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# 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.

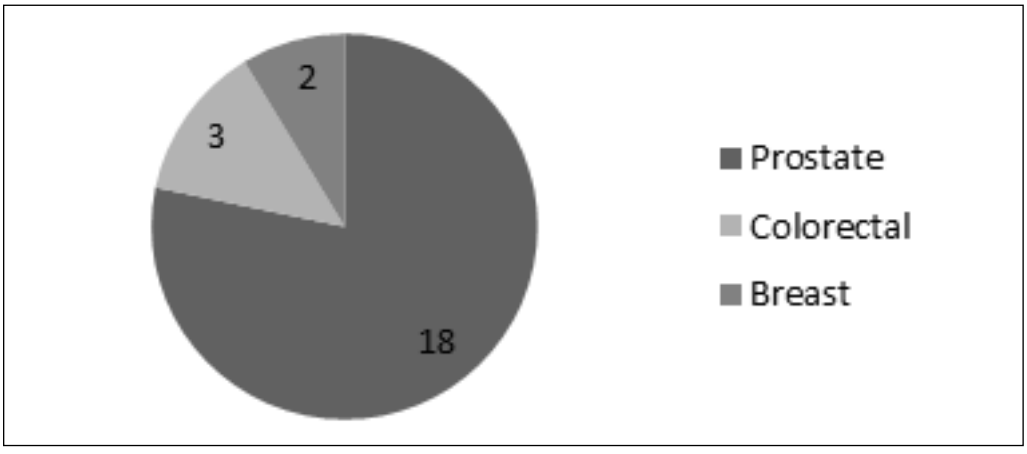
6. We found insufficient evidence regarding the comparative effectiveness of SDM intervention strategies, and whether the effects vary by intervention target population, key SDM intervention content/elements, patient characteristics, or cancer type.

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]<br>↓ 2[b]<br>↔ 1 | | ↔ 1 | | | ↓ 1<br>↔ 1 | ↔ 1 |
| **Colorectal (k=3)** | ↑ 2 | ↔ 1 | ↔ 1 | ↓ 1 | | ↑ 1 | ↑ 1<br>↔ 2 | ↑ 1<br>↔ 2 |
| **Prostate (k=18)** | ↑ 14<br>↔ 1 | ↑ 3<br>↔ 1 | ↑ 6<br>↔ 4 | ↓ 8[c]<br>↔ 3[c] | ↔ 1 | ↑ 1[d]<br>↔ 2[d] | ↓ 5<br>↔ 3 | ↓ 7<br>↑ 1<br>↔ 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:

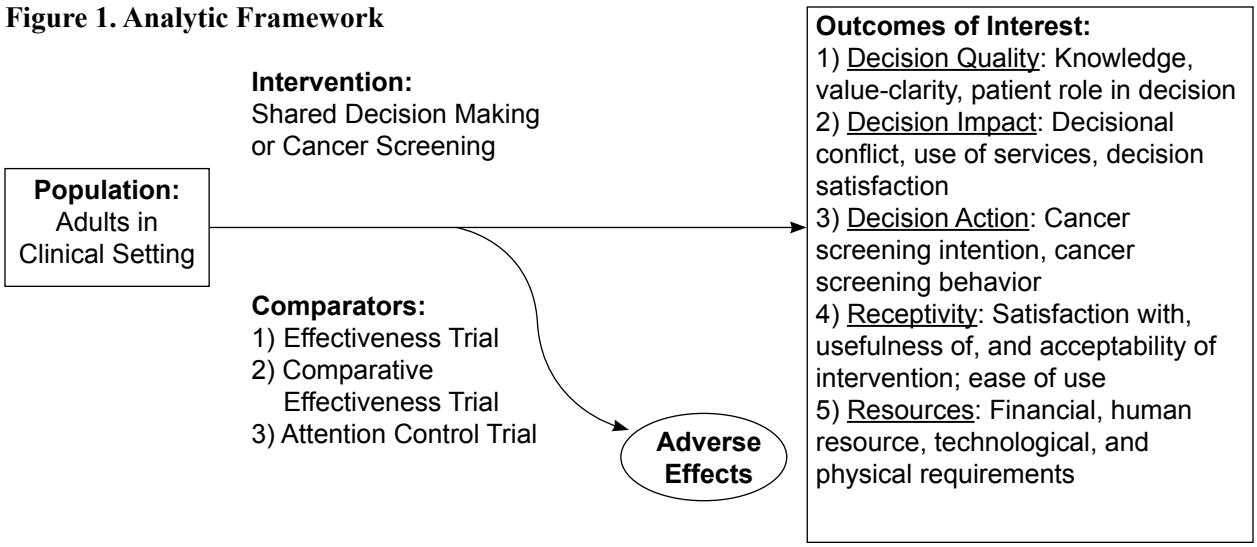
KQ1. In adults, what are the effects of SDM interventions for cancer screening on:
1) Decision Quality;
2) Decision Impact; and
3) Decision Action?

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.

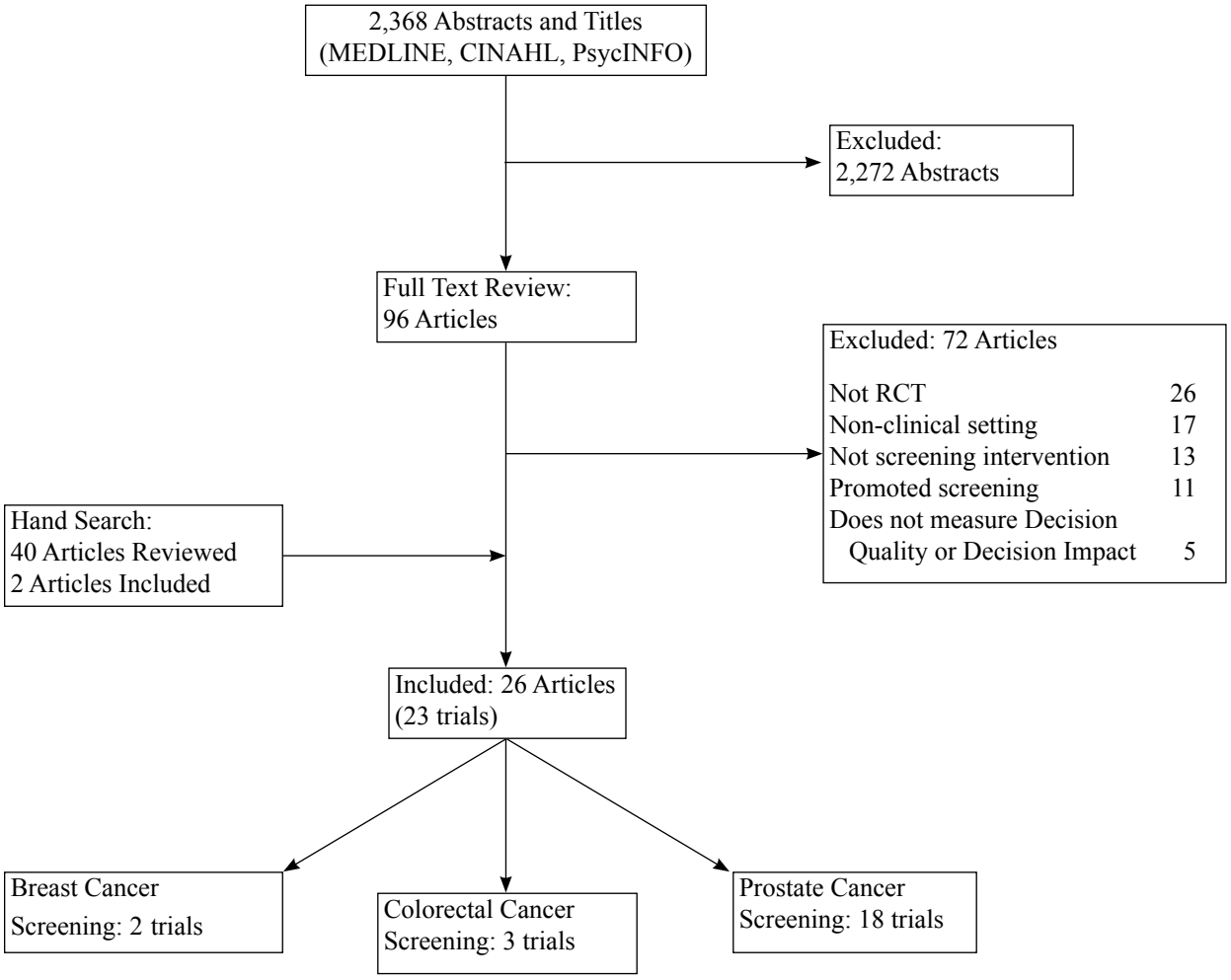
# RESULTS

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 ($\chi^2$=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 ($\chi^2$=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%, $\chi^2$=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%, $\chi^2$=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, $\chi^2$=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]<br>Mathieu 2010[20] | Schroy 2011/2012[22,23]<br>Dolan 2002[21]<br>Trevena 2008[24] | Evans 2010[26]<br>Frosch 2003[27]<br>Frosch 2008[28]<br>Partin 2004/2006[35,36]<br>Taylor 2013[39]<br>Volk 2008[42] |
| Counseling | | | Lepore 2012[33]<br>Myers 2011[34]<br>Sheridan 2012[38] |
| Education program | | | Gattellari 2005[30]<br>Schapira 2000[37]<br>Watson 2006[43]<br>Wilkes 2013[44] |
| **Intervention Format - Delivery Mode** | | | |
| DVD /Videotape | | Schroy 2011/2012[22,23] | Frosch 2003[27]<br>Partin 2004/2006[35,36]<br>Sheridan 2012[38]<br>Volk 2003/1999[40,41] |
| Web-based | Mathieu 2010[20] | | Evans 2010[26]<br>Frosch 2003[27]<br>Frosch 2008[28]<br>Krist 2007[32]<br>Taylor 2013[39]<br>Wilkes 2013[44] |
| Face-to-face | | Dolan 2002[21] | Sheridan 2012[38]<br>Myers 2011[34] |
| Printed | Mathieu 2007[19] | Dolan 2002[21]<br>Schroy 2011/2012[22,23] | Evans 2010[26]<br>Gattellari 2003[29]<br>Krist 2007[32]<br>Kripalani 2007[31]<br>Partin 2004/2006[35,36]<br>Schapira 2000[37]<br>Taylor 2013[39]<br>Volk 2003/1999[40,41]<br>Watson 2006[43] |
| Verbal & written | | | Davison 1999[25]<br>Gattellari 2005[30] |
| Telephone | | | Lepore 2012[33] |
| **Intervention Format - Timing** | | | |
| In-clinic | | Dolan 2002[21]<br>Schroy 2011/2012[22,23] | Davison 1999[25]<br>Frosch 2003[27]<br>Gattellari 2003[29]<br>Kripalani 2007[31]<br>Myers 2011[34]<br>Schapira 2000[37]<br>Sheridan 2012[38]<br>Volk 2008[42]<br>Wilkes 2013[44] |
| At home before appointment | Mathieu 2007[19]<br>Mathieu 2010[20] | Trevena 2008[24] | Evans 2010[26]<br>Frosch 2003[27]<br>Frosch 2008[28]<br>Krist 2007[32]<br>Lepore 2012[33]<br>Partin 2004/2006[35,36]<br>Taylor 2013[39]<br>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]<br>Frosch 2003[27]<br>Gattellari 2005[30]<br>Kripalani 2007[31]<br>Krist 2007[32]<br>Partin 2004/2006[35,36]<br>Schapira 2000[37]<br>Volk 1999/2003[40,41]<br>Watson 2006[43] |
| Worksheet | Mathieu 2007[19]<br>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]<br>Sheridan 2012[38]<br>Volk 2008[42] |
| Discussion/questions of risks and benefits, values | | | Lepore 2012[33]<br>Myers 2011[34]<br>Wilkes 2013[44] |
| **Risk Communication Method** | | | |
| Not specified | | Dolan 2002[21] | Davison 1999[25]<br>Evans 2010[26]<br>Frosch 2003[27]<br>Frosch 2008[28]<br>Gattellari 2005[30]<br>Kripalani 2007[31]<br>Krist 2007[32]<br>Lepore 2012[33]<br>Myers 2011[34]<br>Partin 2004/2006[35,36]<br>Sheridan 2012[38]<br>Volk 2008[42]<br>Volk 1999/2003[40,41]<br>Watson 2006[43] |
| Pictographs | Matheiu 2007[19]<br>Matheiu 2010[20] | Trevena 2008[24] | Gattellari 2003[29]<br>Schapira 2000[37]<br>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.

# REFERENCES


1. Pace LE, Keating NL. A systematic assessment of benefits and risks to guide breast cancer screening decisions. JAMA. 2014;311(13):1327-35.
2. Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L for the U.S. Preventive Services Task Force. Screening for breast cancer: an update for the U.S. Preventive Services Task Force. Ann Intern Med. 2009;151(10):727-37, W237-42.
3. Walter LC, Schonberg MA. Screening mammography in older women: a review. JAMA. 2014;311(13):1336-47.
4. Andriole GL, et al. for the PLCO Project Team. Prostate cancer screening in the randomized Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial: mortality results after 13 years of follow-up. J Natl Cancer Inst. 2012;104(2):125-32.
5. Schröder FH, et al. for the ERSPC Investigators. Prostate-cancer mortality at 11 years of follow-up. N Engl J Med. 2012;366(11):981-90.
6. Moyer VA for the U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;157(2):120-34.
7. U.S. Preventive Services Task Force. Screening for colorectal cancer: recommendation and rationale. Ann Intern Med. 2002;137(2):129-31.
8. Woolf SH. The best screening test for colorectal cancer--a personal choice. N Engl J Med. 2000;343(22):1641-3.
9. Moyer VA for the U.S. Preventive Services Task Force. Screening for cervical cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;156(12):880-91.
10. Elwyn G, Coulter A, Laitner S, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. BMJ. 2010;341:c5146.
11. International Patient Decision Aid Standard Collaboration. Background Document [2005]. Available from: http://ipdas.ohri.ca/IPDASBackground.pd f (accessed 15 Oct 2014).
12. Légaré F, Ratté S, Stacey D, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. Cochrane Database Syst Rev. 2010 May 12;(5):CD006732.
13. O'Connor, AM. Ottawa Decision Support Framework to Address Decisional Conflict ©2006. Available from: www.ohri.ca/decisionaid (accessed 31 Aug 2014).
14. Stacey D, Légaré F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014 Jan 28;1:CD001431.

15. Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from http://handbook.cochrane.org (accessed 31 Aug 2014)

16. Review Manager (RevMan) [Computer program]. Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

17. Higgins JP, Thompson SG, Deeks JJ, et al. Measuring inconsistency in meta-analyses. BMJ. 2003;327(7414):557-60.

18. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. J Clin Epidemiol. 2010;63(5):513-23.

19. Mathieu E, Barratt AL, Davey HM, McGeechan K, Howard K, Houssami N. Informed choice in mammography screening: A randomized trial of a decision aid for 70-year-old women. Arch Intern Med. 2007;167(19):2039-46.

20. Mathieu E, Barratt AL, McGeechan K, Davey HM, Howard K, Houssami N. Helping women makes choices about mammography screening: A randomized trial of a decision aid for 40-year-old women. Patient Educ Couns. 2010;81:63-72.

21. Dolan JG, Frisina S. Randomized controlled trial of a patient decision aid for colorectal cancer screening. Med Decis Making. 2002;22(2):125-39.

22. Schroy PC, Emmons K, Peters E, et al. The impact of a novel computer-based decision aid on shared decision making for colorectal cancer screening: a randomized trial. Med Decis Making. 2011;31(1):93-107.

23. Schroy PC, Emmons KM, Peters E, et al. Aid-assisted decision making and colorectal cancer screening: a randomized controlled trial. Am J Prev Med. 2012;43(6):573-83.

24. Trevena LJ, Irwig L, Barratt A. Randomized trial of a self-administered decision aid for colorectal cancer screening. J Med Screen. 2008;15(2):76-82.

25. Davison BJ, Kirk P, Degner LF, Hassard TH. Information and patient participation in screening for prostate cancer. Patient Educ Couns. 1999;37(3):255-63.

26. Evans R, Joseph-Williams N, Edwards A, et al. Supporting informed decision making for prostate specific antigen (PSA) testing on the web: an online randomized controlled trial. J Med Internet Res. 2010;12(3):e27.

27. Frosch DL, Kaplan RM, Felitti VJ. A randomized controlled trial comparing internet and video to facilitate patient education for men considering the prostate specific antigen test. J Gen Intern Med. 2003;18(10):781-7.

28. Frosch DL, Bhatnagar V, Tally S, Hamori CJ, Kaplan RM. Internet patient decision support: a randomized controlled trial comparing alternative approaches for men considering prostate cancer screening. Arch Intern Med. 2008;168(4):363-9.

29. Gattellari M, Ward JE. Does evidence-based information about screening for prostate cancer enhance consumer decision-making? A randomised controlled trial. J Med Screen. 2003;10(1):7-39.

30. Gattellari M, Donnelly N, Taylor N, Meerkin M, Hirst G, Ward JE. Does 'peer coaching' increase GP capacity to promote informed decision making about PSA screening? A cluster randomised trial. Fam Pract, 2005. 22(3): p. 253-65.

31. Kripalani S, Sharma J, Justice E, et al. Low-literacy interventions to promote discussion of prostate cancer: a randomized controlled trial. Am J Prev Med. 2007;33(2):83-90.

32. Krist AH, Woolf SH, Johnson RE, Kerns JW. Patient education on prostate cancer screening and involvement in decision making. Ann Fam Med. 2007;5(2):112-9.

33. Lepore SJ, Wolf RL, Basch CE, et al., Informed decision making about prostate cancer testing in predominantly immigrant black men: a randomized controlled trial. Ann Behav Med. 2012;44(3):320-30.

34. Myers RE, Daskalakis C, Kunkel EJS, et al. Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counseling. Patient Educ Couns. 2011;83(2):240-6.

35. Partin MR, Nelson D, Radosevich D, et al. Randomized trial examining the effect of two prostate cancer screening educational interventions on patient knowledge, preferences, and behaviors. J Gen Intern Med. 2004;19(8):835-42.

36. Partin MR, Nelson D, Flood AB, Friedemann-Sánchez G, Wilt TJ. Who uses decision aids? Subgroup analyses from a randomized controlled effectiveness trial of two prostate cancer screening decision support interventions. Health Expect. 2006;9(3):285-95.

37. Schapira MM, VanRuiswyk J. The effect of an illustrated pamphlet decision-aid on the use of prostate cancer screening tests. J Fam Pract. 2000;49(5):418-24.

38. Sheridan SL, Golin C, Bunton A. et al. Shared decision making for prostate cancer screening: the results of a combined analysis of two practice-based randomized controlled trials. BMC Med Inform Decis Mak. 2012;12:130.

39. Taylor KL, Williams RM, Davis K, et al. Decision making in prostate cancer screening using decision aids vs usual care: a randomized clinical trial. JAMA Intern Med. 2013;173(18):1704-12

40. Volk RJ, Cass AR, Spann SJ. A randomized controlled trial of shared decision making for prostate cancer screening. Arch Fam Med. 1999;8(4):333-40.

41. Volk RJ, Spann SJ, Cass AR, Hawley ST. Patient education for informed decision making about prostate cancer screening: a randomized controlled trial with 1-year follow-up. Ann Fam Med. 2003;1(1):22-8.

42. Volk RJ, Jibaja-Weiss ML, Hawley ST, et al. Entertainment education for prostate cancer screening: a randomized trial among primary care patients with low health literacy. Patient Educ Couns. 2008;73(3):482-9.

43. Watson E, Hewitson P, Brett J, et al. Informed decision making and prostate specific antigen (PSA) testing for prostate cancer: a randomised controlled trial exploring the impact of a brief patient decision aid on men's knowledge, attitudes and intention to be tested. Patient Educ Couns. 2006;63(3):367-79.

44. Wilkes MS, Day FC, Srinivasan M, et al. Pairing physician education with patient activation to improve shared decisions in prostate cancer screening: a cluster randomized controlled trial. Ann Fam Med. 2013;11(4):324-34.

45. Kaplan SH, Gandek B, Greenfield S, Rogers W, Ware JE. Patient and visit characteristics related to physicians' participatory decision-making style. Results from the Medical Outcomes Study. Med Care. 1995;33(12):1176-87.

46. Radosevich DM, Partin MR, Nugent S, et al. Measuring patient knowledge of the risks and benefits of prostate cancer screening. Patient Educ Couns. 2004;54(2):143-52

47. O'Dell KJ, Volk RJ, Cass AR, Spann SJ. Screening for prostate cancer with the prostate-specific antigen test: are patients making informed decisions? J Fam Pract. 1999;48(9):682-8.

48. Dormandy E, Michie S, Hooper R, Marteau TM. Informed choice in antenatal Down syndrome screening: a cluster-randomised trial of combined versus separate visit testing. Patient Educ Couns. 2006;61(1):56-64.

49. Rakowski W, Andersen MR, Stoddard AM, et al. Confirmatory analysis of opinions regarding the pros and cons of mammography. Health Psychol. 1997;16:433-41.

50. 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.

51. Degner LF, Sloan JA. Decision making during serious illness: What role do patients really want to play? J Clin Epidemiol. 1992;45(9):941-50.

52. Brashers DE, Haas SM, Neidig JL. The patient self-advocacy scale: measuring patient involvement in health care decision-making interactions. Health Commun. 1999;11(2):97-121

53. Strull WM, Lo B, Charles G. Do patients want to participate in medical decision making? JAMA. 1984;252(21):2990-4.

54. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995;15(1):25-30.

55. Dolan JG. A method for evaluating health care providers' decision making: The Provider Decision Process Assessment Instrument. Med Decis Making. 1999;19:38-41.

56. Barry MJ, Cherkin DC, Chang Y, Fowler FJ, Skates S. A randomized trial of a multimedia shared decision-making program for men facing a treatment decision for benign prostatic hyperplasia. Dis Manag Clin Outcomes. 1997;1:5-14.

57. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions: the satisfaction with decision scale. Med Decis Making. 1996;16(1):58-64.

58. Sheridan SL, Harris RP, Woolf SH. Shared decision making about screening and chemoprevention: a suggested approach from the US Preventive Services Task Force. Am J Prev Med. 2004;26(1):56–66.

59. Zahedi F. The analytic hierarchy process-a survey of the method and its applications. Interfaces. 1986;16 (4):96-108.

60. Fagerlin A, Rovner D, Stableford S, Jentoft C, Wei JT, Holmes-Rovner M. Patient education materials about the treatment of early-stage prostate cancer: a critical review. Ann Intern Med. 2004;140(9):721-8.

61. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping patients decide: ten steps to better risk communication. J Natl Cancer Inst. 2011;103(19):1436-43.

62. Chewning B, Bylund CL, Shah B, Arora NK, Gueguen JA, Makoul G. Patient preferences for shared decisions: a systematic review. Patient Educ Couns. 2012;86(1):9-18.

63. Dwamena F, Holmes-Rovner M, Gaulden CM, et al. Interventions for providers to promote a patient-centred approach in clinical consultations. Cochrane Database Syst Rev. 2012 Dec 12;12:CD003267

64. Durand MA, Carpenter L, Dolan H, et al. Do interventions designed to support shared decision-making reduce health inequalities? A systematic review and meta-analysis. PLoS One. 2014;9(4):e94670.

65. Elwyn G, Scholl I, Tietbohl C, et al. "Many miles to go …": a systematic review of the implementation of patient decision support interventions into routine clinical practice. BMC Med Inform Decis Mak. 2013;13 Suppl 2:S14.

66. Evans R, Edwards A, Brett J, et al. Reduction in uptake of PSA tests following decision aids: systematic review of current aids and their evaluations. Patient Educ Counsel. 2005;58:13-26.

67. Gravel K, Légaré F, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. Implement Sci. 2006;1:16.

68. Jimbo M, Rana GK, Hawley S, et al. What is lacking in current decision aids on cancer screening? CA Cancer J Clin. 2013;63(3):193-214.

69. Joosten EA, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CP, de Jong CA. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. Psychother Psychosom. 2008;77(4):219-26.

70. Légaré F, Turcotte S, Stacey D, Ratté S, Kryworuchko J, Graham ID. Patients' perceptions of sharing in decisions: a systematic review of interventions to enhance shared decision making in routine clinical practice. Patient. 2012;5(1):1-19.

71. O'Brien MA, Whelan TJ, Villasis-Keever M, et al. Are cancer-related decision aids effective? A systematic review and meta-analysis. J Clin Oncol. 2009;27(6):974-85.

72. O'Connor AM, Bennett C, Stacey D, et al. Do patient decision aids meet effectiveness criteria of the international patient decision aid standards collaboration? A systematic review and meta-analysis. Med Decis Making. 2007;27(5):554-74.

73. Stacey D, Samant R, Bennett C. Decision making in oncology: a review of patient decision aids to support patient participation. CA Cancer J Clin. 2008;58(5):293-304.

74. Volk RJ, Hawley ST, Kneuper S, et al. Trials of decision aids for prostate cancer screening: a systematic review. Am J Prev Med. 2007;33(5):428-434.

75. Schonberg 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. 2014;174(3):417-24.

76. LeBlanc A, Kenny DA, O'Connor AM, Légaré F. Decisional conflict in patients and their physicians: a dyadic approach to shared decision making. Med Decis Making. 2009;29(1):61-8.

77. Elwyn G, Tsulukidze M, Edwards A, Légaré F, Newcombe R. Using a 'talk' model of shared decision making to propose an observation-based measure: Observer OPTION 5 Item. Patient Educ Couns. 2013;93(2):265-71.

78. Wunderlich T, Cooper G, Divine G, et al. Inconsistencies in patient perceptions and observer ratings of shared decision making: the case of colorectal cancer screening. Patient Educ Couns. 2010;80(3):358-63.