

# *Draft Comparative Effectiveness Review*

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Number XX

## **Decision Aids for People Facing Treatment or Screening Decisions Relevant to Early Cancer**

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## Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see [www.effectivehealthcare.ahrq.gov/reference/purpose.cfm](http://www.effectivehealthcare.ahrq.gov/reference/purpose.cfm). AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site ([www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

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## Abstract

**Background:** Many health decisions about screening and treatment for cancers involve uncertainty or tradeoffs between the expected benefits and harms. Decision aids (DAs) have been developed to help health care consumers and their providers identify the available alternatives and chose the one that aligns with their values. It is unclear whether the effectiveness of DAs for decisions related to cancers differs by peoples' average risk of cancer, or the content and format of the DAs.

**Objectives:** We sought to appraise and synthesize the evidence assessing the effectiveness of DAs targeting health care consumers who face decisions about cancer screening or prevention, or early cancer treatment (Key Question 1), particularly with regard to DA or patient characteristics that might function as effect modifiers. We also reviewed interventions targeting providers for promotion of shared decisionmaking using DAs (Key Question 2).

**Data sources:** We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO, and the Cumulative Index to Nursing and Allied Health (CINAHL) from inception to October 2013.

**Review methods:** For Key Question 1, we included randomized controlled trials comparing interventions that use DAs to other DA interventions, to non-DA interventions, or to no intervention. We included trials of already-developed DAs delivered at the point of the actual decision. We predefined three population groups of interest, based on risk or presence of cancer (average cancer risk, high cancer risk, early cancer). The assessed outcomes pertained to measurements of decisional quality and cognition (e.g. knowledge scores), attributes of the decisionmaking process (e.g. Decisional Conflict Scale, DCS), emotion and quality of life (e.g. decisional regret), and the process and system-level attributes. We assessed for effect modification by population group, by the delivery format or content of the DA or other attributes, or by methodological characteristics of the studies. For Key Question 2, we included studies regardless of study design and outcomes assessed.

**Results:** Of the 15,515 screened citations, 84 publications were eligible, corresponding to 81 (67 trials, 25,199 participants) and 3 reports for Key Questions 1 and 2, respectively. Regarding the evolution of the DA format and content over time, more recent trials increasingly studied decision aids that were more practical to deliver, e.g., over the Internet, or without human mediation, and more often clarified preferences explicitly. Overall, participants using DAs had higher knowledge scores (41 trials, 12,385 participants, standardized mean difference, SMD = 0.23, 95% credible interval [CrI]: 0.06, 0.36) compared to those not using DAs. There were no large differences between using and not using DAs in decisional conflict (DCS) (27 trials, 7,820 participants, weighted mean difference, WMD = -0.22, 95% CrI: -0.38, -0.05), or anxiety (State-Trait Anxiety Inventory) (WMD = -0.11, 95% CrI: -0.98, 0.79). Qualitative synthesis suggested that patients using decision aids are more likely to make informed decisions and have accurate risk perceptions, and further, may make choices that best agree with their values, and may be less likely to remain undecided. Because there was insufficient,

sparse or no information about effects of decision aids on patient-provider communication, patient satisfaction with decisionmaking process, resource use, consultation length, costs, or litigation rates, a quantitative synthesis was not done. There was no evidence for effect modification by population group, the delivery format or content of the DA or other attributes, or by methodological characteristics of the studies. Data on Key Question 2 were very limited.

**Conclusions:** We mapped the evolution over time and captured the considerable diversity in the currently available DA-related randomized evidence. We found strong evidence that DAs increase knowledge without adverse impact on decisional conflict, or anxiety. We found moderate or low strength evidence that patients using decision aids are more likely to make informed decisions, have accurate risk perceptions, make choices that best agree with their values, and not remain undecided. This review adds to the literature that the currently available evidence does not support the notion that effectiveness of decision aids is modified by specific attributes of DA delivery format, contents, or other characteristics of their development and implementation. Very limited information was available on other outcomes or on the effectiveness of interventions that target providers to promote shared decision making by means of DAs.

## Introduction

Many health care decisions involve uncertainty due to the lack of robust evidence and/or tradeoffs between the expected benefits and harms.<sup>a</sup> For such decisions no universally optimal choice exists, because people differ in their attitudes towards risk and how they value outcomes.<sup>1,2</sup> Some decisions about screening for cancer or management of early cancer are examples of value-laden decisions: The available options have comparable or uncertain effects on mortality or disease progression, so that other outcomes take the forefront in the decisionmaking process.

Decision aids have been developed to help health care consumers and their providers identify the available alternatives and choose the one that aligns with their values. They are used to supplement the interaction between patients and providers and promote shared decisionmaking.<sup>3,4</sup> According to the International Patient Decision Aids Standards (IPDAS) collaboration, a decision aid helps the patient recognize that a decision is to be made, provides information about the available options and their expected benefits and harms, and, in some fashion, helps consumers (patients) clarify their risk attitudes or preferences about possible outcomes.<sup>3</sup>

A Cochrane review has summarized the evidence on the effectiveness of decision aids across malignant and nonmalignant conditions,<sup>4</sup> and concluded that, across all examined populations and decision aid formats and contents, using decision aids increases knowledge about options and expected benefits and harms and results in an improved congruence between choices and values. Other published research where such evidence for cancers was systematically reviewed<sup>5-8</sup> reached similar conclusions.

However, it is still unclear whether the effectiveness of decision aids for decisions related to cancers differs by peoples' average risk of cancer, their health literacy and numeracy, or by the specific attributes of the decision aid-based intervention. Such information is important for developing practical guidance about designing and using decision aids, particularly for decisions related to early cancers (decisions related to screening, preventive treatment, or treatment of localized cancers where treatment has curative intent).<sup>9</sup> We triangulated the importance of these issues by engaging a diverse panel of stakeholders, including developers and users of decision aids, representatives of professional societies, patient advocates and non-syndicated patients. Further, the panel also agreed that provider willingness to engage in shared decisionmaking with decision aids is a prerequisite for patient use of decision aids outside the experimental setting of a trial. A Cochrane systematic review summarized evidence on the effectiveness of any intervention to increase the uptake of shared decisionmaking by health professionals

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<sup>a</sup> For example, while it is clear that a person with bacterial pneumonia should receive antibiotics, it is not clear whether a 55 year old man with low grade early prostate cancer should undergo surgery, or proceed with watchful waiting. For this cancer patient, uncertainty exists about the difference in the probability of long term survival or cancer progression with the various options. Further, because options have different risks of adverse outcomes (e.g., incontinence, sexual dysfunction, worry), they are value-sensitive.

through 2009, and concluded that healthcare professional training and use of decision aids may be important.<sup>10</sup> The current systematic review is designed to address these two issues.

## **Key Questions**

Two Key Questions formalize the aims of this work. They were developed over a stakeholder-driven and publicly reviewed topic development and refinement process.<sup>9,11</sup>

The first Key Question pertains to interventions targeting health care consumers who face decisions about cancer screening, or treatment of early cancer. It asks: how do interventions that incorporate decision aids compare with each other or with interventions that do not include decision aids with respect to measurements of decision quality, characteristics of the decisionmaking process, choices and adherence to choices, health outcomes, and health care–system outcomes? For example, does the use of a decision aid –compared to standard care– affect screening behavior in women facing the decision to continue mammography (and at which time intervals) or not?

The second Key Question pertains to interventions targeting providers who care for consumers facing decisions relevant to cancer screening or early cancer. It asks: how do these interventions compare with each other or with no intervention with respect to likelihood of engaging in shared decisionmaking, as well as to the outcomes mentioned in the first Key Question? For example, compared with no training, does training of providers in shared decisionmaking affect the willingness of providers to engage in shared decisionmaking?

For both Key Questions, a central component was the analysis of effect modifiers related to the characteristics of the populations and the attributes of the interventions, as detailed in the Methods section.

## **Methods**

The protocol for the systematic review was prospectively registered with the international prospective register of systematic reviews (PROSPERO – registration number CRD42013006197) and was informed by discussions with the technical experts listed in the beginning of this document over a series of teleconferences.

A Task Order Officer (TOO) with the Agency for Healthcare Research and Quality (AHRQ) oversaw the progress of the project, facilitated a common understanding among all parties involved in the project, and reviewed the report for consistency, clarity, and to ensure that it meets AHRQ standards. The TOO was asked for input, but did not make decisions in the design of the project or its conduct and had no part in the drafting of the report.

### **Eligible studies for Key Question 1**

We included randomized controlled trials comparing use of decision aids with other decision aids or with no decision aid intervention. We included trials of already-developed decision aids delivered at the point of the actual decision. We excluded trials about hypothetical treatment decisions. For example, we excluded hypothetical questions

about early cancer treatment in people not yet diagnosed with cancer, or trials about cancer screening among people who would not be typical screening candidates.

We predefined three populations of interest, based on risk or presence of cancer. The first population included people without cancer who are at *average risk* and face decisions about cancer screening (whether or how to be screened). The second population included people without cancer but with *high risk* of cancer, e.g., because they are suspected or known to have a hereditary cancer-related condition, such as the Lynch or von Hippel-Lindau syndromes, or are carriers of deleterious *BRCA* gene mutations. This group may face decisions about further diagnostic workup or about undergoing preventive interventions. The third population included patients diagnosed with *early cancer*, defined as being at a stage with favorable prognosis (typically, locally not advanced) and where interventions have curative intent (e.g., stage IIa or lower for prostate cancer). We accepted the individual study claims for the definition of early cancer. When a study used an alternative cancer staging, we adjudicated an early cancer stage using information for the National Cancer Institute site. We included only studies in people who were legally able to make decisions for themselves or an underage minor.

We followed the IPDAS collaboration and previous systematic reviews in defining decision aid-based interventions as, at a minimum, (1) informing about available options and the expected associated benefits and harms, and (2) incorporating at least implicit clarification of the decisionmaker's values.<sup>3,4</sup>

## Eligible studies for Key Question 2

For the second Key Question, we included comparative studies informing on the effectiveness of interventions for promoting shared decisionmaking to providers caring for the populations discussed for the first Key Question. Because so few studies have been done on this topic, eligible designs included randomized and cluster-randomized trials, nonrandomized studies with concurrent comparators, before-after studies, and interrupted time series studies.

## Outcomes

We identified outcomes of interest prospectively. Almost by definition, for most situations for which decision aids are proposed, the likelihood of mortality or other hard clinical outcomes across the compared options is either known to be similar or is substantially uncertain. Because there is no single optimal choice, hard clinical outcomes are probably not particularly relevant for measuring the effectiveness of decision-aid-based interventions. Intermediate health outcomes, such as quality of life, anxiety, depression, or decisional regret, are more relevant measures of the effects of decision-aid-based interventions. We organized outcomes in four groups:

- Outcomes related to *measurements of decisional quality and cognition* included differences in knowledge scores (about the condition, options, or expected outcomes as defined in each study); number of people making informed choices (people who have adequate knowledge and make a choice); and number of people with accurate risk perception.
- Outcomes related to *attributes of the decisionmaking process* included differences in the total score on the Decisional Conflict Scale (DCS);<sup>12</sup> patient, provider or third-

party-rated quality of communication (as defined by authors); patient participation in decisionmaking; proportion of undecided patients; patient satisfaction with the decisionmaking process; and intended choices and adherence to them.

- Outcomes related to *affect, emotion, and quality of life* included differences in the state or total scores of the State-Trait Anxiety Inventory (STAI, short or full version);<sup>13,14</sup> the Hospital Anxiety and Depression Scale (HADS);<sup>15</sup> quality of life *Short Form (SF)* 6-, 12-, or 36-item questionnaires;<sup>16</sup> the Impact of Event Scale (IES, for emotional distress);<sup>17</sup> and the Decision Regret Scale (DRS).<sup>18</sup>
- Finally, *process and system-level outcomes* included differences in resource use and valuations thereof, consultation length, and litigation rates.

Table 1 includes brief descriptions of selected instruments, along with comments on the interpretation of the magnitude of differences.

**Table 1. Descriptions of selected instruments and minimal important differences (known or assumed)**

Outcome category, Instrument	Description	Minimal important difference
<i>Attributes of decisionmaking process</i>		
Decisional conflict scale – DCS <sup>12</sup>	Five subscales measuring perceptions of uncertainty in choosing options, modifiable factors (e.g., feeling informed, having unclear values), and effective decisionmaking. Likert scale 1 (least conflicted) through 5 (most conflicted). We are using the total score.	It is unclear what the minimal important difference is. The DCS manual suggests powering studies for an <i>effect size</i> of 0.3, and we use this as a proxy of the minimal important difference. The <i>effect size</i> corresponds to a difference of 1.8 in the 1-5 scale, using a standard deviation in controls of 0.6 (median of observed studies).
<i>Affect, emotion and quality of life</i>		
State-Trait Anxiety Inventory – STAI <sup>13,14</sup>	20 questions on anxiety state, and 20 on trait. Results translated to a Likert scale from 1 (least anxious) to 5 (most anxious). We use results for state, or for the total score.	We found no information on the minimal important difference. We operationally define it as difference bigger than 1 unit, based on the scale range of 1-5.
Hospital Anxiety and Depression Scale – HADS <sup>15</sup>	Measures anxiety and depression domains, over a 0 (least) through 21 (most) scale for each domain. We are interested in the individual domains and the total score.	We found no information on the minimal important difference. We operationally define it as difference bigger than 5 on a 0-21 range (per domain) or bigger than 10 on a 0 to 42 range (total).
Short form (SF) 6, 12 or 36 <sup>16</sup>	Multi-purpose short form health survey covering 8 domains. Results translated to a Likert scale from 0 (worse) to 5 (best). We are interested in the mental health or the general health domain.	The minimal important difference is 1 unit in the 0-5 range.
Impact Event Scale – IES <sup>17</sup>	Measures subjective response to a traumatic event in intrusion and avoidance domains. Expressed in 0 (least impactful) to 1 (most impactful). We are interested in the total scale.	We found no information on the minimal important difference. We operationally define it as difference bigger than 0.25, based on the scale range of 0-1.
Decision Regret Scale – DRS <sup>18</sup>	Measures distress or remorse after a healthcare decision using 5 questions. Scores expressed in 0 (least regret) to 100 scale (most regret).	We found no information on the minimal important difference. We operationally define it as difference bigger than 25 units, based on the scale range of 0-100.

## Study identification

We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO, and the Cumulative Index to Nursing and Allied Health (CINAHL) from inception to October, 2013 using the strategy in Appendix A. We also perused the references included in other systematic reviews<sup>4-8</sup> and in included studies. We screened citations for eligibility using the open-source *abstrackr* software (accessible at [www.cebm.brown.edu/software](http://www.cebm.brown.edu/software)).<sup>19</sup> To ensure consistency, all reviewers screened the first 200 citations, in two rounds of 100 citations each. Disagreements were analyzed to clarify screening criteria. Once it was deemed that all reviewers applied criteria in the same way, we continued with single screening of the remaining abstracts.

All included papers were assessed for eligibility by two reviewers. In screening the full text papers, we identified trials with multiple reports, based on explicit references to other eligible papers and the enrollment sites and periods and numbers randomized. In order to capture sequential collaborative efforts, we paid attention to groups of reports that had at least half or at least three authors in common.

## Data extraction

We used the Systematic Review Data Repository (SRDR) to extract data from each study.<sup>20,21</sup> Extracted data are publicly available at <http://srdhr.gov/projects/143>. Extraction forms were specific to each Key Question and are also available in SRDR. Briefly, for each eligible study we extracted information from one or more associated articles about: (1) the citation; (2) the population (including baseline risk of cancer or cancer stage); (3) the delivery format (printed, audio or video material, computer software, Web site, in-person delivery - person providing logistical help-, use of support groups or patient navigators, decision board/option grid), content (explicit versus implicit elicitation of values; clear description of problem and options; generic versus personalized probabilities; others' opinions; human coaching in decisionmaking; non-human-mediated guidance in decisionmaking) and other attributes of the intervention (e.g., whether it was developed based on theory; was tailored to the populations' health or numerical literacy, language, or culture; or was interactive); (4) definitions of outcomes and outcome-related results; (5) and risk-of-bias-related items (see below). As needed, we back-calculated numbers for quantitative synthesis from graphs or other reported numerical information. We imputed missing standard deviations as the median standard deviation in less than eight percent of arms. Information on the characteristics of the decision aids and numerical information was extracted or cross-checked at least twice.

## Data synthesis and exploration of heterogeneity

For both Key Questions, we first synthesized the results qualitatively. We used sliding mean graphs to depict the evolution of decision aid formats and contents over time. Quantitative analyses were run for outcomes reported in at least 10 trials overall and in at least 2 trials in each population group (average risk, high risk, early cancer), and were carried out for three outcomes pertaining to the first Key Question. We used hierarchical random effects meta-regression analyses to examine associations between the outcomes in each arm, as well as study-level and arm-level characteristics. An explicit description of the analysis model is given in Appendix B.

We assessed effect modification as interaction term with the variable corresponding to the decision aid intervention. We examined effect modification for each population group (screening, high risk, early cancer), and for delivery formats, content, other attributes of the decision aid, and design items (generation of the randomized sequence, blinding of participants and outcome assessors, allocation concealment, and loss to followup larger than 20 percent).

### **Sensitivity analyses**

The recent update of the Cochrane review (current as of 2012) included a subset of the trials identified in the current report (see Appendix C for a description of the discrepancy). We repeated all analyses for this subset of trials.

In addition, we ran sensitivity analyses, including results from trials with incompletely reported results after making assumptions of borderline plausibility, and we checked the robustness of results by imputing 1.20 or 0.80 times the median standard deviation value when this was missing. We also examined alternative priors for model parameters. These results did not change materially and are not shown.

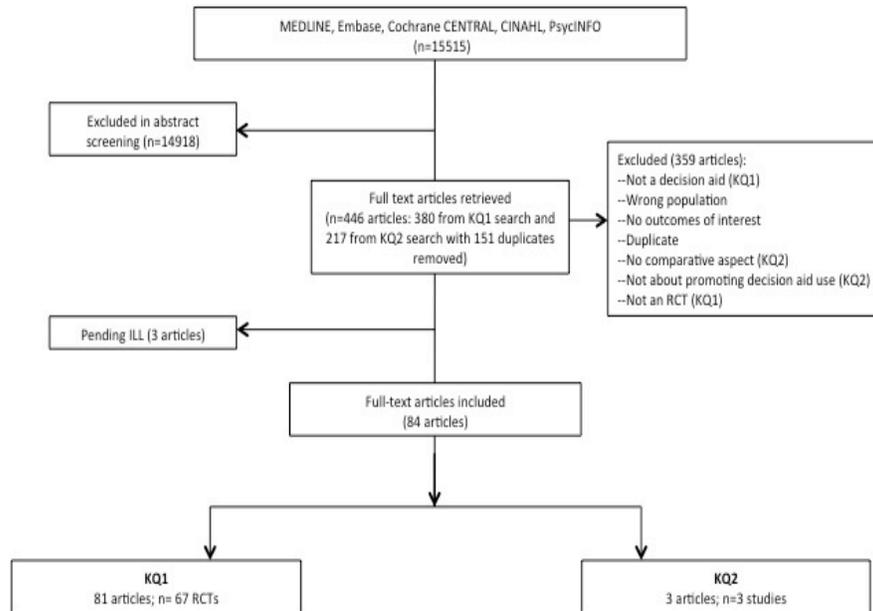
### **Risk of bias in individual studies and strength of the evidence-base**

We used the assessment methods for assessing risk of bias in individual studies and the strength of evidence for each outcome across the evidence base detailed in the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.<sup>22</sup> There are numerous, different study characteristics that may introduce bias in clinical trials; several of these characteristics are domain specific. We have explicitly evaluated risk of selection, performance, attrition, detection, and selective outcome reporting biases. The strength of the available evidence for each outcome was assessed for the body of evidence using four strength of evidence levels: high, moderate, low, and insufficient.<sup>22</sup> These describe our level of confidence that the evidence reflects the true effect for the major comparisons of interest.

## **Results**

Figure 1 summarizes the literature identification process. Overall, 15,515 citations were screened, 446 were retrieved in full text and 84 were eligible. See Appendix D for a list of the included articles and Appendix E for a list of the articles excluded during full text review. Of the eligible studies, 81 articles, corresponding to 67 RCTs, pertained to the first Key Question,<sup>23-103</sup> and 3 articles, corresponding to 3 studies, pertained to the second Key Question.<sup>104-106</sup> One RCT addressed both Key Question 1<sup>102</sup> and Key Question 2<sup>106</sup>.

**Figure 1. Literature flow for the systematic review**



CENTRAL = Cochrane Central Register of Controlled Trials; CINAHL = Cumulative Index to Nursing and Allied Health; ILL = inter-library-loan; KQ1, KQ2 = First, second Key Question; RCT= randomized controlled trial.

## **Comparative effectiveness of decision aids (Key Question 1)**

Table 2 summarizes characteristics of the 67 eligible trials (25,199 enrolled patients). Most trials (64 out of 67) focused on decisions relevant to breast, prostate, or colorectal cancer. The other three topics included thyroid, cervical, and ovarian cancer-related decisions. Thirty-seven (55%) of the studies were conducted in the USA. The next country with a considerable amount of published data was Australia (n=13). Nine studies were cluster randomized trials and 38 studies were multi-center trials. Twenty and 24 studies were conducted in a primary care and specialized care setting, respectively, with 23 in other settings (e.g. over the internet) or not reported. The majority of the studies (n=32) assessed the effect of decision aids on screening-related decisions, while 22 studies assessed treatment-related decisions and 13 studies assessed decisions pertaining to genetic risk. Within each cancer, the predominant type of decision for prostate and colorectal cancer was screening-related, while treatment was the predominant decision type for breast cancer. No trials were identified that examined decisions about malignancies in children. Appendix F Table of Study Characteristics displays the characteristics of each trial addressing Key Question 1.

In total, 54 distinct decision aids were examined in the 67 trials. Nine decision aids were examined in two trials (and two in three). In all cases when more than one trial evaluated a decision aid, the authors overlap, suggesting use of the aid by the same team. Usually, one or more decision aids were compared to usual care or no intervention with

the exception of eight studies where a head-to-head comparison between decision aids without another control group was implemented. The formats and contents of decision aids are summarized in Table 2.

Random sequence generation was clearly reported in 37 of the studies with unclear reporting in the remaining 30. Allocation concealment was achieved in 31 of the studies, primarily through the use of a Web site where allocation was performed automatically. As discussed before, masking was difficult to achieve in most of the studies as a majority of the outcomes were self-reported. For the actual choice assessment, masking would be feasible for those studies where actual choice was not self-reported, and in most studies that methodological parameter was not clearly reported. Finally, large attrition rates were not common when reported. Attrition rates less than 20% were present in 28 studies while large attrition rates (>20%) were observed in six studies, and the attrition was unclear in the remaining studies.

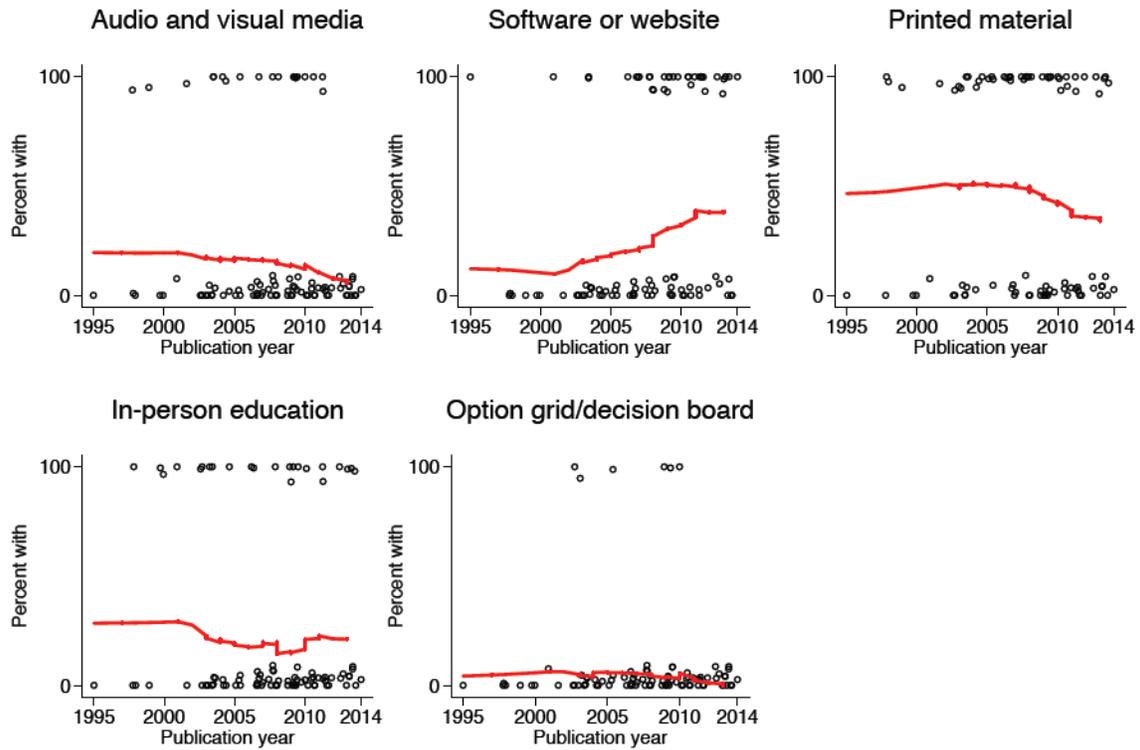
**Table 2. Summary descriptives for included trials and decision aid interventions**

<b>Population group</b>	<b>Average risk of cancer</b>	<b>High risk of cancer</b>	<b>Early cancer</b>
Number of studies (people)	32 (16,054)	13 (3656)	22 (5489)
Cancers considered (number of studies)	Breast (2), prostate (22), colorectal (8)	Breast (11), colorectal (1), ovarian (1)	Breast (9), prostate (10), colorectal (1), cervical (1), thyroid (1)
Mean participant age, median (range)	58.6 (43, 70.35)	44.45 (39, 61.7)	58.6 (45.8, 72)
Sample size median (range)	412 (49, 1960)	153 (30, 1197)	201 (60, 736)
Publication year (range)	2000-2013	1997-2012	1995-2013
Studies conducted in the United States, number (%)	22 (69%)	7 (50%)	9 (41%)
Studies with <50% participants completed high school, number (%)	3 (9%)	1 (7%)	6 (27%)
Comparators, median (range)	2 (2, 4)	2 (2, 3)	2 (2, 4)
<i>Delivery formats, number ( % of decision aids)</i>			
Audio and visual media	15 (19%)	0 (0%)	6 (15%)
Software or Web site	36 (30%)	14 (41%)	21 (53%)
Printed material	24 (45%)	7 (21%)	9 (23%)
Option grid/decision board	0 (0%)	1 (3%)	5 (13%)
In-person education	13 (16%)	18 (53%)	13 (33%)
<i>Content, number (% of decision aids)</i>			
Explicit elicitation of values	21 (26%)	7 (21%)	9 (32%)
Generic risk probabilities	39 (49%)	18 (53%)	12 (30%)
Personalized risk probabilities	6 (8%)	14 (41%)	4 (10%)
Others' opinions	27 (34%)	7 (21%)	12 (30%)
Non-human-mediated guidance in decisionmaking	9 (11%)	4 (12%)	5 (13%)
Human coaching in decisionmaking	9 (11%)	18 (53%)	13 (33%)
<i>Other attributes, number (% of decision aids)</i>			
Interactive	18 (23%)	6 (18%)	10 (25%)
Tailored to target population	14 (18%)	1 (3%)	4 (10%)
Used by consumer & provider	5 (6%)	8 (24%)	6 (15%)
Used by consumer only	66 (83%)	19 (56%)	24 (60%)

*Evolution of formats and contents of decision aid-based interventions over time*

The 67 included trials (Table 2) were published over the last two decades (1995-2013), during which time technologies, such as the Internet and personal computers, have evolved substantially and their availability has increased. Figure 2 shows the evolution over time of the decision aid delivery formats used in the studies assessed in this systematic review. The evolution of formats parallels the increasing penetration of technology in recent years. Internet-based decision aids have become more common, while use of printed materials, audio- and video- cassettes and compact discs, and in-person delivery of educational material by someone other than the provider have become less common.

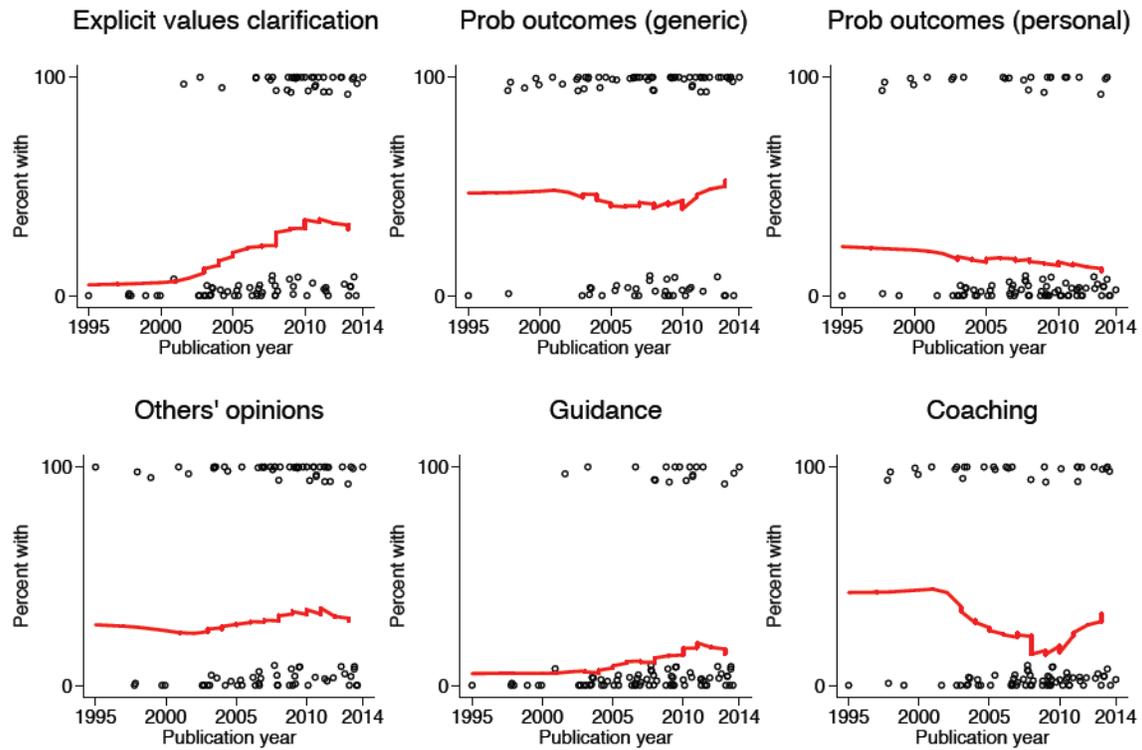
**Figure 2. Evolution of delivery formats over time**



Shown are trial arms including decision aids, denoted by circles. Some trials have more than one decision aid arm. The bold red lines correspond to the percent of trial arms with a respective delivery format over time: An example to help in interpreting the plots: the use of audiotapes and videocassettes or CDs (“audio and visual media”) has declined, whereas the use of software- or Internet-based decision aids has increased.

Figure 3 shows the corresponding evolution of the content-related attributes of decision aids for the included studies. Over recent years, explicit clarification of values has become more common. The proportion of decision aids presenting generic expected probabilities for outcomes has remained approximately constant, while the proportion presenting such probabilities as conditional on patient characteristics has diminished (some decision aids do not present outcome probabilities). The proportion of decision aids employing non-human-mediated guidance in decisionmaking had increased in recent years, while human-mediated coaching in decisionmaking has become less common.

**Figure 3. Evolution of contents over time**



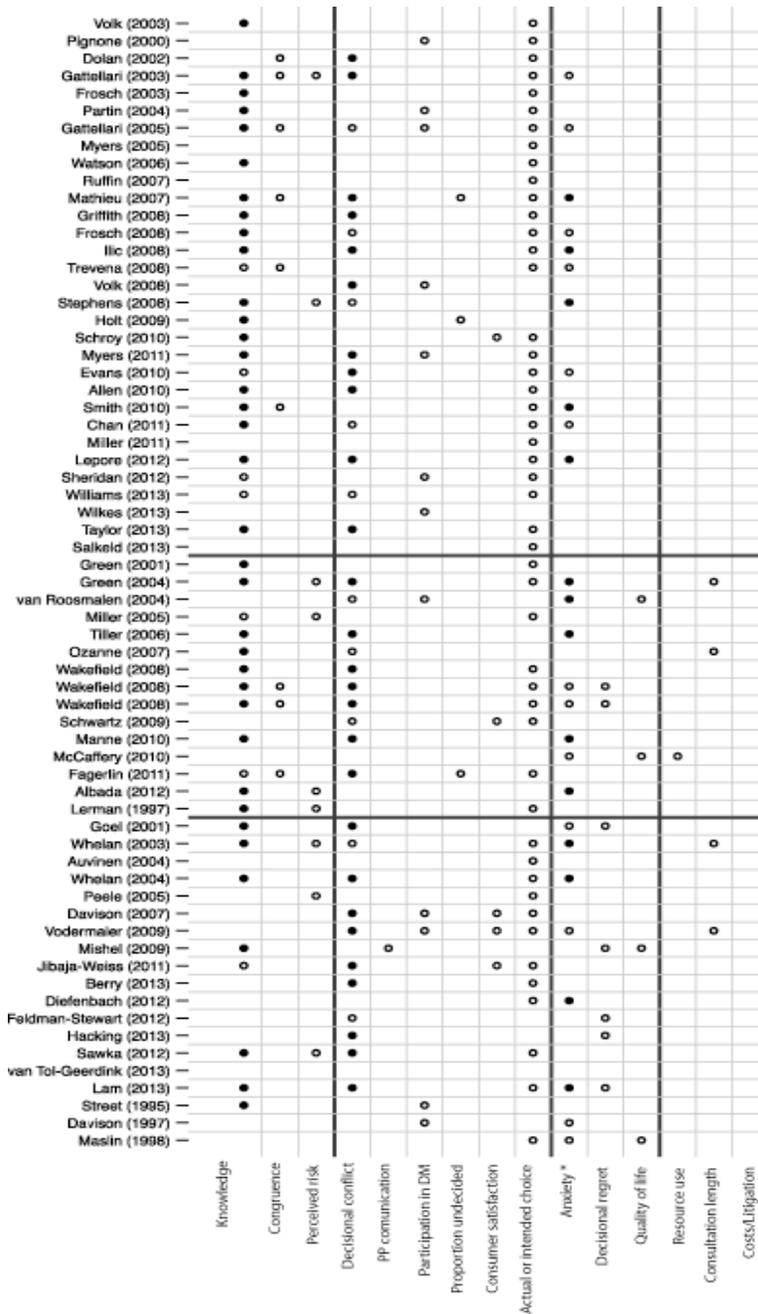
Coaching = human-mediated coaching in decisionmaking; guidance = non-human-mediated guidance in decisionmaking.

The observations in Figures 2 and 3 are congruent with the notion that more recent trials increasingly study decision aids that are more practical to deliver, e.g., over the Web or through computer software, without human mediation, and that they more often elicit preferences explicitly.

### Overview of assessed outcomes in the included studies

As shown in Figure 4, this literature has a proliferation of outcome measures, and few studies use similar outcome definitions, which hinders our ability to perform quantitative analyses. In the figure, filled or empty circles mark which of the 67 trials (rows) reported results on 15 prespecified outcome categories (columns). In three outcome categories (knowledge about condition and options; decisional conflict; and anxiety, depression, worry), black markers denote that the corresponding trials results have been included in a quantitative synthesis. All other trial results (empty circles) are synthesized only qualitatively. Although for some outcome categories many trials provide information, they use very different outcome definitions (e.g. anxiety, depression and worry scales used to assess the effect of a DA) not allowing a quantitative synthesis.

**Figure 4. Overview of outcome categories reported in the eligible trials**



Each row corresponds to a trial. Two horizontal thick black lines separate trials in populations at average risk for cancer (top), high risk for cancer (middle), and with early cancer (bottom). The 15 columns correspond to predefined outcome categories, in the order they are described in the text. Three vertical black thick lines separate outcomes related to measurements of decisional quality and cognition, attributes of the decisionmaking process; affect, emotion, and quality of life; and process and system-level outcomes. An empty cell means that a study (row) did not report on an outcome (column). A cell with an empty marker means that a study reported a result, but that no meta-analysis was done. In three columns, cells with filled black circles correspond to trials include in a quantitative analysis.

### *Knowledge about the condition or the available options*

We identified 43 trials assessing the effect of decision aids on factual knowledge about the decision at hand. In total, 37 trials (12,385 participants) reported analyzable information, and were included in the main analysis.<sup>a</sup> The analysis informs on the effects of using versus not using decision aids, and on the comparative effectiveness of decision aids with different characteristics. Because trials measured knowledge differently, we standardized the mean scores in each arm by the pooled sample standard deviation of responses in each trial, effectively calculating standardized mean differences (SMD). Almost all trials were deemed to be at a low or moderate risk of bias for this outcome.

Overall, using decision aids resulted in higher knowledge scores (SMD = 0.23, 95% credible interval [CrI]: 0.06, 0.36) compared to not using them. An SMD of 0.20-0.30 can be considered a small to moderate effect.<sup>107</sup> The effect appeared to be more pronounced among those at high risk of cancer (0.31, 95% CrI: 0.05, 0.59) compared to people at average risk (0.22, 95% CrI: -0.02, 0.37) or patients with early cancer (0.26, 95% CrI: 0.00, 0.67). However, the observed effects were not statistically significantly different (their differences could be explained by chance alone).

Between-study heterogeneity was substantial. Table 3 lists the results of meta-regressions seeking to explain it. Analyses suggest that effects on knowledge did not differ by most characteristics of decision aids. Decision aids offering a generic probability of outcomes showed a statistically significantly smaller difference in knowledge scores compared to the remaining decision aids (absolute difference in SMD 0.21; 95% CrI 0.02 – 0.44). There were no indications that effectiveness of decision aids differed by whether the delivery of the decision aid included a human (person providing logistical help, a support group, use of a patient navigator), was interactive, comprehensive (interactive and with explicit values clarification), personalized to the patient (as described by the paper), tailored to a target population, used by the patient and the provider, or used by the patient only. Finally, there were no indications that effectiveness of decision aids differed by the presence or absence of methodological quality items.

We also ran analyses where in addition to the factors listed in Table 3, we adjusted for population groups (screening, high risk for cancer, early cancer), and decision aid interactions across these groups. These analyses did not provide evidence that population groups modify the interaction effects (not shown for parsimony).

In summary, use of decision aids increases knowledge moderately albeit variably; the observed efficacy did not vary across population subgroups with different characteristics or across decision aid attributes.

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<sup>a</sup> Results from trials not included in the analyses are not explicitly reported in this document, and are available at the SRDR. Overall, no indication exists that they are incongruent with the herein presented quantitative analysis.

**Table 3. Effects of decision aids on knowledge about the condition or the available options**

Analysis	With factor	Without factor	Difference	Between-study SD
Overall	0.23 (0.06, 0.36)*			0.32
<i>Decision aid format</i>				
Audiovisual material	0.22 (0.08, 0.36)*	0.27 (0.07, 0.48)*	0.04 (-0.11, 0.23)	0.34
Software or website	0.17 (0.05, 0.23)*	0.46 (-0.02, 1.02)	0.29 (-0.18, 0.85)	0.14
Printed material	0.23 (0.10, 0.36)*	0.23 (0.10, 0.36)*	0.00 (-0.05, 0.04)	0.31
In-person education	0.24 (0.13, 0.35)*	0.17 (-1.09, 1.38)	-0.07 (-1.33, 1.15)	0.27
Option grid	0.24 (0.03, 0.40)*	0.04 (-0.92, 1.14)	-0.19 (-1.16, 0.93)	0.46
Decision board	0.24 (0.07, 0.38)*	0.04 (-1.49, 1.73)	-0.20 (-1.74, 1.52)	0.35
<i>Decision aid content</i>				
Explicit values clarification	0.22 (-0.03, 0.39)	0.22 (-0.00, 0.43)	-0.00 (-0.20, 0.25)	0.41
Probability of outcomes (generic)	0.10 (-0.09, 0.24)	0.31 (0.13, 0.49)*	0.21 (0.02, 0.44)*	0.12
Probability of outcomes (personalized)	0.26 (0.12, 0.43)*	0.15 (-0.26, 0.34)	-0.10 (-0.56, 0.08)	0.34
Others' opinions	0.22 (0.08, 0.34)*	0.24 (0.10, 0.36)*	0.02 (-0.02, 0.06)	0.31
Coaching in decisionmaking (human mediated)	0.23 (0.12, 0.34)*	0.17 (-0.29, 0.53)	-0.06 (-0.53, 0.31)	0.23
Guidance in decision making (non-human-mediated)	0.24 (0.11, 0.36)*	0.22 (0.02, 0.45)*	-0.01 (-0.21, 0.20)	0.32
Decision analytic model	0.24 (0.11, 0.37)*	0.14 (-1.19, 1.55)	-0.10 (-1.43, 1.32)	0.32
<i>Other attributes of the decision aid</i>				
Developed based on theory	NE	NE	NE	NE
Needing a human to deliver	0.22 (0.11, 0.34)*	0.24 (0.13, 0.36)*	0.02 (-0.02, 0.08)	0.30
Comprehensive**	0.22 (0.11, 0.35)*	0.32 (-0.37, 1.02)	0.09 (-0.59, 0.80)	0.30
Personalized to patient***	0.24 (0.08, 0.40)*	0.22 (0.08, 0.37)*	-0.02 (-0.16, 0.16)	0.26
Tailored to target population	0.23 (0.03, 0.41)*	0.24 (-0.44, 0.87)	0.01 (-0.71, 0.70)	0.36
Used by patient and provider	0.26 (0.14, 0.41)*	0.07 (-0.33, 0.36)	-0.19 (-0.61, 0.11)	0.32
Used by patient only	0.07 (-0.06, 0.29)	0.27 (0.13, 0.44)*	0.19 (-0.05, 0.40)	0.17
Includes human for logistical support	0.23 (0.09, 0.37)*	0.24 (0.08, 0.38)*	0.00 (-0.04, 0.03)	0.35
Includes support group	0.23 (0.12, 0.35)*	0.39 (-2.22, 3.01)	0.16 (-2.46, 2.79)	0.30
Includes patient navigator	NE	NE	NE	NE
<i>Methodological quality items</i>				
Adequate random sequence generation	NE	NE	NE	NE
Allocation concealment	NE	NE	NE	NE
Outcome assessor masking	NE	NE	NE	NE
Attrition rate >20%	NE	NE	NE	NE

\* 95% credibility interval does not include 0

\*\* Decision aids having both explicit clarification of values and presenting personalized probabilities of outcomes

\*\*\* As described in the primary paper.

NE = not estimable (analysis not converged or very wide 95% Credible Intervals); SD = standard deviation

### *Congruence between choices and values, and informed choices*

Two trials (1079 participants) compared decision aids versus a non-decision aid control with respect to congruence between actual choices and patient values for decisions related to prevention of breast cancer with hormonal therapy,<sup>37</sup> and treatment of localized prostate cancer.<sup>29</sup> Both were deemed to be at low risk of bias. One found that women in the decision aid arm showed alignment between values and choices significantly more often than the control arm.<sup>37</sup> The other documented no statistical difference between actual choices and patient concerns.

Five trials (2406 participants) compared the proportion of people making an informed choice, defined as people who made a choice and had adequate knowledge,<sup>a</sup> between decision aids and a non-decision aid control among people at average<sup>60,61,83,88</sup> and high risk<sup>37</sup> of cancer. All trials were deemed to be at low risk of bias for this outcome. All but one<sup>61</sup> found that the frequency of informed choices was statistically significantly higher in decision aid groups compared to control groups.

Another four trials (970 participants) reported on the proportion of patients who answered a question about whether they believed they had made an informed choice.<sup>41,42,97,98</sup> Three trials documented statistically significantly higher frequency of perception of making an informed choice among those using versus not using decision aids, and one found no significant difference. However, these results are not easy to interpret, because of the high risk of cognitive bias<sup>108</sup> for this outcome.

In summary, in most studies use of decision aids was statistically significantly associated with better indices of informed choice. Yet the assessment of informed choice showed great variety across studies ranging from single unvalidated questions to validated instruments.

#### *Accurate perception of fatality risk*

Eight trials (2316 participants) evaluated the accuracy of perception of fatality risks among people at average risk of cancer,<sup>41,84</sup> at high risk of cancer,<sup>23,46,57</sup> and with early cancer.<sup>72,77,100</sup> Determining each trial's risk of bias for this outcome is greatly hindered by the lack of details about its assessment. Thus, operationally, seven trials were deemed to be at moderate and one<sup>84</sup> at low risk of bias. Results across all trials suggested that participants receiving decision aids more often had accurate perceptions of long-term (e.g., over 10 years) or lifetime risk of dying, or other risks (e.g., developing cancer). Such findings reached statistical significance in five trials.<sup>41,57,72,77,100</sup> Because trials differed in the risks they examined, and how they assessed the accuracy of risk perception, it is not straightforward to characterize the importance of the observed effects of decision aids versus control, and impossible to examine the role of effect modifiers.

#### *Decisional conflict*

We identified 33 trials assessing the effect of decision aids on decisional conflict. In total, 27 trials (7820 participants) reported analyzable data about mean differences in the Decisional Conflict Scale (DCS); the DCS uses item statements and a 5-point agreement scale and has been validated in various geographical and language settings as well as in low literacy groups.<sup>12,b</sup>

No information was available about what difference in DCS is clinically important. However, the manual of the DCS questionnaire suggests to power studies for a clinically significant difference in the effect size of about 0.3, and we use this as a proxy for an important difference; assuming a standard deviation of responses of about 0.6,<sup>c</sup> this translates to a difference of 1.8 points in a DCS scale of 1-5. Almost all trials were

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<sup>a</sup> The definition of informed choice varied across trials.

<sup>b</sup> Results from trials not included in the analyses are not explicitly reported in this document, and are available at the SRDR. Overall, no indication exists that they are incongruent with the herein presented quantitative analysis.

<sup>c</sup> This is (rounded) the median standard deviation for this outcome in the included studies.

deemed to be at a low or moderate risk of bias for this outcome. Overall, there were no large differences in the DCS between using and not using decision aids, assessed shortly after the completion of the intervention. The weighted mean difference (WMD) was -0.22 (95% CrI: -0.38, -0.05), indicating marginally lower mean decisional conflict scores in decision aids compared to controls.

The difference appeared more pronounced among those at high risk of cancer (-0.33, 95% CrI: -0.64, -0.03) compared to people at average risk (-0.18, 95% CrI: -0.46, 0.10) or patients with early cancer (-0.17, 95% CrI: -0.43, 0.10). However, there was no statistical indication that the effects of decision aids differed across population groups, as the credible intervals for such differences were wide and included 0.

Between-study heterogeneity was substantial. Table 4 lists the results of meta-regressions seeking to explain it. Analyses suggest that effects on the DCS did not differ substantially by any of the examined characteristics of decision aids, or studies. Finally, there were no indications that effectiveness of decision aids differed by the presence or absence of methodological quality items with or without adjusting for population group.

In summary, use of decision aids seems to variably but moderately affect aspects of decisional conflict overall and in any subgroup; the observed efficacy was not mediated by characteristics of the decision aid or the methodological quality of the assessed studies.

**Table 4. Effects of decision aids on decisional conflict (Decisional Conflict Scale)**

Analysis	With factor	Without factor	Difference	Between-study SD
Overall	-0.22 (-0.38, -0.05)*			0.35
<i>Decision aid format</i>				
Audiovisual material	-0.22 (-0.39, -0.06)*	-0.20 (-1.47, 0.73)	0.02 (-1.24, 0.95)	0.35
Software or website	-0.15 (-0.21, -0.10)*	-0.26 (-0.61, 0.09)	-0.11 (-0.46, 0.24)	0.06
Printed material	-0.23 (-0.41, -0.05)*	-0.22 (-0.39, -0.04)*	0.01 (-0.10, 0.16)	0.35
In-person education	-0.24 (-0.44, -0.04)*	-0.18 (-0.56, 0.25)	0.06 (-0.36, 0.53)	0.37
Option grid	-0.22 (-0.40, -0.04)*	-0.19 (-1.79, 1.33)	0.03 (-1.56, 1.56)	0.36
Decision board	-0.22 (-0.40, -0.05)*	-0.20 (-1.69, 1.29)	0.02 (-1.48, 1.50)	0.36
<i>Decision aid content</i>				
Explicit values clarification	-0.23 (-0.48, -0.00)*	-0.23 (-0.43, -0.04)*	-0.02 (-0.20, 0.29)	0.36
Probability of outcomes (generic)	-0.36 (-0.67, -0.07)*	-0.15 (-0.37, 0.07)	0.21 (-0.14, 0.58)	0.35
Probability of outcomes (personalized)	-0.18 (-0.34, -0.04)*	-0.26 (-0.62, 0.09)	-0.07 (-0.46, 0.28)	0.27
Others' opinions	-0.24 (-0.42, -0.05)*	-0.21 (-0.40, -0.02)*	0.02 (-0.12, 0.21)	0.35
Coaching in decisionmaking (human mediated)	-0.19 (-0.40, 0.03)	-0.27 (-0.61, 0.06)	-0.09 (-0.48, 0.32)	0.36
Guidance in decision making (non-human-mediated)	-0.24 (-0.42, -0.06)*	-0.19 (-0.42, 0.05)	0.05 (-0.16, 0.29)	0.35
Decision analytic model	-0.23 (-0.41, -0.05)*	-0.10 (-1.64, 1.49)	0.13 (-1.42, 1.73)	0.36
<i>Other attributes of the decision aid</i>				
Developed based on theory	NE	NE	NE	NE
Needing a human to deliver	-0.35 (-0.58, -0.11)*	-0.22 (-0.39, -0.06)*	0.13 (-0.05, 0.29)	0.35
Comprehensive**	-0.22 (-0.39, -0.06)*	-0.13 (-0.46, 0.33)	0.08 (-0.21, 0.54)	0.35
Personalized to patient***	-0.16 (-0.39, 0.09)	-0.23 (-0.39, -0.07)*	-0.07 (-0.30, 0.15)	0.27
Tailored to target population	-0.17 (-0.27, -0.08)*	-0.36 (-1.03, 0.31)	-0.19 (-0.87, 0.48)	0.16
Used by patient and provider	-0.24 (-0.44, -0.04)*	-0.15 (-0.62, 0.30)	0.10 (-0.42, 0.58)	0.37
Used by patient only	-0.14 (-0.29, -0.01)*	-0.24 (-0.45, -0.02)*	-0.10 (-0.35, 0.16)	0.09

Includes human for logistical support	-0.22 (-0.39, 0.05)	-0.21 (-0.39, 0.04)	-0.01 (-0.05, 0.04)	0.35
Includes support group	NE	NE	NE	NE
Includes patient navigator	NE	NE	NE	NE
<i>Methodological quality items</i>				
Adequate random sequence generation	NE	NE	NE	NE
Allocation concealment	NE	NE	NE	NE
Outcome assessor masking	NE	NE	NE	NE
Attrition rate >20%	-0.22 (-0.63, 0.18)	-0.22 (-0.45, 0.00)	0.00 (-0.22, 0.21)	0.33

\* 95% credibility interval does not include 0

\*\* Decision aids having both explicit clarification of values and presenting personalized probabilities of outcomes

\*\*\* As described in the primary paper.

NE = not estimable (analysis not converged or very wide 95% Credible Intervals); SD = standard deviation

### *Patient-provider communication*

A single trial in 256 men with early prostate cancer<sup>66</sup> compared two decision aid-based intervention arms (booklet, DVD, phone call by a nurse; same plus calls to a designated primary support person) and a control arm with respect to the Patient-Provider Communication Scale. Operationally, its risk of bias for the outcome was deemed moderate, because of incomplete reporting of study procedures. People in intervention arms had higher scores than those in the control arm at 1 month but the difference dissipated at 3 months of followup.

### *Patient participation in decisionmaking*

Patient participation in decision-making was reported in four trials totaling 1549 persons facing prostate cancer screening decisions<sup>68,81,94,102</sup>, one trial of 88 women with *BRCA1/2* mutations<sup>89</sup>, and three trials in 536 patients requiring treatment for prostate cancer<sup>32,33</sup> or breast cancer.<sup>91</sup> Six of the eight trials compared decision aids versus control (e.g., usual care, video for irrelevant topic), and the other two compared decision aids between them (entertainment-based versus non-entertainment-based decision aid<sup>94</sup>, individualized decision support versus informational video<sup>33</sup>). Patient participation in decisionmaking was self-reported in seven trials and by a third party in one.<sup>68</sup>

Overall, there were no strong indications for important effects of decision aids on this outcome. Six trials found no significant differences between decision aids and non-decision aid controls, or between different decision aids. Two trials found significant differences indicating higher patient participation in decisionmaking in the decision aid versus control.<sup>33,68</sup> Evaluating trials' risk of bias with respect to this outcome category is hindered by the lack of detail about its quantification; operationally, no trial was deemed to be at a high risk of bias.

### *Proportion undecided*

Two trials (1046 people) of decision aids about mammography screening,<sup>60,61</sup> one (1197 people) on hormonal treatment for breast cancer prevention,<sup>37</sup> and one (240 patients) on treatments of prostate cancer<sup>90</sup> reported differences in the proportion of undecided people between decision aids and non-decision aid controls. Results across all trials suggested that participants receiving decision aids were statistically significantly less likely to be undecided compared to those in the control group. With respect to this outcome, one trial<sup>37</sup> was deemed to be at high risk of bias because of large non-response

rates, and the other three were deemed to be at low risk of bias. Because the trials are about different decisions, it is not straightforward to characterize the importance of the observed effects. It was not possible to examine the role of effect modifiers.

#### *Patient satisfaction with decisionmaking process*

Patient satisfaction with the decisionmaking process<sup>a</sup> was reported in one trial in 665 persons making decisions about colorectal screening,<sup>78</sup> and three trials in 466 women facing decisions about breast cancer treatment.<sup>53,91,101</sup> The trial about screening decisions<sup>78</sup> had three arms (interactive computerized decision aid versus the same plus an online risk calculator versus a website with generic discussion of lifestyle changes), while the other three trials compared decision aids versus non-decision aid controls. In all, for comparisons of decision aids versus control, two of four trials found statistically significantly higher satisfaction with decision aids, and two found no statistically significant differences. In the three-arm trial there was no significant difference between the two decision aid-based arms. Self-rated patient satisfaction scores may favor the decision aid for reasons such as low initial expectations and no experience with a meaningful shared decisionmaking process, or reluctance to second guess a previous decision.<sup>109</sup> Therefore, the importance of differences in the satisfaction scores is not straightforward to assess, and the risk of bias of all studies for this outcome was operationally deemed to be unclear. It was not possible to examine the role of effect modifiers.

#### *Actual or intended choices*

Overall, 48 trials examined the effectiveness of decision aids with respect to actual or intended choices for the decisional problems at hand. The trial reports were published between 1997 and 2013 and almost two-thirds of the studies were conducted in the USA (n=29), with Australia being the second most common country (n=11). Seven trials were cluster-randomized trials and 12 trials included multiple centers. Eighteen and fourteen trials were conducted in a primary care and specialized care setting, respectively. The majority (n=29 trials) were about screening-related decisions, 7 assessed decisions pertaining to high genetic risk of cancer, and 12 assessed cancer-treatment-related decisions.

The 48 trials mostly compared one or more decision aids with a non-decision aid control (e.g., usual care/no intervention, generic information pamphlet), however seven trials compared between decision-aid based interventions without including a control. Most trials (n=20) examined actual choices<sup>b</sup> only, 16 examined only intended choices,<sup>c</sup> and 12 both intended and actual choices. Actual or intended choice was the primary outcome in 20 studies.

Most studies were deemed to be at a low or moderate risk of bias for this outcome. Random sequence generation was clearly reported in two-thirds of the studies

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<sup>a</sup> Measured with the Satisfaction with Decisionmaking Process Scale,<sup>108</sup> with a subscale of the Decisional Conflict Scale,<sup>11</sup> or with a custom question.

<sup>b</sup> Defined as ordering or completing a screening test or completing a treatment, and assessed through self-reporting or by cross-checking health records.

<sup>c</sup> Self-reported response to a single question assessed at the end of the intervention or at a short followup time point.

(n=30) with unclear reporting in the remaining one-third. Allocation concealment was achieved in half of the studies, through central randomization. Masking to group assignment was generally difficult to achieve, but it is not clear how this would bias assessments. Finally, large attrition (over 20%) was not common (reported in five out of 48 trials).

There was considerable diversity in the number and nature of choices across trials, and a quantitative synthesis was not done. However, one can obtain indications about the impact of decision aids on choices, by comparing the distributions of proportions between arms in each trial. Significant differences, irrespective of direction, imply an effect for decision aids. Seventy six such comparisons were done in the 48 trials, and 19 were statistically significant. However, there was no association between a significant association and year of publication, sample size, type of choice (screening or treatment), or methodological items (random sequence generation, allocation concealment, assessor masking, attrition rate over 20%).

The two largest studies evaluating choices pertained to breast<sup>60</sup> and prostate screening.<sup>86</sup> The breast screening trial compared a decision aid providing balanced information with usual care in 734 women in Australia, and found no difference in screening rates at one month. The prostate screening trial compared a print-based decision aid, a web-based interactive decision aid, or usual care in 1879 participants in the US, and also found no significant difference at 13 months. The largest study with statistically significant results for actual choice<sup>83</sup> was done in 572 people in Australia for decisions related to colon cancer screening, and found lower rates of screening participation in the decision aid group compared to usual care. The remaining studies with a statistically significant result for actual choice were of a smaller sample size (<100 participants per arm) or showed the statistically significant result in a subgroup analysis.

### *Anxiety*

We identified 24 trials that assessed anxiety outcomes. The majority used the State-Trait Anxiety Inventory (n=14), eight used the Hospital Anxiety and Depression Score (HADS) and two used other instruments. In total, 14 trials (2898 participants) reported analyzable data about mean differences in the state or total score of the State-Trait Anxiety Inventory (STAI) which is a self-reported psychological inventory based on a 1-5 Likert scale, consists of 40 questions and has been validated in numerous settings.<sup>a</sup> Almost all trials were deemed to be at a low or moderate risk of bias for this outcome.

No information was available about what difference in STAI is clinically important. However, the differences observed in Table 5 appear small with respect to the range of the scale, and are not likely to be clinically important. The weighted mean difference (WMD) was 0.11 (95% CrI: -0.98, 0.79), indicating slightly higher anxiety at the time of measurement when using versus not using decision aids. Mean anxiety did not differ beyond chance between those at average risk of cancer (0.17, 95%CrI: -1.16, 1.11), high risk of cancer (-0.77, 95% CrI: -2.87, 1.38) and early cancer (0.02, 95% CrI -3.55,

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<sup>a</sup> STAI differences are reported in a 1-5 scale (1 lowest, 5 highest anxiety). Results from trials using other instruments were included in a sensitivity analysis using SMDs. The results of the sensitivity analysis were qualitatively similar to the results reported for STAI.

3.56), as the credible intervals for differences across population groups were wide and included 0.

Between-study heterogeneity was substantial. Table 5 lists the results of meta-regressions seeking to explain it. Analyses suggest that effects on STAI did not differ substantially by any of the examined characteristics of decision aids, the studies, or their methodological items (Table 5). Sensitivity analyses adjusting the factors in Table 5 for population groups did not provide additional information (not shown).

**Table 5. Effects of decision aids on anxiety (state or total score of the State-Trait Anxiety Inventory)**

Analysis	With factor	Without factor	Difference	Between-study SD
Overall	0.11 (-0.98, 0.79)			0.44
<i>Decision aid format</i>				
Audiovisual material	0.05 (-1.25, 0.85)	0.39 (-2.80, 3.72)	0.42 (-2.76, 3.78)	0.55
Software or website	0.19 (-1.15, 1.37)	-0.54 (-2.38, 0.85)	-0.78 (-2.24, 0.71)	0.59
Printed material	NE	NE	NE	NE
In-person education	0.19 (-0.97, 1.06)	-0.71 (-3.53, 2.15)	-0.86 (-3.77, 2.20)	0.45
Option grid	0.14 (-1.02, 0.96)	-0.67 (-4.31, 2.80)	-0.75 (-4.48, 2.88)	0.48
Decision board	0.12 (-1.08, 0.93)	-0.60 (-4.18, 2.88)	-0.67 (-4.33, 2.97)	0.49
<i>Decision aid content</i>				
Explicit values clarification	NE	NE	NE	NE
Probability of outcomes (generic)	NE	NE	NE	NE
Probability of outcomes (personalized)	0.14 (-1.14, 1.02)	-0.52 (-3.83, 2.94)	-0.60 (-3.98, 3.04)	0.51
Others' opinions	NE	NE	NE	NE
Coaching in decisionmaking (human mediated)	0.17 (-1.01, 1.05)	-0.52 (-2.96, 1.92)	-0.65 (-3.24, 1.97)	0.45
Guidance in decision making (non-human-mediated)	0.08 (-1.09, 0.82)	0.30 (-5.97, 6.60)	0.30 (-6.05, 6.62)	0.5
Decision analytic model	0.14 (-0.93, 0.90)	-1.84 (-8.09, 4.13)	-1.93 (-8.20, 4.15)	0.45
<i>Other attributes of the decision aid</i>				
Developed based on theory	NE	NE	NE	NE
Needing a human to deliver	0.27 (-0.71, 1.34)	-0.62 (-1.80, 0.60)	-0.91 (-1.96, 0.23)	0.47
Comprehensive**	0.12 (-1.23, 1.00)	-0.20 (-2.62, 2.23)	-0.26 (-2.84, 2.46)	0.51
Personalized to patient***	NE	NE	NE	NE
Tailored to target population	0.11 (-1.17, 0.94)	-0.19 (-4.65, 4.35)	-0.23 (-4.74, 4.49)	0.53
Used by patient and provider	0.08 (-1.16, 0.83)	0.36 (-3.89, 4.99)	0.34 (-3.92, 5.15)	0.51
Used by patient only	NE	NE	NE	NE
Includes human for logistical support	NE	NE	NE	NE
Includes support group	NE	NE	NE	NE
Includes patient navigator	NE	NE	NE	NE
<i>Methodological quality items</i>				
Adequate random sequence generation	NE	NE	NE	NE
Allocation concealment	NE	NE	NE	NE
Outcome assessor masking	0.29 (-2.35, 2.40)	0.09 (-1.43, 1.24)	-0.20 (-1.50, 1.22)	0.53
Attrition rate >20%	NE	NE	NE	NE

\* 95% credibility interval does not include 0

\*\* Decision aids having both explicit clarification of values and presenting personalized probabilities of outcomes

\*\*\* As described in the primary paper.

NE = not estimable (non convergence or very wide 95% credible intervals); SD = standard deviation.

### *Depression, and emotional distress*

For depression and emotional distress (worry or presence of intrusive thoughts) we did not have enough trials to perform quantitative analyses. Nine trials (four in people at high risk of cancer, and five in people with early cancer) reported assessing depression outcomes using the Hospital Anxiety and Depression Scale or the Center for Epidemiologic Studies Depression Scale,<sup>32,55,59,87,89,92,97,98,101</sup> but only four<sup>55,87,89,101</sup> provided analyzable information. Both for comparisons of using versus not using decision aids and for comparisons between decision aids the magnitudes of reported effects were small, and statistically nonsignificant. It was not possible to examine the role of effect modifiers.

Finally, eight trials reported results with respect to emotional distress or worry (three in people at average risk and four in people at high risk of cancer, and one early cancer).<sup>41,42,58,60,62,80,87,89</sup> In all, no large differences were found in any study, both for comparisons of using versus not using decision aids,<sup>42,58,60,62,80,87,89</sup> and for comparisons between decision aids.<sup>41,42</sup> It was not possible to examine the role of effect modifiers.

### *Decision regret*

Seven trials (937 participants) reported results for decision regret from another instrument between 1 month and 1 year of followup.<sup>38,43,48,55,66,97,98</sup> Most studies used the Decision Regret Scale,<sup>18</sup> and one used the decision regret subscale of a quality of life scale.<sup>110</sup> All compared decision aids versus no decision aids, and one<sup>66</sup> also compared between two decision aids. Overall, use of decision aids was not consistently associated with higher or lower decision regret (lower in three trials, higher in three) compared to not using decision aids. No important differences were found in any study, both for comparisons of using versus not using decision aids, and for comparisons between decision aids. It was not possible to examine the role of effect modifiers.

### *Quality of life*

Four trials comparing decision aids versus control reported data on quality of life for a total of 777 patients; one on decisions about cervical cancer screening<sup>62</sup>, one about preventive treatments in women at high genetic risk for breast and ovarian cancer,<sup>89</sup> and two about treatment of early breast cancer<sup>59</sup> or prostate cancer.<sup>66</sup> In all, differences in quality of life favored decision aids versus control interventions; the difference was statistically significant in one trial,<sup>59</sup> and only for long-term followup in another.<sup>89</sup> The magnitude of the differences was small, and thus of unclear clinical importance. Assessment of the risk of bias for this outcome was not straightforward, because of unclear reporting of trial design, trial procedures or of details in outcome assessment. Operationally, the four trials were deemed at moderate risk of bias for this outcome. It was not possible to examine the role of effect modifiers.

### *Resource use*

One Australian trial of 314 women with borderline results in cervical cancer screening compared the number of calls to the provider clinic and visits to the practitioner in three arms: a decision aid about further work-up options versus usual care (Pap smear after 6 months) versus molecular human papillomavirus screening.<sup>62</sup> The trial found no statistically significant difference between the three arms, overall, or across any two.

(The median number of follow-up calls and of visits was 0 in all arms) The risk of bias for this outcome was deemed to be low.

### *Length of consultation*

Three trials (417 participants) compared decision aids versus control with respect to length of consultation in women at high risk of breast cancer facing further diagnostic or preventive treatment decisions<sup>46,69</sup> and in women with early breast cancer facing treatment decisions.<sup>101</sup> In a trial of women at risk to be *BRCA* mutation carriers the length of consultation was shorter in the decision aid arm, but this result was driven by the subgroups who were at low risk. No clinically or statistically significant difference was reported in the two other trials. Because of unclear reporting of trial design, trial procedures or details in outcome assessment, assessment of the risk of bias for this outcome was not straightforward. Operationally, the trials were deemed at moderate risk of bias for this outcome. It was not possible to examine the role of effect modifiers.

### *Other outcomes*

None of the included trials reported data on the prespecified outcomes of costs or litigation rates.

### *Sensitivity analyses*

Results of sensitivity analyses were qualitatively similar with the results described above. Limiting quantitative synthesis to the studies included in the recent update of the Cochrane review did not result in appreciable differences for the main effects of decision aids versus control, or for the modification of effects by population risk of cancer or presence of cancer, characteristics of the decision aid (format, content, need for delivery by a human, or other attributes, as listed in Tables 3, 4 and 5). Use of more uncertain priors for the modeling resulted in somewhat broader confidence intervals; the greatest sensitivity was observed to priors on parameters related to between-study heterogeneity for main or interaction effects. Results were similar when we used alternative imputations for missing standard deviations (1.2 or 0.8 times the median in the observed studies), and when we also included data extracted based on tenuous assumptions.

## **Results for Key Question 2**

Promotion of shared decision making on the part of health care providers in cancer screening or early cancer treatment was examined in only three studies:<sup>104-106</sup> two studies on screening for prostate cancer and one study on screening for colorectal cancer.

One study cluster randomized 227 Australian general practitioners in 220 practices to a combination of informational packages and three motivational peer-coaching sessions over three months, or to mailed summaries of PSA screening guidelines (control).<sup>104</sup> At the end of the three months, practitioners in the active intervention group were more likely to report that they always engaged in several behaviors facilitating informed decisionmaking (e.g., questioned men about whether they understood the pros and cons of PSA testing), and were less likely to agree that patients should remain passive when making decisions about PSA screening (OR=0.11; 95% CI = 0.04 to 0.31).

The second study cluster randomized 120 California primary care physicians in 55 waiting areas to brief Web-based interactive physician education on prostate cancer screening or to a standard Centers for Disease Control and Prevention brochure (control).<sup>106</sup> Standardized patients visited the physicians approximately three months after enrollment in the study, and recorded the encounters. Transcription and coding of the encounters revealed that intervention physicians engaged in a mean of 14 shared decisionmaking behaviors compared to a mean of 11 behaviors in control physicians. However behaviors related to elicitation of patient perspectives were infrequent and did not differ between intervention groups.

The third study examined an intervention to increase the distribution of decision aids at five California primary care clinics.<sup>105</sup> The study team used several strategies over 30 months to promote the distribution of decision aids, including academic detailing and training sessions for providers and staff. Increases in distribution rates in response to promotional activities were brief, and only 9.3% of patients eligible for colorectal cancer screening received a decision aid. The authors suggested several changes in health care practice and policy are necessary for shared decisionmaking to become a part of routine clinical practice, including a supportive team-based clinic culture, ongoing provider training in communication and shared decisionmaking skills, and implementation of incentives for patient engagement.

The three studies were deemed to be at low to moderate risk of bias for the range of outcomes they described. It was not possible to examine the role of effect modifiers because data were not available.

## Discussion

### *Overall summary and strength of evidence*

In the present evidence synthesis, we have systematically appraised the efficacy of decision aids in 67 published randomized controlled trials with over 25,000 participants facing a cancer screening or early-cancer treatment decision. The assessed decision aids showed considerable heterogeneity in terms of format, content, context and theoretical background often made synthesis a challenge. Considerable heterogeneity was also observed with regards to the type of decision and the outcomes assessed.

In sum, we found that decision aids increase knowledge without adverse impact on decisional conflict, anxiety, or possibly depression. There were indications that patients using decision aids are more likely to make informed decisions and have accurate risk perceptions, and further, may make choices that best agree with their values, and may be less likely to remain undecided. There was insufficient, sparse or no information about effects of decision aids on patient-provider communication, patient satisfaction with the decisionmaking process, resource use, consultation length, costs, or litigation rates. Based on the currently available randomized evidence, there was no indication that the effectiveness of decision aids was modified by differences in the population (general risk of cancer, high risk of cancer, or early cancer), delivery format, their contents, or other attributes of their development and implementation. However, the credible intervals were wide and moderate differences could not be excluded. Some isolated differences may be explained by chance (many predictors have been assessed

without any control for type I error),<sup>a</sup> or differences in outcome measurements. Finally, for Key Question 2, very limited information was available on the effectiveness of interventions that target providers to promote shared decision making.

Table 6 summarizes the dispositions of the review team about the strength of the evidence-base with respect to the Key Questions. A description of the methodological characteristics of the individual trials is provided in the Appendix (Appendix G) and a more detailed exposition of the strength of the evidence per population group, outcome category and comparison is provided in the Appendix (Appendix H).

**Table 6. Summary of conclusions and associates strength of evidence dispositions**

Conclusion	Strength of evidence	Comments
<i>Key Question 1 - effectiveness of using vs. not using DAs</i>		
Using DAs increases <b>knowledge</b> without adverse impact on <b>decisional conflict</b> or <b>anxiety</b>	-High (knowledge) -Moderate (decisional conflict), -Moderate/low (anxiety)	Quantitative analyses per outcome - Knowledge, SMD: 0.23 (0.06, 0.36) - Decisional Conflict Scale, WMD: -0.22 (-0.38, 0.05) - State Trait Anxiety Inventory, WMD: 0.11 (-0.98, 0.79)
Using DAs results in more <b>accurate risk perception</b> , <b>informed decisions</b>	Low	- Limited number of studies (less than 8, out of a total 67), each using different outcome definitions - No quantitative synthesis done
Using DAs has no adverse effects on <b>depression</b>	Low	[As above]
Using DAs may result in better <b>congruence between choices and values</b> , and may reduce <b>proportion of undecided patients</b>	Low	[As above]
The DA effect on <b>patient-provider communication, or patient satisfaction with decision-making process, or resource use, or consultation length, or costs, or litigation rates is unknown</b>	[Insufficient]	[As above]
DA efficacy does not vary across populations by risk /presence of cancer for <b>knowledge, decisional conflict, anxiety</b>	Low	- Wide 95% CrI cannot exclude potentially important effect modification
[Varying DA efficacy for other outcomes is unknown]	[Insufficient]	- Limited number of studies
<i>Key Question 1 - Comparative effectiveness of different DAs by delivery formats, content and other attributes*</i>		
There are no differences in efficacy between different DAs <b>knowledge, decisional conflict, and anxiety</b>	Low	- Results from hierarchical meta-regression - Wide 95% CrI cannot exclude potentially important effect modification for knowledge or decisional conflict - Based on 95% CrI width, clinically meaningful effect modification for anxiety is unlikely
[The DA effect modification for other outcomes is unknown]	Not rated	- Limited number of studies (between 0 and 8, out of a total 67), each using different outcome definitions - Cannot assess effect modification by factors - No quantitative synthesis done
<i>Key Question 2 – Effectiveness of interventions to promote shared decision making through DAs</i>		
[Insufficient information to draw conclusions]	[Insufficient]	- No data on most outcomes/ limited evidence-base

\* Formats = Audiovisual material, software or website, printed material, in-person education, option grid, decision board.

<sup>a</sup> We work in the Bayesian framework and use the 95% Credible Intervals to make a (probabilistic) description of whether an effect is different than zero. Doing many such analyses can result in an increased false positive discovery rate, analogous to lack of control for type I error in frequentist analyses.

Content = Explicit values clarification, probability of outcomes (generic), probability of outcomes (personalized), others' opinions, coaching in decisionmaking (human mediated), guidance in decision making (non-human-mediated), decision analytic model.

Other attributes = Developed based on theory, needing a human to deliver, having both explicit clarification of values and presenting personalized probabilities of outcomes, being personalized to patient, tailored to target population, used by patient and provider, used by patient only, includes human for logistical support, includes support group, includes patient navigator.

### Effectiveness and differential effectiveness of decision aids across populations

Arguably, decision aids would be most needed among vulnerable populations, including people with low literacy or numeracy, limited educational attainment, challenged socioeconomic status, or hindered by language and cultural barriers.<sup>111</sup> A proportion of trials evaluated decision aids tailored to a vulnerable population (n=19 of 67), and there was little evidence for difference in the effectiveness of decision aids in them (Tables 3, 4 and 5). The accumulated randomized evidence is insufficient to inform on whether tailored decision aids are more effective than non-tailored ones.

We found few or no trials for decisions relevant to malignancies other than breast, prostate and, to a lesser extent, colorectal cancer. Similar to observations from a Cochrane review on shared decisionmaking for pediatric malignancies,<sup>112</sup> we found no trials in guardians of children with malignancy. Therefore as decision aids are developed for other common cancers such as lung, bladder, uterus/cervix, skin (melanoma), pancreas, and thyroid cancers, or leukemias, it will be important to evaluate whether they have similar effectiveness as in the better-studied cancers.

### Characteristics of effective decision aids

We examined several characteristics of decision aid-based interventions to capture aspects of their “elaborateness”, in terms of their delivery formats, the personnel necessary to administer them, how they are used (by the participant alone, or in conjunction with a provider), and what information they contain. One might expect that decision aids that are interactive, present personalized probabilities of events, involve humans in their delivery, and so on, have different effects than decision aids without such attributes; however, we found little evidence to support that assumption. Although the 95% credibility intervals were wide and did not exclude moderate differences, this lack of effect modification might suggest that a large part of the benefits of decision aids are mediated by indirect mechanisms, e.g., perhaps through stimulating question-asking -and thus knowledge enhancement- and information solicitation on behalf of the patient which facilitates power attainment.<sup>113</sup>

### Role of theory

In the eligible trials, very few decision aids were (described to be) developed based on psychological theory, and it was not possible to detect whether they had different effects from other decision aids.

We took the pragmatic approach of summarizing empirical data. We did not attempt to map trial results on theoretical models about mechanisms through which decision aids can affect outcomes. Such an endeavor, perhaps through a path analysis or a mediation analysis, might help identify the theoretical models that best fit the empirical data, and provide explanations of why and how decision aids work. We cannot comment on the feasibility of such an effort. Even with appropriate individual patient data, it would

be a tall order. Further, such an analysis would interject extra-evidentiary information (through the structure of the theorized model itself), and should probably be treated as a hypothesis forming one. The difficulties of undertaking such an analysis may be exposed with a simple example: We found evidence that decisional conflict (at the shortest available followup) is somewhat lower with decision aids. However, one might expect a transient increase in decisional conflict when using a decision aid, which would subsequently resolve when the decision is cognitively and emotionally processed. It is unclear whether this dissonance is a matter of timing (e.g., trial data were measured after the decisional conflict peaked in the decision aid arm, and during a rebound); whether the decisional conflict measurement instruments have a systematic bias; or whether this theory is simply not supported by the data.

#### Need for standardization of outcomes at the person and system level

This literature has a proliferation of outcome measures. Figure 4 shows 15 categories of predefined outcomes, and trials used various definitions within each category. Developing good outcomes for the target concept of decisional quality as well as for the target of shared decision making happening is challenging,<sup>3</sup> but necessary for measuring the effectiveness of decision aids and for learning from past empirical data.<sup>109</sup> A major research goal should be to develop and promote a limited set of easily measurable and well-characterized outcomes of decisional quality. Further, if decision aids are to be used in routine care, in real-life settings, it is important to develop outcomes for monitoring their uptake, use and impact of decision aids at a systems level.<sup>10</sup>

#### Integration of decision aids in routine care

Decision aids are complex interventions, and their successful integration and continued use in routine care depends on many factors, including patient and provider acceptance, system infrastructure, fit with other processes, and other factors only peripherally related to the patient-provider dyad. Thus, implementation of decision aids interventions in routine practice requires consideration of many additional factors. Although we looked for studies of the effectiveness of interventions to providers for promoting shared decisionmaking through decision aids, we found limited evidence. A more general treatment of shared decisionmaking promotion interventions did not draw strong conclusions.<sup>10</sup> Explicit values clarification may suggest that the field is becoming more mature and the decision aids more sophisticated.

#### Methodological challenges

A most important methodological challenge is the lack of validation studies. Only eight decision aids were validated in a second trial. In all cases members of the same team, which typically includes the developers of the decision aid, conducted both trials. When independent replications do not exist, one cannot distinguish genuine replication from allegiance bias, where research conducted by allegiant teams may be more likely to find similar results. Further, a decision aid might work better in the hands of the developers (and in the system in which it was developed) compared to an implementation in a new setting. Finally, guidance on the reporting of trials of decision aid interventions might help standardize the presentation of research in this field.

### Living (adoptable and easy to update) decision aids

Decision aids should not be static, and should be kept current in terms of informational content and presentation and delivery formats. Decision aids that are one-off developments are likely to not be updated by their primary developers or by others. Thus one might consider the notion of investing in a generic platform for developing and delivering decision aids. The platform could allow for modular expansion of the decision aid content (e.g., to add stories of other people facing a similar problem, or a value clarification exercise) or include web-based ones. It would facilitate development of decision aids in other diseases by removing the need to obtain know how in the technical aspects of the development; translation to other languages; and keeping them current.

### Comparison with prior works

Our findings are in accordance with previous efforts to summarize the evidence on the effectiveness of decision aids in general or for cancer in particular. Prior works concluded that decision aids increase knowledge; increase the likelihood of choosing a less invasive option (for surgical care decisions, and decisions related to treatment of breast cancer), and decrease in decisional conflict, without major adverse impact on anxiety, depression, quality of life, or emotional distress.<sup>4,114-128</sup> These works focus on the overall effectiveness of decision aids, and secondarily, on how “simpler” decision aids compare with “more detailed” ones in head-to-head studies. For example, the 2014 Cochrane review defined as “simpler” the decision aid version that had fewer components or less personalized information, and as “more detailed” the decision aid with the most components or the most personalized information. The review found some evidence that “more detailed” decision aids result in somewhat higher knowledge scores than “simpler” ones.<sup>4</sup> However, the “more detailed” decision aid in one trial can have fewer components than the “simpler” decision aid in another trial. Thus it is not clear how to interpret this finding. A contribution of our systematic review is that it explicitly examined differences in the effectiveness of decision aids by isolating attributes of their delivery format, content, and other factors, and found that none is associated with decision aid effectiveness. Based on 95% credible intervals, none of the examined characteristics explained the effectiveness of decision aids. If there is indeed no difference between decision aids by the examined characteristics, simpler decision aids in terms of format, content or administration method (which might be less costly to develop and maintain, and easier to use) may be as effective as more elaborate ones.

### *Limitations*

Some limitations of this review are inherited from the individual studies, and have been discussed in the paragraphs above. Additional limitations pertain to selection biases that affect the whole evidence-base, including publication bias, and selective outcome or analysis reporting. When such biases operate the probability that a study (or an outcome or an analysis) is published (or reported in sufficient detail) is dependent on the findings. Typically, statistically significant studies or results are more likely to be published fully, compared to statistically nonsignificant ones. Thus, these biases can distort the summary of the evidence-base. No mitigation for the effects of these biases is feasible, and perhaps the only practical approach is the one we took here: be exhaustive in the efforts to

identify studies, run sensitivity analyses, and avoid untempered interpretations of the results.

### *Conclusions*

We mapped the evolution over time and captured the considerable diversity in the currently available decision-aid-related randomized evidence. We found that decision aids increase knowledge without adverse impact on decisional conflict, or anxiety. There were indications that patients using decision aids are more likely to make informed decisions and have accurate risk perceptions, and further, may make choices that best agree with their values, and may be less likely to remain undecided. This review adds to the literature that the currently available evidence does not support the notion that effectiveness of decision aids is modified by specific attributes of decision aid delivery format, contents, or other characteristics of their development and implementation. Very limited information was available on other outcomes or on the effectiveness of interventions that target providers to promote shared decision making by means of decision aids.

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