



# Effective Health Care Program

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Comparative Effectiveness Review  
Number 145

## Decision Aids for Cancer Screening and Treatment



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# *Comparative Effectiveness Review*

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Number 145

## **Decision Aids for Cancer Screening and Treatment**

**Prepared for:**

Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services  
540 Gaither Road  
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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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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 email 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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## Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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# Decision Aids for Cancer Screening and Treatment

## Structured Abstract

**Background.** Many health decisions about screening and treatment for cancers involve uncertainty or tradeoffs between the expected benefits and harms. Patient 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. It is unclear whether the effectiveness of decision aids for decisions related to cancers differs by people's average risk of cancer or by the content and format of the decision aid.

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

**Data sources.** We searched MEDLINE<sup>®</sup>, Embase<sup>®</sup>, the Cochrane Central Register of Controlled Trials (CENTRAL), PsycINFO<sup>®</sup>, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL<sup>®</sup>) from inception to the end of June 2014.

**Review methods.** For Key Question 1, we included randomized controlled trials comparing decision aid interventions among themselves or with a control. We included trials of previously developed decision aids that were 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 decision-making process (e.g., Decisional Conflict Scale), emotion and quality of life (e.g., decisional regret), and process and system-level attributes. We assessed for effect modification by population group, by the delivery format or content of the decision aid or other attributes, or by methodological characteristics of the studies. For Key Question 2, we included studies of any intervention to promote patient decision aid use, regardless of study design and outcomes assessed.

**Results.** Of the 16,669 screened citations, 87 publications were eligible, corresponding to 83 (68 trials; 25,337 participants) and 5 reports for Key Questions 1 and 2, respectively. Regarding the evolution of the decision aid 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 decision aids had higher knowledge scores compared with those not using decision aids (standardized mean difference, 0.23; 95% credible interval [CrI], 0.09 to 0.35; 42 comparison strata with 12,484 participants). Compared with not using decision aids, using decision aids resulted in slightly lower decisional conflict scores (weighted mean difference of -5.3 units [CrI, -8.9 to -1.8] on the 0-100 Decisional Conflict Scale; 28 comparison strata; 7,923 participants). There was no difference in State-Trait Anxiety Inventory scores (weighted mean difference = 0.1; 95% CrI, -1.0 to 0.7 on a 20-80 scale; 16 comparison strata; 2,958 participants). Qualitative synthesis suggested that patients using decision aids are more likely to make informed decisions and have

accurate risk perceptions; further, they 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 decision-making 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, by the delivery format or content of the decision aid or other attributes, or by methodological characteristics of the studies. Data on Key Question 2 were very limited.

**Conclusions.** Cancer-related decision aids have evolved over time, and there is considerable diversity in both format and available evidence. We found strong evidence that cancer-related decision aids 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 effectiveness of cancer-related decision aids does not appear to be modified by specific attributes of decision aid delivery format, content, 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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# Introduction

Many health care decisions involve uncertainty due to the lack of robust evidence 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 decision-making process.

Patient 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 decision making.<sup>3,4</sup> According to the International Patient Decision Aid 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 patient 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 patient 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. For example, research suggests that patients' baseline understanding of issues in cancer screening may affect whether they ultimately made an informed and considered choice,<sup>9,10</sup> and that patients' perception of their own risk was an important predictor of cancer screening uptake.<sup>11</sup> Such information is important for developing practical guidance about designing and using decision aids, particularly for decisions related to screening, prevention, or treatment of early cancers, the target population for this review.<sup>12</sup>

We triangulated the importance of these issues by engaging a diverse panel of stakeholders, including developers and users of patient decision aids, representatives of professional societies, patient advocates and non-syndicated patients, representing the review's intended audiences. The panel agreed that this review's target population should include not only patients with early cancer, but also patients who are either at high risk of cancer or are at average risk and are deciding whether to be screened. These populations can be examined in aggregate because the types of decisions being made are similarly equivocal in terms of both benefits and harms. Further, the panel also agreed that provider willingness to engage in shared decision making 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 decision making by health professionals through

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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.

2009, and concluded that healthcare professional training and use of decision aids may be important.<sup>13</sup> The current systematic review is designed to address issues relating to content and format of patient decision aids in terms of their intended audiences, as well as factors related to provider utilization.

## 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>12,14</sup>

The first Key Question pertains to interventions targeting health care consumers who face decisions about cancer screening and prevention or treatment. It asks: how do interventions that incorporate patient 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 decision-making process, choices and adherence to choices, health outcomes, and health care–system outcomes? For example, does the use of a decision aid—compared with 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 decision making, as well as to the outcomes mentioned in the first Key Question? For example, compared with no training, does training of providers in shared decision making affect the willingness of providers to engage in shared decision making?

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. The reporting of this systematic review follows the PRISMA guidelines.<sup>15</sup> 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 patient decision aids with other patient decision aids or with no decision aid intervention. We included trials of mature patient 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 local disease only) 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 decision making to providers caring for the populations discussed for the first Key Question, specifically provider-targeted interventions to increase shared decision making with the use or increased use of a decision aid. 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 specified outcomes of interest prospectively in the review protocol. Almost by definition, for most situations for which patient 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 no single optimal choice exists, 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); congruence between actual choices and patient values; and number of people with accurate perception of their personal cancer risk.
- Outcomes related to *attributes of the decision-making process* included differences in the total score on the Decisional Conflict Scale (DCS);<sup>16</sup> patient, provider or third-party-rated quality of communication (as defined by authors); patient participation in decision making; proportion of undecided patients; patient satisfaction with the decision-making 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>17,18</sup> the Hospital Anxiety and Depression Scale (HADS);<sup>19</sup> quality of life *Short Form (SF)* 6-, 12-, or 36-item questionnaires;<sup>20</sup> the Impact of Event Scale (IES, for emotional distress);<sup>21</sup> and the Decision Regret Scale (DRS).<sup>22</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 decision-making process</i>		
Decisional conflict scale – DCS <sup>16</sup>	Five subscales measuring perceptions of uncertainty in choosing options, modifiable factors (e.g., feeling informed, having unclear values), and effective decision making. We are using the total score adjusted to a scale of 0 (least conflicted) through 100 (most conflicted).	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. Also often reported as a threshold or percentage who score below 25 with no available consensus on reporting. The <i>effect size</i> corresponds to a difference of 5 in the 0 to 100 scale, using a standard deviation of 15 units (median in observed studies).
<i>Affect, emotion and quality of life</i>		
State-Trait Anxiety Inventory – STAI <sup>17,18</sup>	20 questions on anxiety state, and 20 on trait. Results translated to a scale from 20 (least anxious) to 80 (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 20 units, based on the scale range of 20-80.
Hospital Anxiety and Depression Scale – HADS <sup>19</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>20</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>21</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>22</sup>	Measures distress or remorse after a healthcare decision using 5 questions. Scores expressed in 0 (no 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 Literature (CINAHL) from inception to June, 2014, using two separate strategies, one for each Key Question. The strategies were based on previous Cochrane reviews,<sup>4 13</sup> and are reported 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>23</sup> To ensure consistency, all five reviewers performed a calibration exercise and screened the first 200 citations, in two rounds of 100 citations each, using broad inclusion criteria. Disagreements were discussed and analyzed to clarify screening criteria. Once it was deemed that all reviewers were applying the criteria in the same way, we continued with single screening of the remaining abstracts. All included papers



were assessed for eligibility by two reviewers. Conflicts and questions were resolved by discussion with a third reviewer. 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>24,25</sup> Extracted data are publicly available at <http://srdr.ahrq.gov/projects/143> (last accessed October 12, 2014). 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 or formats (printed, audio or video material not on a computer, computer software, Web site, in-person delivery with a person providing logistical help, use of support groups or patient navigators, decision board/option grid), and content (explicit elicitation of values, e.g., by quantifying preferences on a scale, vs. implicit elicitation of values, e.g., through discussion of what people often care about; generic vs. personalized probabilities; others' opinions; human coaching in decision making; non-human-mediated guidance in decision making; decision analysis model) 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; needing a human to deliver or to support logistically; used by patient, or both patient and provider; included support group or navigator); (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. If that information was not in the paper, we attempted to access the original decision aid or other studies of that decision aid for this information.

## 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. Our main analyses used hierarchical (random effects) regression models adjusted for population group (average risk, high risk, early cancer) and additional intervention characteristics. These models can be difficult to fit with few studies. Thus we ran analyses in outcomes with at least 10 trials overall and with at least 2 trials in each population group. 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. See Appendix B for an explicit description of the meta-analysis model.

We assessed effect modification as interaction term with the variable corresponding to the decision aid intervention. We examined *a priori*-defined effect modification for each population group (screening, high risk, early cancer), and for delivery formats, content, other attributes of the decision aid (whether it was tailored to target population, such as low literacy, or used by consumer and provider together or by the consumer only), and study design items (generation of the randomized sequence, blinding of participants and outcome assessors, allocation concealment, and loss to follow-up smaller 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 which is mainly because of our including more recent literature). To facilitate comparisons with the conclusions of the Cochrane review, which used different analyses, we repeated all analyses for subset of trials included in the Cochrane review.

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. Results of sensitivity analyses were similar to those of the main analyses and are not shown.

## **Risk of Bias in Individual Studies and Strength of the Evidence Base**

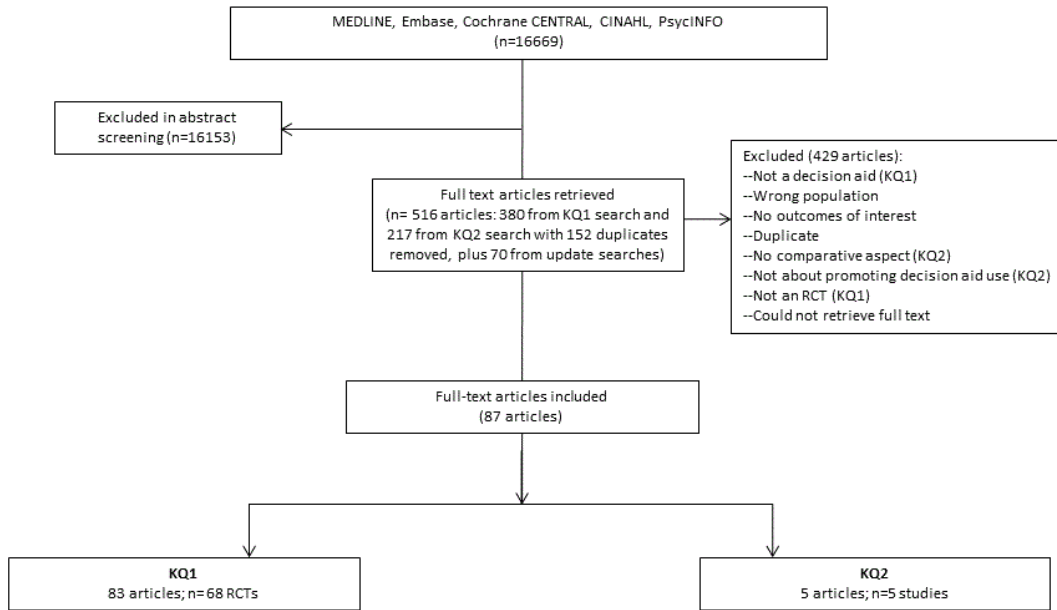
We used the assessment methods for assessing risk of bias in individual studies and the strength of evidence for each outcome across the evidence base detailed in the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.<sup>26</sup> There are numerous, different study characteristics 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>26</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, 16,669 citations were screened, 516 were retrieved in full text and 87 were eligible. See Appendix E for a list of the included articles and Appendix F for a list of the articles excluded during full text review. Of the eligible studies, 88 articles, corresponding to 68 RCTs, pertained to the first Key Question,<sup>27-108</sup> and 5 articles, corresponding to 5 studies, pertained to the second Key Question.<sup>109-113</sup> One RCT addressed both Key Question 1<sup>106</sup> and Key Question 2.<sup>111</sup>

Extracted data are publicly available online at the Systematic Review Data Repository (<http://srdp.ahrq.gov/projects/143>, last accessed October 12, 2014).

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



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

## Comparative Effectiveness of Patient Decision Aids (Key Question 1)

Table 2 summarizes characteristics of the 68 eligible trials (25,337 enrolled patients). Most trials (65 out of 68) focused on decisions relevant to breast, prostate, or colorectal cancer. The other three topics pertained to thyroid, cervical, and ovarian cancer-related decisions. Thirty-seven (out of 68) studies were conducted in the USA, and 14 in Australia. Nine studies were cluster randomized trials. Thirty-eight studies were multi-center trials. Twenty and 24 studies were conducted in a primary care and specialized care setting, respectively, with 24 in other settings (e.g. over the internet) or not reported.

Most studies (n=33) assessed the effect of decision aids on screening-related decisions, 22 studies assessed treatment-related decisions and 13 studies assessed decisions pertaining to genetic risk. No trials were identified that examined decisions about malignancies in children. Appendix D, Table of Study Characteristics, displays the characteristics of each trial addressing Key Question 1.

In total, 55 distinct decision aids were examined in the 68 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 with 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 38 of the studies, and reporting was unclear in the remaining 30. Allocation of interventions was concealed in 32 studies, primarily through the use of a Web site where allocation was performed automatically. By design, masking of patients was impractical in most studies. Masking for outcome assessment would be feasible for outcomes that were not self-reported, but most studies did not explicitly report such information. Finally, attrition rates more than 20 percent were reported in 28 studies. Small attrition rates (<20%) were reported in seven studies, and the attrition was unclear in the remaining studies. However, it is not clear why the attrition rates would be associated with the intervention, or the outcome.

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

Population Group	Average Risk of Cancer (Screening)	High Risk of Cancer (Screening or Treatment)	Early Cancer (Treatment)
Number of studies (people)	33 (17,344)	13 (3656)	22 (5489)
Cancers considered (number of studies)	Breast (2), prostate (23), colorectal (8)	Breast (11), colorectal (1), ovarian (1)	Breast (9), prostate (10), colorectal (1), cervical (1), thyroid (1)
Mean participant age (median, range)	59 (43, 70)	44 (39, 62)	59 (46, 72)
Sample size median (range)	412 (49, 1960)	153 (30, 1197)	201 (60, 736)
Publication year (range)	2000-2014	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)
Total number of trial arms with decision aid interventions	52	18	23
<i>Delivery formats, number (% out of decision aid arms)</i>			
Audio and visual media	13 (25)	0 (0)	6 (26)
Software or Web site	20 (38)	7 (39)	9 (39)
Printed material	26 (50)	7 (39)	13 (57)
Option grid/decision board	0 (0)	1 (6)	5 (22)
In-person education	8 (15)	10 (56)	5 (22)
<i>Content, number (% of decision 93 decision aid arms)</i>			
Explicit elicitation of values	22 (42)	7 (39)	9 (39)
Generic risk probabilities	34 (65)	15 (83)	11 (48)
Personalized risk probabilities	7 (13)	14 (78)	4 (17)
Others' opinions	27 (52)	7 (39)	12 (52)
Non-human-mediated guidance in decision making	9 (17)	4 (22)	5 (22)
Human coaching in decision making	8 (15)	12 (67)	9 (39)

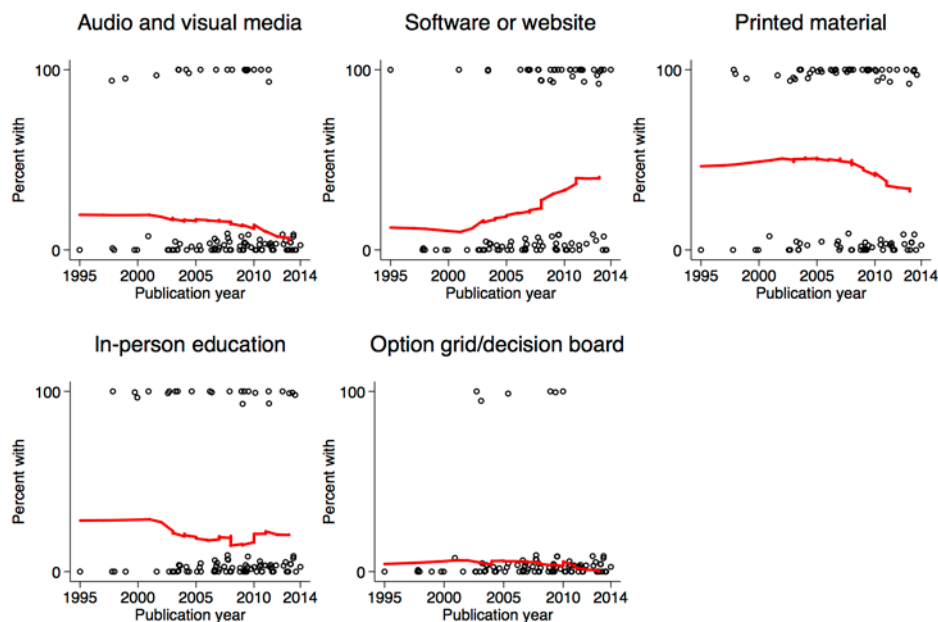
**Table 2. Summary descriptives for included trials of decision aid interventions (continued)**

Population Group	Average Risk of Cancer (Screening)	High Risk of Cancer (Screening or Treatment)	Early Cancer (Treatment)
<i>Other attributes, number (% of decision aids)</i>			
Interactive	24 (46)	12 (67)	16 (70)
Tailored to target population	12 (23)	1 (6)	3 (13)
Used by consumer & provider	4 (8)	8 (44)	4 (17)
Used by consumer only	48 (92)	10 (56)	19 (83)

## Evolution of Formats and Contents of Decision Aid-Based Interventions Over Time

The 68 included trials (Table 2) were published over the last two decades (1995-2014). Figure 2 shows the evolution over time of the decision aid delivery formats used in the studies assessed in this systematic review. Over this period technologies, such as the Internet and personal computers, have evolved substantially and their availability has increased. 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**

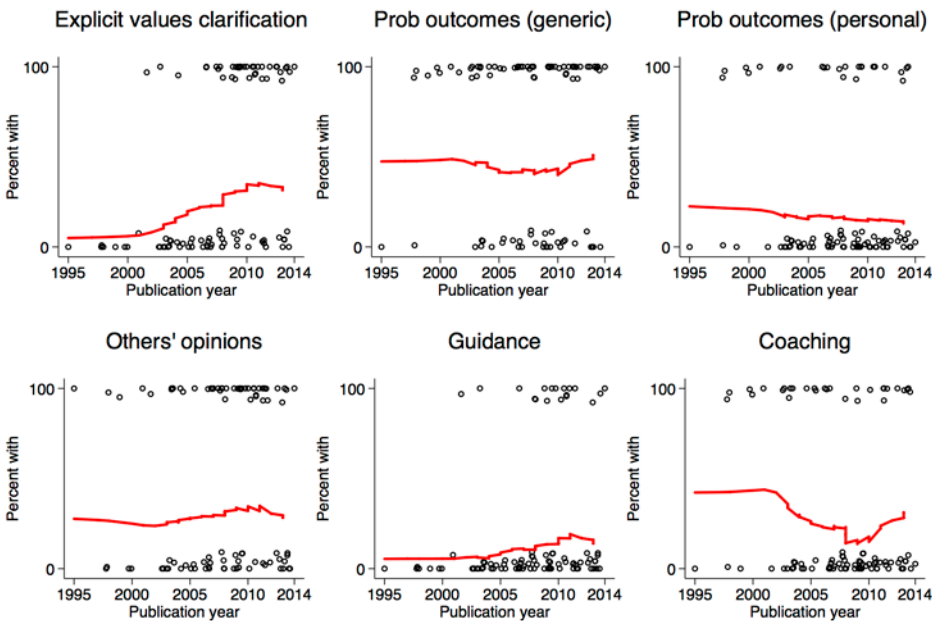


**Notes:** Shown are trial arms including decision aids, denoted by circles. Some trials have more than one decision aid arm. The bold red lines correspond to the percent of trial arms with a respective delivery format over time: An example to help in interpreting the plots: the use of audiotapes and 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 decision making has increased in recent years, while human-mediated coaching in decision making has become less common.

**Figure 3. Evolution of decision-aid content-related attributes over time**



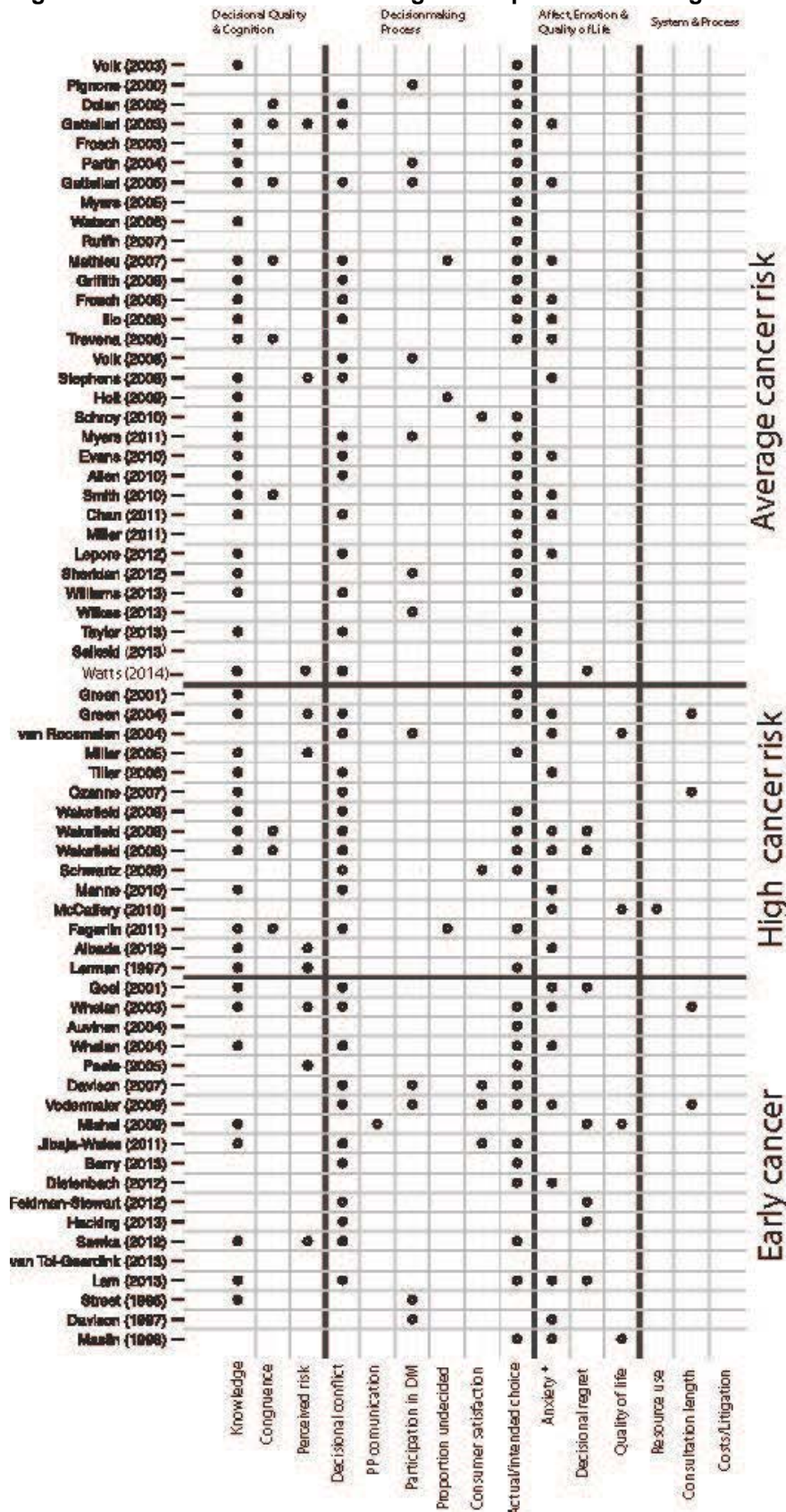
**Notes:** Coaching = human-mediated coaching in decision making; guidance = non-human-mediated guidance in decision making.

Figures 2 and 3 suggest that recent trials are increasingly studying 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 68 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 decision aid) not allowing a quantitative synthesis.

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



**Notes:** 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 decision-making 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 44 trials assessing the effect of decision aids on factual knowledge about the decision at hand. In total, 38 trials (corresponding to 42 compared strata and 12,484 participants) reported numerical data necessary for analysis.<sup>b</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]: 0.05, 0.35) compared with not using them. An SMD of 0.20 to 0.30 can be considered a small to moderate effect.<sup>114</sup> The effect appeared to be more pronounced among those at high risk of cancer (0.35, 95% CrI: 0.05, 0.70) compared with people at average risk (0.22, 95% CrI: 0.04, 0.36) or patients with early cancer (0.25, 95% CrI: -0.02, 0.57). However, the differences in the effect of knowledge across population groups were not beyond what could be explained by chance.

Between-study heterogeneity was substantial. Table 3 lists the results of meta-regressions seeking to explain it. Effects on knowledge did not differ beyond chance by the examined characteristics of decision aids. However, some attributes of the decision aids explain part of the between-study variability. For example, the difference in knowledge scores between decision aids and control appears to be higher (albeit not beyond chance) for decision aids that are implemented as software or on the web, present generic probabilities of outcomes, or are used by only by patients. Although the credible intervals were wide, the effectiveness of decision aids did not appear to differ by whether the delivery of the decision aid included a human (person providing logistical help, a support group, use of a patient navigator), was tailored to a target population, used by the patient and the provider, or used by the patient only. Finally, the effectiveness of decision aids did not differ 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>b</sup>Results from trials not included in the analyses are not explicitly reported in this document, and are available at the SRDR site for this project (<http://srdhr.gov/projects/143>, last accessed October 12, 2014). Overall, data from studies that are not included in the quantitative analysis are congruent with the herein presented quantitative analysis.



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

Analysis (Attribute of the Decision Aid)	Effect Without Attribute	Effect With Attribute	Difference (With Vs. Without)	Between-Study SD
Overall (42 comparison strata, 12,484 participants)	0.23 (0.09, 0.35)*			0.32
<i>Decision aid format</i>				
Audiovisual material	0.23 (0.12, 0.34)*	0.27 (0.10, 0.46)*	0.04 (-0.10, 0.21)	0.29
Software or website	0.17 (0.10, 0.23)*	0.45 (0.02, 0.94)*	0.28 (-0.15, 0.77)	0.14
Printed material	0.23 (0.12, 0.35)*	0.23 (0.13, 0.35)*	0.01 (-0.04, 0.06)	0.30
In-person education	0.23 (0.11, 0.33)*	0.33 (-0.84, 1.49)	0.11 (-1.07, 1.27)	0.27
Option grid	0.24 (0.10, 0.38)*	0.06 (-0.75, 0.86)	-0.19 (-1.01, 0.63)	0.35
Decision board	0.24 (0.08, 0.37)*	0.13 (-1.36, 1.69)	-0.11 (-1.59, 1.47)	0.34
<i>Decision aid content</i>				
Explicit values clarification	0.23 (0.09, 0.36)*	0.23 (0.08, 0.38)*	-0.00 (-0.13, 0.15)	0.31
Probability of outcomes (generic)	0.10 (-0.01, 0.26)	0.30 (0.05, 0.52)*	0.20 (-0.10, 0.43)	0.12
Probability of outcomes (personalized)	0.24 (0.08, 0.38)*	0.19 (-0.07, 0.41)	-0.06 (-0.29, 0.17)	0.35
Others' opinions	0.22 (0.08, 0.34)*	0.24 (0.10, 0.36)*	0.02 (-0.02, 0.06)	0.31
Coaching in decision making (human mediated)	0.23 (0.12, 0.34)*	0.22 (-0.13, 0.55)	-0.02 (-0.37, 0.33)	0.22
Guidance in decision making (non-human-mediated)	0.24 (0.13, 0.36)*	0.22 (0.03, 0.40)*	-0.01 (-0.22, 0.15)	0.29
Decision analytic model	0.24 (0.12, 0.37)*	0.11 (-1.30, 1.59)	-0.13 (-1.53, 1.35)	0.31
<i>Other attributes of the decision aid</i>				
Developed based on theory	NE	NE	NE	NE
Needing a human to deliver	0.20 (0.01, 0.34)*	0.23 (0.07, 0.37)*	0.02 (-0.03, 0.14)	0.36
Tailored to target population	0.23 (0.09, 0.36)*	0.25 (-0.16, 0.66)	0.02 (-0.41, 0.45)	0.33
Used by patient and provider	0.27 (0.15, 0.39)*	0.05 (-0.29, 0.30)	-0.21 (-0.58, 0.04)	0.30
Used by patient only	0.08 (-0.09, 0.30)	0.27 (0.10, 0.45)*	0.18 (-0.09, 0.42)	0.17
Includes human for logistical support	0.23 (0.07, 0.36)*	0.23 (0.07, 0.36)*	-0.00 (-0.02, 0.02)	0.31
Includes support group	0.23 (0.11, 0.35)*	0.42 (-2.13, 3.00)	0.20 (-2.37, 2.77)	0.32
Includes patient navigator	NE	NE	NE	NE
<i>Methodological quality items</i>				
Adequate random sequence generation	0.21 (0.01, 0.48)*	0.24 (0.02, 0.41)*	0.02 (-0.38, 0.30)	0.28
Allocation concealment	0.17 (-0.05, 0.40)	0.27 (0.01, 0.46)*	0.11 (-0.30, 0.37)	0.33
Outcome assessor masking	0.24 (0.06, 0.39)*	0.21 (-0.06, 0.49)	-0.03 (-0.32, 0.30)	0.33
Attrition rate <20%	0.23 (0.10, 0.37)*	0.26 (-0.17, 0.68)	0.02 (-0.43, 0.46)	0.32

\*95% credible interval does not include 0.

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

## **Congruence Between Choices/Values and Informed Choices**

Two trials (1,079 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>41</sup> and treatment of localized prostate cancer.<sup>33</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>41</sup> The other documented no statistical difference between actual choices and patient concerns.

Five trials (2,406 participants) compared the proportion of people making an informed choice between decision aids and a non-decision aid control among people at average<sup>64,65,87,92</sup> and high risk<sup>41</sup> of cancer. Informed choice was defined variably across trials to capture people who made a choice and had adequate knowledge. All trials were deemed to be at low risk of bias for this outcome. All but one<sup>65</sup> found that the frequency of informed choices was statistically significantly higher in decision aid groups compared with 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>45,46,101,102</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>115</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 a single unvalidated question to validated instruments.

## **Accurate Perception of Mortality Risk**

Nine trials (2,454 participants) evaluated the accuracy of perception of mortality risks among people at average risk of cancer,<sup>45,88,108</sup> at high risk of cancer,<sup>27,50,61</sup> and with early cancer.<sup>76,81,104</sup> Determining each trial's risk of bias for this outcome is greatly hindered by the lack of details about its assessment. Thus, operationally, eight trials were deemed to be at moderate and one<sup>88</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>45,61,76,81,104</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, 28 trials (7,923 participants) reported data about mean differences in the Decisional Conflict Scale (DCS).<sup>c</sup> The DCS instrument has been validated in various geographical and language settings as well as in low literacy groups.<sup>16</sup> We translated all DCS scores into a 0-100 scale so that higher scores mean higher levels of conflict. No information was available about what difference in

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<sup>c</sup>Results from trials not included in the analyses are not explicitly reported in this document, and are available at the SRDR site for this project (<http://srdhr.gov/projects/143>, last accessed October 12, 2014). Overall, data from studies that are not included in the quantitative analysis are congruent with the herein presented quantitative analysis.

DCS is clinically important. However, the manual of the DCS questionnaire suggests to power studies for a clinically significant difference in the *effect size*<sup>d</sup> of about 0.3, and we use this as a proxy for an important difference. The effect size translates to a difference of approximately 5 units in a DCS scale of 0 to 100, while the standard deviation of responses is about 15 units on a 0-100 scale.<sup>e</sup> Almost all trials were 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 -5.3 (95% CrI: -8.9, -1.8), indicating slightly lower mean decisional conflict scores in decision aids compared with controls.

The difference appeared more pronounced among those at high risk of cancer (-8.0, 95% CrI: -14.8, -1.3) compared with people at average risk (-4.2, 95% CrI: -10.2, 1.7) or patients with early cancer (-4.2, 95% CrI: -10.1, 1.9). However, differences in effect across population groups was not beyond what was expected by chance.

Between-study heterogeneity was small. Table 4 lists the results of meta-regressions seeking to explain it. The difference in the DCS scale between decision aids and control interventions, was of similar magnitude for all decision aids that have the characteristics examined in Table 4. There were no differences beyond chance when studies were stratified by the presence or absence of methodological quality items after adjusting for population group.

In summary, use of decision aids seems to lower decisional conflict, although the effect is not large. 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 the Decisional Conflict Scale (on a 0–100 scale)**

Analysis (Attribute of the Decision Aid)	Effect Without Attribute	Effect With Attribute	Difference (With Vs. Without)	Between-Study SD
Overall (28 comparison strata, 7,923 participants)	-5.3 (-8.9, -1.8)*			8.1
<i>Decision aid format</i>				
Audiovisual material	-5.3 (-8.9, -1.8)*	-4.2 (-13.3, 4.9)	1.2 (-7.7, 10.0)	8.1
Software or website	-3.8 (-5.4, -2.5)*	-6.0 (-11.4, -0.7)*	-2.2 (-7.7, 3.2)	1.7
Printed material	-5.2 (-9.3, -1.3)*	-5.3 (-9.1, -1.4)*	-0.1 (-2.4, 3.3)	8.2
In-person education	-5.6 (-10.0, -1.4)*	-4.1 (-12.0, 3.9)	1.5 (-7.3, 11.0)	8.3
Option grid	-5.3 (-9.0, -1.5)*	-5.0 (-19.3, 9.4)	0.3 (-14.6, 15.2)	8.3
Decision board	-5.3 (-9.0, -1.6)*	-5.1 (-19.3, 9.6)	0.2 (-14.5, 15.0)	8.2
<i>Decision aid content</i>				
Explicit values clarification	-5.8 (-11.7, -0.8)*	-5.4 (-9.7, -1.1)*	0.1 (-4.3, 7.0)	8.2
Probability of outcomes (generic)	-7.2 (-12.9, -1.6)*	-4.1 (-9.0, 0.6)	3.0 (-4.2, 10.4)	8.0
Probability of outcomes (personalized)	-4.6 (-8.3, -1.0)*	-6.1 (-12.2, -0.2)*	-1.4 (-8.2, 4.6)	6.8
Others' opinions	-5.7 (-9.8, -1.8)*	-5.0 (-9.3, -0.9)*	0.5 (-2.6, 4.9)	8.0
Coaching in decision making (human mediated)	-4.5 (-8.9, -0.3)*	-6.5 (-13.4, 0.2)	-2.0 (-10.0, 5.9)	8.1
Guidance in decision making (non-human-mediated)	-5.7 (-9.6, -1.9)*	-4.5 (-9.5, 0.9)	1.1 (-3.5, 6.7)	8.2
Decision analytic model	-5.5 (-9.2, -1.8)*	-2.1 (-17.3, 12.0)	3.4 (-12.1, 17.8)	8.2

<sup>d</sup>We interpreted “effect size” as standardized effect size.

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

**Table 4. Effects of decision aids on the Decisional Conflict Scale (on a 0–100 scale) (continued)**

Analysis (Attribute of the Decision Aid)	Effect Without Attribute	Effect With Attribute	Difference (With Vs. Without)	Between-Study SD
<i>Other attributes of the decision aid</i>				
Developed based on theory	NE	NE	NE	NE
Needing a human to deliver	-7.9 (-13.4, -2.8)*	-5.3 (-9.0, -1.6)*	2.6 (-1.2, 7.0)	8.2
Tailored to target population	-4.1 (-6.7, -1.8)*	-9.0 (-16.9, -1.1)*	-4.8 (-12.7, 3.1)	4.3
Used by patient and provider	-5.7 (-9.9, -1.6)*	-3.9 (-12.3, 4.0)	1.8 (-7.3, 10.6)	8.3
Used by patient only	-3.5 (-6.9, -0.4)*	-5.7 (-10.0, -1.5)*	-2.3 (-7.3, 3.1)	2.3
Includes human for logistical support	-4.9 (-8.7, -1.1)*	-5.3 (-8.9, -1.7)*	-0.4 (-1.5, 0.9)	8.2
Includes support group	NE	NE	NE	NE
Includes patient navigator	-5.3 (-9.0, -1.7)*	-4.6 (-24.5, 15.8)	0.7 (-19.3, 21.7)	8.2
<i>Methodological quality items</i>				
Adequate random sequence generation	-3.1 (-5.4, -0.8)*	-6.2 (-11.0, -1.5)*	-3.1 (-8.5, 2.1)	1.9
Allocation concealment	-2.9 (-5.7, 0.2)	-8.0 (-13.9, -2.3)*	-5.2 (-11.6, 1.3)	3.7
Outcome assessor masking	-5.7 (-9.7, -1.7)*	-3.5 (-12.9, 6.3)	2.2 (-7.9, 12.7)	8.3
Attrition rate <20%	-5.5 (-9.6, -1.5)*	-4.5 (-12.8, 3.4)	1.0 (-8.1, 9.6)	8.3

\*95% credible interval does not include 0.

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>70</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 Decision Making

Patient participation in decision making was reported in four trials totaling 1,549 people facing prostate cancer screening decisions,<sup>72,85,98,106</sup> one trial of 88 women with *BRCA1/2* mutations,<sup>93</sup> and three trials in 536 patients requiring treatment for prostate cancer<sup>36,37</sup> or breast cancer.<sup>95</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 vs. non-entertainment-based decision aid,<sup>98</sup> individualized decision support vs. informational video<sup>37</sup>). Patient participation in decision making was self-reported in seven trials and by a third party in one.<sup>72</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 decision making in the decision aid versus control.<sup>37,72</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 (1,046 people) of decision aids about mammography screening,<sup>64,65</sup> one (1,197 people) on hormonal treatment for breast cancer prevention,<sup>41</sup> and one (240 patients) on treatments of prostate cancer<sup>94</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 with those in the control group. With respect to this outcome, one trial<sup>41</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 Decision-Making Process

Patient satisfaction with the decision-making process<sup>f</sup> was reported in one trial in 665 persons making decisions about colorectal screening,<sup>82</sup> and three trials in 466 women facing decisions about breast cancer treatment.<sup>57,95,105</sup> The trial about screening decisions<sup>82</sup> had three arms (interactive computerized decision aid vs. the same plus an online risk calculator vs. a Web site 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 decision-making process, or reluctance to second guess a previous decision.<sup>116</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, 49 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 2014 and almost two-thirds of the studies were conducted in the USA (n=29), with Australia being the second most common country (n=12). 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=30 trials) were about screening-related decisions, 7 assessed decisions pertaining to high genetic risk of cancer, and 12 assessed cancer-treatment decisions.

The 49 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>g</sup> only, 16 examined only intended choices,<sup>h</sup> and 13 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 (n=31) 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,

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

but it is not clear how this would bias assessments. Small attrition rates (below 20%) were reported in five out of 49 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 eight such comparisons were done in the 49 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 less than 20%).

The two largest studies evaluating choices pertained to breast<sup>64</sup> and prostate screening.<sup>90</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 1,879 participants in the US, and also found no significant difference at 13 months. The largest study with statistically significant results for actual choice<sup>87</sup> was done in 572 people in Australia for decisions related to colon cancer screening, and found both increased knowledge and lower rates of screening participation in the decision aid group compared with usual care. The authors attribute this to increased “knowledge about the low personal benefit of screening.”<sup>87</sup> 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 using various instruments. 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, 12 trials (16 comparison strata with 2,958 participants) reported mean differences in the state or total score of the State-Trait Anxiety Inventory (STAI), which is a self-reported psychological inventory that has been validated in numerous settings.<sup>i</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 are very small with respect to the range of the scale, which is from 20 to 80 points. The weighted mean difference (WMD) was 0.1 (95% CrI: -1.0, 0.7). Mean anxiety did not differ beyond chance between those at average risk of cancer (0.1, 95%CrI: -1.3, 1.1), high risk of cancer (-0.8, 95% CrI: -2.9, 1.3) and early cancer (0.02, 95% CrI -2.9, 3.4).

Between-study heterogeneity was small. 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).

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<sup>i</sup>STAI differences are reported in a 20-80 scale (20 lowest, 80 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.

**Table 5. Effects of decision aids on the state or total score with the State-Trait Anxiety Inventory (on a 20-80 scale)**

Analysis Attribute of the Decision Aid)	Effect Without Attribute	Effect With Attribute	Difference (With vs. Without)	Between-Study SD
Overall (16 comparison strata with 2958 participants)	0.1 (-1.0, 0.7)			0.5
<i>Decision aid format</i>				
Audiovisual material	0.1 (-1.2, 0.8)	0.4 (-7.2, 8.0)	0.4 (-7.1, 8.0)	0.5
Software or website	0.1 (-1.2, 1.3)	-0.6 (-2.6, 0.9)	-0.8 (-2.4, 0.9)	0.6
Printed material	-0.4 (-2.4, 1.7)	-0.1 (-1.6, 1.1)	0.3 (-2.0, 2.4)	0.5
In-person education	0.2 (-1.0, 1.0)	-0.8 (-4.3, 2.8)	-0.9 (-4.5, 2.8)	0.5
Option grid	0.1 (-1.1, 0.9)	-0.9 (-6.9, 4.8)	-1.0 (-6.9, 4.9)	0.5
Decision board	0.1 (-1.1, 0.9)	-0.8 (-6.7, 4.8)	-0.9 (-6.8, 4.8)	0.5
<i>Decision aid content</i>				
Explicit values clarification	-0.3 (-1.8, 1.2)	-0.1 (-3.1, 2.5)	0.2 (-3.1, 3.2)	0.5
Probability of outcomes (generic)	-0.4 (-2.4, 1.6)	-0.0 (-1.7, 1.2)	0.3 (-2.3, 2.5)	0.6
Probability of outcomes (personalized)	0.1 (-1.1, 1.0)	-0.7 (-7.8, 6.0)	-0.7 (-7.8, 6.0)	0.5
Others' opinions	-0.2 (-1.5, 1.0)	-1.0 (-6.1, 3.4)	-0.9 (-5.7, 3.7)	0.6
Coaching in decision making (human mediated)	0.2 (-1.1, 1.1)	-0.8 (-3.8, 2.3)	-0.9 (-4.1, 2.3)	0.5
Guidance in decision making (non-human-mediated)	0.1 (-1.1, 0.8)	0.1 (-13.0, 13.4)	0.1 (-13.0, 13.5)	0.5
Decision analytic model	0.1 (-1.0, 0.8)	-2.1 (-15.3, 11.3)	-2.2 (-15.3, 11.3)	0.4
<i>Other attributes of the decision aid</i>				
Developed based on theory	NE	NE	NE	NE
Needing a human to deliver	0.3 (-0.7, 1.3)	-0.6 (-1.7, 0.6)	-0.8 (-1.9, 0.2)	0.5
Tailored to target population	0.1 (-1.2, 0.9)	-0.1 (-12.9, 12.5)	-0.2 (-12.9, 12.5)	0.5
Used by patient and provider	0.1 (-1.2, 0.8)	-0.4 (-10.4, 7.5)	-0.4 (-10.4, 7.6)	0.5
Used by patient only	0.3 (-3.5, 4.1)	-0.1 (-1.6, 1.0)	-0.5 (-4.6, 3.6)	0.5
Includes human for logistical support	-0.7 (-2.1, 0.5)	0.1 (-1.1, 1.2)	0.8 (-0.3, 1.8)	0.5
Includes support group	NE	NE	NE	NE
Includes patient navigator	NE	NE	NE	NE
<i>Methodological quality items</i>				
Adequate random sequence generation	-0.0 (-2.7, 2.5)	-0.1 (-1.7, 1.1)	-0.1 (-3.0, 2.8)	0.5
Allocation concealment	-0.4 (-2.7, 1.9)	-0.0 (-1.6, 1.3)	0.3 (-2.4, 2.9)	0.6
Outcome assessor masking	0.1 (-1.1, 1.0)	-0.4 (-3.3, 2.4)	-0.5 (-3.6, 2.5)	0.5
Attrition rate <20%	0.1 (-1.2, 0.9)	-0.5 (-9.0, 7.2)	-0.5 (-9.0, 7.2)	0.5

**Notes:** NE = not estimable (nonconvergence 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>36,59,63,91,93,96,101,102,105</sup> but only four<sup>59,91,93,105</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>45,46,62,64,66,84,91,93</sup> In all, no large differences were found in any study, both for comparisons of using versus not using decision aids,<sup>46,62,64,66,84,91,93</sup> and for comparisons between decision aids.<sup>45,46</sup> It was not possible to examine the role of effect modifiers.

## Decision Regret

Eight trials (1075 participants) reported results for decision regret from another instrument between 1 month and 1 year of followup.<sup>42,47,52,59,70,101,102,108</sup> Most studies used the Decision Regret Scale,<sup>22</sup> and one used the decision regret subscale of a quality of life scale.<sup>117</sup> All compared decision aids versus no decision aids, and one<sup>70</sup> also compared between two decision aids. Overall, use of decision aids was not consistently associated with higher or lower decision regret (lower in four trials, higher in three) compared with 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, using a variety of scales (e.g., generic questions, SF-36); one on decisions about cervical cancer screening,<sup>66</sup> one about preventive treatments in women at high genetic risk for breast and ovarian cancer,<sup>93</sup> and two about treatment of early breast cancer<sup>63</sup> or prostate cancer.<sup>70</sup> In all, differences in quality of life favored decision aids versus control interventions; the difference was statistically significant in one trial,<sup>63</sup> and only for long-term followup in another.<sup>93</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>66</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>50,73</sup> and in women with early breast cancer facing treatment decisions.<sup>105</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 five studies:<sup>109-113</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>109</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 decision making (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.

The second study randomized 120 California primary care physicians in five clinics to brief Web-based interactive physician education on prostate cancer screening or to a standard Centers for Disease Control and Prevention brochure (control).<sup>111</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 decision-making behaviors compared with 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>110</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 percent 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 decision making to become a part of routine clinical practice, including a supportive

team-based clinic culture, ongoing provider training in communication and shared decision-making skills, and implementation of incentives for patient engagement.

The study by Uy<sup>113</sup> explored the impact of a financial incentive on prescribing of decision support interventions across a variety of medical decisions (including a number related to cancer) in 4 practices. The physician or the clinical staff would receive a \$15 incentive per prescription. Overall, the financial incentive increased prescribing by 71 percent although the results of the study were mixed. There were physician views that the financial incentive had no effect on the prescribing pattern, while there were also cases where, once no further incentives were available, prescribing ceased altogether.

Finally, an abstract<sup>112</sup> published in 2014 assessed the impact of an academic detailing intervention consisting of a single interactive case-based discussion. The discussion included 30 minutes of risk/benefits, individual risk assessment, and counseling methods and participants were providers and nursing staff in 13 outpatient Veterans Affairs clinics. The investigators explored the impact of the intervention on knowledge and attitudes of providers regarding breast cancer screening recommendations for women ages 40-50. After the intervention, breast cancer screening recommendations were different, attitudes favoring discussion of benefits increased from 94 percent to 99 percent with no statistically significant difference, and attitudes favoring discussion of risks increased statistically significantly from 34 percent to 90 percent. Moreover, the comfort level of discussing benefits, risks and preferences also increased.

The five 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

We systematically appraised the efficacy of decision aids in 68 published randomized controlled trials with over 25,000 participants facing a cancer screening or early-cancer treatment decision. The assessed decision aids were considerably diverse in terms of delivery format, content, context and theoretical background, which often made synthesis a challenge. Considerable diversity 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 decision-making process, resource use, consultation length, costs, or litigation rates. The effectiveness of decision aids did not appear to be modified by differences in the population (general risk of cancer, high risk of cancer, or early cancer), delivery format, their content, or other attributes of their development and implementation. For knowledge and decisional conflict outcomes, the credible intervals for effect modification were wide and small to moderate differences could not be excluded. No clinically important differences were observed for anxiety. 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. Methodological characteristics of the individual trials are listed in Appendix G. A more detailed description of the strength of the evidence per population group, outcome category and comparison is in Appendix H.

**Table 6. Summary of conclusions and associated 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, anxiety) -Moderate (decisional conflict)	Quantitative analyses per outcome - Knowledge, SMD: 0.23 (0.09, 0.35) - Decisional Conflict Scale, WMD: -5.3 (-8.9, -1.8) on 0-100 scale - State Trait Anxiety Inventory, WMD: 0.1 (-1.0, 0.7) on 20-80 scale
Using DAs results in more <b>accurate risk perception, informed decisions</b>	Low	- Limited number of studies (less than 9, out of a total 68), 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>	-Moderate	- For knowledge and decisional conflict, the width of 95% CrI cannot exclude potentially important effect modification - For anxiety, the width of 95% CrI for the differences excludes substantial effect modification, but there are relatively few studies per subgroup
[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 9, out of a total 68), 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.  
Content = Explicit values clarification, probability of outcomes (generic), probability of outcomes (personalized), others' opinions, coaching in decision making (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.

CrI = credible interval; DA = decision analysis; SMD = standardized mean difference; WMD = weighted mean difference.

Arguably, decision aids would be most needed in vulnerable populations, including people with low literacy or numeracy, limited educational attainment, challenged socioeconomic status, or hindered by language and cultural barriers.<sup>118</sup> A proportion of trials evaluated decision aids tailored to a vulnerable population (n=19 of 68). However, there was no evidence for difference in the effectiveness of decision aids in them (Tables 3, 4 and 5).

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 decision making for pediatric malignancies,<sup>119</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.

We examined several characteristics of decision aid-based interventions to capture how elaborate they are, 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. Perhaps contrary to expectations,<sup>4</sup> we found no evidence for differences in the effectiveness between decision aids that are more or less elaborate in terms of personalized probabilities of events, involve humans in their delivery, and so on. 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>120</sup>

In the eligible trials, very few decision aids were reported to have been developed based on psychological theory, and therefore, it was not possible to detect whether they had different effects from other decision aids. 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 theorize 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 such a theory is not supported by the data.

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>116</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>13</sup>

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 decision making through decision aids, we found limited evidence. A more general treatment of shared decision-making promotion interventions did not draw strong conclusions.<sup>13</sup>

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>4,121-135</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. 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, this definition is subject to confounding by study, and results are difficult to interpret. For example, the “more detailed” decision aid in one trial can have fewer components than the “simpler” decision aid in another trial.

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 the currently accumulated randomized evidence does not support an association between isolated attributes and 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.

## **Methodological Challenges and Implications for Future Research**

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

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 investing in a generic, modular 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 by porting know-how in the technical aspects of the development across diseases; translation to other languages; and keeping decision aids current.

## **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 with 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.

Finally, clinical and especially shared decision making is such a complex phenomenon to execute, to influence and to measure that valuable information could also arise from other study designs such as observational studies and qualitative studies. The systematic appraisal of this kind of research goes beyond the scope of the present systematic review yet remains of great interest

## **Conclusions**

Cancer-related decision aids have evolved over time and there is considerable diversity in both format and available evidence. We found that cancer-related decision aids increase knowledge without adverse impact on decisional conflict, or anxiety with moderate to high strength of evidence. Patients using decision aids may be 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 effectiveness of cancer-related decision aids does not appear to be modified by specific attributes of decision aid delivery format, content, 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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## Appendix A. Search Strategies

KQ1: Adapted from the strategy used in Decision aids for people facing health treatment or screening decisions. Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Légaré F, Thomson R. Cochrane Database Syst Rev. 2011 Oct 5;(10) with the addition of cancer and some publication types.

**PubMed/ MEDLINE® (dates run 10/2/2013 and 6/5/2014; citations retrieved: 7585):**  
("Neoplasms"[Mesh] OR cancer OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous) AND (((choice behavior[MeSH:noexp] OR decision making[MeSH:noexp] OR decision support techniques[MeSH] OR educational technology [MeSH:noexp] OR (decision[tw] OR decisions[tw]) OR (choic\*[tw] OR preference\*[tw]) OR communication package[tw]) AND (health education[MeSH] OR Health Knowledge, Attitudes, Practice [MeSH:noexp] OR informed consent[tw] OR patient[tw] OR consumer[tw])) OR ((consumer\* OR parent OR parents OR woman OR women OR man OR men OR personal OR interpersonal OR patient OR patients OR consumer OR personal OR individual OR nurse OR physician\* OR clinician OR doctor OR "general practitioner" Or "gp") AND (participat\* OR decision OR choice\* OR preference)) OR "Decision Theory"[Mesh] OR "Decision Support Systems, Clinical"[Mesh] OR "Decision Making, Computer-Assisted"[Mesh] OR "shared decision" OR ("professional-patient" OR "provider-patient") AND (relation\* OR communication)) OR ("health care" OR healthcare) AND (providers OR professional)) OR "informed decision" OR "informed choice" OR "decision support" OR choice OR ((patient or consumer) AND involvement)) AND (clinical trial[pt] OR randomized controlled trial[pt] OR random\*[tw] OR (double[tw] AND blind\*[tw]) OR double-blind method [MeSH:noexp]) limit 2008-

**EMBASE® (run 10/17/13 and 6/5/2014; citations retrieved: 1368):**  
#11 AND #17 AND ([controlled clinical trial]/lim OR [randomized controlled trial]/lim) AND [humans]/lim AND [embase]/lim AND [2009-2014]/py  
#17: 'choice behavior':ti OR 'choice behavior':ab OR 'decision making':ti OR 'decision making':ab OR 'decision support techniques':ti OR 'decision support techniques':ab OR 'educational technology':ti OR 'educational technology':ab OR 'communication package':ti OR 'communication package':ab OR 'health education':ti OR 'health education':ab OR 'health knowledge':ti OR 'health knowledge':ab OR 'health attitudes':ti OR 'health attitudes':ab OR 'health practice':ti OR 'health practice':ab OR ('patient'/exp OR patient OR 'consumer'/exp OR consumer\* OR 'parent'/exp OR parent OR 'parents'/exp OR parents OR 'woman'/exp OR woman OR 'women'/exp OR women OR 'man'/exp OR man OR 'men'/exp OR men OR interpersonal OR personal OR individual OR 'nurse'/exp OR nurse OR physician\* OR clinician OR 'doctor'/exp OR doctor OR 'general practitioner'/exp OR 'general practitioner' OR 'gp' AND (decision:ti OR decision:ab OR choice:ti OR choice:ab OR preference:ti OR preference:ab OR participation:ti OR participation:ab)) OR 'decision theory'/exp OR 'decision theory':ti OR 'decision theory':ab OR 'decision support systems, clinical'/exp OR 'decision making, computer-assisted'/exp OR 'shared decision':ti OR 'shared decision':ab OR 'informed decision':ti OR 'informed decision':ab OR 'informed choice':ti OR 'informed choice':ab OR 'decision support'/exp OR 'decision support':ti OR 'decision support':ab OR ('patient'/exp OR patient OR 'consumer'/exp OR consumer AND involvement)  
#11: #9 AND #10

#10: clinical AND trial OR randomized AND controlled AND trial OR random\* OR (double AND blind\*) OR 'double blind' AND ('method' OR 'method'/exp OR method)  
#9: 'neoplasms'/exp OR neoplasms OR 'cancer'/exp OR cancer OR 'cancers'/exp OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous

**Cochrane Central Register of Controlled Trials (run 10/2/13 and 6/5/2014; citations retrieved: 1591)**

(Neoplasm\* OR cancer OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous) and (((choice behavior OR decision making OR decision support techniques OR educational technology OR (decision OR decisions) OR (choic\* OR preference\*) OR communication package) AND (health education OR Health Knowledge, Attitudes, Practice OR informed consent OR patient OR consumer)) OR ((consumer\* OR parent OR parents OR woman OR women OR man OR men OR personal OR interpersonal OR patient OR patients OR consumer OR personal OR individual OR nurse OR physician\* OR clinician OR doctor OR "general practitioner" OR "gp") AND (participat\* OR decision OR choice\* OR preference)) OR "Decision Theory" OR "Decision Support Systems, Clinical" OR "Decision Making, Computer-Assisted" OR "shared decision" OR (("professional-patient" OR "provider-patient") AND (relation\* OR communication)) OR (("health care" OR healthcare) AND (provider OR professional)) OR "informed decision" OR "informed choice" OR "decision support" OR choice OR ((patient or consumer) AND involvement)) AND (clinical trial OR randomized controlled trial OR random\* OR (double AND blind\*) OR double-blind method) from 2008, in Cochrane Reviews (Reviews and Protocols), Other Reviews, Trials, Methods Studies, Technology Assessments, Economic Evaluations (Word variations have been searched)

**Cumulative Index to Nursing and Allied Health Literature (CINAHL®) and PsycINFO (run 10/2/13, 10/17/13 and 6/5/2014; citations retrieved: CINAHL 775; PsycINFO 319)**

S11: S2 AND S4 AND S10 Limiters – Published date 20090101-

S10: ((MH "Clinical Trials") OR (MH "Randomized Controlled Trials") OR "clinical trial") OR ( clinical trial OR randomized controlled trial OR random\* OR (double AND blind\*) OR double-blind method ) or (MH "Double-Blind Studies")

S4: ( (MH "Decision Support Systems, Clinical") OR (MH "Decision Support Systems, Management") OR (MH "Decision Support Techniques") OR (MH "Decision-Making Support (Iowa NIC)") OR "decision support" ) OR ( (((choice behavior OR decision making OR decision support techniques OR educational technology OR (decision OR decisions) OR (choic\* OR preference\*) OR communication package) AND (health education OR Health Knowledge, Attitudes, Practice OR informed consent OR patient OR consumer)) OR ((consumer\* OR parent OR parents OR woman OR women OR man OR men OR personal OR interpersonal OR patient OR patients OR consumer OR personal OR individual OR nurse OR physician\* OR clinician OR doctor OR "general practitioner" OR "gp") AND (participat\* OR decision OR choice\* OR preference)) OR "Decision Theory" OR "Decision Support Systems, Clinical" OR "Decision Making, Computer-Assisted" OR "shared decision" OR (("professional-patient" OR "provider-patient") AND (relation\* OR communication)) OR (("health care" OR healthcare) AND (provider OR professional)) OR "informed decision" OR "informed choice" OR "decision support" OR choice OR ((patient or consumer) AND involvement)) )

S2: (MH "Neoplasms+") or cancer OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous

KQ2: adapted from Interventions for improving the adoption of shared decision making by healthcare professionals. Légaré F, Ratté S, Stacey D, Kryworuchko J, Gravel K, Graham ID, Turcotte S. *Cochrane Database Syst Rev.* 2010 May 12;(5) with the addition of cancer terms from KQ1 and the EPOC strategy for limiting publication types.

**PubMed/ MEDLINE® (date run 10/17/2013 and 6/5/2014; citations retrieved: 2200):**

Search (((((((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]))) OR (((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]))) AND (patient participation[mh] or patient participation\*[tiab] or consumer participation\*[tiab] or patient involvement\*[tiab] or consumer involvement\*[tiab] or “training intervention”[tw] or ((patient[ti] or patients[ti] or consumer\*[ti]) and (involvement\*[ti] or involving\*[ti] or participation\*[ti] or participating\*[ti]))) OR (((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]))) AND (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]))) OR (((patient participation[mh] or patient participation\*[tiab] or consumer participation\*[tiab] or patient involvement\*[tiab] or consumer involvement\*[tiab] or “training intervention”[tw] or ((patient[ti] or patients[ti] or consumer\*[ti]) and (involvement\*[ti] or involving\*[ti] or participation\*[ti] or participating\*[ti]))) AND (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]))) AND (((((((((((((((((((((((intervention\*[tw] or (intervention\*[tw] and (clinician\*[tw] or collaborat\*[tw] or community[tw] or complex[tw] or DESIGN\*[tw] or doctor\*[tw] or educational[tw] or family doctor\*[tw] or family physician\*[tw] or family practitioner\*[tw] or financial[tw] or GP or general practice\*[tw] or hospital[tw] or hospitals[tw] or impact\*[tw] or improv\*[tw] or individualize\*[tw] or individualizing[tw] or interdisciplin\*[tw] or multicomponent or multi-component or multidisciplin\*[tw] or multi-disciplin\*[tw] or multifacet\*[tw] or multi-facet\*[tw] or multimodal\*[tw] or multi-modal\*[tw] or personalize\*[tw] or personalizing or pharmacies or pharmacist\* or pharmacy or physician\* or practitioner\* or prescrib\* or prescription\*[tw] or primary care[tw] or professional\*[tw] or provider\*[tw] or regulatory[tw] or regulatory[tw] or tailor\*[tw] or target\*[tw] or team\*[tw] or usual care[tw]))) OR ((pre-intervention\*[tw] or preintervention\*[tw] or “pre intervention”[tw] or post-intervention\*[tw] or postintervention\*[tw] or “post intervention”[tw]))) OR ((hospital or patient) and (study or studies or care or health or practitioner\* or provider\* or physician\* or nurse\* or nursing or doctor))) OR demonstration project\*[tw]) OR ((pre-post[tw] or “pre test”[tw] or pretest\*[tw] or

posttest\*[tw] or “post test\*”[tw] or (pre[tw] and post[tw])) OR ((pre-workshop[tw] or post-workshop[tw] or (before[tw] and workshop[tw]) or (after[tw] and workshop[tw])) OR (trial[tw] or ((study[tw] and aim\*[tw] or “our study”[tw])) OR ((before[tw] and (after[tw] or during[tw]))) OR ((“quasi-experiment\*” or quasiexperiment\* or “quasi random\*” or quasirandom\* or “quasi control\*” or quasicontrol\* or ((quasi or experimental) and (method or study or trial or design\*)))) OR ((“time series” and interrupt\*)) OR ((time points[tw] and (over[tw] or multiple[tw] or three[tw] or four[tw] or five[tw] or six[tw] or seven[tw] or eight[tw] or nine[tw] or ten[tw] or eleven[tw] or twelve[tw] or month\*[tw] or hour\*[tw] or day[tw] or days[tw] or “more than”[tw]))) OR pilot[tw]) OR “Pilot Projects”[Mesh]) OR ((clinical trial[pt] or controlled clinical trial[pt] or multicenter study[pt])) OR ((multicentre[tw] or multicenter[tw] or multi-centre[tw] or multi-center[tw])) OR (random\*[tw] or controlled[tw])) OR ((control[tw] and (area[tw] or cohort\*[tw] or compare\*[tw] or condition[tw] or design[tw] or group[tw] or groups[tw] or grouping[tw] or intervention\*[tw] or participant\*[tw] or study[tw])) not (controlled clinical trial[pt] or randomized controlled trial[pt])) NOT (((“comment on” or review[tw] or review [pt])) OR ((“Animals”[Mesh] NOT “Humans”[Mesh])) OR ((rat[tw] or rats[tw] or cow[tw] or cows[tw] or chicken\*[tw] or horse[tw] or horses[tw] or mice[tw] or mouse[tw] or bovine[tw] or animal\*[tw]))) OR (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[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])) AND ((“Neoplasms”[Mesh] OR cancer OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous))

This was NOTed with Legare’s original search strategy through 2009 to reduce the number of citations that had to be re-screened.

**EMBASE® (run 10/17/13 and 6/5/2014; citations retrieved: 964):**

#14: #8 AND #9 AND #12 AND [humans]/lim AND [embase]/lim AND [article]/lim

#13: #8 AND #9 AND #12

#12: #10 OR #11

#11: random\* OR 'double blind' OR 'controlled trial'/exp OR 'controlled trial' OR 'clinical trial'/exp OR 'clinical trial' OR pretest\* OR 'pre test' OR posttest\* OR 'post test' OR prepost\* OR pre AND post\* OR controlled AND before\* OR 'before and after' OR 'interrupted time' OR 'time series'/exp OR 'time series' OR intervention\*

#10: 'clinical trial'/exp OR 'clinical trial' OR 'randomized controlled trial'/exp OR 'randomized controlled trial' OR 'controlled clinical trial'/exp OR 'controlled clinical trial' OR 'evaluation'/exp OR 'evaluation' OR 'evaluation studies'/exp OR 'evaluation studies' OR 'comparative study'/exp OR 'comparative study' OR intervention AND studies OR 'evaluation'/exp OR 'evaluation' OR 'evaluation studies'/exp OR 'evaluation studies' OR 'program evaluation'/exp OR 'program evaluation' OR 'random allocation'/exp OR 'random allocation'

#9: 'neoplasms' OR 'neoplasms'/exp OR neoplasms OR 'cancer' OR 'cancer'/exp  
OR cancer OR 'cancers' OR 'cancers'/exp  
OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous

#8: #1 OR #5 OR #6 OR #7

#7: #3 AND #4

#6: #2 AND #4

#5: #2 AND #3

#4: 'patient'/exp OR patient AND participation OR 'patient'/exp  
OR patient AND participation\* OR 'consumer'/exp  
OR consumer AND participation\* OR 'patient'/exp  
OR patient AND involvement\* OR 'consumer'/exp  
OR consumer AND involvement\* OR 'training'/exp OR training AND intervention OR  
('patient'/exp OR patient OR 'patients'/exp OR patients OR consumer\* AND  
(involvement\* OR involving\* AND participation\* OR participating\*))

#3: professional OR patient AND relations OR ('nurses'/exp OR nurses OR 'physicians'/exp  
OR physicians OR nurse\* OR physician\* OR clinician\* OR doctor\* OR general AND practition  
er\* OR gps OR 'health'/exp OR health AND care AND professional\* OR 'healthcare'/exp  
OR healthcare AND professional\* OR 'health'/exp  
OR health AND care AND provider\* OR 'healthcare'/exp OR healthcare AND provider\* OR  
resident\* AND ('patients'/exp OR patients OR 'patient'/exp  
OR patient OR consumer\* OR people\*))

#2: decision AND making OR decision AND support AND techniques OR decision AND support  
AND systems, AND clinical OR choice AND ('behaviour' OR 'behaviour'/exp OR behaviour)  
OR decision AND making\* OR decision AND support\* OR choice AND behaviour\* OR  
(decision\* OR choice\* AND (making\* OR support\* OR behaviour\*))

#1:  
shared AND decision\* OR sharing AND decision\* OR informed AND decision\* OR informed  
AND choice\* OR decision AND aid\* OR (share\* OR sharing\* OR informed\* AND  
(decision\* OR deciding\*))

**Cochrane Central Register of Controlled Trials (run 10/17/13 and 6/5/2014; citations  
retrieved: 690)**

(((((shared decision\* or sharing decision\* or informed decision\* or informed choice\* or  
decision aid\* or ((share\* or sharing\* or informed\*) and (decision\* or deciding\* or choice\*))))  
OR (((decision making or decision support techniques or decision support systems, clinical or  
choice behaviour or decision making\* or decision support\* or choice behaviour\* or ((decision\*  
or choice\*) and (making\* or support\* or behaviour\*)))) AND (patient participation or patient  
participation\* or consumer participation\* or patient involvement\* or consumer involvement\* or  
"training intervention" or ((patient or patients or consumer\*) and (involvement\* or involving\* or  
participation\* or participating\*)))) OR (((decision making or decision support techniques or  
decision support systems, clinical or choice behaviour or decision making\* or decision support\*  
or choice behaviour\* or ((decision\* or choice\*) and (making\* or support\* or behaviour\*))))  
AND (professional-patient relations or ((nurses or physicians 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\*) and (patients or  
patient or consumer\* or people\*)))) OR (((patient participation or patient participation\* or

consumer participation\* or patient involvement\* or consumer involvement\* or “training intervention” or ((patient or patients or consumer\*) and (involvement\* or involving\* or participation\* or participating\*)))) AND (professional-patient relations or ((nurses or physicians 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\*) and (patients or patient or consumer\* or people\*)))) AND (((((((((((((((((((((((intervention\* or (intervention\* and (clinician\* or collaborat\* or community or complex or DESIGN\* or doctor\* or educational or family doctor\* or family physician\* or family practitioner\* or financial or GP or general practice\* or hospital or hospitals or impact\* or improv\* or individualize\* or individualizing or interdisciplin\* or multicomponent or multi-component or multidisciplin\* or multi-disciplin\* or multifacet\* or multi-facet\* or multimodal\* or multi-modal\* or personalize\* or personalizing or pharmacies or pharmacist\* or pharmacy or physician\* or practitioner\* or prescrib\* or prescription\* or primary care or professional\* or provider\* or regulatory or regulatory or tailor\* or target\* or team\* or usual care )))) OR ((pre-intervention\* or preintervention\* or “pre intervention\*” or post-intervention\* or postintervention\* or “post intervention\*”))) OR ((hospital or patient) and (study or studies or care or health or practitioner\* or provider\* or physician\* or nurse\* or nursing or doctor))) OR demonstration project\*) OR ((pre-post or “pre test\*” or pretest\* or posttest\* or “post test\*” or (pre and post ))) OR ((pre-workshop or post-workshop or (before and workshop ) or (after and workshop ))) OR (trial or ((study and aim\*) or “our study”)) OR ((before and (after or during ))) OR ((“quasi-experiment\*” or quasiexperiment\* or “quasi random\*” or quasirandom\* or “quasi control\*” or quasicontrol\* or ((quasi or experimental) and (method or study or trial or design\*)))) OR ((“time series” and interrupt\*)) OR ((time points and (over or multiple or three or four or five or six or seven or eight or nine or ten or eleven or twelve or month\* or hour\* or day or days or “more than”))) OR pilot ) OR “Pilot Projects”) OR ((clinical trial or controlled clinical trial or multicenter study)) OR ((multicentre or multicenter or multi-centre or multi-center ))) OR (random\* or controlled ) OR ((control and (area or cohort\* or compare\* or condition or design or group or groups or grouping or intervention\* or participant\* or study )) not (controlled clinical trial or randomized controlled trial))) NOT (((“comment on” or review or review)) OR ((“Animals” NOT “Humans”))) OR ((rat or rats or cow or cows or chicken\* or horse or horses or mice or mouse or bovine or animal\*)))) OR (clinical trial or randomized controlled trial or controlled clinical trial or evaluation studies or comparative study or intervention studies or evaluation studies or program evaluation or random allocation or random\* or double blind\* or controlled trial\* or clinical trial\* or pretest\* or pre test\* or posttest\* or post test\* or prepost\* or pre post\* or controlled before\* or “before and after” or interrupted time\* or time serie\* or intervention\*)) AND ((“Neoplasms” OR cancer OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous))

NOT KQ1 strategy to bring down the numbers.

**Cumulative Index to Nursing and Allied Health Literature (CINAHL®) and PsycINFO (10/17/13 and 6/5/2014; citations retrieved: CINAHL 716; PsycINFO 301)**

S34: S27 AND S33

S33: S28 OR S29 OR S30 OR S31 OR S32

S32: clinical trial or randomized controlled trial or controlled clinical trial or evaluation studies or comparative study or intervention studies or evaluation studies or program evaluation or random allocation or random\* or double blind\* or controlled trial\* or clinical trial\* or pretest\* or

pre test\* or posttest\* or post test\* or prepost\* or pre post\* or controlled before\* or “before and after” or interrupted time\* or time serie\* or intervention\*

S31: (MH “Program Evaluation”)

S30: (MH “Evaluation Research”)

S29: (MH “Experimental Studies”)

S28: (MH “Randomized Controlled Trials”) OR (MH “Clinical Trials”)

S27: S3 AND S26

S26: (S23 OR S24 OR S25)

S25: S12 AND S22

S24: S8 AND S22

S23: S8 AND S12

S22: (S13 OR S21)

S21: S19 AND S20

S20: S14 OR S15 OR S16

S19: (S17 OR S18)

S18: patient or consumer\* or people\*

S17: (MH “Patients”)

S16: 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\*

S15: (MH “Physicians”)

S14: (MH “Nurses”)

S13: (MH “Professional-Patient Relations”) OR (MH “Professional-Client Relations”) OR (MH “Physician-Patient Relations”) OR (MH “Nurse-Patient Relations”)

S12: (S9 OR S10 OR S11)

S11: ((patient or patients or consumer\*) and (involvement\* or involving\* or participation\* or participating\*))

S10: or patient participation\* or consumer participation\* or patient involvement\* or consumer involvement\* or training intervention

S9: (MH “Consumer Participation”)

S8: S5 OR S6 OR S7

S7: choice behaviour or decision making\* or decision support\* or choice behaviour\* or ((decision\* or choice\*) and (making\* or support\* or behaviour\*))

S6: (MH “Decision Support Techniques+”) OR (MH “Decision Support Systems, Clinical”)

S5: (MH “Decision Making”)

S4: shared decision\* or sharing decision\* or informed decision\* or informed choice\* or decision aid\* or ((share\* or sharing\* or informed\*) and (decision\* or deciding\* or choice\*))

S3: S1 OR S2

S2: Neoplasms OR cancer OR cancers OR neoplasm\* OR malignan\* OR premalignan\* OR precancerous

S1: (MH “Neoplasms+”)

## Appendix B. Meta-Analysis Model

**Analysis model:** Hierarchical random effects meta-regression model

We assumed a normal distribution at the between and within-study levels:

$$y_{ij} \sim N(d_{ij}, \sigma_{ij}^2)$$

where  $y_{ij}$  and  $\sigma_{ij}^2$  are the observed study-level mean response and sampling variance in study  $i$  and arm  $j$ ;  $d_{ij}$  is the unobserved true mean response.

We used a linear form on  $d_{ij}$  to account for decision aid effects and their modification by predictors. For example for a single predictor write

$$d_{ij} = \beta_{0,i} + \beta_{1,i}x_{DA,ij} + \beta_{2,i}x_{pred,ij} + \gamma_i x_{DA,ij}x_{pred,ij}$$

where the  $x$  variables are binary indicators of whether a condition is fulfilled and *pred* stands for predictor.  $x_{DA}$  records the presence of a DA and  $x_{pred}$  indicates whether a study accounts for the predictors of interest listed in Tables 2, 3 and 4 in the main text. We repeated the meta-regression individually for each predictor of interest. We also added terms for population group (high risk population, cancer population) and examined interactions between populations and predictors. To obtain SMDs, we scaled  $y_{ij}$  and  $\sigma_{ij}^2$  with the pooled standard deviation in study  $i$ .

We used a Bayesian framework for the meta-analysis and assigned the following priors to model coefficients:

- $\beta_{0,i} \sim N(0, 0.01)$
- $\beta_{1,i} \sim N(B_{1,i}, \tau_{B_{1,i}}^2)$
- $B_{1,i} \sim N(0, 0.01)$  (for SMDs on knowledge),  $B_{1,i} \sim N(0, 0.0001)$  (for WMDs on decisional conflict and anxiety)
- $\tau_{B_{1,i}} \sim U(0.001, 2)$  (for the SMD model on knowledge),  $\tau_{B_{1,i}} \sim U(0.001, 20)$  (for WMDs on decisional conflict and anxiety)
- $\beta_{2,i} \sim N(0, 0.01)$
- $\gamma_i \sim N(\Gamma_i, \theta_{\Gamma_i}^2)$
- $\Gamma_i \sim N(0, 0.01)$  (for SMDs on knowledge),  $\Gamma_i \sim N(0, 0.0001)$  (for WMDs on decisional conflict and anxiety)
- $\theta_{\Gamma_i} \sim U(0.001, 2)$  (for the SMD model on knowledge),  $\theta_{\Gamma_i} \sim U(0.001, 20)$  (for WMDs on decisional conflict and anxiety)

In sensitivity analyses we increased the variance in the prior distributions (results summarized in the text but not shown in detail).



## **Appendix C. Description of Discrepancies With the 2014 Cochrane Systematic Review**

The most recent update of the Cochrane Systematic Review is searched the literature through June 2012, and included 115 trials in all healthcare conditions. Of these, 47 are in people facing decisions related to screening, diagnosis, or treatment of no worse than early cancer.

Considering cancer and non-cancer conditions, the authors of the Cochrane Review concluded that there is high-quality evidence that decision aids compared to usual care improve people's knowledge regarding options, and reduce their decisional conflict related to feeling uninformed and unclear about their personal values; that there is 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 in decision aids, compared to not being included; and that there is low-quality evidence that decision aids improve congruence between the chosen option and the patient's values.

Regarding randomized evidence, the Cochrane systematic review and the current work have included mostly overlapping sets of studies. Of the 115 trials in the Cochrane review, 47 are in patients facing screening, diagnostic or treatment decisions in early cancer. We have included 67 trials. Overall:

- 41 trials are included in both the Cochrane review and this work,
- 6 trials are included in the Cochrane review but are excluded from our work, because the intervention was not judged to be a decision aid, using our operationalization of the inclusion criteria (e.g., we did not find a description that the intervention included even implicit elicitation of values), and
- 26 trials are included in our work but not in the Cochrane review. Of these, 10 were published after the last search of the Cochrane review (June 2012), 14 were in the excluded studies list, and 2 were not mentioned in the included/excluded lists of the Cochrane review.

We verified our decisions for the 32 trials in which our decisions for eligibility were at odds with those of the Cochrane reviewers. We concluded that the most plausible explanation for the disagreements is in the operationalization of the eligibility criteria.

### **Sensitivity Analysis**

The conclusions in our main report would remain qualitatively the same if we were to consider only the 41 trials included in the Cochrane review. Indicatively, we list the main results for the three meta-analyses including only the subset of our studies that were included in the Cochrane report.

### **Knowledge About the Condition or the Available Options**

In total, 23 trials (7736 participants) would be included in the main analysis. Overall, using decision aids resulted in higher knowledge scores (standardized mean difference or SMD = 0.19, 95% credible interval [CrI]: 0.09, 0.29) compared to not using them. (An SMD of 0.20-0.30 can be considered a moderate effect.) The effect was 0.25, 95% CrI: 0.11, 0.38) among people at average risk of cancer, 0.22 (95% CrI: 0.03, 0.39) among those at high risk, and 0.05 (95% CrI: -0.19, 0.29) among patients with early cancer. However, the observed effects were not different beyond what can be explained by chance. There was no evidence for effect modification by the

delivery format or content of the DA or other attributes, or by methodological characteristics of the studies. There were indications for relatively large between-study heterogeneity.

## **Decisional Conflict**

In total, 18 trials (4176 participants) would be included in the main analysis. Overall, using decision aids resulted in lower decisional conflict scores (weighted mean difference = -0.10, 95% credible interval [CrI]: -0.19, -0.01) compared to not using them. The effect was -0.16, 95% CrI: -0.32, 0.01) among people at average risk of cancer, -0.12 (95% CrI: -0.31, 0.04) among those at high risk, and -0.03 (95% CrI: -0.18, 0.13) among patients with early cancer. The observed effects were not statistically significantly different (their differences could be explained by chance alone). The observed effects were not different beyond what can be explained by chance. There was no evidence for effect modification by the delivery format or content of the DA or other attributes, or by methodological characteristics of the studies. There were indications for relatively large between-study heterogeneity.

## **Anxiety**

In total, 8 trials (1959 participants) would be included in the main analysis. Overall, using decision aids resulted in higher anxiety, as measured by the state anxiety scale of the State-Trait Anxiety Inventory (weighted mean difference = 0.16, 95% credible interval [CrI]: -1.43, 1.29) compared to not using them. There were indications for relatively large between-study heterogeneity. Because there were fewer than 10 studies, we did not run meta-regression analyses by the delivery format or content of the DA or other attributes, or by methodological characteristics of the studies. There were indications for relatively large between-study heterogeneity (see Methods section).

## Appendix D. Table of Study Characteristics

**Table D1. Characteristics of included studies**

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/ Ethnicity	Education >50% completed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/ personalized)	Interactive materials
	<b>Screening</b>									
	<b>Breast</b>									
Mathieu (2007) 17954796	3	Australia	734	70.35	NR	unclear	DA booklet/ Control usual care	yes/ no	generic/ none	no/ NA
	3	Australia	412	41.8	NR	yes	DA website/ control	yes/ no	generic/ none	yes/ NA
	<b>Colorectal</b>									
Trevena (2008) 18573775	11	Australia	314	59 [median between 55-64 which contains 66% of the population]	NR	no	DA booklet/ Control guidelines	yes/ no	generic/ none	no/no
Smith (2010) 20978060	11	Australia	572	NR	men 50%, women 50%	yes	DA booklet, video, question prompt list/ DA booklet, video/ Control booklet	yes/ yes/ no	personalized/ personalized/ generic	no/ no/ no
Schroy (2010) 20484090	9	USA	666	< 65 [86% of the population was under 65]	men 40%; white 34%, African American 63%, Asian 1%, other 2%	yes	DA computer individualized/ DA computer/ Control education on another topic	yes/ yes/ no	personalized/ generic/ none	yes/ yes/ NA
Pignone (2000) 11085838	8	USA	651	62.7	white 90%	yes	DA video/ Control video on another topic	no/ no	none/ none	no/ no

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/ Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/ personalized)	Interactive materials
Griffith (2008) 18218084	8	USA	120	54	white 71%, African American 24%	yes	DA 5 options video/ DA 2 options video	no/no	generic/ generic	no/ no
Miller (2011) 21565651	8	USA	264	57.8	African American 73%	yes	DA Computer/ Control education on another topic	no/ no	generic/ none	yes/ NA
Dolan (2002) 11958495		USA	97	66.1	white 98%	yes	DA booklet and consultation/ Control interview	yes/ no	generic/ none	consultation/ consultation
Ruffin (2007) 17689600		USA	174	57	white 53%, African American 47%	yes	DA computer/ Control computer	yes/ no	generic/ none	yes/ no
	<b>Prostate</b>									
Volk (2008) 18760888	20	USA	525	55.6	white 47%, African American 36%, Hispanic 8%, other 9%	yes	DA video/ DA audio	yes/no	generic/ generic	yes/ no
Taylor (2013) 23896732	10	USA	1879	56.9	white 56%; African American 40%; other 4%	yes	DA computer/ DA booklet/ Control usual care	yes/ yes/ no	generic/ generic/ none	yes/ no/ NA
Williams (2013) 23357414	10	USA	543	54.9	white 30%, Black 61%, Other 9%	yes	DA booklet/ Control usual care booklet	yes/ no	generic/ generic	no/ no
Stephens (2008) 19025266	7	USA	400	54.9	African American 50%	yes	DA booklet/ Control usual care	no/ no	generic/ none	no/ NA
Myers (2005) 16173330	6	USA	242	52	African American 100%	yes	DA booklet and consultation/ Control booklet	yes/ no	none/ none	consultation/ no

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/personalized)	Interactive materials
Myers (2011) 20619576	6	USA	313	56.5	white 56%	yes	DA booklet and consultation/ Control usual care	yes/no	generic/none	consultation/no
Frosch (2008) 18299490	5	USA	611	58.7	white 86%, African American 3%, Hispanic 5%, Asian 4%, other 2%	yes	DA chronic disease trajectory/ DA traditional/ DA combination/ Control	yes/yes/no/no	generic/generic/none	yes/no/yes/no
Frosch (2003) 14521639	4, 5	USA	226	62	white 91%, Asian/Pacific Islander 3.5%, Hispanic, 3.5%, other 2%	yes	DA computer/ DA video	no/no	generic/generic	no/no
Volk (1999) 10418541	4	USA	160	59	white 61%, African American 19%, Mexican American 16%, other 4%	yes	DA videotape and utility assessment/ DA videotape/ Control no intervention	no/no/no	generic/generic/none	no/no/NA
Partin (2004) 15242468	2, 4	USA	1,152	68.4	white 95%	yes	DA video/ DA booklet/ Control	no/no/no	generic/generic/none	no/no/NA
Gattellari (2003) 12790313	1	Australia	248	54	NR	yes	DA booklet/ Control pamphlet	yes/no	generic/none	no/no
Gattellari (2005) 15911190	1	Australia	421	58.1	NR	yes	DA video/ DA booklet/ Control leaflet	yes/no/no	generic/generic/none	no/no/no

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/personalized)	Interactive materials
Watson (2006) 16875796		UK	1960	60 [median between 50-70 which contains 61% of the population]	white 96%	yes	DA booklet/ Control usual care	no/ no	generic/ none	no/ NA
Ilic (2008) 18373146		Australia	161	58.5	NR	yes	DA booklet/ DA video/ DA computer	no/ no/ no	none/ none/ none	no/ no/ yes
Holt (2009) 19718941		USA	49	56	African American 100%	yes	DA booklet and consultation spiritual/ DA booklet and consultation secular	no/ no	generic/ generic	consultation/ consultation
Allen (2010) 20716619		USA	829	>45 [all]	white 89%	yes	DA computer/ Control usual care	yes/ no	generic/none	yes/ NA
Evans (2010) 20693148		UK	514	55 [median between 50-59 which contains 64% of the population]	white 98%	yes	DA computer/ DA booklet/ Control 1 and 2 usual care	yes/ no/ no	generic/ generic/ none/ none	yes/ no/ no/ no
Chan (2011) 21237611		USA	321	60.9	100% Hispanic	no	DA video, booklet, and in-person education/ Control education on another topic	yes/no	generic/ none	consultation/ NA

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/ Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/ personalized)	Interactive materials
Lepore (2012) 22825933		USA	490	62 [median between 55-70 which contains 49% of the population]	African American 100%	yes	DA booklet and consultation/ Control education on another topic	yes/no	personalized/ none	consultation/ NA
Sheridan (2012) 23148458		USA	130	57.5	white 55%	yes	DA video and coaching/ Control education on another topic	yes/no	generic/ none	consultation/ NA
Salkeld (2013) no PMID		Australia	1447	NR	NR	NR	DA computer/ Control education	no/no	generic/ none	yes/ no
Wilkes (2013) 23835818		USA	581	63	white 82%, African American 8%, Hispanic 8%, Asian 5%, other 7%	yes	DA computer for patients/ DA computer for physicians/ Control booklet	no/no/no	generic/ personalized/ generic	yes/ yes/ no
Watts (2013) 24274808		Australia	138	56	NR	yes	DA computer/ Control computer education	yes/no	personalized/ generic	yes/ no
	<b>High risk, but no cancer</b>									
	<b>Breast - preventive treatment</b>									
Fagerlin (2011) 21442198	21	USA	1197	61.7	white 97.5%, Black 0.4%, Asian/Pacific Islander 1.7%, Hispanic 0.4%	yes	DA computer/ Control waiting list/ Control no intervention	yes/no/no	personalized/ none/ none	yes/ NA/ NA

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/personalized)	Interactive materials
Schwartz (2009) 19210013	17	USA	214	44	white 93%; Jewish 49%	yes	DA computer and booklet/ Control usual care booklet	yes/no	personalized/ none	yes/ NA
Ozanne (2007) 17319855		USA	30	44.4	NR	yes	DA computer and consultation/ Control consultation	no/no	personalized/ personalized	yes and consultation/ consultation
van Roosmalen (2004) 15310772		Netherlands	88	39.5	NR	unclear	DA brochure and video plus counseling/ Control usual care	yes/no	generic/ generic	consultation/ NA
	<b>Breast—testing for genetic mutation</b>									
Lerman (1997) 8998184		USA	578	39 [median between 35 and 49 which contains 58% of the population]	white 71%, African American 27%, other 2%	yes	DA education and counseling/ DA education/ Control wait list	no/ no/ no	personalized/ personalized/ none	consultation/ consultation/ NA
Green (2001) 11562929		USA	72	44	white 98%, African American 2%	yes	DA computer/DA counselor/ Control baseline knowledge	no/ no/ no	generic/ personalized/ none	yes/ consultation/ NA
Green (2004) 15280342		USA	211	44.5	white 93%	yes	DA computer/ DA counselor	no/ no	generic/ personalized	yes/ consultation



First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/ Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/ personalized)	Interactive materials
Miller (2005) 16377604		USA	492	46.32	white 89%, African American 5%, Native American 2%, Asian 1%, Hispanic 1%, other 2%	yes	DA telephone education and packet/ Control usual care	yes/ no	personalized/ generic	consultation/ consultation
Albada (2012) 22394647		Netherlands	197	41.4	NR	yes	DA computer/ Control usual care	no/ no	generic/ none	yes/ NA
	<b>Breast/ Ovarian— testing for genetic mutation</b>									
Wakefield (2008) 17333332	13	Australia	145	47.7	NR	yes	DA booklet/ Control usual care booklet	yes/no	personalized/ none	no/ no
Wakefield (2008) 18613319	13	Australia	148	48.7	NR	yes	DA booklet/ Control usual care booklet	yes/no	personalized/ none	no/ no
	<b>Colorectal— testing for genetic mutation</b>									
Wakefield (2008) 18618513	13	Australia	153	50.4	NR	yes	DA booklet/ Control usual care booklet	yes/no	personalized/ none	no/ no
	<b>Ovarian— preventive treatment</b>									
Tiller (2006) 16855125		Australia	131	48.6	NR	yes	DA booklet/ Control booklet	yes/no	generic/ generic	no/no
	<b>Early cancer Breast</b>									

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/personalized)	Interactive materials
Goel (2001) 11206942		Canada	136	57.5	NR	yes	DA audiotape, workbook/ Control pamphlet	yes/no	generic/ none	no/no
Whelan (2004) 12697850	12	USA and Canada	176	51.4	NR	no	DA decision board/ Control usual care	no/no	generic/ none	consultation/ NA
Whelan (2003) 15280341	12	Canada	201	58.1	NR	yes	DA decision board/ Control usual care	no/no	generic/ none	consultation/ NA
Jibaja-Weiss (2011) 20609546	20	USA	138	51	white 16%, African American 38%, Hispanic 45%, Asian American 1%	no	DA computer/ Control usual care	yes/no	generic/ none	yes/ NA
Street (1995) 8635032		USA	60	59.1	white 92%	yes	DA computer/ Control booklet	no/ no	none/ none	yes/no
Vodermaier (2009) 19209172		Germany	152	55.2	NR	yes	DA decision board/ Control usual care	no/ no	generic/ none	consultation/ NA
Peele (2005) 15951457	22	USA	432	NR	white 80%	yes	DA computer/ Control pamphlet	no/ no	personalized/ none	consultation/ consultation
Lam (2013) 23835709		China	276	55.7	Chinese 100%	yes	DA booklet/ Control usual care	yes/ no	generic/ none	no/ NA
Davison (2002) 12464832		Canada	736	58.3	NR	yes	DA computer/ Control no intervention	no/ no	personalized/ none	yes/ NA
Maslin (1998) no PMID		UK	100	52.1	NR	NR	DA video/ Control usual care	no/ no	personalized/ none	yes/ NA

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/ Ethnicity	Education >50% competed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/ personalized)	Interactive materials
<b>Cervical</b>										
McCaffery (2010) 20179125	15	Australia	330	>30 [65% of the population was older than 30]	NR	yes	DA informed consent/ Control HPV triage/ Control repeat testing	yes/ no/ no	generic/ none/ none	no/ NA/ NA
<b>Colorectal</b>										
Manne (2010) 20142594		USA	213	46.3	white 90%; men 55%	yes	DA computer/ Control education	no/ no	generic/ generic	yes/ consultation
<b>Prostate</b>										
Berry (2013) 22153756	19	USA	508	63 [median age]	white 85%	yes	DA computer/ Control usual care	yes/ no	generic/ none	yes/ no
Davison (1997) 9190093		Canada	60	68	NR	no	DA booklet and consultation/ Control booklet	no/ no	generic/ none	consultation/ no
Auvinen (2004) 14678367		Other (Finland)	210	72	NR	NR	DA booklet and consultation/ Control usual care	yes/ no	generic/ none	consultation/ consultation
Davison (2007) 17876177		Canada	324	62.4	NR	no	DA video and booklet individualized/ DA video and booklet generic	yes/ no	personalized/ none	yes/ no

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Country of trial	N enrolled	Age (mean)	Gender/Ethnicity	Education >50% completed high school (yes/no)	Arm	Values clearly explicit (yes/no)	Probabilities (generic/personalized)	Interactive materials
Mishel (2009) 19819096		USA	259	62.5	white 71.5%, African American 28.5%	yes	DA booklet, video, and consultation/ DA booklet, video, and consultation for both patient and primary support person/ Control booklet	yes/ yes/ no	none/ none/ none	consultation/ consultation/ NA
Diefenbach (2012) 22246148		USA	91	61.93	white 59%, African American 27%, Hispanic, Asian, other 14%	yes	DA tailored Web site/ DA generic Web site/ Control usual care	no/ no/ no	generic/ generic/ generic	yes/ yes/ NA
Feldman- Stewart (2012) 22287534		Canada	156	65 [median between 60-99 which contains 47% of the population]	NR	yes	DA computer/ DA computer with values exercise	yes/ no	generic/ generic	yes/ not clear
Hacking (2013) 22570252		UK	123	66.2	white 100%	yes	DA coaching/ Control usual care	yes/ no	none/ none	consultation/ NA
van Tol- Geerdink (2013) 22882966		Netherlands	240	64	NR	unclear	DA consultation/ Control usual care	no/no	generic/ none	consultation/ NA
Sawka (2012) 22753906		Canada	74	45.8	men 16%	yes	DA computer/ Control usual care	no/no	generic/ none	yes/ NA

**Table 1B – Key Question 2**

First Author (date) PMID	Population/ body system and decision type Country of trial	N physicians enrolled	Provider Age (mean)	Provider gender distribution	Patient age	Arm	Timing of intervention
	<b>Screening</b>						
	<b>Prostate</b>						
Gattellari (2005) 15824055	Australia	277	50 [median between 45 and 54 which contains 40.8% of the population]	men 75%	NR	4 month combination of peer coaching and informational packets/ Control wait list	Outside consultation
Feng (2013) 23835817	USA	120	43	NR	NR	Computer education/ Computer education plus activated patients/ Control booklet	Web-based, outside consultation/Web- based curriculum plus patient exposure/NA
	<b>Colorectal</b>						
Lin (2013) 23381524	USA	502	NR	NR	NR	Distribution of 16 DSTs of which one is a colorectal cancer screening DST	The aids were primarily distributed at the point and time of care
	<b>Breast</b>						
Bryan (2013) no PMID	USA	165	NR	NR	NR	Before and after a single interactive case-based discussion (30 minutes of risk/benefits, risk assessment, and counseling methods)	Outside consultation
	<b>Multiple</b>						
Uy (2011) 22212453	USA	4 practices	NR	NR	NR	Distribution of 24 DSTs of which 6 are for early cancer screening or treatment.	The aids were primarily distributed at the point and time of care

## Appendix E. List of Included Studies

Key Question	References
1	1-83
2	82, 84-87

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## Appendix F. List of Excluded Studies

Reason	Citations
KQ1 - Not a DST	1-138
KQ1 - Not an RCT	139-206
KQ2 - No comparative aspect	207-214
KQ2 - Not about promoting DST use	215-285
Duplicate information	15, 27, 286-297
Full text not in English	298-310
Hypothetical choice/scenario	311-316
No outcomes of interest	291,317-319
< 10 in arm	320
Wrong publication type (note: 2 abstracts in this section share a single citation)	321-407
Wrong population	408-426
Could not retrieve full text	427-429

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# Appendix G. Abstraction of Information Related to Risk of Bias in Individual Studies

## Key Question 1

**Table G1. Information related to risk of bias in individual studies for Key Question 1**

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Low Risk of Bias due to Inadequate Randomized Sequence Generation	Low Risk of Bias due to Inadequate Allocation Concealment	Low Risk of Bias due to Inadequate Outcome Assessor Blinding	Low Risk of Bias due to Attrition (Attrition Rate below 20%)
	<b>Screening</b>				
	<b>Breast</b>				
Mathieu (2007) 17954796	3	Yes	Yes	No	No
	<b>Colorectal</b>				
Trevena (2008) 18573775	11	Unclear	Yes	Yes	Unclear
Smith (2010) 20978060	11	Yes	Yes	No	Yes
Schroy (2010) 20484090	9	Unclear	Unclear	No	Unclear
Pignone (2000) 11085838	8	Yes	Yes	Yes	No
Griffith (2008) 18218084	8	Yes	Yes	Unclear	No
Miller (2011) 21565651	8	Yes	Unclear	Unclear	No
Dolan (2002) 11958495		Yes	No	No	No
Ruffin (2007) 17689600		Yes	Yes	Yes	No
	<b>Prostate</b>				
Volk (2008) 18760888	20	Yes	Unclear	No	Yes
Taylor (2013) 23896732	10	Yes	Unclear	Unclear	Unclear
Williams (2013) 23357414	10	Unclear	Unclear	No	No
Stephens (2008) 19025266	7	Yes <sup>a</sup>	Yes	Yes	No
Myers (2005) 16173330	6	Unclear	Unclear	No	No
Myers (2011) 20619576	6	Unclear	Yes	No	Unclear
Frosch (2008) 18299490	5	Yes	Yes	No	No
Frosch (2003) 14521639	4, 5	Yes	Yes	No	Unclear
Volk (1999) 10418541	4	Yes	Unclear	Unclear	No
Partin (2004) 15242468	2, 4	Yes	Yes	Yes	No
Gattellari (2003) 12790313	1	Yes	Unclear	No	Unclear
Gattellari (2005) 15911190	1	Yes	Yes	No	No

First Author, Year (PMID)	Population/body system and decision type Decision Aid ID*	Low Risk of Bias due to Inadequate Randomized Sequence Generation	Low Risk of Bias due to Inadequate Allocation Concealment	Low Risk of Bias due to Inadequate Outcome Assessor Blinding	Low Risk of Bias due to Attrition (Attrition Rate below 20%)
Watson (2006) 16875796		Yes	Yes	Unclear	Unclear
Ilic (2008) 18373146		Yes	Yes	No	No
Holt (2009) 19718941		Unclear	Unclear	No	Unclear
Allen (2010) 20716619		Yes	Unclear	Unclear	Unclear
Evans (2010) 20693148		Yes	Yes	No	Yes
Chan (2011) 21237611		Yes	Unclear	Unclear	No
Lepore (2012) 22825933		Yes	Yes	Unclear	No
Sheridan (2012) 23148458		Yes	Yes	No	Unclear
Salkeld (2013) no PMID		Unclear	Unclear	No	Unclear
Wilkes (2013) 23835818		Yes	Yes	No	No
Watts (2013) 24274808		Yes	Yes	No	Yes
	<b>High risk, but no cancer</b>				
	<b>Breast—preventive treatment</b>				
Fagerlin (2011) 21442198	21	Yes	Yes	Unclear	Unclear
Schwartz (2009) 19210013	17	Yes <sup>b</sup>	No	Unclear	Unclear
Ozanne (2007) 17319855		Unclear	Unclear	Unclear	No
van Roosmalen (2004) 15310772		Yes	Unclear	No	Unclear
	<b>Breast—testing for genetic mutation</b>				
Lerman (1997) 8998184		Unclear	Unclear	No	Unclear
Green (2001) 11562929		Yes	Yes	No	No
Green (2004) 15280342		Unclear	Unclear	No	No
Miller (2005) 16377604		Unclear	Unclear	No	No
Albada (2012) 22394647		Yes	Yes	Unclear	Unclear
	<b>Breast/Ovarian—testing for genetic mutation</b>				
Wakefield (2008) 17333332	13	Unclear	Yes	Yes	No

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Low Risk of Bias due to Inadequate Randomized Sequence Generation	Low Risk of Bias due to Inadequate Allocation Concealment	Low Risk of Bias due to Inadequate Outcome Assessor Blinding	Low Risk of Bias due to Attrition (Attrition Rate below 20%)
Wakefield (2008) 18613319	13	Unclear	Unclear	No	Yes
	<b>Colorectal— testing for genetic mutation</b>				
Wakefield (2008) 18618513	13	Unclear	Unclear	No	Yes
	<b>Ovarian— preventive treatment</b>				
Tiller (2006) 16855125		Unclear	Unclear	Yes	No
	<b>Early cancer Breast</b>				
Goel (2001) 11206942		Yes	Yes	No	No
Whelan (2004) 12697850	12	Unclear	Unclear	Yes	Yes
Whelan (2003) 15280341	12	Yes	Yes	No	No
Jibaja-Weiss (2011) 20609546	20	Yes	Unclear	No	No
Street (1995) 8635032		Unclear	Unclear	Unclear	No
Vodermaier (2009) 19209172		Yes	Unclear	No	Unclear
Peele (2005) 15951457	22	Unclear	Unclear	Unclear	Unclear
Lam (2013) 23835709		Yes	Yes	Yes	Unclear
Maslin (1998) no PMID		Unclear	Unclear	Unclear	No
	<b>Cervical</b>				
McCaffery (2010) 20179125	15	Yes	Unclear	Unclear	Unclear
	<b>Colorectal</b>				
Manne (2010) 20142594		Unclear	Unclear	Unclear	Unclear
	<b>Prostate</b>				
Berry (2013) 22153756	19	Yes	Unclear	Unclear	Unclear
Davison (1997) 9190093		Unclear	Unclear	Unclear	No
Auvinen (2004) 14678367		Yes	Yes	No	No
Davison (2007) 17876177		Unclear	Yes	Unclear	Unclear
Mishel (2009) 19819096		Unclear	Unclear	Unclear	Unclear
Diefenbach (2012) 22246148		Unclear	Unclear	No	Unclear
Feldman-Stewart (2012) 22287534		Yes	Yes	Unclear	Unclear

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Low Risk of Bias due to Inadequate Randomized Sequence Generation	Low Risk of Bias due to Inadequate Allocation Concealment	Low Risk of Bias due to Inadequate Outcome Assessor Blinding	Low Risk of Bias due to Attrition (Attrition Rate below 20%)
Hacking (2013) 22570252		Yes	Yes	No	Unclear
van Tol-Geerdink (2013) 22882966		Unclear	Unclear	Unclear	No
Sawka (2012) 22753906		Yes	Yes	Unclear	No

<sup>a</sup>Based on information from Rubel 2010 PMID 20432110.

<sup>b</sup>Based on Hooker 2011 PMID 20876346.

## Key Question 2

See report text for comments on the risk of bias of studies in Key Question 2. Studies from Key Question 2 were not randomized controlled trials and the criteria in this table are not applicable.

**Table G2. Information related to risk of bias in individual studies for Key Question 2**

First Author, Year (PMID)	Population/ body system and decision type Decision Aid ID*	Low Risk of Bias due to Inadequate Randomized Sequence Generation	Low Risk of Bias due to Inadequate Allocation Concealment	Low Risk of Bias due to Inadequate Outcome Assessor Blinding	Low Risk of Bias due to Attrition (Attrition Rate below 20%)
	<b>Screening</b>				
	<b>Colorectal</b>				
Lin (2013) 23381524		NA	NA	NA	NA
	<b>Prostate</b>				
Gattellari (2005) 15824055		NA	NA	NA	NA
Feng (2013) 23835817		NA	NA	NA	NA
Bryan (2013)	Multiple	NA	NA	NA	NA
Uy (2013)	Multiple	NA	NA	NA	NA

\*NA = Studies from Key Question 2 were not randomized controlled trials and the criteria in this table are not applicable.

## Appendix H. Detailed Strength of Evidence Assessment Table

**Table H1. Detailed strength of evidence assessment**

Key Question or Population	Outcome	Comparison	Risk of Bias for the evidence-base	Consistency	Precision	Directness	Overall Rating	Key Findings and Comments
<i>Key question 1</i>								
All facing decisions in no worse than early cancer	Knowledge about the condition or the options	Using vs. not using DAs	Low to moderate	Somewhat inconsistent (high between study SD)	Mostly precise	Direct	High	- 38 trials (12,484) patients in analysis - SMD: 0.23 (0.09, 0.35) - Outcome is a surrogate of decisional quality (as concept)
		Between DAs, according to delivery formats*	Low to moderate	Mostly consistent	Somewhat imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are wide
		Between DAs, according to their content**	Low to moderate	Mostly consistent	Somewhat imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are wide.
		Between DAs, according to other attributes***	Low to moderate	Mostly consistent	Somewhat imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are wide
	Congruence of choice and values, informed choices, accurate risk perception	Using vs. not using DAs	Low to moderate (few studies report results)	Mostly consistent	Imprecise	Direct	Low	- 11 trials (4455 patients) for congruence/informed choices; 8 trials (2316) patients for risk perception For all listed outcomes: - No quantitative synthesis - Using DAs better than not using in most studies - Outcomes are surrogates of decisional quality (as concept) - Magnitude of clinically important effects unclear

Key Question or Population	Outcome	Comparison	Risk of Bias for the evidence-base	Consistency	Precision	Directness	Overall Rating	Key Findings and Comments
		Between DAs, by formats, contents or other attributes	Low	Undefined	Imprecise	Undefined	Not rated	- [see above for number of trials and patients] - Not feasible to assess because of limited number of trials
	Decisional conflict scale	Using vs. not using DAs	Low to moderate	Mostly consistent	Mostly precise	Direct	Moderate	- 28 trials (7,923 patients) in analysis - WMD: -0.5.3 (-8.9, -1.8) on a 0-100 scale - Clinically important difference unclear; the observed WMD is likely small
		Between DAs, according to delivery formats*	Low to moderate	Mostly consistent	Somewhat imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are somewhat wide
		Between DAs, according to their content**	Low to moderate	Mostly consistent	Somewhat imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are somewhat wide
		Between DAs, according to other attributes***	Low to moderate	Mostly consistent	Somewhat imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are somewhat wide
	Proportion undecided	Using vs. not using DAs	Low to moderate	Consistent	Imprecise	Direct	Low	- 4 trials (2483 patients) - All trials show statistically significant results that the proportion undecided is lower in DAs
		Between DAs, by formats, contents or other attributes	Low	Undefined (sparse data)	Imprecise	Undefined	Not rated	- [see above for number of trials and patients] - Not feasible to assess because of limited number of trials per outcome definition

Key Question or Population	Outcome	Comparison	Risk of Bias for the evidence-base	Consistency	Precision	Directness	Overall Rating	Key Findings and Comments
	Communication with provider, participation in decisionmaking, satisfaction with decisionmaking, actual/intended choices	Using vs. not using DAs	Low to moderate (relatively few studies report results)	Somewhat consistent or undefined, depending on outcome	Imprecise	Direct	Insufficient	- 1 trial (256 patients) for communication; 8 (2173) for participation in decisionmaking; 4 (1131) for patient satisfaction; 48 trials for actual/intended choices For all listed outcomes: - No quantitative synthesis - Outcomes are surrogates of decisional quality (as concept) - Magnitude of clinically important effects unclear
		Between DAs, by formats, contents or other attributes	Low	Undefined (sparse data)	Imprecise	Undefined	Not rated	- [see above for number of trials and patients] - Not feasible to assess because of limited number of trials per outcome definition
	Anxiety	Using vs. not using DAs	Low to moderate	Consistent	Precise	Direct	High	- 14 trials (2958 patients) in analysis - STAI WMD: -0.1 (-1.0, 0.7) - Clinically important difference unclear; indications that the observed WMD is small
		Between DAs, according to delivery formats*	Low to moderate	Mostly consistent	Imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes
		Between DAs, according to their content**	Low to moderate	Mostly consistent	Imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes
		Between DAs, according to other attributes***	Low to moderate	Mostly consistent	Imprecise	Indirect (based on hierarchical regression)	Low	- [see above for number of trials and patients] - No statistical evidence for a difference between DAs with and without attributes

Key Question or Population	Outcome	Comparison	Risk of Bias for the evidence-base	Consistency	Precision	Directness	Overall Rating	Key Findings and Comments
	Depression, emotional distress, decision regret, quality of life	Using vs. not using DAs	Low to moderate (relatively few studies report results)	Somewhat consistent or undefined, depending on outcome	Imprecise	Direct	Low	- 8 trials (1075 patients) for decision regret, 4 (777) for quality of life, 17 (not all analyzable) for depression For all listed outcomes: - No quantitative synthesis - Outcomes are surrogates of decisional quality (as concept) - Magnitude of clinically important effects unclear - No indication for difference
		Between DAs, by formats, contents or other attributes	Low	Undefined	Imprecise	Undefined	Not rated	- [see above for number of trials and patients] - Not feasible to assess because of limited number of trials on the same outcome definition
	Resource use, length of consultation, costs, litigation rates	Using vs. not using DAs	Unclear	Undefined	Imprecise	Undefined	Not rated	- 1 trial (314 patients) for resource use, 3 (417) for length of consultation, no trials on litigation rates - Not feasible to assess because of limited number of trials or no evidence
		Between DAs, by formats, contents or other attributes	Unclear	Undefined	Imprecise	Undefined	Not rated	- [as above]
Separately for populations at average risk, high risk, or with early cancer	Knowledge	Using vs. not using DAs, (evidence for differential effects by population group)	Low	Generally in agreement with respective outcome	Somewhat imprecise	Direct (amounting to a subgroup analysis)	Moderate	- 38 trials (12,484) patients - No statistical evidence for a difference between DAs with and without attributes; however 95% CrI are wide
	Decisional conflict, anxiety	Using vs. not using DAs, (evidence for differential effects by population group)	Low	Generally in agreement with respective outcome	Precise	Direct (amounting to a subgroup analysis)	Moderate	- 28 (7,923) for decisional conflict, 14 (2958) for anxiety - No statistical evidence for a difference between DAs with and without attributes; 95% CrI are somewhat wide (decisional conflict) or narrow (anxiety)



Key Question or Population	Outcome	Comparison	Risk of Bias for the evidence-base	Consistency	Precision	Directness	Overall Rating	Key Findings and Comments
	All other outcomes	Using vs. not using DAs, (evidence for differential effects by population group)	Unclear	Undefined	Imprecise	Undefined	Not rated	- Not feasible to assess because of limited number of trials or no evidence
<i>Key question 2</i>								
<i>All providers or prospective participants</i>	All aforementioned outcomes	Using vs. not using interventions to promote use of DAs	Low	Undefined	Imprecise	Direct	Not rated	- 3 cluster randomized trials with 5, 120, 220 clusters, one study on financial incentives and one on an academic detailing intervention. - No empirical data for most aforementioned outcomes; or from at most one study - This question was used to contextualize the first key question: The overall goal is to promote shared decisionmaking; promotion through DA use is not the only approach.

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

\*\*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

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