013	Not a treatment or screening decision
Herrera 1983	Quasi-RCT: assigned to 1 of 2 alternating groups
Hess 2015	Conjoint analysis for values clarification without information on options, pros and cons
Hewison 2001	Not a patient decision aid; no values clarification
Heyn 2013	Not a randomized controlled trial
Hickish 1995	Not a randomized controlled trial (letter)
Hochlehnert 2006	Not a patient decision aid (general information; no values clarification)
Hofbauer 2008	Not a randomized controlled trial
Hoffman 2009	Not a patient decision aid
Holbrook 2007	Hypothetical choice, not at the point of decision making
Hollen 2013	Not a treatment or screening decision
Holloway 2003	Not focused on making a choice (promotes complying with a recommended option)
Holmes-Rovner 2011	Not a randomized controlled trial
Holt 2009	Study does not evaluate a decision aid; evaluation of spiritual versus non-spiritual framework
Hope 2010	Same content
Huijbregts 2013	Not a patient decision aid
Hunt 2005	Not focused on making a choice (promotes complying with a recommended option)
Hunter 1999	Not focused on making a choice (no specific decision)
Hunter 2005	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Huyghe 2009	Hypothetical choice, not at point of decision making for all participants
Ilic 2008	No difference in content of interventions - testing mode of delivery
Isebaert 2007	Not a randomized controlled trial (English paper published in 2008 *Urologia Internationalis*)
Jackson 2011	Not a patient decision aid

Study	Reason for exclusion
Jerant 2007	Not focused on making a choice - adherence to screening
Jibaja-Weiss 2006	No comparison outcome data provided (only presents data for intervention group)
Joosten 2009	Not a patient decision aid
Joosten 2011	Not a patient decision aid
Jorm 2003	Hypothetical choice, not at point of decision making - community sample asked to evaluate information booklet on depression
Kakkilaya 2011	Hypothetical choice, not at point of decision making
Kaplan 2014a	Not a patient decision aid
Kaplan 2014b	Not randomized controlled trial results; cross-sectional analysis of baseline data
Kassan 2012	Web arm only, not a randomized controlled trial
Kellar 2008	Hypothetical choice, not at point of decision making
Kiatpongsan 2014	No specific decision to be made and not a true randomized controlled trial
Kobelka 2009	Not a randomized controlled trial; not a patient decision aid
Koelewijn-van Loon 2009	Lifestyle only
Krawczyk 2012	Uptake of a recommended option
Kripalani 2007	Not a patient decision aid
Krones 2008	Not a patient decision aid - no benefits and harms
Kuppermann 2009	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Kurian 2009	Not a randomized controlled trial; not a patient decision aid
Köpke 2009	Not a patient decision aid
Köpke 2014	Not a patient decision aid
Labrecque 2010	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
LaCroix 1999	Inadequate comparison outcome data provided, secondary report of pilot study
Lairson 2011	Not a patient decision aid (to increase uptake of screening)
Lalonde 2006	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Lancaster 2009	Not a patient decision aid
Landrey 2013	Not a patient decision aid
Lazcano Ponce 2000	Not a patient decision aid (no values clarification)

Study	Reason for exclusion
Legare 2003	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Leung 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Levin 2011	Not a patient decision aid
Lewis 2003	Hypothetical choice, not at the point of decision making
Lewis 2012	Uptake of a recommended option
Lopez-Jornet 2012	Not a patient decision aid/not at point of decision-making
Lukens 2013	Not a patient decision aid. Results in response to clinical vignettes (hypothetical scenarios)
Lurie 2011	Not a randomized controlled trial (all patients received DA)
Maisels 1983	Not a patient decision aid (no values clarification)
Mancini 2006	Not about evaluating a patient decision aid
Manne 2009	Not focused on making a choice (about adherence not decision making)
Manns 2005	Not focused on making a choice (Promotes complying with a recommended option)
Markham 2003	Not a patient decision aid (review of patient information pamphlets on pre-operative fasting)
Martin 2012	Hypothetical choice, not at the point of decision making
Maslin 1998	Insufficient outcome data provided in publication; requested from author but not provided
Matlock 2014	End of life
Matloff 2006	Not a patient decision aid - genetic counselling only
Mazur 1994	Hypothetical choice, not at the point of decision making
McCaffery 2007	Not a patient decision aid
McGinley 2002	Not a patient decision aid (no values clarification)
McGowan 2008	Not a patient decision aid
McInerney-Leo 2004	Not a patient decision aid (no risk/benefit information; no values clarification)
Mclaren 2012	Not a patient decision aid; hypothetical choice, not at point of decision making
Meropol 2013	Not a patient decision aid
Michie 1997	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid; additional information requested but author was unable to provide the intervention.
Miller 2014a	No specific decision; related to increasing visits to healthcare provider
Miller 2014b	Aims to increase visits to healthcare providers; intervention targeted to partners

Study	Reason for exclusion
Mishel 2009	Not a patient decision aid (information only)
Mohammad 2012	Not a patient decision aid; presents only benefits, not harms
Molenaar 2001	Not a randomized controlled trial
Mulley 2006	Not a randomized controlled trial (editorial)
Myers 2005a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Myers 2005b	Not a randomized controlled trial (editorial)
Myers 2007	Not a patient decision aid
Myers 2011	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Myers 2013	Uptake of screening
Neubeck 2008	Study protocol, does not appear to be patient decision aid
Newton 2001	Not a randomized controlled trial
O'Cathain 2002	Suite of 8 decision aids (not an efficacy trial)
O'Connor 1999a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
O'Connor 1996	No patient decision aid - framing effects
O'Connor 1998a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
O'Connor 2009a	Not a patient decision aid
O'Connor 2011	Not a patient decision aid
Owens 2014A	Not an RCT; doctoral dissertation
Patanwala 2011	Not a patient decision aid
Patel 2014	Not an RCT
Pearson 2005	Not a patient decision aid (focus on provision of information)
Peele 2005	Not a patient decision aid (decision aid only supplies mortality risk information; no risk info; no values clarification)
Petty 2014	Not a randomized controlled trial and not a patient decision aid
Philip 2010	Not a randomized controlled trial, not a patient decision aid (promotes complying with a recommended option)
Phillips 1995	Quasi-RCT: alternating order based on patients' initial appointment sequence
Pignone 2013	Not a patient decision aid; compared the effect of 3 different values clarification methods
Pinto 2008	About clinical trial entry

Study	Reason for exclusion
Powers 2011	Not a patient decision aid
Proctor 2006	Not a patient decision aid (general patient education resource)
Prunty 2008	About a lifestyle choice - whether or not to have a child or have another child if I have multiple sclerosis
Ranta 2015	Not a patient decision aid; intended to increase guideline adherence for transient ischaemic attack/stroke
Rapley 2006	Not a randomized controlled trial
Raynes-Greenow 2009	No difference in intervention content; comparison of presentation formats; audio-guided decision aid versus booklet only
Raynes-Greenow 2010	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Rimer 2001	Not focused on making a choice (promotes complying with a recommended option)
Rimer 2002	Not focused on making a choice (promotes complying with a recommended option)
Robinson 2013	Not a patient decision aid
Ronda 2014	Benefits or harms of self-testing are not provided as information on the website; values clarification exercise asks users to qualify value statements as benefits or harms
Rostom 2002	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Roter 2012	Not a patient decision aid
Rothert 1997	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Rovner 2004	Not a randomized controlled trial
Rubinstein 2011	Not a patient decision aid
Ruddy 2009	Not a patient decision aid
Ruehlman 2012	Not a patient decision aid
Ruland 2013	No specific decision to be made
Ryser 2004	Not focused on making a choice (promotes complying with a recommended option)
Sassen 2014	Not a patient decision aid evaluation study; healthcare professionals were recruited, not patients
Saver 2007	Not a patient decision aid - general information; not a specific decision
Sawka 2011	Not a randomized controlled trial
Scaffidi 2014	Not an RCT
Schapira 2000	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Schapira 2007	Simple versus detailed patient decision aid (excluded in update after 2014 publication)

Study	Reason for exclusion
Schwartz 2009b	Hypothetical choice, not at the point of decision making
Sears 2007	About do not resuscitate versus initiating cardiopulmonary resuscitation decision
Sequist 2011	Not a patient decision aid (promotes complying with a recommended option)
Shah 2012	Not a patient decision aid, lifestyle choices
Sheppard 2012	Not a randomized controlled trial
Sheridan 2004	Not a randomized controlled trial
Sheridan 2010	Hypothetical choice, not at point of decision making
Sheridan 2012	Not a patient decision aid - no benefits and harms
Sherman 2014	Not a randomized controlled trial
Shirai 2012	Not a patient decision aid
Silver 2012	Hypothetical choice, not at point of decision making
Siminoff 2006	Not a patient decision aid (no discussion of harms)
Simon 2012a	Not a patient decision aid
Simon 2012b	Not a patient decision aid
Smith 2011a	No decision regarding treatment or screening to be made (decision regarding full disclosure)
Smith 2011b	Not a patient decision aid, not an RCT
Solberg 2010	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Sorenson 2004	Not a randomized controlled trial
Sparano 2006	Not a patient decision aid
Stalmeier 2009	Not a randomized controlled trial (about instrument development)
Starosta 2015	Not a patient decision aid - benefits and harms of screening are missing.
Stein 2013	End of life
Steiner 2003	Not a patient decision aid (only effectiveness not cons of options; not at point of decision making)
Stephens 2008	Not a randomized controlled trial
Stiggelbout 2008	Not a patient decision aid
Stirling 2012	Not a treatment or screening decision
Street 1995	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Street 1998	Not focused on making a choice (promotes complying with a recommended option)

Study	Reason for exclusion
Sundaresan 2011	Hypothetical choice, not at the point of decision making, not a randomized controlled trial
Tabak 1995	Not a randomized controlled trial
Taylor 2013	Not a patient decision aid - benefits and harms of screening not included
Ten 2008	Not a patient decision aid; about stopping medication use
Thomas 2013	Not a patient decision aid
Thomson 2006	Not a randomized controlled trial; not at point of decision making
Thornton 1995	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Tiller 2006	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Tinsel 2013	Not a patient decision aid
Tomko 2015	Not a patient decision aid - benefits and harms of screening are missing
Ukoli 2013	Not an RCT
Valdez 2001	Not a randomized controlled trial; not focused on making a choice (complying with a recommended option)
Van der Krieke 2013	Not a patient decision aid, no benefits/harms
Van Roosmalen 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Van Steenkiste 2008	Not a randomized controlled trial
Van Til 2009	Hypothetical choice, not at the point of decision making
Van Tol-Geerdink 2013	Not a randomized controlled trial; insufficient information to judge random sequence generation, allocation concealment, and blinding
Veroff 2012	Not a patient decision aid
Volandes 2009	Advanced care planning options
Volandes 2011	Hypothetical choice, end-of-life decision
Volandes 2013	Advanced care planning
Volk 2008	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Von Wagner 2011	Not a randomized controlled trial (commentary)
Wagner 1995	Not a randomized controlled trial
Wakefield 2008a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Wakefield 2008b	Simple versus detailed patient decision aid (excluded in update after 2014 publication)

Study	Reason for exclusion
Wakefield 2008c	simple versus detailed patient decision aid (excluded in update after 2014 publication)
Wallston 1991	Not a patient decision aid - patient preference study
Wang 2004	Not a patient decision aid - intent of intervention to facilitate genetic counselling process, no focused decision
Warner 2015	Not a treatment or screening decision
Watts 2014	Simple versus detailed patient decision aid
Welschen 2012	Not a patient decision aid
Wennberg 2010	Same decision aid in both groups
Westermann 2013	Not a patient decision aid
Weymann 2015	Patients not at the point of decision making
Wilhelm 2009	Not a patient decision aid
Wilkes 2013	Unable to ascertain characteristics of the patient decision aid. Additional information requested from author but not provided (e.g. values clarification)
Wilkie 2013	Not treatment or screening decision
Wilkins 2006	Not a randomized controlled trial
Willemsen 2006	Lifestyle change
Williams-Piehota 2008	Not a randomized controlled trial
Williamson 2014	Lifestyle decision - not treatment or screening
Woltmann 2011	Not a patient decision aid
Wroe 2005	Not focused on making a choice - promotes complying with a recommended option
Yee 2014	Not a patient decision aid
Yun 2011	End-of-life decision
Zajac 2012	Hypothetical
Zapka 2004	Not focused on making a choice - promotes complying with a recommendation
Zikmund-Fisher 2008	No difference in intervention content - comparison of presentation of probabilities
Zoffman 2012	Not a randomized controlled trial, not a patient decision aid

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12615000523505

Trial name or title	The motherhood choices decision aid for women with rheumatoid arthritis increases knowledge and reduces decisional conflict: a randomized controlled study
Methods	RCT
Participants	130 women diagnosed with rheumatoid arthritis and currently under the care of a rheumatologist
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, knowledge, anxiety, depression, self-efficacy
Starting date	May 2015
Contact information	Tanya Meade; School of Social Science and Psychology University of Western Sydney; Sydney, Australia
Notes	Trial #: ACTRN12615000523505

ACTRN12615000843550

Trial name or title	Evaluation of decision aids for parents about the benefits and harms of antibiotic use for coughs and colds in children
Methods	Pilot RCT
Participants	108 adult parents or primary caregivers of a child
Interventions	Patient decision aid vs usual care
Outcomes	Informed choice, knowledge, attitudes towards antibiotic use, intention to use antibiotic, decisional conflict, confidence in decision-making, usability and accessibility of the written materials
Starting date	August 2015
Contact information	Mr Peter D Coxeter; pcoxeter@bond.edu.au; Bond University, Queensland, Australia
Notes	ACTRN12615000843550

Al-Itejawi 2015

Trial name or title	(Cost-)effectiveness and implementation of a decision aid for patients with prostate cancer
Methods	Stepped wedge cluster RCT
Participants	Newly diagnosed adult participants with localized prostate cancer
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, quality of life, treatment preferences, participation in decision making, knowledge, patient-provider communication
Starting date	May 2015

Al-Itejawi 2015 *(Continued)*

Contact information	Hoda Al-Itejawi; Afdeling Urologie, Amsterdam, the Netherlands
Notes	Trial #: NTR5177

Anderson 2014

Trial name or title	Shared decision making in the emergency department: Chest Pain Choice Trial (CPC)
Methods	RCT
Participants	Presenting to the emergency department with chest pain
Interventions	Chest Pain Choice decision aid vs usual care
Outcomes	Knowledge, patient engagement, decisional conflict, satisfaction, adverse events, admissions, healthcare utilization
Starting date	October 2013
Contact information	Erik P Hess, Mayo Clinic
Notes	NCT01969240; verified September 2014, estimated study completion March 2016

Aslani 2014

Trial name or title	Computerized decision aid on mode of delivery
Methods	Cluster RCT
Participants	Pregnant Iranian women
Interventions	Computerized decision aid
Outcomes	Decisional conflict, knowledge
Starting date	Not reported
Contact information	Azam Aslani, Mashhad University, Iran
Notes	—

Buhse 2013

Trial name or title	Efficacy of an evidence-based informed shared decision making program for prevention of myocardial infarction in type 2 diabetes
Methods	RCT
Participants	154 patients with type 2 diabetes

Buhse 2013 *(Continued)*

Interventions	Shared decision-making programme consisting of a decision aid booklet and a curriculum for group counselling vs placebo counselling
Outcomes	Knowledge, sustainability of knowledge, achievement of individual treatment goals, achievement of treatment goals prioritized by individual patients, medication uptake
Starting date	March 2013
Contact information	Matthias Lenz, University of Hamburg
Notes	ISRCTN84636255

Carroll 2012

Trial name or title	Development of and feasibility testing of decision support for patients who are candidates for an implantable defibrillator
Methods	RCT
Participants	Referred for consideration of an implantable cardioverter-defibrillators (non-cardiac resynchronization therapy) for a primary prevention indication
Interventions	Patient decision aid provided prior to the consultation with the physician, which provides a lay summary that outlines the facts, risks, benefits (including probabilities), specific to the option of an implantable defibrillator or the option of medical management vs usual care
Outcomes	Decision aid development and evaluation, decisional conflict and decision quality, sure test, reparation for decision-making scale, medical outcomes trust short form (SF-36v2)
Starting date	June 2012
Contact information	Sandra Carroll, McMaster University
Notes	Trial #: NCT01876173

Chambers 2008

Trial name or title	ProsCan for Men: randomized controlled trial of a decision support intervention for men with localised prostate cancer
Methods	RCT
Participants	700 men newly diagnosed with localized prostate cancer
Interventions	A tele-based nurse delivered 5-session decision support/psychosocial intervention vs usual care
Outcomes	Cancer threat appraisal; decision-related distress and bother from treatment side effects; involvement in decision making; satisfaction with health care; heathcare utilization; use of healthcare resources; and a return to previous activities
Starting date	Not yet assessed

Chambers 2008 *(Continued)*

Contact information	Suzanne K Chambers, Griffith University
Notes	Trials #: ACTRN012607000233426

Coylewright 2012

Trial name or title	Shared decision making in patients with stable coronary artery disease: PCI Choice
Methods	RCT
Participants	—
Interventions	—
Outcomes	—
Starting date	—
Contact information	Megan Coylewright, Mayo Clinic
Notes	Upcoming RCT

Cuypers 2015

Trial name or title	Prostate cancer patient-centered care: impact of a treatment decision aid in a pragmatic, cluster randomized controlled trial
Methods	Pragmatic RCT
Participants	400 men newly diagnosed with early stage prostate cancer
Interventions	Decision aid (online) vs usual care
Outcomes	Decisional conflict, decisional regret, treatment satisfaction, decision making role, knowledge, satisfaction with decision-making process, preparation for decision-making, health-related quality of life, personality (anxiety, depression, optimism), skills measures (self-efficacy, health literacy, numeracy)
Starting date	May 2014
Contact information	M Cuypers; M.Cuypers@uvt.nl; Tilburg University Social and Behavioral Sciences Tilburg, the Netherlands
Notes	NTR4554

Den Ouden 2015

Trial name or title	Shared decision-making in type 2 diabetes with a support decision tool that takes into account clinical factors, the intensity of treatment and patient preferences
Methods	Cluster RCT
Participants	150 adults with type 2 diabetes mellitus for 8-15 years
Interventions	Patient decision aid with training vs usual care
Outcomes	Achievement of diabetes-specific health goals, satisfaction with treatment, quality of life, well-being, coping, evidence of shared decision-making
Starting date	March 2012
Contact information	h.denouden@umcutrecht.nl; Henk den Ouden; Julius Cntre for Health Sciences and Primary Care, University Medical Centre, Utrecht, the Netherlands
Notes	Trial #: NCT02285881

Dirmaier 2013

Trial name or title	Tailored, dialogue-based health communication application for patients with chronic low back pain
Methods	RCT
Participants	414 patients with self-reported chronic low back pain
Interventions	Web-based interactive health communication application (IHCA) vs control (standard info)
Outcomes	Knowledge, patient empowerment, website usage, preparation for decision making, decisional conflict
Starting date	2012
Contact information	Martin Härter, University Medical Center Hamburg-Eppendorf
Notes	International Clinical Trials Registry DRKS00003322

Geiger 2011

Trial name or title	Investigating a training supporting Shared Decision Making (IT'S SDM 2011): study protocol for a randomized controlled trial
Methods	RCT
Participants	40 physicians that contribute a sequence of 4 medical consultations including a diagnostic or treatment decision
Interventions	A training curriculum for the doctors - intend to stimulate efforts to involve their patients in the decision-making process.

Geiger 2011 *(Continued)*

Outcomes	Physician-patient communication, effect of SDM on perceived quality of the decision process and on the elaboration of the decision, decisional conflict
Starting date	Not yet assessed
Contact information	Friedemann Geiger, University Medical Center Schleswig - Holstein
Notes	Trials #: ISRCTN78716079

Hersch 2014

Trial name or title	Effect of information about over detection of breast cancer on women's decision-making about mammography screening
Methods	RCT
Participants	970 women aged 48-50
Interventions	Intervention (evidence-based information booklet including over detection, breast cancer mortality reduction and false positives) vs control information booklet (including mortality reduction and false positives only)
Outcomes	Knowledge, consistency between attitudes and intentions, decision conflict, confidence, regret, anxiety, perceived risk, quality of life
Starting date	June 2014
Contact information	Kirsten McCaffery, University of Sydney
Notes	Australian New Zealand Clinical Trials Registry ACTRN12613001035718

Hess 2014

Trial name or title	Shared decision making in parents of children with head trauma: head CT choice
Methods	RCT
Participants	1004 parent-child dyad, seeking care for a child who had blunt trauma above the eyebrows and is positive for at least 1 PECARN clinical prediction rules
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, engagement in decision-making process, decisional conflict, trust in the physician, satisfaction with the decision-making process, choice, healthcare utilization 7-days post ER visit, rate of clinically important traumatic brain injury
Starting date	April 2014
Contact information	Erik Hess; Mayo Clinic; Rochester, MN
Notes	Trial #: NCT02063087

Jimbo 2012

Trial name or title	Decision aid to technologically enhance shared decision making
Methods	RCT
Participants	Patients who are not current with colorectal cancer screening
Interventions	Web based decision aid + interactive component (preferences and risk assessment) vs web based decision aid only
Outcomes	Uptake of screening on patient determinants/preference/intention before the patient-physician encounter, and on shared decision making, concordance and patient intention during/after the patient-physician encounter
Starting date	May 2012
Contact information	Masahito Jimbo, University of Michigan
Notes	Trial # :NCT01514786; last updated December 2013, estimated study completion October 2014

Layton 2012

Trial name or title	Effects of a web-based decision aid on African American men's prostate screening knowledge and behavior
Methods	—
Participants	128 African American men
Interventions	—
Outcomes	—
Starting date	—
Contact information	Beverly Layton, Walden University
Notes	Unpublished thesis

LeBlanc 2013

Trial name or title	Translating comparative effectiveness of depression medications into practice by comparing the depression medication choice decision aid to usual care: study protocol for a randomized controlled trial
Methods	RCT
Participants	300 patients
Interventions	Use of the Depression Medication Choice decision aid by patients and their primary care clinician during the clinical encounter vs usual care

LeBlanc 2013 *(Continued)*

Outcomes	Decisional conflict, knowledge, satisfaction, preference in decision making style, patient involvement in decision making, depression outcomes, medication adherence
Starting date	December 2011
Contact information	Victor Montori, Mayo Clinic, USA
Notes	NCT01502891

Mann 2012

Trial name or title	Increasing efficacy of primary care-based counselling for diabetes prevention: rationale and design of the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) trial
Methods	RCT
Participants	Primary care providers
Interventions	Using the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) system to enhance providers' effectiveness to counsel about lifestyle behaviour changes
Outcomes	Outcome measurements are designed to detect changes in patient behaviours that are most likely to result from the use of ADAPT tool: difference between intervention and control patients in the change in mean steps per day at baseline and after 6 months, and 6 month difference of differences in haemoglobin A1C and self-reported diet between the 2 groups
Starting date	Not yet assessed
Contact information	Devin Mann, Boston University School of Medicine
Notes	Trial #: NCT01473654

NCT00813033

Trial name or title	Use of a patient decision aid for gastrologic endoscopy in a paediatric setting
Methods	Interventional efficacy study
Participants	80 parents considering gastro-endoscopy for child
Interventions	Not yet assessed
Outcomes	Knowledge, expectations of outcomes, clarity of values, decision, decision conflict
Starting date	December 2008
Contact information	Nancy Neilan, Children's Mercy Hospital, Kansas City
Notes	Trials #: NCT00813033; completed March 2011

NCT01077037

Trial name or title	Shared decision making in the emergency department: the Chest Pain Choice Trial
Methods	RCT
Participants	1500 adults admitted to the emergency department for chest pain, being considered by the treating clinical for admission for cardiac testing
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, healthcare utilization (rate of hospital admission, rate of cardiac testing, etc), patient engagement in decision-making process, decisional conflict, trust in the physician, satisfaction with decision, safety (major adverse cardiac events within 30 days)
Starting date	October 2013
Contact information	hess.erik@mayo.edu; Mayo Clinic, Rochester, Minnesota, USA
Notes	Trial #: NCT01969240

NCT01152294

Trial name or title	Measuring quality of decisions about treatment of menopausal symptoms
Methods	RCT
Participants	Patients talked with healthcare provider about ways to manage menopause or seriously considered taking medicine or supplement to manage menopause
Interventions	Decision aid (DVD/booklet) vs usual care
Outcomes	Knowledge, value concordance
Starting date	June 2010
Contact information	Karen R Sepucha, Massachusetts General Hospital
Notes	NCT01152294; completed, study results on clinicaltrials.gov

NCT01152307

Trial name or title	Measuring quality of decisions about treatment of depression
Methods	RCT
Participants	Patients that talked to a healthcare provider about starting or stopping a treatment (prescription medicine for depression or counselling)
Interventions	Decision aid (DVD/booklet) vs usual care
Outcomes	Knowledge, value concordance
Starting date	June 2010

NCT01152307 *(Continued)*

Contact information	Karen R Sepucha, Massachusetts General Hospital
Notes	NCT01152307; completed, study results on clinicaltrials.gov

NCT01447186

Trial name or title	Informed decisions about lung cancer screening
Methods	RCT
Participants	500 adults between 55 and 77 years olds who are currently smoking or quit within the past 15 years
Interventions	Patient decision aid vs standard educational information
Outcomes	Decisional conflict: value subscale and informed subscale
Starting date	March 2015
Contact information	MD Anderson Cancer Center; USA
Notes	Trial #: NCT02286713

NCT01618097

Trial name or title	Evaluation of DVD and Internet decision aids for hip and knee osteoarthritis: focus on health literacy
Methods	RCT
Participants	Osteoarthritis patients
Interventions	DVD decision aid vs Internet-based decision aid
Outcomes	Decisional conflict, decision self-efficacy, knowledge
Starting date	January 2012
Contact information	Kelli D Allen, Duke University
Notes	Trial #: NCT01618097; last updated March 2014, study completion date January 2014

NCT01713894

Trial name or title	Utility of a clinically relevant decision aid, for parents facing extremely premature delivery
Methods	RCT
Participants	300 women who are receiving counselling at the limits of viability
Interventions	Decision aid vs usual care

NCT01713894 *(Continued)*

Outcomes	Decisional conflict, knowledge
Starting date	May 2013
Contact information	uguillen@christianacare.org; Ursula Guillen, Christiana Care Health Systems; University of Michigan
Notes	Trial # NCT01713894

NCT01771536

Trial name or title	Study to test use of a decision aid in a clinical visit to help patients choose a diabetes medication. Translating Information on Comparative Effectiveness Into Practice (TRICEP)
Methods	RCT
Participants	Type 2 diabetes mellitus patients
Interventions	Diabetes medication decision aid vs usual care
Outcomes	Patient satisfaction and knowledge. Physician adoption and satisfaction with the decision aid
Starting date	January 2011
Contact information	Nilay D Shah, Mayo Clinic
Notes	NCT01293578; estimated completion date December 2014

NCT01851785

Trial name or title	Behavioral and social science research on understanding and reducing health disparities: African American preference for knee replacement: a patient-centred intervention (ACTION)
Methods	RCT
Participants	African-American participants referred to orthopaedic doctor with presence of knee OA
Interventions	Decision aid video + communication, skill-building intervention vs educational programme (an NIH-developed booklet) that summarizes how to live with knee OA but does not mention joint replacement
Outcomes	Recommendation and receipt of knee joint replacement
Starting date	July 2010
Contact information	Said A Ibrahim, University of Pennsylvania
Notes	Trial #: NCT01851785; last verified May 2013, estimated completion date June 2015

NCT01941186

Trial name or title	A family centered intervention to promote optimal child development
Methods	RCT
Participants	64 parent-child dyad in which the child is aged 0-36 months screening positive for developmental concern
Interventions	Patient decision aid vs usual care
Outcomes	Evaluation by early intervention specialist, attitudes, knowledge, uncertainty, intervention acceptability, intervention feasibility
Starting date	December 2013
Contact information	Children's Hospital of Philadelphia Philadelphia, PN, USA, 19104
Notes	Trial #: NCT01941186

NCT01976325

Trial name or title	Incorporation of the 'Ottawa Malaria Decision Aid' into the pre-travel consultation process
Methods	RCT
Participants	100 adults attending a travel clinic before travelling to an area with known chloroquine-resistant malaria
Interventions	Decision aid vs usual care
Outcomes	Knowledge, decisional conflict, preparation for decision-making, medication adherence
Starting date	January 2014
Contact information	amccarthy@toh.on.ca; Anne E McCarthy; Ottawa Hospital Research Institute
Notes	Trial # NCT01976325

NCT02026102

Trial name or title	A pilot trial of patient decision aids for implantable cardioverter-defibrillators (ICDs)
Methods	RCT
Participants	60 patients with heart failure referred for primary prevention implantable cardioverter-defibrillators
Interventions	Decision aid toolkit vs usual care
Outcomes	Intervention acceptability, decision quality (knowledge and values concordance), quality of life, depressive symptoms, health status, spiritual well-being

NCT02026102 *(Continued)*

Starting date	September 2014
Contact information	amy.jenkins@ucdenver.edu; University of Colorado Hospital (UCH)
Notes	Trial #: NCT02026102

NCT02084290

Trial name or title	Evaluating a prediction tool and decision aid for patients with Crohn's disease
Methods	RCT
Participants	300 adults with Crohn's disease
Interventions	Patient decision aid and SDM programme vs usual care
Outcomes	Preferred choice, actual choice, adherence, cost of care, remission, patient on steroids, surgeries, Crohn's disease related hospitalizations
Starting date	March 2014
Contact information	corey.a.siegel@hitchcock.org; Corey A Siegel; Dartmouth-Hitchcock Medical Center
Notes	Trial #: NCT02084290

NCT02110979

Trial name or title	Validation of a patient decision aid for type 2 diabetes
Methods	RCT
Participants	200 type 2 diabetes patients
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict
Starting date	April 2014
Contact information	EPI-Q Inc, Oak Brook, IL, USA, 60523 www.epi-q.com/our-approach
Notes	Trial #: NCT02110979

NCT02145481

Trial name or title	Decisional quality for patients with stable coronary artery disease
Methods	RCT

NCT02145481 *(Continued)*

Participants	846 adults with stable coronary artery disease
Interventions	Patient decision aid vs standard education
Outcomes	Quality of the decision-making process, knowledge, communication, involvement, treatment preferences
Starting date	May 2014
Contact information	R. Adams Dudley; University of California, San Francisco
Notes	Trial # NCT02145481

NCT02198690

Trial name or title	Randomized trial of a mammography decision aid for women aged 75 and older
Methods	RCT
Participants	550 women aged 75-89 years
Interventions	Decision aid vs usual care
Outcomes	Receipt of mammography screening, acceptability, anxiety, decision-making role, decisional conflict, home safety, home safety discussions, knowledge, preparation for decision-making, screening discussions, screening intentions
Starting date	September 2014
Contact information	Mara A Schonberg, MD, MPH; mschonbe@bidmc.harvard.edu; Beth Israel Deaconess Medical Center; Boston, MA, USA
Notes	NCT02198690

NCT02235571

Trial name or title	iChoose kidney decision aid for treatment options among end-stage renal disease (ESRD) patients
Methods	RCT
Participants	450 adults with end-stage renal disease on dialysis for < 1 year and being evaluated for kidney transplant
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, evidence of shared decision-making, access to transplant, treatment preferences
Starting date	September 2014
Contact information	Rachel Patzer; Emory Transplant Center; Atlanta, GA, USA
Notes	Trial # NCT02235571

NCT02248974

Trial name or title	Development and user testing of a decision aid for left ventricular assist device (LVAD) placement
Methods	RCT
Participants	144 adults who are candidates for a left ventricular assist device
Interventions	Patient decision aid vs. standard education
Outcomes	Knowledge, decisional conflict, control preferences scale, CollaboRATE score, perceived quality of care, satisfaction with decision-making process, decisional regret, satisfaction with life, preparation for decision-making, usability and acceptability of the intervention
Starting date	February 2014
Contact information	Jennifer Blumenthal-Barby; Baylor College of Medicine; Houston, TX
Notes	Trial #: NCT02248974

NCT02259699

Trial name or title	Ovarian cancer patient-centered decision aid
Methods	RCT
Participants	221 women with stage III optimally debulked advanced ovarian cancer
Interventions	Patient decision aid vs usual care
Outcomes	Satisfaction with decision, evidence of shared decision-making, quality of life, satisfaction with care and satisfaction with cancer treatment
Starting date	December 2014
Contact information	lwenzel@uci.edu; Lari Wenzel; University of California, Irvine, USA
Notes	Trial #: NCT02259699

NCT02308592

Trial name or title	Patient decision aid for antidepressant use in pregnancy
Methods	RCT
Participants	50 women aged 18 years or older planning a pregnancy or <30 weeks pregnant
Interventions	Patient decision aid vs standard resource sheet
Outcomes	depression, anxiety, decisional conflict, knowledge, intervention acceptability, choice, satisfaction with DA

NCT02308592 *(Continued)*

Starting date	January 2015
Contact information	simone.vigod@wchospital.ca Women's College Hospital, Toronto, Ontario, Canada
Notes	Trial #: NCT02308592

NCT02319525

Trial name or title	
Methods	
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	

NCT02326597

Trial name or title	Decision aid for therapeutic options in sickle cell disease
Methods	RCT
Participants	120 individuals with sickle cell disease ages 8 to 80 years
Interventions	Decision aid vs usual care
Outcomes	Knowledge, self-efficacy, decisional conflict, values, realistic expectations, preparation for decision-making, choice predisposition, stage of decision-making, decisional regret
Starting date	September 2014
Contact information	diana.ross@emory.edu; principal investigator Lakshmanan Krishnamurti; Emory University, Atlanta, GA, USA
Notes	Trial # NCT02326597

NCT02344576

Trial name or title	A multicenter trial of a shared decision support intervention for patients and their caregivers offered destination therapy for end-stage heart failure

NCT02344576 *(Continued)*

Methods	RCT
Participants	400 adults advanced heart failure and are being evaluated for destination left ventricular assist device
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, values, decisional conflict, decisional regret, stress, anxiety, depression, quality of life, control preferences scale, illness acceptance, health status
Starting date	May 2015
Contact information	jocelyn.thompson@ucdenver.edu; University of Colorado, Denver
Notes	Trial #: NCT02344576

NCT02488317

Trial name or title	Empowering patients on choices for renal replacement therapy
Methods	RCT
Participants	150 adults with kidney disease
Interventions	Patient decision aid vs usual care
Outcomes	Preference for shared decision-making (CPS), decisional conflict, decision self-efficacy, knowledge, preparation for decision making
Starting date	May 2015
Contact information	Francesca Tentori; Arbor Research Collaborative for Health; Ann Arbor, MI
Notes	Trial #: NCT02488317

NCT02488603

Trial name or title	Utilization of decision aids for tamoxifen treatment in breast cancer patients
Methods	RCT
Participants	360 breast cancer patients referred for tamoxifen treatment
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict scale, satisfaction with decision, quality of life
Starting date	August 2015
Contact information	Eun Sook Lee; National Cancer Center, Korea
Notes	Trial # NCT02488603

NCT02492009

Trial name or title	Patient decision aid for antidepressant use in pregnancy
Methods	RCT
Participants	50 women aged 18 years or older planning a pregnancy or < 30 weeks pregnant
Interventions	Patient decision aid vs standard resource sheet
Outcomes	Depression, anxiety, decisional conflict, knowledge, intervention acceptability, choice
Starting date	June 2015
Contact information	hind.khalifeh@kcl.ac.uk or ruth.brauer@kcl.ac.uk Section of Women's Mental Health, King's College London
Notes	Trial #: NCT02492009

NCT02503553

Trial name or title	Decision aids in cerebral aneurysm treatment
Methods	RCT
Participants	60 patients undergoing treatment for cerebral aneurysm
Interventions	Patient decision aid vs usual care
Outcomes	Participation in the shared-decision making process; stress levels, patient satisfaction level
Starting date	August 2015
Contact information	Kimon Bekelis; Dartmouth-Hitchcock Medical Center; New Hampshire, USA
Notes	Trial #: NCT02503553

NCT02516449

Trial name or title	Assessment of shared decision making aids in asthma
Methods	RCT
Participants	51 adults with mild to severe asthma
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict, treatment adherence, asthma control
Starting date	March 2013

NCT02516449 *(Continued)*

Contact information	Centre de recherche de l'Institut universitaire de cardiologie et de pneumologie de Québec, Québec, Canada, G1V 4G5
Notes	Trial # NCT02516449

NCT02540044

Trial name or title	Supporting patient care with electronic resource (SuPER): efficacy of an online decision aid for patients considering biologic therapy for rheumatoid arthritis
Methods	RCT
Participants	144 adults with rheumatoid arthritis whose rheumatologists have recommended initiating a biologic/subsequent entry biologic or switching to another biologic agent
Interventions	Online patient decision aid vs online standard information
Outcomes	Decisional conflict, knowledge, self-efficacy, self-management behaviours, health resource utilization, choice, evidence of shared decision-making
Starting date	January 2016
Contact information	Linda Li; University of British Columbia; Vancouver, Canada
Notes	Trial #: NCT02540044

NCT02611050

Trial name or title	Treatment decisions for multi-vessel CAD
Methods	RCT
Participants	160 adults with stable multi-vessel CAD at relative equipoise for at least 2 potential treatment options
Interventions	Option grid decision aid vs usual care
Outcomes	Decisional conflict, CollaboRATE score, knowledge, patient experience, treatment received
Starting date	December 2015
Contact information	Elizabeth L Nichols; the Dartmouth Institute
Notes	Trial #: NCT02611050

Oostendorp 2011

Trial name or title	Assessing the information desire of patients with advanced cancer by providing information with a decision aid, which is evaluated in a randomized trial: a study protocol

Oostendorp 2011 *(Continued)*

Methods	RCT
Participants	Patients with advanced colorectal, breast, or ovarian cancer and have started treatment with first-line palliative chemotherapy
Interventions	Patients are randomized to receive either usual care or usual care + decision aid
Outcomes	Not yet assessed
Starting date	Not yet assessed
Contact information	Linda JM Oostendorp, Radbound University
Notes	Netherlands Trial Register (NTR): NTR1113

Yu 2015

Trial name or title	Impact of an interprofessional shared decision-making and goal setting decision aid for patients with diabetes
Methods	Cluster-randomized controlled trial
Participants	112 patients with diabetes
Interventions	Multicomponent patient decision aid toolkit vs patient education pamphlet
Outcomes	Decisional conflict, diabetes distress, health-related quality of life, chronic illness care, intention to engage in SDM
Starting date	April 2015
Contact information	yuca@smh.ca
Notes	Trial # NCT02379078

CA-125: cancer antigen 125; **CAD**: coronary artery disease; **CT**: computerized tomography; **NIH**: National Institutes of Health; **NSW**: New South Wales; **OA**: osteoarthritis; **RCT**: randomized controlled trial; **SDM**: shared decision making.

DATA AND ANALYSES

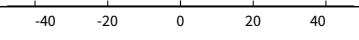
Comparison 1. Knowledge

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Knowledge - all studies	52	13316	Mean Difference (IV, Random, 95% CI)	13.27 [11.32, 15.23]
2 Knowledge - subgroup by timing of intervention (in consultation versus in preparation for consultation)	52		Mean Difference (IV, Random, 95% CI)	Subtotals only

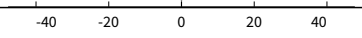
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 In consultation	8	922	Mean Difference (IV, Random, 95% CI)	10.57 [4.79, 16.36]
2.2 In preparation for consultation	44	12394	Mean Difference (IV, Random, 95% CI)	13.77 [11.61, 15.93]
3 Knowledge - studies without high risk of bias	47	12327	Mean Difference (IV, Random, 95% CI)	13.43 [11.37, 15.49]

Analysis 1.1. Comparison 1 Knowledge, Outcome 1 Knowledge - all studies.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Allen 2010	291	66 (35.5)	334	60 (29.2)		2.04%	6[0.86,11.14]
Arterburn 2011	75	72 (12)	77	65 (17)		2.09%	7[2.33,11.67]
Barry 1997	104	75 (45)	123	54 (45)		1.28%	21[9.25,32.75]
Bekker 2004	50	74 (14.5)	56	71.5 (16)		1.96%	2.5[-3.31,8.31]
Bernstein 1998	61	83 (16)	48	58 (16)		1.93%	25[18.95,31.05]
Bjorklund 2012	182	77 (17)	204	71 (20)		2.18%	6[2.31,9.69]
Chabrera 2015	61	75.7 (19)	61	49.9 (16)		1.91%	25.8[19.57,32.03]
Frosch 2008a	155	81.4 (18.7)	151	72.4 (19.7)		2.12%	9[4.69,13.31]
Gattellari 2003	106	50 (18.4)	108	45 (15.9)		2.09%	5[0.39,9.61]
Gattellari 2005	131	57.2 (21.3)	136	42.2 (16.7)		2.09%	15[10.4,19.6]
Green 2001	29	95 (7)	14	65 (21)		1.32%	30[18.71,41.29]
Hanson 2011	127	88.4 (21.6)	129	79.5 (21.6)		2.02%	8.9[3.6,14.2]
Hess 2012	101	51.4 (18.2)	103	42.9 (18.3)		2.05%	8.57[3.56,13.58]
Jibaja-Weiss 2011	44	61.2 (20.4)	39	43.6 (26.6)		1.43%	17.63[7.33,27.93]
Johnson 2006	32	92.6 (11)	35	85.2 (15.6)		1.89%	7.4[0.98,13.82]
Knops 2014	80	76.9 (16.9)	84	72.3 (16.2)		2.04%	4.62[-0.45,9.69]
Krist 2007	196	69 (33.2)	75	54 (33.2)		1.6%	15[6.16,23.84]
Kupke 2013	50	60 (23.3)	31	27 (16.7)		1.61%	33[24.27,41.73]
Kuppermann 2014	357	62.7 (21.3)	353	57.3 (21.3)		2.23%	5.4[2.27,8.53]
Lam 2013	113	61 (21)	112	59 (21)		2%	2[-3.49,7.49]
Laupacis 2006	53	83 (19.5)	53	67.4 (17)		1.82%	15.6[8.64,22.56]
Leighl 2011	100	72.5 (26.9)	100	60 (26.9)		1.76%	12.5[5.05,19.95]
Lepore 2012	215	61.6 (0.1)	216	54.7 (0.1)		2.37%	6.9[6.88,6.92]
Lerman 1997	122	68.9 (19)	164	49 (21.7)		2.08%	19.9[15.17,24.63]
Lewis 2010	93	45.1 (34)	107	46.7 (34)		1.52%	-1.6[-11.05,7.85]
Man-Son-Hing 1999	137	75.9 (15.7)	136	66.5 (16.1)		2.18%	9.45[5.68,13.22]
Mann E 2010	273	64.1 (21.9)	134	41.3 (21)		2.11%	22.85[18.45,27.25]
Mathieu 2010	113	73.5 (27.6)	189	62.7 (27.6)		1.89%	10.8[4.37,17.23]
McCaffery 2010	77	81 (23.5)	71	72 (23.5)		1.75%	9[1.42,16.58]
Montgomery 2003	50	75 (17)	58	60 (18)		1.86%	15[8.39,21.61]
Montgomery 2007	196	69.7 (18)	202	57.5 (18.5)		2.19%	12.2[8.61,15.79]
Montori 2011	49	63.3 (29.6)	46	43.3 (29.6)		1.26%	20[8.09,31.91]
Morgan 2000	86	75 (32)	94	62 (32)		1.53%	13[3.63,22.37]
Mullan 2009	48	63.5 (24.4)	37	53 (18.2)		1.57%	10.5[1.44,19.56]
Nassar 2007	98	88 (19)	90	79 (18)		2.02%	9[3.71,14.29]
Protheroe 2007	54	59.7 (18.4)	54	48.8 (19.6)		1.8%	10.9[3.73,18.07]

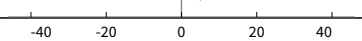


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Sawka 2012	37	97 (6)	37	78 (13)		2.09%	19[14.39,23.61]
Schroy 2011	223	89.2 (15)	231	71.7 (22.5)		2.2%	17.5[13.99,21.01]
Schwalm 2012	76	60 (30)	74	40 (26)		1.58%	20[11.02,28.98]
Schwartz 2001	191	65.7 (14.3)	190	57.1 (15.7)		2.24%	8.57[5.55,11.59]
Shorten 2005	99	75.3 (15)	92	60.5 (17.1)		2.1%	14.8[10.23,19.37]
Smith 2010	357	54.2 (27.8)	173	34.2 (14.3)		2.19%	20[16.42,23.58]
Stacey 2014a	66	71.2 (23.7)	66	46.6 (21.4)		1.73%	24.6[16.9,32.3]
Steckelberg 2011	785	53.8 (28.8)	792	31.3 (15)		2.3%	22.5[20.23,24.77]
Taylor 2006	80	77.3 (15.5)	74	62.7 (11.8)		2.12%	14.6[10.27,18.93]
Thomson 2007	53	62.9 (14.3)	56	62.4 (14.1)		2.01%	0.56[-4.77,5.89]
Van Peperstraten 2010	123	62 (28.3)	132	43 (20.5)		1.92%	19[12.9,25.1]
Vandemheen 2009	70	74 (27.1)	79	49 (23.3)		1.68%	25[16.83,33.17]
Volk 1999	78	48 (21.6)	80	31 (18.8)		1.9%	17[10.68,23.32]
Whelan 2003	82	80.2 (14.4)	93	71.7 (13.3)		2.14%	8.5[4.37,12.63]
Williams 2013	196	64.4 (18.5)	185	61.7 (17.8)		2.19%	2.7[-0.95,6.35]
Wong 2006	154	85 (26.7)	159	60 (21.7)		2.01%	25[19.6,30.4]
Total ***	**6779**		**6537**			**100%**	**13.27[11.32,15.23]**
Heterogeneity: Tau²=41.98; Chi²=717.6, df=51(P<0.0001); I²=92.89%							
Test for overall effect: Z=13.31(P<0.0001)							



Analysis 1.2. Comparison 1 Knowledge, Outcome 2 Knowledge - subgroup by timing of intervention (in consultation versus in preparation for consultation).

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
1.2.1 In consultation							
Bekker 2004	50	74 (14.5)	56	71.5 (16)		13.35%	2.5[-3.31,8.31]
Hess 2012	101	51.4 (18.2)	103	42.9 (18.3)		13.83%	8.57[3.56,13.58]
Johnson 2006	32	92.6 (11)	35	85.2 (15.6)		12.96%	7.4[0.98,13.82]
Kupke 2013	50	60 (23.3)	31	27 (16.7)		11.41%	33[24.27,41.73]
Montori 2011	49	63.3 (29.6)	46	43.3 (29.6)		9.32%	20[8.09,31.91]
Mullan 2009	48	63.5 (24.4)	37	53 (18.2)		11.19%	10.5[1.44,19.56]
Thomson 2007	53	62.9 (14.3)	56	62.4 (14.1)		13.64%	0.56[-4.77,5.89]
Whelan 2003	82	80.2 (14.4)	93	71.7 (13.3)		14.3%	8.5[4.37,12.63]
Subtotal ***	**465**		**457**			**100%**	**10.57[4.79,16.36]**
Heterogeneity: Tau²=56.4; Chi²=46.7, df=7(P<0.0001); I²=85.01%							
Test for overall effect: Z=3.58(P=0)							
1.2.2 In preparation for consultation							
Allen 2010	291	66 (35.5)	334	60 (29.2)		2.38%	6[0.86,11.14]
Arterburn 2011	75	72 (12)	77	65 (17)		2.43%	7[2.33,11.67]
Barry 1997	104	75 (45)	123	54 (45)		1.51%	21[9.25,32.75]
Bernstein 1998	61	83 (16)	48	58 (16)		2.26%	25[18.95,31.05]
Bjorklund 2012	182	77 (17)	204	71 (20)		2.54%	6[2.31,9.69]
Chabrera 2015	61	75.7 (19)	61	49.9 (16)		2.24%	25.8[19.57,32.03]
Frosch 2008a	155	81.4 (18.7)	151	72.4 (19.7)		2.48%	9[4.69,13.31]
Gattellari 2003	106	50 (18.4)	108	45 (15.9)		2.44%	5[0.39,9.61]

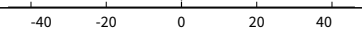


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Gattellari 2005	131	57.2 (21.3)	136	42.2 (16.7)		2.44%	15[10.4,19.6]
Green 2001	29	95 (7)	14	65 (21)		1.57%	30[18.71,41.29]
Hanson 2011	127	88.4 (21.6)	129	79.5 (21.6)		2.36%	8.9[3.6,14.2]
Jibaja-Weiss 2011	44	61.2 (20.4)	39	43.6 (26.6)		1.69%	17.63[7.33,27.93]
Knops 2014	80	76.9 (16.9)	84	72.3 (16.2)		2.39%	4.62[-0.45,9.69]
Krist 2007	196	69 (33.2)	75	54 (33.2)		1.88%	15[6.16,23.84]
Kuppermann 2014	357	62.7 (21.3)	353	57.3 (21.3)		2.6%	5.4[2.27,8.53]
Lam 2013	113	61 (21)	112	59 (21)		2.33%	2[-3.49,7.49]
Laupacis 2006	53	83 (19.5)	53	67.4 (17)		2.14%	15.6[8.64,22.56]
Leighl 2011	100	72.5 (26.9)	100	60 (26.9)		2.07%	12.5[5.05,19.95]
Lepore 2012	215	61.6 (0.1)	216	54.7 (0.1)		2.75%	6.9[6.88,6.92]
Lerman 1997	122	68.9 (19)	164	49 (21.7)		2.43%	19.9[15.17,24.63]
Lewis 2010	93	45.1 (34)	107	46.7 (34)		1.8%	-1.6[-11.05,7.85]
Man-Son-Hing 1999	137	75.9 (15.7)	136	66.5 (16.1)		2.54%	9.45[5.68,13.22]
Mann E 2010	273	64.1 (21.9)	134	41.3 (21)		2.47%	22.85[18.45,27.25]
Mathieu 2010	113	73.5 (27.6)	189	62.7 (27.6)		2.21%	10.8[4.37,17.23]
McCaffery 2010	77	81 (23.5)	71	72 (23.5)		2.05%	9[1.42,16.58]
Montgomery 2003	50	75 (17)	58	60 (18)		2.19%	15[8.39,21.61]
Montgomery 2007	196	69.7 (18)	202	57.5 (18.5)		2.55%	12.2[8.61,15.79]
Morgan 2000	86	75 (32)	94	62 (32)		1.81%	13[3.63,22.37]
Nassar 2007	98	88 (19)	90	79 (18)		2.36%	9[3.71,14.29]
Protheroe 2007	54	59.7 (18.4)	54	48.8 (19.6)		2.11%	10.9[3.73,18.07]
Sawka 2012	37	97 (6)	37	78 (13)		2.44%	19[14.39,23.61]
Schroy 2011	223	89.2 (15)	231	71.7 (22.5)		2.56%	17.5[13.99,21.01]
Schwalm 2012	76	60 (30)	74	40 (26)		1.86%	20[11.02,28.98]
Schwartz 2001	191	65.7 (14.3)	190	57.1 (15.7)		2.61%	8.57[5.55,11.59]
Shorten 2005	99	75.3 (15)	92	60.5 (17.1)		2.45%	14.8[10.23,19.37]
Smith 2010	357	54.2 (27.8)	173	34.2 (14.3)		2.55%	20[16.42,23.58]
Stacey 2014a	66	71.2 (23.7)	66	46.6 (21.4)		2.04%	24.6[16.9,32.3]
Steckelberg 2011	785	53.8 (28.8)	792	31.3 (15)		2.67%	22.5[20.23,24.77]
Taylor 2006	80	77.3 (15.5)	74	62.7 (11.8)		2.47%	14.6[10.27,18.93]
Van Peperstraten 2010	123	62 (28.3)	132	43 (20.5)		2.25%	19[12.9,25.1]
Vandemheen 2009	70	74 (27.1)	79	49 (23.3)		1.97%	25[16.83,33.17]
Volk 1999	78	48 (21.6)	80	31 (18.8)		2.22%	17[10.68,23.32]
Williams 2013	196	64.4 (18.5)	185	61.7 (17.8)		2.55%	2.7[-0.95,6.35]
Wong 2006	154	85 (26.7)	159	60 (21.7)		2.34%	25[19.6,30.4]
Subtotal * **	**6314**		**6080**			**100%**	**13.77[11.61,15.93]**

Heterogeneity: Tau^2=44.14; Chi^2=669.38, df=43(P<0.0001); I^2=93.58%

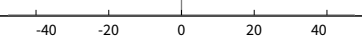
Test for overall effect: Z=12.5(P<0.0001)

Test for subgroup differences: Chi^2=1.03, df=1 (P=0.31), I^2=3.03%



Analysis 1.3. Comparison 1 Knowledge, Outcome 3 Knowledge - studies without high risk of bias.

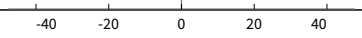
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Allen 2010	291	66 (35.5)	334	60 (29.2)		2.23%	6[0.86,11.14]
Arterburn 2011	75	72 (12)	77	65 (17)		2.29%	7[2.33,11.67]
Barry 1997	104	75 (45)	123	54 (45)		1.41%	21[9.25,32.75]



Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Bekker 2004	50	74 (14.5)	56	71.5 (16)		2.15%	2.5[-3.31,8.31]
Bernstein 1998	61	83 (16)	48	58 (16)		2.12%	25[18.95,31.05]
Bjorklund 2012	182	77 (17)	204	71 (20)		2.4%	6[2.31,9.69]
Chabrera 2015	61	75.7 (19)	61	49.9 (16)		2.1%	25.8[19.57,32.03]
Frosch 2008a	155	81.4 (18.7)	151	72.4 (19.7)		2.33%	9[4.69,13.31]
Gattellari 2003	106	50 (18.4)	108	45 (15.9)		2.3%	5[0.39,9.61]
Gattellari 2005	131	57.2 (21.3)	136	42.2 (16.7)		2.3%	15[10.4,19.6]
Green 2001	29	95 (7)	14	65 (21)		1.46%	30[18.71,41.29]
Hanson 2011	127	88.4 (21.6)	129	79.5 (21.6)		2.21%	8.9[3.6,14.2]
Hess 2012	101	51.4 (18.2)	103	42.9 (18.3)		2.25%	8.57[3.56,13.58]
Jibaja-Weiss 2011	44	61.2 (20.4)	39	43.6 (26.6)		1.57%	17.63[7.33,27.93]
Johnson 2006	32	92.6 (11)	35	85.2 (15.6)		2.07%	7.4[0.98,13.82]
Kuppermann 2014	357	62.7 (21.3)	353	57.3 (21.3)		2.45%	5.4[2.27,8.53]
Lam 2013	113	61 (21)	112	59 (21)		2.19%	2[-3.49,7.49]
Laupacis 2006	53	83 (19.5)	53	67.4 (17)		2%	15.6[8.64,22.56]
Leighl 2011	100	72.5 (26.9)	100	60 (26.9)		1.94%	12.5[5.05,19.95]
Lepore 2012	215	61.6 (0.1)	216	54.7 (0.1)		2.6%	6.9[6.88,6.92]
Lerman 1997	122	68.9 (19)	164	49 (21.7)		2.28%	19.9[15.17,24.63]
Mann E 2010	273	64.1 (21.9)	134	41.3 (21)		2.32%	22.85[18.45,27.25]
Mathieu 2010	113	73.5 (27.6)	189	62.7 (27.6)		2.07%	10.8[4.37,17.23]
McCaffery 2010	77	81 (23.5)	71	72 (23.5)		1.92%	9[1.42,16.58]
Montgomery 2003	50	75 (17)	58	60 (18)		2.05%	15[8.39,21.61]
Montgomery 2007	196	69.7 (18)	202	57.5 (18.5)		2.41%	12.2[8.61,15.79]
Montori 2011	49	63.3 (29.6)	46	43.3 (29.6)		1.39%	20[8.09,31.91]
Morgan 2000	86	75 (32)	94	62 (32)		1.69%	13[3.63,22.37]
Mullan 2009	48	63.5 (24.4)	37	53 (18.2)		1.73%	10.5[1.44,19.56]
Nassar 2007	98	88 (19)	90	79 (18)		2.22%	9[3.71,14.29]
Protheroe 2007	54	59.7 (18.4)	54	48.8 (19.6)		1.97%	10.9[3.73,18.07]
Sawka 2012	37	97 (6)	37	78 (13)		2.3%	19[14.39,23.61]
Schroy 2011	223	89.2 (15)	231	71.7 (22.5)		2.41%	17.5[13.99,21.01]
Schwalm 2012	76	60 (30)	74	40 (26)		1.74%	20[11.02,28.98]
Schwartz 2001	191	65.7 (14.3)	190	57.1 (15.7)		2.46%	8.57[5.55,11.59]
Shorten 2005	99	75.3 (15)	92	60.5 (17.1)		2.3%	14.8[10.23,19.37]
Smith 2010	357	54.2 (27.8)	173	34.2 (14.3)		2.41%	20[16.42,23.58]
Stacey 2014a	66	71.2 (23.7)	66	46.6 (21.4)		1.9%	24.6[16.9,32.3]
Steckelberg 2011	785	53.8 (28.8)	792	31.3 (15)		2.52%	22.5[20.23,24.77]
Taylor 2006	80	77.3 (15.5)	74	62.7 (11.8)		2.33%	14.6[10.27,18.93]
Thomson 2007	53	62.9 (14.3)	56	62.4 (14.1)		2.21%	0.56[-4.77,5.89]
Van Peperstraten 2010	123	62 (28.3)	132	43 (20.5)		2.11%	19[12.9,25.1]
Vandemheen 2009	70	74 (27.1)	79	49 (23.3)		1.84%	25[16.83,33.17]
Volk 1999	78	48 (21.6)	80	31 (18.8)		2.09%	17[10.68,23.32]
Whelan 2003	82	80.2 (14.4)	93	71.7 (13.3)		2.35%	8.5[4.37,12.63]
Williams 2013	196	64.4 (18.5)	185	61.7 (17.8)		2.4%	2.7[-0.95,6.35]
Wong 2006	154	85 (26.7)	159	60 (21.7)		2.2%	25[19.6,30.4]
Total ***	**6223**		**6104**			**100%**	**13.43[11.37,15.49]**

Heterogeneity: Tau^2=42.59; Chi^2=674.45, df=46(P<0.0001); I^2=93.18%

Test for overall effect: Z=12.78(P<0.0001)

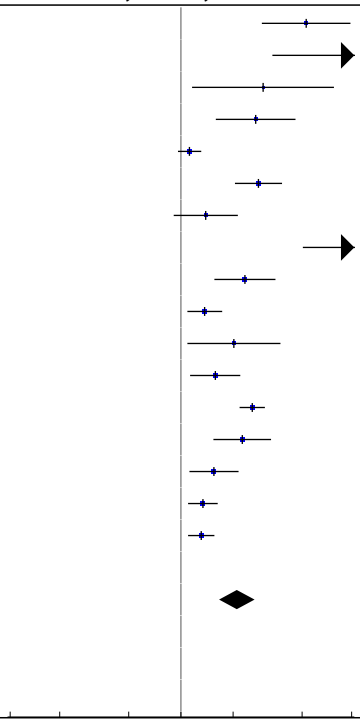


Comparison 2. Accurate risk perceptions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Accurate risk perceptions - all studies	17	5096	Risk Ratio (M-H, Random, 95% CI)	2.10 [1.66, 2.66]
2 Accurate risk perceptions - subgroup by timing of intervention (in consultation versus in preparation for consultation)	17		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 In consultation	6	898	Risk Ratio (M-H, Random, 95% CI)	1.79 [1.28, 2.52]
2.2 In preparation for consultation	11	4198	Risk Ratio (M-H, Random, 95% CI)	2.25 [1.65, 3.07]
3 Accurate risk perceptions - studies without high risk of bias	15	4732	Risk Ratio (M-H, Random, 95% CI)	2.02 [1.57, 2.59]

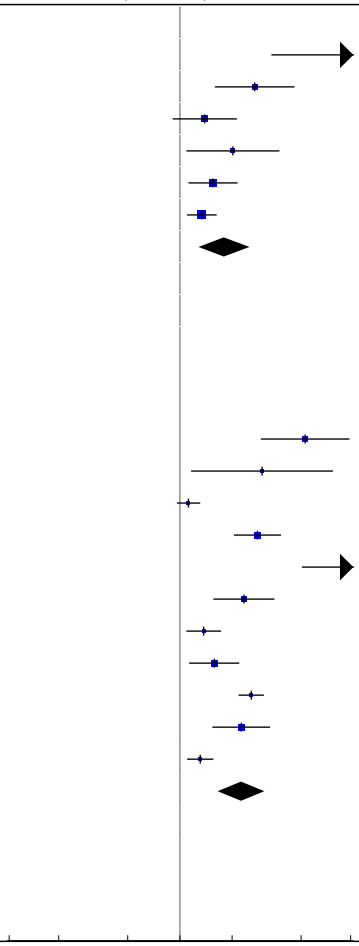
Analysis 2.1. Comparison 2 Accurate risk perceptions, Outcome 1 Accurate risk perceptions - all studies.

Study or subgroup	Decision Aid n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gattellari 2003	57/106	11/108		5.23%	5.28[2.93,9.5]
Hess 2012	24/101	1/103		1.2%	24.48[3.37,177.53]
Laupacis 2006	14/47	5/50		3.47%	2.98[1.16,7.63]
LeBlanc 2015	23/32	12/45		5.56%	2.7[1.59,4.58]
Lerman 1997	90/122	108/164		7.5%	1.12[0.96,1.31]
Man-Son-Hing 1999	92/139	35/148		6.81%	2.8[2.05,3.83]
Mann D 2010	35/80	22/70		6.18%	1.39[0.91,2.13]
Mathers 2012	67/95	4/75		3.38%	13.22[5.05,34.62]
McAlister 2005	66/175	25/155		6.3%	2.34[1.56,3.51]
McBride 2002	109/265	82/274		7.21%	1.37[1.09,1.73]
Montori 2011	23/49	10/43		5.05%	2.02[1.09,3.75]
Schwalm 2012	47/76	29/74		6.7%	1.58[1.13,2.2]
Steckelberg 2011	361/785	141/792		7.45%	2.58[2.18,3.05]
Vandemheen 2009	46/70	23/79		6.43%	2.26[1.54,3.31]
Whelan 2003	47/82	34/92		6.75%	1.55[1.12,2.15]
Whelan 2004	73/94	62/107		7.36%	1.34[1.1,1.63]
Wolf 2000	189/266	72/133		7.43%	1.31[1.1,1.56]
Total (95% CI)	**2584**	**2512**		**100%**	**2.1[1.66,2.66]**
Total events: 1363 (Decision Aid), 676 (Control)					
Heterogeneity: Tau^2=0.19; Chi^2=151.38, df=16(P<0.0001); I^2=89.43%					
Test for overall effect: Z=6.16(P<0.0001)					



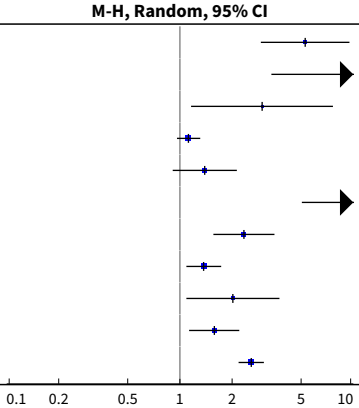
Analysis 2.2. Comparison 2 Accurate risk perceptions, Outcome 2 Accurate risk perceptions - subgroup by timing of intervention (in consultation versus in preparation for consultation).

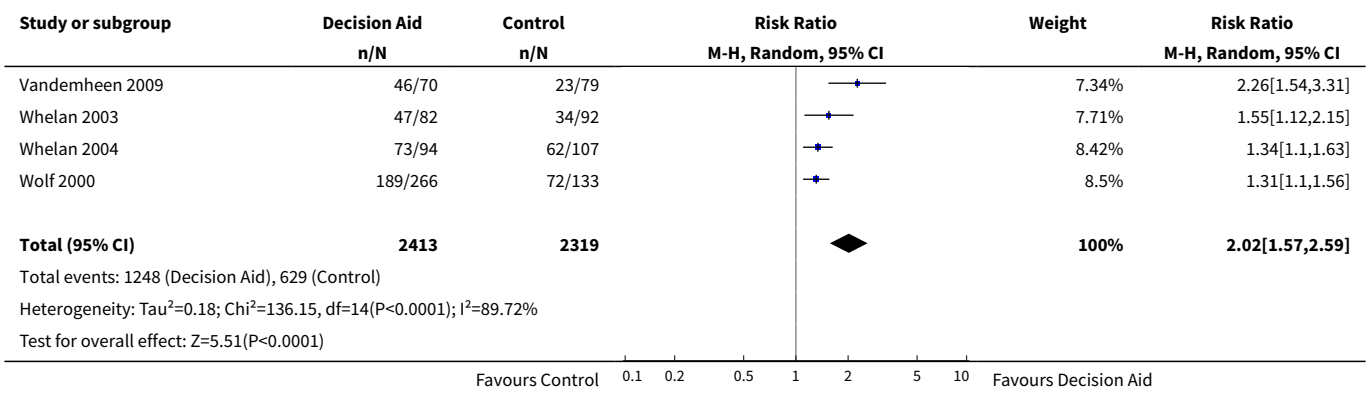
Study or subgroup	Decision Aid n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
2.2.1 In consultation					
Hess 2012	24/101	1/103		2.65%	24.48[3.37,177.53]
LeBlanc 2015	23/32	12/45		16.47%	2.7[1.59,4.58]
Mann D 2010	35/80	22/70		19.22%	1.39[0.91,2.13]
Montori 2011	23/49	10/43		14.37%	2.02[1.09,3.75]
Whelan 2003	47/82	34/92		21.99%	1.55[1.12,2.15]
Whelan 2004	73/94	62/107		25.29%	1.34[1.1,1.63]
Subtotal (95% CI)	**438**	**460**		**100%**	**1.79[1.28,2.52]**
Total events: 225 (Decision Aid), 141 (Control)					
Heterogeneity: Tau^2=0.11; Chi^2=17.62, df=5(P=0); I^2=71.63%					
Test for overall effect: Z=3.37(P=0)					
2.2.2 In preparation for consultation					
Gattellari 2003	57/106	11/108		7.94%	5.28[2.93,9.5]
Laupacis 2006	14/47	5/50		5.5%	2.98[1.16,7.63]
Lerman 1997	90/122	108/164		10.78%	1.12[0.96,1.31]
Man-Son-Hing 1999	92/139	35/148		9.95%	2.8[2.05,3.83]
Mathers 2012	67/95	4/75		5.37%	13.22[5.05,34.62]
McAlister 2005	66/175	25/155		9.31%	2.34[1.56,3.51]
McBride 2002	109/265	82/274		10.43%	1.37[1.09,1.73]
Schwalm 2012	47/76	29/74		9.81%	1.58[1.13,2.2]
Steckelberg 2011	361/785	141/792		10.72%	2.58[2.18,3.05]
Vandemheen 2009	46/70	23/79		9.48%	2.26[1.54,3.31]
Wolf 2000	189/266	72/133		10.7%	1.31[1.1,1.56]
Subtotal (95% CI)	**2146**	**2052**		**100%**	**2.25[1.65,3.07]**
Total events: 1138 (Decision Aid), 535 (Control)					
Heterogeneity: Tau^2=0.23; Chi^2=130.92, df=10(P<0.0001); I^2=92.36%					
Test for overall effect: Z=5.11(P<0.0001)					
Test for subgroup differences: Chi^2=0.94, df=1 (P=0.33), I^2=0%					



Analysis 2.3. Comparison 2 Accurate risk perceptions, Outcome 3 Accurate risk perceptions - studies without high risk of bias.

Study or subgroup	Decision Aid n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gattellari 2003	57/106	11/108		5.95%	5.28[2.93,9.5]
Hess 2012	24/101	1/103		1.35%	24.48[3.37,177.53]
Laupacis 2006	14/47	5/50		3.93%	2.98[1.16,7.63]
Lerman 1997	90/122	108/164		8.58%	1.12[0.96,1.31]
Mann D 2010	35/80	22/70		7.05%	1.39[0.91,2.13]
Mathers 2012	67/95	4/75		3.83%	13.22[5.05,34.62]
McAlister 2005	66/175	25/155		7.18%	2.34[1.56,3.51]
McBride 2002	109/265	82/274		8.24%	1.37[1.09,1.73]
Montori 2011	23/49	10/43		5.74%	2.02[1.09,3.75]
Schwalm 2012	47/76	29/74		7.65%	1.58[1.13,2.2]
Steckelberg 2011	361/785	141/792		8.53%	2.58[2.18,3.05]

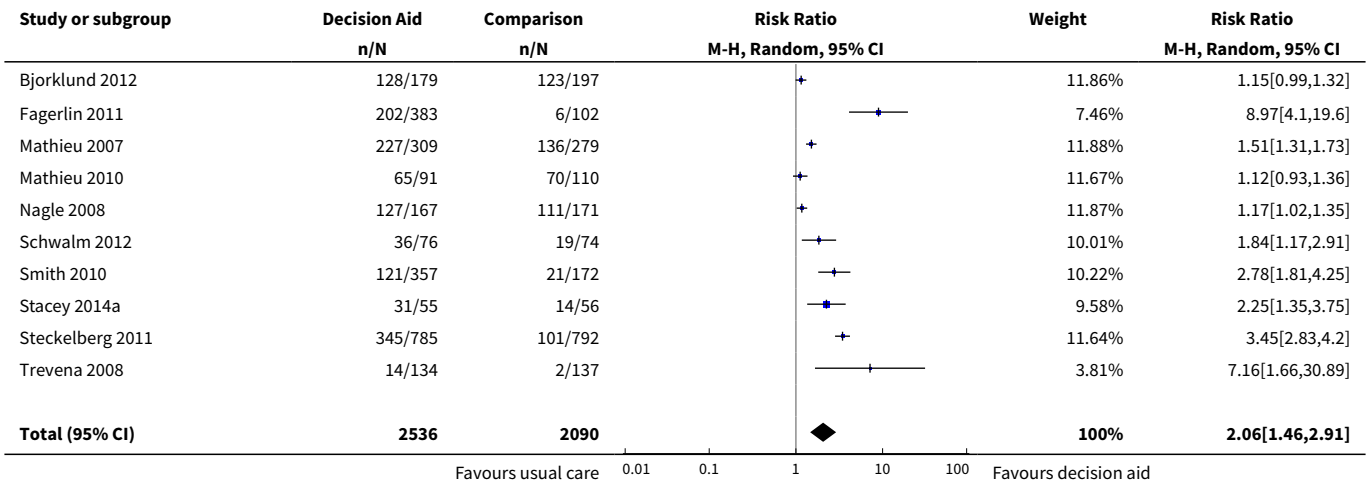


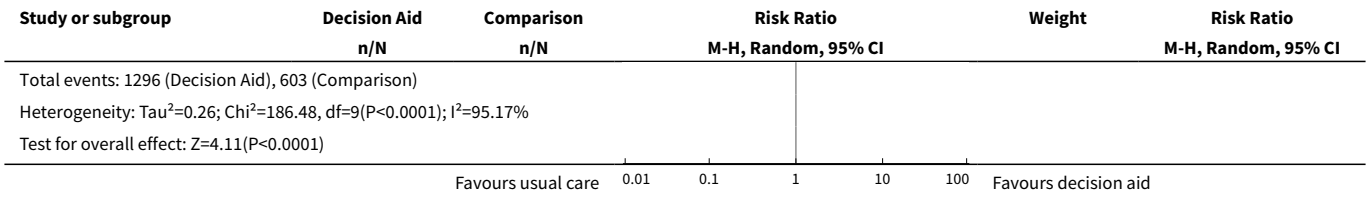


Comparison 3. Informed values-choice congruence

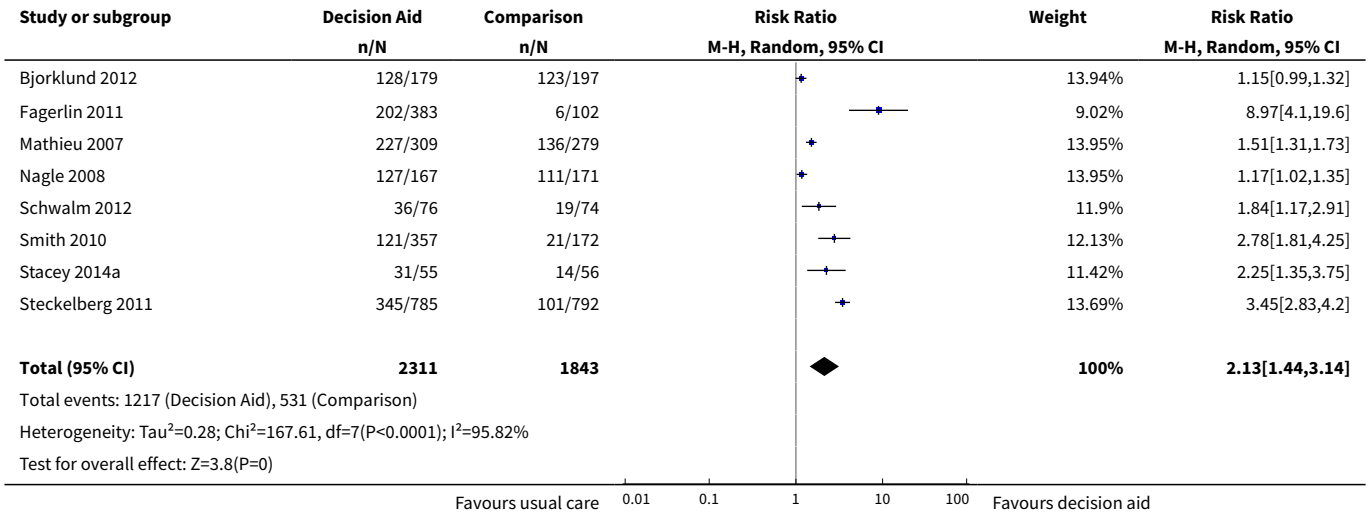
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Informed values-choice congruence - all studies	10	4626	Risk Ratio (M-H, Random, 95% CI)	2.06 [1.46, 2.91]
2 Informed values-choice congruence - actual choice only	8	4154	Risk Ratio (M-H, Random, 95% CI)	2.13 [1.44, 3.14]
3 Informed values-chose congruence -using MMIC	8	4365	Risk Ratio (M-H, Random, 95% CI)	2.08 [1.40, 3.08]
4 Informed values-chose congruence - heterogeneous measures	2	261	Risk Ratio (M-H, Random, 95% CI)	2.02 [1.44, 2.83]
5 Informed values-choice congruence - without studies of high risk of bias	10	4626	Risk Ratio (M-H, Random, 95% CI)	2.06 [1.46, 2.91]

Analysis 3.1. Comparison 3 Informed values-choice congruence, Outcome 1 Informed values-choice congruence - all studies.

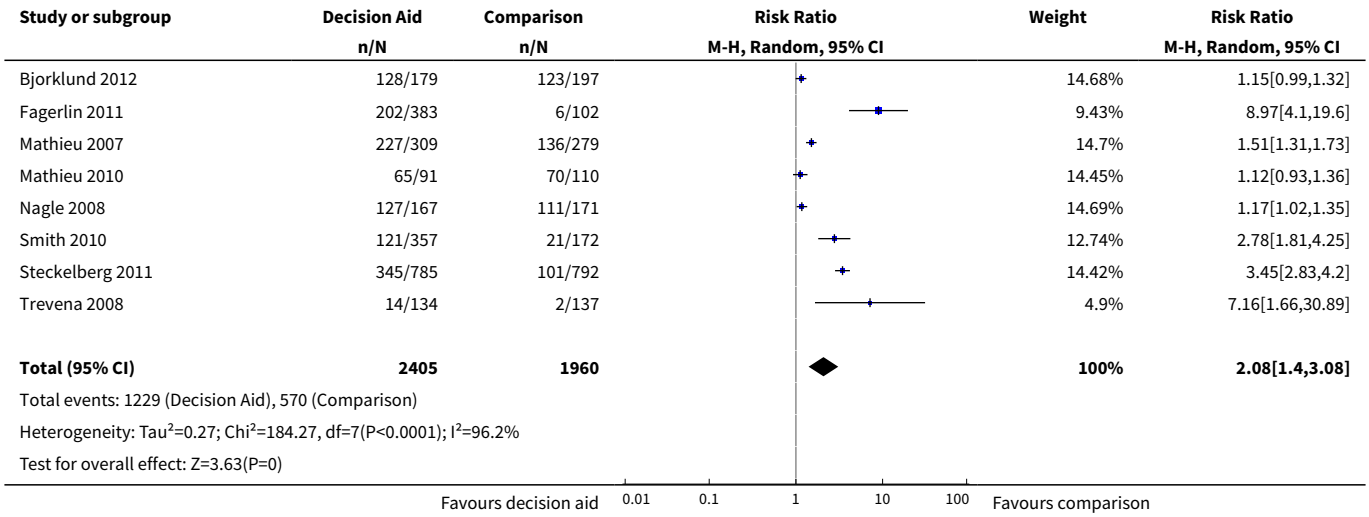




Analysis 3.2. Comparison 3 Informed values-choice congruence, Outcome 2 Informed values-choice congruence - actual choice only.



Analysis 3.3. Comparison 3 Informed values-choice congruence, Outcome 3 Informed values-chose congruence -using MMIC.



Analysis 3.4. Comparison 3 Informed values-choice congruence, Outcome 4 Informed values-chose congruence - heterogeneous measures.

Study or subgroup	Decision Aid n/N	Comparison n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Schwalm 2012	36/76	19/74		55.73%	1.84[1.17,2.91]
Stacey 2014a	31/55	14/56		44.27%	2.25[1.35,3.75]
Total (95% CI)	**131**	**130**		**100%**	**2.02[1.44,2.83]**
Total events: 67 (Decision Aid), 33 (Comparison)					
Heterogeneity: Tau^2=0; Chi^2=0.33, df=1(P=0.56); I^2=0%					
Test for overall effect: Z=4.05(P<0.0001)					

Favours Decision Aid — Favours Comparison

Analysis 3.5. Comparison 3 Informed values-choice congruence, Outcome 5 Informed values-choice congruence - without studies of high risk of bias.

Study or subgroup	Decision Aid n/N	Comparison n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Bjorklund 2012	128/179	123/197		11.86%	1.15[0.99,1.32]
Fagerlin 2011	202/383	6/102		7.46%	8.97[4.1,19.6]
Mathieu 2007	227/309	136/279		11.88%	1.51[1.31,1.73]
Mathieu 2010	65/91	70/110		11.67%	1.12[0.93,1.36]
Nagle 2008	127/167	111/171		11.87%	1.17[1.02,1.35]
Schwalm 2012	36/76	19/74		10.01%	1.84[1.17,2.91]
Smith 2010	121/357	21/172		10.22%	2.78[1.81,4.25]
Stacey 2014a	31/55	14/56		9.58%	2.25[1.35,3.75]
Steckelberg 2011	345/785	101/792		11.64%	3.45[2.83,4.2]
Trevena 2008	14/134	2/137		3.81%	7.16[1.66,30.89]
Total (95% CI)	**2536**	**2090**		**100%**	**2.06[1.46,2.91]**
Total events: 1296 (Decision Aid), 603 (Comparison)					
Heterogeneity: Tau^2=0.26; Chi^2=186.48, df=9(P<0.0001); I^2=95.17%					
Test for overall effect: Z=4.11(P<0.0001)					

Favours usual care — Favours decision aid

Comparison 4. Decisional conflict

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Decisional conflict - all studies	42		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Total decisional conflict score	38	8785	Mean Difference (IV, Random, 95% CI)	-7.22 [-9.12, -5.31]
1.2 Uninformed subscale	27	5707	Mean Difference (IV, Random, 95% CI)	-9.28 [-12.20, -6.36]

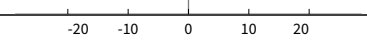
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.3 Unclear values subscale	23	5068	Mean Difference (IV, Random, 95% CI)	-8.81 [-11.99, -5.63]
1.4 Uncertainty subscale	28	6200	Mean Difference (IV, Random, 95% CI)	-4.04 [-6.27, -1.81]
1.5 Unsupported subscale	24	5214	Mean Difference (IV, Random, 95% CI)	-6.27 [-8.86, -3.68]
1.6 Ineffective choice subscale	24	5241	Mean Difference (IV, Random, 95% CI)	-6.31 [-8.93, -3.70]
2 Decisional conflict - in consultation	6		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Uncertainty subscale	2	310	Mean Difference (IV, Random, 95% CI)	-6.45 [-18.29, 5.38]
2.2 Uninformed subscale	4	545	Mean Difference (IV, Random, 95% CI)	-6.37 [-14.58, 1.85]
2.3 Unclear values subscale	1	204	Mean Difference (IV, Random, 95% CI)	-17.2 [-23.77, -10.63]
2.4 Unsupported subscale	2	354	Mean Difference (IV, Random, 95% CI)	-7.16 [-13.28, -1.03]
2.5 Ineffective choice subscale	2	307	Mean Difference (IV, Random, 95% CI)	-2.37 [-7.31, 2.58]
2.6 Total decisional conflict score	5	735	Mean Difference (IV, Random, 95% CI)	-6.46 [-12.78, -0.14]
3 Decisional conflict - in preparation for consultation	36		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Uncertainty subscale	26	5890	Mean Difference (IV, Random, 95% CI)	-3.83 [-6.12, -1.55]
3.2 Uninformed subscale	23	5162	Mean Difference (IV, Random, 95% CI)	-9.81 [-13.00, -6.61]
3.3 Unclear values subscale	22	4864	Mean Difference (IV, Random, 95% CI)	-8.40 [-11.59, -5.21]
3.4 Unsupported subscale	22	4860	Mean Difference (IV, Random, 95% CI)	-6.18 [-8.96, -3.40]
3.5 Ineffective choice subscale	22	4934	Mean Difference (IV, Random, 95% CI)	-6.75 [-9.59, -3.90]
3.6 Total decisional conflict score	33	8050	Mean Difference (IV, Random, 95% CI)	-7.32 [-9.35, -5.28]

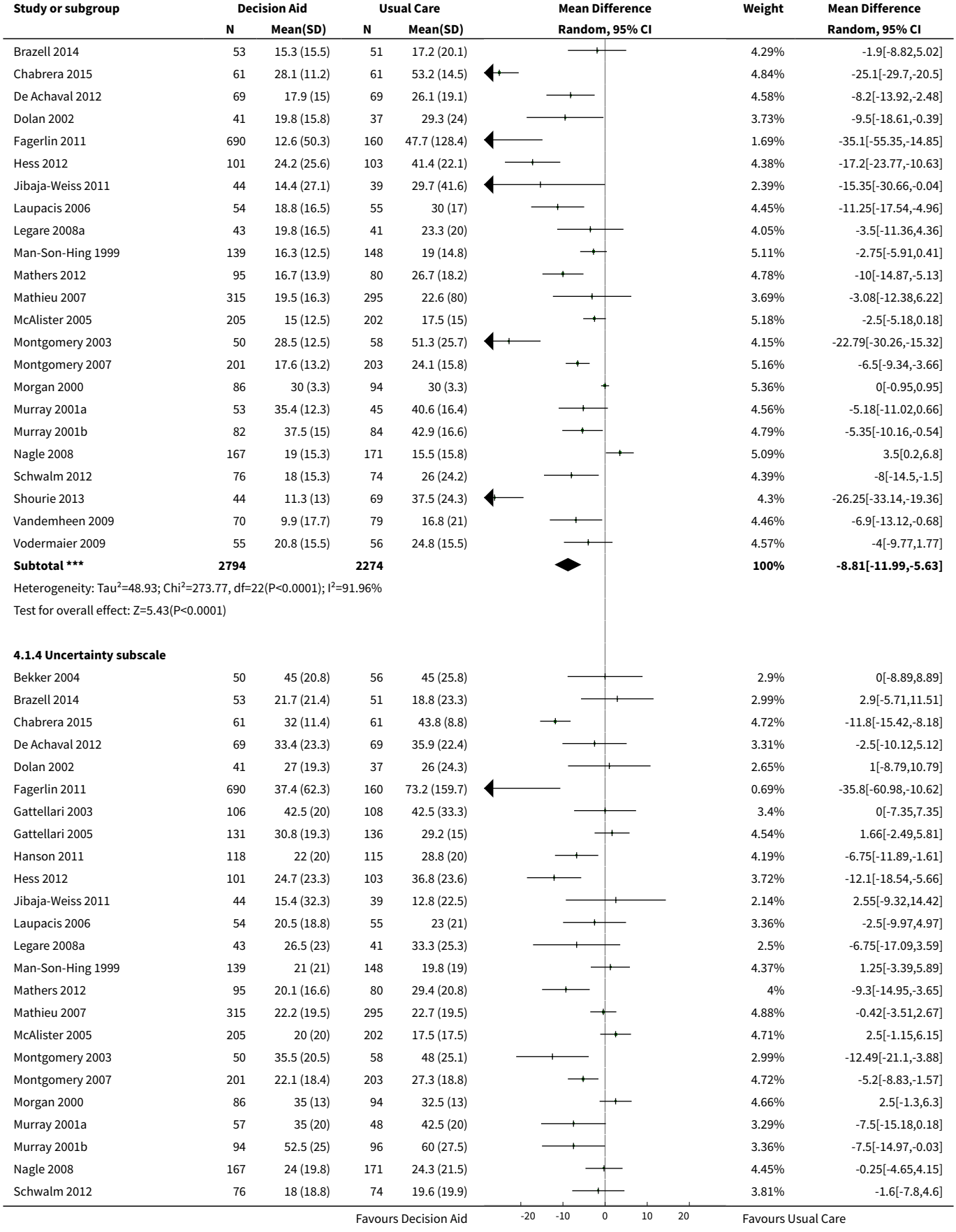
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Decisional conflict - without studies having high risk of bias	39		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 Uncertainty subscale	26	5809	Mean Difference (IV, Random, 95% CI)	-4.53 [-6.87, -2.18]
4.2 Uninformed subscale	25	5316	Mean Difference (IV, Random, 95% CI)	-9.96 [-13.13, -6.78]
4.3 Unclear values subscale	21	4677	Mean Difference (IV, Random, 95% CI)	-9.55 [-13.08, -6.02]
4.4 Unsupported subscale	22	4823	Mean Difference (IV, Random, 95% CI)	-7.00 [-9.76, -4.24]
4.5 Ineffective choice subscale	22	4850	Mean Difference (IV, Random, 95% CI)	-6.97 [-9.76, -4.18]
4.6 Total decisional conflict score	35	8240	Mean Difference (IV, Random, 95% CI)	-7.81 [-9.84, -5.77]

Analysis 4.1. Comparison 4 Decisional conflict, Outcome 1 Decisional conflict - all studies.

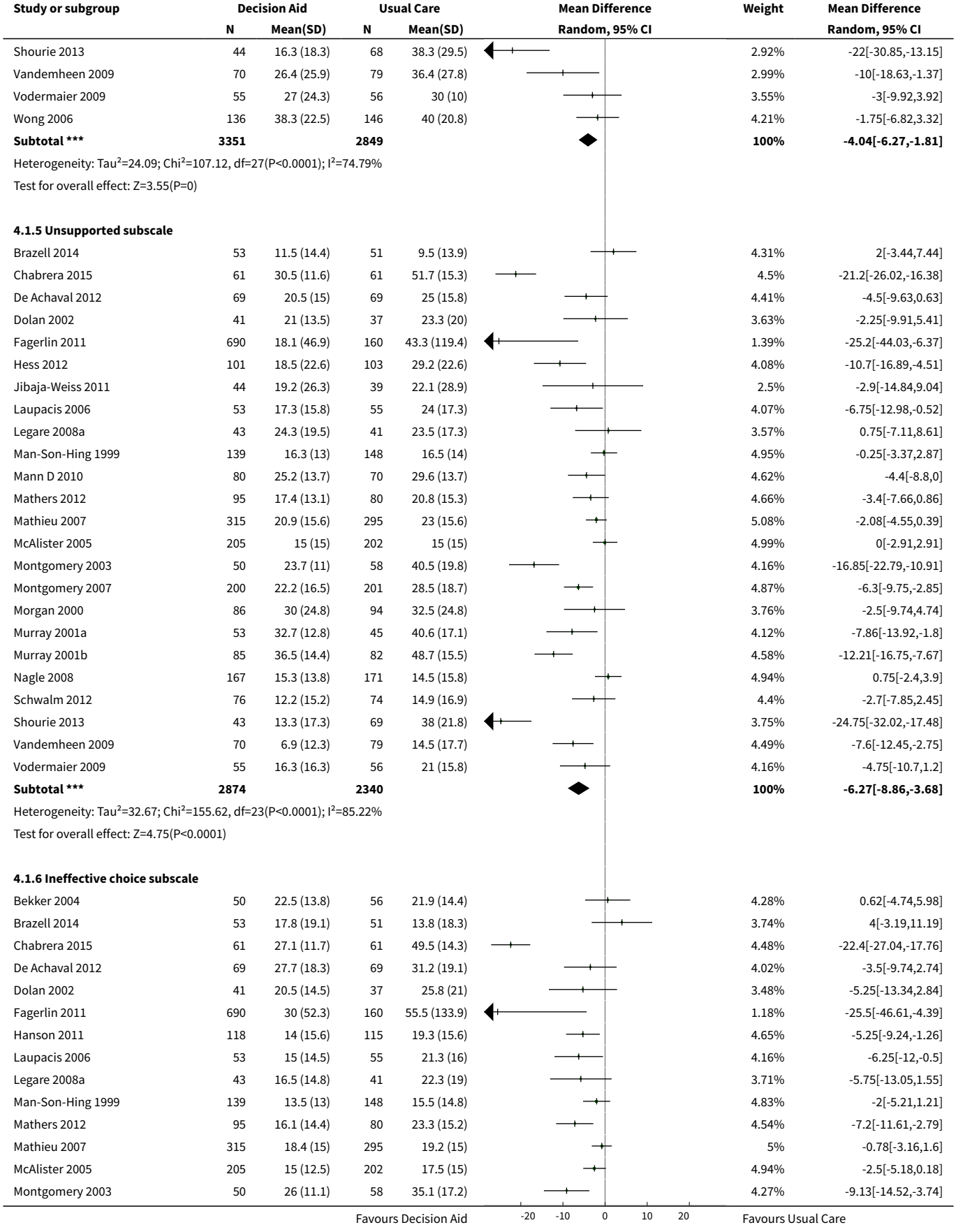
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.1.1 Total decisional conflict score							
Allen 2010	291	14 (34.3)	334	20 (37.8)		2.6%	-6[-11.66,-0.34]
Brazell 2014	53	15.8 (13.9)	51	14.1 (16.1)		2.57%	1.7[-4.09,7.49]
Chabrera 2015	61	31.2 (10.2)	61	51.7 (13.3)		2.9%	-20.5[-24.71,-16.29]
De Achaval 2012	69	23.4 (15)	69	29.2 (16.6)		2.68%	-5.8[-11.07,-0.53]
Dolan 2002	41	20.8 (13)	37	25.8 (20.3)		2.19%	-5[-12.64,2.64]
Evans 2010	89	38.1 (24.2)	103	49.6 (24.2)		2.35%	-11.5[-18.35,-4.65]
Fagerlin 2011	690	22 (42.2)	160	55.7 (108.4)		0.91%	-33.7[-50.79,-16.61]
Hanson 2011	118	16.3 (18.6)	115	24.3 (18.6)		2.79%	-8[-12.76,-3.24]
Hess 2012	101	23.3 (20.8)	103	43.3 (19)		2.64%	-20[-25.46,-14.54]
Jibaja-Weiss 2011	44	16.5 (19.9)	39	22.2 (25.3)		1.77%	-5.63[-15.51,4.25]
Knops 2014	73	22 (17)	81	24 (17)		2.66%	-2[-7.38,3.38]
Kuppermann 2014	357	12.9 (14.1)	353	13.8 (15.6)		3.23%	-0.9[-3.09,1.29]
Lam 2013	113	15.8 (15.5)	112	19.9 (16.3)		2.91%	-4.1[-8.26,0.06]
Laupacis 2006	53	17.5 (13.8)	54	25.3 (14.3)		2.67%	-7.75[-13.06,-2.44]
Legare 2008a	43	23 (14.3)	41	27 (15.3)		2.46%	-4[-10.32,2.32]
Lepore 2012	215	34.2 (24)	216	39.9 (24)		2.83%	-5.7[-10.24,-1.16]
Man-Son-Hing 1999	139	16.3 (11.3)	148	18.5 (13.5)		3.13%	-2.25[-5.12,0.62]
Mann D 2010	80	25.5 (11.1)	70	28.5 (11.1)		3.02%	-3[-6.57,0.57]
Mathers 2012	95	17.4 (12.6)	80	25.2 (14.9)		2.91%	-7.8[-11.93,-3.67]
Mathieu 2007	315	20.1 (14.5)	295	21.9 (14.5)		3.21%	-1.83[-4.13,0.47]
McAlister 2005	205	15 (12.5)	202	17.5 (12.5)		3.2%	-2.5[-4.93,-0.07]
Montgomery 2003	50	27.1 (10)	58	44.2 (19.3)		2.59%	-17.1[-22.79,-11.41]
Montgomery 2007	198	23.6 (15.1)	201	27.8 (14.6)		3.13%	-4.2[-7.12,-1.28]

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Montori 2011	49	14.4 (24.9)	46	16.2 (24.9)		1.74%	-1.8[-11.83,8.23]
Morgan 2000	86	27.5 (37.5)	94	27.5 (37.5)		1.59%	0[-10.97,10.97]
Mullan 2009	48	14.1 (17.9)	37	15 (12.7)		2.42%	-0.85[-7.35,5.65]
Murray 2001a	57	32.5 (10)	48	40 (12.5)		2.86%	-7.5[-11.89,-3.11]
Murray 2001b	94	37.5 (12.5)	96	45 (15)		2.95%	-7.5[-11.42,-3.58]
Nagle 2008	167	17.8 (12.3)	171	16.3 (13.8)		3.15%	1.5[-1.27,4.27]
Nassar 2007	98	4.6 (9)	98	13.5 (19.2)		2.9%	-8.9[-13.1,-4.7]
Protheroe 2007	69	23.4 (14.3)	69	40.5 (18.3)		2.64%	-17.1[-22.58,-11.62]
Sawka 2012	37	25.2 (13.4)	37	52.1 (21.9)		2.06%	-26.9[-35.17,-18.63]
Schwalm 2012	76	14.8 (10.5)	74	19.5 (16.7)		2.84%	-4.7[-9.18,-0.22]
Shorten 2005	99	23.5 (12.5)	88	29.5 (18.3)		2.83%	-6[-10.54,-1.46]
Shourie 2013	43	14.3 (17.3)	67	37.3 (21.5)		2.26%	-23[-30.29,-15.71]
Vandemheen 2009	70	11.6 (13.6)	79	20.4 (16.9)		2.76%	-8.8[-13.7,-3.9]
Vodermaier 2009	55	20.5 (14.8)	56	24.8 (15.5)		2.61%	-4.25[-9.88,1.38]
Whelan 2004	94	10 (12)	107	15.5 (12.9)		3.04%	-5.5[-8.94,-2.06]
Subtotal * **	**4635**		**4150**			**100%**	**-7.22[-9.12,-5.31]**
Heterogeneity: Tau²=28.03; Chi²=255.34, df=37(P<0.0001); I²=85.51%							
Test for overall effect: Z=7.42(P<0.0001)							
4.1.2 Uninformed subscale							
Bekker 2004	50	32.5 (15)	56	31.7 (14.2)		3.85%	0.83[-4.74,6.4]
Brazell 2014	53	12.1 (12.7)	51	11.1 (15.2)		3.89%	1[-4.39,6.39]
Chabrera 2015	61	39.7 (10.6)	61	61.1 (19.7)		3.85%	-21.4[-27.01,-15.79]
De Achaval 2012	69	15.9 (15.8)	69	27.3 (16.6)		3.89%	-11.4[-16.81,-5.99]
Dolan 2002	41	15.8 (13)	37	24.5 (21.3)		3.37%	-8.75[-16.67,-0.83]
Fagerlin 2011	690	8.7 (43.2)	160	57.4 (110.7)		1.72%	-48.7[-66.15,-31.25]
Hess 2012	101	22.8 (22.8)	103	40.6 (21.5)		3.75%	-17.8[-23.89,-11.71]
Jibaja-Weiss 2011	44	15 (22.3)	39	23.4 (28.7)		2.71%	-8.42[-19.58,2.74]
Laupacis 2006	54	16.3 (13.8)	54	27.3 (15)		3.88%	-11[-16.43,-5.57]
Legare 2008a	43	29.8 (22.8)	41	34.3 (26)		2.84%	-4.5[-14.97,5.97]
Man-Son-Hing 1999	139	15.8 (13.3)	148	21 (14.8)		4.25%	-5.25[-8.49,-2.01]
Mann D 2010	80	27.1 (17.6)	70	33.8 (17.6)		3.84%	-6.7[-12.35,-1.05]
Mathers 2012	95	18.1 (13.3)	80	26 (16.6)		4.05%	-7.9[-12.41,-3.39]
Mathieu 2007	315	20.8 (15.6)	295	23.3 (15.6)		4.34%	-2.48[-4.96,-0]
McAlister 2005	205	15 (12.5)	202	20 (15)		4.32%	-5[-7.68,-2.32]
Montgomery 2003	50	22.2 (9.5)	58	49.1 (25.4)		3.55%	-26.97[-34.01,-19.93]
Montgomery 2007	199	35.1 (25.6)	203	35.8 (22.7)		4.01%	-0.7[-5.43,4.03]
Morgan 2000	86	20 (21.5)	94	27.5 (21.5)		3.71%	-7.5[-13.79,-1.21]
Mullan 2009	48	13.7 (19.8)	37	15.3 (15.5)		3.46%	-1.63[-9.14,5.88]
Murray 2001a	52	27.6 (10.5)	45	38.9 (20)		3.67%	-11.32[-17.83,-4.81]
Murray 2001b	93	29.9 (17.3)	93	38.9 (22.5)		3.82%	-8.96[-14.73,-3.19]
Nagle 2008	167	15.3 (14.5)	171	12.8 (14.8)		4.27%	2.5[-0.62,5.62]
Schwalm 2012	76	15.7 (13.5)	74	22.3 (20.5)		3.85%	-6.6[-12.17,-1.03]
Shourie 2013	44	11.3 (15.3)	69	46.3 (26)		3.44%	-35[-42.61,-27.39]
Vandemheen 2009	70	4.5 (9.6)	79	17.2 (20.6)		3.95%	-12.7[-17.77,-7.63]
Vodermaier 2009	55	22 (15.8)	56	30 (22.5)		3.52%	-8[-15.21,-0.79]
Wong 2006	136	21.8 (15)	146	25.8 (15)		4.21%	-4[-7.5,-0.5]
Subtotal * **	**3116**		**2591**			**100%**	**-9.28[-12.2,-6.36]**
Heterogeneity: Tau²=49.45; Chi²=231.76, df=26(P<0.0001); I²=88.78%							
Test for overall effect: Z=6.23(P<0.0001)							
4.1.3 Unclear values subscale							



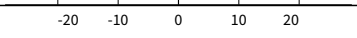


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Brazell 2014	53	15.3 (15.5)	51	17.2 (20.1)		4.29%	-1.9[-8.82,5.02]
Chabrera 2015	61	28.1 (11.2)	61	53.2 (14.5)		4.84%	-25.1[-29.7,-20.5]
De Achaval 2012	69	17.9 (15)	69	26.1 (19.1)		4.58%	-8.2[-13.92,-2.48]
Dolan 2002	41	19.8 (15.8)	37	29.3 (24)		3.73%	-9.5[-18.61,-0.39]
Fagerlin 2011	690	12.6 (50.3)	160	47.7 (128.4)		1.69%	-35.1[-55.35,-14.85]
Hess 2012	101	24.2 (25.6)	103	41.4 (22.1)		4.38%	-17.2[-23.77,-10.63]
Jibaja-Weiss 2011	44	14.4 (27.1)	39	29.7 (41.6)		2.39%	-15.35[-30.66,-0.04]
Laupacis 2006	54	18.8 (16.5)	55	30 (17)		4.45%	-11.25[-17.54,-4.96]
Legare 2008a	43	19.8 (16.5)	41	23.3 (20)		4.05%	-3.5[-11.36,4.36]
Man-Son-Hing 1999	139	16.3 (12.5)	148	19 (14.8)		5.11%	-2.75[-5.91,0.41]
Mathers 2012	95	16.7 (13.9)	80	26.7 (18.2)		4.78%	-10[-14.87,-5.13]
Mathieu 2007	315	19.5 (16.3)	295	22.6 (80)		3.69%	-3.08[-12.38,6.22]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.18%	-2.5[-5.18,0.18]
Montgomery 2003	50	28.5 (12.5)	58	51.3 (25.7)		4.15%	-22.79[-30.26,-15.32]
Montgomery 2007	201	17.6 (13.2)	203	24.1 (15.8)		5.16%	-6.5[-9.34,-3.66]
Morgan 2000	86	30 (3.3)	94	30 (3.3)		5.36%	0[-0.95,0.95]
Murray 2001a	53	35.4 (12.3)	45	40.6 (16.4)		4.56%	-5.18[-11.02,0.66]
Murray 2001b	82	37.5 (15)	84	42.9 (16.6)		4.79%	-5.35[-10.16,-0.54]
Nagle 2008	167	19 (15.3)	171	15.5 (15.8)		5.09%	3.5[0.2,6.8]
Schwalm 2012	76	18 (15.3)	74	26 (24.2)		4.39%	-8[-14.5,-1.5]
Shourie 2013	44	11.3 (13)	69	37.5 (24.3)		4.3%	-26.25[-33.14,-19.36]
Vandemheen 2009	70	9.9 (17.7)	79	16.8 (21)		4.46%	-6.9[-13.12,-0.68]
Vodermaier 2009	55	20.8 (15.5)	56	24.8 (15.5)		4.57%	-4[-9.77,1.77]
Subtotal * **	**2794**		**2274**			**100%**	**-8.81[-11.99,-5.63]**
Heterogeneity: Tau²=48.93; Chi²=273.77, df=22(P<0.0001); I²=91.96%							
Test for overall effect: Z=5.43(P<0.0001)							
4.1.4 Uncertainty subscale							
Bekker 2004	50	45 (20.8)	56	45 (25.8)		2.9%	0[-8.89,8.89]
Brazell 2014	53	21.7 (21.4)	51	18.8 (23.3)		2.99%	2.9[-5.71,11.51]
Chabrera 2015	61	32 (11.4)	61	43.8 (8.8)		4.72%	-11.8[-15.42,-8.18]
De Achaval 2012	69	33.4 (23.3)	69	35.9 (22.4)		3.31%	-2.5[-10.12,5.12]
Dolan 2002	41	27 (19.3)	37	26 (24.3)		2.65%	1[-8.79,10.79]
Fagerlin 2011	690	37.4 (62.3)	160	73.2 (159.7)		0.69%	-35.8[-60.98,-10.62]
Gattellari 2003	106	42.5 (20)	108	42.5 (33.3)		3.4%	0[-7.35,7.35]
Gattellari 2005	131	30.8 (19.3)	136	29.2 (15)		4.54%	1.66[-2.49,5.81]
Hanson 2011	118	22 (20)	115	28.8 (20)		4.19%	-6.75[-11.89,-1.61]
Hess 2012	101	24.7 (23.3)	103	36.8 (23.6)		3.72%	-12.1[-18.54,-5.66]
Jibaja-Weiss 2011	44	15.4 (32.3)	39	12.8 (22.5)		2.14%	2.55[-9.32,14.42]
Laupacis 2006	54	20.5 (18.8)	55	23 (21)		3.36%	-2.5[-9.97,4.97]
Legare 2008a	43	26.5 (23)	41	33.3 (25.3)		2.5%	-6.75[-17.09,3.59]
Man-Son-Hing 1999	139	21 (21)	148	19.8 (19)		4.37%	1.25[-3.39,5.89]
Mathers 2012	95	20.1 (16.6)	80	29.4 (20.8)		4%	-9.3[-14.95,-3.65]
Mathieu 2007	315	22.2 (19.5)	295	22.7 (19.5)		4.88%	-0.42[-3.51,2.67]
McAlister 2005	205	20 (20)	202	17.5 (17.5)		4.71%	2.5[-1.15,6.15]
Montgomery 2003	50	35.5 (20.5)	58	48 (25.1)		2.99%	-12.49[-21.1,-3.88]
Montgomery 2007	201	22.1 (18.4)	203	27.3 (18.8)		4.72%	-5.2[-8.83,-1.57]
Morgan 2000	86	35 (13)	94	32.5 (13)		4.66%	2.5[-1.3,6.3]
Murray 2001a	57	35 (20)	48	42.5 (20)		3.29%	-7.5[-15.18,0.18]
Murray 2001b	94	52.5 (25)	96	60 (27.5)		3.36%	-7.5[-14.97,-0.03]
Nagle 2008	167	24 (19.8)	171	24.3 (21.5)		4.45%	-0.25[-4.65,4.15]
Schwalm 2012	76	18 (18.8)	74	19.6 (19.9)		3.81%	-1.6[-7.8,4.6]



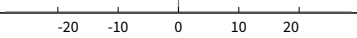
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Shourie 2013	44	16.3 (18.3)	68	38.3 (29.5)		2.92%	-22[-30.85,-13.15]
Vandemheen 2009	70	26.4 (25.9)	79	36.4 (27.8)		2.99%	-10[-18.63,-1.37]
Vodermaier 2009	55	27 (24.3)	56	30 (10)		3.55%	-3[-9.92,3.92]
Wong 2006	136	38.3 (22.5)	146	40 (20.8)		4.21%	-1.75[-6.82,3.32]
Subtotal ***	**3351**		**2849**			**100%**	**-4.04[-6.27,-1.81]**
Heterogeneity: Tau²=24.09; Chi²=107.12, df=27(P<0.0001); I²=74.79%							
Test for overall effect: Z=3.55(P=0)							
4.1.5 Unsupported subscale							
Brazell 2014	53	11.5 (14.4)	51	9.5 (13.9)		4.31%	2[-3.44,7.44]
Chabrera 2015	61	30.5 (11.6)	61	51.7 (15.3)		4.5%	-21.2[-26.02,-16.38]
De Achaval 2012	69	20.5 (15)	69	25 (15.8)		4.41%	-4.5[-9.63,0.63]
Dolan 2002	41	21 (13.5)	37	23.3 (20)		3.63%	-2.25[-9.91,5.41]
Fagerlin 2011	690	18.1 (46.9)	160	43.3 (119.4)		1.39%	-25.2[-44.03,-6.37]
Hess 2012	101	18.5 (22.6)	103	29.2 (22.6)		4.08%	-10.7[-16.89,-4.51]
Jibaja-Weiss 2011	44	19.2 (26.3)	39	22.1 (28.9)		2.5%	-2.9[-14.84,9.04]
Laupacis 2006	53	17.3 (15.8)	55	24 (17.3)		4.07%	-6.75[-12.98,-0.52]
Legare 2008a	43	24.3 (19.5)	41	23.5 (17.3)		3.57%	0.75[-7.11,8.61]
Man-Son-Hing 1999	139	16.3 (13)	148	16.5 (14)		4.95%	-0.25[-3.37,2.87]
Mann D 2010	80	25.2 (13.7)	70	29.6 (13.7)		4.62%	-4.4[-8.8,0]
Mathers 2012	95	17.4 (13.1)	80	20.8 (15.3)		4.66%	-3.4[-7.66,0.86]
Mathieu 2007	315	20.9 (15.6)	295	23 (15.6)		5.08%	-2.08[-4.55,0.39]
McAlister 2005	205	15 (15)	202	15 (15)		4.99%	0[-2.91,2.91]
Montgomery 2003	50	23.7 (11)	58	40.5 (19.8)		4.16%	-16.85[-22.79,-10.91]
Montgomery 2007	200	22.2 (16.5)	201	28.5 (18.7)		4.87%	-6.3[-9.75,-2.85]
Morgan 2000	86	30 (24.8)	94	32.5 (24.8)		3.76%	-2.5[-9.74,4.74]
Murray 2001a	53	32.7 (12.8)	45	40.6 (17.1)		4.12%	-7.86[-13.92,-1.8]
Murray 2001b	85	36.5 (14.4)	82	48.7 (15.5)		4.58%	-12.21[-16.75,-7.67]
Nagle 2008	167	15.3 (13.8)	171	14.5 (15.8)		4.94%	0.75[-2.4,3.9]
Schwalm 2012	76	12.2 (15.2)	74	14.9 (16.9)		4.4%	-2.7[-7.85,2.45]
Shourie 2013	43	13.3 (17.3)	69	38 (21.8)		3.75%	-24.75[-32.02,-17.48]
Vandemheen 2009	70	6.9 (12.3)	79	14.5 (17.7)		4.49%	-7.6[-12.45,-2.75]
Vodermaier 2009	55	16.3 (16.3)	56	21 (15.8)		4.16%	-4.75[-10.7,1.2]
Subtotal ***	**2874**		**2340**			**100%**	**-6.27[-8.86,-3.68]**
Heterogeneity: Tau²=32.67; Chi²=155.62, df=23(P<0.0001); I²=85.22%							
Test for overall effect: Z=4.75(P<0.0001)							
4.1.6 Ineffective choice subscale							
Bekker 2004	50	22.5 (13.8)	56	21.9 (14.4)		4.28%	0.62[-4.74,5.98]
Brazell 2014	53	17.8 (19.1)	51	13.8 (18.3)		3.74%	4[-3.19,11.19]
Chabrera 2015	61	27.1 (11.7)	61	49.5 (14.3)		4.48%	-22.4[-27.04,-17.76]
De Achaval 2012	69	27.7 (18.3)	69	31.2 (19.1)		4.02%	-3.5[-9.74,2.74]
Dolan 2002	41	20.5 (14.5)	37	25.8 (21)		3.48%	-5.25[-13.34,2.84]
Fagerlin 2011	690	30 (52.3)	160	55.5 (133.9)		1.18%	-25.5[-46.61,-4.39]
Hanson 2011	118	14 (15.6)	115	19.3 (15.6)		4.65%	-5.25[-9.24,-1.26]
Laupacis 2006	53	15 (14.5)	55	21.3 (16)		4.16%	-6.25[-12,-0.5]
Legare 2008a	43	16.5 (14.8)	41	22.3 (19)		3.71%	-5.75[-13.05,1.55]
Man-Son-Hing 1999	139	13.5 (13)	148	15.5 (14.8)		4.83%	-2[-5.21,1.21]
Mathers 2012	95	16.1 (14.4)	80	23.3 (15.2)		4.54%	-7.2[-11.61,-2.79]
Mathieu 2007	315	18.4 (15)	295	19.2 (15)		5%	-0.78[-3.16,1.6]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		4.94%	-2.5[-5.18,0.18]
Montgomery 2003	50	26 (11.1)	58	35.1 (17.2)		4.27%	-9.13[-14.52,-3.74]

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Morgan 2000	86	20 (32)	94	22.5 (32)		3.12%	-2.5[-11.86,6.86]
Murray 2001a	57	25 (10)	48	30 (15)		4.38%	-5[-9.97,-0.03]
Murray 2001b	94	30 (15)	96	37.5 (17.5)		4.48%	-7.5[-12.13,-2.87]
Nagle 2008	167	16.3 (13.8)	171	15 (14.3)		4.88%	1.25[-1.74,4.24]
Schwalm 2012	76	11.3 (11.4)	74	15.9 (15.9)		4.53%	-4.6[-9.04,-0.16]
Shourie 2013	44	11 (12.3)	68	30.5 (19.5)		4.12%	-19.5[-25.38,-13.62]
Vandemheen 2009	70	10.4 (16.4)	79	17.9 (20.4)		4.11%	-7.5[-13.42,-1.58]
Vodermaier 2009	55	28.3 (20.8)	56	35 (20)		3.62%	-6.75[-14.33,0.83]
Whelan 2004	94	12.5 (12)	107	17 (13)		4.78%	-4.5[-7.96,-1.04]
Wong 2006	136	19.4 (13.1)	159	36.7 (19.2)		4.72%	-17.29[-21,-13.58]
Subtotal * **	**2861**		**2380**			**100%**	**-6.31[-8.93,-3.7]**
Heterogeneity: Tau²=34.12; Chi²=175.19, df=23(P<0.0001); I²=86.87%							
Test for overall effect: Z=4.73(P<0.0001)							

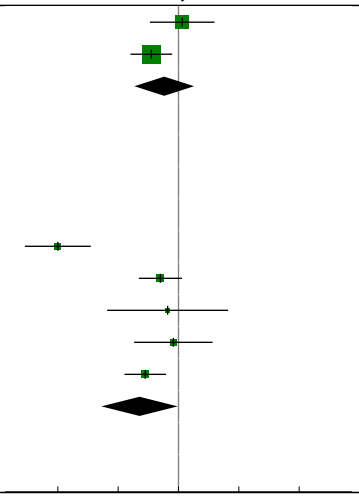


Analysis 4.2. Comparison 4 Decisional conflict, Outcome 2 Decisional conflict - in consultation.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.2.1 Uncertainty subscale							
Bekker 2004	50	45 (20.8)	56	45 (25.8)		46.65%	0[-8.89,8.89]
Hess 2012	101	24.7 (23.3)	103	36.8 (23.6)		53.35%	-12.1[-18.54,-5.66]
Subtotal * **	**151**		**159**			**100%**	**-6.45[-18.29,5.38]**
Heterogeneity: Tau²=57.51; Chi²=4.67, df=1(P=0.03); I²=78.56%							
Test for overall effect: Z=1.07(P=0.28)							
4.2.2 Uninformed subscale							
Bekker 2004	50	32.5 (15)	56	31.7 (14.2)		25.73%	0.83[-4.74,6.4]
Hess 2012	101	22.8 (22.8)	103	40.6 (21.5)		25.16%	-17.8[-23.89,-11.71]
Mann D 2010	80	27.1 (17.6)	70	33.8 (17.6)		25.65%	-6.7[-12.35,-1.05]
Mullan 2009	48	13.7 (19.8)	37	15.3 (15.5)		23.46%	-1.63[-9.14,5.88]
Subtotal * **	**279**		**266**			**100%**	**-6.37[-14.58,1.85]**
Heterogeneity: Tau²=60.19; Chi²=21.5, df=3(P<0.0001); I²=86.04%							
Test for overall effect: Z=1.52(P=0.13)							
4.2.3 Unclear values subscale							
Hess 2012	101	24.2 (25.6)	103	41.4 (22.1)		100%	-17.2[-23.77,-10.63]
Subtotal * **	**101**		**103**			**100%**	**-17.2[-23.77,-10.63]**
Heterogeneity: Not applicable							
Test for overall effect: Z=5.13(P<0.0001)							
4.2.4 Unsupported subscale							
Hess 2012	101	18.5 (22.6)	103	29.2 (22.6)		43.78%	-10.7[-16.89,-4.51]
Mann D 2010	80	25.2 (13.7)	70	29.6 (13.7)		56.22%	-4.4[-8.8,0]
Subtotal * **	**181**		**173**			**100%**	**-7.16[-13.28,-1.03]**
Heterogeneity: Tau²=12.33; Chi²=2.64, df=1(P=0.1); I²=62.15%							
Test for overall effect: Z=2.29(P=0.02)							
4.2.5 Ineffective choice subscale							

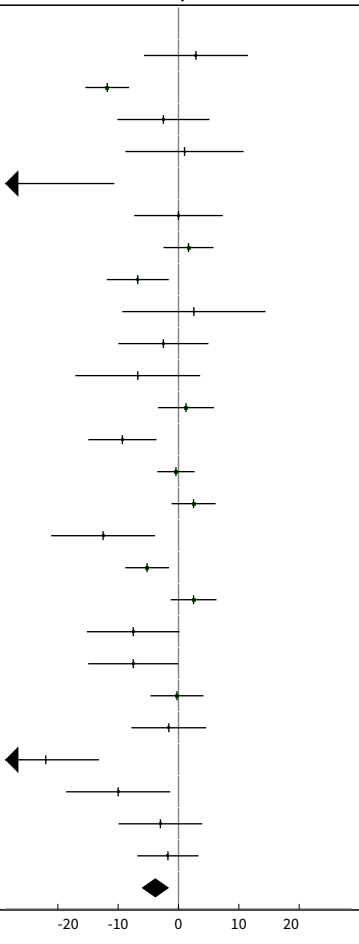


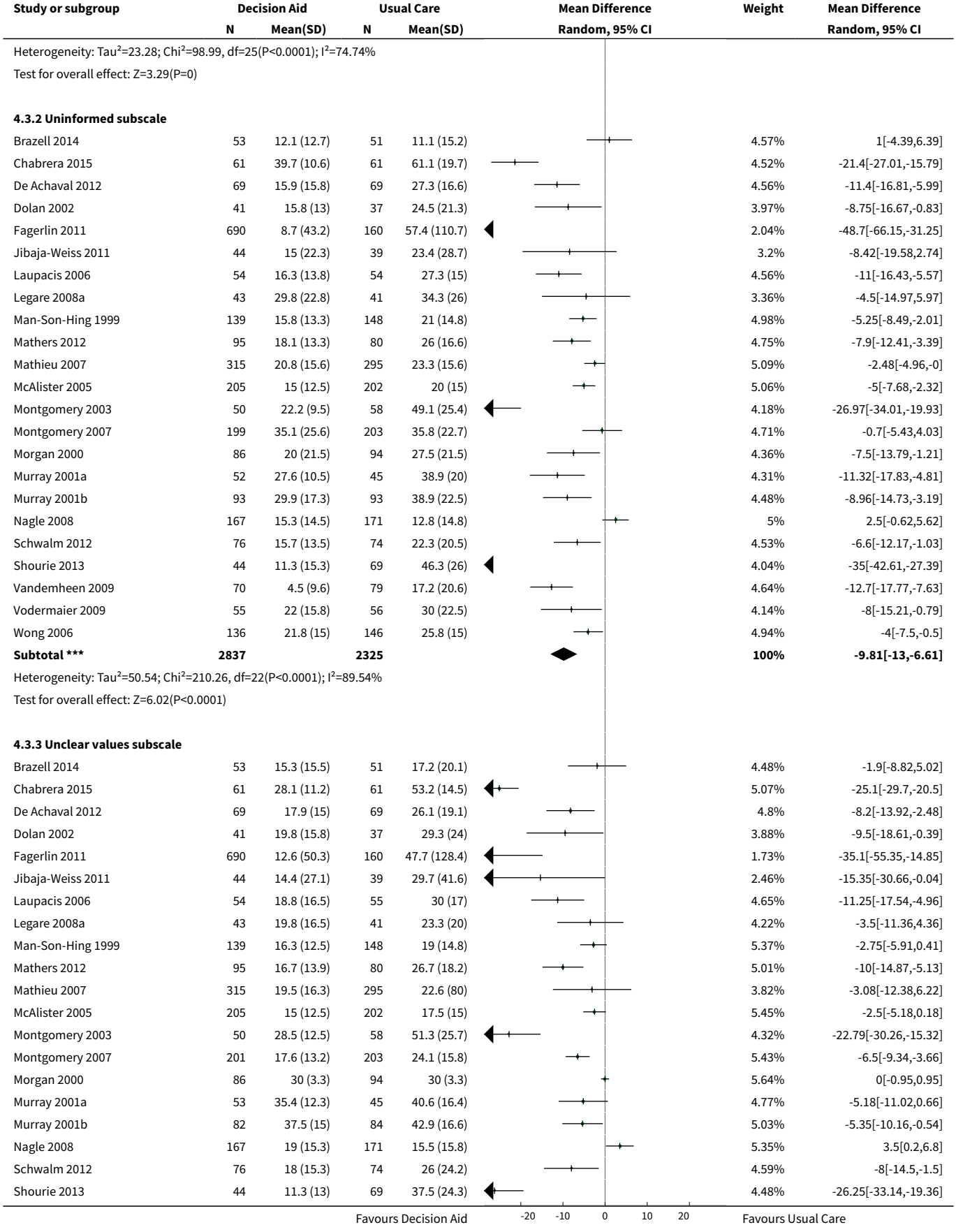
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Bekker 2004	50	22.5 (13.8)	56	21.9 (14.4)		41.68%	0.62[-4.74,5.98]
Whelan 2004	94	12.5 (12)	107	17 (13)		58.32%	-4.5[-7.96,-1.04]
Subtotal ***	**144**		**163**			**100%**	**-2.37[-7.31,2.58]**
Heterogeneity: Tau²=7.81; Chi²=2.48, df=1(P=0.12); I²=59.62%							
Test for overall effect: Z=0.94(P=0.35)							
4.2.6 Total decisional conflict score							
Hess 2012	101	23.3 (20.8)	103	43.3 (19)		20.53%	-20[-25.46,-14.54]
Mann D 2010	80	25.5 (11.1)	70	28.5 (11.1)		22.5%	-3[-6.57,0.57]
Montori 2011	49	14.4 (24.9)	46	16.2 (24.9)		15.06%	-1.8[-11.83,8.23]
Mullan 2009	48	14.1 (17.9)	37	15 (12.7)		19.29%	-0.85[-7.35,5.65]
Whelan 2004	94	10 (12)	107	15.5 (12.9)		22.62%	-5.5[-8.94,-2.06]
Subtotal ***	**372**		**363**			**100%**	**-6.46[-12.78,-0.14]**
Heterogeneity: Tau²=42.94; Chi²=31.11, df=4(P<0.0001); I²=87.14%							
Test for overall effect: Z=2(P=0.05)							



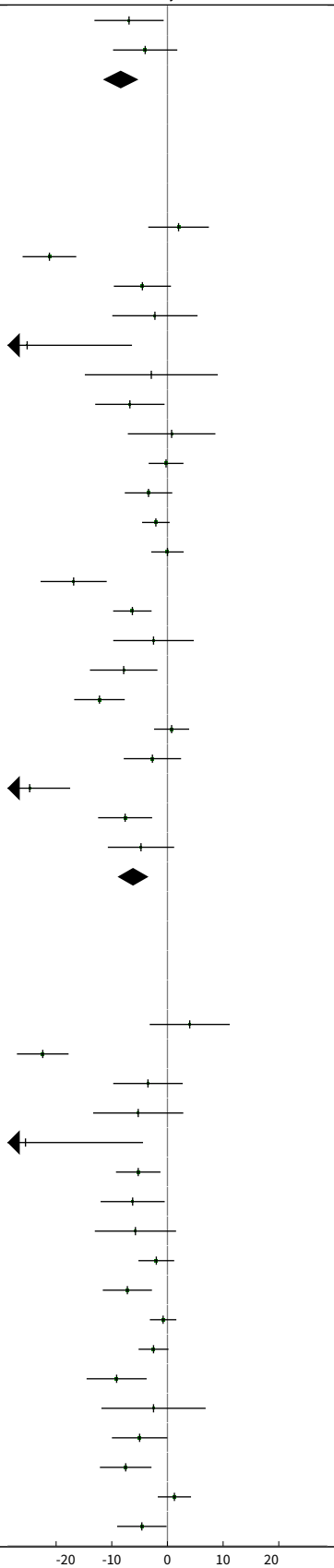
Analysis 4.3. Comparison 4 Decisional conflict, Outcome 3 Decisional conflict - in preparation for consultation.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.3.1 Uncertainty subscale							
Brazell 2014	53	21.7 (21.4)	51	18.8 (23.3)		3.19%	2.9[-5.71,11.51]
Chabrera 2015	61	32 (11.4)	61	43.8 (8.8)		5.08%	-11.8[-15.42,-8.18]
De Achaval 2012	69	33.4 (23.3)	69	35.9 (22.4)		3.53%	-2.5[-10.12,5.12]
Dolan 2002	41	27 (19.3)	37	26 (24.3)		2.81%	1[-8.79,10.79]
Fagerlin 2011	690	37.4 (62.3)	160	73.2 (159.7)		0.72%	-35.8[-60.98,-10.62]
Gattellari 2003	106	42.5 (20)	108	42.5 (33.3)		3.63%	0[-7.35,7.35]
Gattellari 2005	131	30.8 (19.3)	136	29.2 (15)		4.88%	1.66[-2.49,5.81]
Hanson 2011	118	22 (20)	115	28.8 (20)		4.5%	-6.75[-11.89,-1.61]
Jibaja-Weiss 2011	44	15.4 (32.3)	39	12.8 (22.5)		2.26%	2.55[-9.32,14.42]
Laupacis 2006	54	20.5 (18.8)	55	23 (21)		3.59%	-2.5[-9.97,4.97]
Legare 2008a	43	26.5 (23)	41	33.3 (25.3)		2.65%	-6.75[-17.09,3.59]
Man-Son-Hing 1999	139	21 (21)	148	19.8 (19)		4.69%	1.25[-3.39,5.89]
Mathers 2012	95	20.1 (16.6)	80	29.4 (20.8)		4.29%	-9.3[-14.95,-3.65]
Mathieu 2007	315	22.2 (19.5)	295	22.7 (19.5)		5.26%	-0.42[-3.51,2.67]
McAlister 2005	205	20 (20)	202	17.5 (17.5)		5.07%	2.5[-1.15,6.15]
Montgomery 2003	50	35.5 (20.5)	58	48 (25.1)		3.19%	-12.49[-21.1,-3.88]
Montgomery 2007	201	22.1 (18.4)	203	27.3 (18.8)		5.08%	-5.2[-8.83,-1.57]
Morgan 2000	86	35 (13)	94	32.5 (13)		5.01%	2.5[-1.3,6.3]
Murray 2001a	57	35 (20)	48	42.5 (20)		3.51%	-7.5[-15.18,0.18]
Murray 2001b	94	52.5 (25)	96	60 (27.5)		3.59%	-7.5[-14.97,-0.03]
Nagle 2008	167	24 (19.8)	171	24.3 (21.5)		4.79%	-0.25[-4.65,4.15]
Schwalm 2012	76	18 (18.8)	74	19.6 (19.9)		4.07%	-1.6[-7.8,4.6]
Shourie 2013	44	16.3 (18.3)	68	38.3 (29.5)		3.11%	-22[-30.85,-13.15]
Vandemheen 2009	70	26.4 (25.9)	79	36.4 (27.8)		3.18%	-10[-18.63,-1.37]
Vodermaier 2009	55	27 (24.3)	56	30 (10)		3.79%	-3[-9.92,3.92]
Wong 2006	136	38.3 (22.5)	146	40 (20.8)		4.52%	-1.75[-6.82,3.32]
Subtotal ***	**3200**		**2690**			**100%**	**-3.83[-6.12,-1.55]**

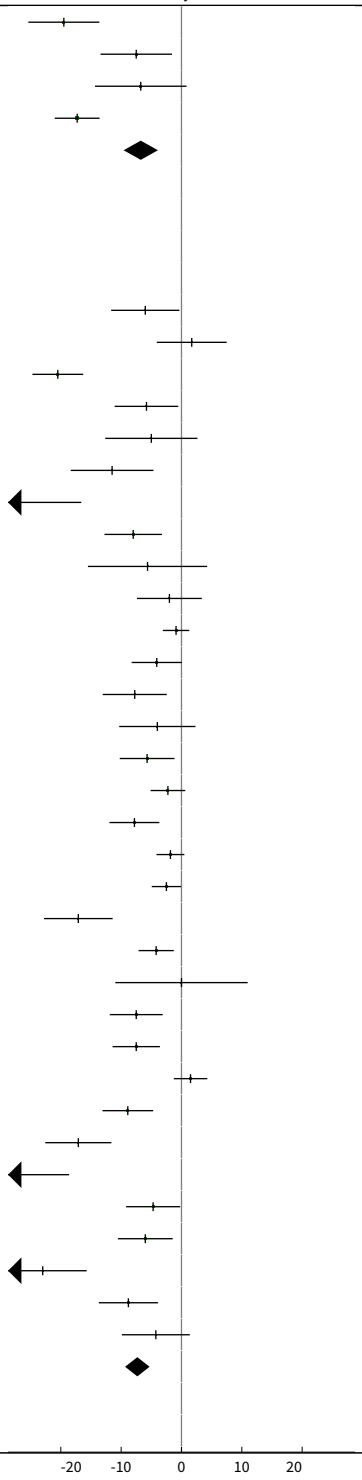




Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Vandemheen 2009	70	9.9 (17.7)	79	16.8 (21)		4.67%	-6.9[-13.12,-0.68]
Vodermaier 2009	55	20.8 (15.5)	56	24.8 (15.5)		4.78%	-4[-9.77,1.77]
Subtotal ***	**2693**		**2171**			**100%**	**-8.4[-11.59,-5.21]**
Heterogeneity: Tau²=46.63; Chi²=255.5, df=21(P<0.0001); I²=91.78%							
Test for overall effect: Z=5.17(P<0.0001)							
4.3.4 Unsupported subscale							
Brazell 2014	53	11.5 (14.4)	51	9.5 (13.9)		4.73%	2[-3.44,7.44]
Chabrera 2015	61	30.5 (11.6)	61	51.7 (15.3)		4.92%	-21.2[-26.02,-16.38]
De Achaval 2012	69	20.5 (15)	69	25 (15.8)		4.82%	-4.5[-9.63,0.63]
Dolan 2002	41	21 (13.5)	37	23.3 (20)		4.01%	-2.25[-9.91,5.41]
Fagerlin 2011	690	18.1 (46.9)	160	43.3 (119.4)		1.58%	-25.2[-44.03,-6.37]
Jibaja-Weiss 2011	44	19.2 (26.3)	39	22.1 (28.9)		2.79%	-2.9[-14.84,9.04]
Laupacis 2006	53	17.3 (15.8)	55	24 (17.3)		4.47%	-6.75[-12.98,-0.52]
Legare 2008a	43	24.3 (19.5)	41	23.5 (17.3)		3.95%	0.75[-7.11,8.61]
Man-Son-Hing 1999	139	16.3 (13)	148	16.5 (14)		5.38%	-0.25[-3.37,2.87]
Mathers 2012	95	17.4 (13.1)	80	20.8 (15.3)		5.08%	-3.4[-7.66,0.86]
Mathieu 2007	315	20.9 (15.6)	295	23 (15.6)		5.52%	-2.08[-4.55,0.39]
McAlister 2005	205	15 (15)	202	15 (15)		5.43%	0[-2.91,2.91]
Montgomery 2003	50	23.7 (11)	58	40.5 (19.8)		4.57%	-16.85[-22.79,-10.91]
Montgomery 2007	200	22.2 (16.5)	201	28.5 (18.7)		5.3%	-6.3[-9.75,-2.85]
Morgan 2000	86	30 (24.8)	94	32.5 (24.8)		4.15%	-2.5[-9.74,4.74]
Murray 2001a	53	32.7 (12.8)	45	40.6 (17.1)		4.53%	-7.86[-13.92,-1.8]
Murray 2001b	85	36.5 (14.4)	82	48.7 (15.5)		5%	-12.21[-16.75,-7.67]
Nagle 2008	167	15.3 (13.8)	171	14.5 (15.8)		5.37%	0.75[-2.4,3.9]
Schwalm 2012	76	12.2 (15.2)	74	14.9 (16.9)		4.82%	-2.7[-7.85,2.45]
Shourie 2013	43	13.3 (17.3)	69	38 (21.8)		4.13%	-24.75[-32.02,-17.48]
Vandemheen 2009	70	6.9 (12.3)	79	14.5 (17.7)		4.91%	-7.6[-12.45,-2.75]
Vodermaier 2009	55	16.3 (16.3)	56	21 (15.8)		4.56%	-4.75[-10.7,1.2]
Subtotal ***	**2693**		**2167**			**100%**	**-6.18[-8.96,-3.4]**
Heterogeneity: Tau²=34.85; Chi²=151.76, df=21(P<0.0001); I²=86.16%							
Test for overall effect: Z=4.36(P<0.0001)							
4.3.5 Ineffective choice subscale							
Brazell 2014	53	17.8 (19.1)	51	13.8 (18.3)		4.15%	4[-3.19,11.19]
Chabrera 2015	61	27.1 (11.7)	61	49.5 (14.3)		4.91%	-22.4[-27.04,-17.76]
De Achaval 2012	69	27.7 (18.3)	69	31.2 (19.1)		4.44%	-3.5[-9.74,2.74]
Dolan 2002	41	20.5 (14.5)	37	25.8 (21)		3.87%	-5.25[-13.34,2.84]
Fagerlin 2011	690	30 (52.3)	160	55.5 (133.9)		1.37%	-25.5[-46.61,-4.39]
Hanson 2011	118	14 (15.6)	115	19.3 (15.6)		5.08%	-5.25[-9.24,-1.26]
Laupacis 2006	53	15 (14.5)	55	21.3 (16)		4.58%	-6.25[-12,-0.5]
Legare 2008a	43	16.5 (14.8)	41	22.3 (19)		4.12%	-5.75[-13.05,1.55]
Man-Son-Hing 1999	139	13.5 (13)	148	15.5 (14.8)		5.26%	-2[-5.21,1.21]
Mathers 2012	95	16.1 (14.4)	80	23.3 (15.2)		4.97%	-7.2[-11.61,-2.79]
Mathieu 2007	315	18.4 (15)	295	19.2 (15)		5.43%	-0.78[-3.16,1.6]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.37%	-2.5[-5.18,0.18]
Montgomery 2003	50	26 (11.1)	58	35.1 (17.2)		4.69%	-9.13[-14.52,-3.74]
Morgan 2000	86	20 (32)	94	22.5 (32)		3.5%	-2.5[-11.86,6.86]
Murray 2001a	57	25 (10)	48	30 (15)		4.81%	-5[-9.97,-0.03]
Murray 2001b	94	30 (15)	96	37.5 (17.5)		4.91%	-7.5[-12.13,-2.87]
Nagle 2008	167	16.3 (13.8)	171	15 (14.3)		5.31%	1.25[-1.74,4.24]
Schwalm 2012	76	11.3 (11.4)	74	15.9 (15.9)		4.96%	-4.6[-9.04,-0.16]

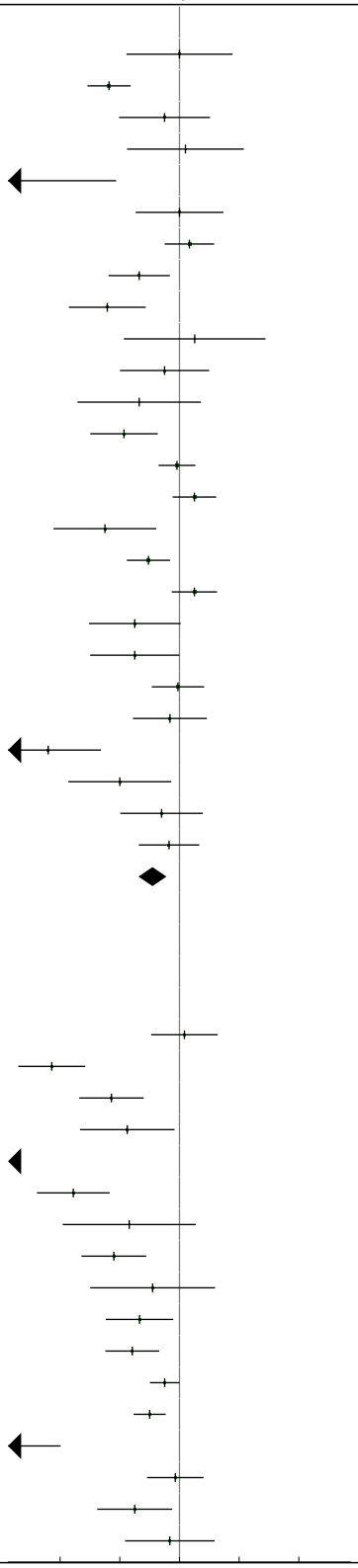


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Shourie 2013	44	11 (12.3)	68	30.5 (19.5)		4.55%	-19.5[-25.38,-13.62]
Vandemheen 2009	70	10.4 (16.4)	79	17.9 (20.4)		4.54%	-7.5[-13.42,-1.58]
Vodermaier 2009	55	28.3 (20.8)	56	35 (20)		4.03%	-6.75[-14.33,0.83]
Wong 2006	136	19.4 (13.1)	159	36.7 (19.2)		5.15%	-17.29[-21,-13.58]
Subtotal * **	**2717**		**2217**			**100%**	**-6.75[-9.59,-3.9]**
Heterogeneity: Tau²=37.39; Chi²=170.48, df=21(P<0.0001); I²=87.68%							
Test for overall effect: Z=4.65(P<0.0001)							
4.3.6 Total decisional conflict score							
Allen 2010	291	14 (34.3)	334	20 (37.8)		2.98%	-6[-11.66,-0.34]
Brazell 2014	53	15.8 (13.9)	51	14.1 (16.1)		2.95%	1.7[-4.09,7.49]
Chabrera 2015	61	31.2 (10.2)	61	51.7 (13.3)		3.33%	-20.5[-24.71,-16.29]
De Achaval 2012	69	23.4 (15)	69	29.2 (16.6)		3.08%	-5.8[-11.07,-0.53]
Dolan 2002	41	20.8 (13)	37	25.8 (20.3)		2.51%	-5[-12.64,2.64]
Evans 2010	89	38.1 (24.2)	103	49.6 (24.2)		2.69%	-11.5[-18.35,-4.65]
Fagerlin 2011	690	22 (42.2)	160	55.7 (108.4)		1.04%	-33.7[-50.79,-16.61]
Hanson 2011	118	16.3 (18.6)	115	24.3 (18.6)		3.2%	-8[-12.76,-3.24]
Jibaja-Weiss 2011	44	16.5 (19.9)	39	22.2 (25.3)		2.03%	-5.63[-15.51,4.25]
Knops 2014	73	22 (17)	81	24 (17)		3.05%	-2[-7.38,3.38]
Kuppermann 2014	357	12.9 (14.1)	353	13.8 (15.6)		3.71%	-0.9[-3.09,1.29]
Lam 2013	113	15.8 (15.5)	112	19.9 (16.3)		3.34%	-4.1[-8.26,0.06]
Laupacis 2006	53	17.5 (13.8)	54	25.3 (14.3)		3.07%	-7.75[-13.06,-2.44]
Legare 2008a	43	23 (14.3)	41	27 (15.3)		2.82%	-4[-10.32,2.32]
Lepore 2012	215	34.2 (24)	216	39.9 (24)		3.25%	-5.7[-10.24,-1.16]
Man-Son-Hing 1999	139	16.3 (11.3)	148	18.5 (13.5)		3.6%	-2.25[-5.12,0.62]
Mathers 2012	95	17.4 (12.6)	80	25.2 (14.9)		3.34%	-7.8[-11.93,-3.67]
Mathieu 2007	315	20.1 (14.5)	295	21.9 (14.5)		3.69%	-1.83[-4.13,0.47]
McAlister 2005	205	15 (12.5)	202	17.5 (12.5)		3.67%	-2.5[-4.93,-0.07]
Montgomery 2003	50	27.1 (10)	58	44.2 (19.3)		2.98%	-17.1[-22.79,-11.41]
Montgomery 2007	198	23.6 (15.1)	201	27.8 (14.6)		3.59%	-4.2[-7.12,-1.28]
Morgan 2000	86	27.5 (37.5)	94	27.5 (37.5)		1.82%	0[-10.97,10.97]
Murray 2001a	57	32.5 (10)	48	40 (12.5)		3.29%	-7.5[-11.89,-3.11]
Murray 2001b	94	37.5 (12.5)	96	45 (15)		3.39%	-7.5[-11.42,-3.58]
Nagle 2008	167	17.8 (12.3)	171	16.3 (13.8)		3.62%	1.5[-1.27,4.27]
Nassar 2007	98	4.6 (9)	98	13.5 (19.2)		3.33%	-8.9[-13.1,-4.7]
Protheroe 2007	69	23.4 (14.3)	69	40.5 (18.3)		3.03%	-17.1[-22.58,-11.62]
Sawka 2012	37	25.2 (13.4)	37	52.1 (21.9)		2.36%	-26.9[-35.17,-18.63]
Schwalm 2012	76	14.8 (10.5)	74	19.5 (16.7)		3.26%	-4.7[-9.18,-0.22]
Shorten 2005	99	23.5 (12.5)	88	29.5 (18.3)		3.25%	-6[-10.54,-1.46]
Shourie 2013	43	14.3 (17.3)	67	37.3 (21.5)		2.59%	-23[-30.29,-15.71]
Vandemheen 2009	70	11.6 (13.6)	79	20.4 (16.9)		3.16%	-8.8[-13.7,-3.9]
Vodermaier 2009	55	20.5 (14.8)	56	24.8 (15.5)		2.99%	-4.25[-9.88,1.38]
Subtotal * **	**4263**		**3787**			**100%**	**-7.32[-9.35,-5.28]**
Heterogeneity: Tau²=27.77; Chi²=223.37, df=32(P<0.0001); I²=85.67%							
Test for overall effect: Z=7.05(P<0.0001)							

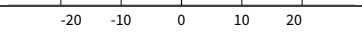


Analysis 4.4. Comparison 4 Decisional conflict, Outcome 4 Decisional conflict - without studies having high risk of bias.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.4.1 Uncertainty subscale							
Bekker 2004	50	45 (20.8)	56	45 (25.8)		3.15%	0[-8.89,8.89]
Chabrera 2015	61	32 (11.4)	61	43.8 (8.8)		5.07%	-11.8[-15.42,-8.18]
De Achaval 2012	69	33.4 (23.3)	69	35.9 (22.4)		3.58%	-2.5[-10.12,5.12]
Dolan 2002	41	27 (19.3)	37	26 (24.3)		2.87%	1[-8.79,10.79]
Fagerlin 2011	690	37.4 (62.3)	160	73.2 (159.7)		0.75%	-35.8[-60.98,-10.62]
Gattellari 2003	106	42.5 (20)	108	42.5 (33.3)		3.68%	0[-7.35,7.35]
Gattellari 2005	131	30.8 (19.3)	136	29.2 (15)		4.88%	1.66[-2.49,5.81]
Hanson 2011	118	22 (20)	115	28.8 (20)		4.52%	-6.75[-11.89,-1.61]
Hess 2012	101	24.7 (23.3)	103	36.8 (23.6)		4.02%	-12.1[-18.54,-5.66]
Jibaja-Weiss 2011	44	15.4 (32.3)	39	12.8 (22.5)		2.33%	2.55[-9.32,14.42]
Laupacis 2006	54	20.5 (18.8)	55	23 (21)		3.63%	-2.5[-9.97,4.97]
Legare 2008a	43	26.5 (23)	41	33.3 (25.3)		2.71%	-6.75[-17.09,3.59]
Mathers 2012	95	20.1 (16.6)	80	29.4 (20.8)		4.32%	-9.3[-14.95,-3.65]
Mathieu 2007	315	22.2 (19.5)	295	22.7 (19.5)		5.24%	-0.42[-3.51,2.67]
McAlister 2005	205	20 (20)	202	17.5 (17.5)		5.06%	2.5[-1.15,6.15]
Montgomery 2003	50	35.5 (20.5)	58	48 (25.1)		3.24%	-12.49[-21.1,-3.88]
Montgomery 2007	201	22.1 (18.4)	203	27.3 (18.8)		5.07%	-5.2[-8.83,-1.57]
Morgan 2000	86	35 (13)	94	32.5 (13)		5.01%	2.5[-1.3,6.3]
Murray 2001a	57	35 (20)	48	42.5 (20)		3.56%	-7.5[-15.18,0.18]
Murray 2001b	94	52.5 (25)	96	60 (27.5)		3.64%	-7.5[-14.97,-0.03]
Nagle 2008	167	24 (19.8)	171	24.3 (21.5)		4.79%	-0.25[-4.65,4.15]
Schwalm 2012	76	18 (18.8)	74	19.6 (19.9)		4.11%	-1.6[-7.8,4.6]
Shourie 2013	44	16.3 (18.3)	68	38.3 (29.5)		3.16%	-22[-30.85,-13.15]
Vandemheen 2009	70	26.4 (25.9)	79	36.4 (27.8)		3.24%	-10[-18.63,-1.37]
Vodermaier 2009	55	27 (24.3)	56	30 (10)		3.84%	-3[-9.92,3.92]
Wong 2006	136	38.3 (22.5)	146	40 (20.8)		4.54%	-1.75[-6.82,3.32]
Subtotal * **	**3159**		**2650**			**100%**	**-4.53[-6.87,-2.18]**
Heterogeneity: Tau²=24.77; Chi²=101.56, df=25(P<0.0001); I²=75.38%							
Test for overall effect: Z=3.79(P=0)							
4.4.2 Uninformed subscale							
Bekker 2004	50	32.5 (15)	56	31.7 (14.2)		4.19%	0.83[-4.74,6.4]
Chabrera 2015	61	39.7 (10.6)	61	61.1 (19.7)		4.18%	-21.4[-27.01,-15.79]
De Achaval 2012	69	15.9 (15.8)	69	27.3 (16.6)		4.22%	-11.4[-16.81,-5.99]
Dolan 2002	41	15.8 (13)	37	24.5 (21.3)		3.7%	-8.75[-16.67,-0.83]
Fagerlin 2011	690	8.7 (43.2)	160	57.4 (110.7)		1.96%	-48.7[-66.15,-31.25]
Hess 2012	101	22.8 (22.8)	103	40.6 (21.5)		4.08%	-17.8[-23.89,-11.71]
Jibaja-Weiss 2011	44	15 (22.3)	39	23.4 (28.7)		3.01%	-8.42[-19.58,2.74]
Laupacis 2006	54	16.3 (13.8)	54	27.3 (15)		4.21%	-11[-16.43,-5.57]
Legare 2008a	43	29.8 (22.8)	41	34.3 (26)		3.16%	-4.5[-14.97,5.97]
Mann D 2010	80	27.1 (17.6)	70	33.8 (17.6)		4.17%	-6.7[-12.35,-1.05]
Mathers 2012	95	18.1 (13.3)	80	26 (16.6)		4.38%	-7.9[-12.41,-3.39]
Mathieu 2007	315	20.8 (15.6)	295	23.3 (15.6)		4.67%	-2.48[-4.96,-0]
McAlister 2005	205	15 (12.5)	202	20 (15)		4.65%	-5[-7.68,-2.32]
Montgomery 2003	50	22.2 (9.5)	58	49.1 (25.4)		3.89%	-26.97[-34.01,-19.93]
Montgomery 2007	199	35.1 (25.6)	203	35.8 (22.7)		4.34%	-0.7[-5.43,4.03]
Morgan 2000	86	20 (21.5)	94	27.5 (21.5)		4.04%	-7.5[-13.79,-1.21]
Mullan 2009	48	13.7 (19.8)	37	15.3 (15.5)		3.79%	-1.63[-9.14,5.88]



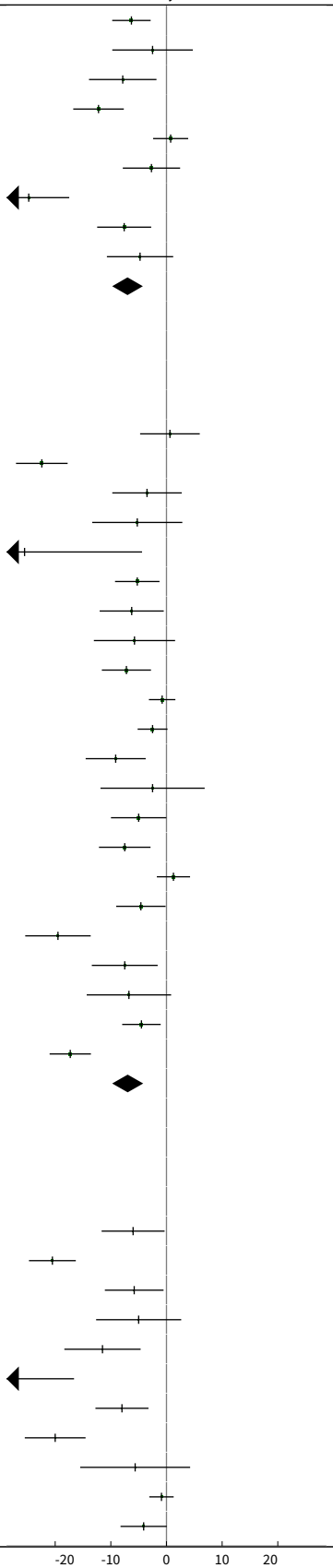
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Murray 2001a	52	27.6 (10.5)	45	38.9 (20)		4%	-11.32[-17.83,-4.81]
Murray 2001b	93	29.9 (17.3)	93	38.9 (22.5)		4.15%	-8.96[-14.73,-3.19]
Nagle 2008	167	15.3 (14.5)	171	12.8 (14.8)		4.59%	2.5[-0.62,5.62]
Schwalm 2012	76	15.7 (13.5)	74	22.3 (20.5)		4.19%	-6.6[-12.17,-1.03]
Shourie 2013	44	11.3 (15.3)	69	46.3 (26)		3.77%	-35[-42.61,-27.39]
Vandemheen 2009	70	4.5 (9.6)	79	17.2 (20.6)		4.28%	-12.7[-17.77,-7.63]
Vodermaier 2009	55	22 (15.8)	56	30 (22.5)		3.85%	-8[-15.21,-0.79]
Wong 2006	136	21.8 (15)	146	25.8 (15)		4.54%	-4[-7.5,-0.5]
Subtotal * **	**2924**		**2392**			**100%**	**-9.96[-13.13,-6.78]**
Heterogeneity: Tau²=54.55; Chi²=223.82, df=24(P<0.0001); I²=89.28%							
Test for overall effect: Z=6.15(P<0.0001)							
4.4.3 Unclear values subscale							
Chabrera 2015	61	28.1 (11.2)	61	53.2 (14.5)		5.29%	-25.1[-29.7,-20.5]
De Achaval 2012	69	17.9 (15)	69	26.1 (19.1)		5.05%	-8.2[-13.92,-2.48]
Dolan 2002	41	19.8 (15.8)	37	29.3 (24)		4.19%	-9.5[-18.61,-0.39]
Fagerlin 2011	690	12.6 (50.3)	160	47.7 (128.4)		2%	-35.1[-55.35,-14.85]
Hess 2012	101	24.2 (25.6)	103	41.4 (22.1)		4.84%	-17.2[-23.77,-10.63]
Jibaja-Weiss 2011	44	14.4 (27.1)	39	29.7 (41.6)		2.78%	-15.35[-30.66,-0.04]
Laupacis 2006	54	18.8 (16.5)	55	30 (17)		4.91%	-11.25[-17.54,-4.96]
Legare 2008a	43	19.8 (16.5)	41	23.3 (20)		4.52%	-3.5[-11.36,4.36]
Mathers 2012	95	16.7 (13.9)	80	26.7 (18.2)		5.24%	-10[-14.87,-5.13]
Mathieu 2007	315	19.5 (16.3)	295	22.6 (80)		4.14%	-3.08[-12.38,6.22]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.63%	-2.5[-5.18,0.18]
Montgomery 2003	50	28.5 (12.5)	58	51.3 (25.7)		4.62%	-22.79[-30.26,-15.32]
Montgomery 2007	201	17.6 (13.2)	203	24.1 (15.8)		5.61%	-6.5[-9.34,-3.66]
Morgan 2000	86	30 (3.3)	94	30 (3.3)		5.79%	0[-0.95,0.95]
Murray 2001a	53	35.4 (12.3)	45	40.6 (16.4)		5.02%	-5.18[-11.02,0.66]
Murray 2001b	82	37.5 (15)	84	42.9 (16.6)		5.25%	-5.35[-10.16,-0.54]
Nagle 2008	167	19 (15.3)	171	15.5 (15.8)		5.53%	3.5[0.2,6.8]
Schwalm 2012	76	18 (15.3)	74	26 (24.2)		4.86%	-8[-14.5,-1.5]
Shourie 2013	44	11.3 (13)	69	37.5 (24.3)		4.76%	-26.25[-33.14,-19.36]
Vandemheen 2009	70	9.9 (17.7)	79	16.8 (21)		4.93%	-6.9[-13.12,-0.68]
Vodermaier 2009	55	20.8 (15.5)	56	24.8 (15.5)		5.04%	-4[-9.77,1.77]
Subtotal * **	**2602**		**2075**			**100%**	**-9.55[-13.08,-6.02]**
Heterogeneity: Tau²=55.88; Chi²=273.66, df=20(P<0.0001); I²=92.69%							
Test for overall effect: Z=5.3(P<0.0001)							
4.4.4 Unsupported subscale							
Chabrera 2015	61	30.5 (11.6)	61	51.7 (15.3)		4.95%	-21.2[-26.02,-16.38]
De Achaval 2012	69	20.5 (15)	69	25 (15.8)		4.85%	-4.5[-9.63,0.63]
Dolan 2002	41	21 (13.5)	37	23.3 (20)		4.02%	-2.25[-9.91,5.41]
Fagerlin 2011	690	18.1 (46.9)	160	43.3 (119.4)		1.57%	-25.2[-44.03,-6.37]
Hess 2012	101	18.5 (22.6)	103	29.2 (22.6)		4.51%	-10.7[-16.89,-4.51]
Jibaja-Weiss 2011	44	19.2 (26.3)	39	22.1 (28.9)		2.79%	-2.9[-14.84,9.04]
Laupacis 2006	53	17.3 (15.8)	55	24 (17.3)		4.5%	-6.75[-12.98,-0.52]
Legare 2008a	43	24.3 (19.5)	41	23.5 (17.3)		3.95%	0.75[-7.11,8.61]
Mann D 2010	80	25.2 (13.7)	70	29.6 (13.7)		5.08%	-4.4[-8.8,0]
Mathers 2012	95	17.4 (13.1)	80	20.8 (15.3)		5.12%	-3.4[-7.66,0.86]
Mathieu 2007	315	20.9 (15.6)	295	23 (15.6)		5.57%	-2.08[-4.55,0.39]
McAlister 2005	205	15 (15)	202	15 (15)		5.48%	0[-2.91,2.91]
Montgomery 2003	50	23.7 (11)	58	40.5 (19.8)		4.59%	-16.85[-22.79,-10.91]

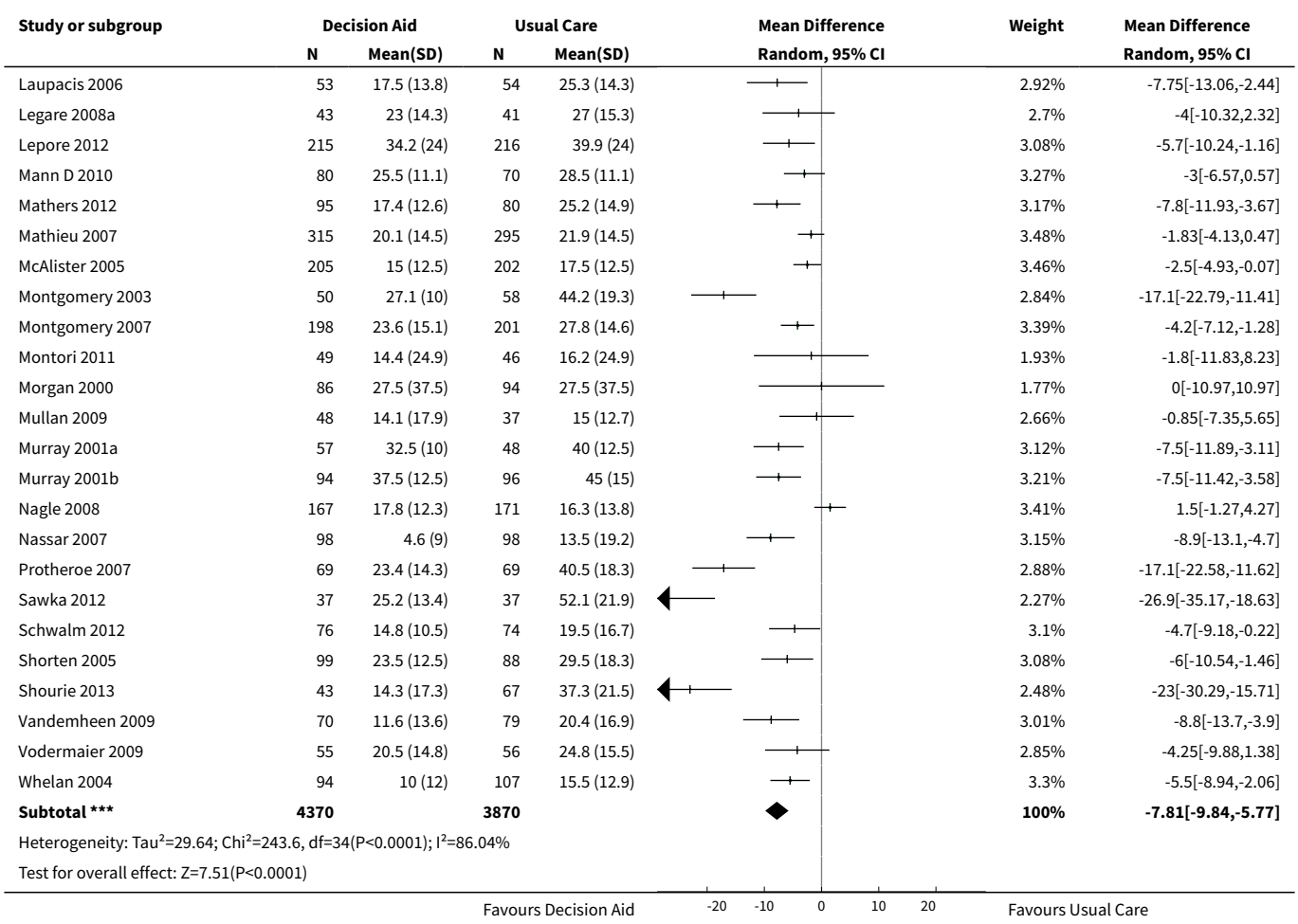


Favours Decision Aid

Favours Usual Care

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Montgomery 2007	200	22.2 (16.5)	201	28.5 (18.7)		5.34%	-6.3[-9.75,-2.85]
Morgan 2000	86	30 (24.8)	94	32.5 (24.8)		4.16%	-2.5[-9.74,4.74]
Murray 2001a	53	32.7 (12.8)	45	40.6 (17.1)		4.55%	-7.86[-13.92,-1.8]
Murray 2001b	85	36.5 (14.4)	82	48.7 (15.5)		5.04%	-12.21[-16.75,-7.67]
Nagle 2008	167	15.3 (13.8)	171	14.5 (15.8)		5.42%	0.75[-2.4,3.9]
Schwalm 2012	76	12.2 (15.2)	74	14.9 (16.9)		4.85%	-2.7[-7.85,2.45]
Shourie 2013	43	13.3 (17.3)	69	38 (21.8)		4.15%	-24.75[-32.02,-17.48]
Vandemheen 2009	70	6.9 (12.3)	79	14.5 (17.7)		4.94%	-7.6[-12.45,-2.75]
Vodermaier 2009	55	16.3 (16.3)	56	21 (15.8)		4.58%	-4.75[-10.7,1.2]
Subtotal * **	**2682**		**2141**			**100%**	**-7[-9.76,-4.24]**
Heterogeneity: Tau²=33.9; Chi²=141.02, df=21(P<0.0001); I²=85.11%							
Test for overall effect: Z=4.98(P<0.0001)							
4.4.5 Ineffective choice subscale							
Bekker 2004	50	22.5 (13.8)	56	21.9 (14.4)		4.68%	0.62[-4.74,5.98]
Chabrera 2015	61	27.1 (11.7)	61	49.5 (14.3)		4.89%	-22.4[-27.04,-17.76]
De Achaval 2012	69	27.7 (18.3)	69	31.2 (19.1)		4.41%	-3.5[-9.74,2.74]
Dolan 2002	41	20.5 (14.5)	37	25.8 (21)		3.83%	-5.25[-13.34,2.84]
Fagerlin 2011	690	30 (52.3)	160	55.5 (133.9)		1.33%	-25.5[-46.61,-4.39]
Hanson 2011	118	14 (15.6)	115	19.3 (15.6)		5.07%	-5.25[-9.24,-1.26]
Laupacis 2006	53	15 (14.5)	55	21.3 (16)		4.56%	-6.25[-12,-0.5]
Legare 2008a	43	16.5 (14.8)	41	22.3 (19)		4.08%	-5.75[-13.05,1.55]
Mathers 2012	95	16.1 (14.4)	80	23.3 (15.2)		4.95%	-7.2[-11.61,-2.79]
Mathieu 2007	315	18.4 (15)	295	19.2 (15)		5.43%	-0.78[-3.16,1.6]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.37%	-2.5[-5.18,0.18]
Montgomery 2003	50	26 (11.1)	58	35.1 (17.2)		4.67%	-9.13[-14.52,-3.74]
Morgan 2000	86	20 (32)	94	22.5 (32)		3.45%	-2.5[-11.86,6.86]
Murray 2001a	57	25 (10)	48	30 (15)		4.79%	-5[-9.97,-0.03]
Murray 2001b	94	30 (15)	96	37.5 (17.5)		4.89%	-7.5[-12.13,-2.87]
Nagle 2008	167	16.3 (13.8)	171	15 (14.3)		5.31%	1.25[-1.74,4.24]
Schwalm 2012	76	11.3 (11.4)	74	15.9 (15.9)		4.95%	-4.6[-9.04,-0.16]
Shourie 2013	44	11 (12.3)	68	30.5 (19.5)		4.52%	-19.5[-25.38,-13.62]
Vandemheen 2009	70	10.4 (16.4)	79	17.9 (20.4)		4.51%	-7.5[-13.42,-1.58]
Vodermaier 2009	55	28.3 (20.8)	56	35 (20)		3.99%	-6.75[-14.33,0.83]
Whelan 2004	94	12.5 (12)	107	17 (13)		5.2%	-4.5[-7.96,-1.04]
Wong 2006	136	19.4 (13.1)	159	36.7 (19.2)		5.14%	-17.29[-21,-13.58]
Subtotal * **	**2669**		**2181**			**100%**	**-6.97[-9.76,-4.18]**
Heterogeneity: Tau²=35.8; Chi²=164.67, df=21(P<0.0001); I²=87.25%							
Test for overall effect: Z=4.9(P<0.0001)							
4.4.6 Total decisional conflict score							
Allen 2010	291	14 (34.3)	334	20 (37.8)		2.84%	-6[-11.66,-0.34]
Chabrera 2015	61	31.2 (10.2)	61	51.7 (13.3)		3.15%	-20.5[-24.71,-16.29]
De Achaval 2012	69	23.4 (15)	69	29.2 (16.6)		2.93%	-5.8[-11.07,-0.53]
Dolan 2002	41	20.8 (13)	37	25.8 (20.3)		2.41%	-5[-12.64,2.64]
Evans 2010	89	38.1 (24.2)	103	49.6 (24.2)		2.58%	-11.5[-18.35,-4.65]
Fagerlin 2011	690	22 (42.2)	160	55.7 (108.4)		1.02%	-33.7[-50.79,-16.61]
Hanson 2011	118	16.3 (18.6)	115	24.3 (18.6)		3.04%	-8[-12.76,-3.24]
Hess 2012	101	23.3 (20.8)	103	43.3 (19)		2.89%	-20[-25.46,-14.54]
Jibaja-Weiss 2011	44	16.5 (19.9)	39	22.2 (25.3)		1.96%	-5.63[-15.51,4.25]
Kuppermann 2014	357	12.9 (14.1)	353	13.8 (15.6)		3.49%	-0.9[-3.09,1.29]
Lam 2013	113	15.8 (15.5)	112	19.9 (16.3)		3.16%	-4.1[-8.26,0.06]





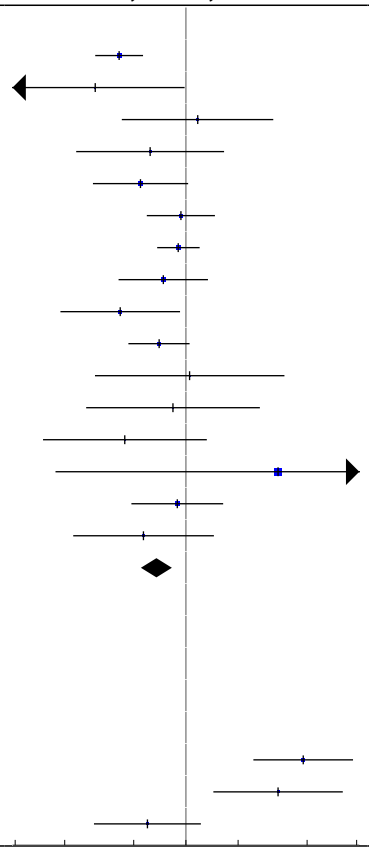
Comparison 5. Participation in decision making

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participation in decision making - all studies	16		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Clinician-controlled decision making	16	3180	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.55, 0.83]
1.2 Patient-controlled decision making	15	3009	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.05, 1.55]
1.3 Shared decision making	15	2973	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.83, 1.10]
2 Participation in decision making - in consultation	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Clinician-controlled decision making - in consultation	3	650	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.70, 1.12]

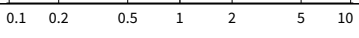
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.2 Patient-controlled decision making - in consultation	2	479	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.80, 1.27]
2.3 Shared decision making - in consultation	2	479	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.84, 1.55]
3 Participation in decision making - in preparation for consultation	13		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Clinician-controlled decision making	13	2530	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.48, 0.75]
3.2 Patient-controlled decision making	13	2530	Risk Ratio (M-H, Random, 95% CI)	1.37 [1.08, 1.73]
3.3 Shared decision making	13	2494	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.80, 1.09]

Analysis 5.1. Comparison 5 Participation in decision making, Outcome 1 Participation in decision making - all studies.

Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
5.1.1 Clinician-controlled decision making					
Auvinen 2004	31/103	73/100		13.89%	0.41[0.3,0.57]
Davison 1997	3/30	10/30		2.62%	0.3[0.09,0.98]
Dolan 2002	7/43	6/43		3.48%	1.17[0.43,3.19]
Kasper 2008	6/134	10/139		3.6%	0.62[0.23,1.66]
Krist 2007	20/196	14/75		7.05%	0.55[0.29,1.03]
Legare 2011	26/81	24/70		10.33%	0.94[0.59,1.47]
Legare 2012	58/163	65/165		14.99%	0.9[0.68,1.2]
Man-Son-Hing 1999	16/137	23/146		7.59%	0.74[0.41,1.34]
Mathers 2012	8/92	16/77		5.08%	0.42[0.19,0.92]
Morgan 2000	25/86	39/94		11.42%	0.7[0.47,1.05]
Murray 2001a	5/57	4/48		2.37%	1.05[0.3,3.7]
Murray 2001b	5/94	6/95		2.76%	0.84[0.27,2.67]
Sawka 2012	4/37	9/37		3.05%	0.44[0.15,1.32]
Smith 2010	3/357	0/173		0.47%	3.4[0.18,65.5]
Vodermaier 2009	14/53	16/54		7.36%	0.89[0.48,1.64]
Whelan 2003	6/80	12/91		3.93%	0.57[0.22,1.45]
Subtotal (95% CI)	**1743**	**1437**		**100%**	**0.68[0.55,0.83]**
Total events: 237 (Decision Aid), 327 (Usual Care)					
Heterogeneity: Tau^2=0.05; Chi^2=23.59, df=15(P=0.07); I^2=36.42%					
Test for overall effect: Z=3.74(P=0)					
5.1.2 Patient-controlled decision making					
Auvinen 2004	44/103	9/100		4.83%	4.75[2.45,9.2]
Davison 1997	17/30	5/30		3.5%	3.4[1.44,8.03]
Dolan 2002	9/43	15/43		4.46%	0.6[0.29,1.22]

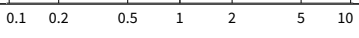


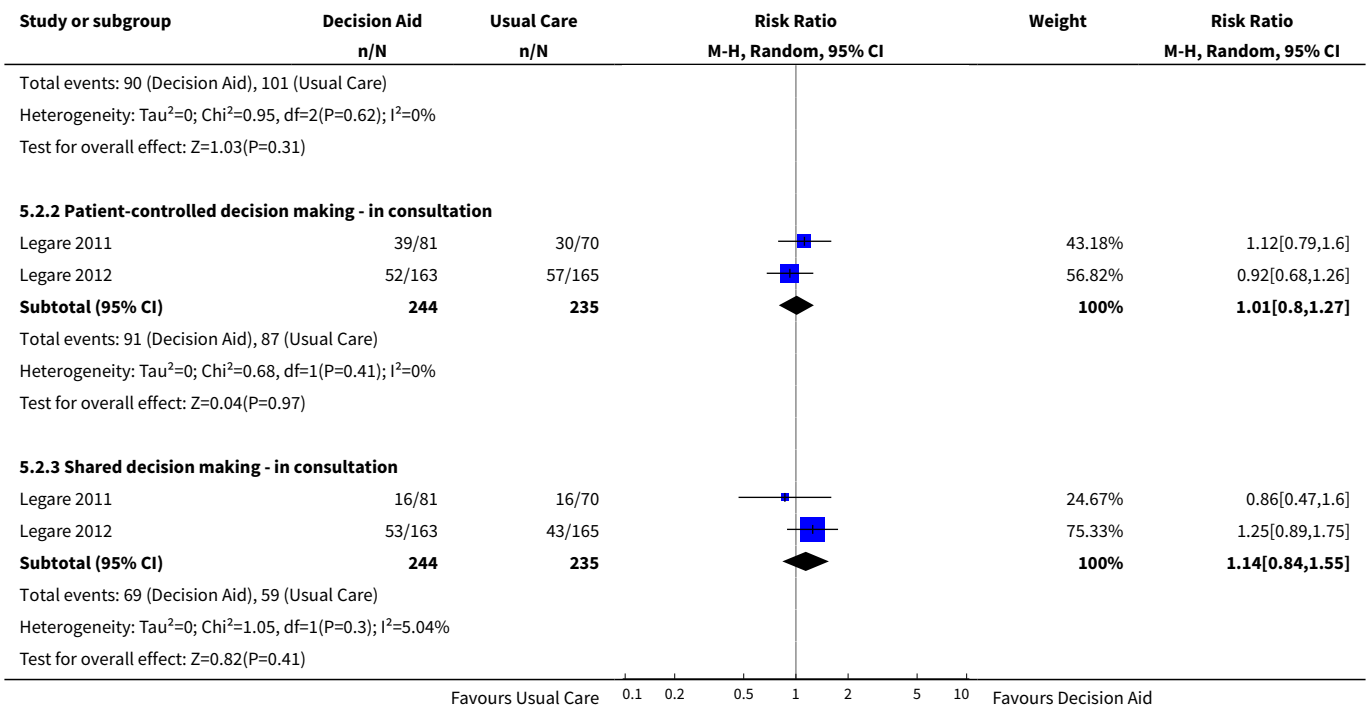
Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Kasper 2008	109/134	103/139		10.44%	1.1[0.97,1.25]
Krist 2007	106/196	35/75		8.99%	1.16[0.88,1.52]
Legare 2011	39/81	30/70		8.05%	1.12[0.79,1.6]
Legare 2012	52/163	57/165		8.59%	0.92[0.68,1.26]
Man-Son-Hing 1999	85/137	80/146		9.83%	1.13[0.93,1.38]
Mathers 2012	59/92	33/77		8.68%	1.5[1.11,2.02]
Morgan 2000	17/86	14/94		4.98%	1.33[0.7,2.53]
Murray 2001a	18/57	2/48		1.63%	7.58[1.85,31.03]
Murray 2001b	49/94	53/95		9.11%	0.93[0.72,1.22]
Sawka 2012	17/37	9/37		4.79%	1.89[0.97,3.68]
Smith 2010	335/357	166/173		10.88%	0.98[0.94,1.02]
Vodermaier 2009	4/53	2/54		1.23%	2.04[0.39,10.66]
Subtotal (95% CI)	**1663**	**1346**		**100%**	**1.28[1.05,1.55]**
Total events: 960 (Decision Aid), 613 (Usual Care)					
Heterogeneity: Tau^2=0.09; Chi^2=109.06, df=14(P<0.0001); I^2=87.16%					
Test for overall effect: Z=2.47(P=0.01)					
5.1.3 Shared decision making					
Auvinen 2004	25/103	17/100		4.64%	1.43[0.82,2.48]
Davison 1997	10/30	15/30		3.91%	0.67[0.36,1.24]
Dolan 2002	27/43	22/43		7.6%	1.23[0.85,1.78]
Kasper 2008	19/134	26/103		4.87%	0.56[0.33,0.96]
Krist 2007	71/196	27/75		7.98%	1.01[0.71,1.43]
Legare 2011	16/81	16/70		3.96%	0.86[0.47,1.6]
Legare 2012	53/163	43/165		8.34%	1.25[0.89,1.75]
Man-Son-Hing 1999	36/137	43/146		7.5%	0.89[0.61,1.3]
Mathers 2012	25/92	28/77		6.16%	0.75[0.48,1.17]
Morgan 2000	42/86	38/94		8.63%	1.21[0.87,1.68]
Murray 2001a	34/57	42/48		11.03%	0.68[0.54,0.87]
Murray 2001b	40/94	36/95		8.12%	1.12[0.79,1.59]
Sawka 2012	15/37	19/37		5.31%	0.79[0.48,1.3]
Smith 2010	17/357	5/173		1.83%	1.65[0.62,4.39]
Vodermaier 2009	35/53	36/54		10.14%	0.99[0.76,1.3]
Subtotal (95% CI)	**1663**	**1310**		**100%**	**0.95[0.83,1.1]**
Total events: 465 (Decision Aid), 413 (Usual Care)					
Heterogeneity: Tau^2=0.03; Chi^2=25.31, df=14(P=0.03); I^2=44.69%					
Test for overall effect: Z=0.64(P=0.52)					



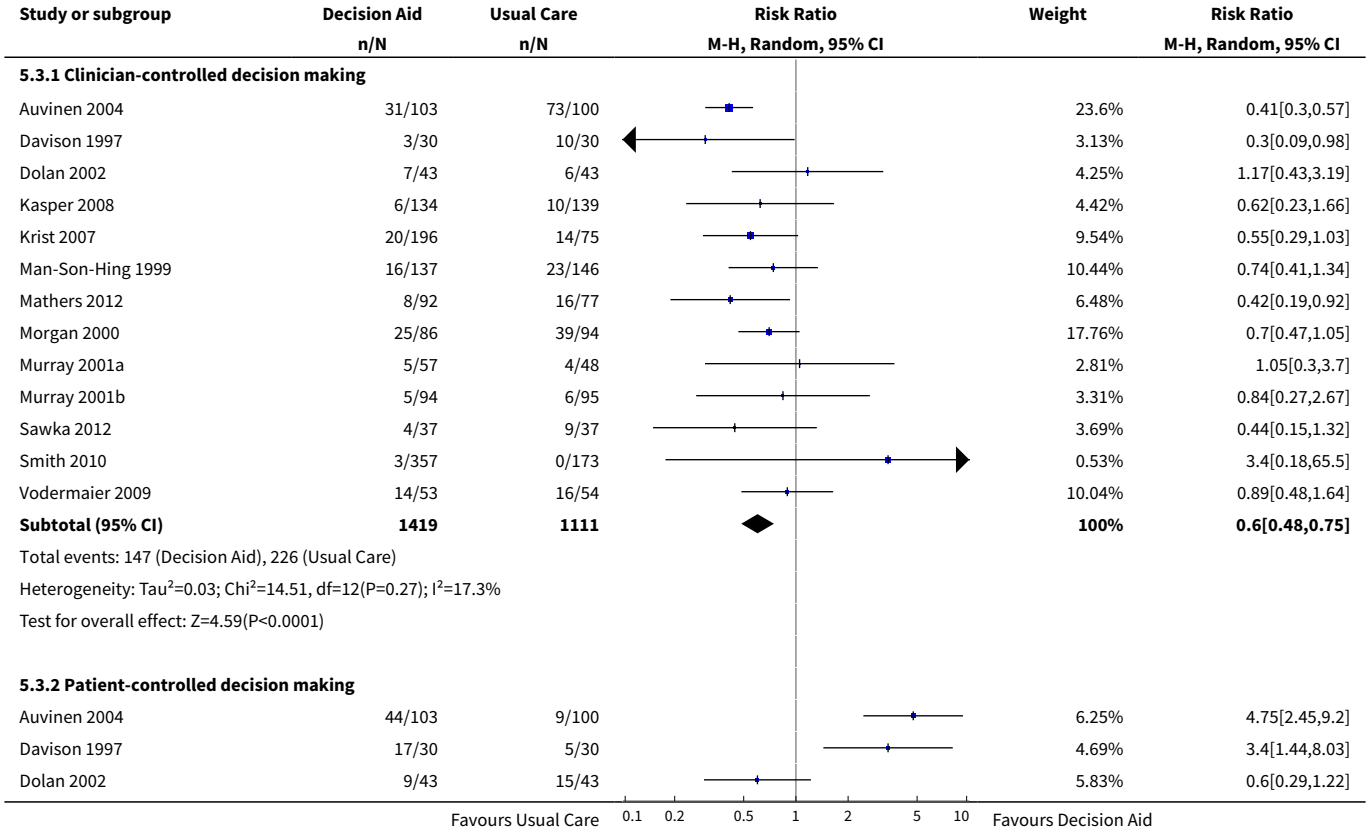
Analysis 5.2. Comparison 5 Participation in decision making, Outcome 2 Participation in decision making - in consultation.

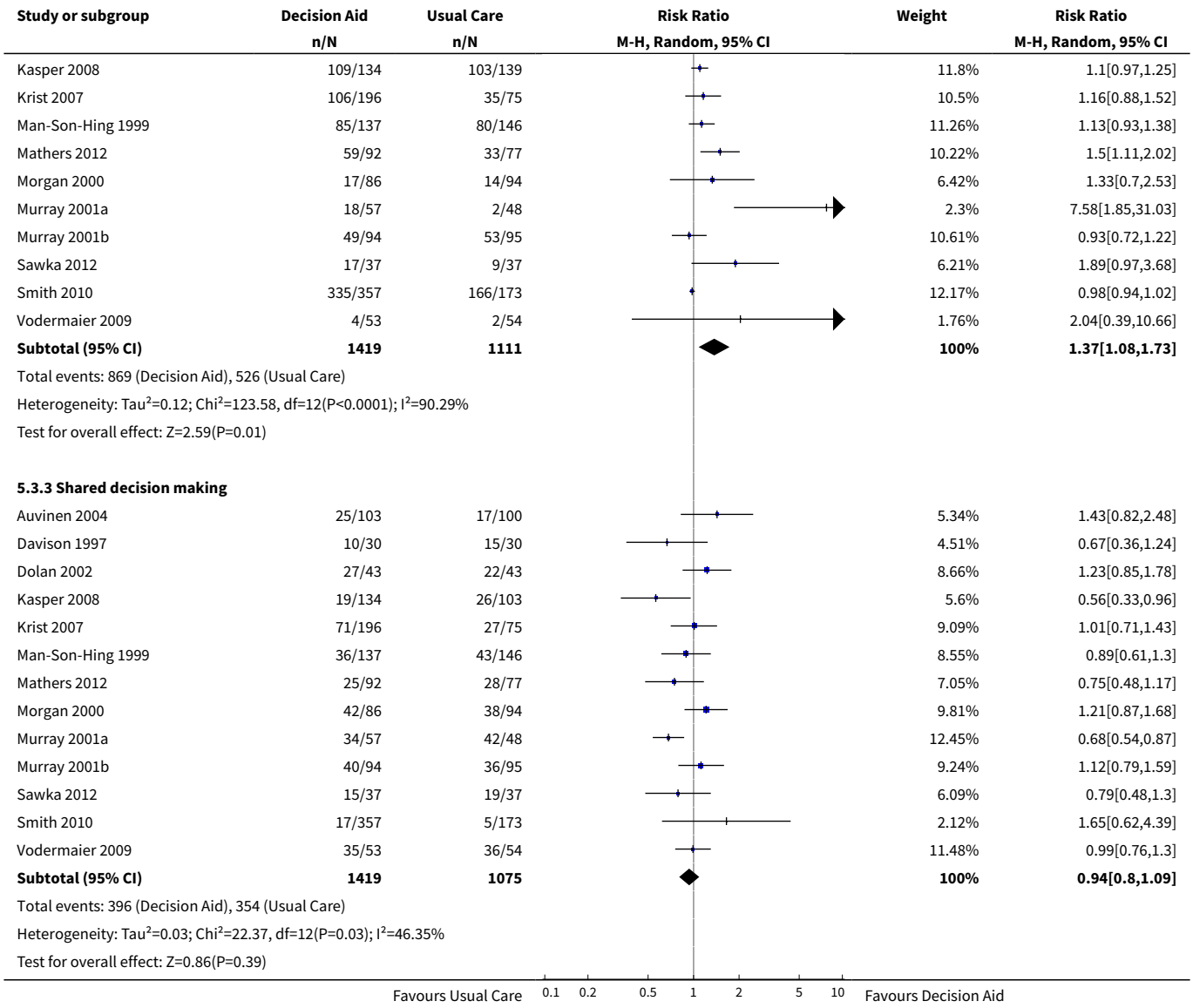
Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
5.2.1 Clinician-controlled decision making - in consultation					
Legare 2011	26/81	24/70		25.94%	0.94[0.59,1.47]
Legare 2012	58/163	65/165		67.93%	0.9[0.68,1.2]
Whelan 2003	6/80	12/91		6.13%	0.57[0.22,1.45]
Subtotal (95% CI)	**324**	**326**		**100%**	**0.89[0.7,1.12]**





Analysis 5.3. Comparison 5 Participation in decision making, Outcome 3 Participation in decision making - in preparation for consultation.

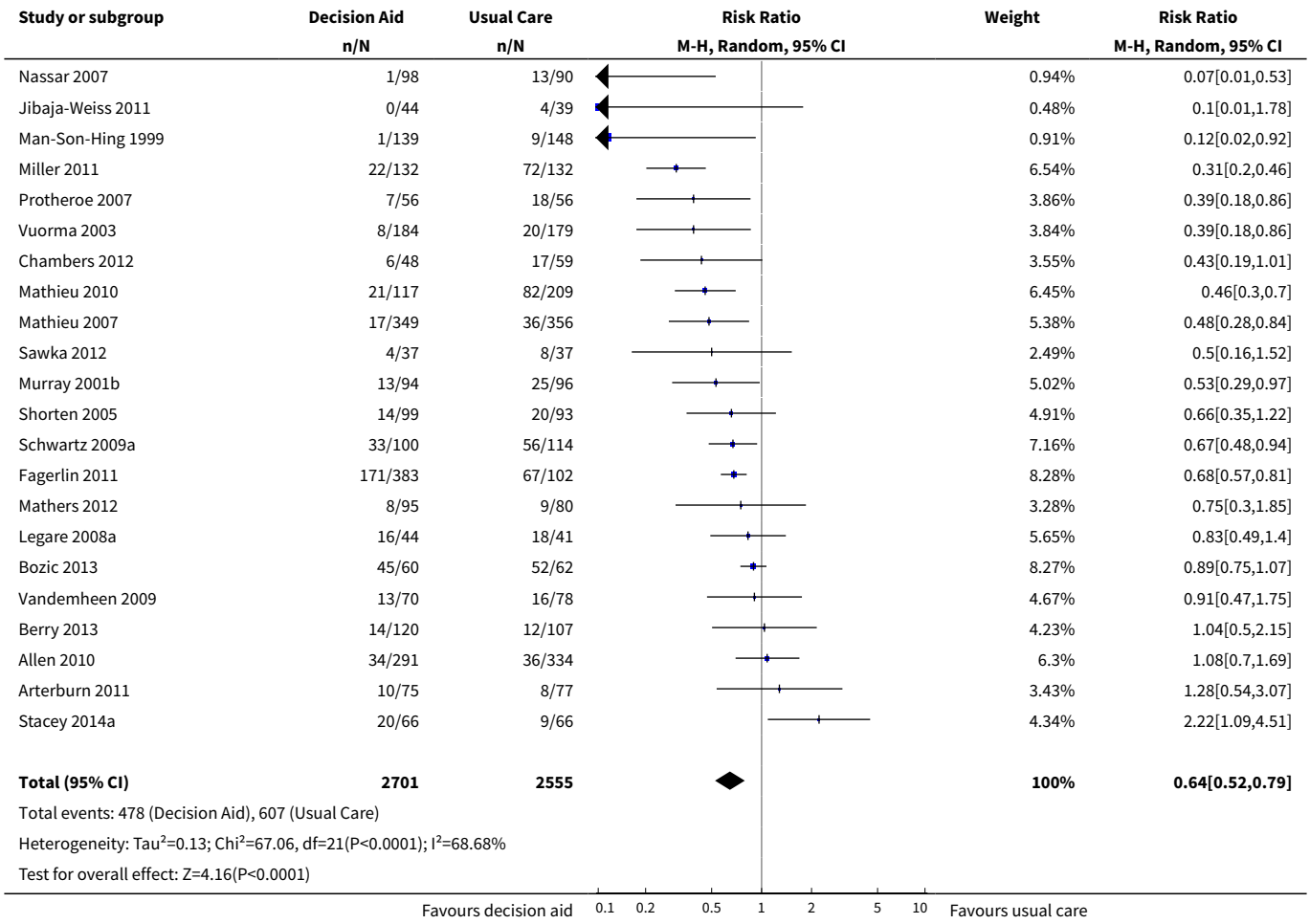




Comparison 6. Proportion undecided

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion undecided - all studies	22	5256	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.52, 0.79]

Analysis 6.1. Comparison 6 Proportion undecided, Outcome 1 Proportion undecided - all studies.



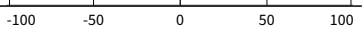
Comparison 7. Satisfaction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Satisfaction with the choice - all studies	11		Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Satisfaction with the choice - in consultation	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
3 Satisfaction with the choice - in preparation for consultation	10		Mean Difference (IV, Random, 95% CI)	Totals not selected
4 Satisfaction with the decision making process - all studies	9		Mean Difference (IV, Random, 95% CI)	Totals not selected
5 Satisfaction with the decision making process - in consultation	1		Mean Difference (IV, Random, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Satisfaction with the decision making process - in preparation for consultation	8		Mean Difference (IV, Random, 95% CI)	Totals not selected

Analysis 7.1. Comparison 7 Satisfaction, Outcome 1 Satisfaction with the choice - all studies.

Study or subgroup	Decision aid		Usual care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	75.9 (17.2)	117	73.9 (18)		1.99[-2.65,6.63]
Bernstein 1998	61	73.1 (20.9)	48	77.7 (20.5)		-4.6[-12.42,3.22]
Chabrera 2015	61	95.7 (6.9)	61	79.3 (10.3)		16.4[13.29,19.51]
Hanson 2011	126	84.8 (15.2)	127	83.5 (16.2)		1.3[-2.57,5.17]
Jibaja-Weiss 2011	43	93.5 (12)	38	92.5 (15)		1[-4.97,6.97]
Laupacis 2006	54	73 (21.7)	56	61 (25.4)		12[3.18,20.82]
Montgomery 2007	212	85 (15)	209	80 (15)		5[2.13,7.87]
Morgan 2000	86	80 (26)	94	77.5 (26)		2.5[-5.1,10.1]
Nassar 2007	86	87.9 (12.5)	84	84.2 (15)		3.7[-0.46,7.86]
Ozanne 2007	15	82.5 (14.8)	15	80 (12.3)		2.5[-7.2,12.2]
Smith 2010	357	80.3 (11)	173	80.3 (10.8)		0[-1.97,1.97]

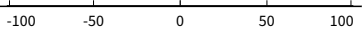


Analysis 7.2. Comparison 7 Satisfaction, Outcome 2 Satisfaction with the choice - in consultation.

Study or subgroup	Decision aid		Usual care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Ozanne 2007	15	82.5 (14.8)	15	80 (12.3)		2.5[-7.2,12.2]

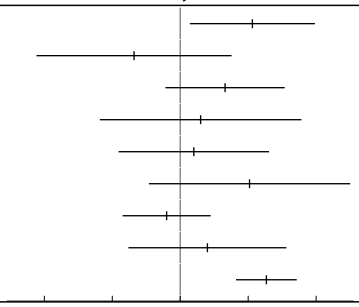
Analysis 7.3. Comparison 7 Satisfaction, Outcome 3 Satisfaction with the choice - in preparation for consultation.

Study or subgroup	Decision aid		Usual care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	75.9 (17.2)	117	73.9 (18)		1.99[-2.65,6.63]
Bernstein 1998	61	73.1 (20.9)	48	77.7 (20.5)		-4.6[-12.42,3.22]
Chabrera 2015	61	95.7 (6.9)	61	79.3 (10.3)		16.4[13.29,19.51]
Hanson 2011	126	15.3 (15.2)	127	16.5 (16.2)		-1.25[-5.12,2.62]
Jibaja-Weiss 2011	43	93.5 (12)	38	92.5 (15)		1[-4.97,6.97]
Laupacis 2006	54	73 (21.7)	56	61 (25.4)		12[3.18,20.82]
Montgomery 2007	212	85 (15)	209	80 (15)		5[2.13,7.87]
Morgan 2000	86	80 (26)	94	77.5 (26)		2.5[-5.1,10.1]
Nassar 2007	86	87.9 (12.5)	84	84.2 (15)		3.7[-0.46,7.86]
Smith 2010	357	80.3 (11)	173	80.3 (10.8)		0[-1.97,1.97]



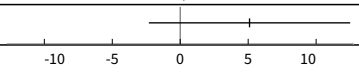
Analysis 7.4. Comparison 7 Satisfaction, Outcome 4 Satisfaction with the decision making process - all studies.

Study or subgroup	Decision Aid		Usual Care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	76.4 (16.5)	117	71.1 (18.4)		5.31[0.71,9.91]
Bernstein 1998	61	73.1 (20.6)	48	76.5 (17.6)		-3.4[-10.58,3.78]
Bozic 2013	60	94.4 (10)	62	91.1 (14.4)		3.3[-1.09,7.69]
Jibaja-Weiss 2011	43	94 (17)	38	92.5 (17)		1.5[-5.92,8.92]
Knops 2014	74	74 (16)	80	73 (19)		1[-4.53,6.53]
Kupke 2013	50	91.4 (12.5)	31	86.3 (18.6)		5.1[-2.31,12.51]
Man-Son-Hing 1999	146	83.8 (14.8)	138	84.8 (13)		-1[-4.24,2.24]
Morgan 2000	86	72 (19.9)	94	70 (19.9)		2[-3.81,7.81]
Schroy 2011	214	84.2 (10.3)	217	77.8 (13.2)		6.34[4.11,8.57]



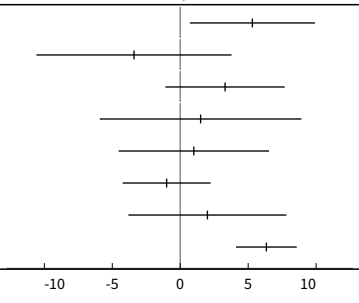
Analysis 7.5. Comparison 7 Satisfaction, Outcome 5 Satisfaction with the decision making process - in consultation.

Study or subgroup	Decision Aid		Usual Care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Kupke 2013	50	91.4 (12.5)	31	86.3 (18.6)		5.1[-2.31,12.51]



Analysis 7.6. Comparison 7 Satisfaction, Outcome 6 Satisfaction with the decision making process - in preparation for consultation.

Study or subgroup	Decision Aid		Usual Care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	76.4 (16.5)	117	71.1 (18.4)		5.31[0.71,9.91]
Bernstein 1998	61	73.1 (20.6)	48	76.5 (17.6)		-3.4[-10.58,3.78]
Bozic 2013	60	94.4 (10)	62	91.1 (14.4)		3.3[-1.09,7.69]
Jibaja-Weiss 2011	43	94 (17)	38	92.5 (17)		1.5[-5.92,8.92]
Knops 2014	74	74 (16)	80	73 (19)		1[-4.53,6.53]
Man-Son-Hing 1999	146	83.8 (14.8)	138	84.8 (13)		-1[-4.24,2.24]
Morgan 2000	86	72 (19.9)	94	70 (19.9)		2[-3.81,7.81]
Schroy 2011	214	84.2 (10.3)	217	77.8 (13.2)		6.34[4.11,8.57]



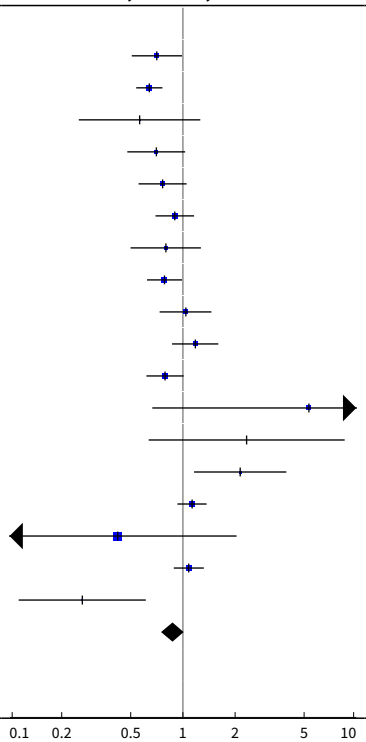
Comparison 8. Choice

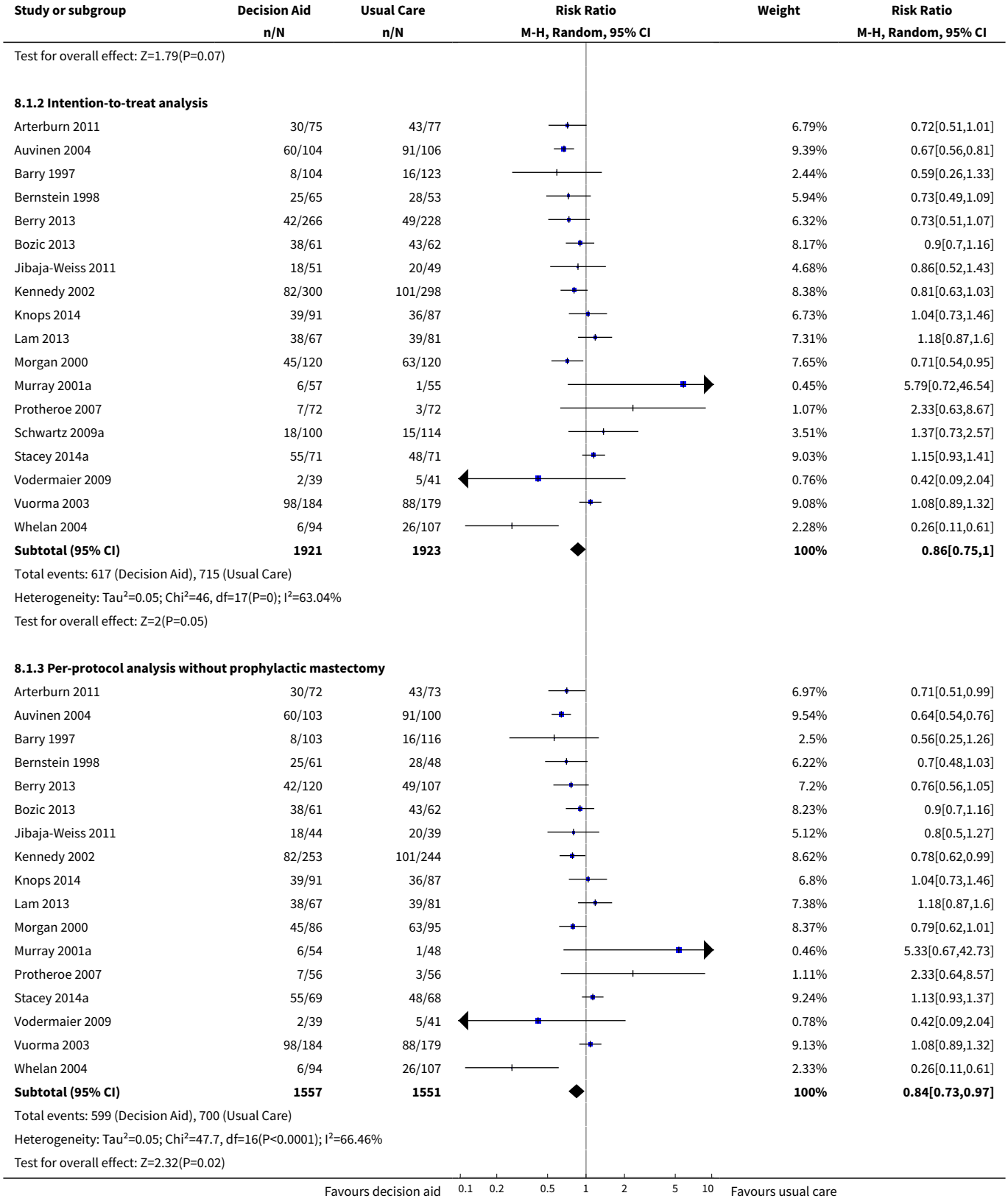
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Choice: surgery over conservative option	18		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Per-protocol analysis	18	3286	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.75, 1.01]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2 Intention-to-treat analysis	18	3844	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.75, 1.00]
1.3 Per-protocol analysis without prophylactic mastectomy	17	3108	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.73, 0.97]
2 Choice for screening	25		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 PSA screening	10	3996	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.80, 0.98]
2.2 Colorectal cancer screening	10	4529	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.95, 1.31]
2.3 Breast cancer genetic testing	3	738	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.71, 1.38]
2.4 Prenatal diagnostic testing	2	1100	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.91, 1.09]
3 Choice: diabetes medication (uptake new medication)	4	447	Risk Ratio (M-H, Random, 95% CI)	1.65 [1.06, 2.56]

Analysis 8.1. Comparison 8 Choice, Outcome 1 Choice: surgery over conservative option.

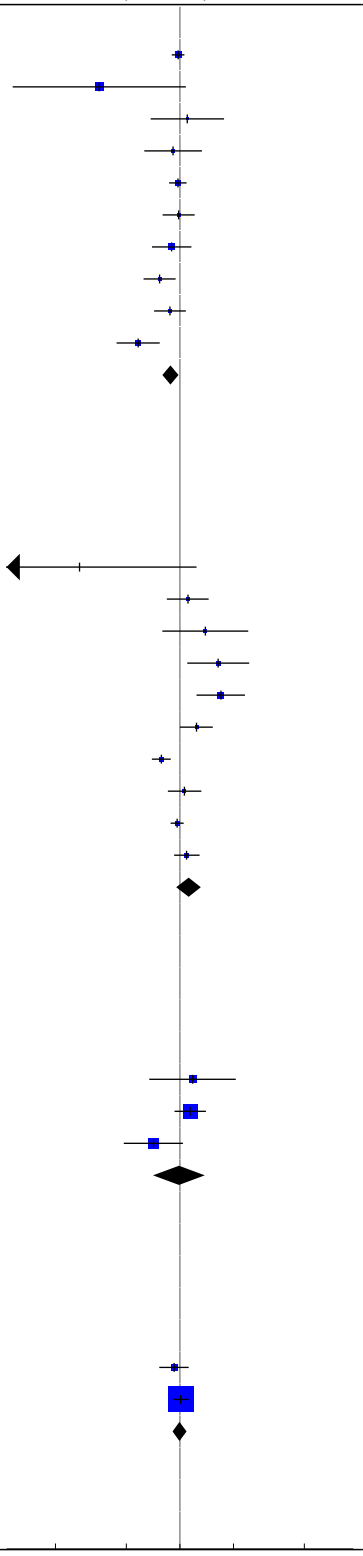
Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
8.1.1 Per-protocol analysis					
Arterburn 2011	30/72	43/73		6.76%	0.71[0.51,0.99]
Auvinen 2004	60/103	91/100		8.87%	0.64[0.54,0.76]
Barry 1997	8/103	16/116		2.62%	0.56[0.25,1.26]
Bernstein 1998	25/61	28/48		6.11%	0.7[0.48,1.03]
Berry 2013	42/120	49/107		6.95%	0.76[0.56,1.05]
Bozic 2013	38/61	43/62		7.82%	0.9[0.7,1.16]
Jibaja-Weiss 2011	18/44	20/39		5.13%	0.8[0.5,1.27]
Kennedy 2002	82/253	101/244		8.14%	0.78[0.62,0.99]
Knops 2014	39/91	36/87		6.62%	1.04[0.73,1.46]
Lam 2013	38/67	39/81		7.11%	1.18[0.87,1.6]
Morgan 2000	45/86	63/95		7.93%	0.79[0.62,1.01]
Murray 2001a	6/54	1/48		0.5%	5.33[0.67,42.73]
Protheroe 2007	7/56	3/56		1.2%	2.33[0.64,8.57]
Schwartz 2009a	18/64	15/114		3.8%	2.14[1.16,3.95]
Stacey 2014a	55/69	48/68		8.63%	1.13[0.93,1.37]
Vodermaier 2009	2/39	5/41		0.84%	0.42[0.09,2.04]
Vuorma 2003	98/184	88/179		8.54%	1.08[0.89,1.32]
Whelan 2004	6/94	26/107		2.44%	0.26[0.11,0.61]
Subtotal (95% CI)	**1621**	**1665**		**100%**	**0.87[0.75,1.01]**
Total events: 617 (Decision Aid), 715 (Usual Care)					
Heterogeneity: Tau^2=0.06; Chi^2=55.99, df=17(P<0.0001); I^2=69.63%					



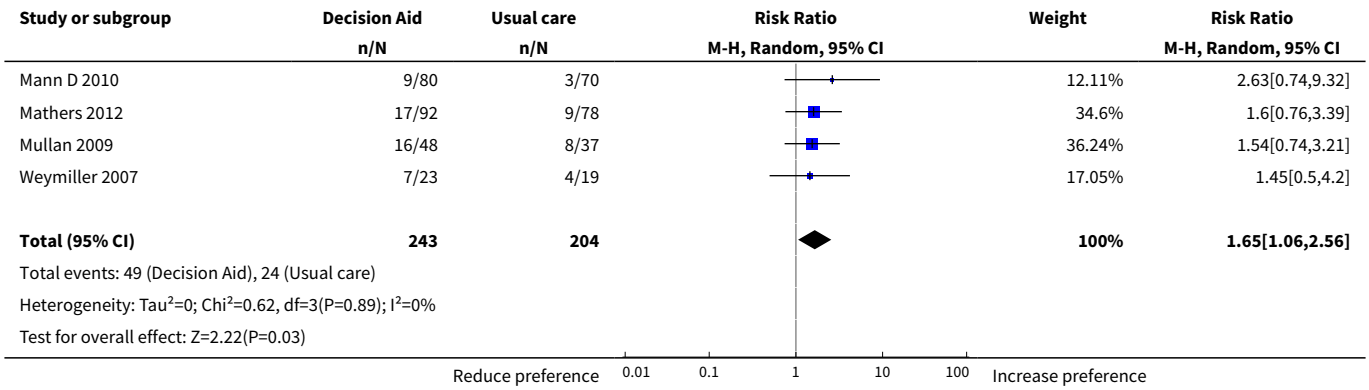


Analysis 8.2. Comparison 8 Choice, Outcome 2 Choice for screening.

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
8.2.1 PSA screening					
Allen 2010	225/291	264/334		19.01%	0.98[0.9,1.06]
Evans 2010	4/127	11/123		0.84%	0.35[0.12,1.08]
Gattellari 2003	27/106	25/108		3.97%	1.1[0.69,1.77]
Gattellari 2005	37/131	42/136		5.79%	0.91[0.63,1.33]
Krist 2007	163/196	64/75		17.25%	0.97[0.87,1.09]
Lepore 2012	97/215	99/216		11.7%	0.98[0.8,1.21]
Partin 2004	83/308	87/290		9.47%	0.9[0.7,1.16]
Volk 1999	48/78	64/80		11.69%	0.77[0.63,0.95]
Watson 2006	119/465	149/512		11.76%	0.88[0.72,1.08]
Wolf 1996	40/103	68/102		8.52%	0.58[0.44,0.77]
Subtotal (95% CI)	**2020**	**1976**		**100%**	**0.88[0.8,0.98]**
Total events: 843 (Experimental), 873 (Control)					
Heterogeneity: Tau^2=0.01; Chi^2=21.43, df=9(P=0.01); I^2=58.01%					
Test for overall effect: Z=2.3(P=0.02)					
8.2.2 Colorectal cancer screening					
Dolan 2002	2/45	7/43		1.02%	0.27[0.06,1.24]
Lewis 2010	71/207	70/226		10.56%	1.11[0.84,1.45]
Miller 2011	25/132	18/132		5.3%	1.39[0.8,2.42]
Pignone 2000	46/124	28/124		7.77%	1.64[1.1,2.45]
Ruffin 2007	56/87	33/87		9.62%	1.7[1.24,2.32]
Schroy 2011	116/269	96/276		12%	1.24[1,1.53]
Smith 2010	211/357	130/173		14.03%	0.79[0.7,0.89]
Steckelberg 2011	141/785	134/792		11.93%	1.06[0.86,1.32]
Trevena 2008	117/134	124/137		14.66%	0.96[0.89,1.05]
Wolf 2000	173/266	79/133		13.1%	1.09[0.93,1.29]
Subtotal (95% CI)	**2406**	**2123**		**100%**	**1.12[0.95,1.31]**
Total events: 958 (Experimental), 719 (Control)					
Heterogeneity: Tau^2=0.04; Chi^2=48.11, df=9(P<0.0001); I^2=81.29%					
Test for overall effect: Z=1.37(P=0.17)					
8.2.3 Breast cancer genetic testing					
Green 2001	13/29	16/42		21.9%	1.18[0.67,2.06]
Lerman 1997	74/122	87/164		46.01%	1.14[0.93,1.4]
Schwartz 2001	35/191	49/190		32.09%	0.71[0.48,1.04]
Subtotal (95% CI)	**342**	**396**		**100%**	**0.99[0.71,1.38]**
Total events: 122 (Experimental), 152 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=5.15, df=2(P=0.08); I^2=61.19%					
Test for overall effect: Z=0.07(P=0.94)					
8.2.4 Prenatal diagnostic testing					
Bjorklund 2012	92/184	111/206		21.75%	0.93[0.77,1.12]
Kuppermann 2014	244/357	238/353		78.25%	1.01[0.92,1.12]
Subtotal (95% CI)	**541**	**559**		**100%**	**0.99[0.91,1.09]**
Total events: 336 (Experimental), 349 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.66, df=1(P=0.42); I^2=0%					
Test for overall effect: Z=0.12(P=0.9)					



Analysis 8.3. Comparison 8 Choice, Outcome 3 Choice: diabetes medication (uptake new medication).



ADDITIONAL TABLES

Table 1. Decision aids evaluated in the trials

Study	Topic	Availability	Source	Contact Information
Allen 2010	Prostate cancer screening	No	Allen, Center for Community-Based Research, Dana-Farber Cancer Institute, Boston, MA, USA, 2010	Requested access
Arterburn 2011	Bariatric surgery	Yes	Informed Medical Decisions Foundation, MA,USA, 2010	informedmedicaldecisions.org/imdf_decision_aid/making-decisions-about-weight-loss-surgery/
Auvinen 2004	Prostate cancer treatment	Yes	Auvinen, Helsinki, Finland, 1993	Included in publication
Barry 1997	Benign prostate disease treatment	Yes	Informed Medical Decisions Foundation, MA, USA, 2001	informedmedicaldecisions.org/imdf_decision_aid/treatment-options-for-benign-prostatic-hyperplasia/
Bekker 2004	Prenatal screening	Yes	Bekker, Leeds, UK, 2003	Included in publication
Bernstein 1998	Ischaemic heart disease treatment	Yes	Informed Medical Decisions Foundation, MA,USA, 2002	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-carotid-artery-disease/
Berry 2013	Prostate cancer treatment	No	Berry, Phyllis F. Cantor Center, MA, USA, 2011	donna_berry@dfci.harvard.edu

Table 1. Decision aids evaluated in the trials *(Continued)*

Bjorklund 2012	Antenatal Down syndrome screening	Yes	Södersjukhuset, Department of Obstetrics and Gynecology, Stockholm, Sweden	vimeo.com/34600615/
Bozic 2013	Osteoarthritis of the knee or hip	No	Informed Medical Decisions Foundation and Health Dialog; USA	www.healthdialog.com
Brazell 2014	Pelvic Organ Prolapse	Yes	Healthwise, USA	decisionaid.ohri.ca
Chabrera 2015	Prostate cancer treatment	No	C Chabrera. School of Health Sciences, Department of Nursing. Mataro, Spain	cchabrera@tecnocampus.cat
Chambers 2012	Healthcare personnel's influenza immunization	Yes	A McCarthy. Ottawa Influenza Decision Aid Planning Group, CA, 2008	decisionaid.ohri.ca/decaids.html#oida
Clancy 1988	Hepatitis B Vaccine	No	Clancy, Richmond VA, USA, 1983	—
Davison 1997	Prostate cancer treatment	No	Davison, Manitoba CA, 1992-1996	—
De Achaval 2012	Total knee arthroplasty treatment	Yes	Informed Medical Decisions Foundation, MA,USA	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-knee-osteoarthritis/
Dolan 2002	Colon cancer screening	No	Dolan, Rochester NY, USA, 1999	—
Evans 2010	Prostate cancer screening	Yes	Elwyn, Cardiff, UK	www.prosdex.com
Fagerlin 2011	Breast cancer prevention	Yes	Fagerlin, Ann Arbor, MI, USA	—
Fraenkel 2007	Osteoarthritis knee treatment	No	Fraenkel, New Haven CT, USA	Author said DA never fully developed, all info in paper
Fraenkel 2012	Atrial fibrillation	No	Veterans Affairs Connecticut Healthcare System, USA	Obtained from author terri.fried@yale.edu
Frosch 2008a	Prostate cancer screening	No	Frosch, Los Angeles, USA	Screenshots from author
Gattellari 2003	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	included in publication
Gattellari 2005	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	Included in publication
Green 2001	Breast cancer genetic testing	Yes	Green, Hershey PA, USA, 2000	1-800-757-4868 dwc@mavc.com
Hamann 2006	Schizophrenia treatment	Yes	Hamann, Munich, GER	Emailed by author (in German)

Table 1. Decision aids evaluated in the trials *(Continued)*

Hanson 2011	Feeding options in advanced dementia	Yes	Mitchell, Tetroe, O'Connor; 2001 (updated 2008)	decisionaid.ohri.ca/decaids.html#feedingtube
Heller 2008	Breast reconstruction	Yes	University of Texas MD Anderson Cancer Center, Houston TX, USA, 2003	Disc mailed
Hess 2012	Stress testing for chest pain	Yes	Hess, Rochester, MN, USA, 2012	Included in publication
Jibaja-Weiss 2011	Breast cancer treatment	Yes	Jibaja-Weiss, Baylor College of Medicine, 2010	www.bcm.edu/patchworkoflife
Johnson 2006	Endodontic treatment	Yes	Johnson, Chicago, USA, 2004	Included in publication
Kasper 2008	Multiple sclerosis	No	Jürgen Kasper	—
Kennedy 2002	Abnormal uterine bleeding treatment	No	Kennedy/Coulter, London UK, 1996	—
Knops 2014	Asymptomatic Abdominal Aortic Aneurysm treatment	Yes	Amsterdam, The Netherlands	www.keuzehulp.info/amc/AAA/landing-page
Krist 2007	Prostate cancer screening	Yes	Krist, Fairfax VA, USA	www.familymedicine.vcu.edu/research/misc/psa/index.html
Kupke 2013	Dental - posterior tooth decay	Yes	University of Cologne, Cologne, Germany	jana.kupke@uk-koeln.de
Kuppermann 2014	Prenatal screening	No	Kuppermann, San Francisco CA, USA	Interactive web-based decision aid
Lam 2013	Breast cancer treatment	Yes	Kwong Wah Hospital, Hong Kong, China	Obtained from author. wwtlam@hku.hk
Langston 2010	Contraceptive method choice	Yes	World Health Organization, 2005	www.who.int/reproductive-health/publications/family_planning/9241593229index/en/index.html
Laupacis 2006	Pre-operative autologous blood donation	No	Laupacis, Ottawa, CA, 2001	Decisionaid.ohri.ca/decaids-archive.html
LeBlanc 2015	Treatment for osteoporosis	Yes	Mayo Clinic	—
Legare 2008a	Natural health products	No	Legare, Quebec City, CA, 2006	—
Legare 2011	Use of antibiotics for acute respiratory infections	Yes	Legare, Quebec City, CA, 2007	www.decision.chaire.fmed.ulaval.ca/index.php?id=192&L=2

Table 1. Decision aids evaluated in the trials *(Continued)*

Legare 2012	Antibiotics for acute respiratory infections	Yes	Legare, Quebec City, CA	www.decision.chaire.fmed.ulaval.ca/index.php?
Leighl 2011	Advanced colorectal cancer chemotherapy	Yes	Princess Margaret Hospital, Toronto, 2011	Natasha.Leighl@uhn.on.ca
Lepore 2012	Prostate cancer screening	Yes	Sally Weinrich University of Louisville, USA	Obtained from author slepore@temple.edu
Lerman 1997	Breast cancer genetic testing	No	Lerman/Schwartz, Washington DC, USA, 1997	—
Lewis 2010	Colorectal cancer screening	Yes	Lewis, University of North Carolina, Chapel Hill, NC, USA, 2010	decisionsupport.unc.edu/CHOICE6/
Loh 2007	Depression treatment	Yes	Loh, Freiburg, GER	Emailed to us by author - in German
Man-Son-Hing 1999	Atrial fibrillation treatment	No	McAlister/Laupacis, Ottawa CA, 2000	decisionaid.ohri.ca/decaids-archive.html
Mann D 2010	Diabetes treatment - statins	Yes	Montori, Rochester MN, USA	mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm
Mann E 2010	Diabetes screening	Yes	Marteau, King's College London, London, England, 2010	Additional file 2 of publication
Marteau 2010	Diabetes screening	Yes	Marteau, King's College London, London, England, 2010	Provided by author, same DA as Mann E 2010
Mathieu 2007	Mammography	Yes	Mathieu, Sydney, AU	DA emailed by author
Mathers 2012	Diabetes treatment	Yes	The University of Sheffield, Sheffield, UK, 2008	Obtained from author C.Ng@sheffield.ac.uk
Mathieu 2010	Mammography	Yes	Mathieu, University of Sydney, AUS, 2010	www.psych.usyd.edu.au/cemped/com_decision_aids.shtml
McAlister 2005	Atrial fibrillation treatment	No	McAlister/Laupacis, Ottawa CAN, 2000	decisionaid.ohri.ca/decaids-archive.html
McBride 2002	Hormone replacement therapy	Yes, update in progress	Sigler/Bastien, Durham NC, USA, 1998	basti001@mc.duke.edu
McCaffery 2010	Screening after mildly abnormal pap smear	Yes	Screening & test evaluation program, School of public health, University of Sydney 2007	kirstenm@health.usyd.edu.au
Miller 2005	BRCA1/BRCA2 gene testing	No	Miller, Fox Chase PA, USA	—

Table 1. Decision aids evaluated in the trials *(Continued)*

Miller 2011	Colorectal cancer screening	Yes	University of North Carolina, Chapel Hill, NC, USA, 2007	intmedweb.wakehealth.edu/choice/choice.html (no longer available)
Montgomery 2003	Hypertension treatment	No	Montgomery, UK, 2000	—
Montgomery 2007	Birthing options after caesarean	Yes	Montgomery, Bristol, UK, last update 2004	www.computing.dundee.ac.uk/acstaff/cjones/diamond/Information.html
Montori 2011	Osteoporosis treatment	Yes	Montori, Mayo Foundation for Medical Education and Research, 2007	shareddecisions.mayoclinic.org/decision-aids-for-diabetes/other-decision-aids/
Morgan 2000	Ischaemic heart disease treatment	Yes	Informed Medical Decisions Foundation, MA, USA, 2002	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-carotid-artery-disease/
Mott 2014	PTSD treatment	Yes	Michael E DeBakey Veterans Affairs Medical Center, Houston, USA	Obtained from author juliette.mott@va.gov
Mullan 2009	Diabetes treatment	Yes	Montori or Mayo Foundation(?) Rochester MN, USA,	Included in publication
Murray 2001a	Benign prostate disease treatment	Yes	Informed Medical Decisions Foundation, MA, USA, 2001	informedmedicaldecisions.org/imdf_decision_aid/treatment-options-for-benign-prostatic-hyperplasia/
Murray 2001b	Hormone replacement therapy	No, update in progress	Informed Medical Decisions Foundation, MA, USA	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-managing-menopause/
Nagle 2008	Prenatal screening	Yes	Nagle, Victoria, AU	www.mcri.edu.au/Downloads/PrenatalTestingDecisionAid.pdf
Nassar 2007	Birth breech presentation	Yes	Nassar, West Perth WA, AU	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
Oakley 2006	Osteoporosis treatment	No	Cranney, Ottawa CA, 2002	decisionaid.ohri.ca/decaids-archive.html
Ozanne 2007	Breast cancer prevention	No	Ozanne, Boston MA, USA	—
Partin 2004	Prostate cancer screening	Yes	Informed Medical Decisions Foundation, MA,USA, 2001	informedmedicaldecisions.org/imdf_deci-

Table 1. Decision aids evaluated in the trials *(Continued)*

				sion_aid/deciding-if-the-psa-test-is-right-for-you/
Pignone 2000	Colon cancer screening	Yes	Pignone, Chapel Hill NC, USA, 1999	www.med.unc.edu/medicine/edusrc/colon.htm
Protheroe 2007	Menorrhagia treatment	No	Protheroe, Manchester, UK	Computerized decision aid, Clinical Guidance Tree - no longer in existence, author sent chapter in thesis
Rubel 2010	Prostate cancer screening	No	Centers for Disease Control and Prevention (CDC), USA, 2010	No longer available
Ruffin 2007	Colorectal cancer screening	Yes	Regents of the University of Michigan (copyright info), Ann Arbor MI, USA, 2006	colorectalweb.org
Sawka 2012	Adjuvant radioactive iodine treatment for patients with early-stage papillary thyroid cancer	No	University Health Network, Toronto, Canada, 2009	—
Schroy 2011	Colorectal cancer screening	Yes	Schroy III, Boston, USA	Paul.schroy@bmc.org
Schwalm 2012	Coronary angiogram access site	Yes	Schwalm, Hamilton, ON, Canada, 2009	www.phri.ca/workfiles/studies/presentations/PtDA%20Vascular%20Access%2023-May–2012.pdf
Schwartz 2001	Breast cancer genetic testing	No	Schwartz/Lerman, Washington DC, USA, 1997	—
Schwartz 2009a	BRCA mutation prophylactic surgery	No	Schwartz, Washington DC, USA	—
Sheridan 2006	Cardiovascular prevention	Yes	Sheridan, Chapel Hill, NC, USA	www.med-decisions.com/cvtool/
Sheridan 2011	Coronary heart disease prevention	Yes	Sheridan, University of North Carolina at Chapel Hill, Division of General Internal Medicine, North Carolina, USA, 2011	www.med-decisions.com/h2hv3/
Shorten 2005	Birthing options after previous caesarean	Yes (updated 2006)	Shorten, Wollongong, AU, 2000	ashorten@uow.edu.au or www.capersbookstore.com.au/product.asp?id=301
Shourie 2013	Measles mumps and rubella vaccination	Yes	University of Leeds, UK & NSIRS Australia	www.leedsmmr.co.uk
Smith 2010	Bowel cancer screening	Yes	Smith, Sydney, AU 2008	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php

Table 1. Decision aids evaluated in the trials *(Continued)*

Stacey 2014a	Osteoarthritis of the hip and knee	No	Informed Medical Decisions Foundation and Health Dialog; USA	www.healthdialog.com
Steckelberg 2011	Colorectal cancer screening	Yes	Steckelberg, Hamburg, Germany	—
Taylor 2006	Prostate cancer screening	Yes	Georgetown University Medical Center, Washington DC, USA, 2000	Obtained from author taylorkl@georgetown.edu
Thomson 2007	Atrial fibrillation treatment	Yes	Thomson, Newcastle Upon Thyne, UK	Disc sent by mail
Trevena 2008	Colorectal cancer screen	Yes	Trevena, Sydney, AU	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
Van Peperstraten 2010	Embryos transplant	Yes	Radboud University Nijmegen Medical Centre; 2006	www.umcn.nl/ivfda-en
Vandemheen 2009	Cystic Fibrosis referral transplant	Yes	Aaron, Ottawa ON, CA, 2009 (last update 2011)	decisionaid.ohri.ca/decaids.html#cfda
Vodermaier 2009	Breast cancer surgery	Yes	Vodermaier, Vancouver BC, CA	Received by email (in German)
Volk 1999	Prostate cancer screening	Yes	Informed Medical Decisions Foundation, MA, USA, 1999	informedmedicaldecisions.org/imdf_decision_aid/deciding-if-the-psa-test-is-right-for-you/
Vuorma 2003	Menorrhagia treatment	No	Vuorma, Helsinki Finland, 1996	—
Watson 2006	Prostate cancer screening	Yes	Oxford, UK	Included in publication
Weymiller 2007	Diabetes mellitus type 2 treatment	Yes	Montori, Rochester MN, USA	mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm
Williams 2013	Prostate cancer screening	Yes	Georgetown University, Washington, DC, USA	Obtained from author taylorkl@georgetown.edu
Whelan 2003	Breast cancer chemotherapy	Yes	Whelan, Hamilton CA, 1995	Included in publication
Whelan 2004	Breast cancer surgery	Yes	Whelan, Hamilton CA, 1997	Included in publication
Wolf 1996	Prostate cancer screening	Yes	Wolf, Charlottesville VA, USA, 1996	Script in publication
Wolf 2000	Colon cancer screening	Yes	Wolf, Charlottesville VA, USA, 2000	Script in publication
Wong 2006	Pregnancy termination	No	Bekker, Leeds, UK, 2002	—

Table 2. Knowledge

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Bozic 2013	Decision quality instrument, 19 items re knowledge (> 50%)	After 1st consultation with surgeon	60	58.3%	60	33.3%	P = 0.01
Evans 2010	12 true or false questions; scores ranging from −12 to 12	Immediately post	89	4.9	103	2.17	P < 0.001
Fagerlin 2011	Insufficient (≤ 50% correct)	Immediately post	383	31.8%	102	93.1%	P < 0.001
	Sufficient	Immediately post	383	61.9%	102	6.9%	—
Fraenkel 2012	Open-ended questions about medication options to reduce stroke - knows medications	Postintervention	66	61%	62	31%	OR 3.5 (95% CI: 1.6 to 7.7, P = 0.001)
	Open-ended questions about side effects of medications - knows side effects	Postintervention	53	49%	46	37%	OR 1.9 (95%CI: 0.9 to 4.0; P = 0.07)
Hamann 2006	7-item multiple choice knowledge test (unable to standardize results)	On discharge (˜ 1 month)	49	15 (4.4 SD)	58	10.9 (5.4 SD)	P = 0.01
Heller 2008	12-item multiple choice	Pre-operatively	66	14%*	67	8%*	*mean increase from baseline P = 0.02
LeBlanc 2015 (in consultation)	13-item questionnaire (median, IQR) total score	Immediately post	32	7 (4.5 to 9.0)	45	5.5 (2.5 to 8.0)	P = 0.11
	9-items knowledge based on decision aid	Immediately post	32	6 (3.5 to 6.5)	45	4 (2.0 to 8.0)	P = 0.01
Legare 2008a	10-item yes/no/unsure general knowledge test about natural health products (not specific to outcomes of options)	Change scores from baseline to 2 weeks	43	0.86 ± 1.77 P = 0.002	41	0.51 ± 1.47 P = 0.031	No difference between groups (P = 0.162)

Table 2. Knowledge *(Continued)*

Mann D 2010 (in consultation)	14-item survey	Immediately post	—	—	—	—	No difference in level of knowledge between groups
Mathers 2012	Correctly answers question about best option to lower blood sugar	6 months postintervention	95	51.6%	80	28.8%	P < 0.001
	Correctly answers question about best option to lower complications	6 months postintervention	95	31.0%	80	29%	P = 0.90
Mathieu 2007	9-item - 4 concept questions and 5 numeric questions	—	351	—	357	—	Significantly higher mean increase for the intervention group (2.62) compared to control group (0.68) from baseline, P < 0.001
Miller 2005	8-item survey	2-week, 2-month, and 6-month follow-ups	—	—	—	—	Intervention type had no impact on general or specific knowledge
Nagle 2008	Good level knowledge was scored higher than the mid point of the knowledge scale (greater than 4)	—	—	—	—	—	88% (147/167) in DA group compared to 72% (123/171) pamphlet group. OR 3.43 (95% CI 1.79 to 6.58)
Ozanne 2007 (in consultation)	Change in knowledge from baseline	Post-test	15	48% to 64%	15	45% to 57%	change in knowledge score was significant for decision aid (P = 0.01) but not control (P = 0.13)
Partin 2004	10-item knowledge index score	2 weeks	308	7.44	290	6.9	P = 0.001
Rubel 2010	24-items adapted from existing prostate cancer knowledge measures	Immediately post	100	—	100	—	The total mean standardized knowledge score was 84.38 (SD 12.38)
Trevena 2008	Adequate knowledge (positive score: understanding benefits/harms)	1 month	134	28/134	137	8/137	P = 0.0001

Table 2. Knowledge *(Continued)*

Watson 2006	12-item true/false/don't know	Post-test	468	75% (range 0 to 100)	522	25% (range 0 to 100)	P < 0.0001
Weymiller 2007 (in consultation)	14-item - 9 addressed by decision aid; 5 were not	Immediately post	52		46	—	Mean difference between groups 2.4 (95% CI 1.5 to 3.3) P < 0.05 (when decision aid administered during the consultation only - not if prior to the consultation)

CI: confidence interval; **DA**: decision aid; **OR**: odds ratio; **SD**: standard deviation.

Table 3. Accurate risk perceptions

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Fraenkel 2012	Accuracy of stroke risk (reported by taking the absolute value of the difference between the participant's risk as estimated by the DA and the estimate provided by the participant - out of 100; lower score indicates more accurate estimation of risk)	Postintervention	69	9.1 (SD 13.3)	66	14.2 (SD 13)	P = 0.002
	Accuracy of bleeding risk (reported same as above)	Postintervention	69	8.7 (SD 12.5)	66	13.1 (SD 12.2)	P = 0.004
Hanson 2011	Expectation of benefit index 11 items score from 1 to 4 with lower score indicating better knowledge	Post (after reviewing DA)	127	2.3	129	2.6	P = 0.001
Kuppermann 2014	Correct estimate of amniocentesis miscarriage risk	3-6 months postintervention	357	263 (73.8%)	353	208 (59.0%)	P < 0.001
	Correct estimate of Down syndrome risk	3-6 months postintervention	357	210 (58.7%)	353	163 (46.1%)	P = 0.001

Table 3. Accurate risk perceptions *(Continued)*

Mann E 2010	3 of 8 multiple choice items in the knowledge test (question 4, 5, 7)	2 weeks post	—	—	—	—	Total knowledge reported only
Mathieu 2010	5 item numerical questions (max = 5)	Post	113	3.02	189	2.45	P < 0.001
Miller 2005	—	2-week, 2-month, and 6-month follow-ups	—	—	—	—	Intervention type had no impact on risk perceptions
Smith 2010	8 numerical questions (max = 8)	—	357	2.93 (SD 2.91)	173	0.58 (SD 1.28)	P < 0.001
Weymiller 2007 (in consultation)	—	Immediately	52	—	46	—	Difference between group OR 22.4 (95% CI 5.9 to 85.8) when decision aid administered during the consultation only (not if prior to) OR 6.7 (95% CI 2.2 to 19.7) when the decision aid administered prior to or during the consultation

CI: confidence interval; **DA**: decision aid; **OR**: odds ratio; **SD**: standard deviation.

Table 4. Values congruent with chosen option

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Arterburn 2011	Percent match procedures described by Sepucha et al (2007; 2008). For values items were most predictive and used to specify logistic models to estimate predicted probability of selecting surgery > 0.5.	Postintervention	75	—	77	—	The intervention group experienced a more rapid early improvement in value concordance immediately after the intervention compared to control

Table 4. Values congruent with chosen option *(Continued)*

Berry 2013	Concordant when men reported:a) sexual function influenced decision and they had radiation therapy; b) bowel function influenced decision and they had surgery; c) all effects influenced decision and they had surveillance	6 months postintervention	239	—	209	—	No difference OR = 0.82; 95% CI 0.56 to 1.2
Frosch 2008a	Concordance between participant's preferences and values for potential outcomes related to the decision and the choice made	within weeks	155	—	151	—	Men assigned to the decision aid who chose not to have a PSA test rated their concern about prostate cancer lower than did men who requested a PSA test. Men assigned to usual care provided similar ratings of concern about prostate cancer regardless of their PSA decision. There was no statistically significant difference between groups.
Legare 2008a	—	—	—	—	—	—	Women valuing of non-chemical aspect of natural health products was positively associated with their choice of nature health products, P = 0.006. No difference between groups
Lerman 1997	Association between values and choice	—	—	—	—	—	No difference; between-group differences were not reported
Vandemheen 2009	Congruence between personal values and decision	3 weeks	70	—	70	—	Patient choices were consistent with their values across both randomized groups

DA: decision aid; **SD**: standard deviation.

Table 5. Decisional Conflict Score

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes

Table 5. Decisional Conflict Score *(Continued)*

Arterburn 2011	Total decisional conflict- change from baseline (standardised values)	Immediately post	75	Mean −20 SD 19.44	77	Mean −11.8 SD 22.83	P = 0.03
Berry 2013	Decisional conflict scale	Uncertainty	—	−3.61 units	—	—	P = 0.04
		Uninformed	—	—	—	—	No significant difference
		Unclear values	—	−3.57 units	—	—	P = 0.002
		Unsupported	—	—	—	—	No significant difference
		Ineffective decision	—	—	—	—	No significant difference
		Total	—	−1.75 units	—	—	P = 0.07
Fagerlin 2011	Decisional conflict scale	Immediately post	—	—	—	—	DCS was higher in the intervention group compared to control, P < 0.001.
Frosch 2008a	Decisional conflict - subscales only	Feeling uninformed	155	23.37	151	29.68	P < 0.05
		Feeling unclear values	155	32.25	151	37.93	P < 0.05
		Feeling supported	155	30.51	151	35.21	P < 0.05
		Feeling uncertain	155	—	151	—	No difference
		Effective decisions	155	—	151	—	No difference
Knops 2014	Decisional conflict (total score)	4 months	73	19 SD 14	81	22 SD 17	No difference
		10 months	73	21 SD 17	81	18 SD 17	No difference
Krist 2007	Decisional conflict	Immediately after office visit	196	1.54	75	1.58	No difference

Table 5. Decisional Conflict Score *(Continued)*

LeBlanc 2015 (in consult)	Decision conflict (overall) median, IQR	Immediately post	28	10.9 (95% CI 1.6 to 26.6)	36	22.7 (95% CI 7.8 to 28.5)	P = 0.18
	Informed subscale	Immediately post	28	4.2 (95% CI 0 to 25)	36	20.8 (95% CI 0 to 33.3)	P = 0.14
	Values subscale	Immediately post	28	16.7 (95% CI 0 to 25)	36	25.0 (95% CI 8.3 to 33.3)	P = 0.25
	Support subscale	Immediately post	28	8.3 (95% CI 0 to 25)	36	16.7 (95% CI 0 to 25)	P = 0.35
	Certainty subscale	Immediately post	28	8.3 (95% CI 0 to 25)	36	25 (95% CI 0 to 25)	P = 0.3
	Effectiveness sub-scale	Immediately post	28	12.5 (95% CI 0 to 25)	36	18.8 (95% CI 0 to 25)	P = 0.15
Legare 2012 (in consult)	Decisional conflict - proportion who had a value of 2.5 or more on the 1−5 DCS. (n,%)	Immediately post	163	4.6% (95% CI 2.6 to 7.4)	165	6.3% (95% CI 0 to 12.8)	Absolute difference 1.7; RR 0.8 (95% CI 0.2 to 2.4)
Leighl 2011	Decisional conflict scale median (range)	1-2 weeks postin-tervention	107	26 (range 0-79)	100	26 (range 0-67)	No difference
Mathieu 2010	Based on approach-es suggested by Marteau et al. (in-formed choice)	Immediately after intervention	91	71%	110	64%	P = 0.24
Ozanne 2007 (in consult)	Decisional conflict	Postconsultation	15	—	15	—	Both groups showed lower decision-al conflict postconsultation (P < 0.001) but no difference between groups
Rubel 2010	Decisional conflict	Immediately post	—	—	—	—	The total mean score was 24.5 with a SD of 15.25 (N = 200)
Schwartz 2009a	Decisional conflict	12 of 16 items of the original scale	—	—	—	—	Significant longitudinal impact of the decision aid was moderated by base-line decision status; decision aid led

Table 5. Decisional Conflict Score *(Continued)*

							to significant decreases in decisional conflict for those who were undecided at the time of randomisation
Thomson 2007 (in consult)	Decisional conflict	Postconsultation	53	—	56	—	Difference between decision aid and control group were −0.18 (95% CI −0.34 to −0.01). P = 0.036
		3-months post	51	—	55	—	Difference between decision aid and control group were −0.15 (95% CI −0.37 to 0.06), no significant difference
Van Peperstraten 2010	15 item questionnaire (1-5) - satisfaction-uncertainty	Postintervention, pre IVF	124	72.5	128	75	P = 0.76
	15 item questionnaire (1-5) - informed (includes some items from DCS)	Postintervention, pre IVF	124	77.5	128	87.5	P = 0.001
Weymiller 2007 (in consult)	Decisional conflict	Immediately post	52	—	46	—	Mean difference indicates statistically significantly lower decisional conflict for decision aid compared to usual care. Total DCS −10.6 (95% CI −15.4 to −5.9) Uncertain −12.8 (95% CI −18.4 to −7.3) Informed −17.3 (95% CI −22.6 to −12.0) if administered during consult −6.6 (95% CI −14.3 to −1.1) if administered prior to consult Values clarity −8.5 (95% CI−15.7 to −1.3) Support −9.4 (95% CI −14.8 to −3.9) Effective decision −10.0 (95% CI −15.0 to −5.0)

CI: confidence interval; **DA**: decision aid; **DCS**: decisional conflict scale; **IVF**: in vitro fertilisation; **SD**: standard deviation.

Table 6. Decisional Conflict Score - low literacy version

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Fraenkel 2012	Informed	Immediately post	69	13.0	66	24.8	P = 0.01
	Values	Immediately post	69	6.4	66	21.0	P <.001
Smith 2010	Total DCS	2 week follow-up	357	13.63 (SD 20.55)	173	14.91 (SD 18.34)	P = 0.02
Taylor 2006	Total DCS	Used 8 of 10 items only 1 month post	80	24.1% high	74	41.9% high	Results were dichotomized (items removed choosing without pressure from others; know what options are available to you)
Williams 2013	Total DCS	2 months post	153	27.5%	136	38.2%	Significant decrease for DA group compared to usual care in the home condition site
		13 months post	153	38.6%	136	31.6%	No difference

DA: decision aid; **DCS**: decisional conflict scale; **SD**: standard deviation.

Table 7. Decisional Conflict Score - SURE test

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Stacey 2014a	SURE tool Item: 'Feels sure about the best choice'	Postintervention; prior to surgical consult	65	72.3%	66	80.3%	No difference
	'Knows the benefits and harms . . .'	Postintervention; prior to surgical consult	65	92.3%	66	66.7%	No difference
	'Clear about which benefits and harms . . .'	Postintervention; prior to surgical consult	65	87.7%	66	74.2%	No difference
	'Has enough support and advice . . .'	Postintervention; prior to surgical consult	65	76.9%	66	77.3%	No difference

Table 7. Decisional Conflict Score - SURE test *(Continued)*

	Total SURE score	Postintervention; prior to surgical consult	65	69.2%	66	57.6%	No difference

Table 8. Patient-clinician communication

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Fraenkel 2012	Discussed risk of stroke	Immediately post	69	71%	66	12%	P < 0.001
	Discussed risk of major bleeding	Immediately post	69	69%	66	20%	P < 0.001
Hanson 2011	Discussed feeding with physician, nurse clinician, or physician's assistant	3 months	126	46%	127	33%	P = 0.04
	Discussed feeding with other nursing home staff	3 months	126	64%	127	71%	P = 0.42
Hess 2012 (in consult)	OPTION scale	Analysis of the consultation using video-recordings	101	Mean 26.6% (95% CI 24.9 to 8.2)	103	Mean 7% (95% CI 5.9 to 8.1)	Significantly greater in the intervention arm
LeBlanc 2015 (in consult)	OPTION scale	Analysis of the consultation using video-recordings	25	Mean 57% (95% CI 50 to 64)	13	Mean 43% (95% CI 37 to 48)	P = 0.001
Lepore 2012	Discussed PSA testing with physician postintervention	8 months postintervention	215	15.8%	216	8.3%	P < 0.001
Montori 2011 (in consult)	OPTION 100-point scale	Analysis of the consultation using video-recorded consultations	38	49.8	32	27.3	P < 0.001
Mullan 2009 (in consult)	OPTION scale	Analysis of the consultation using video-recorded consultations	48 used decision aid within consultation	Mean 49.7% (SD 17.74)	37 usual care	Mean 27.7% (SD 11.75)	MD 21.8 (95% CI 13.0 to 30.5) for decision aid vs usual care. All but 2 of the 12 items significant-

Table 8. Patient-clinician communication *(Continued)*

							ly favoured the decision aid
Sheridan 2006	Discussed CHD with doctor	Patient reported Immediately post	16/41 decision aid pre-consult with summary report to bring to consult	—	8/34 usual care	—	Absolute difference 16% (95% CI −4 to 37)
	Plan to reduce CHD risk and discussed with doctor	Patient reported Immediately post	15/41 decision aid pre-consult with summary report to bring to consult	—	8/34 usual care	—	Absolute difference 13% (95% CI −7 to 34).
	Plan to reduce CHD risk and not discussed with doctor	Patient reported Immediately post	37/41 decision aid pre-consult with summary report to bring to consult	—	25/34 usual care	—	Absolute difference 16% (95% CI −1 to 33)
Sheridan 2011	Had CHD discussion with provider	Patient reported Immediately post	79	89%	78	58%	Absolute difference 31% (95% CI 15 to 45; P < 0.001)
	Patient-raised discussion	Patient reported Immediately post	79	63%	78	35%	Absolute difference 28% (95% CI 9 to 45; P = 0.02)
	Modified Healthcare Climate Questionnaire: 1. "My provider provided me with choices and options about lowering my chances of heart disease"	Patient reported Immediately post	79	91%	78	76%	Absolute difference 15% (95% CI −0.1 to 31; P = 0.02)
	2. "My provider understands how I see things with respect to lowering my chances of heart disease."	Patient reported Immediately post	79	95%	78	86%	Absolute difference 9% (95% CI −7 to 25; P = 0.21)

Table 8. Patient-clinician communication *(Continued)*

	3. "My provider conveyed confidence in my ability to make changes regarding lowering my chances of heart disease"	patient reported Immediately post	79	88%	78	77%	Absolute difference 11% (95% CI −5 to 27; P = 0.15)
	4. "My provider encouraged me to ask questions"	Patient reported Immediately post	79	78%	78	67%	Absolute difference 11% (95% CI −4% to 27%; P = 0.13)
	5. "My provider listened to how I would like to do things"	Patient reported Immediately post	79	92%	78	71%	Absolute difference 21% (CI 95% 6 to 37; P < 0.01)
	6. "My provider tried to understanding how I see things before suggesting new ways to lower my chances of heart disease."	Patient reported Immediately post	79	84%	78	69%	Absolute difference 15% (CI 95% −0.3 to 31; P = 0.05)
Weymiller 2007 (in consult)	OPTION Scale	Analysis of the consultation using video-recorded consultations	1/2 used decision aid prior to consult and 1/2 used it during consult	—	Usual care	—	Greater patient participation MD 4.4 (95% CI 2.9 to 6.0) in decision aid compared to usual care

CHD: coronary heart disease;**CI**: confidence interval; **DA**: decision aid; **DCS**: decisional conflict scale; **ICC**: intraclass correlation coefficient;**MD**: mean difference; **OPTION scale**: observing patient involvement scale; **RR**: risk ratio; **SD**: standard deviation

Table 9. Participation in decision making

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Allen 2010	Control preferences - patients choosing active/collaborative decision making	Postintervention	291	95%	334	92%	No difference
	Control preferences did not change	Postintervention	291	92%	334	87%	No difference

Table 9. Participation in decision making *(Continued)*

	Control preferences changed to passive	Postintervention	291	3%	334	5%	No difference
	Control preferences changed to active/ collaborative	Postintervention	291	3%	334	7%	No difference
Hamann 2006	COMRADE used to measure patients' perceived involvement in decisions	Postconsultation	49	79.5 (SD 18.6) 76.8 (SD 20.9)	58	69.7 (SD 20.0) 73.5 (SD 19.3)	Increased patient involvement in decision aid group postintervention compared to usual care at baseline. At discharge there was no difference between groups.
Hanson 2011	Surrogates feeling somewhat or very involved in decision making	Postintervention	—	83%	—	77%	P = 0.18
Leighl 2011	Achieved decision involvement	Postintervention	—	32%	—	35%	No difference
Loh 2007 (in consult)	Patients' perceived involvement in decision making	Postconsultation	191	26.3 pre 28.0 post	96	24.5 pre 25.5 post	Improved patient participation from baseline to post exposure to the decision aid (P = 0.010) and in comparison to the usual care group (P = 0.003) but there was no change in the control group for the pre-post comparison
Rubel 2010	Adapted from the Control Preferences Scale	Postintervention	—	—	—	—	The total mean scores were: 2.74 (SD 1.25) (N = 99) pre and 2.83 (SD 1.16) (N = 199) post, no statistically significant difference
Sheridan 2011	Patient participation: 'Any'	Immediately post	79	79%	78	51%	Absolute difference 28% (95% CI 9 to 45; P = 0.01)
	'None'	Immediately post	79	21%	78	49%	Absolute difference −28% (95% CI −45 to −9)
Van Peperstraten 2010	Decision Evaluation scale (15 item questionnaire) Decision control subscale	Postconsultation	124	85	128	87.5	P = 0.33

DA: decision aid; **SD**: standard deviation.

Table 10. Proportion undecided

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Kasper 2008	Single item - ranging from '0 = completely undecided' to '100 = made my decision'	—	—	—	—	—	No difference
Sawka 2012	Answer "I don't know" to question "I favor taking adjuvant radioactive iodine"	Immediately post - treatment preference	37	10.8%	37	21.6%	—
		6.3 months (mean) post - actual decision	37	13.5%	37	8.1%	—
	Answer "I don't know" to question "I favor not taking adjuvant radioactive iodine"	Immediately post - treatment preference	37	43.2%	37	37.8%	—
		6.3 months (mean) post - actual decision	37	40.5%	37	51.4%	—

DA: decision aid

Table 11. Satisfaction with the choice

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Heller 2008	1-item; pleased with treatment choice	1 month post-surgery	62/66	—	55/67	—	P = 0.03
Legare 2012 (in consult)	Single question Likert scale to assess the quality of the decision made (0 = very low quality; 10 = very high quality)	Immediately post	162	8.54 (SD 1.56)	159	8.53 (SD 1.51)	No difference; MD 0.0 (95% CI −0.4 to 0.4)
Leighl 2011	Satisfaction with decision scale: median (range)	1 month postintervention	107	22 (13-25)	100	21(15-25)	No difference

Table 11. Satisfaction with the choice *(Continued)*

Marteau 2010	Scale: ranging from 1−7 and standardized out 100	4 weeks	—	91.17 (SD 14)	—	91.33 (SD 14.50)	No difference
Schwartz 2009b	6-item	1, 6, 12 months	100	—	114	—	Overall, no difference between groups; decision aid led to significantly increased satisfaction compared to usual care among those who were undecided at randomization but not among those who had made a decision before randomization; (only graph in paper with no raw data)
Taylor 2006	Single item - "Are you satisfied with your decision about prostate cancer testing?	1 month	80	79.7%	74	75.7%	—
Trevena 2008	Satisfaction with the decision	Immediately post	134	—	137	—	No difference (P = 0.56)
Williams 2013	6-item Satisfaction with Decision Scale	Baseline	—	> 95%	—	> 95%	—

DA: decision aid.

Table 12. Satisfaction with the decision-making process

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Satisfaction with the decision-making process							
Hess 2012 (in consult)	Satisfaction with decision process (0 for strongly agree to 5 for strongly disagree)	—	101	—	103	—	Patients in DA group reported greater satisfaction with the DM process (strongly agree, 61% DA vs 40% usual care)
Vodermaier 2009	Satisfied with process	1 week follow-up	53	42	56	50	High satisfaction with no difference by group

Table 12. Satisfaction with the decision-making process *(Continued)*

Satisfaction with participating in decision making							
Kennedy 2002	Measured satisfaction with opportunities to participate in decision making using a single item	—	—	—	—	—	Compared to usual care, women who received the decision aid followed by nurse coaching were significantly more satisfied with the opportunities to participate in decision making (OR 1.5, 95% CI 1.1 to 2.0).
Satisfaction with the information provided							
LeBlanc 2015 (in consult)	Amount of information was just right	Postconsultation	29	25 (86%)	37	34 (92%)	P = 0.69
	Information received was clear	Postconsultation	27	17 (63%)	36	26 (72%)	P = 0.43
	Information received was helpful	Postconsultation	28	21 (75%)	34	23 (68%)	P = 0.53
	Would recommend method to others	Postconsultation	28	24 (86%)	35	27 (77%)	P = 0.52
Laupacis 2006	Satisfaction with information received subscale 4-item (0 to 100; low to high)	Average 10 days	54	76 (15.5 SD)	56	59 (23.3 SD)	P = 0.001
Montori 2011 (in consult)	(7 point scales) *Participants' satisfaction with knowledge transfer* • Amount of information • Clarity of information • Helpfulness of the information • Would want other decisions • Recommend to others	Postintervention	49	6.6 6 6 6.1 6.4	46	6.3 6 5.8 5.8 6.2	P = 0.798 P = 0.296 P = 0.624 P = 0.248 P = 0.435
	Clinicians' satisfaction with knowledge transfer • Helpfulness of the information	Postintervention	39	5.8 6.1	33	5.2 4.9	P = 0.006 P < 0.001

Table 12. Satisfaction with the decision-making process *(Continued)*

	• Would want other decisions • Recommend to others			5.9		4.8	P < 0.001
Oakley 2006	Satisfaction with information about medicines	4 months post	16	10.4 (SD 2.9)	17	10.1 (SD 2.2)	No difference
Satisfaction with the clinician							
Laupacis 2006	Satisfaction with practitioner treatment during decision process subscale 4-item (0 to 100; low to high)	Average 10 days	54	69 (25.3 SD)	56	54 (26.7 SD)	P = 0.004
Miller 2005	Satisfaction with cancer information service 1-item (1 to 5; low to high)	2 weeks	—	4.37 (0.84 SD)	—	4.38 (0.86 SD)	No difference
		6 months	—	4.51 (0.75 SD)	—	4.51 (0.64 SD)	No difference
Vodermaier 2009	• Physician helped me understand • Physician understood important to me • Physician answered questions • Satisfied with involvement • Satisfied with physician's involvement	1 week follow-up	53	49 (92.5%) 47 47 44 36	56	53 (94.6%) 50 51 45 36	High satisfaction with no difference by group

DA: decision aid; **SD**: standard deviation.

Table 13. Preparation for decision making

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Fraenkel 2007	Preparation for Decision Making Scale	Pre-consultation	43	35 (median)	40	20.5 (median)	P < 0.001
Stacey 2014a	Preparation for Decision Making Scale item (5-point scale from: 1 not at all to 5 a great deal) 'Help recognize decision to be made'	Postintervention; pre-consultation	66	4.12 (SD 1.21)	64	3.78 (SD 1.25)	No difference
	Preparation for Decision Making Scale item	Postintervention; pre-consultation	66	4.48 (SD 0.85)	64	4.14 (SD 1.10)	No difference

Table 13. Preparation for decision making *(Continued)*

	'Help know decision depends on what matters most'						
	Preparation for Decision Making Scale item 'Help think about how involved you want to be in decision'	Postintervention; pre-consultation	66	4.48 (SD 0.81)	64	4.25 (SD 1.05)	No difference
	Preparation for Decision Making Scale item 'Prepare you to talk to your doctor about what matters most'	Postintervention; pre-consultation	66	4.36 (SD 0.91)	64	4.23 (SD 1.04)	No difference
Vandemheen 2009	Preparation for Decision Making Scale	3 weeks	70	65.1 (SD 24.9)	79	53.9 (SD 27.1)	P = 0.009

DA: decision aid; **SD:** standard deviation.

Table 14. Choice

Study	Type of comparison	N decision-aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Surgery - elective more minor surgery						
Hanson 2011	Actual choice (feeding tube)	127	1	129	3	No difference
Wong 2006	Actual choice (abortion)	—	—	—	—	No difference
Screening - breast cancer genetic testing						
Miller 2005	Preference	—	—	—	—	Intervention decreased intention for genetic testing in women at average risk; increased in women at high risk
Screening - breast screening						
Mathieu 2007	Actual choice	—	—	—	—	No difference in women who participated in screening within 1 month
Mathieu 2010	Preference of women who were decided	96	52%	127	65%	P = 0.05
Screening - cardiac stress testing						
Hess 2012 (in consult)	Actual choice	101	58%	100	77%	P < 0.001
Screening - diabetes						
Marteau 2010	Actual choice	633	353	639	368	P = 0.51
Mann E 2010	Preference	273	—	134	—	No difference
Screening - prenatal						
Bekker 2004 (in consult)	Actual choice	—	—	—	—	No difference
Nagle 2008	Actual choice	—	—	—	—	No difference
Screening - prostate cancer testing						
Frosch 2008a	Actual choice	—	—	—	—	The experimental interventions led to significant reductions in requests for prostate-specific antigen tests (˜2 times greater decline).
Lepore 2012	Actual choice 2 years postintervention	215	62.7%	216	66.7%	No difference Exp (B) = 0.829

Table 14. Choice *(Continued)*

						CI 95% 0.564 to 1.218
Williams 2013	Actual choice	—	—	—	—	No difference (P > 0.3)
Lepore 2012	Preference	215	80.9%	216	80.1%	No difference Exp (B) = 0.994 95% CI 0.614 to 1.610
Diagnostic testing - prenatal genetic testing						
Kuppermann 2014	Invasive diagnostic testing without screening test	357	11 (3.0%)	353	16 (4.6%)	P = 0.37
	Screening test followed by invasive diagnostic test	357	10 (2.9%)	353	27 (7.7%)	Not reported
Medication - antibiotics for upper respiratory infections						
Legare 2011 (in consult)	Actual choice	81	33	70	49	P = 0.08
Legare 2012 (in consult)	Actual choice	—	27.2%	—	52.2%	Absolute difference 25.0; RR 0.5 (95% CI 0.3 to 0.7)
Medication - atrial fibrillation anti-thrombosis - uptake						
Man-Son-Hing 1999	Actual choice	—	—	—	—	25% decrease in DA group, not statistically significant
McAlister 2005	Actual choice	—	—	—	—	No difference
Thomson 2007 (in consult)	Actual choice	—	93.8%	—	25%	RR 0.27 (95% CI 0.11 to 0.63)
Medication - breast cancer prevention						
Fagerlin 2011	Actual choice	383	0.5%	102	0%	No difference
Medication - cardiovascular disease prevention						
Sheridan 2011	DA versus usual care. Any effective CHD risk reducing strategy	79	63%	78	42%	Absolute difference 21%, 95% CI 5 to 37
	Blood pressure medication, if hypertensive (n = 55)	—	26%	—	29%	Absolute difference −3%, 95% CI −30 to 25
	Cholesterol medication, if abnormal cholesterol (n = 69)	—	39%	—	9%	Absolute difference 30%, 95% CI 14 to 46

Table 14. Choice *(Continued)*

	Smoking cessation, if smoking (n = 21)	—	80%	—	50%	Absolute difference 30%, 95% CI −16 to 76
	Aspirin, if CHD risk > 6% (n = 140)	—	43%	—	24%	Absolute difference 19%, 95% CI −1 to 39
	Diet low in saturated fat	79	29%	78	40%	Absolute difference −11%, 95% CI −27 to 6
	Regular exercise	79	53%	78	54%	Absolute difference −1%, 95% CI −17 to 16
Medication - chemotherapy						
Leighl 2011	For advanced cancer	107	77%	100	71%	No difference
Whelan 2003 (in consult)	For early breast cancer	—	—	—	—	No difference
Medication - diabetes management insulin						
Mathers 2012	Preference for insulin	92	18.5%	78	11.5%	P = 0.41
Medication - hypertension						
Montgomery 2003	Uptake	—	—	—	—	No difference
Medication - menopausal symptom treatment						
Murray 2001b	Uptake hormone therapy	—	—	—	—	8% decrease in DA group, not statistically significant
Legare 2008a	preference for natural health products		41%		41%	No difference
Medication - multiple sclerosis immunotherapy						
Kasper 2008	Uptake	—	—	—	—	No difference
Medication - osteoporosis						
LeBlanc 2015 (in consult)	Preference	29	12 (41%)	38	11 (29%)	P = 0.57
	Prescription during encounter	29	13 (41%)	38	12 (27%)	P = 0.2
Montori 2011 (in consult)	Uptake	52	44%	48	40%	No difference
Mental health treatment						
Hamann 2006	Uptake prescribed medication	—	—	—	—	No difference
Hamann 2006	Uptake psychoeducation	—	—	—	—	Higher uptake in DA group (P = 0.003)

Table 14. Choice *(Continued)*

Mott 2014	Uptake of 9 psychoeducation sessions	9	44%	11	9%	All 4 decision aid participants received 9 or more sessions. 1 of 5 usual care received 9 or more sessions.
Obstetrics - birth control method						
Langston 2010	Preference	114	—	108	—	No difference in the methods chosen between groups, participants in the intervention group were not more likely to initiate the requested method immediately compared to those in the usual care group (OR 0.65, 95% CI 0.31 to 1.34)
Obstetric - childbirth procedure						
Montgomery 2007	Uptake	—	—	—	—	No difference
Nassar 2007	Uptake	—	—	—	—	No difference
Shorten 2005	preference	—	—	—	—	No difference
Obstetric - embryo transplant						
Van Peperstraten 2010 - single embryo transfer	Uptake	152	43%	156	32%	P = 0.05
Other- lung transplant referral						
Vandemheen 2009		—	—	—	—	No difference
Other - pre-operative blood transfusion						
Laupacis 2006	Uptake	—	—	—	—	No difference
Other - pelvic organ prolapse treatment						
Brazell 2014	Uptake	—	—	—	—	No difference; P = 0.835
Other - thyroid cancer adjuvant radioactive iodine treatment						
Sawka 2012	Preferred treatment Immediately post	37	35.1%	37	32.4%	—
	Uptake at follow-up (˜ 6.3 months post)	37	29.7%	37	18.9%	No difference. (Chi^2=1.18; df = 1; P = 0.28)
Vaccines						

Table 14. Choice *(Continued)*

Chambers 2012	Uptake flu shot	48	46%	59	27%	No difference
Clancy 1988	Uptake hepatitis B	—	—	—	—	Significant increase of 76% in the DA group
Shourie 2013	Measles, mumps, rubella in infant	48	48 (100%)	71	70 (99%)	No difference

CHD: congenital heart disease;**DA**: decision aid; **OR**: odds ratio; **RR**: risk ratio.

Table 15. Adherence with chosen option

Reference	Scale used	N decision aid	Mean (SD) Decision aid	N comparison	Mean (SD) Comparison	Notes
Langston 2010	3 months - using a contraceptive method that was in the same effectiveness group as the method requested at enrolment, 'very effective', as chosen option - e.g. if chose sterilization and ended up using an IUD counted as adhering	48	85%	52	77%	P = 0.28 No difference in adherence to baseline choice
	3 months - using a contraceptive method that was in the same effectiveness group, 'effective', as chosen option	41	68%	31	68%	P = 0.96 No difference in adherence to baseline choice
LeBlanc 2015 (in consult)	Filled prescription (of those who were given prescriptions), n/N (%)	29	10/13 (83%) (1 missing)	38	4/12 (40%) (2 missing)	P = 0.07 No difference in adherence to baseline choice
	% of days covered out of 180 (median, 95% CI)	29	46.7% (95% CI 39.2 to 46.7)	38	85% (95% CI 55.3 to 92.6)	P = 0.08 No difference in adherence to treatment
Legare 2012 (in consult)	2 weeks post - single question asking if the patient maintained the decision made, n (%)	163	143 (87.7%)	165	150 (91.5%)	Absolute difference 3.8; RR 1.0 (95% CI 0.9 to 1.0) No difference in adherence to baseline choice
Lepore 2012	Congruence between intention to test and verified PSA test - 1 year	244	55.3%	246	58.1%	No difference in adherence to baseline choice. 95% CI 0.62 to 1.28
	Congruence between intention to test and verified PSA test - 2 year	244	59.0%	246	59.3%	No difference in adherence to baseline

Table 15. Adherence with chosen option *(Continued)*

						choice. 95% CI 0.69 to 1.42
Loh 2007 (in consult)	6-8 weeks - patient reported - 5-point Likert scale on steadiness of following the treatment plan: 1 = very bad to 5 = very good	191	4.3 (0.9)	96	3.9 (1.0)	No difference in adherence to treatment P = 0.073
	6-8 weeks - physician reported - 5-point Likert scale steadiness of following the treatment plan: 1 = very bad to 5 = very good	191	4.8 (0.6)	96	4.3 (1.1)	No difference in adherence to treatment P = 0.56
Mann D 2010 (in consult)	3 months - telephone administration of the 8-item Morisky adherence (7 yes/no items and 1 item with 5-point Likert scale to elicit behaviours such as skipping medicines when they have no symptoms)	—	—	—	—	No difference in adherence to treatment 70% reported good adherence to statins; no difference between groups
	6 months - telephone administration of the 8-item Morisky adherence (7 yes/no items and 1 item with 5-point Likert scale to elicit behaviours such as skipping medicines when they have no symptoms)	—	—	—	—	No difference in adherence to treatment 80% reported good adherence to statins; no difference between groups
Man-Son-Hing 1999	6 months - self-reported – measured % of participants taking therapy initially chosen	129	95.35%	134	93.28%	No difference in adherence to baseline choice P = 0.44
Mathers 2012	6 months - Self-reported. Measured % of patients who did not change their initially chosen treatment.	95	68.1%	80	56.3%	PtDA higher aderence to baseline choice P = 0.041
Montgomery 2003	˜ 3 years - self-reported – 6-item adherence questionnaire: from 'I take all my tablets at the same time of day' to 'I take hardly any of my tablets'	—	—	—	—	No difference to adherence to baseline choice or adherence to treatment
Montori 2011 (in consult)	6 months - percentage of participants that self-reported currently taking medication who have not missed 1 dose within last week	17	65%	19	63%	No difference in adherence to treatment P = 0.92
	6 months - percentage of participants who opted to take bisphosphonates who took their medication on more than 80% of the days for which it was prescribed, based on pharmacy records	23	100%	19	74%	No difference in adherence to baseline choice P = 0.009

Table 15. Adherence with chosen option *(Continued)*

Mott 2014	4 months - percentage of participants who engaged in psychotherapy sessions	9	44%	11	45%	—
	4 months - number of participants who engaged in 9 or more psychotherapy sessions	4	100%	5	20%	Adherence to treatment
Mullan 2009 (in consult)	6 months - pharmacy records - days covered (range)	48	97.5% (range 0 to 100)	37	100 (range 73.9 to 100)	Higher adherence to treatment for usual care AMD −8.88 (−13.6% to −4.14%) Statistically significant
	6 months - self-reported by telephone call – did not miss a dose in last week	41	76%	31	81%	No difference in adherence to treatment OR 0.74 (95% CI 0.24 to 2.32)
Oakley 2006	4 months - extent to which the participants' behaviour in taking medications coincides with the clinical prescription	16	10.4% (32) (improvement from baseline)	17	2% (26) (improvement from baseline)	No difference in adherence to treatment
Sheridan 2011	3 month - adherence to treatment					
	Any therapy promoted in decision aid	76	45 (59%)	73	25 (34%)	P < 0.01 DA group showed higher adherence to treatment
	Any therapy promoted in decision aid + others (e.g. diet or physical activity)	77	64 (83%)	77	52 (68%)	P = 0.02
	Aspirin	32	30 (94%)	19	11 (58%)	P < 0.01
	Cholesterol medicine	14	12 (86%)	6	5 (83%)	The intervention had little effect blood pressure or cholesterol medication, however, the sample sizes for these estimates were small and underpowered
	Blood pressure medicine	9	9 (100%)	12	11 (92%)	
	Stop smoking	8	25%	5	20%	No effect on smoking, although subgroups were small and underpowered

Table 15. Adherence with chosen option *(Continued)*

Trevena 2008	1 month - faecal occult blood test uptake	134	5.2%	137	6.6%	No difference in adherence to baseline choice P = 0.64
Weymiller 2007 (in consult)	3 months - self-reported – mailed surveys and telephone call to non-respondents On adherence to statin use: missed 1 dose or more within the last week	33	93.94%	29	79.31%	No difference in adherence to baseline choice or treatment when analysis adjusted by sex, cardiovascular disease, and number of medications

AMD: absolute mean difference; DA: decision aid; OR: odds ratio

Table 16. General quality of life

Reference	Timing	N decision aid	Mean Decision aid (SD)	Change from baseline	N comparison	Mean comparison (SD)	Change from Baseline	Notes
General health								
Barry 1997 (SF-36)	Baseline	104	67.2 (19.0)	—	123	71.1 (17.6)	—	P = 0.02
	3 months	—	—	−0.96 (1.41)	—	—	−3.59 (1.57)	
	6 months	—	—	−1.46 (1.41)	—	—	−4.93 (1.45)	
	12 months	—	—	0.61 (1.58)	—	—	−4.99 (1.44)	
Legare 2011 (percentage of people who felt they had a stable and better health, (SF-12))	2 weeks post	Not reported	94	+7	Not reported	85	−6	P = 0.08
Morgan 2000 (SF-36)	6 months post	72	62 (23)	+ 4.0	88	65 (20)	+ 7.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
Vuorma 2003 (RAND-36)	1 year	156	—	2.2	159	—	2.8	No difference
Physical function								
Barry 1997 (SF-36)	Baseline	104	81.9 (20.0)	—	123	83.0 (18.9)	—	P = 0.02
	3 months	—	—	−0.34 (1.61)	—	—	−1.81 (1.07)	
	6 months	—	—	0.10 (1.28)	—	—	−3.26 (1.37)	
	12 months	—	—	0.15 (1.40)	—	—	−3.74 (1.18)	
Knops 2014 (SF-12)	Baseline	91	45	—	87	44	—	—
	1 month	80	44	—	84	43	—	—
	4 months	80	43	—	84	43	—	—
	10 months	80	44	—	84	42	—	—

Table 16. General quality of life *(Continued)*

Legare 2012 (SF-12)	2 weeks post	160	49.4 (SD 7.5)	+ 0.08	162	48.16 (7.80)	+ 0.43	Absolute difference 1.2; MD 0.4 (95% CI −2.6 to 3.3)
Morgan 2000 (SF-36)	6 months post	72	67 (29)	+ 7.0	88	71 (24)	+ 10.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
Vuorma 2003 (RAND-36)	1 year	156	—	2.4	159	—	2.2	No difference
Bernstein 1998 (SF-12)	3 months post	61	38 (12.1)	+ 0.6	48	37.6 (10.6)	+ 3.8	No difference
Social function								
Barry 1997 (SF-36)	Baseline	104	90.6 (15.5)		123	91.7 (15.7)		P = 0.17
	3 months	—	—	0.34 (1.58)	—	—	−2.26 (1.36)	
	6 months	—	—	−0.05 (1.92)	—	—	−2.46 (1.45)	
	12 months	—	—	−1.46 (1.85)	—	—	−3.52 (1.71)	
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
McCaffery 2010 (SF-36)	2 weeks	77	84.7	—	71	82.1	—	P = 0.39
Vuorma 2003 (RAND-36)	1 year	156	—	5.2	159	—	7.1	No difference
Mental function								
Legare 2012 (SF-12)	2 weeks post	160	50.79 (SD 9.28)	−0.38	162	51.21 (8.36)	+ 2.7	Absolute difference 0.4; MD −1.9 (95% CI −4.9 to 1.1)
McCaffery 2010 (SF-36)	2 weeks	77	71.3	—	71	71.6	—	P = 0.46
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
Vuorma 2003 (RAND-36)	1 year	156	—	4.7	159	—	5.3	No difference
Bernstein 1998 (SF-12)	3 months post	61	49.1 (11.4)	0.0	48	48.9 (10.8)	+ 0.9	No difference

Table 16. General quality of life *(Continued)*

Role function								
Morgan 2000 (SF-36)	6 months post	72	62 (44)	+ 20.0	88	58 (43)	+ 15.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	P = 0.04
Vuorma 2003 (RAND-36)	1 year		—	9.2	—	—	6.3	No difference
Bodily pain								
Morgan 2000 (SF-36)	6 months post	72	81 (22)	+ 6.0	88	77 (24)	+ 5.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—		157	—		No difference
Vuorma 2003 (RAND-36)	1 year	156	—	6.5	159	—	6.2	No difference
Role emotional								
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
McCaffery 2010 (SF-36)	2 weeks	77	80.3	—	71	77.4	—	P = 0.61
Vuorma 2003 (RAND-36)	1 year	156	—	12.6	159	—	1.9	P = 0.01
Energy/vitality								
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
McCaffery 2010 (SF-36)	2 weeks	77	55.2	—	71	54.1	—	P = 0.09
Vuorma 2003 (RAND-36)	1 year	156	—	8.9	159	—	8.8	No difference
SF-3***6 all dimensions***								
McCaffery 2010 (SF-36)	2 weeks	77	47	—	71	46.3	—	P = 0.35
Murray 2001b (SF-36)	9 months	93	—	—	94	—	—	No difference
Murray 2001a (SP−36)	9 months	54	—	—	48	—	—	No difference
Health utilities								

Table 16. General quality of life *(Continued)*

Murray 2001a (Euroqol EQ-5D)	—	—	—	—	—	—	—	No difference
Murray 2001b (Euroqol EQ-5D)	—	—	—	—	—	—	—	No difference
Euroqol 5D - Health Thermometer (scale of 0 to 100)								
LeBlanc 2015	Postconsultation	29	85 (IQR 80, 95)	—	85 (IQR 73, 90)	—	—	P = 0.19

DA: decision aid; SF-36: Medical Outcomes Study 36-item Short-Form Health Survey; SF-12: 12-item Short-Form Health Survey; RAND-36: the 36-item short form survey from the RAND Medical Outcomes Study

Table 17. Condition-specific quality of life

Study	Outcome	Scale used	Timing	N decision aid	Decision aid mean change (SD)	N comparison	Comparison mean change (SD)	Notes
Barry 1997	Urinary symptoms	AUA Symptom Index (0 to 100)	3 months	104	−4.80% (1.74)	117	−1.40% (1.37)	No difference; trend toward DA
	Urinary symptoms	AUA	6 months	104	−3.66% (2.06)	117	−3.17% (1.77)	No difference
	Urinary symptoms	AUA	12 months	104	−2.51% (2.11)	117	−4.14% (1.66)	No difference; trend toward control
	Impact of symptoms	BPH Impact Index (0 to 100)	3 months	104	−6.58% (1.10)	117	−3.00% (1.05)	No difference; trend toward DA
	Impact of symptoms	BPH	6 months	104	−4.37% (1.32)	117	−3.89% (1.16)	No difference; trend toward DA
	Impact of symptoms	BPH	12 months	104	−5.53% (1.32)	117	−2.63% (1.32)	No difference; trend toward DA
Bernstein 1998	Satisfaction	SAQ (0 to 100)	3 months	61	+ 6.2%	48	+ 10.5%	Control significantly more satisfied

Table 17. Condition-specific quality of life *(Continued)*

	Angina stability	SAQ	3 months	61	+ 17.2%	48	+ 28.3%	No difference
	Angina frequency	SAQ	3 months	61	+ 5.5%	48	+ 15.3%	No difference
	Disease Perception	SAQ	3 months	61	+ 14.1%	48	+ 18.8%	No difference
	Physical Capacity	SAQ	3 months	61	−0.5%	48	+ 7.1%	No difference
Leighl 2011 (FACT-G) median (range)	Functional status at 1 month post	74	17 (6-28)	—	68	17.5 (7-28)	—	P = 0.02
	Physical function at 1 month post	74	21 (0-28)	—	68	20 (4-28)	—	No difference
	Role emotional at 1 month post	74	17 (0-20)	—	68	17(7-20)	—	No difference
Murray 2001a	Urinary symptoms	AUA symptom Index (0 to100)	—	—	—	—	—	No difference
Murray 2001b	Menopausal symptoms	MenQol	—	—	—	—	—	No difference
Protheroe 2007	Menorrhagia specific utility scale	(0 to 100)	6 months	60	59.3 (30.0)	56	50.9 (25.1)	P = 0.03 higher menorrhagia quality of life favouring DA group
Vuorma 2003	Inconvenience due to menstrual bleeding	(5 to 25)	1 year	156	10.4	159	10.5	No difference
	Menstrual pain	(0 to 12)	1 year	156	4.7	159	4.6	No difference

AUA: American Urological Association; **BPH**: benign prostatic hyperplasia; **DA**: decision aid; **SAQ**: Seattle Angina Questionnaire; **FACT-G**: Functional Assessment of Cancer Therapy-General.

Table 18. Other condition-specific health outcomes

Study	Outcome	Scale used	Timing	N decision aid	Decision aid outcome	N comparison	Comparison outcome	Notes

Table 18. Other condition-specific health outcomes *(Continued)*

Auvinen 2004	Death	—	5 years	104	41 (39%)	106	33 (31%)	No difference
	Disease-free survival	—	10 years	104	74 (70.8%)	106	66 (62.5%)	P = 0.14
	Biochemical failure (rising serum PSA)	—	5 years	100	42 (42%)	96	34 (35%)	P = 0.57
	Disease progression	—	5 years	97	31 (32%)	92	28 (30%)	P = 0.94
Knops 2014	Postoperative mortality	—	10 months	91	0 (0%)	87	0 (0%)	
	Postoperative major morbidity	—	10 months	91	0 (0%)	87	2 (6%)	P = .23
	Aneurysm rupture during watchful waiting	—	10 months	91	0 (0%)	87	3 (8%)	P = 0.12
Mathers 2012	HbA1c (change from baseline)	—	6 months	95	−0.37%	80	−0.24%	P = 0.12
Morgan 2000	No angina	CCVA	6 months	72	+ 49%	88	+ 48%	No difference
	Class I angina	CCVA	6 months	72	−1%	88	+ 6%	No difference
	Class II angina	CCVA	6 months	72	−23%	88	−26%	No difference
	Class III angina	CCVA	6 months	72	−26%	88	−28%	No difference
	Class IV angina	CCVA	6 months	72	0%	88	0%	No difference
Thomson 2007	Strokes or bleeds requiring admission	—	3 months	51	—	55	—	No strokes and no bleeds requiring admission. 1 bleed and 1 transient stroke both in control group that required GP consultation
Van Peperstraten 2010	Ongoing pregnancies (> 12 weeks gestation)	—	After 1st IVF cycle	152	—	156	—	32% of participants in the intervention group and 38% of participants in the control group had ongoing pregnancies, P = 0.25

Table 18. Other condition-specific health outcomes *(Continued)*

	Twin pregnancies (> 12 weeks gestation)	—	After 1st IVF cycle	152	—	156	—	4% of participants in intervention group and 6% of participants in control group had twin pregnancies, P = 0.33
Vuorma 2003	Inconvenience due to menstrual bleeding	(5 to 25)	1 year	156	10.4	159	10.5	No difference
	Menstrual pain	(0 to 12)	1 year	156	4.7	159	4.6	No difference

AUA: American Urological Association; **CCVA**: Canadian Cardiovascular Angina; **BPH**: benign prostatic hyperplasia; **DA**: decision aid; **SAQ**: Seattle Angina Questionnaire.

Table 19. Anxiety

Study	Timing	N decision aid	Mean decision aid (SD)	Change from baseline	N comparison	Mean comparison(SD)	Change from baseline	Notes
State Anxiety Inventory: < 30 days postintervention (standardized scores)								
Bekker 2004; prenatal screening	Immediately post	50	58.9 (16.6)	—	56	61.2 (13.7)	—	No difference
Evans 2010; PSA screening	Immediately post-DA	89	4.98	—	103	4.88	—	No difference P = 0.98
Fraenkel 2012; atrial fibrillation	Immediately post-DA	69	13.0	—	66	13.4	—	No difference P =0.48
Leighl 2011	Post consult, 1-2 weeks and 4 weeks post	—	—	—	—	—	—	No difference
Mathieu 2007; mammography screening	Immediately after	321	29.61	—	315	29.34	—	No difference
McCaffery 2010; HPV screening (state trait anxiety inventory)	2 weeks	77	10.5	—	71	10.6	—	No difference P = 0.25

Table 19. Anxiety *(Continued)*

Montgomery 2003; hypertension	Immediately post-DA	44	35.45 (10.52)	—	50	37.67 (13.92)	—	No difference
Montgomery 2007; previous cesarean section	37 weeks gestation	196	38.7 (12.2)	—	195	42.1 (12.2)	—	P = 0.016
Nassar 2007; breech presentation	1 week	98	41.4 (12.5)	—	90	44.4 (13.9)	—	No difference
Protheroe 2007; menorrhagia	2 weeks	59	11.6 (3.7)	—	61	12.2 (3.7)	—	P = 0.016
Rubel 2010; PSA screening	Immediately after 20 items adapted from state portion of State-Trait Anxiety Inventory Scale STAI - Form Y;	—	—	—	—	—	—	No difference Mean score = 1.66 (SD 0.59) (N = 200) for both groups
Smith 2010; bowel cancer screening	2-week follow-up	357	13.67	—	173	14.05	—	No difference P = 0.80
Thomson 2007; anti-thrombotic treatment for atrial fibrillation	Immediately after	53	—	—	56	—	—	Significant fall in anxiety (−4.57) but no difference between groups (P = 0.98)
Trevena 2008 colorectal cancer screening	Immediately after	134	—	—	137	—	—	No difference (P = 0.59)
Van Peperstraten 2010; number of embryos transferred	Immediately after	152	27.33%	—	156	24.5%	—	No difference P = 0.14
Whelan 2004; breast cancer surgery	7 days post-DA	94	42.3 (1.3)	—	107	41.9 (1.3)	—	No difference
Whelan 2003; breast chemotherapy	7 days post-DA	82	45.6	+ 2.2	93	47.4	+ 0.8	No difference

Table 19. Anxiety *(Continued)*

Wong 2006; pregnancy termination	Immediately post	154	54 (15.8)	—	159	54 (16.1)	—	No difference
State Anxiety Inventory: 1 month postintervention (standardized scores)								
Bekker 2004; prenatal screening	1 month post-DA	29	35.3 (12.5)	—	39	34.7 (14.8)	—	No difference
Davison 1997; prostate cancer treatment	5-6 weeks post-DA	30	35.5	−9.0	30	34.5	−2.5	No difference
State Anxiety Inventory: 3 months postintervention (standardized scores)								
Murray 2001a; benign prostatic hypertrophy	3 months post-DA	55	36.36 (14.99)	+2.4	48	32.08 (9.836)	+0.7	No difference
Murray 2001b; hormone replacement therapy	3 months post-DA	93	38.42 (10.83)	−0.5	95	40.53 (12.96)	+1.8	No difference
Nagle 2008; prenatal screening	˜1 to 12 weeks post-DA	167	37.2 (12.1)	—	171	37.36 (12.6)	—	No difference
Nassar 2007; breech presentation	3 months post-DA	86	29.2 (9.9)	—	84	30.8 (10.5)	—	No difference
Vuorma 2003; menorrhagia treatment	3 months post-DA	184	37.1	+1.0	179	35.9	−1.0	No difference
Whelan 2003; breast chemotherapy	3 months post-DA	82	36.0	—	93	37.8	—	No difference
State Anxiety Inventory: 6 months postintervention (standardized scores)								
Lepore 2012; prostate screening	8 months post-DA	215	9.6 (10.3)	—	216	10.3 (10.2)	—	No difference No condition by time interaction on anxiety. Low in both groups.
Protheroe 2007; menorrhagia	6 months post-DA	47	11.2 (4.2)	—	52	13.3 (4.9)	—	No difference P = 0.067

Table 19. Anxiety *(Continued)*

Whelan 2004; breast cancer surgery	6 months post-DA	94	39.3 (1.3)	—	107	38.9 (1.6)	—	No difference
Whelan 2003; breast chemotherapy	6 months post-DA	82	38.2	—	93	38.2	—	No difference
State Anxiety Inventory: 12 months postintervention (standardized scores)								
Whelan 2004; breast cancer surgery	12 months post-DA	94	37.5 (1.4)	—	107	36.6 (1.5)	—	No difference
Whelan 2003; breast chemotherapy	12 months post-DA	82	39.2	—	93	40.2	—	No difference
Anxiety subscale of the Hospital Anxiety and Depression Scale (HADS)								
Knops 2014; asymptomatic abdominal aortic aneurysm	1 month post-DA - (HADS standardized)	81	21.0 (17.1)	—	85	23.8 (19.1)	—	No difference P = 0.73
	4 months post-DA (HADS)	81	20.0 (19.1)	—	85	21.9 (17.6)	—	—
	10 months post-DA (HADS)	81	20.5 (20.0)	—	85	21.4 (20.5)	—	—
Lam 2013; breast cancer surgery	1 week post-DA Hospital Anxiety and Depression Scale (HADS standardized	101	25.2 (22.4)	—	97	24.8 (23.3)	—	No difference P = 0.655
	1 month postsurgery	101	11.9 (15.2)	—	97	12.4 (15.7)	—	No difference P = 0.859
	4 months postsurgery	91	10.5 (15.2)	—	88	10.0 (14.8)	—	No difference P = 0.908
	10 months postsurgery	88	12.9 (16.8)	—	90	13.3 (17.1)	—	No difference P = 0.553
Other measures indicating anxiety								
Chabrera 2015; prostate cancer	Seeking and using social support	61	22.3 (5.20)	+ 7.8	61	16.2 (5.44)	+ 1.8	P < 0.001

Table 19. Anxiety *(Continued)*

	Focusing on the positive	61	15.1 (6.93)	+ 0.3	61	16.2 (9.47)	+ 0.9	P < 0.001
	Behavioural escape-avoidance	61	23.7 (5.53)	+ 4.5	61	22.0 (4.22)	+ 1.2	P < 0.001
	Cognitive escape avoidance	61	11.7 (5.37)	+ 4.47	61	10.5 (4.65)	+ 1.84	P < 0.001
	Distancing	61	8.75 (3.90)	+ 1.85	61	8.54 (4.28)	+ 0.47	P < 0.001
Fraenkel 2012; atrial fibrillation	Worry about having a stroke over next 5 years (10 point scale - lower scores=less worry)	69	1.8 (SD 1.7)	—	66	1.6 (SD 1.6)	—	P = 0.47
	Worry about having a bleed over next 5 years (10 point scale - lower scores = less worry)	69	1.5 (SD 3.3)	—	66	1.9 (SD 3.2)	—	P = 0.24
Johnson 2006; endodontic treatment	Immediately post - single question 7-point Likert scale	32	3.2 (1.7)	—	35	3.8 (2.1)	—	P = 0.27
Lewis 2010; colorectal cancer screening	Intrusive thoughts - 3 items; 4 point scale - not at all	139	66.2%	—	157	68.0%	—	P = 0.92
	Intrusive thoughts - 3 items; 4 point scale - sometimes	66	31.4%	—	69	29.9%	—	
	intrusive thoughts - 3 items; 4 point scale - often	5	2.4%	—	5	2.2%	—	
McCaffery 2010	Intrusive thoughts - measured using 1 item from the impact of events scale	77	43%	—	71	32%	—	No difference
Smith 2010	Worry about developing bowel cancer - quite or very	357	6%	—	173	8%	—	P = 0.78

Table 19. Anxiety *(Continued)*

	Worry about developing bowel cancer - none or a bit	357	94%	—	173	92%	—

DA: decision aid; **HPV**: human papilloma virus; **PSA**: prostate-specific antigen.

Table 20. Depression

Study	Timing	N decision aid	Mean decision aid (SD)	Change from baseline	N comparison	Mean comparison (SD)	Change from Baseline	Notes
Davison 1997 (20-item CES-D)	5-6 weeks	30	29.8	−0.6	30	29.5	+ 1.3	No difference
Lam 2013 (Hospital and Anxiety Depression Scale)	1 week post-DA	101	16.7 (17.1)	—	97	16.7 (19.5)	—	No difference P = 0.849
	1 month postsurgery	101	11.0 (12.9)	—	97	11.0 (12.9)	—	No difference P = 0.649
	4 months post-surgery	91	10.0 (15.7)	—	88	9.0 (11.4)	—	No difference P = 0.637
	10 months post-surgery	88	6.7 (9.0)	—	90	11.9 (16.2)	—	P = 0.001
Loh 2007 (Brief Patient Health Questionnaire-D)	6 to 8 weeks	191	29.8 (2.7)	—	96	27.0 (3.6)	—	No difference P = 0.236
Nagle 2008 (Edinburgh Postnatal Depression Scale)	˜1-12 weeks post-DA	167	19 (11.6)	—	171	19 (11.2)	—	No difference
Van Peperstraten 2010 (Beck Depression Inventory)	After multifaceted intervention/ before IVF	126	16 (13%)	—	136	5 (4%)	—	P = 0.01
	At uptake of IVF	147	16 (11%)	—	151	113 (9%)	—	No difference

Table 20. Depression *(Continued)*

Whelan 2004 (20-item CES-D)	1 week post-DA	94	13.8 (1.0)	—	107	13.4 (1.1)	—	No difference
	6 months post-DA	94	15.1 (1.1)	—	107	14.2 (1.2)	—	No difference
	12 months post-DA	94	13.2 (1.3)	—	107	12.8 (1.2)	—	No difference

CES-D: Centre for Epidemiology Studies Depresion Scale; **DA**: decision aid; **IVF**: in vitro fertilization.

Table 21. Decisional regret

Author	Item	N decision aid	Proportion or mean (SD)	N control	Proportion or mean (SD)	Notes
Brazell 2014	Decision Regret Scale at 3 months postchoice	28	12.1 (18.5)	26	10 (20.1)	No difference P = 0.969
Hanson 2011	5-item Decisional Regret Index	126	11.9	127	14.3	No difference P = 0.14
Kupper-mann 2014	Decision Regret Scale (out of 100) at 3-6 months postintervention	357	8.29 (12.5)	353	6.83(10.8)	No difference P = 0.12; 95% CI 1.46 (−0.36 to 3.29)
Lam 2013	Decision Regret Scale at 1 month postsurgery	101	21.4 (17.2)	97	23.1 (18.3)	No difference Adjusted P = 1.0
	Decision Regret Scale at 4 months postsurgery	91	18.8 (15.8)	88	24.4 (18.9)	P = 0.026
	Decision Regret Scale at 10 months postsurgery	88	20.1 (14.5)	90	24.6 (18.8)	P = 0.014
Legare 2011	Proportion of patients with decisional regret	—	7%	—	9%	No difference P = 0.91
Legare 2012	Decision Regret Scale 2 weeks postconsultation	162	12.38(19.08)	164	7.59 (13.67)	No clinically significant difference; Absolute difference 4.8; MD 4.8 (95% CI 0.9 to 8.7)
Mathers 2012	Decision Regret Scale at 6 months postintervention	95	44.63	80	44.57	No difference P = 0.872

DA: decision aid.

Table 22. Confidence

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Allen 2010	11-item self-efficacy scale	Postintervention	291	83% (SD 40.26)	334	79% (SD 33.08)	No difference
Arterburn 2011	Decisional self-efficacy	Changes from baseline	75	+ 3.0 (95% CI 0.6 to 5.4)	77	+ 2.8 (95% CI 0.9 to 4.8)	No difference P = 0.78
Chambers 2012	Mean confidence with decision: scale from 1 (low confidence) to 5 (high confidence)	Postintervention	48	4	59	3.6	P = 0.02
Fraenkel 2007	Decisional self-efficacy scale	Pre-consultation	43	32 (median)	40	27 (median)	P = 0.001
Gattellari 2003	Perceived ability to make an informed choice 1-item; 5-point Likert scale	3 days post	106	—	108	—	P = 0.008; DA group more likely to agree that they could make an informed choice about PSA screening
Gattellari 2005	Perceived ability to make an informed choice 1-item; 5-point Likert scale	Immediately post	131	—	136	—	No difference
McBride 2002	Confidence with ability to understand outcomes of hormone therapy, make a decision, engage in discussion with practitioner, 3 items (0 to 10; low to high confidence)	1 month post	273	78% (18% SD)	284	70% (19% SD)	P < 0.001
		9 months post	261	80% (17%SD)	278	75% (20% SD)	P = 0.0004
Smith 2010	3 items adapted from the Decisional self-efficacy scale	2-week follow-up	357	4.67 (0.54 SD)	173	4.61 (0.62 SD)	No difference P = 0.26

CI: confidence interval; **DA**: decision aid; **SD**: standard deviation.

Table 23. Healthcare system effects

Study	Scale used	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Difference between groups	Notes
Consultation length							
Bekker 2004 (in consultation)	Consultation length using DA in the consultation (minutes)	50	32.2 (SD 13.0)	56	26.3 (SD 11.5)	+ 5.9 minutes	P = 0.01 (longer with decision aid)
Bozic 2013	Consultation length with practitioner post-DA (minutes)	61	20.9 (SD 6.8)	62	21.0 (SD 7.2)	−0.1 minutes	No difference; P = 0.91
Krist 2007	Time spent discussing prostate cancer with practitioner post-DA (minutes) - patient reported	196	5.3	75	5.2	+ 0.1 minutes	No difference between groups
	Time spent discussing prostate cancer with practitioner post-DA (minutes) - physician reported	196	3.8	75	4.2	−0.4 minutes	No difference between groups but physicians thought they spent less time than patients (P < 0.001)
LeBlanc 2015 (in consultation)	Consultation length with practitioner using DA in consultation (median, range in minutes)	29	11.5 (5.4 to 21.4)	37	10.7 (2.5 to 54.9)	+ 0.8 minutes (−33.6 to 3.0)	—
Loh 2007 (in consultation)	Consultation length using DA in consultation (minutes)	191	29.2 (10.7)	96	26.7 (12.5)	+2.5 minutes	P = 0.681
Ozanne 2007 (in consultation)	Consultation length using DA in consultation (minutes)	15	24	15	21	+3 minutes	P = 0.42
Thomson 2007 (in consultation)	Consultation length using DA in consultation (minutes)	8	44 (39 to 55)	10	21 (19 to 26)	+23 minutes	P = 0.001 Compared computerized decision aid with standard gamble within the consultation to guideline driven consultation

Table 23. Healthcare system effects *(Continued)*

Vodermaier 2009	Consultation length with practitioner post-DA						
	5 to 10 min	53	6 (11.3%)	54	5 (9.3%)	—	P = 0.91
	10 to 15 min		17 (32.1%)		19 (35.2%)	—	
	15 to 25 min		15 (28.3%)		14 (25.9%)	—	
	25 to 35 min		7 (13.2%)		5 (9.3%)	—	
	Above 35 min		8 (15.1%)		11 (20.4%)	—	
Whelan 2003 (in consultation)	Consultation length using DA in consultation (minutes)	50	68.3	50	65.7	+ 2.6 minutes	P = 0.53
Weymiller 2007 (in consultation)	Consultation length using DA in consultation (minutes)	52	—	46	—	+ 3.8 minutes in DA group	Not statistically significant 3.8 min (95% CI −2.9 to 10.5)
Cost and resource use							
Hollinghurst 2010; Montgomery 2007	Total costs in the UK for decision about mode of delivery post previous cesarean	235	GBP 2019 (SD 741)	238	GBP 2033 (SD 677)	—	No difference
Kennedy 2002	Cost-effectiveness in the UK for decision about benign heavy menstruation	296 300	USD 2026 (DA alone) USD 1556 (DA plus nurse coaching	298	USD 2751	—	Mean differences: DA versus usual care USD 461 (95% CI 236 to 696) DA plus coaching versus usual care USD 1184 (95% CI 684 to 2110)
Murray 2001a	Total costs excluding intervention in the UK for decision about treatment of benign enlarged prostate	57	GBP 310.3 (SD 602.0)	48	GBP 188.8 (SD 300.4)	—	Mean difference GBP 121.5 (95% CI −58.9 to 302.0)

Table 23. Healthcare system effects *(Continued)*

	Total costs including intervention (interactive video disk equipment) in the UK for decision about treatment of benign enlarged prostate	57	GBP 594.10 (SD 602)	48	GBP 188.8 (SD 300.4)	—	Mean difference GBP 405.4 (95% CI GBP 224.9 to GBP 585.8) P < 0.001
Murray 2001b	Total costs excluding intervention in the UK for decision about hormone replacement therapy	85	GBP 90.5	84	GBP 90.9 (SD 39.2)	—	No difference
	Total costs including intervention (interactive video disk equipment) in the UK for decision about hormone replacement therapy	85	GBP 306.5 (SD 42.8)	84	GBP 90.9 (SD 39.2)	—	Mean difference GBP 215.5 (95% CI 203.1 to 228.0) P < 0.001
Van Peperstraten 2010	Mean total savings per couple in the Netherlands for decision about embryo transfer for invitro fertilization	—	—	—	—	—	Mean total saving per couple in the intervention group were EUR 169.75 (USD 219.12)
Vuorma 2003	Total estimated costs in Finland for treatment decision about heavy benign menstruation	184	EUR 2760	179	EUR 3094	—	P = 0.1 No difference between intervention and control
Resource use							
Legare 2012 (in consultation)	Repeat consultation for the same reason, n (%)	163	37 (22.7%)	165	25 (15.2%)	Absolute difference 7.5	RR 1.3 (95% CI 0.7 to 2.3)
Thomson 2007 (in consultation)	GP consultations postintervention	51	39 (76.5%)	54	32 (59.3%)	—	P = 0.35
	Hospital appointments postintervention	51	29 (56.9%)	54	10 (18.5%)	—	P = 0.06
Wait time from screening of eligibility to decision							
Stacey 2014a	Wait time in weeks	69	33.4 weeks	71	33 weeks	—	No difference

CI: confidence interval; **DA**: decision aid; **RR**: risk ratio; **SD**: standard deviation.

Table 24. Subanalysis using higher quality trials

Outcome	Overall mean effect (95% CI), 105 total studies	Without trials having high risk of bias on at least 1 of 7 criteria (N = 16)
Knowledge	13.27 (95% CI 11.32 to 15.25) 52 studies	13.43 (95% CI 11.37 to 15.49) 47 studies
Accurate risk perceptions - with probabilities versus no probabilities	2.10 (95% CI 1.66 to 2.66) 17 studies	2.02 (95% CI 1.57 to 2.59) 15 studies
Values congruent with chosen option	2.06 (95% CI 1.46 to 2.91) 10 studies	2.06 (95% CI 1.46 to 2.91) 10 studies
Uninformed subscale of Decisional Conflict Scale	−9.28 (95% CI −12.20 to −6.36) 27 studies	−9.96 (95% CI −13.13 to −6.78) 25 studies
Unclear values subscale of Decisional Conflict Scale	-8.81 (95% Ci −11.99 to −5.63) 23 studies	−9.55 (95% CI −13.08 to −6.02) 21 studies

CI: confidence interval.

Table 25. Heterogeneity (based on 55 trials in search to 2006)

Outcome	Overall effect	Treatment decision	Screening decision	Video/computer decision aid	Audio/pamphlet Decision aid	Base risk control	Removal of outliers*
Knowledge - decision aid versus usual care	15.2 (11.7 to 18.7)	16.5 (11.9 to 21.2)	13.1 (7.7 to 18.5)	21.3 (16.3 to 26.2)	11.9 (8.3 to 15.6)	15.5 (11.3 to 19.8)	17.3 (13.6 to 20.9) (*Bekker 2004, Gattellari 2003, Johnson 2006)
Accurate risk perceptions - probabilities versus no probabilities	1.6 (1.4 to 1.9)	1.6 (1.4 to 1.9)	1.6 (1.1 to 2.3)	No data	1.6 (1.4 to 1.9)	1.3 (1.2 to 1.5) (P = 0.3)	1.5 (1.3 to 1.7) (*Gattellari 2003)
Uninformed subscale of the Decisional Conflict Scale - decision aid versus usual care	−8.4 (−11.9 to −4.8)	−9.4 (−13.3 to −5.5)	−3.5 (−12.9 to 5.8)	−12.6 (−19.5 to −5.8)	−4.9 (−7.6 to −2.3) (P = 0.06)	−5.4 (−7.7 to −3.2) (P = 0.11)	−6.2 (−8.4 to −4.1) (P = 0.06) (*Montgomery 2003)
Unclear values subscale of the Decisional Conflict Scale - decision aid versus usual care	−6.3 (−10.0 to −2.7)	−6.0 (−9.8 to −2.3)	Insufficient data	−8.0 (−15.1 to −1.0)	−4.5 (−8.4 to −0.6)	−3.6 (−6.8 to −0.5)	−4.0 (−6.7 to −1.3) (*Montgomery 2003)

APPENDICES

Appendix 1. Revised Search Strategies January 2009 to April 2015

CENTRAL via the Cochrane Library

1. (decision-support or decision-aid):kw in Trials
2. decision-tree:kw in Trials
3. patient-decision-making:kw
4. (decision-making or choice-behavior):ti,ab,kw and (informed-consent:kw,ti or (patient or parent* or carer or caregiver or care-giver):ti,ab,kw) in Trials
5. ((decision or decid*) near/4 (support* or aid* or tool or instrument or technolog* or technique or system or program* or algorithm or process or method or intervention or material)):ti,ab,kw
6. (decision next (board or guide or counseling)):ti,ab,kw
7. ((risk-communication or risk-assessment or risk-information) near/4 (tool or method)):ti,ab,kw
8. (computer* near/2 decision-making):ti,ab,kw
9. (interactive-health-communication or (interacti* near/4 tool)):ti,ab,kw
10. (interactive next (internet or online or graphic* or booklet)):ti,ab,kw
11. ((interactiv* or evidence-based) near/3 (risk-information or risk-communication or risk-presentation or risk-graphic*)):ti,ab,kw
12. shared-decision-making:ti,ab,kw
13. (informed next (choice or decision)):ti,ab,kw
14. adaptive-conjoint-analysis:ti,ab,kw
15. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14), from 2009 to 2015

(Last line **restricted** to "Trials", and to date range 2009 to 2015)

MEDLINE Ovid

1. decision support techniques/

2. decision support systems clinical/

3. decision trees/

4. (decision making or choice behavior).mp. and informed consent.sh.

5. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw.

6. (decision adj (board* or guide* or counseling)).tw.

7. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw.

8. decision-making computer assisted/

9. (computer* adj2 decision making).tw.

10. interactive health communication*.tw.

11. (interactive adj (internet or online or graphic* or booklet*)).tw.

12. (interacti* adj4 tool*).tw.

13. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw.

14. shared decision making.tw.

15. (informed adj (choice* or decision*)).tw.

16. adaptive conjoint analys#s.tw.

17. or/1-16

18. randomized controlled trial.pt.

19. controlled clinical trial.pt.

20. randomized.ab.

21. placebo.ab.

22. clinical trials as topic.sh.

23. randomly.ab.

24. trial.ti.

25. or/18-24

26. exp animals/ not humans.sh.

27. 25 not 26

28. 17 and 27

29. limit 28 to yr="2009 -Current"

Embase Ovid

1. decision support system/

2. patient decision making/

3. decision aid/

4. "decision tree"/

5. decision making.hw,kw,tw. and informed consent.hw,kw.

6. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw,kw.

7. (decision adj (board* or guide* or counseling)).tw,kw.

8. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw,kw.

9. (computer* adj2 decision making).tw,kw.

10. interactive health communication*.tw,kw.

11. (interactive adj (internet or online or graphic* or booklet*)).tw,kw.

12. (interacti* adj4 tool*).tw,kw.

13. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw,kw.

14. shared decision making.tw,kw.

15. (informed adj (choice* or decision*)).tw,kw.

16. adaptive conjoint analys#s.tw,kw.

17. or/1-16

18. randomized controlled trial/

19. controlled clinical trial/

20. single blind procedure/ or double blind procedure/

21. crossover procedure/

22. random*.tw.

23. placebo*.tw.

24. ((singl* or doubl*) adj (blind* or mask*)).tw.

25. (crossover or cross over or factorial* or latin square).tw.

26. (assign* or allocat* or volunteer*).tw.

27. or/18-26

28. nonhuman/ not (human/ and nonhuman/)

29. 27 not 28

30. 17 and 29

31. 30 and 20012:2015.(sa_year).

32. limit 31 to exclude medline journals

PsycINFO Ovid

1. decision support systems/

2. (decision making or choice behavior).mp. and (informed consent.sh. or (patient* or parent* or carer* or caregiver* or care giver*).mp.)

3. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab,id.

4. (decision adj (board* or guide* or counseling)).ti,ab,id.

5. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab,id.

6. computer assisted therapy/

7. (computer* adj2 decision making).ti,ab,id.

8. interactive health communication*.ti,ab,id.

9. (interactive adj (internet or online or graphic* or booklet*)).ti,ab,id.

10. (interacti* adj4 tool*).ti,ab,id.

11. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).ti,ab,id.

12. shared decision making.ti,ab,id.

13. (informed adj (choice* or decision*)).ti,ab,id.

14. adaptive conjoint analys#s.ti,ab,id.

15. or/1-14

16. random*.ti,ab,hw,id.

17. intervention.ti,ab,hw,id.

18. trial.ti,ab,hw,id.

19. placebo*.ti,ab,hw,id.

20. ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.

21. (cross over or crossover).ti,ab,hw,id.

22. latin square.ti,ab,hw,id.

23. (assign* or allocat* or volunteer*).ti,ab,hw,id.

24. treatment effectiveness evaluation/

25. mental health program evaluation/

26. exp experimental design/

27. or/16-26

28. 15 and 27

29. limit 28 to yr="2009 -Current"

CINAHL (EBSCO)

#	Query	Limiters/Expanders
S31	S30	**Limiters - Exclude MEDLINE records** Search modes - Boolean/Phrase
S30	S28 and S29	Search modes - Boolean/Phrase
S29	EM 2009-	Search modes - Boolean/Phrase
S28	S17 and S27	Search modes - Boolean/Phrase
S27	S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26	Search modes - Boolean/Phrase
S26	TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)	Search modes - Boolean/Phrase
S25	AB (singl* or doubl* or tripl* or trebl*) and AB (blind* or mask*)	Search modes - Boolean/Phrase
S24	AB (random* or trial or placebo*) or TI (random* or trial or placebo*)	Search modes - Boolean/Phrase
S23	MH Quantitative Studies	Search modes - Boolean/Phrase
S22	MH Placebos	Search modes - Boolean/Phrase
S21	MH Random Assignment	Search modes - Boolean/Phrase
S20	MH Clinical Trials+	Search modes - Boolean/Phrase
S19	PT Clinical Trial	Search modes - Boolean/Phrase
S18	PT "randomi?ed controlled trial"	Search modes - Boolean/Phrase
S17	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16	Search modes - Boolean/Phrase
S16	"informed choice*" or "informed decision*"	Search modes - Boolean/Phrase
S15	"shared decision making"	Search modes - Boolean/Phrase
S14	"adaptive conjoint analys?s"	Search modes - Boolean/Phrase

(Continued)

S13	(interactive N2 "risk information") or (interactive N2 "risk communication") or (interactive N2 "risk presentation") or (interactive N2 "risk graphic*")	Search modes - Boolean/Phrase
S12	"interactive internet" or "interactive online" or "interactive graphic*" or "interactive booklet*" or (interacti* N3 tool*)	Search modes - Boolean/Phrase
S11	"interactive health communication*"	Search modes - Boolean/Phrase
S10	computer* N1 "decision making"	Search modes - Boolean/Phrase
S9	("risk communication" N3 tool*) or ("risk communication" N3 method*) or ("risk information" N3 tool*) or ("risk information" N3 method*) or ("risk assessment" N3 tool*) or ("risk assessment" N3 method*)	Search modes - Boolean/Phrase
S8	"evidence based risk communication" or "evidence based risk information"	Search modes - Boolean/Phrase
S7	"decision board*" or "decision guide*" or "decision counseling"	Search modes - Boolean/Phrase
S6	(decision* N3 support*) or (decision* N3 aid*) or (decision* N3 tool*) or (decision* N3 instrument*) or (decision* N3 technolog*) or (decision* N3 technique*) or (decision* N3 system*) or (decision* N3 program*) or (decision* N3 algorithm*) or (decision* N3 process*) or (decision* N3 method*) or (decision* N3 intervention*) or (decision* N3 material*)	Search modes - Boolean/Phrase
S5	("decision making" or "choice behavior") and MH consent	Search modes - Boolean/Phrase
S4	MH decision making, computer assisted	Search modes - Boolean/Phrase
S3	MH decision making, patient	Search modes - Boolean/Phrase
S2	MH decision support systems, clinical	Search modes - Boolean/Phrase
S1	MH decision support techniques+	Search modes - Boolean/Phrase

Appendix 2. Search strategies to 2009

CENTRAL

CENTRAL in the Cochrane Library was searched using the MEDLINE search above in Ovid to the end of 2006; for the 2011 update, the CENTRAL search was conducted at www.thecochranelibrary.com to the end of 2009 using the following search strategy:

1. decision.tw,hw.

2. patient.tw,hw.

3. consumer.tw,sh.

4. 1 and (2 or 3)

5. shared decision making.tw.

6. decision aid$.tw.

7. informed choice.tw.

8. or/4-7

9. clinical trial.pt.

10. randomized controlled trial.pt.

11. random$.tw.

12. or/9-11

13. 8 and 12

MEDLINE Ovid (1966 to December 2009)

1. choice behavior/

2. decision making/

3. exp decision support techniques/

4. Educational Technology/

5. decision$.tw.

6. (choic$ or preference$).tw.

7. communication package.tw.

8. or/1-7

9. exp health education/

10. Health Knowledge, Attitudes, Practice/

11. informed consent.tw,hw.

12. patient.tw,hw.

13. consumer.tw,hw.

14. or/9-13

15. 8 and 14

16. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

17. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

18. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

19. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

20. shared decision making.tw.

21. decision aid$.tw.

22. informed choice.tw.

23. or/16-22

24. 15 or 23

25. clinical trial.pt.

26. randomized controlled trial.pt.

27. random$.tw.

28. (double adj blind$).tw.

29. double-blind method/

30. or/25-29

31. 24 and 30

CINAHL Ovid (1982 to September 2008)

1. exp Decision Making/

2. information seeking behavior/

3. Help Seeking Behavior/

4. (choic$ or preference$).tw.

5. decision$.tw.

6. Educational Technology/

7. or/1-6

8. exp Health Behavior/

9. consumer participation/

10. exp Health Education/

11. health knowledge/ or exp professional knowledge/

12. exp Consent/

13. informed consent.tw.

14. patient.tw,hw.

15. consumer.tw,sh.

16. or/8-15

17. 7 and 16

18. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

19. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

20. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

21. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

22. shared decision making.tw.

23. decision aid$.tw.

24. informed choice.tw.

25. or/18-24

26. 17 or 25

27. exp clinical trials/

28. Clinical trial.pt.

29. (clinic$ adj trial$1).tw.

30. random$.tw.

31. Random assignment/

32. placebo$.tw,sh.

33. Quantitative studies/

34. Allocat$ random$.tw.

35. ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$3 or mask$3)).tw.

36. or/27-35

37. 26 and 36

Embase Ovid (1980 to December 2009)

1. decision making/

2. decision theory/

3. decision$.tw.

4. Educational Technology/

5. or/1-4

6. exp health behavior/

7. exp Patient Attitude/

8. exp health education/

9. informed consent.tw,sh.

10. patient.tw,sh.

11. consumer.tw,sh.

12. or/6-11

13. 5 and 12

14. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

15. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

16. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

17. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

18. shared decision making.tw.

19. decision aid$.tw.

20. informed choice.tw.

21. or/14-20

22. 13 or 21

23. Controlled Study/

24. Randomized Controlled Trial/

25. Clinical Study/

26. Clinical Trial/

27. Major Clinical Study/

28. Prospective Study/

29. Multicenter Study/

30. Randomization/

31. Double Blind Procedure/

32. Single Blind Procedure/

33. Crossover Procedure/

34. Placebo.tw,sh.

35. random$.tw.

36. (double adj blind$).tw.

37. or/23-36

38. 22 and 37

PsycINFO Ovid (1806 to December 2009)

1. decision$.tw.

2. (choic$ or preference$).tw.

3. exp decision making/

4. computer assisted instruction/

5. or/1-4

6. exp health education/

7. exp health personnel attitudes/

8. informed consent.tw,sh.

9. patient.tw,hw.

10. consumer.tw,hw.

11. exp health behavior/

12. or/6-11

13. 5 and 12

14. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

15. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

16. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

17. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

18. shared decision making.tw.

19. decision aid$.tw.

20. informed choice.tw.

21. or/14-20

22. 13 or 21

23. random$.tw.

24. (double adj blind$).tw.

25. placebo$.tw,hw.

26. or/23-25

27. 22 and 26

WHAT'S NEW

Date	Event	Description
6 April 2017	New search has been performed	We updated the search in April 2015 and added 18 new studies comparing decision aids to usual care. For this update, we removed 28 studies that were focused on detailed versus simple decision aids. We also conducted a subanalysis of decision aids used within the consultation and those used in preparation for the consultation.
6 April 2017	New citation required and conclusions have changed	New for this update is growing evidence that decision aids may improve informed values-congruence choices and the sub-analysis indicated improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation.

HISTORY

Protocol first published: Issue 1, 1999
Review first published: Issue 3, 2001

Date	Event	Description
5 December 2013	New citation required and conclusions have changed	This update added 33 new studies for a total of 115 studies involving 34,444 participants. GRADE was used to summarize the quality of the evidence, and findings were reported using a 'Summary of findings' table. We excluded three previously-included trials on the basis of their quasi-randomized controlled trial (q-RCT) design identified using the more rigorous 'Risk of bias' assessment tool, as well as one other study that used the same decision aid content for both groups but varied the format used. Overall, the results are similar to the previous update, but this update indicates the quality of the evidence to support the reported outcomes (high-quality evidence that decision aids compared to usual care improve people's knowledge and reduce their decisional conflict related to feeling uninformed and unclear about their personal values; moderate-quality evidence that decision aids compared to usual care stimulate people to take a more active role in decision making and improve accurate risk perceptions when probabilities are included; and low-quality evidence that decision aids improve the congruence between the chosen option and their values). We added two new authors to the review, LT in Sydney and JW in Ottawa who helped coordinate this update.

Date	Event	Description
30 June 2012	New search has been performed	Search strategies were updated and new searches run in June 2012.
18 January 2012	Amended	Minor change to wording, Plain Language Summary.
5 September 2011	New search has been performed	An update of this review was conducted in 2010 and published on issue 10 2011 of *The Cochrane Library*. Citations were searched from 2006 to December 2009.
5 September 2011	New citation required but conclusions have not changed	This update added 31 new studies, and all 86 included studies were assessed for risk of bias. Overall the results were consistent with the previous update. New in this update is the meta-analysis of informed values-based choices for decision aids including explicit values-clarification compared to those with no explicit values-clarification. We have also conducted a post-hoc analysis to evaluate the effect of risk of bias assessment ratings on outcomes.
29 April 2009	New search has been performed	See the 'History' items dated 29 April 2009 and 28 July 2006.
29 April 2009	New citation required and conclusions have changed	A substantially updated version of this review was published on issue 1 2009 of *The Cochrane Library*. The changes are outlined in the 'History' (date 28 July 2006). The updated review ought to have had a new citation to reflect the new authorship and substantial changes to the review and its conclusions; however because of a technical error this new citation was not given to the updated review. The new citation for this review for issue 3 2009 (O'Connor 2009b) reflects the updated review contents as actually published from issue 1 2009 onwards.
28 April 2009	Amended	Corrected mislabelled table 'Summary of pooled outcomes'.
17 July 2008	Amended	Converted to new review format.
28 July 2006	New search has been performed	Changes for the 2006 update (first published on issue 1 2009 of *The Cochrane Library)*: • Outcomes focus on the new effectiveness criteria of the International Patient Decision Aids Standards (IPDAS) Collaboration. • There are now 55 randomized controlled trials evaluating decision aids in the review. Twenty-five new randomized controlled trials have been added for this update. Four trials that were previously included were excluded from this review as the decision support intervention was not available to determine whether it met the inclusion criteria - a requirement for this update in light of the new IPDAS standards. There are an additional 15 trials in progress. • The number of included countries has doubled from the last update. We now have results from 7 countries (AU, CA, China, Finland, Netherlands, US, UK). Findings from the 2006 update (*new to this update): • * Thirty-eight trials used at least one measure that mapped onto an IPDAS effectiveness criterion. No trials evaluated the ex-

Date	Event	Description
		tent to which patient decision aids achieve the IPDAS decision process criteria: helped patients to recognize that a decision needs to be made, understand that values affect the decision, or discuss values with their practitioner. • * Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions; the effect was stronger when probabilities were measure quantitatively rather than qualitatively. • Compared to usual care, exposure to decision aids improved knowledge, decreased decisional conflict, reduced the proportion of people who were passive in decision making, reduced the proportion who remained undecided, and reduced rates of elective invasive surgery. • Detailed decision aids (compared to simpler decision aids) improved knowledge and reduced the uptake of hormone replacement therapy. • * Compared to usual care, exposure to decision aids reduced prostate-specific antigen (PSA) screening. • There are too few studies to comment on the effects of decision aids on length of the consultation, patient-practitioner communication, persistence with chosen option, costs, and resource use.
21 February 2003	New search has been performed	For the 2002 update (O'Connor 2003), the following changes were made: • There are now 221 decision aids (increased from 87) that have been identified for the inventory with 131 available and up-to-date: many of which are available on the Internet. However few have undergone any form of evaluation for impact on decision making. • There are now 35 randomized controlled trials evaluating decision aids in the review. Eleven new randomized controlled trials have been added for this update including 1 large scale trial that evaluated a suite of 8 decision aids in a number of health services. • There are an additional 6 trials pending publication and 24 trials in progress. • In conjunction with the benefits reported in the earlier reports, there is now evidence that decision aids compared to usual care also help with making actual choices and there is a statistically-significant reduction in major elective surgery by a quarter. Detailed compared to simple decision aids also show an improved agreement between values and actual choice. • There continues to be too few studies to comment on the effects of decision aids on persistence with chosen therapy, costs, resource use, or efficacy of dissemination.

CONTRIBUTIONS OF AUTHORS

1999 Review (O'Connor 1999b):
AO, AR, VF, JT, VE, HLT, MHR, VF, MB, and JJ contributed to the design of the protocol, the interpretation of results, and the revision and approved the final paper.
AO led the team, and JT coordinated the project.
AO, MH-R, AR, VF, and JT pilot tested the data extraction forms.
AR, VF, and JT screened studies and extracted data.

AR, JT, and AO analyzed the results.

2001 Review (O'Connor 2001):
AO, DS, DR, MHR, HLT, VE, MB, JT, VF, and AR contributed to the interpretation of results and the revision and approved the final paper.
AO led the team, and DS coordinated the update.
AO, DR, MHR, HLT, JT, DS, and JP screened studies and extracted data.
DS and JP evaluated decision aids using the CREDIBLE criteria.
AO and DS analyzed the results.

2002 Review (O'Connor 2003):
AO, DS, DR, MHR, HLT, VE, MB, JT, and VF contributed to the interpretation of results and the revision and approved the final paper.
AO led the team, and DS coordinated the update.
DS, JP, VT, and JT screened studies and extracted data.
DS, JP, VT, and SK evaluated decision aids using the CREDIBLE criteria.
AO and DS analyzed the results.

2006 Review (O'Connor 2009b):
AO, CB, DS, MB, NC, KE, VE, VF, MHR, SK, HLT, DR, contributed to the interpretation of results, and the revision and final approval of the paper.
AO led the team and CB coordinated the update.
CB, SK, DS, AO, VF screened studies and extracted data.
AO and CB analyzed the results.

2009 Review (Stacey 2011):

DS, CB, MB, NC, KE, FL, AL, MHR, HLT, and RT contributed to the interpretation of results, and the revision and approved the final paper.
DS led the team, and CB coordinated the update.
CB and DS screened studies; SM and AD extracted data; CB entered the data; DS verified the data entered.
DS and CB analyzed the results.

2013 Review (Stacey 2014b):

DS, CB, MB, NC, KE, FL, AL, MHR, HLT, RT, and LT contributed to the interpretation of results and the revision and approved the final paper.
DS led the team with help coordinating the update from SB and JW.
CB, DS, RT, MB, MHR, NC, KE, BV, DR, and AS screened studies; SB, RW, JW, and CC extracted data; SB and JW entered the data; DS verified the data entered.
DS and JW analyzed the results.

2016 (current) Review:

DS, CB, MB, KE, FL, AL, MHR, HLT, RT, LT, and KL contributed to the interpretation of results and the revision and approved the final paper.
DS led the team with help coordinating the update from KL.
CB, DS, RT, MB, MHR, KE, DR, and AS screened studies; KL and IS extracted data; KL entered the data; DS verified the data entered.
DS analyzed the results.

DECLARATIONS OF INTEREST

Several of the investigators have developed patient decision aids (DS, FL, HL, MHR, MB, KE, RT, LT, KL), but none reviewed their own studies.

Within the last five years, two investigators (HL, MB) have received financial support from the not-for-profit Informed Medical Decisions Foundation (IMDF). MB serves on the Board of and received salary and grant support as President of the Foundation. In 2014, the Foundation merged with another not-for-profit, Healthwise. MB continues to receive salary and grant support as Chief Science Officer at Healthwise. Healthwise develops, licenses, and distributes patient decision aids. Several investigators (DS, FL, HL, MHR, MB, KE, RT, LT) who were involved in a special issue in *BMC Medical Informatics and Decision Making* that included a series of 14 papers focused on the theoretical and empirical evidence underlying the International Patient Decision Aid Standards (IPDAS), received partial funding from the Foundation to cover publishing costs.

SOURCES OF SUPPORT

Internal sources

- University of Ottawa, Canada.

  University Research Chair in Knowledge Translation to Patients

- Ottawa Hospital Research Institute, Canada.

  Scientific Director, Patient Decision Aids Research Group

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are three main differences between the original protocol and the review. We re-structured the 2009 update, O'Connor 2009b, to organize the long list of outcomes into primary and secondary outcomes based on the new effectiveness criteria of the International Patient Decision Aid (IPDAS) Collaboration (Elwyn 2006). For the 2011 update, Stacey 2011, we changed the study quality assessment to the 'Risk of bias' assessment (Higgins 2011). For the 2014 update, Stacey 2014b, we used GRADE to summarize the quality of the evidence and reported the results using Summary of findings for the main comparison.

For the 2016 (current) update, we removed 28 studies that compared detailed versus simple decision aids. This update is limited to comparisons of patient decision aids versus usual care to provide a more focused review. This change resulted in removal of these comparisons for pooled results including knowledge scores, decisional conflict, perceived participation in decision making, proportion undecided, choice, and satisfaction. For other outcomes including congruence between chosen option-values and accurate risk perception, the new pooled comparisons only focus on patient decision aid versus usual care, rather than previous comparisons that reported on patient decision aids with explicit values clarification and probabilities of outcomes versus any comparisons without these features.

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Support Techniques; *Health Knowledge, Attitudes, Practice; *Patient Participation; Communication; Conservative Treatment; Elective Surgical Procedures; Patient Education as Topic [*methods]; Physician-Patient Relations; Publication Bias; Randomized Controlled Trials as Topic

MeSH check words

Humans

JAMA Clinical Evidence Synopsis

Patient Decision Aids to Engage Adults in Treatment or Screening Decisions

Dawn Stacey, RN, PhD; France Légaré, MD, PhD; Krystina B. Lewis, RN, MN

CLINICAL QUESTION Are patient decision aids (PtDAs) associated with (1) improved decision quality defined as a decision informed by the evidence and a value-based decision; (2) improved decision-making processes defined as feeling informed, defining clear values related to the decision, and active participation in making the decision; and (3) better patient and health system outcomes compared with either usual care or a non-PtDA intervention?

BOTTOM LINE Patient decision aids are associated with improved decision quality and decision-making processes without worse patient or health system outcomes.

Introduction

This JAMA Clinical Evidence Synopsis summarizes a recent Cochrane review[1] on patient decision aids (PtDAs), which are printed booklets, videos, or web-based tools created for patients. They provide (1) evidence-based information on the options available for a specific health condition along with the benefits and harms of each option and (2) allow patients to consider what is important and establish their preferred screening or treatment option.

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Summary of Findings

Patient decision aids were associated with improved decision quality as evidenced by a greater knowledge of options compared with usual care (70% vs 57%, respectively; mean difference, 13.27% [95% CI, 11.32%-15.23%]), and by an increased rate of selecting the option that matches the patients' values (595 vs 289/1000 patients; risk ratio, 2.06 [95% CI, 1.46-2.91]) (**Table**).[1] Patient decision aids presenting numeric estimates to quantify the likelihood of outcomes of treatment and screening options were associated with accurate risk perceptions (565 vs 269/1000 patients; risk ratio, 2.10 [95% CI, 1.66-2.66]).

Patient decision aids were associated with improved decision-making processes as evidenced by improved scores on the decisional conflict feeling uninformed subscale compared with usual care (21.2% vs 30.5%, respectively; mean difference, −9.28% [95% CI, −12.20% to −6.36%]) and the unclear values subscale (21.3% vs 30.1%; mean difference, −8.81% [95% CI, −11.99% to −5.63%).[1,2] Patient decision aids were associated with fewer clinicians making decisions without patient participation (155 vs 228/1000 patients; risk ratio, 0.68 [95% CI, 0.55-0.83]) (Table).

Treatment or screening rates varied.[1] Patient decision aids evaluated in multiple studies were associated with higher intention of initiating new medications for diabetes (194 vs 118/1000 patients; risk ratio, 1.65 [95% CI, 1.06-2.56]), lower rates of prostate-specific antigen testing (389 vs 442/1000 patients; risk ratio, 0.88 [95% CI, 0.80-0.98]), and fewer elective surgeries (379 vs 451/1000 patients; risk ratio, 0.84 [95% CI, 0.73-0.97]) (Table). There was no association with PtDA use and rates of breast cancer genetic testing or rates of colon cancer screening. For other decisions, there were too few trials to evaluate the association on the patient's selected option.

Patient decision aids were not associated with increased anxiety or depression, or with worsening general health outcomes vs comparators.[1] Patient decision aids were associated with 7.5% longer consultation (median, 2.6 minutes; range, −0.4 to 23.0 minutes) in 10 trials; the median length of consultation with PtDA was 24 minutes vs 21 minutes with comparators.

Evidence Profile

No. of randomized clinical trials: 105

Study years: Conducted, 1983-2013 (data in 86 trials); published, 1988-2015

No. of participants: 31 043

Men: 45.3% **Women:** 54.7% (data in 102 trials; 30 642 participants)

Race/ethnicity: White, 60.4%; black, 13.9%; Asian, 3.0%; aboriginal, 0.1%; other, 6.7%; unknown, 16.5% (data in 42 trials; 13 724 participants)

Education: Secondary school diploma or less, 43.9%; postsecondary education, 46.3%; unknown, 9.8% (data in 85 trials; 26 595 participants)

Settings: Primary care, specialty care, public health, emergency department

Countries: Australia, Canada, China, Finland, Germany, the Netherlands, Spain, Sweden, United Kingdom, United States

Intervention: Patient decision aids (PtDAs)

Comparisons: Usual care, no intervention, or non-PtDA intervention (eg, guideline, placebo intervention, or general information). Comparisons between PtDAs were excluded.

Primary outcomes: Choice attributes: patient having knowledge and accurate risk perceptions with selected option congruent with their values; decision-making process attributes: decisional conflict, clinician-controlled decision making.

Secondary outcomes: Behavior: selected health care option; health outcomes: general or condition-specific health outcomes (eg, anxiety or depression); health care system: consultation length.

Table. Meta-Analysis Findings in the Systematic Review of Patient Decision Aids (N = 105 Randomized Clinical Trials)

	No. of Trials	Participants, No.		Rates/1000 Patients[a]		Effect (95% CI)[b]	GRADE Quality Rating
		PtDA	Control	PtDA	Control		
Primary Outcome: Attributes of the Choice Made							
Knowledge of options and outcomes	52	6779	6537	70[c]	57[c]	MD, 13.27 (11.32 to 15.23)[c]	High
Selected option congruent with patients' values	10	2536	2090	595	289	RR, 2.06 (1.46 to 2.91)	Low
Accurate risk perception of outcomes	17	2584	2512	565	269	RR, 2.10 (1.66 to 2.66)	Moderate
Primary Outcome: Attributes of the Decision-Making Process							
Feeling uninformed[d]	27	3116	2591	21.2[e]	30.5[e]	MD, −9.28 (−12.20 to −6.36)[e]	High
Unclear values[d]	23	2794	2274	21.3[f]	30.1[f]	MD, −8.81 (−11.99 to −5.63)[f]	High
Clinician makes decisions without patient participation	16	1743	1437	155	228	RR, 0.68 (0.55 to 0.83)	Moderate
Secondary Outcome: Actual or Preferred Option Chosen							
New medication for diabetes	4	243	204	194	118	RR, 1.65 (1.06 to 2.56)	Low
Prostate-specific antigen testing	10	2020	1976	389	442	RR, 0.88 (0.80 to 0.98)	Moderate
Elective surgery							
All studies	18	1921	1923	320	372	RR, 0.86 (0.75 to 1.00)	Moderate
Excludes prophylactic mastectomy	17	1557	1551	379	451	RR, 0.84 (0.73 to 0.97)	Moderate
Breast cancer genetic testing	3	342	396	380	384	RR, 0.99 (0.71 to 1.38)	Very low
Colon cancer screening	10	2406	2123	379	339	RR, 1.12 (0.95 to 1.31)	Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development and Evaluation; MD, mean difference; PtDA, patient decision aids; RR, risk ratio.

[a] Unless otherwise indicated.

[b] Data were pooled across studies in cases in which similar outcome measures were used and the effects were expected to be independent of the type of decision studied.

[c] Range from 0 (no knowledge) to 100 (perfect knowledge). Expressed as a percentage.

[d] Identified by the International Patient Decision Aid Standards Collaboration as important decision-making process outcome measures.

[e] Subscale of the Decisional Conflict Scale; 0 represents feeling informed and 100 represents uninformed. Expressed as a percentage.

[f] Subscale of the Decisional Conflict Scale; 0 represents clear values and 100 represents unclear values. Expressed as a percentage.

Discussion

Among 105 randomized clinical trials, PtDAs were associated with increased decision quality and improved decision-making processes as measured by patients' knowledge, risk perceptions, patient decision selection matching with patient values, and lower decisional conflict. Decisional conflict is a state of uncertainty about the course of action to take.[2] Patient decision aids were not associated with apparent harms (eg, anxiety or depression or worsened health outcomes).[1]

Limitations

There were multiple types of PtDAs and comparators. There is inadequate statistical power to detect differences across distinct types of PtDAs, across specific PtDA content elements (eg, illustrative examples of others' experiences through patient stories; and values clarification methods, which are intended to help patients evaluate the desirability or attributes of options to identify which option is preferred), or by type of comparison. Several outcomes demonstrated statistically significant heterogeneity.[1]

Comparison of Findings With Current Practice Guidelines

The guideline on patient experience[3] from the UK National Health Service recommends using high-quality PtDAs if available. Since 2015, the US Centers for Medicare & Medicaid Services has required use of a PtDA before the first lung cancer screening with low-dose computed tomography.[4] These recommendations are consistent with the conclusions in this evidence synopsis.

Areas in Need of Future Study

Little is known about the effect of PtDAs on patients' confidence with decision making, cost, resource use, adherence to the selected option, and regret.[1]

ARTICLE INFORMATION

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Section Editor: Mary McGrae McDermott, MD, Senior Editor.

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Stacey and Légaré reported developing, evaluating, and holding a copyright on PtDAs (freely available for use at https://decisionaid.ohri.ca) for natural health products during menopause (both), vasectomy (both), and antibiotics for upper respiratory infection (Dr Légaré only). No other disclosures were reported.

Submissions: We encourage authors to submit papers for consideration as a JAMA Clinical Evidence Synopsis. Please contact Dr McDermott at mdm608@northwestern.edu.

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Aides à la décision dans un processus de décision partagée entre médecin et patient *(shared decision making)*

Référence
Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2017, Issue 4. DOI: 10.1002/14651858.CD001431.pub5

Analyse de
Nicolas Delvaux et Bert Aertgeerts, Academisch Centrum Huisartsgeneeskunde, KU Leuven

Question clinique

Quelle est l'influence des aides déterminantes dans le processus de décision concernant les traitements et les examens de dépistage ?

Contexte

Pour formuler des recommandations, les développeurs de guides de pratique clinique s'appuient sur une évaluation approfondie des faits probants scientifiques disponibles, et ils pèsent les avantages et les inconvénients des différentes options stratégiques. Certaines recommandations sont fortes parce que les avantages dépassent nettement les inconvénients. Le rapport entre les avantages et les inconvénients des différentes options stratégiques est rarement aussi évident, et les développeurs de guides de pratique clinique doivent plutôt formuler des recommandations conditionnelles. On attend alors du médecin qu'il présente de manière compréhensible les différents arguments pour et contre au patient en vue d'une prise de décision partagée (*shared decision making,* SDM). La prise de décision partagée est universellement reconnue comme un principe de base des services médicaux de qualité (1-4). Cette approche nécessite non seulement un changement de culture parmi les prestataires de soins, mais aussi le développement d'aides à la décision qui soutiennent les patients lorsqu'ils doivent choisir entre des options stratégiques concernant leur santé (5). Toutes les aides à la décision donnent des informations factuelles concernant les problèmes de santé, les options stratégiques, les avantages et les inconvénients associés, les chances et les incertitudes scientifiques. Toutes ont également ceci en commun qu'elles mentionnent explicitement la décision à prendre en matière de stratégie et qu'elles aident les patients à peser eux-mêmes les avantages et les inconvénients associés à une décision donnée, sans pour autant leur imposer une option déterminée.

Résumé

Méthodologie

Synthèse méthodique et méta-analyses

Sources consultées

- Cochrane Central Register of Controlled Trials (jusqu'au 24 avril 2015), MEDLINE Ovid (de 1966 au 24 avril 2015), Embase Ovid (de 1980 au 24 avril 2015), PsycINFO Ovid (de 1806 au 24 avril 2015), CINAHL Ovid et Ebsco (de 1982 au 24 avril 2015)
- WHO trial register, ClinicalTrials.gov, Google Scholar et Google, Decision Aid Library Inventory.

Études sélectionnées

- études randomisées, contrôlées comparant une aide à la décision pour les patients avec la prise en charge habituelle, les informations générales, un placebo ou une absence d'intervention
- exclusion des études portant sur des modifications du mode de vie, sur des programmes d'éducation qui ne visaient pas une décision spécifique, sur des interventions visant à

accroître l'observance du traitement ; ont également été exclues les études dans lesquelles les participants devaient faire un choix hypothétique suivant une étude de cas ainsi que les études qui comparaient deux aides à la décision
- au total, 105 études ont été incluses.

Population étudiée
- adultes âgés d'au moins 18 ans qui devaient prendre une décision concernant une option de dépistage ou de traitement pour eux-mêmes, pour un enfant ou pour une personne incapable
- au total, 31043 patients ont été inclus.

Mesure des résultats
- critères de jugement primaires :
    - basés sur les critères IPDAS (International Patient Decision Aids Standards) :
        - connaissance, bonne évaluation des risques, choix d'une option en harmonie avec les valeurs du patient informé
        - conscience qu'un choix doit être posé, sentiment d'être informé, description des principales caractéristiques des options, discussion des valeurs avec le médecin, implication dans la prise de décision
    - autres critères : conflit de décision, communication entre le médecin et le patient, participation à la prise de décision, part d'indécision, satisfaction avec le choix, le processus décisionnel et la préparation à la prise de décision

- critères de jugement secondaires :
    - comportement : tant le choix lui-même que le respect de l'option choisie
    - critères de santé : statut de santé et qualité de vie, anxiété, dépression, détresse émotionnelle, regret, confiance
    - système des soins de santé : coûts et rentabilité, durée de la consultation, taux de litiges.

Résultats
- résultats des critères de jugement primaires (*voir tableau 1*) :
    - versus groupe contrôle, les patients qui disposaient d'une aide à la décision avaient un meilleur score en termes de connaissances, et ce de manière statistiquement significative, et deux fois plus de patients évaluaient correctement les risques et/ou posaient un choix qui correspondait à leurs valeurs
    - versus groupe contrôle, les patients qui disposaient d'une aide à la décision se sentaient mieux informés, et ce de manière statistiquement significative, et ils avaient une vision plus claire de leurs valeurs
    - versus groupe contrôle, il y avait, dans le groupe de patients qui disposaient d'une aide à la décision, environ deux fois moins de décisions prises unilatéralement par le médecin

Tableau 1. Critères de jugement primaires entre le groupe contrôle et le groupe avec aide à la décision.

Critère de jugement	**Comparaison entre**		**Effet relatif (IC à 95%)**	**Nombre de participants (études ; I^2)**	**Qualité de la preuve (GRADE)**
	groupe contrôle	**groupe avec aide à la décision**			
Score de connaissances (standardisé de 0 (aucune connaissance) à 100 (connaissance parfaite), peu de temps après l'utilisation de l'aide à la décision)	Score moyen 56,9 (IC à 95% de 27,0 à 85,2)	Score moyen **13,27 plus élevé** (IC à 95% de 11,32 à 15,23%)	-	13316 (52 ; I^2 = 93%)	Elevée
Evaluation correcte des risques (peu de temps après l'utilisation de l'aide à la décision)	269 sur 1000	565 sur 1000 (447 à 716 sur 1000)	**RR 2,10** (IC à 95% de 1,66 à 2,66)	5096 (17 ; I^2 = 89%)	Modérée
Choix en harmonie avec les valeurs (peu de temps après l'utilisation de l'aide à la décision)	289 sur 1000	595 sur 1000 (422 à 841 sur 1000)	**RR 2,06** (IC à 95% de 1,46 à - 2,91)	4626 (10 ; I^2 = 95%)	Faible
Conflit de décision : sous-échelle insuffisamment informé (standardisé de 0 (informé) à 100 (non informé), peu de temps après l'utilisation de l'aide à la décision)	Score moyen de 11,1 à 61,1	Score moyen **9,28 plus faible** (IC à 95% de 12,20 à 6,36)	-	5707 (27 ; I^2 = 89%)	Elevée
Conflit de décision : sous-échelle incertitude concernant les valeurs propres (standardisé de 0 (pas d'incertitude) à 100 (incertitude), peu de temps après l'utilisation de l'aide à la décision)	Score moyen de 15,5 à 53,2	Score moyen **8,81 plus faible** (IC à 95% de 11,99 à - 5,63)	-	5068 (23 ; I^2 = 92%)	Elevée
Proportion de décisions contrôlées par le médecin	228 sur 1000	155 sur 1000 (125 à 189 sur 1000)	**RR 0,68** (IC à 95% de 0,55 à 0,83)	3810 (16 ; I^2 = 36%)	Modérée

- résultats des critères de jugement secondaires :
    - le nombre de décisions pour une intervention chirurgicale majeure non urgente a diminué avec les aides à la décision, versus prise en charge habituelle (RR 0,84 avec IC à 95% de 0,73 à 0,97 ; n = 3 108 ; N = 17 études ; I^2 = 66%), après exclusion d'une étude portant sur la mastectomie prophylactique
    - le nombre de décisions pour le dépistage du cancer de la prostate a diminué avec les aides à la décision, versus prise en charge habituelle (RR 0,88 avec IC à 95% de 0,80 à 0,98 ; n = 3 996 ; N = 10 études ; I^2 = 58%), mais pas le nombre de décisions pour le dépistage du cancer du côlon (n = 4 529 ; N = 10 études)
    - le nombre de diabétiques choisissant de débuter un nouveau traitement a augmenté avec les aides à la décision, versus la prise en charge habituelle (RR 1,65 avec IC à 95% de 1,06 à 2,56 ; n = 447 ; N = 4 études ; I^2 = 0%)
    - les consultations duraient plus longtemps avec l'utilisation des aides à la décision pendant la consultation : médiane 2,6 minutes (IQR -0,4 à +23)
    - aucune étude n'a rapporté d'effets indésirables associés à l'utilisation des aides à la décision.

Conclusion des auteurs
Les auteurs concluent que versus prise en charge normale, les patients qui peuvent disposer d'aides à la décision pour différentes décisions stratégiques disposent de plus de connaissances, se sentent mieux informés et ont une meilleure idée de leurs valeurs et de leurs préférences. Il est probable que les aides à la décision assurent aux patients un rôle plus actif dans la prise de décision et leur permet de mieux évaluer les risques. En outre, il existe de plus en plus de preuves que les aides à la décision permettent d'opérer un choix plus en harmonie avec les valeurs. Il n'y a aucun effet indésirable en termes de santé et de satisfaction. Une recherche plus poussée est nécessaire pour connaître l'influence des aides à la décision sur l'observance de l'option choisie, la rentabilité et l'utilisation des aides à la décision chez les personnes moins éduquées.

Financement de l'étude
L'Université d'Ottawa, Canada, et l'Institut de recherche de l'hôpital d'Ottawa ; pas d'autres sources (externes) de financement.

Conflits d'intérêts des auteurs
La plupart des auteurs étaient impliqués dans les études randomisées contrôlées incluses dans cette synthèse méthodique. Il n'était pourtant pas permis que les auteurs effectuent une évaluation méthodologique de leurs propres études. Plusieurs auteurs ont également été impliqués dans la rédaction des critères IPDAS et ont reçu une rémunération à ce titre.

Discussion

Considérations sur la méthodologie
Cette synthèse méthodique avec méta-analyse de la Cochrane Collaboration, qui a été conçue de manière rigoureuse, a examiné l'effet des aides à la décision pour le dépistage et le traitement. Elle a été menée suivant un protocole préalablement déterminé, et les résultats ont été rapportés suivant les lignes directrices PRISMA. Par comparaison avec d'autres synthèses méthodiques portant sur des interventions complexes, il y avait très peu d'études avec un risque élevé de biais. C'est un peu étonnant car l'intervention examinée n'était en aveugle ni pour le prestataire de soins ni pour le patient, et il s'agissait le plus souvent de critères de jugement subjectifs. Pour la plupart des 40 critères de jugement différents, la qualité de la preuve était faible à très faible. Cinq des six critères de jugement primaires avaient une qualité de preuve de niveau modéré à élevé selon GRADE. Les auteurs ont décidé de ne pas tenir compte de l'**hétérogénéité statistique** des résultats parce qu'elle se limitait à l'ampleur de l'effet et ne concernait pas la direction de l'effet (les résultats étaient les mêmes). Or l'importante hétérogénéité statistique est probablement bien le reflet d'une importante

hétérogénéité clinique comme conséquence d'une grande diversité quant aux aides à la décision et aux situations dans lesquelles elles sont utilisées. Il est donc difficile d'interpréter correctement les effets sommés. Les critères de jugement examinés étaient presque tous des critères d'évaluation du processus. Il n'y avait aucune étude rapportant des critères de jugement cliniques.

Interprétation des résultats
Les résultats montrent que les aides à la décision ont une influence favorable sur la prise de décision partagée et qu'elles permettent aux patients non seulement de prendre des décisions en étant mieux informés et en disposant de plus de connaissances, mais aussi de poser des choix plus en harmonie avec leurs valeurs et leurs préférences. Pour la plupart des critères de jugement primaires, l'**ampleur absolue de l'effet** est modérée à élevée. Ainsi, les aides à la décision ont doublé le nombre de patients avec une évaluation correcte des risques associés aux différents choix possibles (de 25% à plus de 50%). De plus, le nombre de patients qui ont fait un choix correspondant à leurs valeurs et à leurs préférences a augmenté d'environ 30% à plus de 50%. En outre, avec les aides à la décision, les patients renoncent aux interventions chirurgicales majeures non urgentes. Les patients ont également moins choisi le dépistage du cancer de la prostate par dosage du PSA, mais il n'y a pas eu d'influence sur le choix du dépistage du cancer du côlon, du dépistage du cancer du sein d'origine génétique et du dépistage prénatal. L'utilisation des aides à la décision était toutefois associée à une augmentation de la durée des consultations de près de 3 minutes.

Conclusion de Minerva

Cette synthèse méthodique avec méta-analyse d'études randomisées, contrôlées, qui a été menée correctement, montre que les aides à la décision assurent une meilleure information des patients, une meilleure connaissance de leurs valeurs et de leurs préférences (preuve de qualité élevée). Elle montre aussi que les aides à la décision peuvent garantir un rôle plus actif des patients lors de la prise de décision et une meilleure évaluation par les patients des risques réels des différentes options stratégiques (preuve de qualité moyenne). Les résultats de cette synthèse méthodique ne permettent toutefois pas de se prononcer sur le type d'aide à la décision qui est le plus efficace ou dans quel contexte on obtient le meilleur résultat.

Pour la pratique

Une prise de décision partagée entre médecin et patient est particulièrement pertinente et actuelle, en Flandre également (6,7). Les aides à la décision peuvent constituer un dispositif important pour soutenir les patients dans ce processus décisionnel complexe. Il en existe de plusieurs formes et en différents formats. Les sites Internet www.mongeneraliste.be, www.gezondheidenwetenschap.be et www.thuisarts.nl sont des sources d'informations en français et en néerlandais qui peuvent aider lors de la prise de décision, mais on n'y trouve pas d'aides à la décision à proprement parler. Via la Cebam Digital Library for Health (www.cdlh.be), on a accès à la base de données Dynamed Plus. Pour différents sujets, tels que le dépistage du cancer de la prostate, différentes aides à la décision EBSCO Health Option Grids® sont proposées ici en anglais. La présente synthèse méthodique avec méta-analyse de la Cochrane Collaboration étaye l'importance de la poursuite du développement des aides à la décision dans le processus décisionnel concernant la santé.

Références voir site web

Box 4: Examples of tools for assessing the quality of consumer health information

DISCERN **(www.discern.org.uk)**—developed to assess the quality of health information on treatment choices.[13 14] A number of hints are given after each question to guide the user. Areas covered are: bias in the material, a clear statement of aims, references and additional sources of support and information, uncertainty, risks and benefits (including those of opting for no treatment), and treatment options. DISCERN also alerts the user to concepts such as shared decision making, and quality of life. An online version (www.discern.org.uk) is currently being tested.

The Health Information Quality Assessment Tool **(hitiweb.mitretek.org/iq)**—the Health Summit Working Group in North America (hitiweb.mitretek.org/hswg) is currently developing a reliable and valid appraisal tool for users of health information on the internet.[15] The tool is interactive and is potentially useful for patients wishing to evaluate the overall quality of health related websites. The main areas currently covered are credibility, content, disclosure, links, design, interactivity, and caveats (information on the function of the site).

leaflets for patients, Smith emphasised the time it takes to produce clear, unambiguous material that patients will use.[20] In addition to following validated quality criteria, writers should take patients' information needs into account and be aware of how people will read what they have written.[21 22] This will require involving patients in developing and testing materials.[10] Before embarking on this lengthy process, however, a first step is to check if high quality information already exists.

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Competing interests: SS receives royalties from the DISCERN handbook.

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Framework for teaching and learning informed shared decision making

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Patients should be involved in making decisions about their health care. The ethical imperative of autonomy is reflected in legal trends that require a high standard of disclosure for informed consent, amounting to a principle of informed choice.[1–3] Outcomes of care and adherence to treatment regimens improve when patients are more involved.[4 5] Consumerism is part of the social spirit, and governments exhort citizens to take more responsibility.

Models of doctor-patient encounters that result in increased involvement of patients and that are informed by good evidence have been termed, for example, "informed patient choice"[6–8] but do not describe the interactive process clearly. We use the term informed shared decision making to describe decisions that are shared by doctor and patient and informed by best evidence, not only about risks and benefits but also patient specific characteristics and values. It occurs in a partnership that rests on explicitly acknowledged rights and duties and an expectation of benefit to both.

We propose that a demonstrated capacity to engage in informed shared decision making is characterised by a set of necessary and sufficient competencies. By competencies we mean the knowledge, skills, and abilities that represent the instructional intents of a programme, stated as specific goals.[9] They are a framework for teaching, learning, practice, and investigation

Summary points

Competencies for the practice of informed shared decision making by physicians and patients are proposed

The competencies are a framework for teaching, learning, practice, and research

Challenges to putting informed shared decision making into practice are perceived lack of time, physicians' predisposition and skill, and patients' inexperience with making decisions about treatment

of what should be a coherent process and an accomplishment of any doctor-patient encounter in which a substantive decision is made about treatment or investigation for which reasonable choices exist. They are mainly related to communications skills, but at a higher level than those typically taught in medical schools and continuing medical education, where the emphasis tends to be on obtaining information from patients (diagnostics), breaking bad news, and health promotion. We present them with an intent of parsimony and coherence. The sequence is not intended to be prescriptive, nor do they describe verbal phrases or a check list of behaviours. The time and attention paid to the separate elements will vary with circumstances; they may occur over several encounters and will probably be iterative.

It seems logical that if informed shared decision making takes place in partnership then patients should bring certain abilities to the encounter. If the sole responsibility for informed shared decision making rests with physicians then we tend to perpetuate the paternalistic "doctor knows best" relationship. Others (such as a doctor's nurse or receptionist and a patient's spouse or parent) may also make important contributions to informed shared decision making. Although our work has mainly focused on the development of competencies for physicians, we have developed a preliminary set of complementary competencies for patients.

Methods

We performed a literature search using electronic databases (Medline, CINAHL, and HealthSTAR) and references listed in textbooks to produce a draft list of competencies. We then tested their validity in semistructured interviews with five family doctors, four patients, and three patient educators (health professionals whose role is to educate and counsel patients about their condition) who were identified by their peers as having good communication skills. We also tested the validity of the competencies in focus groups with cancer patients, diabetic patients, and patient educators.

Physician competencies

We defined a working set of eight competencies for physicians through the literature review, interviews, and focus groups (see box). The basic concepts inherent to informed shared decision making, and thus underlying the competencies, are partnership (competency 1), explicit dialogue (all, but especially 2 and 3), an informed patient (4 and 6) and physician (4 and 5), shared decision making (6 and 7), and completeness.[8]

Partnership

The defining characteristics of partnership derive from the models of mutual participation and contracts.[10–12] From the literature and our interviews and observations, we conclude that partnership

- Implies mutual responsibilities (both physician and patient have something to gain and contribute)
- Requires attention to, and explicit discussion about, the relationship
- Is dynamic and adapts to changing circumstances of either party
- Can be initiated at any time, but takes time to develop; most encounters ought to provide opportunities for partnership building
- Is key to the other informed shared decision making competencies.

Competencies for physicians for informed shared decision making

1 Develop a partnership with the patient

2 Establish or review the patient's preferences for information (such as amount or format)

3 Establish or review the patient's preferences for role in decision making (such as risk taking and degree of involvement of self and others) and the existence and nature of any uncertainty about the course of action to take

4 Ascertain and respond to patient's ideas, concerns, and expectations (such as about disease management options)

5 Identify choices (including ideas and information that the patient may have) and evaluate the research evidence in relation to the individual patient

6 Present (or direct patient to) evidence, taking into account competencies 2 and 3, framing effects (how presentation of the information may influence decision making), etc. Help patient to reflect on and assess the impact of alternative decisions with regard to his or her values and lifestyle

7 Make or negotiate a decision in partnership with the patient and resolve conflict

8 Agree an action plan and complete arrangements for follow up.

- Informed shared decision making may also:
  Involve a team of health professionals
  Involve others (partners, family)
  Differ across cultural, social, and age groups

Explicitness

In the absence of explicit discussion, physicians make incorrect assumptions and unilateral decisions about patients' information needs and preferences, and incorrectly assess their own information giving behaviour.[13–15] A consistent theme in the literature is that patients want more information than they get, although studies on patients' preferences for decision making show more variation. The obvious solution is to engage in an explicit

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Competencies for patients for informed shared decision making*

1 Define (for oneself) the preferred doctor-patient relationship
2 Find a physician and establish, develop, and adapt a partnership
3 Articulate (for oneself) health problems, feelings, beliefs, and expectations in an objective and systematic manner
4 Communicate with the physician in order to understand and share relevant information (such as from competency 3) clearly and at the appropriate time in the medical interview
5 Access information
6 Evaluate information
7 Negotiate decisions, give feedback, resolve conflict, agree on an action plan

*Preliminary list

discussion. Preferences should be rechecked since needs vary over time and at different stages of illness.[16] Some decisions are inherently more difficult, and uncertainty remains about the course of action to take—for example, because of a lack of information about alternatives and consequences, emotional distress, or perceived pressures from others.[17] Through discussion the physician may help to clarify the existence, nature, and degree of these uncertainties.

The informed patient

Patients bring information to the consultation that needs to be shared. In relation to decision making patients bring three perspectives to the problem: information, expectations, and preference.[18] Eliciting these concerns, ideas, and expectations is at the heart of patient centred care (finding common ground)[19] and again needs to be done explicitly. The patients we interviewed gave examples of how doctors make assumptions and inaccurate guesses about patients' concerns,[20] and there is always the potential for misunderstanding. For example, a reassurance such as "It's nothing to worry about" may be interpreted as ignoring important anxieties.

The informed physician

Physicians need to be able to find and evaluate current evidence.[21 22] Two points emerged from our interviews: the patients assumed that this is what doctors do already, and they wanted physicians to consider all options available (not just drugs) including those suggested by the patient. Alternative and complementary therapies are a challenge. The patients noted that physicians are often not open to or informed about such therapies ("Saying 'It can't do you any harm' is no discussion"), and there is rarely any evidence about their efficacy. Even if these are not included as valid choices they cannot be ignored. Many patients contemplate and use them, and only a minority disclose this to physicians.[23]

Shared decision making

A rich and complex literature on decision making, decision analysis, communication of risk information, and framing effects underlies this competency.[24 25] Theories about decision making suggest that people do not have stable and pre-existing beliefs about self interest but construct them in the process of eliciting information or deciding a course of action.[26] The way information is provided by the physician is therefore crucial in assisting patients to construct preferences.

Practising the competencies for informed shared decision making should lead to an agreed decision. Problems may arise if there is no obvious best option (for example, because of lack of good evidence) or disagreement about the best option. Physician and patient are then in conflict, and a solution needs to be negotiated. If decision making is not explicit, conflict may go unrecognised by the physician, with consequences such as patient dissatisfaction and non-adherence with treatment. In the context of informed shared decision making, we take negotiation to mean "a back and forth communication designed to reach an agreement when you and the other side have some interests that are shared and others that are opposed."[27 28]

Completeness

Informed and shared decisions do not just happen. Both parties need to be clear on what decision has been made, the plan to carry it out, the expectations, roles and responsibilities, and arrangements for follow up.[29] All encounters for informed shared decision making should conclude with an action plan. This may range from an informal verbal agreement to a formal written contract.

Patient competencies

In the absence of good literature on communication skills for patients, we asked our informants what patients should be able to do to play their part in informed shared decision making. The family physicians found it difficult to identify specific skills that patients should possess, but the patient educators and patients (particularly those with chronic diseases) had many suggestions, which we distilled into a preliminary set of competencies (see box).

Patients who are active in managing their health and illness are also active in managing the relationship with their doctor.[30] The patients with chronic conditions confirmed that they learn how to engage in partnership and improve their communication through experience. Patients can be taught these skills formally,[31–33] although experiments have been piecemeal. The refinement of patient competencies and ways to teach them are major challenges for successful implementation of informed shared decision making.

Other challenges

We have met three recurring objections in the course of our work.

"It would take too much time to do all that"

Several studies have shown that doctors trained in some of these communications skills do not take significantly longer to conduct patient interviews.[34–36] An encounter involving informed shared decision making may take longer but may still be more efficient because of improved health outcomes. Well developed skills may permit time savings. These are research questions. Our preliminary experiments with standardised patients (patients or actors trained to present with a consistent history) and physicians willing and

able to practise informed shared decision making suggest that competence in such decision making can be demonstrated in a 10 minute encounter.

"But we [physicians] already do that"

There is a wealth of somewhat depressing evidence that physicians and patients do not communicate well. Patients rarely give direct feedback about communication problems. This may encourage physicians to believe that the studies do not apply to them personally. Skills in communications and critical appraisal can be improved by training. In our experience the use of standardised patients with common problems has the advantage that good communications are focused on improved health outcomes, and physicians tend to be more accepting of, and responsive to, feedback about communications from patients (even standardised patients) than from peers or educators.

"What about patients who don't want to be involved?"

Specialist knowledge and the law create an imbalance in the power relationship between physician and patient. Any shift from a paternalistic physician practice toward a "meeting between experts"[37] requires the physician to encourage patient autonomy.[38] Most studies and theories of shared decision making are illustrated by "hard cases"—that is, situations in which decisions are for high stakes (such as treatment options for cancer). If physicians and patients are to become proficient at making informed and shared decisions it would be sensible to begin with common problems.[39] We are not surprised that patients shun making decisions about treatment for breast cancer if their prior experience gave little opportunity or encouragement in relatively minor medical situations.

Our informants noted the much commoner occurrence of elements of informed shared decision making in encounters about chronic disease such as diabetes or arthritis. Presumably, practice improved performance. Social, cultural, and language factors may be barriers to putting informed shared decision making into practice, but these probably occur as serious problems in only a minority of encounters for most physicians, and possible solutions have been proposed.[40] There are many situations in which informed shared decision making could be practised, in which patients wish it were practised, and in which the major barriers are lack of predisposition and skill.

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Commentary: Competencies for informed shared decision making

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As Towle and Godolphin have shown here, the best way to define the competences for a particular job is to ask the people who do it best, as well as those on the receiving end of the goods or services, and to use a second round of interviews to gain feedback on a first draft.[1] We are given few details of the recruitment methods used in this study, but it comes as no surprise that important outputs from health professionals for informed shared decision making include developing a partnership with patients, establishing their preference for the amount and format of information, finding and evaluating evidence on the different options, and presenting the data to patients in a way that doesn't blind them with science.

I have three main difficulties with this paper. Firstly, while it is useful to have the competences (outputs) for informed shared decision making spelt out, Towle and Godolphin seem to confuse these outputs with the component competencies (inputs) that might be expected to produce these outputs (and which might be improved by training). For example, we can infer obliquely from this article that the core competence "Develop a partnership" requires a number of separate inputs, which include being prepared to take responsibility (for this task), being able to communicate ("discussing the relationship") with a patient, and being sensitive (to the patient's changing circumstances)—but who is to say that these inputs are sufficient as well as necessary to produce that output, or that the same outputs could not be obtained from a different combination of inputs? The core competence "Identify choices and evaluate evidence" is given little attention here, yet there are probably over 20 separate inputs in terms of knowledge, skills, and attitudes required to achieve this complex task effectively.[2]

My second reservation concerns the theoretical notion of professional competency, which Towle and Godolphin treat as entirely unproblematic. Others have argued that the deconstruction of professional competence into component competencies is a flawed approach, being based on a behaviourist (and therefore reductionist), task oriented model that ignores the complexities of clinical practice.[3–6] Tanenbaum talks of the "practical wisdom" that forms the bedrock of clinical experience and which simply cannot be broken down into a straightforward cluster of tasks or traits.[7] I have argued elsewhere that the "competencies" model, extensively used in the industrial and commercial sectors, should not be grafted wholesale onto the performance of health professionals.[2]

Finally, this paper lacks a clear statement of how Towle and Godolphin's lists of "competencies" (strictly, competences) should be used. The eight for health professionals might, for example, be used to define professional standards, provide selection criteria, set training targets, or manage performance. Those for patients might inform the design of educational materials—but they could potentially be misused if they led to patients being formally defined as "not competent" for informed shared decision making (akin to being branded a "poor historian").

The fact that professional practice is difficult to define and impossible to deconstruct should not stop us from using sentences which begin, "The competent health professional should be able to …." Despite its limitations, Towle and Godolphin's analysis is an important first step towards a systematic approach to recruitment, training, and professional development in shared decision making.

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Commentary: Proposals based on too many assumptions

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From a patient's perspective, the outline premise of Towle and Godolphin's article is most welcome, but there are some major assumptions made that make informed shared decision making look a practical impossibility.

The most immediate issue is the presumption throughout of a "one to one" relationship between doctor and patient. Nothing in the article addresses patients' access to their general practitioner. To cite my personal experience, my general practitioner's practice has four doctors. With whom should the doctor-patient relationship exist, given that I might need speedy access to a doctor and that the general practitioner of my choice may, understandably, not be available on demand? Furthermore, what price the quality of informed shared decision making once patients leave their general practitioner's direct care, such as when they are referred to a specialist? Since my prostate tumour was diagnosed, I have been seen by a surgical urologist (twice), his locum (once), a clinical oncologist (twice), and her two locums (once each). How can there be a close working relationship between patient and

physician in such circumstances? And of course, each consultation, scan, treatment, or whatever requires a follow up consultation at my general practice, where it is quite likely that the general practitioner who referred me is not the general practitioner who deals with the consequences of the referral.

Towle and Godolphin make much of the need for patients to formally take a measure of responsibility in planning their treatment, and this requires that they are well informed about their condition and possible treatment options. Excellent. In my case I can and do monitor the scientific and academic press, websites, and news groups to stay aware of any developments that may have a bearing on my future treatment. But this is only possible because I am 51 years old, literate, articulate and have access to and an understanding of the techniques of information gathering and evaluation. What chance is there for elderly, poorly educated, and socially disadvantaged patients with the same condition that I have? Must they rely on the posters on their general practitioner's surgery wall?

Furthermore, not all patients will see informed shared decision making as desirable. Many patients—young and old—much prefer to believe that "Doctor knows best," and this cannot be lightly dismissed, even though it might be unacceptable to Towle and Godolphin, and perhaps to many other doctors. For such patients, informed shared decision making will be seen as doctors opting out of their responsibilities rather than an improvement in the doctor-patient relationship.

Finally, I wonder how such a tiny sample size of physicians, patients, and "patient educators" can be cited as valuable in making "a set of necessary and sufficient competencies."

Desirable though it might be for some patients to be more closely involved in managing their condition, the authors' suggestion that informed shared decision making become standard working practice presumes too much about the role of patients.

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Acknowledging the expertise of patients and their organisations

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The proportion of people living with a long term medical condition, both in the United Kingdom and throughout the world, is rising.[1 2] By living with and learning to manage a long term illness many people develop a high degree of expertise and wisdom. This article suggests ways in which people with a long term medical condition and their organisations can help develop partnerships between healthcare professionals and patients and questions how much their potential contribution is appreciated and capitalised on.

The US Centers for Disease Control and Prevention defines chronic diseases as "illnesses that are prolonged, do not resolve spontaneously and are rarely cured completely."[3] The Long-term Medical Conditions Alliance is developing a much broader definition that emphasises the effect that this type of illness has on people's emotional and social wellbeing; on their social, community, and working lives; and on their relationships. The alliance's definition emphasises the opportunities available to improve a person's quality of life, even when there is no cure for a particular condition. All these issues must be taken into account in planning when assessing a person's needs and how best to meet them.

The Long-term Medical Conditions Alliance is the umbrella body in the United Kingdom for 96 national voluntary organisations. Formed initially because of concerns arising from the reforms to the NHS in 1990, during which market principles were adopted to increase the efficiency of the service, the alliance enables organisations to work together to gain mutual support, to identify common concerns, to develop solutions, and to influence policy and practice.

Summary points

People living with a long term illness develop expertise and wisdom about their condition and want to play a part making decisions about their own health care

Partnerships should be encouraged between individual patients and healthcare professionals and between patients' organisations and the healthcare system

Developing partnerships between patients and healthcare professionals is not good in itself but offers a chance to improve health care and to make better use of resources

Partnerships can only be developed if there is investment by governments, if patients' capacity for self care is increased, and if the role of patients' organisations is developed

Partnerships between individuals

The concept of patients working in partnership includes the idea of patients working with healthcare professionals. Research in the Netherlands has shown that people with a long term condition want their relationships with clinicians to be based on mutual trust and respect. Most want to be responsible consumers of health care if the providers of that care create an environment in which patients receive guidance when choosing between alter-