QUERI

The Effects of Shared Decision Making on Cancer Screening – A Systematic Review

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PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for four ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at Nicole.Floyd@va.gov.

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EXECUTIVE SUMMARY

INTRODUCTION

Decisions about cancer screening have become increasingly complex. Patients must decide whether to get screened, which screening modality to use, and how often to undergo and when to stop screening. Some cancer screening decisions are considered "preference-sensitive," meaning that, due to closely-balanced benefits and harms, the "right" decision is in part dependent on an individual's values and preferences for particular outcomes. Most organizations publishing clinical practice guidelines for cancer screening now recommend that preference-sensitive cancer screening decisions be made individually, using a process that considers the available evidence on the benefits and harms of particular options, and incorporates patient values and preferences relevant to those options. This approach is sometimes referred to as shared decision making (SDM). The goal of SDM interventions is to facilitate this approach. Adjuncts for the usual counseling for specific decisions, SDM interventions may include: (1) tools to help patients comprehend information about the risks and benefits of options, clarify their personal values related to these options, and participate in decisions consistent with these values and preferences (sometimes referred to as "decision aids") and (2) other interventions to prepare health care providers and/or systems to support this process. SDM interventions differ from many health-related interventions in that they primarily seek to elicit and support patient values and preferences in making health care-related decisions rather than to promote a particular health care strategy per se.

In this review we examine the effects of SDM interventions for cancer screening in adults on constructs from the Ottawa Decision Support Framework, a commonly-used theoretical model of decision making. We examined the constructs of Decision Quality, Decision Impact, and, for studies reporting those outcomes, Decision Action. Decision Quality includes knowledge, values clarity (patients' clarity of their personal values regarding the risks and benefits of decision options), and the patients' participatory role in decision making. Decision Impact includes decisional conflict (personal uncertainty about which course of action to take), use of services (*eg*, consultation length), and satisfaction with the decision. Decision Action includes screening intention and behavior. The ideal SDM intervention would enhance Decision Quality *(ie,* increase knowledge and values clarity) and Impact *(ie,* increase satisfaction, reduce decision conflict, and have minimal impact on service utilization). The desired impact on Decision Action depends on the screening decision. For decisions about how to screen (such as colorectal cancer screening), the ideal SDM intervention would exert the desired effects on Decision Quality and Impact without reducing measures of Decision Action such as screening intention and behavior. For decisions about whether to screen (such as breast, cervical, and prostate cancer in some age groups and risk categories), the goal is to facilitate personalized decision making based on values and preferences. Hence, there are no desired effects on Decision Action per se in this context. We examine patient, provider, system, and multi-level SDM interventions, and therefore do not restrict this review to the most commonly employed SDM intervention of patient-directed decision aids.

This topic was nominated by Linda Kinsinger, MD, MPH, VA Chief Consultant for Preventive

Medicine at the VA National Center for Health Promotion and Disease Prevention (NCP). The evidence review is intended to examine the effects of SDM interventions for cancer screening practices and to inform what types of interventions NCP will disseminate with their cancer screening guidelines.

The key questions and scope were refined with input from a technical expert panel.

Specifically, we addressed the following key questions:

KQ1. In adults, what are the effects of SDM interventions for cancer screening on:
1) Decision Quality;
2) Decision Impact; and
3) Decision Action?

KQ1a. Are there differential effects of the interventions based on:
1) The intervention target (*eg,* provider-focused, patient-focused, system/organizational-focused, multi-level);
2) Key content/elements of the SDM intervention (*eg,* format, values clarification exercise, risk communication method);
3) Patient characteristics (*eg,* race, gender, age, health literacy); and
4) Cancer type (*eg,* breast, cervical, colorectal, prostate, lung)?

KQ2. Within the included studies, what is the receptivity to SDM interventions for cancer screening for:
1) Patients and
2) Providers?

KQ3. Within the included studies, what are the resources required to implement a SDM intervention for cancer screening?

METHODS

Data Sources and Searches

We developed an *a priori* study protocol and analytic framework that included our key study questions, populations, interventions, and outcomes of interest as well as our conceptual framework operationalizing SDM. We searched MEDLINE (Ovid), CINAHL, and PsycINFO for randomized controlled trials (RCTs) and systematic reviews published from January 1, 1995 to July 2014. We limited searches to articles published in the English language. Electronic database search terms included terms for cancer screening, SDM, and the following cancers whereby SDM is likely to have an important role: breast, cervical, colorectal, lung, and prostate cancer. Search strategies are presented in detail in Appendix A. We reviewed additional studies from the reference lists of included and excluded studies and relevant systematic reviews. We searched tables of contents from 12 key journals identified by study investigators. We reviewed studies suggested by technical expert panel members.

Study Selection

Two investigators independently screened abstracts from MEDLINE and reviewed each article identified for full-text review. Abstracts from the CINAHL and PsycINFO searches

were reviewed by a co-investigator. We excluded studies for the following reasons: (1) intervention was not designed for cancer screening; (2) stated goal of the intervention was to promote screening; (3) study was conducted in a non-clinical setting; (4) study was not an RCT comparing an intervention to usual care (UC) or to another intervention; (5) study was conducted in a pediatric population; or (6) study assessed only Decision Action (not Decision Quality or Decision Impact measures). A list of excluded studies can be found in Appendix B.

Data Abstraction and Quality Assessment

One investigator extracted study characteristics, intervention characteristics, and outcomes onto evidence tables and a second investigator verified the extraction. Trained research methodologists rated the risk of bias of individual studies as low, moderate, or high risk. Risk of bias ratings were based the following criteria: allocation sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting – a modification of the Cochrane approach to determining risk of bias.

Data Synthesis and Analysis

We organized evidence tables by cancer type and outcome. We critically analyzed and compiled a summary of findings for each key question. Due to heterogeneity of the interventions, outcome measures, and timing of outcomes assessment, few data could be pooled. Therefore, conclusions are largely based on qualitative synthesis of the findings. To facilitate comparisons across studies, standard mean differences and risk ratios were calculated where possible. We assessed the overall strength of evidence for the outcomes of Decision Quality, Decision Impact, and Decision Action using standard methods. The overall evidence was rated as: (1) high, meaning high confidence that the evidence reflects the true effect; (2) moderate, indicating moderate confidence that further research may change our confidence in the estimate of effect and may change the estimate; (3) low, meaning there is low confidence that the evidence reflects the true effect; or (4) insufficient, indicating that evidence either is unavailable or does not permit a conclusion.

RESULTS

Key Messages

1. No studies evaluated SDM interventions for cervical or lung cancer screening.

2. The vast majority of studies evaluated SDM for prostate cancer screening and had moderate risk of bias. Furthermore, results may have limited applicability because they were conducted prior to publication of randomized trials of prostate cancer screening and the subsequently developed clinical practice guidelines.

3. We found moderate strength of evidence that SDM interventions for breast, colorectal, and prostate cancer screening increase knowledge. We found low strength of evidence that these interventions reduce decisional conflict and improve values clarity.

4. We found low to insufficient strength of evidence that SDM interventions for colorectal and prostate cancer screening affect other measures of Decision Quality and Impact such as patients' role in the decision or decision satisfaction. We found insufficient evidence to indicate an effect of SDM interventions for breast cancer screening on these outcomes.

5. We found low strength of evidence for an association between SDM interventions and Decision Action.

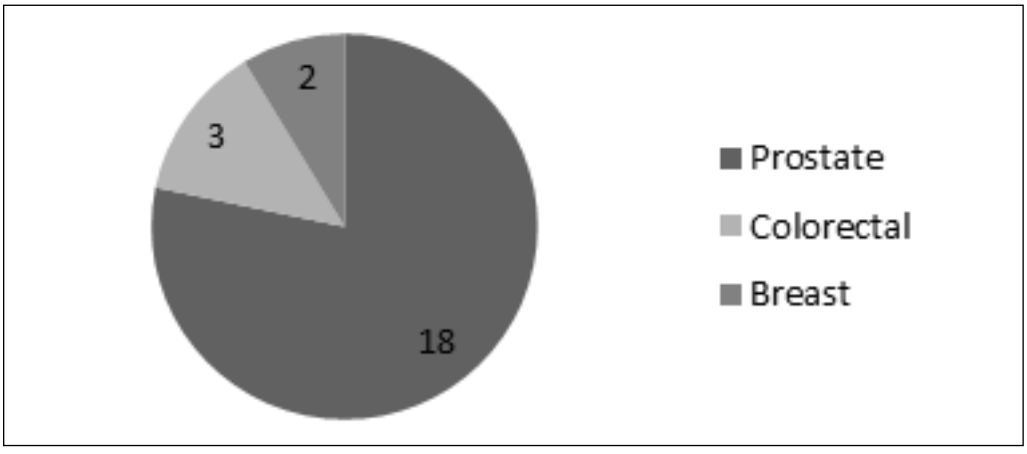
6. We found insufficient evidence regarding the comparative effectiveness of SDM intervention strategies, and whether the effects vary by intervention target population, key SDM intervention content/elements, patient characteristics, or cancer type.

7. Patient receptivity to SDM interventions is positive, as measured by stated opinions and reported reading or viewing of the intervention. We found insufficient evidence on provider receptivity to SDM interventions.

Results of Literature Search

We reviewed 2,368 titles and abstracts from the electronic searches and excluded 2,272 that did not meet our inclusion criteria. We retrieved 96 full-text articles for further review and excluded another 72 references, leaving 24 articles representing 21 unique trials eligible for inclusion. From our hand search we identified 2 studies eligible for inclusion. Thus, this review includes 26 articles representing 23 unique trials. The vast majority (k=18) assessed prostate cancer screening and all but one were judged moderate risk of bias. Two moderate risk of bias studies assessed breast cancer screening; one study evaluated facilitating decisions about whether to be screened for breast cancer in women who are younger than typically recommended, the other study in women who are older than typically recommended. No study assessed screening intervals (*eg,* annual vs biennial) or modalities (*eg,* use of tomosynthesis). Three moderate risk of bias studies assessed SDM for colorectal cancer screening; all assessed screening modalities and none assessed age to start or stop. No studies evaluated SDM for cervical or lung cancer screening. See Executive Summary Figure 1 for a distribution of included RCTs by cancer type and Executive Summary Table 1 for an overview of findings.

Executive Summary Figure 1. Distribution of Included RCTs by Cancer Type



Summary of Results for Key Questions

KQ1. In adults, what are the effects of shared decision making interventions for cancer screening on 1) Decision Quality; 2) Decision Impact; and 3) Decision Action?

Effect on Decision Quality

Overall, SDM interventions had a small but promising effect on most measures of Decision Quality. SDM interventions designed to facilitate decisions about whether to be screened for breast cancer in women who are younger or older than typically recommended for screening improved knowledge (2 of 2 studies). The intervention effect on values clarity was measured a number of ways; clarity was either higher (1 study) or not significantly different (1 study) as a result of the intervention, though indecision about screening mammography was lower (2 studies). SDM interventions to facilitate selection of colorectal cancer screening method increased knowledge (2 of 3 studies), but did not affect other Decision Quality measures of values clarity (1 study) or patients' role in decision making (1 study). SDM interventions to facilitate decisions about whether to receive prostate cancer screening (10 of 14 studies measuring screening behavior with the prostate specific antigen [PSA] test only) consistently increased patient knowledge (14 studies), and either enhanced (6 studies) or had no effect (4 studies) on patient participation in decision making. Intervention groups either had higher scores on measures of values clarity (3 studies) or were not significantly different from comparators (1 study).

Effect on Decision Impact

Overall, SDM interventions had varied effects on Decision Impact. The SDM intervention designed to facilitate decisions about whether women who are older than typically recommended for breast cancer screening should be screened for breast cancer had no effect on its Decision Impact measure of decisional conflict. However, SDM interventions to facilitate selection of colorectal cancer screening method improved Decision Impact, with intervention groups reporting lower decisional conflict (1 study) and higher decision satisfaction (1 study). SDM interventions to facilitate decisions about whether to receive prostate cancer screening either led to lower (7 unique studies, plus half of the participants of a study that separated its study population), or no significant change in (2 unique studies, plus the other half of the study population), decisional conflict. Such interventions also led to higher (1 study) or had no effect on (1 unique study, time 2 of a second study) decision satisfaction. Only one study assessed use of health care services in populations exposed to prostate cancer screening SDM interventions; this intervention had no effect.

Effect on Decision Action

SDM interventions designed to facilitate the choice of screening modality had varied effects on Decision Action. Specifically, SDM interventions to facilitate selection of colorectal cancer screening method either lead to higher colorectal cancer screening intention or behavior (1 study), or had no effect (2 studies). SDM interventions designed to facilitate the choice of whether or not to be screened had varied effects on Decision Action. SDM interventions to facilitate decisions about mammography decreased the proportion of younger women (age 38-45 years) who intended to start screening mammography (1 study) and had no effect on the proportion of older women (age 70-71) who either intended to or actually did stop screening mammography (1 study). SDM interventions to facilitate decisions about whether to receive

prostate cancer screening reported lower screening intention (5 studies) or behavior (7 studies), showed no intervention effect (3 studies and 7 studies, respectively), or, in one case, increased prostate cancer screening behavior.

Executive Summary Table 1. Overview of Findings

Cancer	Decision Quality			Decision Impact			Decision Action	
	Knowledge	Values Clarity	Patient's Role in Decision	Decisional Conflict	Use of Services	Decision Satisfaction	Screening Intention	Screening Behavior
Breast (k=2)	↑ 2	↓ 1[a] ↓ 2[b] ↔ 1		↔ 1			↓ 1 ↔ 1	↔ 1
Colorectal (k=3)	↑ 2	↔ 1	↔ 1	↓ 1		↑ 1	↑ 1 ↔ 2	↑ 1 ↔ 2
Prostate (k=18)	↑ 14 ↔ 1	↑ 3 ↔ 1	↑ 6 ↔ 4	↓ 8[c] ↔ 3[c]	↔ 1	↑ 1[d] ↔ 2[d]	↓ 5 ↔ 3	↓ 7 ↑ 1 ↔ 7

↑ = SDM intervention group had higher outcome measure; ↓ = SDM intervention group had lower outcome measure; ↔ = No effect of SDM intervention on outcome

k=number of studies

[a]Lower scores indicate clearer values

[b]Measure of indecision about intention, lower scores indicate less indecision/clearer values

[c]One study is included in both counts: one study population showed an intervention effect on decisional conflict and the second study population showed no effect

[d]One study is included in both counts: it showed an intervention effect on decision satisfaction at Time 1 and no effect at Time 2

The strength of evidence to indicate an effect of SDM interventions to facilitate breast or colorectal cancer screening decisions on Decision Quality was low; however for prostate cancer screening SDM interventions, strength of evidence was moderate. The strength of evidence for an association between prostate or colorectal cancer screening SDM interventions and Decision Impact was low; however for breast cancer screening SDM interventions, strength of evidence was insufficient. The strength of evidence to indicate an effect of SDM interventions to facilitate cancer screening decisions (prostate, breast, or colorectal) on Decision Action was low. See Executive Summary Table 2 for an overview of the strength of evidence.

KQ1a. Are there differential effects of the interventions based on: 1) The intervention target (ie, provider-focused, patient-focused, system/organizational focused, multi-level); 2) Key content/elements of the intervention (eg, format, values clarification exercise, risk communication method); 3) Patient characteristics (eg, race, gender, age, health literacy); and 4) Cancer type (eg, breast, cervical, colorectal, prostate, lung)?

SDM Intervention Target

Nearly all of the included RCTs (21 of 23 studies) were patient-directed SDM interventions, with 2 exceptions, a clinician-level intervention and a multi-level intervention to facilitate SDM for PSA-based prostate cancer screening. Although we could not compare across interventions targeting different cancer screening decisions, the practitioners in the clinician-level intervention

group had higher knowledge, greater inclination to *not* order PSA, and lower PSA ordering rates after 6 weeks. The multi-level intervention did not affect patient outcomes; physicians appeared more neutral regarding PSA recommendations.

Executive Summary Table 2. Overview of Strength of Evidence (SOE)[a]

Outcome Category	Outcome (# of Studies Reporting)	Risk of Bias of Individual Studies	SOE: Individual Outcomes	SOE: Outcome Categories
Breast Cancer (k=2)				
Decision Quality	Knowledge (2)	Moderate	Moderate	Low
	Values Clarity (2)	Moderate	Low	
	Patient's Role in Decision (0)		Insufficient	
Decision Impact	Decisional Conflict (1)	Moderate	Low	Insufficient
	Use of Services (0)		Insufficient	
	Decision Satisfaction (0)		Insufficient	
Decision Action	Screening Intention (2)	Moderate	Low	Low
	Screening Behavior (1)	Moderate	Low	
Colorectal Cancer (k=3)				
Decision Quality	Knowledge (2)	Moderate	Moderate	Low
	Values Clarity (1)	Moderate	Low	
	Patient's Role in Decision (1)	Moderate	Low	
Decision Impact	Decisional Conflict (1)	Moderate	Low	Low
	Use of Services (0)		Insufficient	
	Decision Satisfaction (1)	Moderate	Low	
Decision Action	Screening Intention (3)	Moderate	Low	Low
	Screening Behavior (3)	Moderate	Low	
Prostate Cancer (k=18)				
Decision Quality	Knowledge (12)	Moderate (11); Low (1)	Moderate	Moderate
	Values Clarity (4)	Moderate	Low	
	Patient's Role in Decision (7)	Moderate (6); Low (1)	Low	
Decision Impact	Decisional Conflict (8)	Moderate (7); Low (1)	Low	Low
	Use of Services (1)	Moderate	Low	
	Decision Satisfaction (2)	Moderate (1); Low (1)	Low	
Decision Action	Screening Intention (7)	Moderate	Low	Low
	Screening Behavior (10)	Moderate (8); Low (2)	Low	

[a] Strength of evidence determined for patient-directed interventions with a usual care or attention control group

Key SDM Intervention Content

The majority of studies included paper-based (14 studies) or web-based (7 studies) SDM interventions; few were face-to-face (3 studies) or telephone (1 study) interventions. More than half of SDM interventions (14 studies) included an explicit values clarification exercise, such as social matching exercises or benefits and harms balance worksheets. The types of values clarification methods varied, with no clear predominate method. RCTs evaluating SDM interventions including a values clarification exercise more often reported a decrease in decisional conflict than those evaluating SDM interventions without a values clarification exercise. For the few SDM trials specifying the method of risk communication, the majority

used pictographs (6 of 8 studies). However, results did not differ for interventions that used pictographs and those that used other risk communication methods.

Patient Characteristics

A number of SDM interventions (10 studies) considered low health literate users in the intervention development stage, testing the intervention and then modifying it to be accessible by a low health literate audience. Only one study tested a SDM prostate cancer screening intervention in a low health literacy site; this study compared use of a SDM intervention in a low health literacy site to use in a high health literacy site, finding increased knowledge for participants at both sites. There were no differential effects for other outcomes. Few studies directly addressed race. A single study targeted black men of African descent for a SDM prostate cancer screening intervention, and another study stratified its sample by race. However, effects did not differ by race. All prostate cancer screening studies included only male participants and all breast cancer screening studies included only female participants; colorectal cancer screening studies ranged from 41% to 48% male, none of which examined differences in effects by gender.

Cancer Type

Breast, colorectal, and prostate cancer screening decisions are different at their core, in their population, timing, and decision type. Thus, included studies are categorized by cancer type and we are unable to compare decision outcomes across cancer types. Both studies of SDM for breast cancer screening evaluated interventions to facilitate decisions about whether to be screened for breast cancer in women who are younger or older than typically recommended. No study assessed screening intervals (*eg,* annual vs biennial) or modalities (eg, use of tomosynthesis). All studies of SDM for colorectal cancer screening evaluated ways SDM interventions facilitate decisions about how to be screened (by what modality) and none assessed age to start or stop. All studies of prostate cancer screening involved SDM on whether or not to undergo prostate cancer screening with the Prostate Specific Antigen (PSA) blood test. As noted no studies assessed SDM for cervical or lung cancer screening.

KQ2. Within the included studies, what is the receptivity to SDM interventions for cancer screening for: 1) Patients and 2) Providers?

Patient receptivity to SDM interventions was generally positive as measured by opinions and reported compliance with reading or viewing of the intervention. Of the included studies, 14 unique studies reported patient receptivity to SDM interventions including use of the interventions (6 studies) or content of interventions (9 studies). SDM intervention use was assessed for prostate cancer screening SDM interventions only, and the majority of patients in all studies reported having read or viewed most or all of the intervention, ranging from 50% (pamphlet format) to 98% (video format). Although one comparative effectiveness trial found a significant difference in SDM intervention use between a web-based and a video decision aid (DA), a separate comparative effectiveness trial found no difference in intervention use between a video DA and a pamphlet. Sociodemographic characteristics associated with SDM intervention use included marital status, level of education, and PSA history.

Patients' ratings of the intervention content reflected positive reactions, and opinions that the intervention materials were easy to understand and balanced. One study included in our review reported provider receptivity; SDM intervention increased providers' receptivity to patient SDM.

KQ3. Within the included studies, what are the resources required to implement a SDM intervention for cancer screening?

Very limited evidence suggests that more resource-intensive interventions were not more effective than less resource-intensive ones. The most human resource-intensive SDM interventions were the provider-level (1 study) and multi-level (1 study) interventions, as well as those involving patient counseling sessions in person (3 studies) or on the telephone (1 study). Interventions requiring administered pre-tests (3 studies) or interviewer- or team member-assessed outcomes (4 studies) were also human resource intensive. One study compared a moderate-cost SDM intervention (mailed video) and a low-cost SDM intervention (mailed pamphlet); the lower-cost intervention either performed similarly or outperformed the moderate-cost intervention. However, we cannot draw conclusions about the relative benefits of additional intervention components from this single study. Technological resource-heavy interventions included web-based SDM interventions (7 studies), which required programmers and bandwidth, and interventions using in-clinic videos and laptops.

DISCUSSION

Limited evidence suggests that SDM interventions for breast, colorectal, and prostate cancer screening improve patient knowledge and may reduce decisional conflict. Focusing on Decision Action, SDM interventions designed to facilitate the decision of whether to be screened *(ie,* breast and prostate cancer screening interventions) have mixed effects (decrease or have no effect) on screening intention or behavior. SDM interventions designed to facilitate decisions about screening modality *(ie,* colorectal cancer screening interventions) also have mixed effects (either increase or have no effect) on screening intention, and have no effect on screening behavior. No studies evaluated SDM interventions for cervical or lung cancer screening.

Overall, SDM interventions were more often paper than web-based; all interventions after 2008 were either exclusively web-based or compared web-based interventions to another format. SDM interventions often used values clarification exercises, though differential effects by patient characteristics were rarely assessed and were non-significant when they were. Patients respond positively to SDM interventions for cancer screening, but evidence regarding physician reactions to SDM interventions for cancer screening included in this review is lacking. Human, financial, and technical resources varied by type of intervention (*eg,* web-based DA versus counseling), but intervention effectiveness did not vary by resource intensity.

Limitations

Our results are limited by the quality, quantity, and consistency of the available literature. Few studies assessed breast or colorectal cancer, none evaluated SDM for lung or cervical cancer, and studies of prostate cancer screening were conducted largely prior to recent findings from screening trials or current clinical practice guidelines. The populations and screening focus of breast and colorectal cancer SDM interventions are assessed in few studies, resulting in insufficient to low strength of evidence for all outcomes of interest except the evidence that SDM interventions for prostate cancer affect knowledge.

Applicability

Findings are likely applicable to the development of future SDM interventions for cancer screening. However, it is worth noting the limits of our key messages' applicability. No studies addressed screening for cervical or lung cancer. Included SDM interventions often did not use the most recent findings from randomized screening trials (especially prostate cancer), modeling studies, or cost effectiveness analyses and thus may not include the most up-to-date evidence or be fully applicable to current screening questions or published clinical practice guidelines. Studies did not address clinically important screening comparative effectiveness decisions, including the value of different screening strategy intensities (*eg,* annual versus biennial mammography, or cervical cancer screening with cytology alone every 3 years versus cytology plus HPV testing every 5 years for women ages 30-65).

Despite these limitations, our findings are relevant to future VA efforts regarding implementation of SDM interventions. Two studies specifically targeted a VA population. Though both studies evaluated SDM interventions for prostate cancer screening, they can be seen as a template upon which to guide current and future efforts, such as lung cancer screening. This outline of the effects of and required resources (specifically the human resource requirements) for SDM cancer screening interventions to date would help guide VA use and development of such interventions.

Future Research

Gaps remain in the field of SDM cancer screening intervention research. These involve the methodological rigor of SDM studies as well as the populations, cancers, and screening strategies studied. A list of future research priorities connected to our key questions might include:

(1) SDM interventions for cervical and lung cancer screening;
(2) PSA interventions incorporating the newest evidence;
(3) Effect of SDM interventions on decision quality measures other than knowledge;
(4) Effect of SDM interventions on decision impact measures other than decisional conflict;
(5) Variation in effects of SDM interventions by intervention targets and patient characteristics;
(6) Provider receptivity to SDM interventions for cancer screening; and
(7) Relative importance of key intervention content to overall effects.

Conclusions

There is moderate evidence that SDM interventions for prostate cancer screening improve knowledge, but low evidence of effects on other measures of Decision Quality, Impact, or Action *(ie,* cancer screening intention and behavior). There is low to insufficient evidence that SDM interventions for breast and colorectal cancer screening affect measures of Decision Quality, Impact, or Action. No studies evaluated SDM interventions for cervical or lung cancer screening. Little information exists regarding the comparative effectiveness of SDM intervention strategies, or whether the effects vary by intervention target population, key SDM intervention content/elements, patient characteristics, or cancer type. While SDM is widely viewed as an important patient-centered approach to preference-sensitive decisions, current evidence does not clearly demonstrate that studied approaches have consistent effects beyond increasing patient knowledge. Additional research is needed to identify interventions that can effectively and efficiently improve patient Decision Quality and Impact across a wide range of cancers and screening strategies.

ABBREVIATIONS TABLE

CRC	Colorectal Cancer
DA	Decision aid
DCS	Decision Conflict Scale
DRE	Digital rectal examination
FOBT	Fecal occult blood test
GP	General practitioner
IPDAS	International Patient Decision Aids Standards
ODSF	Ottawa Decision Support Framework
PSA	Prostate specific antigen
RCT	Randomized controlled trial
SDM	Shared decision making
UC	Usual care

EVIDENCE REPORT

INTRODUCTION

BACKGROUND

Decisions about cancer screening have become increasingly complex. Patients must decide whether to get screened, which screening modality to use, and how often to undergo and when to stop screening. Many cancer screening decisions are increasingly recognized as "preference sensitive," meaning that due to closely-balanced benefits and harms, the "right" decision is in part dependent on an individual's values and preferences for particular outcomes. Most organizations publishing clinical practice guidelines for cancer screening now recommend that preference sensitive cancer screening decisions be made individually, using a process that considers the available evidence on the benefits and harms of particular options, and incorporates patient values and preferences relevant to those options. This approach is sometimes referred to as shared decision making (SDM). The goal of SDM interventions is to facilitate this approach. Adjuncts for the usual counseling for specific decisions, SDM interventions may include: (1) tools to help patients comprehend information about the risks and benefits of options, clarify their personal values related to these options, and participate in decisions consistent with these values and preferences (sometimes referred to as "decision aids") and (2) other interventions to prepare health care providers and/or systems to support this process. They differ from many health-related interventions in that they primarily seek to elicit and support patient values and preferences in making health care-related decisions rather than to promote a particular health care strategy, per se.

Addressing Cancer Screening Decisions through SDM – Screening Use

SDM can aid patients in the decision whether or not to be screened. For example, some cancer screening tests have been shown to reduce mortality and provide benefits that exceed harms (net benefit) at a population level. However, for some patient subgroups (*eg,* older or younger) they may have fewer benefits and more harms than a core group. Screening mammography reduces breast cancer mortality by 32% in relative terms for women in their 60s and 15% for women in their 50s.[1] The absolute risk reduction is reflected in the number needed to screen to prevent one cancer death at 10-15 years (approximately 1300 for women in their 50s versus 600 in their 60s).[2] Because breast cancer mortality reductions due to screening clearly outweigh the harms, mammography is recommended for these age groups. In contrast, for women younger or older than these age groups or for women with less than a 10-year life expectancy, evidence indicates that screening benefits are reduced while harms (mostly false positive mammograms, breast biopsies and overdiagnosed and overtreated breast cancers) are increased.[1] Thus the net benefit becomes smaller and the decision to undergo screening is a "close call" that primarily is determined by patient values and preferences for various known outcomes. Furthermore, at a certain point the benefits do not exceed harms. Thus patients are faced with a decision whether to undergo screening, when to begin, and when to stop screening.[3] Other cancer screening tests have less evidence of effectiveness and greater evidence of harm. Screening for prostate cancer with the Prostate Specific Antigen (PSA) blood test is one example. Prostate cancer is the most commonly diagnosed cancer in men, and screening with the PSA test is common. However,

randomized screening trials demonstrate that any reduction in prostate cancer mortality through 10-14 years due to PSA screening is at most small (less than 1 in 1000 men screened) and results in harms due to diagnostic testing, overdiagnosis, and overtreatment.[4,5] United States Preventive Services Task Force (USPTF) guidelines recommend against PSA screening, concluding that the benefits do not exceed the harms, but suggest that men should not be screened without balanced information about the benefits and harms of PSA screening, and they should make an informed decision that reflects their values and preferences.[6]

Addressing Cancer Screening Decisions through SDM – Screening Modality

For some cancers, multiple effective cancer screening modalities exist with no convincing evidence that one approach is superior to another. Therefore an individual has a choice of different screening options. Colorectal cancer screening is effective and suggested for average-risk individuals starting at age 50.[7] However, colorectal cancer screening has multiple modalities (fecal occult blood testing [FOBT], colonoscopy, sigmoidoscopy). The harms and benefits associated with each of these tests vary.[8] Individual patient values and preferences can guide decision making in determining which test is right for the patient. Similarly, cervical cancer screening is recommended; the benefits of such screening exceed the harms for women aged 30-65, when the screening decision primarily involves choosing a screening modality (cytological testing every 3 years or cytological testing plus human papillomavirus testing every 5 years).[9]

SHARED DECISION MAKING INTERVENTIONS

Shared decision making (SDM) has been defined as "an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences".[10] SDM interventions are programs designed to facilitate this process. The most commonly implemented and evaluated SDM interventions are decision aids (DAs), defined by the International Patient Decision Aids Standards (IPDAS) collaboration as "tools designed to help people participate in decision making about 2 or more health care options" by providing information about the options and helping patients clarify and communicate the personal values they associate with different features of the options.[11] However, SDM interventions may also include provider-directed strategies to enhance SDM receptivity and skills, and system-level modification to provide incentives and resources to facilitate patient and provider-directed strategies.[12]

Because the goal of SDM is to facilitate the decision making process rather than to promote a particular decision action, effective assessment of the clinical value of SDM must separate the decision making process from the outcome. Therefore, we used a framework that makes this distinction (the Ottawa Decision Support Framework (ODSF)[13] to guide our review. The ODSF is an evidence-based theory that separates the decision making process into 3 constructs: Decision Quality, Decision Impact, and Decision Action. The ideal SDM intervention would enhance Decision Quality *(ie,* increase knowledge and values clarity) and Impact *(ie,* increase satisfaction, reduce decision conflict, and have minimal impact on service utilization). The desired impact on Decision Action depends on the decision being made. For decisions about how to screen (such as colorectal cancer screening), the ideal SDM intervention would exert the desired effects on Decision Quality and Impact without reducing measures of Decision Action

such as screening intention and behavior. For decisions about whether to screen (such as breast, cervical, and prostate cancer in some age groups and risk categories), the goal is to facilitate personalized decision making based on values and preferences. Hence, there are no desired effects on Decision Action per se in this context.

In accordance with the ODSF, we focused on evaluations of SDM interventions that measured the decision making process, and that did not promote a specific screening outcome. Therefore, we excluded interventions that measured only Decision Action outcomes *(ie,* screening intention and/or screening behavior), even if the authors referred to the intervention as a SDM intervention or as a DA. Additionally, we included any SDM interventions that assessed Decision Quality or Impact in our review, which means that not all included SDM interventions involved the use of DAs as defined by IPDAS.

OBJECTIVES

The purpose of this review is to examine the effects of SDM interventions for cancer screening in adults on Decision Quality and Impact. For studies reporting Decision Quality or Impact, we also reported Decision Action. We conducted a systematic review of published randomized controlled trials (RCTs) evaluating SDM interventions for cancer screening.

To enhance applicability to current cancer screening evidence and recommendations, we targeted our review to studies published after 1995. We included only studies involving subjects over age 18, as no cancer screening is recommended nor is there an indication for SDM in individuals younger than age 18. Our analytic framework, shown in Figure 1, outlines our PICOS: Population (adults), Interventions (SDM cancer screening interventions), Comparators (usual care, alternative SDM approaches or a combination of both), Outcomes (Decision Quality, Decision Impact, Decision Action, Receptivity, Resources), and Setting (clinic).

Our key questions were:

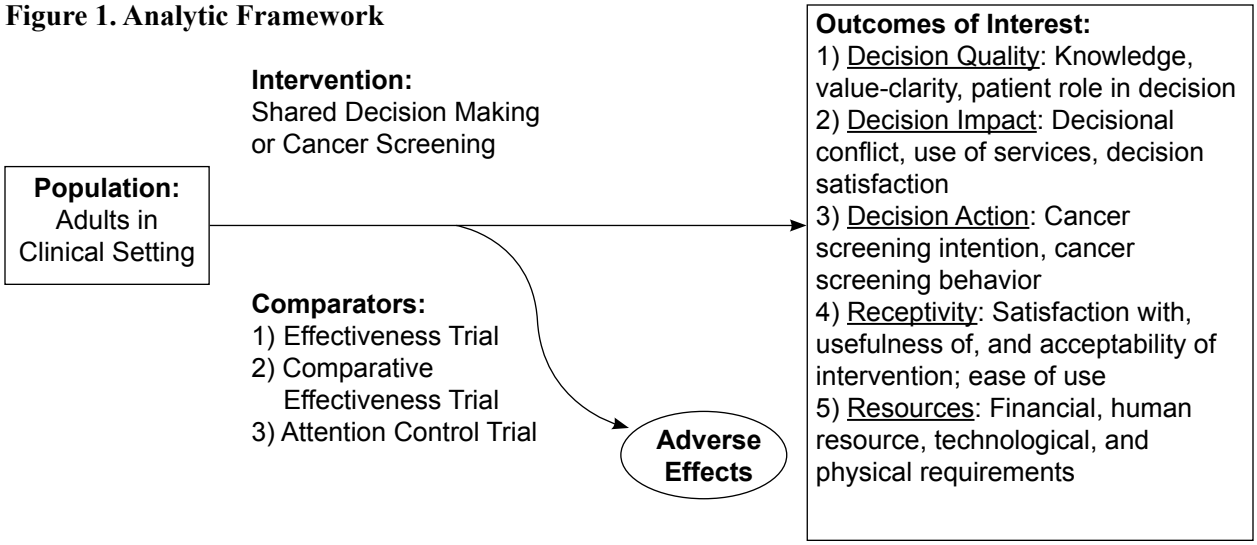
KQ1. In adults, what are the effects of SDM interventions for cancer screening on:
1) Decision Quality;
2) Decision Impact; and
3) Decision Action?

KQ1a. Are there differential effects of the interventions based on:
1) The intervention target (*eg,* provider-focused, patient-focused, system/organizational focused, multi-level);
2) Key content/elements of the intervention (*eg,* format, values clarification exercise, risk communication method);
3) Patient characteristics (*eg,* race, gender, age, health literacy); and
4) Cancer type (*eg,* breast, cervical, colorectal, prostate, lung)?

KQ2. Within the included studies, what is the receptivity to SDM interventions for cancer screening for:
1) Patients and
2) Providers?

KQ3. Within the included studies, what are the resources required to implement a SDM intervention for cancer screening?

Figure 1. Analytic Framework



Moderators:
1) Population for SDM intervention (patients, providers)
2) Key elements of SDM intervention
3) Patient characteristics
4) Cancer type

METHODS

TOPIC DEVELOPMENT

This topic was nominated by Linda Kinsinger, MD, MPH, VA Chief Consultant for Preventive Medicine at the VA National Center for Health Promotion and Disease Prevention (NCP). The evidence review is intended to examine the effects of SDM interventions for cancer screening practices and to inform what types of interventions NCP will disseminate with their cancer screening guidelines.

SEARCH STRATEGY

We searched MEDLINE (Ovid), CINAHL, and PsycINFO for randomized controlled trials (RCTs) and systematic reviews published from January 1995 to July 2014 using standard search terms. We limited the searches to articles involving adults and published in the English language. Search terms included terms for cancer screening, and breast, cervical, colorectal, lung, and prostate cancer, and the following SDM terms: decision making; shared decision making; decision aid; informed decision making; values clarification; patient participation; directive counseling; and decision support. The search strategies are presented in detail in Appendix A.

We obtained additional articles from systematic reviews, including a recent Cochrane review of Decision Aids,[14] reference lists of included and excluded studies, and suggestions from members of our technical expert panel. We also searched tables of contents from 12 key journals identified by the study investigators and peer reviewers: American Journal of Preventive Medicine; The Annals of Family Medicine; Annals of Internal Medicine; BMC Medical Informatics & Decision Making; British Medical Journal; Cancer Epidemiology, Biomarkers & Prevention; Health Affairs; Health Expectations; Journal of General Internal Medicine; Journal of Medical Screening; Medical Decision Making; and Patient Education & Counseling.

STUDY SELECTION

Abstracts from the MEDLINE search (n=1640) were reviewed in duplicate, independently by investigators and co-investigators. Abstracts from the CINAHL (n=460) and PsycINFO (n=268) searches were reviewed by a co-investigator. Each article identified for full-text review was independently reviewed by 2 investigators or co-investigators.

We included RCTs comparing a SDM intervention to usual care (UC), alternative SDM interventions, or a combination. We included studies that evaluated SDM interventions for cancer screening as part of the study, excluding studies in which participants made hypothetical cancer screening choices. We included studies involving adults in a clinic setting, either at or shortly before an appointment, as a component to encourage SDM with the clinician. To ensure that we did not include interventions that encouraged screening, we excluded studies that measured only Decision Action (not Decision Quality or Decision Impact) and studies evaluating interventions with the stated goal of promoting screening. Excluded articles are presented in Appendix B.

DATA ABSTRACTION

Study characteristics (population; sample age, gender, and race; study setting; length of follow-up), SDM intervention characteristics (format, delivery mode, delivery timing/location, inclusion of values clarification exercise, risk communication method, consideration of vulnerable populations, resources required), and outcomes (Decision Quality, Decision Impact, and Decision Action) were extracted onto evidence tables by one investigator or co-investigator and verified by a second.

QUALITY ASSESSMENT

Individual randomized studies were rated as low, moderate, or high risk of bias based on the following criteria: allocation sequence generation, allocation concealment, blinding, incomplete outcome data, and selective outcome reporting – a modification of the Cochrane approach to determining risk of bias.[15]

DATA SYNTHESIS

We organized evidence tables by cancer type and outcome. We critically analyzed studies to compare their characteristics, methods, and findings and compiled a summary of findings for each key question. Due to heterogeneity of the SDM interventions, outcome measures, and timing of outcomes assessment, few data could be pooled, and therefore conclusions are largely based on qualitative synthesis of the findings. To facilitate comparisons across studies, standard mean differences (for continuous outcomes) and risk ratios (for categorical outcomes) were calculated using Review Manager 5.2.[16] Where pooling was possible, statistical heterogeneity was summarized using the I^2 statistic (50 percent indicates moderate heterogeneity and 75 percent or greater indicates substantial heterogeneity).[17]

RATING THE BODY OF EVIDENCE

We assessed the overall strength of evidence for the outcomes of Decision Quality, Decision Impact, and Decision Action using the method reported by Owens et al.[18] One co-investigator with methodology training evaluated strength of evidence and the findings were verified by a second trained co-investigator. The overall evidence was rated as: (1) high, meaning high confidence that the evidence reflects the true effect; (2) moderate, indicating moderate confidence that further research may change our confidence in the estimate of effect and may change the estimate; (3) low, meaning there is low confidence that the evidence reflects the true effect; or (4) insufficient, indicating that evidence either is unavailable or does not permit a conclusion.

PEER REVIEW

A draft version of this report was reviewed by clinical content experts as well as clinical leadership. Their comments and our responses are presented in Appendix C and the report was modified as needed.

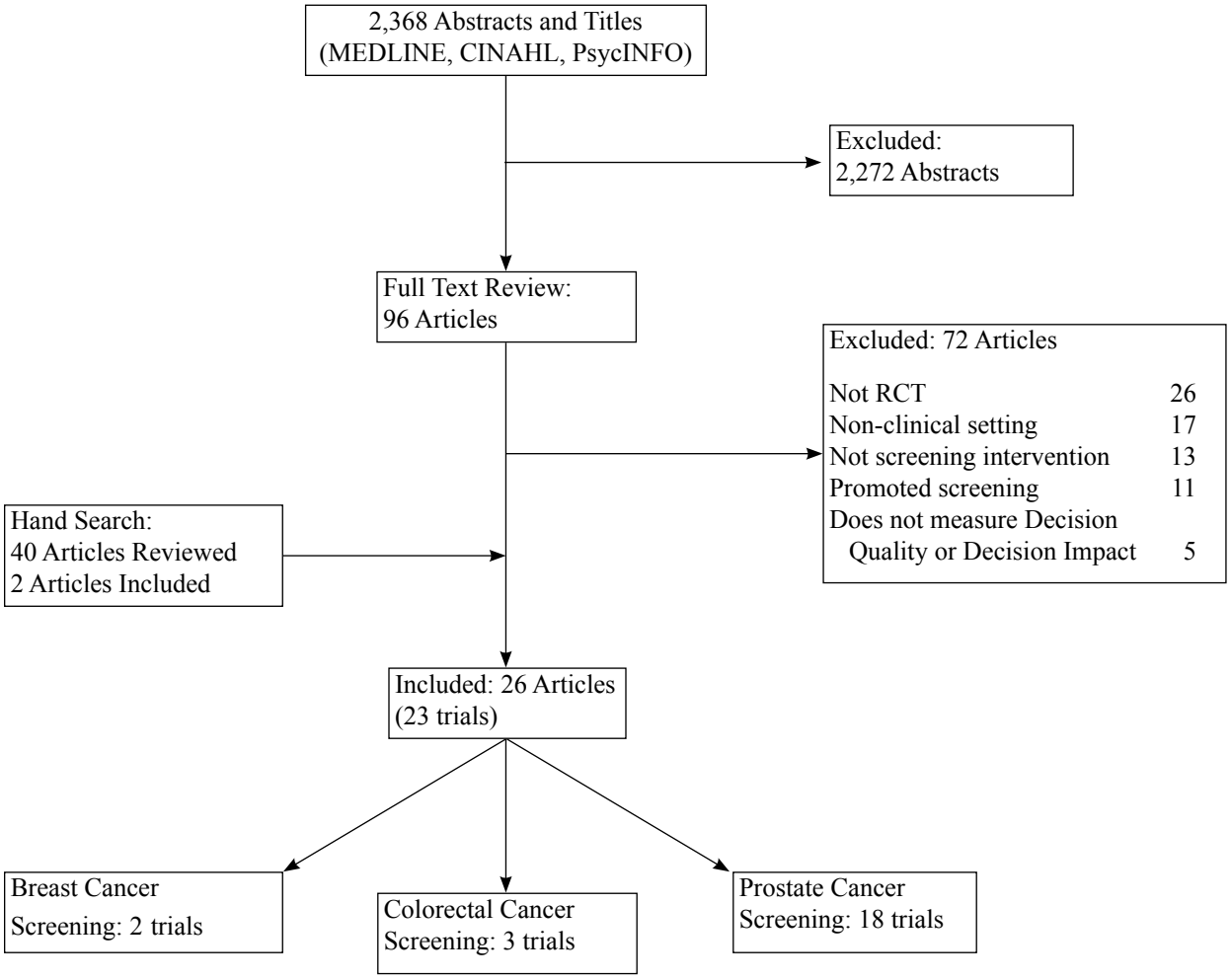
RESULTS

We identified 26 references for inclusion, representing 23 unique trials of SDM interventions in breast (k=2), colorectal (k=3), and prostate cancer (k=18) screening. No SDM interventions for cervical or lung cancer screening met our inclusion criteria. We grouped the studies by cancer and addressed the key questions for each condition. All studies reported on Decision Quality and either Decision Action or Decision Impact.

LITERATURE FLOW

As shown in our literature flow diagram (Figure 2), we reviewed 2,368 titles and abstracts from the electronic searches. After excluding 2,272 abstracts that did not meet our inclusion criteria, we retrieved 96 full-text articles for further review. Using our inclusion/exclusion criteria we excluded another 72 references, leaving 24 references eligible for inclusion. From our hand search we reviewed 40 full-text articles and identified 2 additional articles by hand search (*eg,* review of citations in previously identified articles, suggestions from reviewers), for a final 26 references of 23 unique studies.

Figure 2. Literature Flow Diagram



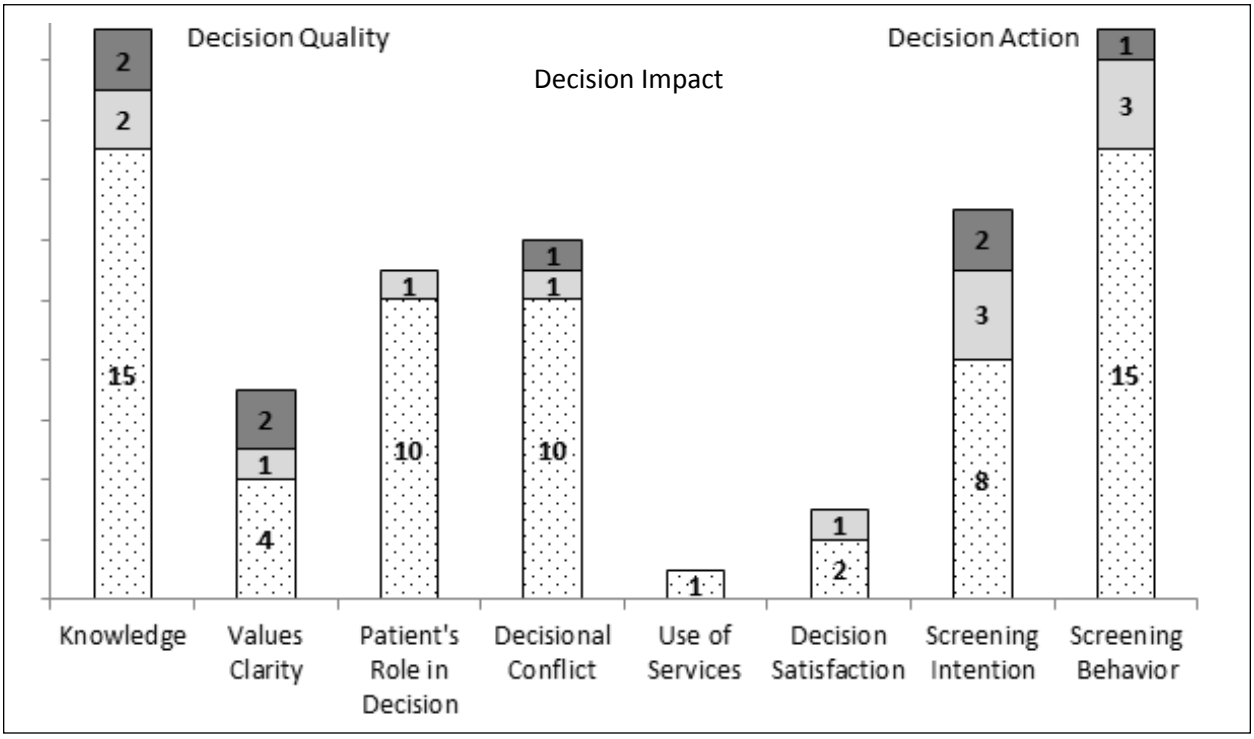
KEY QUESTION #1. In adults, what are the effects of shared decision making interventionS FOR CANCER SCREENING on 1) Decision Quality; 2) Decision Impact; and 3) Decision Action?

Overview of Findings

RCTs evaluated SDM interventions in breast (k=2),[19,20] colorectal (k=3),[21-24] and prostate (k=18)[25-44] cancer screening. Studies ranged in size from 95[21] to 1,879[39] participants. The duration of the SDM intervention to follow-up periods varied, ranging from immediately post-intervention delivery to 13 months.[39] Studies were predominately set in General Medicine clinics and were predominately completed in the United States; however, there were also studies from Australia,[19,20,24,29,30] Canada,[25] and the United Kingdom.[26,43] See Appendix D Evidence Tables for detailed study information.

Almost all studies measured screening behavior (k=19) and knowledge (k=19), the latter most often with a measure the investigators created. Use of services was rarely assessed (k=1). See Figure 3 for an overview of the outcomes in the included RCTs and Appendix E for a summary of the measures.

Figure 3. Overview of Outcomes in Included RCTs



Effect on Decision Quality

Overall, SDM interventions had a small but promising effect on most measures of Decision Quality. Participants given SDM interventions consisting of paper or DVD DAs to facilitate selection of colorectal cancer screening method had higher knowledge scores (2 of 3 studies), but the SDM interventions did not affect other Decision Quality measures including values clarity (1 study) or patients' participatory role in decision making (1 study). SDM interventions designed to facilitate decisions about whether to be screened for breast cancer in women who are younger (< 50 years of age) or older (> 70 years of age) than typically recommended for

screening resulted in higher knowledge scores (2 of 2 studies). The intervention effect on values clarity was measured a number of ways; intervention groups had either increased values clarity (1 study), or there was no intervention effect (1 study), and reported lower indecision about screening mammography (2 studies). Participants given SDM interventions to facilitate decisions about whether to receive prostate cancer screening (10 of 14 screening with the prostate specific antigen [PSA] test only) consistently showed higher knowledge scores (14 studies), and improved (6 studies) or had no effect on (4 studies) patient participation in decision making. Interventions either improved measures of values clarity (3 studies) or had no effect (1 study).

Effect on Decision Impact

Overall, SDM interventions had varied effects on Decision Impact. SDM interventions to facilitate selection of colorectal cancer screening method improved Decision Impact with intervention groups reporting lower decisional conflict (1 study) and greater decision satisfaction (1 study). The SDM intervention designed to facilitate decisions about whether women who are older than typically recommended for breast cancer screening should be screened for breast cancer had no effect on its Decision Impact measure, decisional conflict (1 study). SDM interventions to facilitate decisions about whether to receive prostate cancer screening either led to lower (7 unique studies, plus one-half of study population of a single study), or had no effect on (2 unique studies, plus one-half of study population of a single study), decisional conflict. Such interventions also resulted in greater (1 study) or had no effect on (1 unique study, time 2 of a second study) decision satisfaction. Only one study assessed use of health care services in populations exposed to prostate cancer screening SDM interventions; this intervention had no effect.

Effect on Decision Action

SDM interventions designed to facilitate the choice of screening modality had varied effects on Decision Action. Specifically, SDM interventions to facilitate selection of colorectal cancer screening method either lead to greater colorectal cancer screening intention or behavior (1 study), or had no effect (2 studies). SDM interventions designed to facilitate the choice of whether or not to be screened had varied effects on Decision Action. SDM interventions to facilitate decisions about mammography decreased the proportion of younger women (age 38-45 years) who intended to start screening mammography (1 study) and had no effect on the proportion of older women (age 70-71) who either intended to or actually did stop screening mammography (1 study). SDM interventions to facilitate decisions about whether to receive prostate cancer screening lowered screening intention (5 studies) or behavior (7 studies), showed no intervention effect (3 studies and 7 studies, respectively), or, in one case, increased prostate cancer screening behavior.

Study results are presented by cancer type below, with prostate cancer screening studies further categorized by study design: 1) effectiveness trials, or studies that compared a SDM intervention to UC,[29,30,37,40,41,43] 2) comparative effectiveness trials, or studies that compared a SDM intervention to one or more separate SDM interventions, with or without a UC gro up,[26,27,28,31,32,34,35,36,39,42,44] and 3) attention control trials, studies that compared a SDM intervention to an intervention similar in format but focused on a topic other than cancer screening.[25,33,38] An overview of findings is presented in Table 1; evidence tables with details of study characteristics and outcomes for each included study can be found in Appendix D.

Table 1. Overview of Findings

AUTHOR, YEAR	DECISION QUALITY			DECISION IMPACT			DECISION ACTION	
	Knowledge	Values Clarity	Patient's Role in the Decision	Decisional Conflict	Use of Services	Decision Satisfaction	Screening Intention	Screening Behavior[a]
BREAST CANCER								
Mathieu, 2007[19]	↑	↓[b] ↓ Indecision		↔			↔	↔ 1 Month
Mathieu, 2010[20]	↑	↔ ↓ Indecision					↓	
COLORECTAL CANCER								
Dolan, 2002[21]			↔	↓			↔	↔ 2-3 Months
Schroy, 2011[22] Schroy, 2012[23]	↑					↑	↑	↑ 1 year
Trevena, 2008[24]	↑	↔					↔	↔ 1 Month
PROSTATE CANCER								
Effectiveness Trials								
Gattellari, 2003[29]	↑	↔		↓			↔	
Gattellari, 2005[30]	↑		↑	↓			↓ propensity to order PSA	↓ #PSA ordered 6 weeks
Schapira, 2000[37]	↑							↔ PSA & DRE 2 weeks
Volk, 1999[40] Volk, 2003[41]	↑					↔	↓ (1999)	↓ 1 year (2003) ↔ DRE
Watson, 2006[43]	↑	↑	↔				↔	
Comparative Effectiveness Trials								
Evans, 2010[26]	↑			↓			↓	↓ 6 months

AUTHOR, YEAR	DECISION QUALITY			DECISION IMPACT			DECISION ACTION	
	Knowledge	Values Clarity	Patient's Role in the Decision	Decisional Conflict	Use of Services	Decision Satisfaction	Screening Intention	Screening Behavior[a]
Frosch, 2003[27]	↑							↓ Immediately
Frosch, 2008[28]	↑	↑		↓				↓ PSA requests
Kripalani, 2007[31]			↑					↑ PSA requests Immediately
Krist, 2007[32]	↑		↑	↔	↔			↓ Immediately
Myers, 2011[34]	↑			↔				↔ 4 months
Partin, 2004[35] Partin, 2006[36]	↑		↑				↓	↔ 2 weeks and 1 year (2004)
Taylor, 2013[39]	↑			↓		↑time1 ↔ time2		↔ PSA & DRE 13 months
Volk, 2008[42]	↔		↔	↔ high lit[c] ↓ low lit[c]				
Wilkes, 2013[44]			↔					↔[d]
Attention Control Trials								
Davison, 1999[25]			↑	↓				↔[d] PSA & DRE (unclear time frame)
Lepore, 2012[33]	↑		↑	↓			↔	↔ 1-2 years
Sheridan, 2012[38]	↑	↑	↔				↓	↓ Immediately, 9 months

↑ = SDM intervention group had higher outcome measure; ↓ = SDM intervention group had lower outcome measure; ↔ = SDM intervention had no effect on outcome measure; DRE = digital rectal examination, PSA = prostate specific antigen

[a] Screening is PSA only unless otherwise noted

[b] Lower scores indicate clearer values

[c] Low literacy version (10 item) of Decisional Conflict Scale (DCS) used at low literacy site and standard 16-item version used at high literacy site - scores across sites should not be compared

[d] Study reported no difference but no statistical results

SDM Interventions Included in Systematic Review

Breast Cancer

Breast Cancer Screening SDM

Given the overall effectiveness of mammography for women ages 50-70,[3] the central breast cancer screening issues to be addressed with SDM are whether to start screening below the age of 50 and whether to stop screening above the age of 70 (or at any age when there is less than a 10-year life expectancy). There has been a push to make the mammography screening decision a shared decision that is informed by patient values and preferences.[58]

Key Findings

- SDM Interventions were mailed or online DAs.
- SDM Interventions increased knowledge, but had a varied impact on other Decision Quality and Decision Impact measures.
- SDM Interventions had an effect on whether women made a decision, decreasing indecision and intention to start mammography screening, but had no effect on intention to stop mammography screening.

Study, Patient, and SDM Intervention Characteristics

Two trials assessed the effects of a breast cancer screening SDM interventions.[19,20] Study and patient characteristics are summarized in Table 2 below and detailed in Appendix D. Both trials focused on age groups for whom there is uncertainty about the benefits of breast cancer screening and who are outside the ages typically recommended for screening, and both consisted of a single educational session and a DA.

Table 2. Summary of Study and Patient Characteristics for Breast Cancer Trials

Characteristic	Mathieu 2007[19]	Mathieu 2010[20]
Total number of patients randomized	734	511
Total number of patients evaluated	Up to 712 for questionnaire; 710 for screening outcome	302 for knowledge; 201 for informed choice analysis
Study withdrawals, % of patients	3% did not return questionnaire	19% withdrew before randomization; 22% of those randomized subsequently withdrew
Age of subjects, years	70[a]	42[b]
Gender, male, % of patients	0	0
Race/ethnicity, white, % of patients	NR	NR
Previously screened, % of patients	100	11
Studies conducted in Australia, % of patients	100	100

NR=not reported
[a] Study enrolled women 70-71 years of age
[b] Study enrolled women 38-45 years of age

The first trial[19] included women aged 70-71 years not previously diagnosed with breast cancer and due for their next mammogram within the next 3 months. Eligible women were randomized

to receive either a DA SDM intervention or UC. The self-administered, paper booklet DA consisted of breast cancer screening information, the potential outcomes of choosing to be or not to be screened, a values clarification worksheet, and an appendix with examples of how other women completed the values clarification worksheet. After completing the DA, participants completed a questionnaire and mammography participation was assessed one month later. The second trial[20] included women aged 38-45 years not previously diagnosed with breast cancer. Eligible women were given a web-based baseline questionnaire and then randomized into either immediate or delayed (control group) access to a DA SDM intervention. The DA provided age-related information regarding breast cancer screening, potential benefits and harms of screening before age 50, and a values clarification worksheet with examples of how to complete the worksheet. Intervention participants were then given access to the web-based DA worksheet and completed a questionnaire. Control subjects were immediately directed to the outcome questions upon randomization and given delayed access to the DA upon completion.

Outcomes

Decision Quality: Knowledge and values clarity were measured in both studies (for a description of measures see Appendix E). Mathieu et al[19] showed an effect of the SDM intervention on knowledge, with 77% of the intervention group having adequate knowledge of breast cancer screening (defined by authors as 6 or more correct questions out of 10), compared to 57% of controls (χ^2=31.15, P = .02). Seventy-four percent of women in the intervention group were considered to have made an 'informed choice' (as defined by demonstrating adequate knowledge and clear values towards screening that matched the intention to either continue or stop mammography screening) compared to 49% of controls (χ^2=37.92, P < .001). Similarly, Mathieu et al[20] showed a greater proportion of intervention participants than control participants with adequate knowledge (94% vs 83%, χ^2=7.25, P = .01). Concerning values clarity, Mathieu et al[19] showed women in the intervention group had clearer values about mammography than controls (as indicated by lower scores on a scale ranging from 0-100, where scores ≤25 indicate "clear" values) though absolute differences were small (mean 19.5 vs 22.6, respectively, T_{545}=2.27, P = .02). However, in the later study there was no statistically significant difference in the proportion of women who had clear values towards mammography.[20] Both studies measured indecision, a marker of having clear values, and both SDM interventions reduced the proportion of women undecided in the intervention groups as compared to control groups (2007: 5% vs 10%, OR 0.32 [95% CI 0.17, 0.63], P < .001; 2010: 18% vs 39%, χ^2=15.72, P < .001).[19,20]

Decision Impact: Mathieu assessed decisional conflict and found that the SDM intervention did not affect this outcome compared to a control.[19]

Decision Action: Both studies measured intention to either start or stop screening. Although there was no intervention effect on intention to stop screening,[19] women given a SDM intervention were less likely to intend to start mammography screening (52% intervention group vs 65% control group, χ^2=4.00, P = .05).[20] Mathieu 2007 also measured screening outcomes one month post-intervention and found that SDM had no effect on having made or planning to make a mammography appointment.[19]

Colorectal Cancer

Colorectal Cancer Screening SDM

Colorectal cancer screening reduces colorectal cancer incidence, morbidity, and mortality and is recommended.[7] However, multiple effective screening modalities exist which have different schedules and associated harms and benefits. Decisions about which screening modality to use and when to discontinue screening lend themselves to a SDM approach.

Key Findings

- Paper or DVD DA SDM interventions about screening modalities increased knowledge, but did not affect other measures of Decision Quality.
- SDM interventions had a small effect on Decision Impact.
- SDM interventions had mixed effects on Decision Action.
- No SDM interventions evaluated colorectal cancer screening discontinuation.

Study, Patient, and SDM Intervention Characteristics

Three unique RCTs of colorectal cancer SDM interventions met inclusion criteria, represented by 4 references. Study and patient characteristics are summarized in Table 3 below and detailed in Appendix D.

Table 3. Summary of Study and Patient Characteristics for Colorectal Cancer Trials

Characteristic	Mean (range) *Unless otherwise noted*	Number of trials reporting
Total number of patients evaluated	1236 (97 to 825)	3
Study withdrawals, % of patients	11 (2 to 14)	2[a,b]
Age of subjects, years	66	1
Age of subjects <65 years, % of patients	84	1[b]
Age of subjects ≥65 years, % of patients	16	1[c]
Gender, male, % of patients	(41 to 48)	3
Race/ethnicity, white, % of patients	(34 to 98)	2[d]
Previously screened, % of patients	(13 to 27)	2[a,c]
Studies conducted in United States, % of patients	75	2[a,c]
Studies conducted in Australia, % of patients	25	1[b]

[a] Dolan 2002[21]
[b] Trevena 2008[24]
[c] Schroy 2011/2012[22,23]
[d] 62% of the participants in the Schroy 2011/2012[22,23] trial were African American

Dolan tested a pre-clinic appointment interview plus printed DA SDM intervention against a pre-clinic appointment interview plus general printed educational materials on colorectal cancer screening modalities.[21] A post-visit questionnaire assessed whether the patient and physician discussed colorectal cancer screening and which screening modality the patient had chosen, if any. A follow-up chart review 2-3 months later evaluated Decision Action outcomes. Similarly, Schroy compared the effectiveness of 2 different SDM interventions (intervention 1: an audio-visual DA outlining different colorectal cancer screening modalities; intervention 2: the same DA plus a personalized risk assessment tool, Your Disease Risk [YDR]) and a UC control group given general health promotion materials.[22,23] A post-visit questionnaire and a 6- and 12-month follow-up assessed which colorectal

cancer screening test was completed, if any. Trevena tested a DA SDM intervention about FOBT for colorectal cancer screening against a UC control group given a government consumer guidelines booklet. A one month follow-up telephone interview assessed outcomes, including FOBT use.[24]

Outcomes

Decision Quality: SDM interventions improved patient knowledge, but not other measures of Decision Quality. Using different tests to assess knowledge, both Schroy[22,23] and Trevena[24] reported a significant improvement in knowledge scores in all the SDM intervention groups compared to control groups. Schroy demonstrated that both intervention groups had larger increases in knowledge scores from pre-test to post-test and versus controls, both at 6 months (mean change DA: 3.2 vs YDR: 3.1 vs control: 1.1; d=1.15, P < .001)[22] and 1 year (mean change DA: 3.0 vs YDR: 3.0 vs control: 1.1; d=1.27, P < .001).[23] However, there was no significant difference between the 2 interventions at either time point. [22,23] The DA SDM intervention improved knowledge about FOBT screening compared to controls (20.9% vs 5.8% adequate knowledge; P = .0001).[24] Trevena also examined values clarity as a subscale of the Decision Conflict Scale (DCS) and found no significant effect; however, there was an intervention effect on integrated knowledge and values, defined as both clear values and adequate knowledge (10.4% vs 1.5%, P = .002).[24] Dolan measured preference for patients' role in the decision and perceptions on how the decisions were made, but found no differences.[21] Standard mean differences[23] and risk ratios[24] for knowledge and risk ratios for perception of how screening decisions were made[21] are presented in Appendix G.

Decision Impact: SDM had a small effect on Decision Impact. Dolan reported that the SDM intervention group had significantly lower decisional conflict, indicated by a lower DCS score of small magnitude compared to the control group (1.83 (0.52) vs 2.03 (0.81), effect size=0.29, P = .01).[21] Schroy reported both intervention groups had significantly higher mean scores on the Satisfaction with the Decision Making Process Scale compared to the control group at both 6 months (mean score DA: 50.7 vs YDR: 50.5 vs control: 46.7; P < .001)[22] and 1 year (mean score DA: 49.7 vs YDR: 49.0 vs control: 45.5; P < .001).[23] See Appendix G for standard mean differences for these outcomes.

Decision Action: SDM had mixed effects on Decision Action. Baseline screening intention was high amongst all the study populations and remained high after SDM interventions. Neither Dolan[21] nor Trevena[24] reported a significant difference between intervention and control groups on screening intention. However, intervention patients in the Schroy study had higher scores on a measure of intention (measured from 1=very unsure to 5=very sure) to schedule colorectal cancer screening compared to the control group at both 6 months (DA: 4.4 vs YDR: 4.3 vs control: 3.9; P < .001)[22] and 1 year (DA: 4.4 vs YDR: 4.3 vs control: 3.9; P < .001)[23], and a measure to complete colorectal cancer screening compared to the control group at both 6 months (on the same scale of 1 to 5, DA: 4.3 vs YDR: 4.3 vs control: 3.9; P < .001)[22] and 1 year (DA: 4.3 vs YDR: 4.4 vs control: 4.0; P < .001).[23] For both measures, at both time points, there was no difference between intervention groups. Neither Dolan[21] nor Trevena[24] reported significant differences in colorectal cancer screening behavior. However, Schroy reported test completion was higher for the DA group at 12 months (43% vs 35%, OR 1.30, 95% CI 0.90, 1.87, P = .046),[23] but showed no difference between interventions. Screening intention and test ordering were lower when patient and provider

screening preferences differed, regardless of patient's desired role in the decision making process. At 12 months the most commonly-ordered test was colonoscopy (79-81%), followed by Fecal Occult Blood Test (13-19%), flexible sigmoidoscopy (<2%), and barium enema. Mean differences and risk ratios for these outcomes are presented in Appendix G.

Prostate Cancer

Prostate Cancer Screening SDM

Randomized screening trials have demonstrated that any reduction in prostate cancer mortality through 10-14 years due to PSA screening is at most small (less than 1 in 1000 men screened), and screening results in harms due to diagnostic testing, overdiagnosis, and treatment.[4,5] USPSTF guidelines recommend against PSA screening, concluding that the benefits do not exceed the harms, but suggest that men should not be screened without balanced information about the benefits and harms of PSA screening, and they should make an informed decision that reflects their values and preferences.[6]

Prostate Cancer Studies

Eighteen RCTs of prostate cancer screening SDM interventions (in 21 references) met inclusion criteria. Study and patient characteristics are summarized in Table 4 below and detailed in Appendix D. Study results are presented by study type: effectiveness trial, comparative effectiveness trial, or attention control trial.

All studies excluded men with a history of prostate cancer. The mean of the ages of study participants ranged from 54[29] to 70[37] years, and the majority of general practitioners (GPs) in the clinician-level intervention were aged 45-54.[30] Almost all studies reported percentage of men with previous PSAs, ranging from 16%[43] to 83%.[44] Non-targeted studies included predominately white men, with the majority ranging from 56%[34] to 100%,[25,29] with one exception of an inner-city study, with the majority of participants African American (90%).[31] A study from the United States targeting African descendants enrolled 77% Caribbean immigrants.[33]

Table 4. Summary of Study and Patient Characteristics for Prostate Cancer Trials

Characteristic	Mean (range) *Unless otherwise noted*	Number of trials reporting
Total number of patients evaluated	9818 (100 to 1960)	17[a]
Study withdrawals, % of patients	13 (0 to 17)[b]	16
Age of subjects, years[c]	60 (54 to 70)	15
Gender, male, % of patients	100	17
Race/ethnicity, white, % of patients	78 (8 to 97)[b]	14
Previously screened, % of patients	52 (0 to 86)[b]	11
Studies conducted in United States, % of patients	71	13

[a] One study enrolled providers and is not included on this table

[b] One study reported values for low literacy and high literacy subgroups as follows: withdrawals 40% low literacy, 16% high literacy; race (% white) 18% low literacy, 65% high literacy; previously screened 37% low literacy, 75% high literacy (mean of subgroups used in overall calculation)

[c] Studies typically included men in specified age range *(ie,* between 50 and 70 years or greater than 50 years)

Prostate Cancer – Effectiveness Trials (k=5)

Key Findings

- SDM Interventions improved Decision Quality measures, including knowledge and values clarity.
- SDM interventions decreased decisional conflict, but had no effect on patient satisfaction with the decision, the only other Decision Impact measure assessed.
- SDM interventions did not consistently affect Decision Action.
- Most SDM interventions were targeted to patients.
- A clinician-level SDM intervention increased GPs support of shared decision making.

Study, Patient, and SDM Intervention Characteristics

We identified 5 SDM cancer screening intervention effectiveness trials.[29,30,37,40,41,43] These studies were conducted in the United States,[37,40,41] the United Kingdom,[43] and Australia.[29,30] All studies but one were targeted towards patients; one study[30] targeted physicians.

Schapira conducted a RCT at a VA outpatient clinic and included men aged 50-80 years.[37] A pamphlet DA with information about prostate cancer screening and treatment was compared to the UC pamphlet that included basic information about prostate cancer. Follow up was post-intervention and 2 weeks after initial study visit, and screening options included both PSA and DRE. Volk targeted men aged 45-70 at a Family Medicine clinic and assessed the effect of an educational video (developed by the Foundation for Informed Medical Decision Making, Inc.) compared to a UC brochure.[40,41] Outcomes were assessed at 2 weeks[40] and 1 year.[41] In the study from the United Kingdom, men aged 40-75 years were recruited from 11 GP practices in England and Wales.[43] A brief print DA about PSA screening (SDM intervention) was compared to no intervention. In the patient-level Australian study, an evidence-based booklet distributed in general practice clinics in urban areas was compared to the UC pamphlet about prostate cancer published by the Australian government.[29] Men were aged 40-70. Outcomes were assessed within 6 weeks. In the clinician-level Australian study, GPs who had ordered at least one PSA in past 12 months were recruited through 220 clinics in the New South Wales referral network.[30] GPs were predominately male (75.1%). Intervention GPs were mailed information and given telephone peer coaching and education sessions. The SDM intervention was compared to UC – distribution of PSA screening guidelines. Follow-up was 0-6 weeks, depending on the outcome.

Outcomes

Decision Quality: SDM interventions improved knowledge in all 5 effectiveness trials. Two trials included values assessment and found mixed results. Gattellari 2003 used a measure indicating strength of agreement with reasons for and against PSA screening and found no significant difference between groups in of the strength of their favoring PSA testing.[29] Watson developed a decisional balance measure to represent a person's attitudes about the relative positive aspects of the PSA test ('pros') versus the perceived negative aspects of the PSA test ('cons').[43] The intervention group had a less favorable assessment of the PSA compared to the control group (score -3.5 (SE 0.9) vs +3.3 (SE 0.8), $P < .0001$). Gattellari 2005, showed a significant intervention effect on GPs' attitudes towards the patient's role in decision making; they were less likely to agree that patients should remain passive when making decisions about PSA screening (OR 0.11 [95% CI 0.04, 0.31]; $P = .001$].[30] However, Watson found no intervention effect on

patients' reporting of their preferred role in the decision.[43] See Appendix G for standard mean differences and risk ratios for the Decision Quality outcomes.

Decision Impact: SDM interventions decreased decisional conflict, but had no effect on patient satisfaction with the decision, the only other Decision Impact measure assessed. Decisional conflict was reported in 2 studies, one patient-level study[29] and one clinician-level study.[30] Gattellari's patient-level study showed a lower level of decision uncertainty in the intervention group versus the control group (score 22 vs score 24 [95% CI 23.4, 25.2], P < .001).[29] Gattellari's clinician-level study showed intervention groups had lower levels of personal decisional conflict compared to the control group (mean 25 [95% CI 24.5, 26.3] vs 28 [95% CI 26.6, 29.0]; P = .0002).[30] One study assessed patient satisfaction with the decision, but reported no significant SDM intervention effect.[40,41] Standard mean differences are presented in Appendix G.

Decision Action: SDM interventions had varying effects on Decision Action. Gattellari and Watson reported no effect on PSA intention[29,43] and Schapira reported no effect on PSA behavior.[37] However, Volk reported that at 2 weeks, fewer intervention subjects planned to have a PSA compared with control subjects (62% vs 80%, P = .009), and at one year fewer intervention subjects received a PSA compared with control subjects (34% vs 55%, P = .01).[40,41] Clinicians receiving a SDM intervention ordered fewer PSA tests at 6 weeks follow-up (range 1-2 vs range 0-5, P < .001).[30] Risk ratios for screening intention and screening behavior are presented in Appendix G.

Prostate Cancer – Comparative Effectiveness Trials (k=10)

Key Findings

- SDM interventions, primarily targeted at patients, influenced Decision Quality measures, notably increasing knowledge.
- SDM interventions had inconsistent effects on Decision Impact.
- SDM interventions had inconsistent effects on Decision Action.

Study, Patient, and SDM Intervention Characteristics

We identified 10 SDM prostate cancer screening intervention comparative effectiveness trials.[26-28,31,32,34-36,39,42,44] Studies were conducted in the United States[27,28,31,32,34-36,39,42,44] and the United Kingdom.[26] All but one were targeted towards patients. Wilkes was multi-level and targeted both patients and physicians.[44]

Evans compared 2 SDM interventions (intervention 1: Prosdex, a web-based DA; intervention 2: a paper version of Prosdex) and 2 control groups (control group 1: UC with a baseline survey; control group 2: UC with no survey) to evaluate testing effects. Men over age 50 were recruited from GPs in South Wales. Follow-up was 6 months.[26] Frosch recruited men over age 50 from a Preventive Medicine Clinic and compared 2 SDM interventions (intervention 1: a web-based DA; intervention 2: a video DA), with an immediate follow up.[27] A later trial by Frosch et al recruited men over age 50 to compare 3 SDM interventions to UC (intervention 1: a traditional DA; intervention 2: a web-based decision support tool based on the Chronic Disease Trajectory Model; intervention 3: a combination of interventions 1 and 2).[28] Kripalani recruited men age 45-70 in an inner-city clinic to 2 paper-based interventions (intervention 1: PtEd – a

patient-based education handout; intervention 2: Cue – a handout encouraging prostate cancer screening discussions).[31] Krist randomized men age 50-70 at a large community-based family practice center to one of 2 SDM interventions (intervention 1: a web-based DA; intervention 2: a paper version of intervention 1) or a UC group. There was immediate post-visit follow up.[32] As part of the Decision Counseling Trial, Myers recruited men age 50-69 from 2 primary care practice sites and randomized them to one of 2 SDM interventions (intervention 1: Enhanced Intervention – structured decision counseling sessions about prostate cancer, mean time of 28 minutes; intervention 2: Standard Intervention – a patient satisfaction survey and generic note in chart). Outcomes were assessed during a telephone survey 7 days post-visit and a medical record review.[34] Partin recruited male Veterans age over 50 from 4 VA General Internal Medicine clinics. Men were shown one of 2 SDM interventions (intervention 1: a pamphlet; intervention 2: a video developed by the Foundation for Informed Medical Decision Making, Inc.) or assigned to UC. Telephone follow up was at 1 week.[35] Taylor recruited men aged 45-70 to one of 2 interventions (intervention 1: a web-based DA; intervention 2: a print-based DA).[39] Volk recruited men 50-70 if they were not of African descent and 40-70 if they were African American, from 2 sites: a General Medicine clinic at a publicly funded hospital (labeled a low health literacy site) and a university-affiliated family medicine clinic (labeled a high health literacy site). At both sites participants were randomized to one of 2 SDM interventions (intervention 1: an interactive multimedia DA; intervention 2: an audio booklet without interactivity or entertainment).[42] Wilkes recruited men age 55-65 from group practices and primary care networks and randomized them to one of 2 SDM interventions (intervention 1: an interactive web-based educational program for their physician; intervention 2: a multi-level intervention that included the physician intervention and a patient intervention) or UC.[44]

Outcomes

Decision Quality: SDM interventions, primarily targeted at patients, influenced Decision Quality measures, notably increasing knowledge. Knowledge was higher in the intervention group for 7 of the 8 studies that included a knowledge measure. Five studies measured the patients' role in the cancer screening decision, and 3 found intervention effects. Krist reported that, compared to the UC group, the SDM intervention group had a significantly lower proportion of patients reporting a passive role in decision making (18% UC vs 10% brochure [P = .03] and 8% web-based intervention [P= .03]).[32] Partin reported that more men in the pamphlet DA group discussed PSA with their provider compared to the UC group (41% vs 32%, P = .03), but this was not different from the video DA group (35% vs 32%, P = .33).[35] Kripalani reported discussions more frequently in Cue group (59% vs 50% vs 37%).[31] See Appendix G for standard mean differences and risk ratios for Decision Quality outcomes.

Decision Impact: SDM interventions had inconsistent effects on Decision Impact. Studies measured decisional conflict using the Decisional Conflict Scale (such that lower scores reflect lower levels of conflict). Evans reported significantly lower decisional conflict for the online DA Prosdex compared to both the paper DA and the control survey group (40 vs 38 vs 48, P < .001).[26] Frosch reported significantly lower scores for the traditional DA group on three subscales of the DCS.[28] The Volk study saw a significant decrease in decisional conflict in the low literacy study site (mean score 22 vs 12, P = .04), but no significant change in the high literacy study site.[42] Taylor found significantly lower decision conflict in web DA group, but this

difference disappeared after 13 months.[39] Krist and Myers found no significant effect.[32,34] Only one study assessed use of healthcare services, finding no significant difference in consultation length.[34] Appendix G contains standard mean differences and risk ratios for the Decision Impact outcomes.

Decision Action: Decision Action was measured predominately with screening behavior (9 studies); however, some studies measured intent (2 studies). Frosch reported men in the video intervention group had significantly fewer PSAs than men in the web-based intervention group at post-visit weeks/months follow-up (82% vs 92%, P < .05). In a later study, Frosch reported a greater reduction in PSA screening in the intervention groups compared to the control group.[28] Krist reported men in the brochure SDM intervention group had fewer PSAs at post-visit weeks/months follow-up than the control group (85% vs 94%, P= .04), although there was not a significant difference between the web-based intervention group and the control group.[32] Myers reported that, overall, there was no SDM intervention effect on PSA screening at 120 days follow-up.[34] However, after stratifying the study sample by men with physicians aware of the PSA controversy and men with physicians who were not, for men with physicians aware of the controversy only, the SDM intervention did have an effect. Evans measured both PSA intention and behavior, and found men given the web-based DA, Prosdex, had lower intention to undergo PSA than men given the paper intervention or control survey (40% vs 53% vs 58%, P = .02).[26] The Prosdex group was also less likely than both groups to get a PSA 6 month post-test (3% vs 9% vs 9%, P = .014).[26] Partin reported no effect on screening behavior, at either 2 weeks or 1 year follow-up, but the intervention group had a lower PSA intention (video 63% vs pamphlet 65% vs UC 74%, P < .05).[35,36] One study reported a significantly higher percentage of PSA tests ordered in the SDM intervention groups compared to usual care.[31]Taylor and Wilkes found no significant differences.[39,44] See Appendix G for risk ratios for screening behavior and screening intention.

Prostate Cancer – Attention Control Trials (k=3)

Key Findings

- SDM Interventions increased knowledge, but had inconsistent effects on other Decision Quality measures
- SDM interventions decreased Decisional Conflict, the measure of Decision Impact
- SDM interventions had inconsistent effects on Decision Action

Study, Patient, and SDM Intervention Characteristics

We identified 3 studies that compared a SDM intervention for prostate cancer screening to attention control.[25,33,38]

Two studies were conducted in the United States[33,38] and one in Canada.[25] The study in Canada was conducted in one family practice clinic. The SDM intervention included written and verbal information about prostate cancer screening presented prior to a periodic health examination. In the control group, the discussion was about general issues.[25] One of the studies from the United States was conducted at home and information about prostate cancer screening (SDM intervention) or fruit and vegetable consumption (control) was delivered by telephone.[33] In the second study from the United States, conducted in 4 internal medicine practices prior to a

scheduled appointment, the SDM intervention consisted of a video, a coaching session, and a brochure about prostate cancer screening.[38] The control condition was an educational video on highway safety. One of the SDM interventions was based on a theoretical framework,[33] 2 included values clarification exercises,[33,38] and one considered the health literacy of the participants.[33]

Mean ages of the study participants ranged from 55 years[33] to 62 years.[25] In the study from Canada, 100% of the participants were white and 61% reported Canadian ethnicity.[25] One of the studies from the United States enrolled men of black African descent; 77% were Caribbean immigrants.[33] In the second United States study, 64% of men enrolled were white, 18% were African American, and 18% were not specified.[38] Two studies reported whether the men had previously been screened for prostate cancer, finding 28%[33] and 52%[38] had been screened.

Davison assessed outcomes immediately following the health examination with no further follow-up.[25] Sheridan assessed outcomes following the SDM intervention session and following the health examination. Medical records were reviewed for approximately 9 months after the visit to determine whether participants were screened for prostate cancer.[38] Lepore conducted an interview 8 months after randomization and reviewed claims data for 2 years after enrollment to identify screening completion.[33] Twelve percent of the participants (59/490) did not complete the second interview; claims data were available for all participants.

Outcomes

Decision Quality: SDM interventions increased knowledge, but had inconsistent effects on other Decision Quality measures. Two studies reported knowledge scores. Lepore reported a significantly greater change in the percentage of correct answers on a 14-item knowledge test at 8 months post-randomization for the intervention group compared to the control group (10% vs 5%, $P < .001$).[33] Similarly, Sheridan reported a greater percentage of participants correctly answering all items on a 4-item knowledge test compared to the highway safety video group (RR 3.63 [95% CI 1.86, 7.08]).[38] Sheridan included a values assessment, whether men thought of PSA as a decision to make, and found a significant difference (64% intervention group vs 23% in control group, absolute difference 41% [95% CI 25, 57%]).[38]

The patient's role in the screening was assessed in 3 studies. Davison found men in the intervention group were more likely to assume an active role in decision making than men in the attention control group (a discussion about general issues) (62% vs 22%; $P < .001$).[25] Lepore reported that a higher percentage of men in the intervention group talked to their provider about prostate cancer screening (16% vs 8%, $P < .001$).[33] Among men who discussed PSA testing with their physician, Sheridan found no significant difference across experimental groups in the percentage of men reporting shared decisions or participation in decision making at the preferred level.[38] See Appendix G for standard mean differences and risk ratios for the Decision Quality outcomes.

Decision Impact: Decisional conflict was reported in 2 studies with promising results. Davison reported lower decisional conflict in the group that received verbal and written information about prostate cancer screening than in the group that had a discussion of general issues (mean 29 vs 35, $P < .0001$).[25] Lepore reported that men who received information about prostate cancer screening had lower levels of decisional conflict 8 months after randomization than men who received information about fruits and vegetables (mean 34 vs 40; standard mean difference -0.24 [95% CI

-0.43, -0.05]).[33] See Appendix G for standard mean differences for Decision Impact outcomes.

Decision Action: Screening intention was reported in 2 studies with inconsistent results. Lepore found no difference between SDM intervention and control in plan to receive a test for prostate cancer (81% in both groups when assessed 8 months after randomization; RR 1.00 [95% CI 0.91, 1.09]).[33] Sheridan reported that the video/coaching/brochure group was less likely to report intent to be screened (45%) than the control group (79%) (RR 0.57 [95% CI 0.42, 0.78]).[38] Each of the studies reported a screening outcome. Davison reported 28% of the intervention group and 21% of the control group underwent both a DRE and PSA test.[25] Lepore reported non-significant differences in the percentages of patients with a verified PSA test at both 1 and 2 years.[33] Sheridan reported patient-report of screening that occurred during the study visit as well as medical record review 9 months after the SDM intervention. Immediately following the study visit, 11% of the intervention group and 31% of the control group reported having a PSA test (RR 0.42 [95% CI 0.14, 1.24]).[38] The percentage of participants with actual screening at 9 months post-intervention were 19% for the intervention group and 41% for the control group (RR 0.76 [95% CI 0.50, 0.97]). See Appendix G for risk ratios for screening intention and screening behavior.

KEY QUESTION #1A. Are there differential effects of the interventions based on: 1) The intervention target; 2) Key content/elements of the intervention; 3) Patient characteristics; AND 4) Cancer type?

SDM Intervention Target

No studies directly compared SDM interventions with different targets (*eg,* patient vs clinician). Furthermore, due to the small number of clinician-directed SDM interventions and the variability in SDM interventions, we could not indirectly assess whether the effect of SDM interventions varied qualitatively according to the intervention target. Only 2 studies included clinician-directed SDM interventions. One prostate cancer screening SDM intervention targeted general practitioners in Australia who had ordered at least one PSA in the past year.[30] The intervention consisted of mailed information, telephone peer coaching, and education. The SDM intervention increased practitioners' knowledge and decreased their PSA ordering rate after 6 weeks. Another prostate cancer SDM intervention trial compared a physician-level intervention with a multi-level intervention targeting both physicians and their patients.[44] The multi-level SDM intervention was comprised of an interactive web education program for primary care physicians and a similar interactive web-based program for patients encouraging them to participate actively in the prostate cancer screening decision. Post intervention, patients' ratings of SDM did not differ between intervention groups. However, physicians in the multi-level SDM intervention were more neutral regarding PSA recommendations than those in the physician-level SDM intervention, being less likely to make a recommendation either for or against PSA.

Key SDM Intervention Content

A priori, and in consultation with our Technical Expert Panel (TEP), we selected 3 key content areas and extracted SDM intervention information based on those areas: (1) intervention format; (2) values clarification exercises; and (3) risk communication method. A summary of the SDM intervention content is presented in Table 5.

Table 5. Summary of SDM Intervention Content[a]

Intervention Characteristics	Breast Cancer (k=2)	Colorectal Cancer (k=3)	Prostate Cancer (k=18)
Intervention Format - Delivery			
Decision aid (DA)	Mathieu 2007[19] Mathieu 2010[20]	Schroy 2011/2012[22,23] Dolan 2002[21] Trevena 2008[24]	Evans 2010[26] Frosch 2003[27] Frosch 2008[28] Partin 2004/2006[35,36] Taylor 2013[39] Volk 2008[42]
Counseling			Lepore 2012[33] Myers 2011[34] Sheridan 2012[38]
Education program			Gattellari 2005[30] Schapira 2000[37] Watson 2006[43] Wilkes 2013[44]
Intervention Format - Delivery Mode			
DVD /Videotape		Schroy 2011/2012[22,23]	Frosch 2003[27] Partin 2004/2006[35,36] Sheridan 2012[38] Volk 2003/1999[40,41]
Web-based	Mathieu 2010[20]		Evans 2010[26] Frosch 2003[27] Frosch 2008[28] Krist 2007[32] Taylor 2013[39] Wilkes 2013[44]
Face-to-face		Dolan 2002[21]	Sheridan 2012[38] Myers 2011[34]
Printed	Mathieu 2007[19]	Dolan 2002[21] Schroy 2011/2012[22,23]	Evans 2010[26] Gattellari 2003[29] Krist 2007[32] Kripalani 2007[31] Partin 2004/2006[35,36] Schapira 2000[37] Taylor 2013[39] Volk 2003/1999[40,41] Watson 2006[43]
Verbal & written			Davison 1999[25] Gattellari 2005[30]
Telephone			Lepore 2012[33]
Intervention Format - Timing			
In-clinic		Dolan 2002[21] Schroy 2011/2012[22,23]	Davison 1999[25] Frosch 2003[27] Gattellari 2003[29] Kripalani 2007[31] Myers 2011[34] Schapira 2000[37] Sheridan 2012[38] Volk 2008[42] Wilkes 2013[44]
At home before appointment	Mathieu 2007[19] Mathieu 2010[20]	Trevena 2008[24]	Evans 2010[26] Frosch 2003[27] Frosch 2008[28] Krist 2007[32] Lepore 2012[33] Partin 2004/2006[35,36] Taylor 2013[39] Watson 2006[43]

Intervention Characteristics	Breast Cancer (k=2)	Colorectal Cancer (k=3)	Prostate Cancer (k=18)
Other			Gattellari 2005[30]
Explicit Values Clarification Exercise			
None			Davison 1999[25] Frosch 2003[27] Gattellari 2005[30] Kripalani 2007[31] Krist 2007[32] Partin 2004/2006[35,36] Schapira 2000[37] Volk 1999/2003[40,41] Watson 2006[43]
Worksheet	Mathieu 2007[19] Mathieu 2010[20]	Trevena 2008[24]	Taylor 2013[39]
Time trade-off exercise			Frosch 2008[28]
Discrete choice		Schroy 2011/2012[22,23]	
Analytic Hierarchy Process (Zahedi 1986)		Dolan 2002[21]	
Decision stacker			Evans 2010[26]
Social matching			Gattellari 2003[29] Sheridan 2012[38] Volk 2008[42]
Discussion/questions of risks and benefits, values			Lepore 2012[33] Myers 2011[34] Wilkes 2013[44]
Risk Communication Method			
Not specified		Dolan 2002[21]	Davison 1999[25] Evans 2010[26] Frosch 2003[27] Frosch 2008[28] Gattellari 2005[30] Kripalani 2007[31] Krist 2007[32] Lepore 2012[33] Myers 2011[34] Partin 2004/2006[35,36] Sheridan 2012[38] Volk 2008[42] Volk 1999/2003[40,41] Watson 2006[43]
Pictographs	Matheiu 2007[19] Matheiu 2010[20]	Trevena 2008[24]	Gattellari 2003[29] Schapira 2000[37] Taylor 2013[39]
Web-based "Your Disease Risk" (personalized risk estimates); audio/visual		Schroy 2011/2012[22,23]	
Diagrams			Wilkes 2013[44]

[a] Comparative effectiveness trials *(ie,* more than 1 intervention) may have multiple characteristics

Intervention Format & Delivery

The majority of studies were DAs. They included paper-based (14 studies) or web-based (7 studies) SDM interventions; few were delivered face-to-face (3 studies) or by telephone (1 study). Interventions were delivered before appointments to promote SDM during the cancer screening decision process. They were predominately delivered on-site, or provided at home, either by mail or accessed on the Internet, before the appointment.

Values Clarification Exercises

Fourteen of 23 SDM interventions included a values clarification exercise. All of the colorectal cancer screening[21-24] and breast cancer screening[19,20] SDM interventions, and 9 of 18 prostate cancer screening SDM interventions[26,28,29,33,34,38,39,42,44] included values clarification exercises. The types of values clarification methods varied, with no clear predominate method. The breast cancer screening SDM intervention exercises, developed by the same study team, were worksheets with examples of how to complete them. The colorectal cancer screening SDM intervention values clarification exercises were theoretically different from those of the breast and prostate cancer screening SDM interventions; these exercises helped the patient identify a screening modality preference based on his or her own values. The other SDM interventions helped patients clarify what is important to them, and how that translates into being screened for cancer or not being screened for cancer.

Risk Communication Method

Although effective communication of screening risks and benefits is essential to SDM interventions, few studies specified exactly how their interventions communicated risk. Studies that did predominately used pictographs.[19,20,24,29,37,29] This follows earlier research that few prostate cancer DAs included any numerical information.[60] The earlier Mathieu intervention used 1000-face pictograms to communicate the event rate per 1000 women screened for breast cancer with mammography every 2 years over 10 years, starting at age 70.[19] Mathieu 2010 also included 1000-face pictograms to communicate event rates per 1000 women aged 38-45 who are not screened over 10 years in addition to those screened every 2 years.[20] Wilkes used diagrams of visual risk comparison as vignettes to convey the risk for potential harms.[44] Schroy used a web-based program, "Your Disease Risk", to display personalized risk estimates.[22,23] Fagerlin concluded that the most important element of risk communication is the presentation of numbers as frequencies or percentages rather than risk ratios or absolute risk.[61]

Patient Characteristics

Race

Only one SDM intervention was developed for a specific racial/ethnic group. Lepore targeted the prostate cancer screening SDM intervention to black men of African descent.[33] No other studies reported outcomes by race and ethnicity or created a SDM intervention targeted towards a specific cultural group. Most SDM interventions were not racially/ethnically diverse. However, some studies did use inner-city clinics for SDM interventions for colorectal cancer screening[22,23] and prostate cancer screening.[31] The percentage of white subjects for colorectal cancer screening SDM intervention studies ranged from 34% to 98%, and for prostate cancer screening SDM intervention studies from 8% to 97%.

Gender

All prostate cancer screening studies included only male participants and all breast cancer screening studies included only female participants; colorectal cancer screening studies ranged from 41% to 48% male, none of which examined differences in effects by gender.

Age

The breast cancer screening SDM intervention studies were the only 2 to directly address the issue of screening outside of the generally recommended or core age group, with one intervention targeted at women aged 38-45 years, and the second targeted at women aged 70-71. The mean age of subjects in SDM intervention studies for colorectal cancer was 66 years; 84% of subjects were less than 65 years and 16% were 65 years or older. The mean age of subjects in SDM intervention studies for prostate cancer was 61 years.

Health Literacy

Ten SDM interventions specified considering low health literate users in the intervention development or pilot-testing testing stage.[22-24,29,31,33,35-37,39,40-42] Two of these studies specifically developed interventions for a low-literacy audience.[31,33] Volk developed 2 separate SDM prostate cancer screening interventions; one for a high health literacy site (a university-affiliated family medicine clinic) and another for a low health literacy site (a general medicine clinic at a publicly-funded hospital).[42] Both SDM interventions improved knowledge and the intervention developed for the low-literacy site lowered decisional conflict, although the intervention developed for the high-literacy site did not.

Cancer Type

Breast, colorectal, and prostate cancer screening decisions are different at their core, in their population, timing, and decision type. For example, for the age group of adults 50-74 years old, colorectal cancer screening is recommended. Therefore the SDM approach for colorectal cancer screening primarily involves decisions regarding the choice between different screening modalities (typically annual FOBT or colonoscopy every 10 years). Prostate cancer screening decisions involve the choice to have a PSA or not to be screened at all. Because of differences in the inherent purposes for the SDM interventions, we were unable to compare decision outcomes across cancer types. As noted we found no studies assessing SDM for cervical or lung cancer screening.

KEY QUESTION #2. Within the included studies, what is the receptivity to shared decision making interventions for cancer screening for: 1) patients and 2) providers?

Patient Receptivity

Fourteen unique studies reported on patient receptivity to SDM interventions and one study reported on physician receptivity to SDM intervention.

Use of the SDM Intervention

In 6 prostate cancer studies, "receptivity" was measured by SDM intervention use. Frosch assigned patients to receive educational information about PSA testing either over the internet at their convenience or via video prior to their clinic appointment.[27] Men in the video group were significantly more likely to view the video than completely view the presentation on the website (98% vs 54% $P < .001$). Nearly 40% of the web-based group did not review any of the presentation. In a subsequent study of different web-based interventions, authors monitored patient access to the DAs and sent reminders to increase compliance; 84% of all participants reviewed the interventions.[28]

Partin mailed male Veterans a prostate cancer DA in either pamphlet or video format.[35,36] Participants were contacted by telephone and asked if they recalled receiving the DA and, if so, whether they looked at the DA. Significantly more participants recalled receiving the video (78% vs 64%, $P < .01$) but there was no significant difference in the percentage having looked at either the pamphlet (50%) or the video (56%). Participants who were married, had education beyond high school, and had no prior abnormal PSA tests were more likely to report use of the video. None of the patient characteristics assessed was significantly associated with use of the pamphlet.

In a study that randomized participants to a web-based DA, a paper-based version of the DA, or usual care, there was no significant difference in the proportion of participants reporting reviewing the DAs before their visit (web-based 85%, paper-based 88%).[32]

In a study that mailed participants a brief prostate cancer DA and a questionnaire about prostate cancer screening (knowledge, attitude, intention) or the questionnaire alone, 93% of those in the intervention group reported having read most or all of the information.[43]

In a study of a low-literacy handout to encourage discussions about prostate cancer screening, nearly all (99.6%) patients reported looking at the handout and most (94.6%) reported reading it.[31]

SDM Intervention Content

Patients' ratings of the SDM intervention contents regarding information bias, clarity, and helpfulness were reported in 9 studies of SDM interventions for breast, colorectal, and prostate cancer screening. One of the studies also reported on use of the SDM intervention.[43] Most respondents indicated that SDM intervention content was balanced, clear, helpful, and of appropriate length and detail. Overall, participants rated materials as balanced and fair.

A SDM DA intervention designed to inform the decision by women age 70-71 years to continue or stop mammography screening and presented in booklet form was pilot tested in a group of 29 women.[19] Approximately half of the women thought the information was balanced and fair, one quarter thought the information was biased toward screening, and one quarter thought the information was biased toward stopping screening. In a subsequent study of a paper-based DA for mammography screening in women 38-45 years, 49% reported that the information was completely balanced.[20] Participants believed that SDM intervention material was easy to understand. The breast cancer screening SDM intervention was reported as clear by 97% and

understandable by 97%[19] and clear by 56% and understandable by 73%.[20] The contents of the first breast cancer screening SDM intervention were viewed as the right length by 86% and containing about the right amount of information to make the decision by 72%;[19] the second SDM intervention was viewed as the right length by 67% and containing about the right amount of information by 65%.[20] The booklet was rated as "very helpful" by 44% and 47% reported they would "definitely recommend" the booklet.[20]

Two studies of colorectal cancer screening SDM interventions reported patients' perceptions of the contents. In one study, all patients had an in-person interview session.[21] Participants in the intervention group completed a detailed analysis of the screening decision using an analytic hierarchy process while control group participants received educational materials. No significant differences were reported in mean Likert Scale responses to "Did you like the interview?" or "Doctors should use routinely". In the second study, participants received either a DA SDM intervention or were assigned to UC and given the consumer version of government-issued guidelines for colorectal cancer screening.[24] Compared to respondents in the UC group, significantly more respondents in the intervention group thought the DA they received integrated knowledge and values, provided adequate knowledge, had about the right amount of information, was about the right length, and presented completely balanced information. The groups did not differ on whether they would definitely recommend the resource.

Several of the prostate cancer studies also obtained patient evaluations of the SDM interventions. An educational video from the Foundation for Informed Medical Decision Making, Inc. was found to have about the right amount of information (79%), be the right length (86%), present most or everything clearly (88%), and be balanced (79%).[40,41] Only 7% of study participants reported that their decision about screening was not at all influenced by the video and 92% would recommend that others watch the video before making a decision about PSA testing.

Another study compared a 32 page evidence-based booklet on PSA screening to a government-developed pamphlet.[29] The government pamphlet was shorter and non-numeric while the evidence-based booklet included data and was designed for maximum readability. No significant differences were reported for the percentage of study participants who read all of the material, who found the information useful, or who found the information was easy to read. The groups did differ significantly on whether the amount of information was right, including whether there was the right amount of information about risk and benefits of PSA testing, and on whether they would recommend the material to a friend or relative their own age.

The study of an in-clinic video presentation versus an web-based presentation, described above, found no differences between groups in ratings of the interventions.[27] Participants were asked about convenience, effort required, satisfaction with the presentations, and "overall sentiments about participating in these types of interventions." However, overall, 81% of all participants were "somewhat" or "very positive" about their participation.

The brief DA SDM intervention evaluated by Watson was found to provide "most or all" new information to 67% of the men who received it.[43] Most participants thought the information was easy to read (93%), had about the right level of detail (87%), and presented information in a "balanced way" (94%).

A study with high-literacy and low-literacy sites obtained measures of acceptability for an entertainment-based DA (interactive, multi-media approach) and an audiobooklet DA (no interactivity or entertainment components).[42] Participants from the low-literacy site were less likely than those from the high-literacy site to respond that the both the entertainment-based DA and the audiobooklet had about the right amount information (51% vs 86%, P < 0.01; 59 vs 86%, P < 0.01, respectively), although they were also less likely to rate the program length of both interventions as too long (11% vs 43%, P = .00; 3% vs 5%, P < 0.01, respectively). Participants from the low-literacy site less often reported that everything was clear in the entertainment-based aid (52% vs 71%, P = .05), but no differences were noted for clarity of presentation of the audiobooklet. Finally, although there were no differences in the reported balance of the entertainment-based DA, participants at the low-literacy site were more likely than their counterparts to report the audiobooklet as "slanted toward screening" (7% vs 0%, P = .01).

Provider Receptivity

One study assessed the effect of a SDM intervention on provider receptivity to SDM.[30] General practitioners reported how much they supported the response options in the Control Preferences Scale, a measure of patients' involvement in decisions. SDM decreased the proportion of the intervention group supporting passive patient decision making (intervention group change -14.1% vs control group change +0.2%; P < .05).

KQ3. Within the included studies, what are the resources required to implement a shared decision making intervention for cancer screening?

One challenge in clinic implementation of SDM interventions is required resources, for example, staff time and effort, financial commitment, and technological and facility requirements. We highlight any studies that outlined the resources required for SDM implementation. Overall, there was no evidence that more resource-intensive SDM interventions were more effective than less resource-intensive ones.

Human Resources

There was a variety of reported staff resources in terms of time commitment and type of staff required. The most human resource-intensive patient-level SDM interventions involved patient counseling sessions, either face-to-face[21,34,38] or on the telephone.[33] These studies used nurse educators,[34] graduate-level health educators,[33] or research assistants,[38] who had to be trained themselves. Some studies required that participants have assistance while completing interventions.[37,44]

Provider-level and multi-level SDM interventions required the most provider time, an important factor in implementing any intervention. The multi-level intervention required physician education using standardized patients – trained actors that received 20 hours of training.[44] The physician-level intervention required both telephone peer coaching and medical peer educators who delivered peer coaching sessions.[30]

Financial Resources

One study directly outlined SDM intervention costs. Partin specifically noted the costs of both a moderate-cost SDM intervention (mailed video) and a low-cost SDM intervention (mailed pamphlet).[35,36] The cost of the intervention video was $37.00 per patient, and the cost of the intervention pamphlet was less than $2 per patient. Compared to the UC condition, knowledge increased and PSA intention decreased for both SDM intervention groups. However, there was no difference between SDM intervention groups on these measures. Patients in the pamphlet intervention group were more likely to discuss screening with their physicians than those in the video intervention group and PSA rates did not differ between groups. The low-cost SDM intervention either performed equally or outperformed the moderate-cost SDM intervention.

Technological Resources

Few studies specifically outlined the technological resources required for the SDM interventions. However, the web-based interventions would require a certain amount of bandwidth and programming capability.[20,26-28,32,39,44] Wilkes required laptop computers for study participants, to allow research assistants to assist with intervention delivery.[44] Similarly, video SDM interventions viewed in the clinic would require resources such as viewing rooms, televisions, and DVD players.[22,23,38,40] SDM intervention effectiveness did not vary by technological resource intensity; in fact, studies that compared web-based SDM interventions to paper ones did not consistently show web-based interventions to be superior.[26,32,39]

SUMMARY AND DISCUSSION

KEY MESSAGES

In this systematic review we found that SDM interventions for breast, colorectal, and prostate cancer screening improve knowledge and may reduce decisional conflict, but that they do not affect other measures of Decision Quality and Impact. The review suggests that SDM interventions designed to facilitate the choice of screening modality did not increase Decision Action, and SDM interventions designed to facilitate the choice of whether or not to be screened had varied effects on Decision Action. Little information exists regarding the comparative effectiveness of SDM intervention strategies, or whether the effects vary by intervention target population, key SDM intervention content/elements, patient characteristics, or cancer type. Patient receptivity to SDM interventions was generally positive as measured by stated opinions and reported reading or viewing of the intervention. Almost no data exist on providers. Additionally, no studies evaluated SDM interventions for cervical or lung cancer screening.

SUMMARY OF EVIDENCE BY KEY QUESTION

KQ1. In adults, what are the effects of shared decision making interventions for cancer screening on 1) Decision Quality; 2) Decision Impact; and 3) Decision Action?

Strength of evidence was moderate for the effect of SDM interventions for prostate cancer screening on Decision Quality; but low for the effect on Decision Impact and Decision Action. Strength of evidence was either low or insufficient for all constructs (Decision Quality, Decision Impact, and Decision Action) for both breast cancer and colorectal cancer SDM interventions (see Table 6 for a summary of strength of evidence and Appendix F for detailed information). In determining strength of evidence we only included studies that reported outcomes for a SDM intervention versus UC or placebo, including attention control, and not studies that compared one SDM intervention to another SDM intervention. For studies with multiple arms, we focused on the comparisons with UC rather than the comparisons between 2 SDM interventions. We only included data from patient-level interventions given the small number of physician-directed and multi-level interventions.

Table 6. Summary of Strength of Evidence for KQ1[a]

Outcome Category	Outcome (# of Studies Reporting)	Risk of Bias of Individual Studies	Strength of Evidence for Individual Outcomes	Strength of Evidence for Outcome Category
Breast Cancer (k=2)				
Decision Quality	**Knowledge (2)**	Moderate	Moderate	Low
	Values Clarity (2)	Moderate	Low	
	Patient's Role in Decision (0)		Insufficient	
Decision Impact	**Decisional Conflict (1)**	Moderate	Low	Insufficient
	Use of Services (0)		Insufficient	
	Decision Satisfaction (0)		Insufficient	
Decision Action	**Screening Intention (2)**	Moderate	Low	Low
	Screening Behavior (1)	Moderate	Low	
Colorectal Cancer (k=3)				
Decision Quality	**Knowledge (2)**	Moderate	Moderate	Low
	Values Clarity (1)	Moderate	Low	
	Patient's Role in Decision (1)	Moderate	Low	
Decision Impact	**Decisional Conflict (1)**	Moderate	Low	Low
	Use of Services (0)		Insufficient	
	Decision Satisfaction (1)	Moderate	Low	
Decision Action	**Screening Intention (3)**	Moderate	Low	Low
	Screening Behavior (3)	Moderate	Low	
Prostate Cancer (k=18)				
Decision Quality	Knowledge (12)	Moderate (11); Low (1)	Moderate	Moderate
	Values Clarity (4)	Moderate	Low	
	Patient's Role in Decision (7)	Moderate (6); Low (1)	Low	
Decision Impact	Decisional Conflict (8)	Moderate (7); Low (1)	Low	Low
	Use of Services (1)	Moderate	Low	
	Decision Satisfaction (2)	Moderate (1); Low (1)	Low	
Decision Action	Screening Intention (7)	Moderate	Low	Low
	Screening Behavior (10)	Moderate (8); Low (2)	Low	

[a] Strength of evidence determined for patient-directed interventions with a usual care or attention control group

KQ1a. Are there differential effects of the interventions based on: 1) The intervention target population (*eg,* provider-focused, patient-focused, system/ organizational focused, multi-level); 2) Key content/elements of the intervention (*eg,* format, values clarification exercise, risk communication method); 3) Patient characteristics (*eg,* race, gender, age, health literacy); and 4) Cancer type (*eg,* breast, cervical, colorectal, prostate, lung)?

The majority of the included RCTs were patient-directed SDM interventions, with 2 exceptions, one clinician-level intervention and one multi-level intervention. The practitioners in the clinician-level intervention group had significantly higher knowledge, greater inclination *not* to order PSA, and lower PSA ordering rates after 6 weeks. The multi-level intervention did not affect patient outcomes; however, physicians participating in the clinician-level intervention appeared more neutral regarding PSA recommendations compared to physicians in the control condition.

The majority of RCTs included SDM interventions that were paper-based (14 studies) or web-based (7 studies). There were no differential effects by format.

Values clarification exercises were a positive contribution; RCTs with SDM interventions including a values clarification exercise reported a decrease in decisional conflict more often than those evaluating SDM interventions without a values clarification exercise. The outcome results did not differ for interventions that specified versus did not specify the method of risk communication.

A number of SDM interventions (10 studies) considered low health literate users in the intervention development stage, testing the intervention and then modifying it to be accessible by a low-literate audience, and a minority of these (3 studies) developed low-literacy-specific interventions. One study compared use of a SDM intervention in a low health literacy site to use in a high health literacy site, finding increased knowledge for participants at both sites.[42] Only one study targeted its intervention towards a racial/ethnic group, focusing on African American men and prostate cancer screening SDM.[33] Studies set in inner-city clinics had a majority of African American participants.

Breast, colorectal, and prostate cancer screening decisions are different at their core, in their population, timing, and decision type, and therefore we are unable to compare decision outcomes across cancer types.

KQ2. Within the included studies, what is the receptivity to shared decision making interventions for: 1) Patients and 2) Providers?

Several of the included studies reported on patient receptivity to shared decision making interventions including use of the interventions or content of interventions. Patients' ratings of the intervention content reflected positive reactions and reports that the intervention materials were balanced. One study assessed the effect of a SDM intervention change on provider receptivity to SDM, finding a decrease in the proportion of the intervention group supporting passive patient decision making.[30] This suggests that SDM interventions improve physicians' acceptance of SDM.

KQ3. Within the included studies, what are the resources required to implement a shared decision making intervention?

The most human resource-intensive SDM interventions were the provider-level (1 study) and multi-level (1 study) interventions, as well as those involving patient counseling sessions in person (3 studies) or on the telephone (1 study). One study specifically detailed the financial resources required of both a moderate-cost SDM intervention (mailed video) and a low-cost SDM intervention (mailed pamphlet). The lower-cost intervention either performed equally or outperformed the moderate-cost intervention, though we caution against generalizing the results from a single study. Web-based SDM interventions (7 studies) required technological resources such as programmers and bandwidth, but web-based interventions did not consistently outperform paper comparators. Interventions using in-clinic videos and laptops also required technological resources but intervention effectiveness did not vary by resource intensity.

PREVIOUS REVIEWS

A number of reviews have been published on both SDM and cancer screening DAs, all of which were used in our literature search.[62-74] Our review is unique because it expanded the review beyond DAs, including SDM interventions such as telephone counseling, but focused specifically on cancer screening. Additionally, by anchoring our search strategy in the ODSF, our review excluded studies that promoted a specific screening decision and included studies that focused on the decision making process. Finally, we presented key components of SDM cancer screening interventions that previous reviews have not looked at, such as inclusion of values clarification exercises and method of risk communication, to provide an overview of the state of SDM interventions.

CLINICAL SIGNIFICANCE

Despite limitations in the existing literature our findings provide important clinical information. The available information suggests that SDM interventions can improve patient knowledge but have mixed and limited effect on other aspects of Decision Impact, Quality, and Action. To aid in future dissemination of SDM interventions, this review identified studies that specified the human resources required for intervention implementation, including physician time. Clinician interest in shared decision making is critical to the implementation of SDM interventions, though many barriers exist.[67]

LIMITATIONS

Our findings are limited to a large extent by the existing literature. We identified no studies assessing SDM for cervical or lung cancer. We also found few RCTs of SDM interventions for breast and colorectal cancer screening, especially comparative effectiveness trials. Because our strict criterion required studies to be RCTs and to assess either Decision Quality or Decision Impact, we excluded many quasi-experimental SDM intervention studies and other potentially relevant SDM interventions based on their limited choice of measures. As with any systematic review, our search may have been subject to publication bias. To mitigate this, we used

comprehensive search terms, searched several large databases linked to different disciplines in which the topic is studied, hand searched high-priority journals and reference lists, and sought input from our TEP members and peer reviewers. However, it is possible that relevant, unpublished data exist or that papers may have been missed, either published in a language other than English or in abstract form only. Finally, we acknowledge that the included studies did not use consistent outcomes, or consistent outcome measures. The most commonly used measure was the Decisional Conflict Scale.[54] Generally, study authors created their own assessments of knowledge. Therefore, we were not able to perform a meta-regression to assess heterogeneity.

APPLICABILITY OF FINDINGS TO THE VA POPULATION

Our review revealed gaps in VA SDM cancer screening intervention research and provides a roadmap for future efforts. Only 2 studies specifically targeted a VA population; both were SDM interventions for prostate cancer screening.[35-37] The first study included male Veterans aged 50 and older in general medicine clinics at 4 VA facilities.[35,36] This comparative effectiveness trial compared a pamphlet DA to a video DA to UC. This SDM intervention has been widely distributed within the VA, and is available online. The second study included Veterans aged 50-80 at a VA Medical Center outpatient clinic.[37] This effectiveness trial compared a pamphlet DA to a basic prostate cancer screening brochure.

SDM interventions for cancer screening did more good than harm, increasing knowledge and, more often than not, decreasing decision conflict. Although included trials were predominately outside of a VA setting, the findings are applicable to both current (*eg,* prostate cancer) and future (*eg,* lung cancer) VA decision making intervention efforts. Developing VA-specific SDM interventions, which address the particular characteristics of the population, will require commitment to the SDM medical model as well as an understanding of the current SDM field. These findings are especially relevant as VAs pilot lung cancer screening programs and develop associated patient materials. This outline of the effects of and required resources for SDM cancer screening interventions to date will help guide VA use and development of such interventions.

RESEARCH GAPS/FUTURE RESEARCH

Research gaps remain in the field of SDM cancer screening interventions. First, there is a lack of SDM interventions for cervical and lung cancer. Given the potentially values-sensitive nature of the new recommendations for both cancers, there is a need to develop such interventions. Second, given the varying healthcare systems of, and level of enthusiasm for, cancer screening in different countries, it is particularly important to develop country- and culturally-specific SDM interventions. For instance, only recently has a DA to facilitate breast cancer screening decisions been developed in the United States; however, its quasi-experimental design excluded the study from this review.[76] Third, surprisingly few (2) trials were either clinician-level or multi-level. SDM is ideally achieved by both members of the patient-health professional dyad.[77] This points to a great gap in current SDM intervention research; multi-level SDM interventions that target both clinicians and patients have the potential to change healthcare professionals' decision making processes and receptivity to shared decision making, as well as support patient SDM. Additionally, neither patient literacy nor cultural competency was addressed in the majority of

SDM interventions, a general criticism of decision support tools. Given the cultural differences in decision making values, cross-cultural research is called for in SDM intervention development and measurement.

In addition to addressing the gaps revealed by this systematic review, future research should focus on identifying best practices to disseminate SDM interventions and measure outcomes to allow for consistent evaluation across trials. There is also a need to address the impact of SDM interventions on additional outcomes, including relevant health outcomes (in addition to the immediate screening decision) and measures of the concordance between patients' preferred level of participation in decisions and their actual level of participation. In addition to subjective measures, investigators are developing objective measures of SDM between the patient and the clinician.[78,79] Such measures can standardize the SDM process and aid clinician training. Finally, many of our included SDM interventions were developed and evaluated prior to the most recent guideline changes for each respective cancer. Investigators need to both update existing SDM interventions to reflect current guidelines, as well as develop new ones that address such changes.

CONCLUSIONS

SDM interventions for breast, colorectal, and prostate cancer screening improve knowledge, but there is low to insufficient evidence that they affect other measures of Decision Quality. SDM interventions had varied effects on Decision Impact and Action, with no consistent effect on screening behavior. Little information exists regarding the comparative effectiveness of SDM intervention strategies, or whether the effects vary by intervention target population, key SDM intervention content/elements, patient characteristics, or cancer type. No studies evaluated SDM interventions for cervical or lung cancer screening. While SDM is widely viewed as an important patient-centered approach to preference-sensitive decisions, current evidence does not clearly demonstrate that studied approaches have consistent effects beyond increasing patient knowledge. Future research is needed to identify interventions that can effectively and efficiently improve patient Decision Quality and Impact across a wide range of cancers and screening strategies.

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APPENDIX A. SEARCH STRATEGIES

DATABASE: OVID MEDLINE(R)

1 decision making/ or patient participation/ or directive counseling/
2 decision support technique/
3 (decision making or decision-making or decision support or decis$ aid$ or shared decis$ or shared decision making or informed decision making or valu$ or valu$ clarific$).mp.
4 or/1-3 [decision making search terms]
5 limit 4 to (english language and humans and yr=”1995 -Current”)
6 limit 5 to (“all adult (19 plus years)” or “young adult (19 to 24 years)” or “adult (19 to 44 years)” or “young adult and adult (19-24 and 19-44)” or “middle age (45 to 64 years)” or “middle aged (45 plus years)” or “all aged (65 and over)” or “aged (80 and over)”)
7 limit 5 to (“newborn infant (birth to 1 month)” or “infant (1 to 23 months)” or “preschool child (2 to 5 years)” or “child (6 to 12 years)” or “adolescent (13 to 18 years)”)
8 5 not 7
9 6 or 8 [decision making limited to English, humans, 1995-Current, adult]
10 Randomized controlled trials as topic/
11 Randomized controlled trial/
12 Random allocation/
13 Double blind method/
14 Single blind method/
15 Clinical trial, phase iii.pt.
16 Clinical trial, phase iv.pt.
17 Controlled clinical trial.pt.
18 Randomized controlled trial.pt.
19 ((singl$ or doubl$ or treb$ or trip$) adj (blind$3 or mask$3)).mp.
20 Random$ allocat$.mp.
21 (allocat$ adj2 random$).mp.
22 or/10-21 [RCT terms]
23 Meta analysis/
24 Meta analys$.mp.
25 (systematic adj (review or overview)).mp.
26 meta analysis.pt.
27 or/23-26 [SR/MA terms]
28 (neoplasm$ or cancer$).mp. or exp Neoplasms/ [cancer terms]
29 screen$.mp. or screening/ or cancer screen$.mp. or “Early Detection of Cancer”/
30 colonoscopy/ or sigmoidoscopy/ or colonography, computed tomographic/ or barium sulfate/ or Occult Blood/
31 (fobt or fecal occult or colonoscop$ or sigmoidoscop$ or ct colonograph$ or virtual colonoscop$ or barium enema or lower GI series or lower gastrointestinal series or lower gastrointestinal exam$ or FIT or fecal immunochemical test).mp.
32 vaginal smears/ or DNA Probes, HPV/ or Papillomavirus Infections/ or Human Papillomavirus DNA tests/ or CA-125 Antigen/
33 (pap test$ or pap smear$ or hpv or human papillomavirus or TVUS or (transvag$ adj ultraso$)

or CA-125).mp.
34 mammography/ or (mammography/ and Magnetic Resonance Imaging/) or (MRI mammogra$ or mammogra$).tw. or ultrasonography, mammary/
35 prostate-specific antigen/ or (PSA or prostate specific antigen).tw.
36 Tomography, X-Ray Computed/ or Tomography, Emission-Computed, Single-Photon/ or (computed tomography or tomography).tw.
37 or/29-36 (1087048) [screening terms]
38 9 and 28 and 37
39 38 and 22 [RCTs]
40 38 and 27 [SRs/MAs]

DATABASE: CINAHL

1 (MM "Decision Making") OR (MM "Decision Making, Clinical") OR (MM "Decision Making, Patient")
2 (MM "Cancer Screening")
3 TX directive counseling OR TX decision support OR TX shared decision OR TX shared OR TX informed OR TX patient participation
4 TX screen* AND TX cancer
5 1 OR 3
6 2 OR 4
7 5 AND 6
8 Narrow by SubjectAge (all adult) AND SubjectMajor (cancer screening)

DATABASE: PSYCINFO

1 TX Shared OR TX Shared Decision OR TX Decision Support OR TX Informed OR TX Directive Counseling OR TX Decision OR TX Preference OR TX Choice
2 MJ "Cancer Screening"
3 TX PSA OR TX Colonoscopy OR TX Sigmoidoscopy OR TX Colonography OR TX Fecal Occult OR TX FOBT OR TX Pap OR TX cervical OR TX mammography OR TX prostate OR TX tomography
4 1 AND 2 AND 3
5 Narrow by Methodology (treatment outcome/clinical trial), Narrow by Methodology (quantitative study), Narrow by SubjectAge (adulthood [18 yrs & older])
6 (MJ "Decision Making") AND (MJ "Cancer Screening")
7 5 OR 6

APPENDIX B. EXCLUDED ARTICLES

Study	Reason for exclusion	Reference
Adab 2003	**Decision Action outcome only**	Adab P, Marshall T, Rouse A, Randhawa B, Sangha H, Bhangoo N. Randomised controlled trial of the effect of evidence based information on women's willingness to participate in cervical cancer screening. *J Epidemiol Comm Health*. 2003;57(8):589-93.
Agrez 1998	**Not RCT**	Agrez MV, Coory M, Cockburn J. Population screening for colorectal carcinoma with fecal-occult blood testing: are we sufficiently informed? *Cancer*. 1998;82(10):1803-7.
Allen 2010	**Non-clinic setting**	Allen JD, Othus MK, Hart A Jr, et al. A randomized trial of a computer-tailored decision aid to improve prostate cancer screening decisions: results from the Take the Wheel trial. *Cancer Epidemiol Biomarkers Prev*. 2010;19(9):2172-86.
Auvinen 2001	**Not cancer screening**	Auvinen A, Vornanen T, Tammela TL, et al. A randomized trial of the choice of treatment in prostate cancer: design and baseline characteristics. *BJU Int*. 2001;88(7):708-15.
Banks 2014	**Not cancer screening**	Banks J, Hollinghurst S, Bigwood L, Peters TJ, Walter FM, Hamilton W. Preferences for cancer investigation: a vignette-based study of primary-care attendees. *Lancet Oncol*. 2014;15(2):232-40.
Berry 2013	**Not cancer screening**	Berry DL, et al. The Personal Patient Profile-Prostate decision support for men with localized prostate cancer: A multi-center randomized trial. *Urol Oncol*. 2013; 31(7):1012-1021
Chan 2011	**Non-clinic setting**	Chan EC, et al. A community-based intervention to promote informed decision making for prostate cancer screening among Hispanic American men changed knowledge and role preferences: a cluster RCT. *Patient Educ Couns*. 2011;84(2):e44-51.
Christy 2013	**Screening promotion**	Christy SM, et al. Promoting colorectal cancer screening discussion: a randomized controlled trial. *Am J Prev Med*. 2013;44(4):325-9.
Costanza 2011	**Not RCT**	Costanza ME, Luckmann RS, Rosal M, et al. Helping men make an informed decision about prostate cancer screening: a pilot study of telephone counseling. *Patient Educ Couns.* 2011;82(2):193–200.
Davis 2013	**Not RCT**	Davis TC, et al. Contrasts in Rural and Urban Barriers to Colorectal Cancer Screening. *Am J Health Behav*. 2013; 37(3):289-298
Dolan 2005	**Not RCT (secondary observational study from included Dolan 2002)**	Dolan JG. Patient priorities in colorectal cancer screening decisions. *Health Expect*. 2005;8(4):334-44.
Dorfman 2010	**Not RCT (development/usability testing for included Taylor 2013)**	Dorfman CS, et al. The development of a web- and a print-based decision aid for prostate cancer screening. *BMC Med Inform Decis Mak*. 2010;10:12.
Driscoll 2008	**Non-clinic setting**	Driscoll DL, Rupert DJ, Golin CE, McCormack LA, Sheridan SL, Welch BM. Promoting prostate-specific antigen informed decision-making. Evaluating two community-level interventions. *Am J Prev Med*. 2008;35(2):87–94.
Edwards 2013	**Not RCT**	Edwards AGK, et al. Personalised risk communication for informed decision making about taking screening tests. *Cochrane Database Syst Rev.* 2013. 2: CD001865.
Edwards 2006	**Not RCT**	Edwards AGK, et al. Personalised risk communication for informed decision making about taking screening tests. *Cochrane Database Syst Rev.* 2006(4): CD001865.
Edwards 2003	**Not RCT**	Edwards A, et al. Personalised risk communication for informed decision making about entering screening programs. *Cochrane Database Syst Rev.* 2003(1): CD001865.

Study	Reason for exclusion	Reference
Ellison 2008	**Non-clinic setting**	Ellison GL, Weinrich SP, Lou M, Xu H, Powell IJ, Baquet CR. A randomized trial comparing web-based decision aids on prostate cancer knowledge for African-American men. *J Natl Med Assoc*. 2008;100(10):1139-45.
Elwyn 2012	**Not RCT**	Elwyn G, Rix A, Holt T,et al. Why do clinicians not refer patients to online decision support tool? Interviews with front line clinics in the NHS. *BMJ Open*. 2012; 2
Evans 2007	**Not RCT (protocol for included Evans 2010)**	Evans R, et al. A randomised controlled trial of the effects of a web-based PSA decision aid, Prosdex. Protocol. *BMC Fam Pract*. 2007;8:58
Feldman-Stewart 2012	**Not cancer screening**	Feldman-Stewart D, Tong C, Siemens R, et al. The impact of explicit values clarification exercises in a patient decision aid emerges after the decision is actually made: evidence from a randomized controlled trial. *Med Decis Making*. 2012;32(4):616-26.
Feng 2013	**Not RCT**	Feng B, Srinivasan M, Hoffman JR, et al. Physician communication regarding prostate cancer screening: analysis of unannounced standardized patient visits. *Ann Fam Med*. 2013;11(4):315-23.
Flight 2012	**Non-clinic setting**	Flight IH, Wilson CJ, Zajac IT, Hart E, McGillivray JA. Decision Support and the Effectiveness of Web-based Delivery and Information Tailoring for Bowel Cancer Screening: An Exploratory Study. *JMIR Res Protoc*. 2012;1(2):e12.
Frosch 2008	**Not RCT**	Frosch DL, Légaré F, Mangione CM. Using decision aids in community-based primary care: a theory-driven evaluation with ethnically diverse patients. *Patient Educ Couns*. 2008;73(3):490-6.
Frosch 2001	**Not RCT**	Frosch DL, Kaplan RM, Felitti V. Evaluation of two methods to facilitate shared decision making for men considering the prostate-specific antigen test. *J Gen Intern Med*. 2001;16(6):391–8.
Flood 1996	**Not RCT**	Flood AB, et al. The importance of patient preference in the decision to screen for prostate cancer. Prostate Patient Outcomes Research Team. *J Gen Intern Med*. 1996;11(6):342-9.
Gattellari 2005	**Non-clinic setting**	Gattellari M, Ward JE. A community-based randomised controlled trial of three different educational resources for men about prostate cancer screening. *Patient Educ Couns*. 2005;57(2):168-82.
Griffith 2008	**Non-clinic setting**	Griffith JM, Lewis CL, Brenner AR, Pignone MP. The effect of offering different numbers of colorectal cancer screening test options in a decision aid: a pilot randomized trial. *BMC Med Inform Decis Mak*. 2008;8:4.
Griffith 2008	**Not RCT**	Griffith JM, Fichter M, Fowler FJ, Lewis C, Pignone MP. Should a colon cancer screening decision aid include the option of no testing? A comparative trial of two decision aids. *BMC Med Inform Decis Mak*. 2008;8:10.
Hall 2011	**Not cancer screening**	Hall MJ, et al. Effects of a decision support intervention on decisional conflict associated with microsatellite instability testing. *Cancer Epidemiol Biomarkers Prev*. 2011; 20(2):249-54.
Han 2013	**Not RCT**	Han PKJ, et al. National Evidence on the Use of Shared Decision Making in Prostate-Specific Antigen Screening. *Ann Fam Med*. 2013; 11(4) 360-314
Hayat Roshanai 2013	**Not RCT**	Hayat Roshanai A, Nordin K, Berglund G. Factors influencing primary care physicians' decision to order prostate-specific antigen (PSA) test for men without prostate cancer. *Acta Oncol.* 2013; 52(8):1602-1608.
Hayes 2014	**Not RCT**	Hayes JH, Barry MJ. Screening for Prostate Cancer With the Prostate Specific Antigen Test A Review of Current Evidence. *JAMA*. 2014; 311(11):1143-1149.
Holloway 2003	**Screening promotion**	Holloway RM, et al. Cluster-randomised trial of risk communication to enhance informed uptake of cervical screening. *Br J Gen Pract.* 2003. 53(493):620-5.

Study	Reason for exclusion	Reference
Hooker 2011	**Not cancer screening**	Hooker GW, et al. Longitudinal changes in patient distress following interactive decision aid use among BRCA1/2 carriers: a randomized trial. *Med Decis Making*. 2011; 31(3):412-21
Ilic 2008	**Non-clinic setting**	Ilic D, Egberts K, McKenzie JE, Risbridger G, Green S. Informing Men about Prostate Cancer Screening: A Randomized Controlled Trial of Patient Education Materials. *J Gen Intern Med*. 2007; 23(4): 466-471.
Inadomi 2012	**Screening promotion**	Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med*. 2012;172(7):575-82.
Jerant 2013	**Not RCT (secondary study from unpublished RCT)**	Jerant A,, et al. Effects of Tailored Knowledge Enhancement on Colorectal Cancer Screening Preference across Ethnic and Language Groups. *Patient Edu Couns*. 2013;90(1):103-110
Jerant 2007	**Screening promotion**	Jerant A, Kravitz RL, Rooney M, Amerson S, Kreuter M, Franks P. Effects of a tailored interactive multimedia computer program on determinants of colorectal cancer screening: a randomized controlled pilot study in physician offices. *Patient Educ Couns*. 2007;66(1):67–74.
Joseph-Williams 2010	**Not RCT (secondary observational study from included Evans 2010)**	Joseph-Williams N, et al. Supporting informed decision making online in 20 minutes: an observational web-log study of a PSA test decision aid. *J Med Internet Res*. 2010; 12(2):e15
Kassan 2012	**Not RCT (secondary observational study from included Taylor 2013)**	Kassan EC, et al. Men's use of an Internet-based decision aid for prostate cancer screening. *J Health Commun*. 2012;17(6):677-97.
Katsumura 2008	**Not RCT**	Katsumura Y, Yasunaga H, Imamura T, Ohe K, Oyama H. Relationship between risk information on total colonoscopy and patient preferences for colorectal cancer screening options: analysis using the analytic hierarchy process. *BMC Health Serv Res*. 2008; 8:106
Kerns 2008	**Not RCT (secondary observational study from included Krist 2007)**	Kerns JW, Krist AH, Woolf SH, Flores SK, Johnson RE. Patient perceptions of how physicians communicate during prostate cancer screening discussions: a comparison of residents and faculty. *Fam Med*. 2008;40(3):181-7.
Kim 2005	**Not RCT**	Kim J, Whitney A, Hayter S, et al. Development and initial testing of a computer-based patient decision aid to promote colorectal cancer screening for primary care practice. *BMC Med Inform Decis Mak*. 2005;5:36.
Korfage 2013	**Not cancer screening**	Korfage IJ, Fuhrel-Forbis A, Ubel PA, et al. Informed choice about breast cancer prevention: randomized controlled trial of an online decision aid intervention. *Breast Cancer Res*. 2013;15(5):R74.
Krist 2007	**Not RCT (secondary observational study from included Krist 2007)**	Krist AH, Woolf SH, Johnson RE. How physicians approach prostate cancer screening before and after losing a lawsuit. *Ann Fam Med*. 2007;5(2):120-5.
Lairson 2011	**Screening promotion**	Lairson DR, Chan W, Chang YC, del Junco DJ, Vernon SW. Cost-effectiveness of targeted versus tailored interventions to promote mammography screening among women military veterans in the United States. *Eval Program Plann*. 2011;34(2):97–104.
Lawrence 2000	**Not RCT**	Lawrence VA, Streiner D, Hazuda HP, Naylor R, Levine M, Gafni A. A cross-cultural consumer-based decision aid for screening mammography. *Prev Med*. 2000;30(3):200-8.
Leader 2012	**Not RCT (secondary observational study from included Myers 2011)**	Leader A, Constantine Daskalakis C, Braddock III CH, et al. Measuring Informed Decision Making about Prostate Cancer Screening in Primary Care. *Med Decis Making*. 2012; 32(2): 327-36.
Legare 2010	**Not RCT**	Legare F. Ratte S, Stacey D, Kryworuchko J, Gravel K, Graham ID, Turcotte S. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev.* 2010;12(5):CD006732

Study	Reason for exclusion	Reference
Lerman 1997	**Not cancer screening**	Lerman C, et al. Controlled trial of pretest education approaches to enhance informed decision-making for BRCA1 gene testing. *J Natl Cancer Inst.* 1997; 89(2):148-57.
Lewis 2012	**Screening promotion**	Lewis CL, Brenner AT, Griffith JM, Moore CG, Pignone MP. Two controlled trials to determine the effectiveness of a mailed intervention to increase colon cancer screening. N C Med J. 2012;73(2):93-8.
Lewis 2010	**Not RCT**	Lewis CL, Golin CE, DeLeon C, et al. A targeted decision aid for the elderly to decide whether to undergo colorectal cancer screening: development and results of an uncontrolled trial. *BMC Med Inform Decis Mak*. 2010;10:54.
Lewis 2010	**Not RCT**	Lewis CL, Pignone MP, Schild L, et al. Effectiveness of a patient and practice-level colorectal cancer screening intervention in health plan members: design and baseline findings of the CHOICE trial. *Cancer.* 2010;116(7):1664–73.
Lin 2013	**Not RCT**	Lin GA, Halley M, Rendle KA, et al. An effort to spread decision aids in five California primary care practices yielded low distribution, highlighting hurdles. *Health Aff (Millwood)*. 2013;32(2):311-20.
Linder 2011	**Not RCT (secondary psychometric study from included Volk 2008)**	Linder SK, Swank PR, Vernon SW, Mullen PD, Morgan RO, Volk RJ. Validity of a low literacy version of the Decisional Conflict Scale. *Patient Edu Couns*. 2011; 85:521-524
Lindbloom 2012	**Non-clinic setting**	Lindblom K, Gregory T, Wilson C, Flight IH, Zajac I. The impact of computer self-efficacy, computer anxiety, and perceived usability and acceptability on the efficacy of a decision support tool for colorectal cancer screening. *J Am Med Inform Assoc*. 2012;19(3):407-412.
McCormack 2011	**Non-clinic setting**	McCormack L, Treiman K, Bann C, et al. Translating medical evidence to promote informed health care decisions. *Health Serv Res*. 2011;46(4):1200-23.
Miller 2011	**Screening promotion**	Miller DP, Spangler JG, Case D, Goff DC, Singh S, Pignone M. Effectiveness of a Web-Based Colorectal Cancer Screening Patient Decision Aid: A Randomized Controlled Trial in a Mixed-Literacy Population. *Am J Prev Med.* 2011; 40(6):608-615.
The Multicentre Australian Colorectal neoplasia Screening Group 2006	**Non-clinic setting**	Multicentre Australian Colorectal-neoplasia Screening Group. A comparison of colorectal neoplasia screening tests: a multicentre community-based study of the impact of consumer choice. *Med J Aust* 2006;184(11):546-50.
Murphy 2014	**Not RCT**	Murphy DG, et al. The Melbourne Consensus Statement on the early detection of prostate cancer. *BJU Int*. 2014; 113:186-188
Myers 2011	**Not cancer screening**	Myers RE, et al. A randomized trial of genetic and environmental risk assessment (GERA) for colorectal cancer risk in primary care: trial design and baseline findings. Contemp Clin Trials. 2011;32(1):25-31.
Myers 2007	**Screening promotion**	Myers RE, Sifri R, Hyslop T, et al. A randomized controlled trial of the impact of targeted and tailored interventions on colorectal cancer screening. *Cancer.* 2007;110(9):2083–91.
Myers 2005	**Decision Action outcome only**	Myers RE, et al. Preparing African-American men in community primary care practices to decide whether or not to have prostate cancer screening. J Natl Med Assoc. 2005;97(8): 1143-54.
Myers 2005	**Not RCT**	Myers RE. Decision counseling in cancer prevention and control. *Health Psychol*. 2005;24(4 Suppl):S71–7.
Myers 1999	**Decision Action outcome only**	Myers RE, et al. Adherence by African American men to prostate cancer education and early detection. *Cancer*. 1999;86(1):88-104.

Study	Reason for exclusion	Reference
Nijs 1997	**Non-clinic setting**	Nijs HG, Tordoir DM, Schuurman JH, Kirkels WJ, Schröder FH. Randomised trial of prostate cancer screening in The Netherlands: assessment of acceptance and motives for attendance. *J Med Screen*. 1997;4(2):102-6.
O'Brien 2010	**Screening promotion**	O'Brien MJ, Halbert CH, Bixby R, Pimentel S, Shea JA. Community health worker intervention to decrease cervical cancer disparities in Hispanic women. *J Gen Intern Med*. 2010;25(11):1186-92.
O'Neill 2010	**Not cancer screening**	O'Neill SC, et al. BRCA1/2 test results impact risk management attitudes, intentions, and uptake. Breast Cancer Res Treat. 2010;124(3):755-64.
Pace 2014	**Not RCT**	Pace LE, Keating NL. A systematic assessment of benefits and risks to guide breast cancer screening decisions. *JAMA*. 2014;311(13):1327-35.
Park 2005	**Screening promotion**	Park S, Chang S, Chung C. Effects of a cognition-emotion focused program to increase public participation in Papanicolaou smear screening. *Public Health Nurs*. 2005;22(4):289-98.
Perneger 2011	**Non-clinic setting**	Perneger TV, Schiesari L, Cullati S, Charvet-Bérard A. Does information about risks and benefits improve the decision-making process in cancer screening - randomized study. *Cancer Epidemiol.* 2011; 35(6):574-9.
Pignone 2013	**Non-clinic setting**	Pignone MP, et al. Comparing 3 techniques for eliciting patient values for decision making about prostate-specific antigen screening: a randomized controlled trial. *JAMA Intern Med*. 2013;173(5):362-8.
Pignone 2012	**Non-clinic setting**	Pignone MP, Brenner AT, Hawley ST, et al. Conjoint analysis versus rating and ranking for values elicitation and clarification in colorectal cancer screening. *J Gen Intern Med.* 2012; 27(1):45–50.
Pignone 2011	**Not RCT**	Pignone MP, Winquist A, Schild L, et al. Effectiveness of a patient and practice-level colorectal cancer screening intervention in health plan members. *Cancer.* 2011;117(15):3252–62.
Pignone 2000	**Decision Action outcome only**	Pignone M, Harris R, Kinsinger L. Videotape-based decision aid for colon cancer screening. A randomized, controlled trial. *Ann Intern Med*. 2000;133(10): 761-9.
Price-Haywood 2014	**Screening promotion**	Price-Haywood EG, Harden-Barrios J, Cooper LA. Comparative effectiveness of audit-feedback versus additional physician communication training to improve cancer screening for patients with limited health literacy. *J Gen Intern Med.* 2014; 29(8):1113-21.
Price-Haywood 2010	**Not RCT (baseline assessments from Price-Haywood 2014)**	Price-Haywood E, Roth KG, Shelby K, Cooper LA. Cancer Risk Communication with Low Health Literacy Patient: A Continuing Medical Education Program. *J Gen Intern Med.* 2010; 25(2): 126-129
Rimer 2001	**Screening promotion**	Rimer BK, et al. The short-term impact of tailored mammography decision-making interventions. *Patient Educ Couns*. 2001;43(3): 269-85.
Rimer 2002	**Screening promotion**	Rimer BK, et al. Effects of a mammography decision-making intervention at 12 and 24 months. *Am J Prev Med.* 2002;22(4):247-57.
Rubel 2010	**Non-clinic setting**	Rubel SK, et al. Testing the effects of a decision aid for prostate cancer screening. *J Health Comm*. 2010;15(3):307-21.
Ruffin 2007	**Screening promotion**	Ruffin MT 4th, Fetters MD, Jimbo M. Preference-based electronic decision aid to promote colorectal cancer screening: results of a randomized controlled trial. *Prev Med.* 2007;45(4):267-73.
Schoenberg 2013	**Not RCT**	Schoenberg MA, Hamel MB, Davis RB, et al. Development and evaluation of a decision aid on mammography screening for women 75 and older. *JAMA Intern Med*. 2013;174(3):417-24.
Schroy 2011	**Not RCT**	Schroy PC 3rd, Mylvaganam S, Davidson P. Provider perspectives on the utility of a colorectal cancer screening decision aid for facilitating shared decision making. *Health Expect*. 2011;17(1):27-35.

Study	Reason for exclusion	Reference
Sheridan 2004	**Not RCT**	Sheridan SL, Felix K, Pignone MP, Lewis CL. Information needs of men regarding prostate cancer screening and the effect of a brief decision aid. *Patient Educ Couns*. 2004;54(3):345–51.
Smith 2014	**Non-clinic setting**	Smith SK, Simpson JM, Trevena LJ, McCaffery KJ. Factors Associated with Informed Decisions and Participation in Bowel Cancer Screening among Adults with Lower Education and Literacy. *Med Decis Making*. 2014;34(6):756-72.
Smith 2013	**Not RCT (discussion paper based on Smith 2010)**	Smith SK, Nutbeam D, McCaffery KJ. Insights into the concept and measurement of health literacy from a study of shared decision making in a low literacy population. *J Health Psychol*. 2013; 18(8):1011–22.
Smith 2012	**Not RCT (secondary psychometric study from Smith 2010)**	Smith SK, Barratt A, Trevena L, Simpson JM, Jansen J, McCaffery KJ. A theoretical framework for measuring knowledge in screening decision aid trials. *Patient Educ Couns*. 2012. 89(2):330-6.
Smith 2010	**Non-clinic setting**	Smith SK, Trevena L, Simpson JM, Barratt A, Nutbeam D, McCaffery KJ. A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial. *BMJ*. 2010;341: c5370.
Stalmeier 2009	**Not cancer screening**	Stalmeier PFM, Roosmalen MS. Concise evaluation of decision aids. *Patient Educ Couns*. 2009;74(1):104-9.
Stamatiou 2008	**Screening promotion**	Stamatiou K, Skolarikos A, Heretis I, Papadimitriou V, Alevizos A, Ilias G, Karanasiou V, Mariolis A, Sofras F. Does educational printed material manage to change compliance with prostate cancer screening? *World J Urol*. 2008;26(4):365-73.
Steckelberg 2011	**Non-clinic setting**	Steckelberg A, Hülfenhaus C, Haastert B, Mühlhauser I. Effect of evidence based risk information on “informed choice” in colorectal cancer screening: randomised controlled trial. *BMJ*. 2011;342:d3193.
Stephens 2008	**Not RCT**	Stephens RL, Xu Y, Volk RJ, Scholl LE, Kamin SL, Holden EW. Influence of a patient decision aid on decisional conflict related to PSA testing: a structural equation model. *Health Psychol*. 2008;27(6):711–21.
Street 1998	**Screening promotion**	Street RL Jr, Van Order A, Bramson R, Manning T. Preconsultation education promoting breast cancer screening: does the choice of media make a difference? *J Cancer Educ*. 1998;13(3):152-61.
Taylor 2006	**Non-clinic setting**	Taylor KL, et al. Educating African American men about the prostate cancer screening dilemma: a randomized intervention. *Cancer Epidemiol Biomarkers Prev*. 2006;15(11):2179-88.
Tiller 2006	**Not cancer screening**	Tiller K, Meiser B, Gaff C, et al. A randomized controlled trial of a decision aid for women at increased risk of ovarian cancer. *Med Decis Making*. 2006;26(4):360-72.
Valdez 2001	**Not RCT**	Valdez A, Banerjee K, Fernandez M, Ackerson L. Impact of a multimedia breast cancer education intervention on use of mammography by low-income Latinas. *J Cancer Educ*. 2001;16(4):221–4.
van Roosmalen 2004	**Not cancer screening**	van Roosmalen MS, et al. Randomized trial of a shared decision-making intervention consisting of trade-offs and individualized treatment information for BRCA1/2 mutation carriers. *J Clin Oncol*. 2004;22(16):3293-301.
van Roosmalen 2004	**Not cancer screening**	van Roosmalen MS, et al. Randomised trial of a decision aid and its timing for women being tested for a BRCA1/2 mutation. *Br J Cancer*. 2004;90(2):333-42.
Vernon 2011	**Screening promotion**	Vernon SW, Bartholomew LK, McQueen A, et al. A randomized controlled trial of a tailored interactive computer-delivered intervention to promote colorectal cancer screening: sometimes more is just the same. *Ann Behav Med*. 2011;41(3):284-99.

Study	Reason for exclusion	Reference
Wahab 2008	**Screening promotion**	Wahab S, Menon U, Szalacha L. Motivational interviewing and colorectal cancer screening: a peek from the inside out. *Patient Educ Couns*. 2008;72(2):210-7.
Weinrich 2008	**Non-clinic setting**	Weinrich SP. A decision aid for teaching limitations of prostate cancer screening. *JNBNA*. 2008;19(1):1-11.
Weinrich 2007	**Non-clinic setting**	Weinrich SP, Seger R, Curtsinger T, Pumphrey G, NeSmith EG, Weinrich MC. Impact of pretest on posttest knowledge scores with a Solomon Four research design. *Cancer Nurs.* 2007;30(5):E16-28.
Wilkinson 2002	**Not cancer screening**	Wilkinson CR, Williams M. Strengthening patient-provider relationships. *Lippincotts Case Manag*. 2002;7(3): 86-99; quiz 100-2.
Williams 2008	**Non-clinic setting**	Williams RM, Zincke NL, Turner RO, et al. Prostate cancer screening and shared decision-making preferences among African-American members of the Prince Hall Masons. *Psychooncology*. 2008;17(10):1006-13.
Williams-Piehota 2008	**Not RCT (secondary observational study from McCormack 2011)**	Williams-Piehota PA, McCormack LA, Treiman K, Bann CM. Health information styles among participants in a prostate cancer screening informed decision-making intervention. *Health Educ Res*. 2008;23(3):440–53.
Wilson 2010	**Not RCT**	Wilson CJ, Flight IH, Zajac IT, et al. Protocol for population testing of an Internet-based Personalised Decision Support system for colorectal cancer screening. *BMC Med Inform Decis Mak.* 2010;10:50.
Wolf 2000	**Decision Action outcome only**	Wolf AM, Schorling JB. Does informed consent alter elderly patients' preferences for colorectal cancer screening? Results of a randomized trial. *J Gen Intern Med*. 2000;15(1):24-30.
Wolf 1996	**Decision Action outcome only**	Wolf AM, Nasser JF, Wolf AM, Schorling JB. The impact of informed consent on patient interest in prostate-specific antigen screening. *Arch Intern Med*. 1996;156(12):1333-6.
Yasunaga 2006	**Non-clinic setting**	Yasunaga H, Ide H, Imamura T, Ohe K. Benefit evaluation of mass screening for prostate cancer: willingness-to-pay measurement using contingent valuation. *Urology*. 2006;68(5):1046-50.

APPENDIX C. PEER REVIEW COMMENTS/AUTHOR RESPONSES

REVIEWER COMMENT	RESPONSE
1. Are the objectives, scope, and methods for this review clearly described?	
No. Objectives and scope are clearly described. I would like to see more details in the methods section about: 1) USE OF HEALTH SERVICES. This is eventually defined on P 38, but a more detailed explanation should appear earlier. My first thought was that it was measuring utilization related to undergoing testing. 2) COMPARATORS: Clarify earlier in the methods section that "usual care" comparators = effectiveness studies, "alternative SDM" = comparative effectiveness studies. 3) VALUE-CONCORDANCE: Clarify the meaning of the concepts of values clarity and value concordance and explain how these concepts are being measured with the various instruments. Would also suggest explaining a "values clarification exercise." I found the values concepts to be incompletely described and/or used interchangeably, making it difficult to interpret the findings ("clearer values, higher values clarity, "decreased value assessments," "clear values that matched the intention," *etc.*) I would suggest explicitly explaining the reason for excluding studies that measured only Decision Action—presumably your reliance on the OSDF framework. I would also have liked to seen the reference list for the studies excluded for this criterion. From reading meta-analyses of cancer screening trials, I know that many RCT of decision aids have been excluded—and I suspect that it was for their limited outcome focus.	Thank you. We included more details and definitions throughout the report, including : 1) Use of health services: We included a definition in both the executive summary (pg 1, paragraph 2) and the main report (pg 12, paragraph 1). 2) Comparators: We made our language consistent and used effectiveness studies, comparative effectiveness studies, and attention control studies throughout, and included definitions (pg 21 paragraph 1). 3) Value-concordance: We made our language consistent, using *values clarity* and defining the construct (pg 1 paragraph 2) and describing it with the authors' measurement in a new table with information about measures (Appendix E). We also included a definition of a values clarification exercise (pg 7, paragraph 1). We added information on the Ottawa Decision Support Framework and how it guided our review (pg 13 paragraph 3; pg 14 paragraph 1), and why some key decision aid studies were excluded (pg 14 paragraph 1; pg 16 paragraph 5). Additionally, we prepared a table of excluded studies (Appendix B).
Yes. In general, the objectives, scope, and methods for this review are clear. However, in the summary, I would add to KQ1 "for cancer screening" after SDM interventions (line 25 p. 1). I would also consistently say "SDM interventions" and not just interventions (line 29 p. 1, line 12, p. 2, line 28 p. 11, and others throughout). Also, my biggest concern is that the authors should clarify what they mean by SDM and whether they mean any form of SDM or specifically patient decision aids? It seems they mean any form of SDM, but a definition of SDM and SDM interventions is lacking detail in the evidence summary as well as the evidence report. Charles 1997 is cited and later Makoul 2006, both of whom have slightly different definitions of SDM. What about Whitney 2004 who differentiates SDM from informed decision making and informed consent? What about Elwyn, Frosch, *etc.* recent definition of SDM and decision support interventions? Or Elwyn's IPDASi checklist? This is very important to define for readers to better understand the context of the review and to better understand whether key SDM interventions are missing from the review.	Thank you for the suggestion. We made the requested edit throughout the report. We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13 paragraph 3; pg 14, paragraph 1), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5). It should now be clearer why some key decision aid studies were excluded. Additionally, we prepared a table of excluded studies (Appendix B) The reviewer makes a valid point. We edited this sentence (pg 4 paragraph 2) and added context for the interventions throughout the executive summary to improve the clarity.

The authors should specifically refer to the context for their findings when discussing them. For example, line 18, p. 3, should say "whether to be screened for breast cancer…" (the words "for breast cancer" are missing and then it is unclear if it is for another cancer such as CRC). Please check throughout. Some word choice is unclear. E.g. p. 1, line 15, "policy SDM needs…" policy doesn't have needs. SDM interventions could have policy implications but patient and clinical needs are separate from policy implications. This part needs rewording.	Thank you for the suggestion. We made the requested edit throughout the report. Thank you for the suggestion. We reworded this section (pg 1 paragraph 1).
Yes. The objectives, scope, and methods are generally well described. Although SDM is defined, there are no explicit criteria that I could find for interventions that are considered SDM interventions. For example, was a criterion for inclusion of a study to have an intervention with an explicit component to encourage collaborative or shared decision making with the clinician (such as coaching patients to speak with their clinician about the decision or the timing of an intervention prior to a clinician visit)? Was the search limited to decision-aids or did it include other interventions that support SDM but may not have incorporated all of the components of a decision aid? Did the investigators seek to identify whether studies documented the occurrence of shared decision-making (through, for example, audio-recordings of the doctor patient interaction or patient self-report of shared decision making)? Or, did the investigators assume that if an intervention was designed with the goal of supporting shared decision-making that shared decision-making occurred? These points highlight the distinction between a review of decision-aid studies and a review of studies designed to support SDM.	Thank you. We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13 paragraph 3; pg 14, paragraph 1), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5).
Yes	Thank you
No. Reading this report makes me appreciate how difficult this topic was to review. The purpose of engaging in shared decision making is not really clearly stated – page 1, line 13 says it's to "improve clinical care" but is the desired outcome to encourage patients to get recommended cancer screening tests or to discourage inappropriate ones or to help them make choices that they're happy with, regardless of whether the healthcare team considers them "right" or "wrong"? Is there evidence that patients aren't making the "best" decisions? The report makes me realize that the whole concept of SDM assumes that people make rational decisions when presented with the evidence and an opportunity to think it through (values clarification, *etc.*) but what if that's not how most people make their decisions? Is it okay for the labeling of a decision as "preference sensitive" to be done by healthcare professionals, rather than by patients? I think so, but perhaps a comment about that should be included. The Ottawa Decision Support Framework is mentioned as the framework used but is not described or explained as to why it was chosen. Some of the studies reviewed seem to have used DAs as stand-alone interventions with patients, without "sharing" the decision with a healthcare provider, even though SDM is described as involving both. For example, the two breast cancer screening SDM trials described on pages 22-23 both involved providing participants with a DA but don't mention discussion of their screening decisions with their healthcare providers. Perhaps these studies are better described as "informed decision making."	We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13-14). We added detailed information on the Ottawa Decision Support Framework, and how it guided our review, (pg 13 paragraph 3, pg 14 paragraph 1). Facilitating informed decision making could be a stand-alone strategy for facilitating the broader goal of SDM, or could be one component of a multi-faceted SDM intervention. We do not exclude SDM interventions restricted to informed decision making processes from the review. We added a detailed section on SDM, and SDM interventions (pg 12-14). Hopefully it is clearer how we conceptualized SDM interventions, and the scope of our review.

The multiple outcomes measured (components of Decision Quality, Decision Impact, and Decision Action) seem to be closely related and a bit hard to differentiate at times. Are they all of equal importance? In the Conclusions paragraph (page 45, lines 31-33), it'd be helpful to say what effect on Decision Quality and Impact would have been expected/ desired from SDM. I assume they should ideally have increased but I'm not sure.	As specified in our revised background section and description of the Ottawa Decision Making Framework, measures of the decision making process (i.e., decision quality and decision impact) receive priority over decision action in selecting studies. We excluded studies that only examined decision action outcomes. In both the Executive Summary and the main report we discuss ideal cancer screening SDM intervention outcomes in SDM interventions (e.g., decrease decisional conflict, increase patient satisfaction, increase knowledge) (pg 1 paragraph 2; pg 13 paragraph 3).
No. The objectives, scope, and methods are mostly described well. One exception is that I am unclear by your use of the term SDM interventions. You don't really define it and it's a term commonly used in the literature. I assume you are referring to decision aids and decision support interventions (which becomes clear after the executive summary I am not sure why you are using that term but given its lack of use in the literature you should define it and give examples of what you mean (both in the executive summary and in the main document). Click here to enter text. Also, it may be beneficial to describe a little better the measures used in the studies.	We added a detailed section on SDM and SDM interventions (pg 12-14). We prepared a table describing the measures used in the included studies (Appendix E).
Yes. The methods are clearly described. The division into decision quality, decision impact, and decision action doesn't work very well for me but is clearly described.	Thank you
2. Is there any indication of bias in our synthesis of the evidence?	
No	Thank you
I am not sure why authors excluded those studies looking at decision action alone. It isn't clear why they chose to include studies that included all three types of outcomes (decision action, decision quality, and decision impact). I would include studies that assessed *any* of the outcomes and just report on those outcomes with slightly different Ns in each. Otherwise they exclude quite a few studies that might be relevant (starting with 2368 hits, going down to 22 unique trials). I now see in the limitations section that the authors state they excluded studies looking at decision action alone because they didn't want to include studies encouraging screening, but with a clear definition of SDM this can be mitigated rather than excluding potentially relevant SDM interventions just because of choice of outcome measures. I am also not sure why authors excluded studies in settings other than primary care or studies in non-clinical settings. This needs clarification.	We added a detailed section on SDM and SDM interventions (pg 12-14), including the scope of our review including definitions, purpose, evidence-based framework utilized (ODSF) (pg 13 paragraph 3; pg 14 paragraph 1), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5). Additionally, we prepared a table of excluded studies (Appendix B). We clarified our inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5); to be consistent with the definition guiding this review, which defines SDM as a process that involves interaction between patients and clinical providers, we sought to identify interventions implemented and evaluated in clinical settings where such a dialogue could possibly occur. Clinic settings, either at or shortly before an appointment, were a component to encourage SDM with the clinician.

Study selection in general does not match up with definitions of SDM. So did authors consider an intervention an "SDM intervention" only if it provided both risk and benefit information? What about values clarification? (p. 13, lines 23-29). This again leads back to clarifying what definition they are using. I am not sure whether the list of hand-searched journals is complete. What about BMJ or HEX, for example?	We selected studies based on the stated goals of the interventions and outcomes measured, rather than on content of the intervention per se. There are many ways to facilitate SDM and interventions that increase patient knowledge of risks and benefits, even without explicit values clarification are still SDM interventions. We added a detailed section on SDM and SDM interventions (pg 12-14), and inclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), We hope it is now clearer why we included the studies. A complete list of hand-searched journals (including British Medical Journal and Health Expectations) is provided in the Methods section (pg 16 paragraph 3).
No	Thank you
Yes. The appearance of bias comes from uncertainty in the threshold to conclude SDM interventions for cancer screening do more good than harm. The review notes in Executive Summary Table 1 that 18/19 trials show improved knowledge. If one believes in truly informed consent for screening tests (and national guidelines certainly stress that point, particularly for prostate cancer screening), isn't that the key outcome? In addition, 3/6 trials show an increase in values clarity, 7/13 show a reduction in decisional conflict, 3/6 show reduced use of services, and 1/2 show an increase in decision satisfaction. Moreover, among the prostate trials, 5/9 show a reduction in screening intention, and 7/12 show a reduction in screening test use. These results seem more impressive than the tone of the discussion in the paper suggests, particularly as there seems to be little evidence of harm.	The reviewer makes a valid point. In the discussion we made an effort to emphasize that SDM interventions for cancer screening did more good than harm, while accurately presenting the state of the evidence (pg 49 paragraph 2).
No.	Thank you
No. More details on your search terms is necessary (perhaps also include in exec summary—found them in main body). I was surprised that none of the following were search terms: decision aids, decision support interventions, patient education, shared decision making.	We added more information about our search in the review (pg 16 paragraphs 2-3) and executive summary (pg 2 paragraph 2) and clarified that the mentioned terms were included. These terms are also presented in Appendix A.
No.	Thank you
3. Are there any <u>published</u> or <u>unpublished</u> studies that we may have overlooked?	
Yes. Taylor KL, et al. Decision making in prostate cancer screening using decision aids vs. usual care: a randomized clinical trial. JAMA Intern Med 2013;173:1704.	Thank you for this suggestion. We agreed that this study was overlooked and we included it in the revised report.
Yes. What about Jane Kim et al. 2004 BMC Medical Informatics and Decision Making, 5:36, and Carmen Lewis et al. 2010 BMC Medical Informatics and Decision Making (both about colorectal cancer screening decision aids). For decision aids specifically, why not look at the Cochrane Review and then look for RCTs of cancer screening decision aids? Can the authors search Dawn Stacey's review of decision aids for cancer specifically (in CA: A Cancer Journal for Clinicians)?	Thank you for these suggestions. These articles were assessed and excluded during our search; we added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B).We did use the Cochrane Review, Dr. Stacey's review, as well as others as part of search strategy to identify relevant studies.

No. Not that I am aware of.	Thank you
No.	Thank you
Yes. There are many studies of decision aids not included in the review – perhaps appropriately, but it's not always clear why some were and some weren't	We added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B).
Dawn Stacey's 2014 Cochrane review of decision aids, Mara Schonberg's 2014 JAMA: IM article on a screening decision aid for women > 75. Maybe John Inadomi's 2012 JAMA: IM article. Sarah Hawley has finished 2 studies looking at CRC screening interventions (one in the VA). Frosch, Legare, Mangione 2008, patient education and counseling (screening in ethnically diverse clinics). Lin et al health Affairs 2013 vol. 32no. 2 311-320	Thank you for these suggestions. We used Dr. Stacey's review in our search strategy to identify relevant articles and these articles were assessed and excluded during our search; we added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B).We were unable to include Dr. Hawley's studies as they were unpublished as of July, 2014.
Yes. The decision to not include the studies that focus only on decision action doesn't make sense to me, if you want to make conclusions about that set of outcomes.	We aimed to review studies that evaluated the decision making process. Studies that focused on Decision Action did not fit this criterion and were excluded, as well as interventions that promoted screening. We added more information about our exclusion criteria (pg 14 paragraph 1; pg 16 paragraph 5), and we prepared a table of excluded studies (Appendix B).
4. Please write any additional suggestions or comments below. If applicable, please indicate the page and line numbers from the draft report.	
P 1, line 22: Typo: Should read that decision quality is characterized by knowledge, value-concordance, and patient role.	Thank you for the suggestions. We made this edit (pg 1 paragraph 2).
P 1, line 30: Would suggest just using the phrase "intervention target," the system/organization does not seem to be a population.	We agree with the reviewer and made the requested edit throughout the report.
P 3, lines 4-5 (and elsewhere [KQ3]): Would clarify whether results are from lack of effectiveness and/or insufficient sample size.	The reviewer makes a valid point and we clarified this throughout the report.
P 10, line 41. USPSTF does not consider barium enema as an acceptable test; would delete or add CT colonography.	We made this edit (pg 13 paragraph 1).
	We made this edit (pg 27 paragraph 1).
P 24, line 30: CRC screening is also effective in reducing cancer-related mortality and cancer incidence.	We edited the comparative effectiveness trials section to clarify which interventions were favored (pg 32 paragraph 3 – pg 33 paragraph 3)
P 37, line 36-8: Which intervention (booklet or pamphlet) was favored for these outcomes?	
P 42, line 10: Typo. Should read "decreased their intention to order PSA"	We clarified that the intervention group had a lower intention to order PSA (pg 47 paragraph 2; pg 6 paragraph 3)

Line 14, p. 35: the highest standard in risk communication is not necessarily pictographs…I would rephrase. Newer research suggests bar graphs might be ok, and the most important standard is to use frequencies or percentages rather than RR, AR, NNT, *etc.* Also see Fagerlin et al 2011, JNCI, 10 steps to better risk communication, for a more recent reference. Although there is no evidence that more resource intensive SDM interventions do better than less resource intensive SDM interventions, few studies assessed this. I would clarify that throughout the review as it has clear policy implications and it might be premature to say a pamphlet (that might not be read by everyone in standard practice vs. in the context of a voluntary research study) does better than other interventions. Could be added to the conclusions section. In general the conclusions are well written and clear.	Thank you for this suggestion. We rephrased to reflect the most current research and included Fagerlin et al 2011 (pg 39 paragraph 2). We agree and we clarified throughout the report that conclusions should not be drawn from a single study. Thank you
There is an error in line 21 when Decision Quality is defined using the same outcomes as Decisional Impact.	We made the requested edit (pg 1 paragraph 2).
In the analyses of decision action for SDM interventions for prostate cancer screening, the heterogeneity and differential effects among studies may reflect confounding by the baseline rate. In theory, whether decision action changes and in what direction might depend on whether PSA screening at baseline was overutilized or underutilized. Can the results be stratified based on testing rates in the control group, perhaps comparing the mean baseline rates in the control group for the 7 studies showing a drop in utilization with SDM, versus the 5 showing no effect?	There is a limited range in PSA rates across the prostate cancer studies; the range of mean PSA screening rates is narrow, and thus stratifying would not be a productive.
Page 1, lines 21-22: text in the parentheses after Decision Quality and Decision Impact is repeated. Page 10, lines 14-16: the sentence starting “SDM involves…” could be better written as “SDM involves integrating the knowledge of health care professionals and the values and preferences of patients to arrive at a final decision.” Page 10, line 20: please consider (here and throughout) using the word “use” or “used” rather than “utilization” or “utilized” Page 17, lines 25: the definition of “attention control” trials is not provided here, when the term is first used. Page 18, Table 1: it’s not clear what the “0” means in this table. Does it mean no effect or not studied or something else? Page 24, line 8: are the percents listed (95.5% and 9.3%) correct? They’re described as showing no effect between the 2 groups. Page 31, line 20: refer the reader to Appendix C, Table 1 to understand how the risk of bias was determined	We made this edit (pg 1 paragraph 2). Thank you for the suggestion. We reworded this paragraph (pg 11 paragraph 1). We agree with the reviewer’s suggestion and made the requested clarifications throughout the report. We added a definition of ‘attention control trials’ (pg 21 paragraph 1). The ‘0’ referred to no effect. However, we made this table consistent with others and added foot notes to all tables. The percentages from Mathieu 2007 (9.5% and 9.3%) can be found in Table 4 (pg 76); the text now reads “Mathieu 2007 also measured screening outcomes one month post-intervention and found that SDM had no effect on having made or planning to make a mammography appointment” (pg 26 paragraph 4). Thank you for the suggestion. Strength of Evidence and Risk of Bias are described fully in the methods and separately in the results. We added a reference to Appendix F (pg 45 paragraph 2).

The executive summary is hard to understand without context. For example: "A single SDM intervention designed to facilitate decisions about whether women who are younger or older than typically recommended for breast cancer screening should be screened had no effect on decisional conflict." What was the intervention? Executive summary table #2: How were these ratings done? Hard to evaluate the table. You discuss the methods in the main body, so maybe just not include the table in the ES unless you provide some detail there. Another area that needs more research is how to get SDM interventions/decision aid implemented into clinical practice. Often research finds them beneficial in a variety of ways, but once the research staff is no longer engaged (i.e., the research is done), the decision aids never get to patients. How can that change? On page 41 you write: Given the large body of research outlining the most effective ways to communicate risk and decision making theory, it is possible that authors did not report this information. I think you are optimistic. Granted it was 10 years ago, but Fagerlin et al's review of prostate cancer treatment decision aids found that few included any numerical information at all. We are currently reviewing cancer screening guidelines and you would be stunned by the number that don't include numbers (particularly for benefit of screening). When discussing previous reviews, you do not cite Stacey et al 2014 Cochrane review of decision aids or the most recent updating of the IPDAS guidelines which will be valuable to you: http://www.biomedcentral.com/bmcmedinformdecismak/supplements/13/S2	The reviewer makes a valid point. We rewrote the executive summary to improve its clarity throughout and added context for interventions. The reviewer makes a valid point. To improve readability of the Executive Summary, we removed the complete evidence table and included this in the main body where we explained our ratings methods. The reviewer brings up an interesting point. We addressed implementation challenges in the discussion, citing Dr. Gravel's 2006 review (pg 48 paragraph 3). We tempered our optimism and cited the Fagerlin et al review (pg 39 paragraph 2). We look forward to reading the upcoming review of cancer screening guidelines. Thank you for the suggestion We included the most recent Cochrane review in our discussion of previous reviews (pg 48 paragraph 2) and discuss IPDAS guidelines in our introduction (pg 13 paragraph 3). We did use these resources reports in our search strategy, but this was not made clear in our report. We have clarified this in the revised report, and added more information about our search strategy (pg 16 paragraphs 2-3).
Page 10, lines 32-34 – I think this should be "mortality" rather than "morbidity"; I would say the benefits and harms are closely balanced and that the decision is preference-sensitive (not the balance) My only other comment is that the text descriptions of the individual studies are long and somewhat hard to read- better to use the tables to convey that information.	Thank you for the suggestions. In the course of our edits this sentence was deleted. We reworded the section the reviewer referred to. Thank you for the suggestion. We edited the text descriptions of the individual studies slightly and directed the reader to evidence tables (Appendix D).
5. Please provide any recommendations on how this report can be revised to more directly address or assist implementation needs.	
Could identify available VA decision support tools (either developed by VA or accessible through CPRS); for example, the recently developed VA decision tool for prostate cancer screening.	We discussed VA-developed decision support tools, both currently available and potential in the future (pg 49 paragraphs 1-2).
The report does a good job of highlighting the need for additional studies in lung and cervical cancer and for studies that have a clinician-intervention component	Thank you
Given the mostly low-quality evidence, it'd be helpful to say what should be done at present, if anything, about using SDM for cancer screening.	We added additional suggestions and commentary about how to use SDM in cancer screening, despite the quality of evidence (pg 53 paragraph 3).
It may be useful to discuss implementation issues outside of cancer screening. Please see France Legare's and Dominick Frosch's work	Thank you for the suggestion. In our discussion we addressed implementation challenges, citing Dr. Gravel's 2006 review (of which Dr. Légaré is a co-author) (pg 53 paragraph 3).

APPENDIX D. EVIDENCE TABLES

BREAST CANCER

Table 1. Characteristics of Breast Cancer Studies (k=2)

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	INTERVENTION TARGET	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWLS	RISK OF BIAS
Mathieu, 2007[19] (Australia)	Mammography	70 y/o women in Australia who accessed gov't on line mammography site; 2 screening mammograms in past 5 years; due for next screening within next 3 months; no prior diagnosis of breast cancer	I: Mailed DA (367) C: Standard screening brochure (367)	Age: 70 yrs Race/Ethnicity: NR Previous Screen (%): 100	Australian population screening program, BreastScreen Australia	Immediately, 1 month 3% did not return questionnaire 3% did not complete follow-up interview	Sequence generation: adequate Allocation concealment: adequate Blinding: telephone follow-up blinded; other data by self-administered questionnaire Incomplete outcome data: 3% no questionnaire; 11%[a] of questionnaires incomplete; 3% no interview Selective outcome reporting: no **Risk of Bias: Moderate**
Mathieu, 2010[20] (Australia)	Mammography	38-45 y/o women in Australia who accessed gov't web site for mammography; no prior diagnosis of breast cancer	I: Web-based DA (189) C: Survey and delayed DA (223)	Age: 42 yrs Race/Ethnicity: NR Previous Screen (%): 11	Australian population screening program, BreastScreen Australia	Immediately 19% withdrew or excluded before accessing DA; outcome data for 63% of patients randomized	Sequence generation: adequate Allocation concealment: adequate Blinding: unclear Incomplete outcome data: 37% missing outcome data;61% did not complete informed choice analysis Selective outcome reporting: no **Risk of Bias: Moderate**

k = number of studies; DA=Decision Aid

[a] Data analysis included all who completed specific sections of the questionnaire

Table 2. Characteristics of Interventions from Breast Cancer Studies

AUTHOR, YEAR	DELIVERY MODE	DELIVERY TIMING and LOCATION	VALUES CLARIFICATION EXERCISE	RISK COMM. METHOD	CONSIDERED HEALTH LITERACY or NUMERACY	RESOURCES (COST, STAFF, PHYSICAL)
Mathieu, 2007[19]	Mailed booklet	Home	Worksheet with examples provided	1000-face pictograms: Event rate per 1000 women screened every 2 years over 10 years, starting at age 70	Not specified	Unclear
Mathieu, 2010[20]	Website	Home	Worksheet with examples provided	Diagrams as event rates per 1000 women screened every 2 years over 10 years, and per 1000 women who are not screened over 10 years	Not specified	Unclear

DA=Decision Aid

Table 3. Decision Quality Outcomes Assessed in Breast Cancer Studies

AUTHOR, YEAR	KNOWLEDGE		PATIENT ROLE IN DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Mathieu, 2007[19]	76.6% adequate knowledge[a] Informed choice[b] 73.5%	56.9% adequate knowledge χ^2=31.15, p = .02 Informed choice 48.8%, (χ^2=37.92; P<.001).	-	-	*Clear Values*[c] Mean = 19.51 *Decided* Undecided: 4.9% Decided: 95.1%	*Clear Values* Mean = 22.59, T_{545}=2.27, p= .02 *Decided* Undecided: 10.1% Decided: 89.9% OR 0.32 (0.17, 0.63), P < .001
Mathieu, 2010[20]	Mean 7.35 94% adequate[a] Informed choice[b] 71%	Mean 6.27, p<.001 83% adequate, p<.001 Informed choice 64%, p=NS	-	-	*Decided* Undecided: 18% Intention – Decided: 82%	*Decided* Undecided: 39% Intention – Decided: 61% χ^2=15.72, P<0.001

[a] Adequate knowledge defined as a score of 6/10 or higher
[b] Participants were classified as having made an informed choice if they had either (1) adequate knowledge, positive values towards screening, and intention to attend screening; or (2) adequate knowledge, negative values towards screening, and intention to decline screening
[c] Decisional Conflict Scale – Values Subscale: values considered "clear" if score is ≤ 25

Table 4. Decision Impact Outcomes Assessed in Breast Cancer Studies

AUTHOR, YEAR	DECISIONAL CONFLICT		USE OF HEALTH SERVICES		DECISION SATISFACTION	
	Intervention	Control	Intervention	Control	Intervention	Control
Mathieu, 2007[19]	*DCS*[a] Mean = 20.06	*DCS* Mean = 21.89, p= .12	-	-	-	-
Mathieu, 2010[20]	-	-	-	-	-	-

[a] Decisional Conflict Scale – higher scores indicate greater decisional conflict or uncertainty.

Table 5. Decision Action Outcomes Assessed in Breast Cancer Studies

AUTHOR, YEAR	SCREENING INTENTION		SCREENING BEHAVIOR	
	Intervention	Control	Intervention	Control
Mathieu, 2007[19]	Intention – Stop screening: 9.5% Intention –Continue screening: 85.7%[a]	Intention – Stop screening: 9.3% Intention – Continue screening: 80.6% OR 1.28 (0.63, 2.61), p=.50	Screened: 5.9% Unscreened, but have made appointment, or planning to make appointment: 75.7% Unscreened: 18.4%	Screened: 7.0% Unscreened, but have made appointment, or planning to make appointment: 74.7% Unscreened : 18.3% P=NS
Mathieu, 2010[20]	Intention – Screen: 52% Intention – Not screen: 48%[b] χ^2=4.00, P = .05	Intention – Screen: 65% Intention – Not screen: 35%	-	-

[a] Percent of total group (decided and undecided)
[b] Percent of women who had made a decision

COLORECTAL CANCER

Table 6. Characteristics of Colorectal Cancer Studies (k=3)

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	INTERVENTION TARGET	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWLS	RISK OF BIAS
Dolan, 2002[21] (United States)	FOBT, FS, FOBT+FS, BE, COL	Men and women at average risk for CRC; CRC screening eligible	I: Interview plus printed DA (N=49) C: Interview plus printed educational materials (N=46)	Age (yr): 66.1 Gender (Male%): 47.5 Race/Ethnicity (%): white 98 Previously screened (%): 27.3	2 Internal Medicine practices	Follow up 1) Immediate 2) 2-3 mo. chart review 1% withdrawals	Sequence generation: Adequate Allocation concealment: Unclear Blinding: Yes (chart review) Incomplete outcome data: No Selective outcome reporting: No **Risk of Bias: Moderate**
Schroy, 2011[22] Schroy, 2012[23] (United States)	FOBT, FS, FOBT+FS, BE, COL	Average risk patient under care of primary care provider at study sites; 50 to 75 years old; no prior CRC screening examinations Excluded: prior CRC screening other than FOBT; high-risk conditions (personal history of CRC or polyps, family history of CRC or polyps, chronic IBD); comorbidities that preclude CRC screening by any method	I1: DA plus "Your Disease Risk" tool (YDR)(n=223) (n=280 for Schroy 2012) I2: DA (n=212) (n=269 for Schroy 2012) C: Control (modified version of "9 Ways to Stay Healthy and Prevent Disease") (n=231) (n=276 for Schroy 2012)	Schroy 2011 Age (yr): 83% <65 years; 17% 65+ years Gender (Male%): 41 Race/Ethnicity (%): black 62, white 34, Asian 2 Previously screened (%): 14 (FOBT only) Schroy 2012 Age (yr): 84% <65 years; 16% 65+ years Gender (Male%): 41 Race/Ethnicity (%): black 62, white 34, Asian 2 Previously screened (%): 13 (FOBT only)	2 urban ambulatory care clinics (1 private, academic-affiliated, 1 community clinic affiliated with academic clinic) 50 providers (47 MDs, 3 NPs) participated; pre-study seminars about CRC screening, SDM, overview of study	Schroy 2011 Follow up 1) Immediate (post-visit) 2) Medical record review for screening test ordered (time of review not reported) % withdrawals not reported Schroy 2012 Follow up 12 months post-visit 0% withdrawals	Sequence generation: Unclear Allocation concealment: Adequate Blinding: Unclear Incomplete outcome data: No Selective outcome reporting: No **Risk of Bias: Moderate**
Trevena, 2008[24] (Australia)	FOBT	Between 50 and 74 years old Excluded: poor English, significant cognitive impairment, serious physical or mental illness, resident of nursing homes, personal history of colorectal cancer; previous FOBT, FS, or COL (past 2 years); strong family history of CRC	I: DA (age, gender, family history specific) (n=157) C: Government consumer guidelines on FOBT (n=157) Both groups received self-administered questionnaire	Age (yr): 50-54 years 23%; 55-64 years 41%; 65-74 years 35% Gender (Male %): 42 Race/Ethnicity (%): NR Previously screened (%): NR	1 rural and 5 urban family practices	Follow-up: 1 month after mailing 14.3% withdrawals	Sequence generation: Adequate Allocation concealment: Adequate Blinding: Participants were blinded to study hypothesis; researchers were blinded to allocations for telephone interviews (questionnaires were self-administered) Incomplete outcome data: Selective outcome reporting: **Risk of Bias: Moderate**

k = number of studies; BE = barium enema; COL = colonoscopy; CRC = colorectal cancer; DA = decision aid; FOBT = fecal occult blood test; FS = flexible sigmoidoscopy; IBD = inflammatory bowel disease

Table 7. Characteristics of Interventions from Colorectal Cancer Studies

AUTHOR, YEAR	DELIVERY MODE	DELIVERY TIMING and LOCATION	VALUES CLARIFICATION EXERCISE	RISK COMM. METHOD	CONSIDERED HEALTH LITERACY or NUMERACY	RESOURCES (COST, STAFF, PHYSICAL)
Dolan, 2002[21]	Counseling and print	Prior to routine appointment	Analytic hierarchy process	Not specified	Not specified	Study team member-administrated intervention prior to appointment
Schroy, 2011[22] Schroy, 2012[23]	DVD	1 hr prior to prearranged office visit with primary care provider Private office	Discrete choice method to identify screening preference	Web-based "Your Disease Risk" (YDR), personalized risk estimates; audio/ visual	Conducted focus groups to determine key factors (including literacy) to include in DA; Prototype modified after usability testing	Research assistants administered pre-test, web-based program
Trevena, 2008[24]	Booklet Question set	Home	Personal worksheet required participants to indicate what was important to them	1000-face diagrams	Readability score: Grade 10	Unclear

DA = decision aid

Table 8. Decision Quality Outcomes Assessed in Colorectal Cancer Studies

AUTHOR, YEAR	KNOWLEDGE		PATIENT'S ROLE IN THE DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Dolan, 2002[21]	-	-	*Perception of how screening decisions were made:* Primarily MD 7 (16.3%) Shared 27 (62.8%) Primarily patient 9 (20.9%)	*Perception of how screening decisions were made:* Primarily MD 6 (13.9%) Shared 22 (51.2%) Primarily patient15 (34.9%), P = .35	-	-
Schroy, 2011[22]	*Baseline* DA+YDR: 7.6 (2.8)* DA: 7.7 (2.9)[a] *Post-visit* DA+YDR: 10.7 (1.8)* DA: 10.9 (1.6)[a] EFFECT sizes (vs control) DA+YDR: d=1.15 DA: d=1.27	*Baseline* Control: 7.5 (2.7)* Overall P=0.91 *Post-visit* Control: 8.6 (2.7)* P<0.001 for 2 intervention groups vs control	-	-	-	-
Schroy, 2012[23] Continuation of Schroy 2011[22]	*Baseline* DA+YDR: 7.7 (2.9)* DA: 7.9 (2.8)[a] *Post-visit* DA+YDR: 10.7 (1.9)[a] DA: 10.9 (1.6)*	*Baseline* Control: 7.5 (2.8)* Overall P=0.36 *Post-visit* Control: 8.6 (2.6)* P <.001 for 2 intervention groups vs control	-	-	-	-

AUTHOR, YEAR	KNOWLEDGE		PATIENT'S ROLE IN THE DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Trevena, 2008[24]	*Adequate knowledge*[b] 28/134 (20.9%); P= .0001 *Integrated knowledge and values*‖ 14/134 (10.4%); P= .002	*Adequate knowledge* 8/137 (5.8%) *Integrated knowledge values*‖ 2/137 (1.5%)	-	-	*Clear values*[c] 83/134 (62%)	*Clear values* 81/137 (59%) P= .63

CRC = colorectal cancer; DA = decision aid; DA+YDR = decision aid plus "Your Disease Risk"; MD=physician

[a] 12 item true/false questionnaire about CRC risk factors, rationale and goals of screening, age at which screening should begin; 0 = no correct responses, 12 = all correct responses

[b] Adequate knowledge defined as positive scores for understanding the potential benefits and potential arms of screening; integrated knowledge and values defined as clear values and adequate knowledge

[c] Decisional Conflict Scale – Values Subscale: values considered "clear" if score is ≤ 25

Table 9. Decision Impact Outcomes Assessed in Colorectal Cancer Studies

AUTHOR, YEAR	DECISIONAL CONFLICT[a]		USE OF HEALTH SERVICES		DECISION SATISFACTION	
	Intervention	Control	Intervention	Control	Intervention	Control
Dolan, 2002[21]	1.83 (0.52)[b] P = .01 effect size=0.29	2.03 (0.81)	-	-	-	-
Schroy, 2011[22]	-	-	-	-	Mean *SDMP* scores[c] DA + YDR: 50.5 (6.2), N=214 DA: 50.7 (6.2) N=205	Mean *SDMP* scores Control: 46.7 (7.9) N=217 P <.001
Schroy, 2012[23] Continuation of Schroy, 2011[22]	-	-	-	-	Mean *SDMP* scores[c] DA+YDR: 49.0 (6.2), n=271 DA: 49.7 (6.4), n=262	Mean *SDMP* scores †† Control: 45.5 (7.8), n=261; P < .001
Trevena, 2008[24]	-	-	-	-	-	-

[a] Scores are means (standard deviation) unless indicated; DA+YDR = decision aid plus "Your Disease Risk"

[b] Decisional Conflict Scale (low literacy version) - Maximum = 100; 0 = no decisional conflict, 100 = extreme decisional conflict

[c] 12-item Satisfaction with the Decision-Making Process Scale, each item scored from 1 (strongly disagree or "poor") to 5 (strongly agree or "excellent"); maximum score = 60

Table 10. Decision Action Outcomes Assessed in Colorectal Cancer Studies

AUTHOR, YEAR	SCREENING INTENTION		SCREENING BEHAVIOR	
	Intervention	Control	Intervention	Control
Dolan, 2002[21]	FOBT 23 (51%) W&S 8 (18%) FOBT+FS 6 (13%) FS 6 (13%) BE 1 (2%) COL 1 (2%)	FOBT 17 (39%) W&S 16 (37%) FOBT+FS 8 (18%) FS 2 (5%) BE 0 COL 0 All P = ns	FOBT 11 (48%) W&S 8 (100%) FOBT+FS 2 (33%) FS 4 (67%) BE 0 COL 1 (100%)	FOBT 6 (35%) W&S 15 (94%) FOBT+FS 7 (88%) FS 1 (50%) BE 0 COL 0

AUTHOR, YEAR	SCREENING INTENTION		SCREENING BEHAVIOR	
	Intervention	Control	Intervention	Control
Schroy, 2011[22]	*DA+YDR:* COL 132/223 (60%) FOBT 53/223 (24%) FS 13/223 (6%) FOBT+FS 6/223 (2%) BE 8/223 (4%) None 8/223 (4%) *DA:* COL 120/212 (57%) FOBT 58/212 (28%) FS 11/212 (5%) FOBT+FS 5/212 (3%) BE 9/212 (4%) None 7/212 (3%) P = ns (between groups) *Intention to Schedule Screening*† DA+YDR: 4.3 (1.0) DA: 4.4 (1.0) *Intention to Complete Screening Test*† DA+YDR: 4.3 (1.0) DA: 4.3 (1.0) EFFECT sizes: Ranged from 0.36 to 0.44 for intention to schedule or complete for 2 intervention groups vs control	NR *Intention to Schedule Screening*† Control: 3.9 (1.4) P < .001 vs 2 intervention groups *Intention to Complete Screening Test*† Control: 3.9 (1.3) P < .001 vs 2 intervention groups	-	-
Schroy, 2012[23] Continuation of Schroy 2011[22] N=825	*Intention to Schedule Screening*[a] DA+YDR: 4.3 (1.0) (n=280) DA: 4.4 (1.0) (n=269) *Intention to Complete Screening Test*[a] DA+YDR: 4.4 (1.0) (n=280) DA: 4.3 (1.0) (n=269) Test Ordered by 12 months After Vsit DA+YDR: 73.6% DA: 80.7% DA+YDR vs DA: P = .048	*Intention to Schedule Screening* Control: 3.9 (1.3) (n=276) P < .001 vs 2 intervention groups *Intention to Complete Screening Test* Control: 4.0 (1.3) (n=269) P < .001 vs 2 intervention groups *Test Ordered by 12 months Aafter Visit* Control: 71.4%, P = .011 vs DA	*Test Completed by 12 Months After Visit* DA+YDR: 37.1% OR 1.03 (0.72, 1.48) vs control DA: 43.1% OR 1.30 (0.90, 1.87) vs control DA+YDR vs DA, P = .153	*Test Completed by 12 Months After Visit* Control: 34.8%, P = .046 vs DA
Trevena, 2008[24]	*Intention to Screen* Baseline 142/157 (90.4%) *Post-intervention* 117/134 (87.3%)	*Intention to Screen* Baseline 139/157 (88.5%) *Post-intervention* 124/137 (90.5%), P = .40	*At One Month Completed FOBT* 5.2%	*At One Month Completed FOBT* 6.6% P = .64

DA = decision aid; DA+YDR = decision aid plus "Your Disease Risk"; BE = barium enema; COL = colonoscopy; FOBT = fecal occult blood test; FS = flexible sigmoidoscopy; ns = not statistically significant;

[a] 5 point scale with 1 = not at all sure, 5 = completely sure

PROSTATE CANCER

Table 11. Characteristics of Prostate Cancer Studies (k=18)

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Davison, 1999[25] (Canada)	Screening defined as both DRE & PSA	Male patients age 50-79 with a periodic health examination appointment with no prostate cancer diagnosis or evidence of mental confusion.	I: verbal & written information, including prostate cancer screening controversies, pros & cons, encouragement to discuss with MD (n=50) C: Attention control involving discussion about general issues (n=50)	Age(yrs): Mean 62.2 50 to 59: 21.5% 60 to 69: 17% 70 to 79: 12%	1 family medicine clinic	Immediate Withdrawals: 0%	Sequence generation: Adequate Allocation concealment: Adequate Blinding: no Incomplete outcome data: unclear Selective outcome reporting: unclear **Risk of Bias: Moderate**
Evans, 2010[26] (United Kingdom)	PSA	Men aged >50	I1: Web-based DA, Prosdex (n=89) I2: paper version of Prosdex text (n=86) C1: Questionnaire control group (n=103) C2: no questionnaire control group (n=126)	Age 50-59 65% White 92.9% Black 0.4% Indian 0.4% Mixed Race 1.2% Other 1.1% Mean # previous PSAs 2.15	25 General practices from 9 Local Health Board areas in South Wales	Immediate, 6 months Loss to initial follow up: I1: 31% (40/129) I2: 32% (40/126) C1: 19% (24/127) Loss to 6 month follow up: I1: 46% (41/89) I2: 34% (29/86) C1: 33% (34/103) C2: 24% (32/132)	Sequence generation: Adequate Allocation concealment: Adequate Blinding: adequate Incomplete outcome data: Yes Selective outcome reporting: No **Risk of Bias: Moderate**
Frosch, 2003[27] (United States)	PSA	Men aged >50	I1: Web-based DA (N=114) I2: Video DA (N=112)	Age 62.1 White 91.1% African American 0.4% Hispanic 3.5% Asian 3.2% Other 0.4% Mean # previous PSAs 2.15	1 Preventive Medicine Clinic	Immediately post-visit Withdrawals: Video 5.7% Web: 17.5%	Sequence generation: Adequate – random number generator Allocation concealment: Adequate Blinding: no Incomplete outcome data: Yes – there was incomplete outcome data, handled by imputing the mean for some and pretest scores for others. This is a less rigorous approach than multiple imputation. Selective outcome reporting: Yes **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Frosch, 2008[28] (United States)	PSA	Male patients >50	I1: Web-based Traditional Decision Aid (TDA) (n=155) I2: Web-based Chronic Disease Trajectory Model (DTM) (n=153) I3: combined TDA and DTM (n=152) C: links to public ACS and CDC prostate cancer screening websites (n=151)	Age 58.6 White 86% African American 2.8% Hispanic 5.2% Asian 3.9% Other 2.0 % Mean # previous PSAs 3.4	1 Preventive Medicine Clinic	Length of follow-up unclear (participants approached "after appointment completed" to assess outcomes) Withdrawals: TDA 23% DTM 25% TDA&DTM 22% Control 34%	Sequence generation: Computer algorithm used to randomize – Adequate Allocation concealment: Adequate Blinding: Unclear whether participants, providers, investigators, and/or outcome assessors were blinded. Incomplete outcome data: Yes – there was incomplete outcome data, handled by imputing the mean for some and pretest scores for others. This is a less rigorous approach than multiple imputation. Selective outcome reporting: Yes **Risk of Bias: Moderate**
Gattellari, 2003[29] (Australia)	PSA	Male patients fluent in English, age 40-70 with no prostate cancer diagnosis	I: 32-page (3085 word) Evidence Based booklet distributed in clinic (n=126) C: 968 word pamphlet published by the Australian government (n=122)	Mean Age 54.0 Male 100% Previous PSA 36%	Practices of 13 General Practitioners in urban Sydney	Unclear Withdrawal I: 16% (n=106) C: 11% (n=108), NS	Sequence generation: Adequate (pre-randomized code). Allocation concealment: Adequate – pre-randomized assignment concealed from receptionists and General Practitioners by sealed envelope handed to patients. Blinding: Receptionists, general practitioners, and patients were blinded. It is not clear whether individuals conducting analysis were blinded. Incomplete outcome data: Yes –11-16% were not followed up, but no statistically differences across experimental groups on follow-up rates. Selective outcome reporting: unclear **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Gattelari, 2005[30] (Australia)	PSA	General Practitioners (GPs) who had ordered at least one PSA in past 12 months	I: Mailed information, telephone peer coaching, and education sessions (n=110 practices, 136 GPs) C: Mailed summary of PSA screening guidelines (n=110 practices, 141 GPs)	Age <35 3.3% 35-44: 22.7% 45-54: 40.8% 55-64: 19.8% 65+: 11.9% Missing: 1.4% Gender Male: 75.1% Female: 24.9%	Referral network of GPs in New South Wales Australia's most populous state, recruited through large pathology service. 220 Clinics	Length of follow-up: 0-6-weeks (depending on outcome) Withdrawals: 1%	Sequence generation: Computer generated random number used to randomize – Adequate Allocation concealment: Adequate – GPs were randomized at the same time, Investigator responsible for randomization not involved in data collection. Blinding: Adequate Incomplete outcome data: Yes – there was incomplete outcome data, but no differences across experimental groups, and only 1% had no data, and outcome-specific missing rates unclear. Selective outcome reporting: unclear **Risk of Bias: Moderate**
Kripalani 2007[31] (United States)	PSA, DRE	Men age 45-70; waiting for primary care appointment Excluded: history of prostate cancer, in police custody, not scheduled to see a primary care provider, ill, not fluent in English, corrected visual acuity worse than 20/60	I1: High-detail patient educational pamphlet, PtEd, to promote shared decision making (n=86) I2: Low-detail 'Talk to doctor" Cue handout (n=81) C: Traditional food pyramid (attention control) (n=83)	Age (yr): 56.5 Gender (Male %): 100 Race/Ethnicity (%): African American 90.4, white 8.0, other 1.6 Previous Screen (%): 68 Reading below 9th grade level (%): 79	One inner-city primary care clinic	Immediately post-visit 4% of patients could not be located for post-visit questions	Sequence generation: adequate Allocation concealment: adequate Blinding: health care providers and outcomes assessors were blinded Incomplete outcome data: no Selective outcome reporting: no **Risk of Bias: Low**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Krist, 2007[32] (United States)	PSA	Men age 50 to 70 years; scheduled health maintenance examination Excluded: history of prostate cancer, no Internet access, planned to have blood work before visit, enrolled in another prostate cancer investigation, already enrolled in present study	I1: Web-based decision aid (n=226) I2: Paper version of decision aid (n=196) C: No pre-visit educational material (n=75)	Age (yr): 57 Gender (Male %): 100 Race/Ethnicity (%): white 91, African American 3 Previous Screen (%): 68 (PSA)	One large family practice center with a community-based family practice residency program	Immediately post-visit 87% of patients and 91% of physicians completed post-visit questionnaire	Sequence generation: adequate Allocation concealment: adequate Blinding: none Incomplete outcome data: 13% of patients did not complete post-visit questionnaire No Selective outcome reporting: No **Risk of Bias: Moderate**
Lepore, 2012[33] (United States)	PSA	Men 45 to 70 years old, black African descent, accessible by telephone, have a primary care physician Excluded: prostate cancer test in past 12 months, history of prostate cancer	I: tailored telephone education about prostate cancer testing (n=244) C: telephone education about fruit and vegetable consumption (attention control) (n=246) All patients received an educational pamphlet	Age (yr): 55 Gender (Male %): 100 Race/Ethnicity (%): Caribbean 77 Previous Screen (%): 28	Health insurance company of a healthcare workers' union	Interview 8 months after randomization Claims data collected for 2 years after enrollment 59/490 (12%) did not complete second survey; medical claims data available for all patients randomized	Sequence generation: adequate Allocation concealment: adequate Blinding: data collectors were blind to condition Incomplete outcome data: follow-up survey data missing for 12% Selective outcome reporting: No **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Myers, 2011[34] (United States) Decision Counseling Trial (DCT)	PSA	Men 50 to 69 years old, no history of prostate cancer or benign prostatic hyperplasia, no PSA test in past 11 months	I: Structured decision counseling session (mean of 28 minutes) about prostate cancer screening plus generic note in medical chart to prompt physician to discuss prostate cancer (n=156) C: practice quality assessment survey (to match face time of intervention group) plus generic note in chart to prompt discussion of prostate cancer screening (n=157) All patients received a 12 page informational brochure on prostate cancer and screening	Age (yr): 56 Gender (Male %): 100 Race/Ethnicity (%): while 56, non-white 43 Previous Screen (%): NR	2 primary care practice sites	Telephone survey about 7 days after office visit Medical records review about 120 days after visit Primary outcomes: data for 91% IDM outcome: data for 43% (required consent to audiotape) Screening outcome: data for 97%	Sequence generation: unclear Allocation concealment: unclear Blinding: NR Incomplete outcome data: 9% missing data for primary outcome (reasons not reported) Selective outcome reporting: No **Risk of Bias: Moderate**
Partin, 2004[35] Partin 2006[36] (United States)	PSA	Male veterans, age 50 and older, no prostate cancer, scheduled for general internal medicine appointment	I1: pamphlet (developed for study) (n=384) I2: video (23 min; developed by FIMDM) (n=384) C: usual care (n=384)	Age (yr): 68 Gender (Male %): 100 Race/Ethnicity (%): non-Caucasian 5 Previous Screen (%): 70	General internal medicine clinics at 4 VA facilities	Telephone survey 1 week after visit Medical record review at 2 weeks and 1 year 42/1152 (4%) found to be ineligible; 893/1110 (80%) completed follow-up survey	Sequence generation: adequate Allocation concealment: unclear Blinding: providers and outcomes assessors were blinded Incomplete outcome data: outcome data for 76% of patients randomized; explained Selective outcome reporting: No **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Schapira, 2000[37] (United States)	PSA DRE	Men aged 50 to 80 years; outpatient encounter at VA Medical Center Excluded: history of prostate or other cancer, previous prostate ultrasound study or biopsy, cystoscopy, prior prostate surgery, active genitourinary symptoms, cognitive impairment, expected life expectancy <2 years, employee of the VA Medical Center	I: Pamphlet – decision aid with information about screening and treatment (plus educational information included in comparator pamphlet) (8 pages) (n=122) C: Pamphlet – basic prostate cancer information (no information on risks and benefits of screening) (5 pages) (n=135)	Age (yr): 70 Gender (Male %): 100 Race/Ethnicity (%): white 92, black 3 Previous Screen (%): NR	VA Medical Center outpatient clinic	Post-intervention Follow-up visit 2 weeks after initial study visit	Sequence generation: Unclear Allocation concealment: Unclear Blinding: Unclear Incomplete outcome data: No Selective outcome reporting: Not all items from belief assessment were reported **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Sheridan, 2012[38] (United States) (NOTE: study was originally designed as 2 studies – 1) intervention vs attention control [highway safety video] and 2) intervention plus additional information on 2 other men's health screening services vs attention control [highway safety video]; results were combined)	PSA	Men who were age-eligible for prostate cancer screening (40-80 years old, no prior history of prostate cancer, seen in the practice for at least 1 year, physician agreed to participate in study Excluded: acute medical visit, evidence of serious medical illness	I: Video, coaching session, brochure (n=60) C: educational video on highway safety (n=70)	Age (yr): 58 Gender (Male %): 100 Race/Ethnicity (%): white 64, African American 18 Previous Screen (%): 52 (44 intervention, 59 control)	4 Internal medicine practices (1 academic, 1 community in 2 cities)	Follow-up questionnaires a. post-intervention b. post-appointment (same day) Review of medical records approximately 9 months after visit to determine whether screening was done Withdrawals: 2/130 (1.5%) from intervention group	Sequence generation: Adequate Allocation concealment: Unclear Blinding: physicians were unaware of patient group assignment Incomplete outcome data: Yes – no data from 2 patients Selective outcome reporting: No **Risk of Bias: Moderate**
Taylor, 2013[39] (United States)	PSA, DRE	Men age 45-70, English speaking, ability to provide informed consent, independent living, appointment in next 24 months Excluded: history of prostate cancer	I1: Web DA (n=625) I2: Print DA (n=628) C: UC (n=626)	Age (yr): 56.9 Gender (Male %): 100 Race/Ethnicity (%): white 56.2, African American 39.9, other 3.9 Previous Screen (%): 86.3	3 health systems in 1 city	Follow up at 1 month and 13 months Retention rate 1 month 89%, 13 months 84%	Sequence generation: Adequate Allocation concealment: Unclear Blinding: yes Incomplete outcome data: Yes – Retention rate 1 month 89%, 13 months 84% Selective outcome reporting: No **Risk of Bias: Low**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Volk, 1999[40] Volk, 2003[41] (1 year follow-up) (United States)	PSA	Men 45-70 years old, no history of prostate cancer	I: Educational video (from Foundation for Informed Medical Decision Making, Inc.) and accompanying brochure (n=80) C: No intervention before visit; brochure sent after 2 week follow-up assessment (n=80)	Age (yr): 59 Gender (Male %): 100 Race/Ethnicity (%): white 61, African American 19, Mexican American 16 other 4 Previous Screen (%): 41	Family medicine clinic	Videotape evaluated after viewing 2 week follow-up assessment (Volk 1999) 1 year follow-up[assessment (Volk 2003) Withdrawals at 2 weeks: 2/160 (1.3%) from intervention group Withdrawals at 1 year (total): 23/160 (14%)	Sequence generation: Adequate Allocation concealment: Adequate Blinding: Physicians were unaware of patient assignment; interviewers and patients were not blinded Incomplete outcome data: Yes – no data from 2 intervention group patients (1 died, 1 unavailable) Selective outcome reporting: No **Risk of Bias: Moderate**
Volk, 2008[42] (United States)	PSA	Men 50 to 70 years old if not African American (40 to 70 if African American), visit to clinic for non-acute care, no history of prostate cancer	I: Interactive multimedia decision aid (n=224; 76 at low literacy site, 148 at high literacy site) C: Audiobooklet without interactivity and entertainment factors (n=226; 73 at low literacy site, 153 at high literacy site)	*Patients completing 2 week follow-up* n=89 at low literacy site Age (yr): 56 Gender (Male %): 100 Race/Ethnicity (%):African American 73, , Hispanic 9, white 18 Previous Screen (%): 37 n=263 at high literacy site Age (yr): 57 Gender (Male %): 100 Race/Ethnicity (%):African American 17 , Hispanic 8, white 65 Previous Screen (%): 75%	General medicine clinic at publicly funded hospital (low health literacy site) and university-affiliated family medicine clinic (high health literacy site)	Post-intervention and 2 weeks Withdrawals: 13/450 (2.9%) at post-intervention follow-up 85/437 (19%) at 2 week follow-up 98/450 (21.8%) total (including 16% from high literacy site and 40% from low literacy site)	Sequence generation: Unclear Allocation concealment: Unclear Blinding: Unclear Incomplete outcome data: Total of 21.8% lost at 2 week follow-up Selective outcome reporting: No **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Watson, 2006[43] (United Kingdom)	PSA	Men age 40 to 75 years, no history of prostate cancer	I: Copy of brief patient decision aid and questionnaire (n=980 randomized; 468 analyzed) C: Questionnaire only (n=980 randomized, 522 analyzed)	Age (yr): sample was stratified by age group (40-49, 50-59, 60-69, 70-75) Gender (Male %): 100 Race/Ethnicity (%): white 97%, black 1%, Asian 1% Previous Screen (%): 16	11 general practices in England and Wales	Intervention and control components were sent to patients followed by a single reminder 5.6% did not receive intervention 54% of delivered questionnaires were returned and eligible 7 questionnaires (of 475 returned by intervention group) were excluded; no exclusions in control group	Sequence generation: Adequate Allocation concealment: Adequate (mailed intervention) Blinding: N/A – self-administered questionnaire Incomplete outcome data: Yes Selective outcome reporting: No **Risk of Bias: Moderate**

AUTHOR, YEAR (COUNTRY)	SCREENING OPTIONS	TARGET POPULATION	INTERVENTION (I) (n) COMPARATOR (C) (n)	SAMPLE CHARACTERISTICS	SETTING	LENGTH OF FOLLOW-UP % WITHDRAWALS	RISK OF BIAS
Wilkes, 2013[44] (United States)	PSA	Men age 55 to 65 years, no serious comorbidity, English speaking	I1: Interactive Web-based educational program (MD-Ed); 30 min (19 waiting areas; 41 physicians with 246 patients) 12: MD-Ed plus Web-based patient activation (30 min) (MD-Ed+A) (19 waiting areas; 36 physicians with 113 patients) C. usual practice (17 waiting areas; 43 physicians with 353 patients) All patients had access to CDC brochure in waiting area	*Patients (n=581 analyzed)* Age (yr): 63 Gender (Male %): 100 Race/Ethnicity (%): 82% white, 8% Hispanic, 8% African American, 5% Asian Previous Screen (%): 83%	2 large primary care networks associated with academic medical center, 2 staff model HMOs; 1 medical group practice network (all in California)	Length of follow-up: Varied (study complete after standardized patient visit) Withdrawals: No physicians withdrew, 15 (12.5%) did not start intervention and were analyzed with usual practice group 14% of patients did not return questionnaire or had incomplete data; additional 5% were found to have prior prostate cancer; 33 patients of physicians who did not start intervention were analyzed with usual practice group	Sequence generation: Adequate Allocation concealment: Adequate Blinding: patients were not aware of physician assignment (cluster randomized trial with waiting areas randomized); physicians were not aware of which patients were involved in the study or who completed the educational program Incomplete outcome data: Yes; 14% of patients did not return questionnaire and 5% who returned questionnaire had prior prostate cancer Selective outcome reporting: No **Risk of Bias: Moderate**

k = number of studies; DA=Decision Aid; DRE = digital rectal examination; FIMDM = Foundation for Informed Medical Decision Making, Inc.; HMO = health maintenance organization; PSA = prostate-specific antigen

Table 12. Characteristics of Interventions from Prostate Cancer Studies

AUTHOR, YEAR	DELIVERY MODE	DELIVERY TIMING and LOCATION	VALUES CLARIFICATION EXERCISE	RISK COMM. METHOD	CONSIDERED HEALTH LITERACY or NUMERACY	RESOURCES (COST, STAFF, PHYSICAL)
Davison, 1999[25]	Verbal & written	Before a periodic health examination (PHE) in clinic	None	Not clear	Not clear	Not clear
Evans, 2010[26]	Web / text of web	Identified from patient registry but not tied to appointment At home	Decision stacker (web)	Not clear	Not clear	Not clear
Frosch, 2003[27]	Web version of video DA	Before health appraisal appointment Anywhere (web) in clinic (video)	None	Not clear	Not clear	Not clear
Frosch, 2008[28]	Internet (4 conditions)	2-3 weeks before Health Appraisal appointment Anywhere	DTM: Time trade off exercise and visual analog ratings	Not clear	Not clear	Not clear
Gattellari, 2003[29]	Print – distributed in clinic	Prior to appointment in general practice clinic	Social matching - Series of statements consistent with PSA- - determine which statements "sound like them"	Pictograms and flow diagrams	Flesch-Kinkaid grade level for intervention booklet =7.3 Flesch-Kinkaid level for comparison booklet 11.2	Not clear
Gattelari, 2005[30]	Audio, video information packages; Booklets and peer coaching	Not tied to a specific appointment Unclear	None	Not clear	Not clear	Medical peer educators to deliver peer coaching sessions
Kripalani, 2007[31]	Pamphlets (High-detail, low-detail)	In waiting room before appointment	No	Pictograph	Written at 6th grade level, designed for low-literacy patients; assessed subject literacy	Trained interviewers
Krist, 2007[32]	Internet or paper version	Within 2 weeks of visit Home	None	Not clear	Not clear	Not clear

AUTHOR, YEAR	DELIVERY MODE	DELIVERY TIMING and LOCATION	VALUES CLARIFICATION EXERCISE	RISK COMM. METHOD	CONSIDERED HEALTH LITERACY or NUMERACY	RESOURCES (COST, STAFF, PHYSICAL)
Lepore, 2012[33]	Telephone (Initial 20 min call, brief follow-up call approx. 1 week later)	Health insurance o appointment Home	Interventionists described 5 potential risks and 5 potential benefits of testing and asked participant after each one whether the information influenced interest in getting tested	Not clear	Pamphlet was designed for men with low literacy Knowledge test items were piloted to ensure comprehension	Telephone interventionists (graduate level health-educators)
Myers, 2011[34]	Face-to-face counseling session	Scheduled visit for non-acute care Clinic	Counseling session included discussion of factors influencing screening decision and relative influence and strength	Not clear	Not clear	Study nurse educator (training sessions and patient sessions)
Partin, 2004[35] Partin, 2006[36]	Video or pamphlet	Mailed 2 weeks before appointment Home	None	Not clear	Pamphlet written at 6th grade level Video designed for 100% comprehension at 10th grade level	Not clear
Schapira, 2000[37]	Pamphlet	2 weeks before appointment with physician or research physicians Clinic	None	Pictograph to show frequencies of outcomes per 100 men	Research assistant present and available to answer questions when patients read pamphlets Assessment tools were pilot-tested	Research assistant present
Sheridan, 2012[38]	1. Video (12 minutes) 2. Coaching session (8 minutes) led by trained health counselor 3. Supplemental brochure	1 hour prior to appointment Private room at the clinic	a. In video: social matching with 2 men making opposite decisions using the same facts b. In coaching session: men to read series of 2 opposing statements and chose which best represented their thinking	Not clear	Not clear	1 hour educational session for physicians 8 min coaching time
Taylor, 2013[39]	Web-based or Print DA	Reviewed at home	Yes	Pictographs	DAs have 8th grade reading level; assessed health-related numeracy	Not clear

AUTHOR, YEAR	DELIVERY MODE	DELIVERY TIMING and LOCATION	VALUES CLARIFICATION EXERCISE	RISK COMM. METHOD	CONSIDERED HEALTH LITERACY or NUMERACY	RESOURCES (COST, STAFF, PHYSICAL)
Volk, 1999[40] Volk, 2003[41] (1 year follow-up)	Video (20 min) Or brochure on risks & benefits	Before scheduled office visit In clinic	None	Not clear	Knowledge assessment tool written at 5th grade reading level; Spanish version available if patient requested	Office visit for video
Volk, 2008[42]	"Edutainment" decision aid combining storyline with factual medical information	Before scheduled office visit In clinic	Social-matching – patient asked to pick character who most resembles how they feel	Not clear	Had low health literacy and high health literacy sites	Not clear
Watson, 2006[43]	Printed material	Not associated with a visit Reviewed at home	None	Not clear	"conformed to accepted standards for the provision of patient information;" decision aid was field-tested with the target population	Not clear
Wilkes, 2013[44]	Interactive Web-based education program	Physician education prior to all patient visits (location not specified) Patient education 60 min prior to visit (in clinic)	Educational programs included questions about individual's values and preferences	Visual risk comparison diagrams (MD and patient programs) Vignettes for potential harms (patient program)	Not specified	Research associate to assist patients in completing Web-based program Standardized patients (8 actors, 20 hours of training each, 120 physician visits)

Table 13. Decision Quality Outcomes Assessed in Prostate Cancer Studies

AUTHOR, YEAR	KNOWLEDGE		PATIENT ROLE IN DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Davison, 1999[25]	-	-	Active 31/50 (62%) Passive 9/50 (18%) Collaborative 10/50 (20%) Z=-4.07, P < .001	Active 11/50 (22%) Passive 19/50 (38%) Collaborative 20/50 (40%)	-	-
Evans, 2010[26]	*Mean (Range -12 to +12)* Prosdex 4.90 Paper 5.40 Prosdex vs paper U/mn=0.47 (95%CI 0.39, 0.55), P = .48	Questionnaire control group (QCG) 2.17 Prosdex vs QCG U/mn=0.70 (95%CI=0.62, 0.76), P < .001	-	-	-	-
Frosch, 2003[27]	*Knowledge about prostate cancer screening and testing (0-5 scale):* Pretest 1.84 (0.10) Posttest 1.92 (0.90)	Pretest 2.90 (0.12) Posttest 3.47 (0.12) P < .001	-	-	-	-
Frosch, 2008[28]	Mean (SD) – imputed TDA 8.14 (0.15) DTM 7.69 (0.15) Combined 7.71 (0.15) Mean (SD) – complete data TDA 8.65 (0.18) DTM 8.03 (0.18) Combined 8.03 (0.18)	Mean (SD) – imputed 7.24 (0.16) Mean (SD) – complete data 7.49 (0.19)	-	-	*DCS Values clarity subscale* TDA 32.25 DTM 36.62 Combined 38.24 TDA vs other groups, P < .05	*DCS Values clarity subscale* 37.93
Gattellari, 2005[29]	Mean 6.1	4.8 P ≤ .001	*Decisional Control-Patient passive* 5/135 (3.7)	*Decisional Control-Patient passive* 35/139 (25.2) OR=0.11 (0.04-0.31), P < .001	-	-
Gattellari, 2003[30]	Mean % correct = 50% (no SD provided) P = .049	Mean % correct = 45%	-	-	Mean (SD) Pretest 2.2 (1.31) Posttest 1.7 (1.4-2.0)	Mean (SD) Pretest 2.4 (1.33) Posttest 1.4 (1.0-1.6)

AUTHOR, YEAR	KNOWLEDGE		PATIENT ROLE IN DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Kripalani, 2007[31]	-	-	*Frequency of prostate cancer discussion with health care provider* PtEd: 50.0%, aOR=1.92 (95%CI 1.01, 3.65), P < .05 Cue: 58.0%, aOR=2.39 (95%CI=1.26, 4.52), P = .008 *Proportion of patients who initiated the discussion:* PtEd: 47.6%, P < .01 Cue: 40.0%, P < .01	*Frequency of prostate cancer discussion with health care provider* Control: 37.3, P = .03 *Proportion of patients who initiated the discussion:* Control: 9.7%	-	
Krist, 2007[32]	*% of knowledge questions answered correctly:* Web-based: 69% Brochure: 69%	*% of knowledge questions answered correctly:* Control: 54% P < .001 vs either Web-based or brochure interventions	*CPS (n=431)* Web-based: increased involvement in relative to control (P = .03) A (Complete patient control) = 17% B = 39% C (Collaborative) = 36% D = 3% E (Complete physician control) = 5% Brochure: increased involvement relative to control (P = .03) A = 23% B = 31% C = 36% D = 4% E = 6%	*CPS* Control: A (Complete patient control) = 11% B = 34% C(Collaborative) = 36% D = 10% E (Complete physician control) = 9%	-	
Lepore, 2012[33]	*% Correct* Pretest 51.7% (SE 0.012) Posttest 61.6% (SE 0.009)	*% Correct* Pretest 49.6% (SE 0.012) Posttest 54.7% (SE 0.009) Condition by time interaction; P < .001	*Talked to MD about PC screening* Intervention: 34/215 (15.8%) Exp(B) 2.127, P < .001	*Talked to MD about PC screening* Control: 18/216 (8.3%)	-	-
Myers, 2011[34]	*10 items, range 1 to 10* Baseline: 3.8 (1.9) Endpoint : 5.3 (2.0)	Baseline: 3.6 (2.1) Endpoint: 4.4 (2.1); P = .001	-	-	-	-

AUTHOR, YEAR	KNOWLEDGE		PATIENT ROLE IN DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Partin, 2004[35] Partin, 2006[36]	*10 items, range 1 to 10* Pamphlet: 7.3 [7.0, 7.5]; P = .001 vs control Video: 7.4 [7.2, 7.7]; P = .03 vs control	Usual care: 6.9 [6.7, 7.1]	*Discussed PSA* Video: 35% P = .33 vs control Pamphlet: 41% P = .03 vs control	*Discussed PSA* Control: 32%	-	-
Schapira, 2000[37]	*18 items* Baseline: 11.7 (2.4) Post-intervention: 15 (2.3)	*18 items* Baseline: 11.4 (2.4); P = .32 Post-intervention: 14.1 (2.7); P < .01	-	-	-	-
Sheridan, 2012[38]	*% men have "key knowledge" (correct responses to 4 key questions)* 47% (27/58)	*% men have "key knowledge" (correct responses to 4 key questions)* 13% (9/70) Absolute difference 34% [95%CI 19, 50] aRR 4.28 [95% CI 2.30, 6.45]	*% men reporting shared decisions, post-visit* 74% (28/38)	*% men reporting shared decisions, post-visit* 76% (39/51) Absolute difference -3% [95% CI -21, +15%] aRR 0.96 [95%CI 0.67, 1.15]	*'PSA is a Decision' score* 64% (37/58)	*'PSA is a Decision' score* 23% (16/70) Absolute difference 41% [95% CI 25, 57%] aRR 2.79 [95%CI 1.96, 3.47]
Taylor, 2013[39]	*PCa screening knowledge, mean (SD)* *1 mo* Web DA: 13.5 (3.4) Print DA: 13.5 (3.5) Print vs web P = .90 *13 mo* Web DA: 12.6 (3.4) Print DA: 12.7 (3.3) Print vs web P = .65	*PCa screening knowledge, mean (SD)* *1 mo* 11.1 (3.1) UC vs web P = .001 UC vs print P = .001 *13 mo* 11.0 (3.0) UC vs web P = .001 UC vs print P = .001	-	-	-	-
Volk, 1999[40] Volk, 2003[41] (1 year follow-up)	Baseline: 2.7 (of 10 questions) correct 2 weeks: 4.8 Change: +2.1, P = .001 1 year follow-up: 3.8 (of 10 questions) correct	Baseline: 2.8 (of 10 questions) correct 2 weeks: 3.1 Change: +0.3, P = .19 1 year follow-up: reported unchanged Across data collection periods: P < .001 for group differences	-	-	-	-

AUTHOR, YEAR	KNOWLEDGE		PATIENT ROLE IN DECISION		VALUES CLARITY	
	Intervention	Control	Intervention	Control	Intervention	Control
Volk, 2008[42]	Both low- and high-literacy site patients had significant improvements in knowledge regardless of decision aid received; no significant differences between the decision aids in subject's knowledge gains		*PSAS-Low Literacy Site*[a] Total: 1.66 [1.56, 1.76] *PSAS-High Literacy Site*[a] Total: 2.41 [2.34, 2.47]	*PSAS-Low Literacy Site* Total: 1.75 [1.67,1.84]; P=0.15 *PSAS-High Literacy Site* Total: 2.45 [2.39, 2.47]; P = .38	-	-
Watson, 2006[43]	*U.K. specific measure developed for the study (12 items)* Median 9.0 (range 0-12)	*U.K. specific measure developed for the study (12 items)* Median 3.0 (range 0-12); P < .0001)	Patient makes decision: 106/985 (11%) Patient makes decision after considering doctor's opinion: 421/985 (43%) Shared decision: 324/985 (33%) Doctor makes final decision after considering patient's opinion: 64/985 (6%) Doctor makes decision: 70/985 (7%)		Decisional balance score (mean) -3.5 (SE 0.9)	+3.3 (SE 0.8); P < .0001 indicating less favorable assessment of the "pros" of screening vs the "cons" in the intervention group
Wilkes, 2013[44]	-	-	*Physician report: Change in Shared Decision Making (Kaplan Scale), sum mean score (SD)* MD-Ed: 0.2 (1.5) (AMD -0.05 [-0.72, 0.61] vs control) MD-Ed+A: 0.1 (1.5) (AMD -0.10 [-0.77, 0.56] vs control) *Patient report: Perception of shared decision making post-visit*[b] MD-Ed: 11.4 (3.0) (AMD -0.29 [-1.30, 0.71] vs control) MD-Ed+A: 12.3 (3.0) (AMD 0.87 [-0.17, 1.90] vs control)	*Physician report: Change in Shared Decision Making (Kaplan Scale), sum mean score (SD)* Control: 0.2 (1.5) *Patient report: Perception of shared decision making post-visit* Control: 11.8 (3.0)	-	-

aOR = adjusted odds ratio; aRR = adjusted risk ratio; AMD = adjusted mean difference; NR = not reported; MD-Ed = physician education; MD-Ed+A = physician education with patient activation

[a] Low literacy version of Patient Self-Advocacy Scale (PSAS) used at low literacy site; standard 12-item version used at high literacy site; lower scores indicate greater self-advocacy but scores across sites should not be compared

[b] Kaplan shared decision making instrument (modified to be specific for prostate cancer screening); sum of 4 elements; 4=strongly disagree, 16=strongly agree

Table 14. Decision Impact Outcomes Assessed in Prostate Cancer Studies

AUTHOR, YEAR)	DECISIONAL CONFLICT[a]		USE OF HEALTH SERVICES		DECISION SATISFACTION	
	Intervention	Control	Intervention	Control	Intervention	Control
Davison, 1999[25]	28.52 Effect size: *Z*= -3.602, P < .00001	35.20	-	-	-	-
Evans, 2010[26]	Prosdex 40.37 Paper 38.49 Prosdex vs paper U/mn=0.56 (95%CI=0.47-0.64), P = .18	QCG 47.73 Prosdex vs control U/mn=0.32 (95%CI=0.25-0.40), P < .001	-	-	-	-
Frosch, 2003[27]	-	-	-	-	-	-
Frosch, 2008[28]	*DCS subscale scores* Feel informed TDA 23.4 DTM 27.23 Combined 27.3 Value clarity TDA 32.3 DTM 36.6 Combined 38.2 Feel supported TDA 30.5 DTM 33.8 Combined 35.4	*DCS subscale scores* Feel informed 29.7 Value clarity 37.9 Feel supported 35.2 P < .05 TDA vs other groups for 3 subscales	-	-	-	-
Gattellari, 2003[29]	*DCS Uncertainty subscale mean* 8.1 (no sd) p=.93 *Factors contributing to uncertainty subscale mean* 21.6 (no SD) P ≤ .001	*DCS Uncertainty subscale mean* 8.1 *Factors contributing to uncertainty mean* 24.3	-	-	-	-
Gattellari, 2005[30]	*Mean score (range 9-45)* *No SD provided* 25.4 (95%CI 24.5-26.3)	*Mean score (range 9-45)* *No SD provided* 27.8 (95%CI 26.6-29.0), P = .0002	-	-	-	-
Kripalani, 2007[31]	-	-	-	-	-	-
Krist, 2007[32]	Web-based: 1.55 (range 1, 2.7) Brochure: 1.54 (range 1, 2.8)	Control: 1.58 (range 1, 3.2) p=NS vs intervention groups	*Patient report of minutes discussing PCa, mean* Internet: 5.1 (range 0, 15) Brochure: 5.3 (range 0, 25)	*Patient report of minutes discussing PCa, mean* UC: 5.2 (range 0, 20) NS	-	-
Lepore, 2012[33]	34.15 (SE 1.64)	39.85 (SE 1.64) F(1,427)=6.05, P < .05			-	-

AUTHOR, YEAR)	DECISIONAL CONFLICT[a]		USE OF HEALTH SERVICES		DECISION SATISFACTION	
	Intervention	Control	Intervention	Control	Intervention	Control
Myers, 2011[34]	*0-4 (higher scores indicated higher decisional conflict)* *0.29 (0.34)*	0.32 (0.49) P = .62	-	-	-	-
Partin, 2004[35] Partin, 2006[36]	-	-	-	-	-	-
Schapira, 2000[37]	-	-	-	-	-	-
Sheridan, 2012[38]	-	-	-	-	-	-
Taylor, 2013[39]	*1 mo* Web DA: 12.7 (21.0) Print DA: 12.2 (19.3) Print vs web P = .70 *13 mo* Web DA: 11.4 (19.5) Print DA: 10.7 (16.9) Print vs web P = .61	*1mo* 20.0 (23.7) UC vs web P = .001 UC vs print P = .001 *13 mo* 15.0 (21.2) UC vs web P = .001 UC vs print P = .001	-	-	*Satisfaction with Decision Scale*[b]; % high satisfaction: *1 mo* Web DA: 52.2 Print DA: 60.4 Print vs web P = .01 *13 mo* Web DA: 50.4 Print DA: 55.7 Print vs web P = .10	*Satisfaction with Decision Scale*; % high satisfaction: *1 mo* 45.5 UC vs web P = .001 UC vs print P = .03 *13 mo* 49.8 UC vs web P = .85 UC vs print P = .06
Volk, 1999[40] Volk, 2003[41] (1 year follow-up)	-	-	-	-	*SWD*[b] Mean = 24.3 [23.7, 25.0]	*SWD* Mean = 23.8 [22.9, 24.7] NS
Volk, 2008[42]	*Low Literacy Site DCS*[c] Total: 12 [5, 19] *High Literacy Site DCS*[c] Total: 13 [10, 15]	*Low Literacy Site DCS* Total: 22 [15, 28]; P = .04 *High Literacy Site DCS* Total: 15 [13, 17]; P = .15	-	-	-	-
Watson, 2006[43]	-	-	-	-	-	-
Wilkes, 2013[44]	-	-	-	-	-	-

DA = decision aid; NA = not applicable; SA = strongly agree; SD = strongly disagree

[a] Scores are mean of Decisional Conflict Scale (DCS) unless otherwise noted; higher scores indicate greater decisional conflict

[b] Satisfaction with Decision Scale (SWD): 6 items, 5 point scale

[c] Low literacy version (10 item) of DCS used at low literacy site; standard 16-item version used at high literacy site; scores across sites should not be compared

Table 15. Decision Action Outcomes Assessed in Prostate Cancer Studies

AUTHOR, YEAR	SCREENING INTENTION		SCREENING BEHAVIOR	
	Intervention	Control	Intervention	Control
Davison, 1999[25]	-	-	DRE and PSA: 28%	DRE and PSA: 21% "no significant differences"
Evans, 2010[26]	*% men who were very likely to or definitely would get PSA* Prosdex: 40 (n=89) Paper: 53 (n=86) Prosdex vs paper: U/mn=0.43 (95%CI 0.35, 0.51), P = .10	*% men who were very likely to or definitely would get PSA* QCG: 58 (n=103) Prosdex vs QCG: U/mn=0.40 (95%CI 0.32, 0.48), P = .02	*6 month PSA uptake - % (n)* Prosdex: 3.1 (4/127) Paper: 9.1	*6 month PSA uptake - % (n)* QCG: 8.9 (11/123) Prosdex vs QCG: Pearson chi-square P = .014 No QCG: 1.6 (2/126)
Frosch, 2003[27]			91.9% PSA request	81.5% PSA request P < .05
Frosch, 2008[28]	-	-	*Reduction in PSA sx pre-post (%)* TDA 9.1 DTM 8.7 Combined 5.3	*Reduction in PSA sx pre-post (%)* 3.3 Single intervention vs combined or control group (OR=3.31, 95% CI 1.01, 10.74, P = .047)
Gattellari, 2005[29]	*Would not opportunistically discuss PSA* 112/135 (83) *Would not opportunistically sx* 102/135 (75.6) *Would not order PSA for men with LUTS* 90/135 (66.7)	*Would not opportunistically discuss PSA* 93/140 (66.4) *Would not opportunistically sx* 41/140 (29.3) *Would not order PSA for men with LUTS* 4/140 (2.9)	*Median # tests ordered per provider (IQR)* 1 (0-2)	*Median # tests ordered per provider (IQR)* 2 (0-5) RR 0.52 (95% CI 0.38, 0.75), P = .0004
Gattellari, 2003[30]	Definitely interested in PSA in next 12 months 27/106 (26%) Quite a lot 11/106 (11%) Somewhat 19/106 (18%) Definitely not interested in PSA in next 12 months 23/106 (22%)	Definitely interested in PSA in next 12 months 25/108 (23%) Quite a lot 14/108 (13%) Somewhat 21/108 (20%) Definitely not interested in PSA in next 12 months 25/108 (23%)	-	-
Kripalani, 2007[31]	-	-	*PSA test ordered, % (N)* PtEd 14.1% (12) vs control: aOR=7.62, 95%CI 1.62, 35.83, P = .01 Cue 12.3% (10) vs control: aOR=5.86, 95%CI 1.24, 27.81, P = .03 *DRE documented, % (N)* PtEd 4.7% (4) vs control: aOR=0.85, 95%CI 0.21, 3.37, P = .81 Cue 6.2% (5) vs control: aOR=1.04, 95%CI 0.29, 3.76, P = .95	*PSA test ordered, % (N)* 2.4% (2) *DRE documented, % (N)* 6.0 (5)

AUTHOR, YEAR	SCREENING INTENTION		SCREENING BEHAVIOR	
	Intervention	Control	Intervention	Control
Krist, 2007[32]	-	-	*PSA test ordered* Web-based Patient report: 86% Physician report: 86% (P = .06 vs control) Brochure Patient report: 83% Physician report: 85% (P = .04 vs control)	Control Patient report: 85% Physician report: 94% (P = .06 for patient vs physician)
Lepore, 2012[33]	Plan to test for prostate cancer Pretest: 61% Posttest: 81%	Plan to test for prostate cancer Pretest: 59% Posttest: 81% P = ns	*Verified PSA* 1 year: 45% 2 year: 63%	*Verified PSA* 1 year: 46% 2 year: 67% P = ns
Myers, 2011[34]	-	-	*Within 120 days of visit* 63% (n=152) *Visit with physician aware of screening controversy:* 64% *Visit with physician unaware of screening controversy*: 60%	*Within 120 days of* visit 71% (n=153) OR 0.67 [0.41, 1.08]; P = .102 *Physician aware of controversy:* 81% (P = .004) *Physician unaware of controversy:* 50% (P = .37)
Partin, 2004[35] Partin, 2006[36]	Intend to have PSA in next year Video: 63%; P < .05 vs control Pamphlet: 65%; P < .05 vs control	Control: 74%	*PSA within 2 weeks* Video: 29% Pamphlet: 28% *PSA within 1 year* Video: 70% Pamphlet: 67%	*PSA within 2 weeks* Control: 29% *PSA within 1 year* Control: 69% All P = ns
Schapira, 2000[37]	-		*Prostate cancer screening completed* 82%	84% (P = .60)
Sheridan, 2012[38]	26/58 (45%)	55/70 (79%) Absolute difference -34% [-50, -18] aRR 0.18 [0.06, 0.48]	*After visit* 4/58 (11%) *At 9 month review* 11/58 (19%)	*After visit* 16/70 (31%) Absolute difference -21% [-38, -4] aRR 0.42 [0-.14, 1.24] *At 9 month review* 29/70 (41%) Absolute difference -22% [-38, -7] aRR 0.76 [0.50, 0.97]
Taylor, 2013[39]	-	-	*Self-reported screening (PSA or DRE), % (n)* Web DA: 59.3 (258) Print DA: 59.5 (282) Web vs Print P = .95	*Self-reported screening (PSA or DRE), % (n)* 56.3 (281) Wed vs UC P = .35 Print vs UC P = .25

AUTHOR, YEAR	SCREENING INTENTION		SCREENING BEHAVIOR	
	Intervention	Control	Intervention	Control
Volk, 1999[40] Volk, 2003[41] (1 year follow-up)	Preferring to have PSA test Baseline: 62/78 (79%) 2 weeks: 48/78 (62%) P = .01	Preferring to have PSA test Baseline: 62/80 (78%) 2 weeks: 64/80 (80%) P = .82 Absolute difference 18.5% [4.6, 32.4]; P = .009	*During 1 year follow-up* DRE: 26/70 (37%) PSA: 24/70 (34%)	*During 1 year follow-up* DRE: 26/67 (39%); P = .84 PSA: 37/67 (55%); P = .01
Volk, 2008[42]	-	-	-	-
Watson, 2006[43]	119/465 (25.6%) reported positive testing intentions	149/512 (29.1%) reported positive testing intentions OR 0.82 [0.61, 1.09]; P = .17	-	-
Wilkes, 2013[44]	-	-	Reported that PSA tests were ordered for 32% of patients overall with similar frequency among groups	

k = number of studies; DRE = digital rectal examination; FOBT = fecal occult blood test; W&S = wait and see; BE = barium enema; COL = colonoscopy; PSA = prostate specific antigen; ns = not statistically significant; OR = odds ratio; aOR = adjusted odds ratio; aRR = adjusted risk ratio; sx = screen

APPENDIX E. DECISION QUALITY AND DECISION IMPACT MEASURE PATTERNS IN INCLUDED STUDIES

Measure	Measure Description	SDM Intervention ↑	No Intervention Effect	SDM Intervention ↓
Decision Quality				
Knowledge				
Investigator-developed measure	(number of items)	Evans 2010 (12)[26] Frosch 2003 (5)[28] Gattellari 2005 (7)[29] Lepore 2012 (14)[33] Mathieu 2007 (10)[19] Mathieu 2010 (10)[20] Myers 2011 (10)[34] Schapira 2000 (18)[37] Schroy 2011/2012 (12)[22,23] Taylor 2013 (18)[39] Trevena 2008 (10)[24] Watson 2006 (18)[43]		
Previously validated index (Radosevich 2004)[46]	10 items; sum of correct responses	Frosch 2008[28] Partin 2004/2006[35,36] Sheridan 2012 (4 items)[38]		
PC-Know (O'Dell 1999);[47] developed for Volk 1999/2003[40,41]	10 items; scored % of correct answers	Krist 2007[32] Gattellari 2003[29] Volk 1999/2003[40,41]	Volk 2008[42]	
Values Clarity				
Decision Conflict Scale: Values Subscale (O'Connor 1995)[54]	0-100; values considered "clear" if score is ≤ 25	Frosch 2008[28]	Trevena 2008[24]	Mathieu 2007[19]
Decisional Balance Score (created by authors)	12 items; Summary measure	Watson 2006[43]		
Dormandy Scale (Dormandy 2006)[48]	0-100; score≥ 50 = positive mamm. attitudes, score < 50 = negative mammo. attitudes		Mathieu 2010[20]	
Indecision about screening intention	Made a decision about intention			Mathieu 2007[19] Mathieu 2010[20]
Strength of agreement with PSA, modified from previous attitude measures (Rakowski 1997)[49]	range -5 to +5		Gattellari 2003[29]	
"PSA is a Decision" item (1 of 3) (McCormack 2011)[50]	1 item; 5 responses	Sheridan 2012[38]		

Measure	Measure Description	SDM Intervention ↑	No Intervention Effect	SDM Intervention ↓
Patient's Role in Decision				
Control Preferences Scale (CPS) (Degner 1992)[51]	1 item; 5 responses reflecting SDM preference	Davison 1999[25] Gattellari 2005[30] Krist 2007[32]	Sheridan 2012[38] Watson 2006[43]	
Discussed PSA		Kripalani 2007[31] Lepore 2012[33] Partin 2004/2006[35,36]		
Modified from Kaplan's SDM instrument (Kaplan 1995)[45]	Perception of SDM 4 4-point scales		Wilkes 2013[44]	
Patient Self Advocacy Scale (PSAS) (Brashers 1999)[52]	12 item; 5 point scale		Volk 2008[42]	
Patient perception of how screening decision was made (Strull 1984)[53]	1 item; 5 responses		Dolan 2002[21]	
Decision Impact				
Decision Conflict				
Decision Conflict Scale (DCS) (O'Connor 1995)[54]	16-item; 0 = no decisional conflict, 100 = extreme decisional conflict		Krist 2007[32] Mathieu 2007[19] Myers 2011[34] Volk 2008[42a]	Davison 1999[25] Dolan 2002[21] Evans 2010[26] Frosch 2008[28] Gattellari 2003[29] Lepore 2012[33] Taylor 2013[39] Volk 2008[42a]
Provider Decision Process Assessment Instrument (Dolan 1999)[55]	Extent to which GPs experience uncertainty; 9 items (range 9-45)			Gattellari 2005[30]
Decision Satisfaction				
Satisfaction with the Decision-Making Process Scale (SDMP) (Barry 1997)[56]	12-item; scores range from 5 to 60	Schroy 2011/2012[22,23]		
Satisfaction with Decision (SWD) (Holmes-Rovner 1996)[57]	6-item; 5 point responses	Taylor 2013[39b]	Taylor 2013[39b] Volk 1999/2003[40,41]	
Use of Services				
Consultation length	Minutes		Krist 2007[32]	

[a] High literacy version of DCS no intervention effect; low literacy version of DCS intervention group lower DCS score
[b] Intervention group had higher SWD scores at time 1 (1 month), but no significant difference at time 2 (13 months)

APPENDIX F. STRENGTH OF EVIDENCE

Outcome Category	Outcome (# of Studies Reporting)	Results Shared Decision Making vs Control	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Breast Cancer (k=2)							
Decision Quality ***Overall Strength of Evidence: Low***	**Knowledge (2)**	77% (Intervention) vs 57% (Control); P = .02 (Mathieu 2007)[19] 94% (Intervention) vs 83% (Control); P < .001 (Mathieu 2010)[20]	Moderate (2)	Consistent (based on direction)	Direct	Precise (based on p-values)	Moderate
	Values Clarity (2)	Means: 19.5 (Intervention) vs 22.6 (Control); P = .02 (Mathieu 2007)[19] Positive values: 79% (Intervention) vs 79% (Control); p=ns (Mathieu 2010)[20]	Moderate (2)	Inconsistent	Direct	Imprecise	Low
	Patient's Role in Decision (0)						Insufficient
Decision Impact ***Overall Strength of Evidence: Insufficient***	**Decisional Conflict (1)**	Means: 20.1 (Intervention) vs 21.9 (Control); P = .12 (Mathieu 2007)[19]	Moderate	NA	Direct	Unclear	Low
	Use of Services (0)						Insufficient
	Decision Satisfaction (0)						Insufficient
Decision Action ***Overall Strength of Evidence: Low***	**Screening Intention (2)**	OR=1.28 [0.63, 2.61]; P = .50 (Mathieu 2007)[19] Intention to Screen: 52% (Intervention) vs 65% (Control); P = .05 (Mathieu 2010)[20]	Moderate (2)	Inconsistent	Direct	Imprecise	Low
	Screening Behavior (1)	Screened: 6% (Intervention) vs 7% (Control); p=ns (Mathieu 2007)[19]	Moderate	NA	Direct	Unclear	Low
Colorectal Cancer (k=3)							
Decision Quality ***Overall Strength of Evidence: Low***	**Knowledge (2)**	DA: SMD=1.06 [0.88, 1.24] (Schroy 2012)[23] DA+YDR: SMD=0.92 [0.75, 1.10] (Schroy 2012)[23] RR 3.58 [1.69, 7.57] (Trevena 2008)[24]	Moderate (2)	Consistent (based on direction)	Direct	Precise	Moderate
	Values Clarity (1)	62% vs 59%, P = .63 (Trevena 2008)[24]	Moderate	NA	Direct	Unclear	Low
	Patient's Role in Decision (1)	Perception of how screening decision were made: Shared: RR=1.23 [0.85, 1.78] (Schroy 2012)[23] Physician: RR=1.17 [0.43. 3.19] (Schroy 2012)[23] Patient: RR 0.60 [0.29, 1.22] (Schroy 2012)[23]	Moderate	NA	Direct	Imprecise	Low
Decision Impact ***Overall Strength of Evidence: Low***	**Decisional Conflict (1)**	SMD=-0.29 [-0.74, 0.15] (Dolan 2002)[21]	Moderate	NA	Direct	Imprecise	Low
	Use of Services (0)						Insufficient
	Decision Satisfaction (1)	DA: SMD=0.59 [0.41, 0.78] (Schroy 2012)[23] DA+YDR: SMD=0.50 [0.32, 0.67] (Schroy 2012)[23]	Moderate	NA	Direct	Precise	Low

Outcome Category	Outcome (# of Studies Reporting)	Results Shared Decision Making vs Control	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Decision Action ***Overall Strength of Evidence: Low***	**Screening Intention (3)**	RR=0.48 [0.23, 1.00] (Dolan 2010)[21] DA: SMD=0.30 [0.11, 0.49] (Schroy 2012)[23] DA+YDR: SMD=0.40 [0.21, 0.59] (Schroy 2012)[23] RR=0.96 [0.89, 1.05] (Trevena 2008)[24]	Moderate (3)	Inconsistent	Direct	Imprecise	Low
	Screening Behavior (3)	RR=0.94 [0.57, 1.53] (Dolan 2012)[21] DA: RR=1.24 [1.00, 1.53] (Schroy 2012)[23] DA+YDR: RR=1.07 [0.86, 1.33] (Schroy 2012)[23] Completed FOBT: 5.2% (Intervention) vs 6.6% (Control); P = .64 (Trevena 2008)[24]	Moderate (3)	Inconsistent	Direct	Imprecise	Low
Prostate Cancer (k=18)							
Decision Quality ***Overall Strength of Evidence: Moderate***	**Knowledge (12)** **Did not include Gattellari 2205 (MDs)** **Volk 2008 (No data – reported improved knowledge with no difference between 2 decision aids)** **Frosch 2003 (Comparison of 2 DAs with greater knowledge in video DA group)**	SMD=0.29 [0.02, 0.56] (Gattellari 2003)[29] SMD=0.36 [0.11, 0.60] (Schapira 2000)[37] 48% vs, 31%; P < .001 (Volk 1999/2003)[40,41] Median difference 4.0 [4.0, 5.0] (Watson 2006)[43] Means: 4.90 (Prosdex) vs 5.40 (Paper version) vs 2.17 (Control); P < .001 for Prosdex vs Control (Evans 2010)[26] SMD=0.46 [0.23, 0.69] (Internet vs Control) (Frosch 2008)[28] SMD=0.26 [0.03, 0.48] (CDTM vs Control) (Frosch 2008)[28] Means: 69% (Internet) vs 69% (Brochure), 54% (Control); both P < .001 vs Control (Krist 2007)[32] SMD=0.44 [0.20, 0.67] (Myers 2011)[34] SMD=0.24 [0.10, 0.38] (Video vs UC) (Partin 2004)[35] SMD=0.18 [0.03, 0.32] (Pamphlet vs UC) (Partin 2004)[35] 61.6 (Intervention) vs 54.7 (Control); P < .001 (Lepore 2012)[33] AD=34% [19, 50] (Sheridan 2012)[38] SMD=0.54 [0.42, 0.66] (Taylor 2013 Print)[39] SMD=0.50 [0.38, 0.62] (Taylor 2013 Web)[39]	Moderate (11) Low (1)	Generally Consistent (based on direction)	Direct	Generally Precise	Moderate
	Values Clarity (4)	1.7 (Intervention) vs 1.4 (Control); P = .056 (Gattellari 2003)[29] -3.5 (Intervention) vs +3.3 (Control) (P < .0001); SMD==0.37 [-0.50,-0.24] (Watson 2006)[43] Means: 32.3 (Traditional DA) vs 36.6 (CDTM) vs 37.9 (Control); P < .05 TDA vs others (Frosch 2008)[28] RR=2.79 [1.96, 3.47] (Sheridan 2012)[38]	Moderate (4)	Inconsistent	Direct	Imprecise	Low
	Patient's Role in Decision (7) **Did not include Gattellari 2005 (MDs)** **Volk 2008 (Comparison of 2 DAs with no significant difference)** **Watson 2006 (Baseline only)**	RR=1.28 [1.03, 1.59] (Partin 2004, Pamphlet)[35] RR=1.09 [0.87, 1.37] (Partin 2004, Video)[35] RR=1.55 [1.11,2.17] (Kripalani 2007 Cue)[31] RR=1.34 [0.94,1.90] (Kripalani 2007 Patient Ed)[31] RR=1.22 [0.91, 1.63] (Krist 2007 Active Internet vs UC)[32] RR=1.17 [0.87, 1.58] (Krist 2007 Active Brochure vs UC)[32] Means: 11.4 (MD-Ed) vs 12.3 (MD-Ed+A) vs 11.8 (UC); p=ns (interventions vs control) (Wilkes 2013)[44] RR=2.82 [1.60, 4.96] (Davison 1999 Active)[25] RR=0.90 [1.11, 3.25] (Lepore 2012)[33] RR=0.96 [0.76, 1.23] (Sheridan 2012)[38]	Moderate (6) Low (1)	Inconsistent	Direct	Imprecise	Low

Outcome Category	Outcome (# of Studies Reporting)	Results Shared Decision Making vs Control	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Decision Impact ***Overall Strength of Evidence: Low***	**Decisional Conflict (8)** **Did not include Volk 2008 (Comparison of 2 DAs with significant difference at low literacy site)** **Gattellari 2005 (MDs)**	SMD=0.00 [-0.27, 0.27] (Gattellari 2003)[29] Means: 40.4 (Prosdex) vs 38.5 (Paper version) vs 47.7 (Control); P < .001 (Prosdex vs Control) (Evans 2010)[26] Mean of Reported DCS subscale scores: 28.7 (I1) vs 32.5 (I2) vs 34.3 (UC); P < .05 for I1 vs Control (Frosch 2008)[28] Means: 1.6 (Internet) vs 1.5 (Brochure) vs 1.6 (UC); p=ns (Krist 2007)[32] SMD=-0.07 [-0.30, 0.16] (Myers 2011)[34] Means: 28.5 (Intervention) vs 35.2 (Control); P < .0001 (Davison 1999)[25] SMD=-0.24 [-0.43, -0.05] (Lepore 2012)[33] SMD=-0.22 [-0.34, -0.10] (Taylor 2013 Print)[39] SMD=-0.18 [-0.30, -0.05] (Taylor 2013 Web)[39]	Moderate (7) Low (1)	Inconsistent	Direct	Imprecise	Low
	Use of Services (1)	Means: 5.1 (Internet) vs 5.3 (Brochure) vs 5.2 (UC); p=ns (Krist 2007)[32]	Moderate (1)	NA	Direct	Precise	Low
	Decision Satisfaction (2)	Means: 24.3 (Intervention) vs 23.8 (Control); p=ns (Volk 1999/2003)[40,41] RR=1.12 [0.99, 1.26] (Taylor 2012 Print)[39] RR=1.01 [0.89, 1.15] (Taylor 2012 Web)[39]	Moderate (1) Low (1)	Consistent	Direct	Precise	Low

Outcome Category	Outcome (# of Studies Reporting)	Results Shared Decision Making vs Control	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence
Decision Action ***Overall Strength of Evidence: Low***	**Screening Intention (7)** **Did not include Gattellari 2005 (MDs)**	RR=1.02 [0.88, 1.18] (Gattellari 2003)[29] RR=0.77 [0.63, 0.95] (Volk 1999)[40] RR=0.88 [0.72, 1.08] (Watson 2006)[43] Means: 40% (Prosdex) vs 53% (Paper) vs 58% (Control); P = .02 (Prosdex vs Control) (Evans 2010)[26] RR=0.69 [0.51, 0.94] (Evans 2010 Prosdex vs Control)[26] RR=0.90 [0.69, 1.18] (Evans 2010 Paper vs Control)[26] RR=0.85 [0.76, 0.95] (Video vs UC) (Partin 2004)[35] RR=0.89 [0.80, 0.99] (Pamphlet vs UC) (Partin 2004)[35] RR=1.00 [0.91, 1.09] (Lepore 2012)[33] RR=0.57 [0.42, 0.78] (Sheridan 2012)[38]	Moderate (7)	Inconsistent	Direct	Generally Precise	Low
	Screening Behavior (10) **Did not include Davison 1999 (No statistical test of results possible)** **Frosch 2003 (Comparison of 2 DAs with significantly fewer PSAs in video group)** **Frosch 2008 (Reduction in PSA pre to post)** **Wilkes 2013 (Overall PSA ordering; no data for groups)** **Gattellari 2005 (MDs)**	RR=0.98 [0.88, 1.09] (PSA+DRE) (Schapira 2000)[37] RR=0.62 [0.42, 0.92] (PSA) (Volk 1999)[40] RR=0.96 [0.62, 1.47] (DRE) (Volk 1999)[40] Means: 3% (Prosdex) vs 9% (Paper) vs 9% (Control); P = .014 (Prosdex vs Control) (Evans 2010)[26] RR=0.35 [0.12, 1.08] (Evans 2012 Prosdex vs Control)[26] RR=1.02 [0.46, 2.26] (Evans 2012 Paper vs Control)[26] RR=0.91 [0.84, 0.99] (Internet vs UC) (Krist 2007)[32] RR=0.90 [0.83, 0.98] (Brochure vs UC) (Krist 2007)[32] RR=5.12 [1.18, 22.67] (Kripalani 2007 PSA Cue vs UC)[31] RR=5.86 [1.35, 25.38] (Kripalani 2007 PSA Patient Ed vs UC)[31] RR=1.02 [0.31, 3.41] (Kripalani 2007 DRE Cue vs UC)[31] RR=0.78 [0.22, 2.81] (Kripalani 2007 DRE Patient Ed vs UC)[31] RR=0.88 [0.75, 1.04] (Myers 2011)[34] RR=0.96 [0.86, 1.07] (Video vs UC) (Partin 2004)[35] RR=0.96 [0.86, 1.07] (Pamphlet vs UC) (Partin 2004)[35] RR=0.94 [0.82, 1.08] (Lepore 2012)[33] RR=0.46 [0.25, 0.83] (Sheridan 2012)[38] RR=1.01 [0.91, 1.13] (Taylor 2012 Print)[39] RR=0.97 [0.86, 1.08] (Taylor 2012 Web)[39]	Moderate (8) Low (2)	Inconsistent	Direct	Generally Precise	Low

k = number of studies; ns = not statistically significant; SMD = standard mean difference; RR = risk ratio; AD = absolute difference; UC = usual care; DA = decision aid; YDR = "Your Disease Risk"; CDTM = Chronic Disease Trajectory Model; MD-Ed = Physicians participated in Web-based educational program ; MD-Ed+A = Physician Web-based educational program plus activated patients (patients who viewed different but related educational program); C1 = control with survey; I1 = traditional decision aid; I2 = chronic disease trajectory model

[a] Standard mean differences and risk ratios were calculated for inclusion on the strength of evidence table if authors provided data necessary for these calculations.

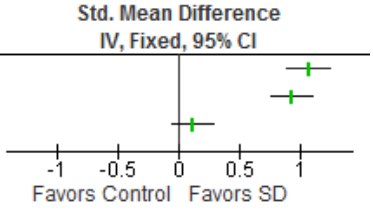
APPENDIX G. FOREST PLOTS FOR STRENGTH OF EVIDENCE ANALYSIS

COLORECTAL CANCER

1. Knowledge

Knowledge: CRC Risk Factors[a,b,c]

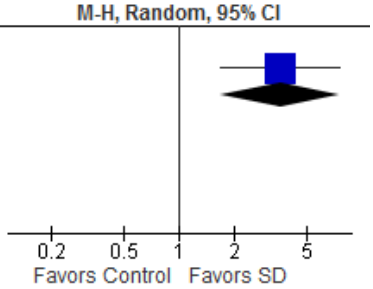
Study or Subgroup	Shared Decision Mean	SD	Total	Control Mean	SD	Total	Std. Mean Difference IV, Fixed, 95% CI
Schroy 2012 DA	10.9	1.6	269	8.6	2.6	276	1.06 [0.88, 1.24]
Schroy 2012 DA+YDR	10.7	1.9	280	8.6	2.6	276	0.92 [0.75, 1.10]
Schroy DA vs DA+YDR	10.9	1.6	269	10.7	1.9	280	0.11 [-0.05, 0.28]



[a] Range 0-None Correct to 12-All Correct)
[b] First two comparisons versus control
[c] Schroy 2012[23]

Adequate Knowledge[a]

Study or Subgroup	Shared Decision Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
2.2.1 Adequate Knowledge						
Trevena 2008	28	134	8	137	100.0%	3.58 [1.69, 7.57]
Subtotal (95% CI)		**134**		**137**	**100.0%**	**3.58 [1.69, 7.57]**
Total events	28		8			
Heterogeneity: Not applicable						
Test for overall effect: Z = 3.34 (P = 0.0008)						



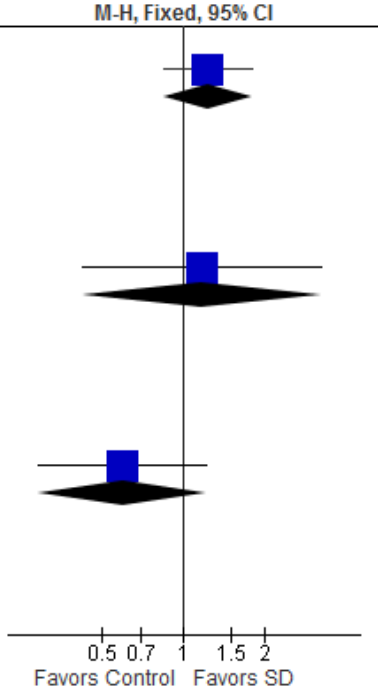
Test for subgroup differences: Not applicable

[a] Trevena 2008[24]

2. Patient's Role in Decision

Perception of How Screening Decisions Were Made[a]

Study or Subgroup	Shared Decision Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.5.1 Shared						
Dolan 2002	27	43	22	43	100.0%	1.23 [0.85, 1.78]
Subtotal (95% CI)		**43**		**43**	**100.0%**	**1.23 [0.85, 1.78]**
Total events	27		22			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.08 (P = 0.28)						
1.5.2 Primarily physician						
Dolan 2002	7	43	6	43	100.0%	1.17 [0.43, 3.19]
Subtotal (95% CI)		**43**		**43**	**100.0%**	**1.17 [0.43, 3.19]**
Total events	7		6			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.30 (P = 0.76)						
1.5.3 Primarily patient						
Dolan 2002	9	43	15	43	100.0%	0.60 [0.29, 1.22]
Subtotal (95% CI)		**43**		**43**	**100.0%**	**0.60 [0.29, 1.22]**
Total events	9		15			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.41 (P = 0.16)						



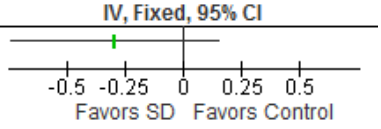
Test for subgroup differences: Chi² = 3.10, df = 2 (P = 0.21), I² = 35.5%

[a] Dolan 2002[21]

3. Decisional Conflict

Decisional Conflict Scale (Lower Score = Better Decision Making Process)[a,b]

Study or Subgroup	Shared Decision Mean	SD	Total	Control Mean	SD	Total	Std. Mean Difference IV, Fixed, 95% CI
Dolan 2002	1.83	0.52	41	2.03	0.81	37	-0.29 [-0.74, 0.15]



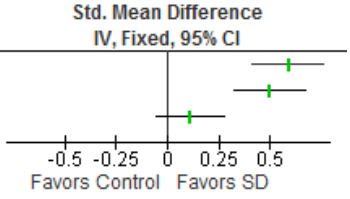
[a] Note: scores reversed from how reported in paper so effect size is now a negative number)

[b] Dolan 2002

4. Decision Satisfaction

Satisfaction with the Decision-Making Process Scale (SDMP)[a,b,c]

Study or Subgroup	Shared Decision Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Schroy 2012 DA	49.7	6.4	262	45.5	7.8	261		0.59 [0.41, 0.76]
Schroy 2012 DA+YDR	49	6.2	271	45.5	7.8	261		0.50 [0.32, 0.67]
Schroy DA vs DA+YDR	49.7	6.4	262	49	6.2	271		0.11 [-0.06, 0.28]



[a] 12 items, each scored from 1 (strongly disagree or "poor") to 5 (strongly agree or "excellent") with a maximum score of 60

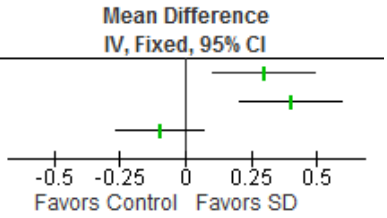
[b] First two comparisons versus control

[c] Schroy 2012[23]

5. Screening Intention

Intention to Complete Screening Test[a,b,c]

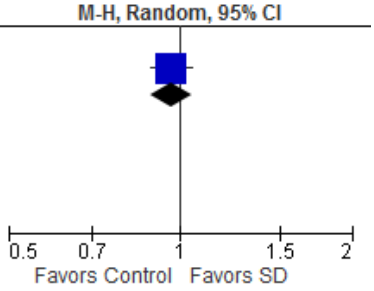
Study or Subgroup	Shared Decision Mean	SD	Total	Control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Schroy 2012 DA	4.3	1	269	4	1.3	276	0.30 [0.11, 0.49]
Schroy 2012 DA+YDR	4.4	1	280	4	1.3	276	0.40 [0.21, 0.59]
Schroy DA vs DA+YDR	4.3	1	269	4.4	1	280	-0.10 [-0.27, 0.07]



[a] 5 point scale (1 not sure to 5 completely sure)
[b] First two comparisons versus control
[c] Schroy 2012[23]

Screening Intention[a]

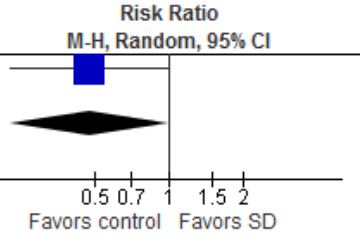
Study or Subgroup	Shared Decision Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
2.12.2 Intention to Screen: Post-intervention						
Trevena 2008	117	134	124	137	100.0%	0.96 [0.89, 1.05]
Subtotal (95% CI)		**134**		**137**	**100.0%**	**0.96 [0.89, 1.05]**
Total events	117		124			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.84 (P = 0.40)						
Test for subgroup differences: Not applicable						



[a] Trevena 2008[24]

Intention to Screen[a]

Study or Subgroup	Shared Decision Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Dolan 2002	8	45	16	43	100.0%	0.48 [0.23, 1.00]
Total (95% CI)		**45**		**43**	**100.0%**	**0.48 [0.23, 1.00]**
Total events	8		16			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.96 (P = 0.05)						

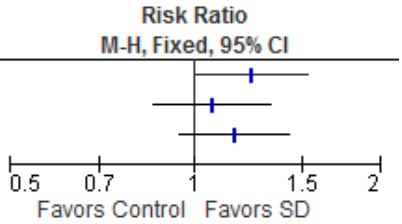


[a] Dolan 2002[21]

6. Screening Behavior

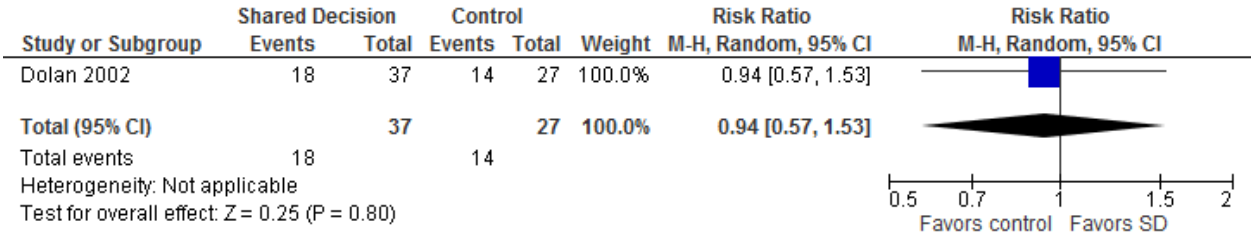
Test Completed by 12 Months after Visit[a,b]

Study or Subgroup	Shared Decision Events	Total	Control Events	Total	Risk Ratio M-H, Fixed, 95% CI
Schroy 2012 DA	116	269	96	276	1.24 [1.00, 1.53]
Schroy 2012 DA+YDR	104	280	96	276	1.07 [0.86, 1.33]
Schroy DA vs DA+YDR	116	269	104	280	1.16 [0.95, 1.43]



[a] First two comparisons versus control
[b] Schroy 2012[23]

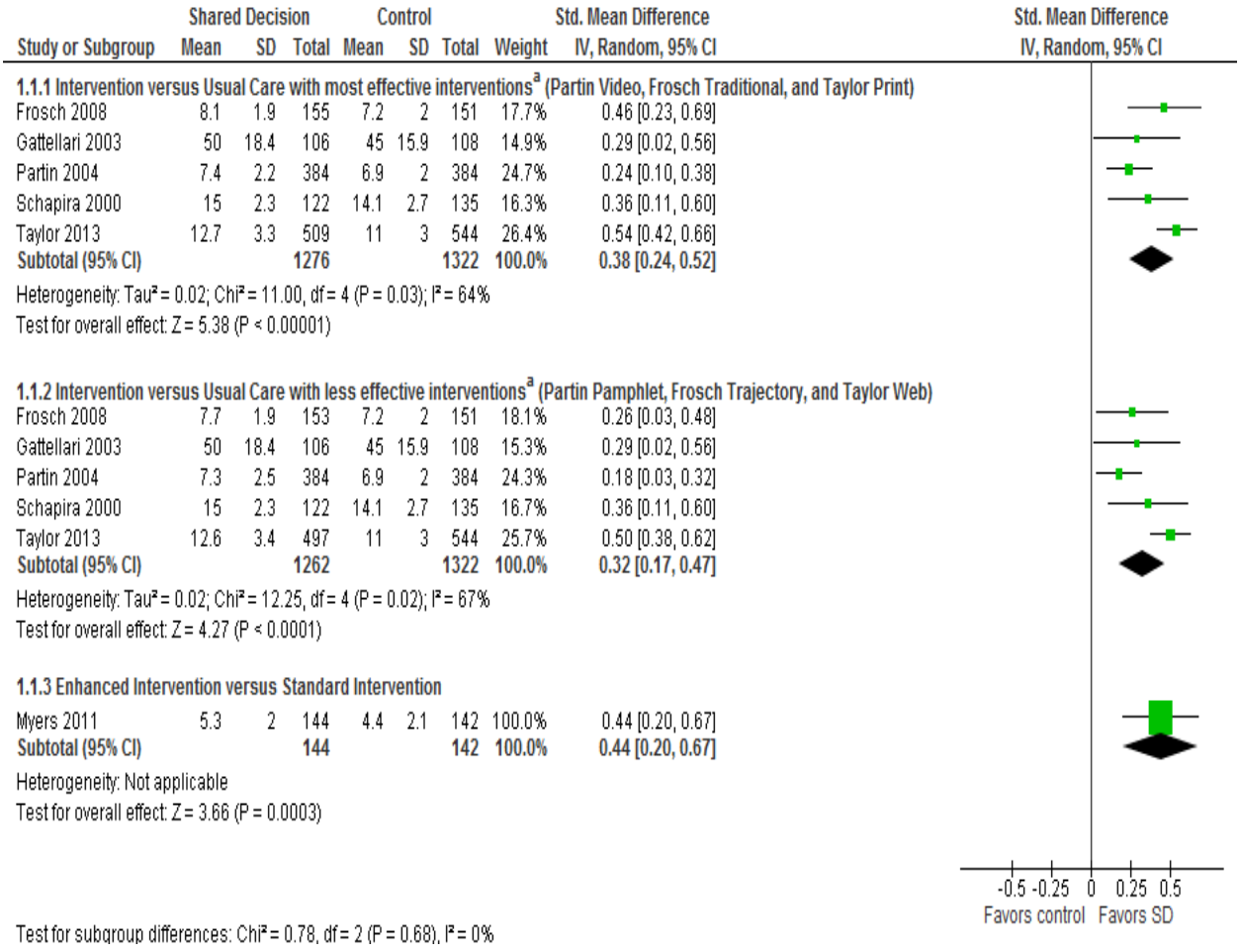
Screening Completed[a]



[a] Dolan 2002[21]

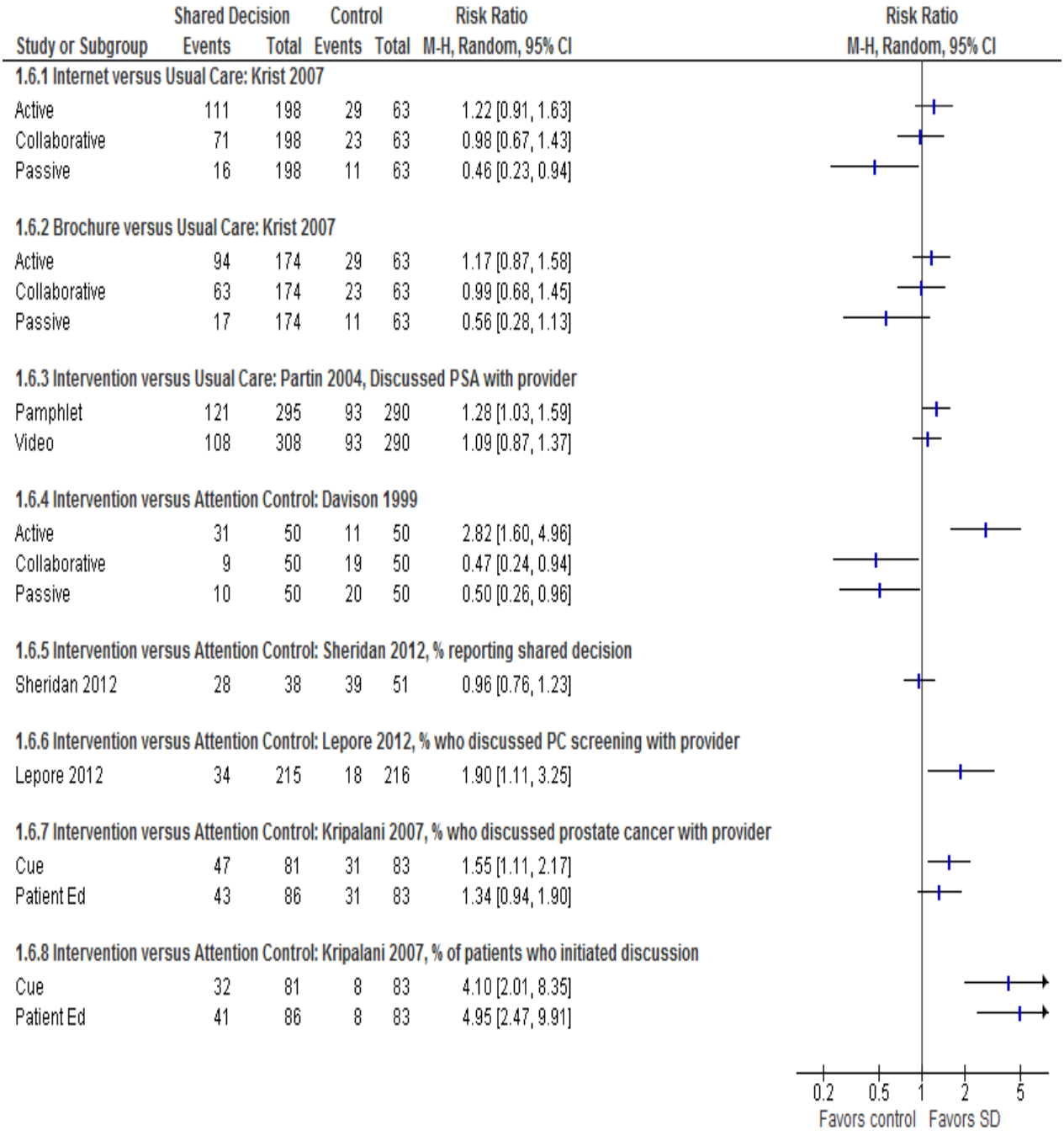
PROSTATE CANCER

1. Knowledge[a,b]



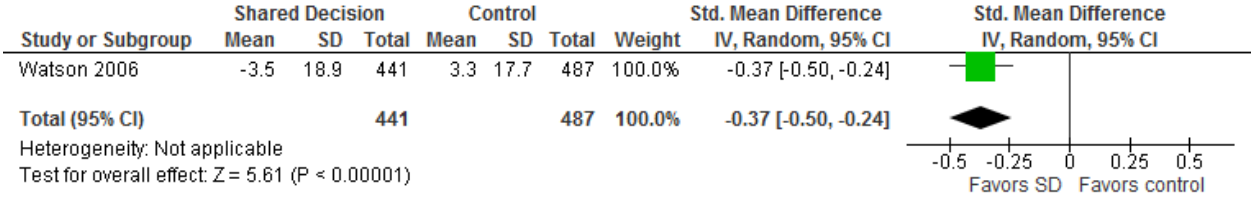
[a] Multi-armed trials
[b] Frosch 2008,[28] Gattellari 2003,[29] Partin 2004,[35] Schapira 2000,[37] Taylor 2013,[39] Myers 2011[34]

2. Patient's Role in the Decision - Usual Care Trials[a]



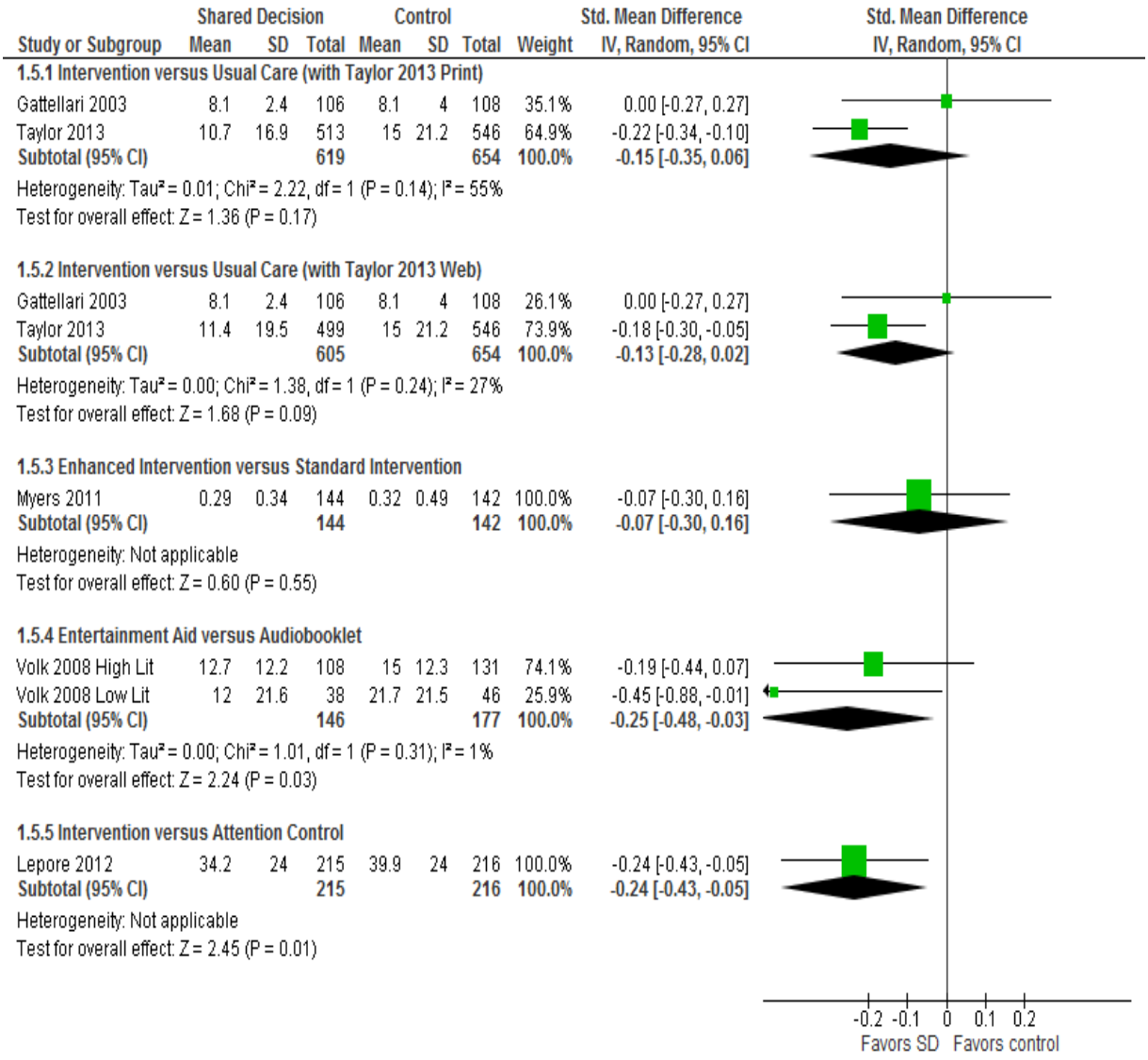
[a] Krist 2007,[32] Partin 2004,[35] Davison 1999,[25] Sheridan 2012,[38] Lepore 2012,[33] Kripalani 2007[31]

3. Value's Clarity[a]



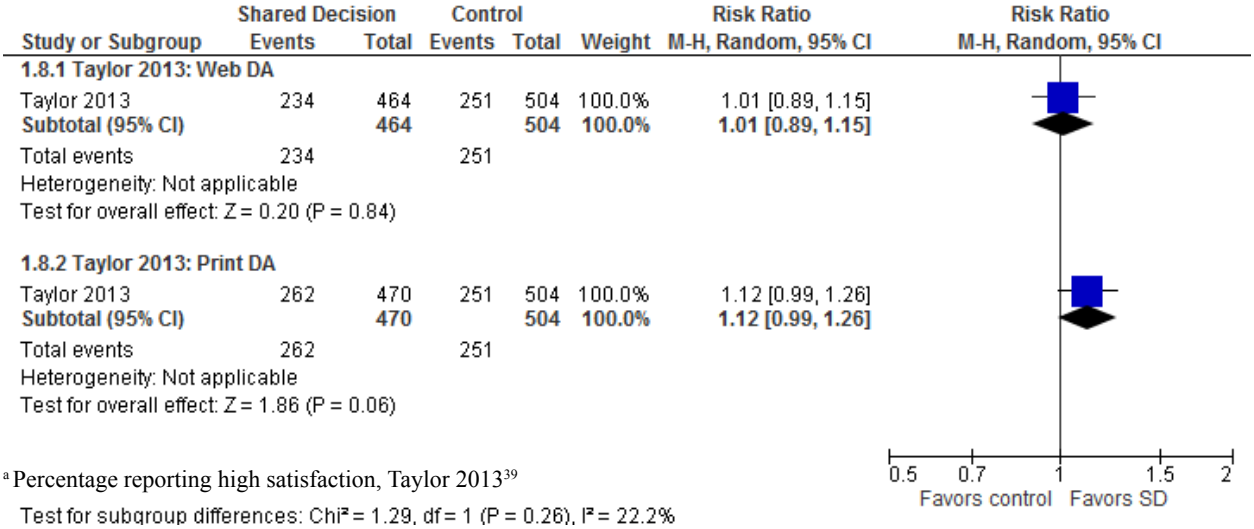
[a] Watson 2006[43]

4. Decision Conflict - Usual Care Trials[a]



[a] Gattellari 2003,[29] Taylor 2013,[39] Myers 2011,[34] Volk 2008,[42] Lepore 2012[33]

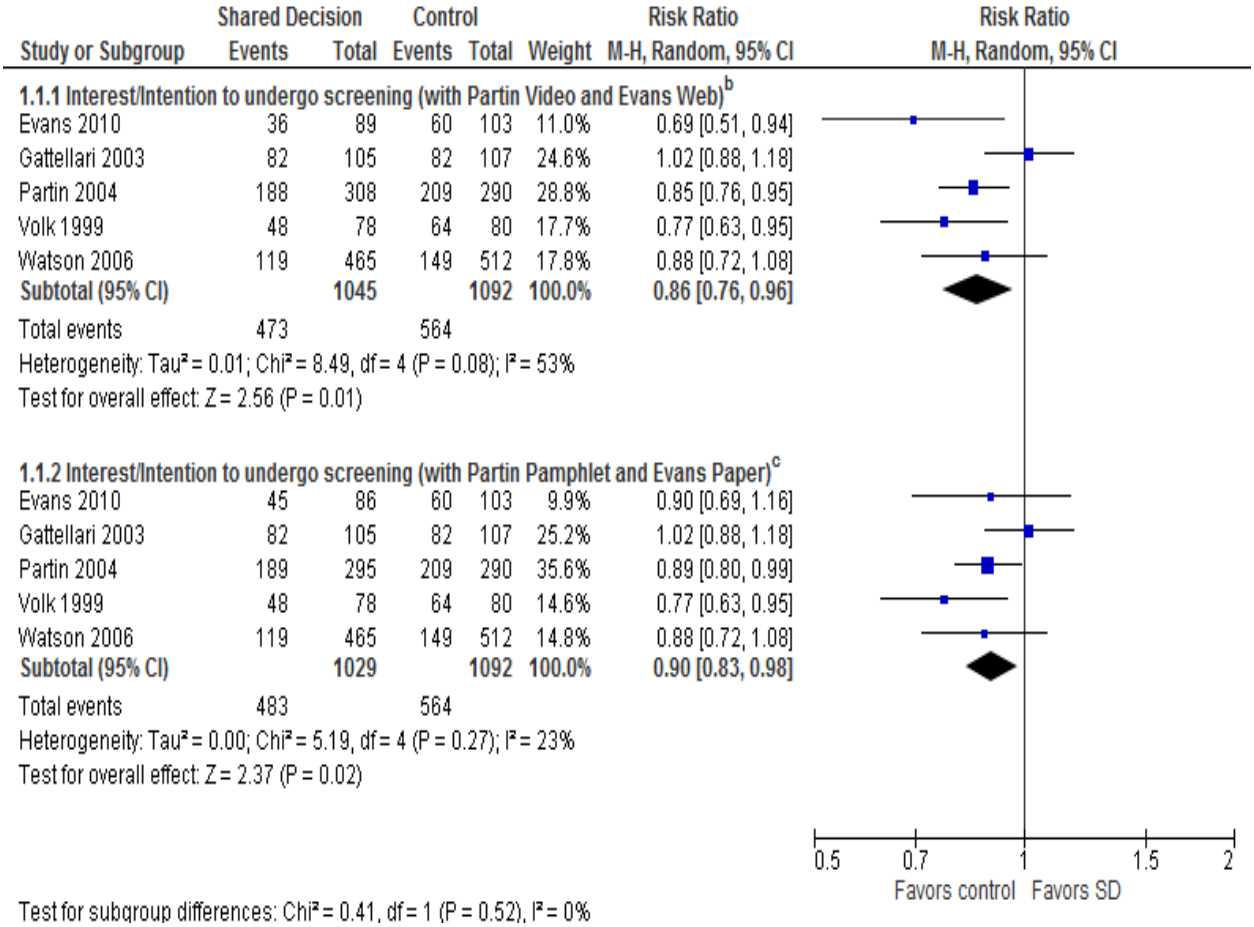
5. Decision Satisfaction[a]



[a] Percentage reporting high satisfaction, Taylor 2013[39]

Test for subgroup differences: Chi² = 1.29, df = 1 (P = 0.26), I² = 22.2%

6. Screening Preference/Intention - Usual Care Trials[a]



Test for subgroup differences: Chi² = 0.41, df = 1 (P = 0.52), I² = 0%

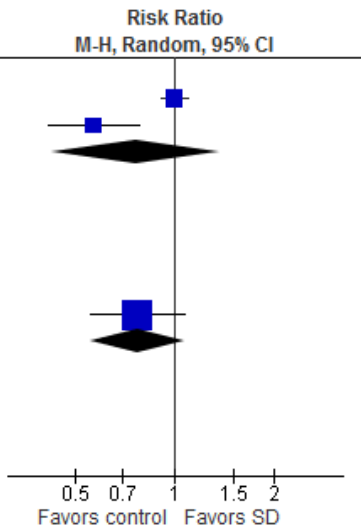
[a] Evans 2010,[26] Gattellari 2003,[29] Partin 2004,[35] Volk 1999,[40] Watson 2006[43]

[b] Includes Evans and Partin studies with significant or more significant results.

[c] Includes Evans and Partin studies with non-significant or less significant results.

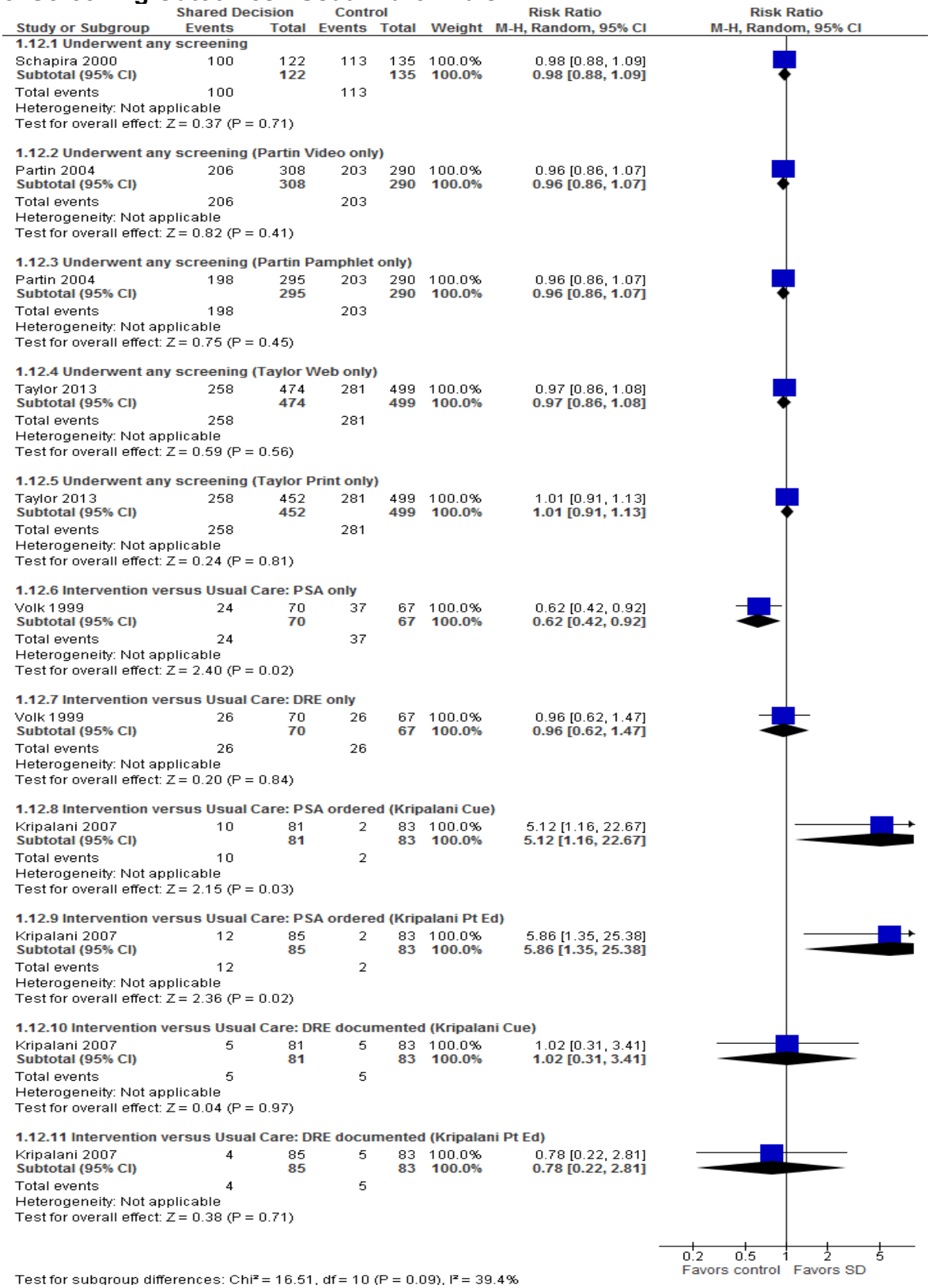
7. Screening Preference/Intention - Other Trials[a]

Study or Subgroup	Shared Decision Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.11.1 Intervention versus Attention Control: Interest/Intention to undergo screening - Yes						
Lepore 2012	174	215	175	216	53.2%	1.00 [0.91, 1.09]
Sheridan 2012	26	58	55	70	46.8%	0.57 [0.42, 0.78]
Subtotal (95% CI)		**273**		**286**	**100.0%**	**0.77 [0.43, 1.38]**
Total events	200		230			
Heterogeneity: Tau² = 0.16; Chi² = 13.02, df = 1 (P = 0.0003); I² = 92%						
Test for overall effect: Z = 0.88 (P = 0.38)						
1.11.2 Evans 2010: Web versus paper decision aid						
Evans 2010	36	89	45	86	100.0%	0.77 [0.56, 1.07]
Subtotal (95% CI)		**89**		**86**	**100.0%**	**0.77 [0.56, 1.07]**
Total events	36		45			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.56 (P = 0.12)						
Test for subgroup differences: Chi² = 0.00, df = 1 (P = 0.99), I² = 0%						



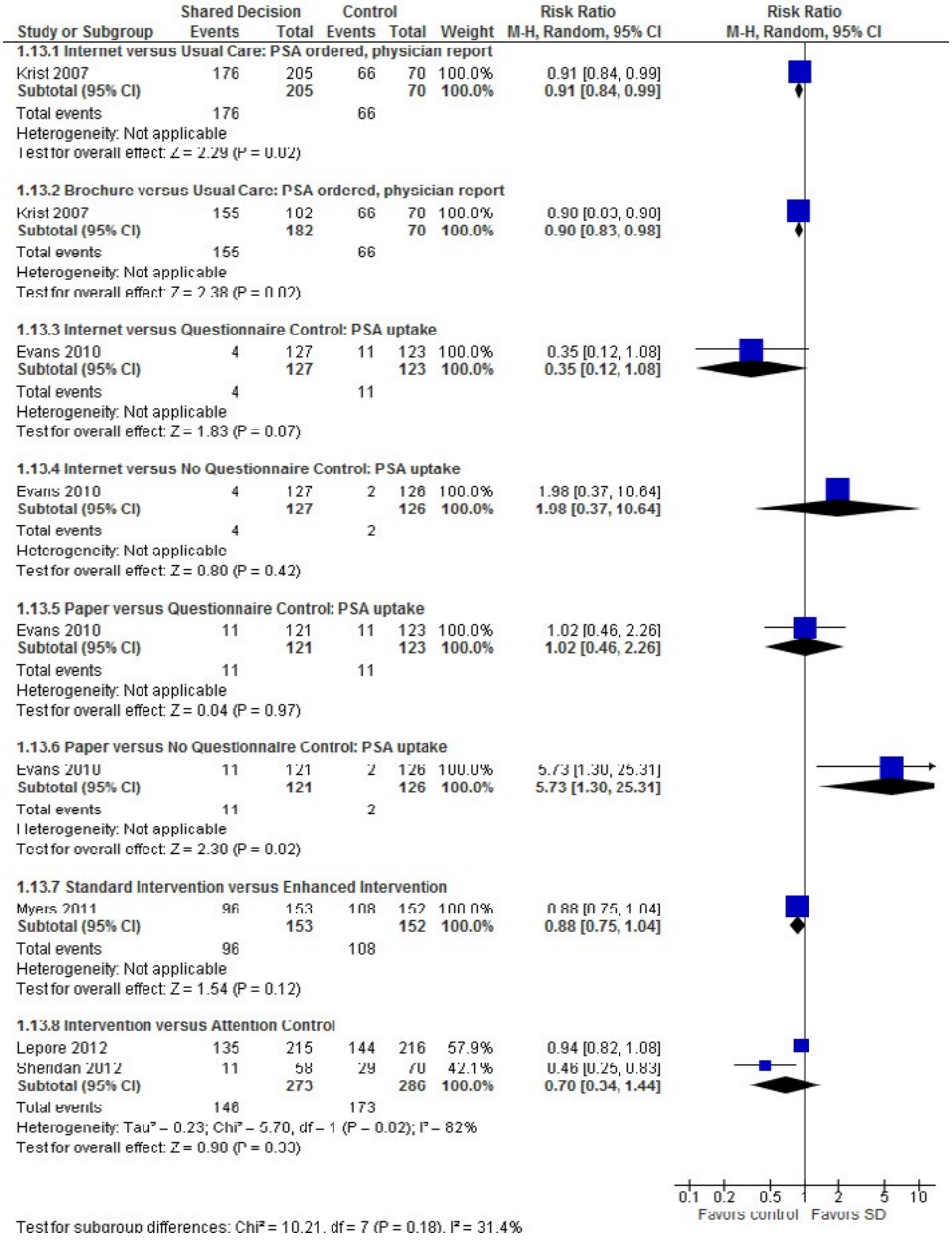
[a] Lepore 2012,[33] Sheridan 2012,[38] Evans 2010[26]

8. Screening Outcomes - Usual Care Trials[a]



[a] Schapira 2000,[37] Partin 2004,[35] Taylor 2013,[39] Volk 1999,[40] Kripalani 2007[31]

9. Screening Outcomes - Other Trials[a]



[a] Krist 2007,[32] Evans 2010,[26] Myers 2011,[34] Lepore 2012,[33] Sheridan 2012[38]