What Is Lacking in Current Decision Aids on Cancer Screening?

Masahito Jimbo, MD, PhD, MPH; Gurpreet K. Rana, MLIS; Sarah Hawley, PhD, MPH; Margaret Holmes-Rovner, PhD; Karen Kelly-Blake, PhD; Donald E. Nease, Jr, MD; Mack T. Ruffin IV, MD, MPH

Recent guidelines on cancer screening have provided not only more screening options but also conflicting recommendations. Thus, patients, with their clinicians’ support, must decide whether to get screened, which modality to use, and how often to undergo screening. Decision aids could potentially lead to better shared decision-making regarding screening between the patient and the clinician. A total of 73 decision aids concerning screening for breast, cervical, colorectal, and prostate cancers were reviewed. The goal of this review was to assess the effectiveness of such decision aids, examine areas in need of more research, and determine how the decision aids can be currently applied in the real-world setting. Most studies used sound study designs. Significant variation existed in the setting, theoretical framework, and measured outcomes. Just over one-third of the decision aids included an explicit values clarification. Other than knowledge, little consistency was noted with regard to which patient attributes were measured as outcomes. Few studies actually measured shared decision-making. Little information was available regarding the feasibility and outcomes of integrating decision aids into practice. In this review, the implications for future research, as well as what clinicians can do now to incorporate decision aids into their practice, are discussed.

CA Cancer J Clin 2013;63:193-214. © 2013 American Cancer Society.

Keywords: mass screening, decision aid, neoplasms, decision-making

Introduction

In recent years, screening strategies for many conditions have become increasingly complex. Guidelines now recommend more options for cancer screening. Some guidelines also have conflicting recommendations. Thus, patients, with their clinicians’ support, must decide whether to get screened, which modality to choose, and how often to undergo screening. These considerations are foundational to informing patients’ preferences, and make these decisions “preference-sensitive.” Decision aids could be an ideal tool to help patients understand their risk of developing a particular cancer, the screening options available (including the possible option of not getting screened), recommended screening time intervals, and their own values and preferences for a particular option and outcome. Consequently, decision aids have proliferated in recent years. They usually include information on the disease/condition and the associated tests/treatments, probabilities of outcomes (benefits and harms) for each test/treatment option, and some form of a values clarification exercise to help patients determine which option would best match their values. Decision aids may also include guidance or coaching in the process of decision-making.1 They are not meant to replace the discussion between the patient and his/her clinician, but rather to complement it.

Cancer screening decisions are increasingly recognized as being preference-sensitive, due to the increased recognition of harms from sequelae of screening, the need to tailor screening recommendations to the patient’s risk, the multiple options available in some screening tests, and conflicting recommendations from guidelines. The potential of harm from screening was highlighted recently when the US Preventive Services Task Force recommended against routine screening for prostate cancer.2 They made this recommendation while other guidelines had similarly weighed the benefits and harms of prostate...
cancer screening and instead of discouraging screening, stressed shared decision-making between the patient and the clinician to decide whether the patient should undergo screening. Other cancer screenings involve preference-sensitive decisions as well, such as colorectal cancer screening, in which options include stool blood testing, flexible sigmoidoscopy, colonoscopy, and other modalities. Even screening for cancers that traditionally are without many options has become more complex, with some recent guidelines recommending shared decision-making between the patient and clinician to determine whether to get screened for breast cancer among women aged 40 years to 49 years, consideration of magnetic resonance imaging for women with a high risk of breast cancer, and the option of cytological testing every 3 years or cytological testing plus human papillomavirus testing every 5 years to screen for cervical cancer. The purpose of this review is to summarize what is known about the effect of decision aids on cancer screening, and to explore areas in which more information is needed to fully understand the impact of decision aids on the process and outcomes of shared decision-making between the patient and the clinician.

Materials and Methods

Screened Cancers

We focused our attention on cancers for which the national guidelines recommend screening the general population. Thus, we selected the decision aids for the screening of breast, cervical, and colorectal cancers. In addition, we looked at genetic testing for women considered to be at high risk of breast cancer, since it was believed to be an important option for selected high-risk women desiring further screening evaluation for breast cancer. Finally, we included prostate cancer screening in our search, since all guidelines except those by the US Preventive Services Task Force recommend that at least a discussion occur between the patient and clinician to decide whether screening for prostate cancer would be warranted in the particular patient.

Study Identification

The literature search was conducted for English language articles in 5 databases: MEDLINE (January 1980-May 2012), Cumulative Index to Nursing and Allied Health Literature (CINAHL; January 1980-May 2012), EMBASE (1980-May 2012), Cochrane Central Register of Controlled Trials (CCRCT; updated May 2012), and Science Citation Index (SCI; January 1980-May 2012). The MEDLINE, CINAHL, EMBASE, and CCRCT searches were conducted via the Ovid Technologies Inc interface. The majority of the topical search retrieval was obtained via MEDLINE using Medical Subject Headings, including "breast neoplasms;" "colorectal neoplasms;" "uterine cervical neoplasms;" "prostatic neoplasms;" "mass screening;" "decision support techniques;" "decision-making;" "decision-making, computer-assisted;" and "decision support systems, clinical.” In addition, limited text word searching was used. Corresponding keyword searches with Boolean syntax were conducted in CCRCT and SCI.

Theoretical Framework

In order to provide a theoretical organizing framework for our evaluation of studies, we have adapted the Integrative Model of Behavior by Frosch et al, which combines the 4 theories most frequently applied in health behavior research within the past 30 years (Theory of Reasoned Action, Theory of Planned Behavior, Health Belief Model, and Social Cognitive Theory). This theory combines measurable constructs of behavior (attitudes, perceived social norms, self-efficacy, and behavioral intention) to the actual behavior. Because an important aspect of decision aids is the clarification of preferences and values, we have added that component, as well as how the subsequent patient/clinician discussion ensues in terms of shared decision-making and patient/clinician concordance (match between the patient’s preferred screening option and the clinician’s recommended option). Figure 1 illustrates our adapted framework with relevant examples. Applied to the topic of this review, the use of decision aids to affect the patient’s behavior regarding cancer screening, this theoretical framework provides a helpful structure for understanding where decision aids intervene and exert their influence on screening behavior. It influenced the selection of the decision attributes evaluated. Our analysis focused on understanding the impact of the decision aid on patient’s attributes, shared decision-making, and patient/clinician concordance. Our model suggests that all of these are important to understanding the impact on patient screening behavior and determined the questions posed in the review.

Procedure

Two evaluators (M.J. and M.R.) reviewed each of the identified articles independently to determine if the study was relevant to the topic. Publications were excluded if the article was a review; an opinion article; an abstract; descriptive of a new decision aid without an intervention/trial component; or measured for usability but not for effects on patient knowledge, attitude, or behavior. Articles also were excluded if the study patients had an established cancer diagnosis, since our focus was on cancer screening. For the same reason, we excluded the study if it included treatment (eg, prophylactic mastectomy) as an option.
We selected the studies if the decision aid contained information on the disease/condition and the associated tests/treatments and probabilities of outcomes (benefits and harms) for each test/treatment option. We excluded studies in which the intervention was provided solely through a health care professional (eg, a script) since decision aids by definition are separate tools that complement the patient/clinician discussion and aid in decision-making. We did not directly contact the study authors but thoroughly reviewed the relevant articles for the original and detailed description of the decision aid intervention and, when necessary, reviewed the references for the original description of the intervention. We also directly accessed the decision aids if available. We included preintervention/postintervention and other nonrandomized designs as well as randomized controlled designs because we wanted to be as inclusive as possible to capture innovative decision aids. For that reason, we also included pilot studies as long as they had intervention and evaluation components. A number of publications were found that were duplicate reports of a single study or serial reports from the same study. In these cases, the study was counted as one, although all pertinent publications were reviewed. The cited literature referenced in relevant studies was also examined for possible additional studies.

Study Questions/Measures

We categorized the measures into the following questions.

1) **Does the Decision Aid Used in the Study Address the Issues That Need to Be Addressed in a Screening Decision Aid?**

We determined whether the decision aid included information on the cancer and the screening test options involved, probabilities of outcomes including the benefits and harms for each option, an explicit value clarifications exercise to help the patient determine which option would best match his/her values, and guidance or coaching in the process of decision-making. For values clarification, we specifically looked for the existence of a process (eg, exercise) that would actively engage the patient in clarifying his/her values. For guidance or coaching, we examined the specific ways in which the decision aid or the study addressed the discussion with the clinician.

2) **Does the Study Measure the Effect of the Decision Aid on the Patient Attributes Established in the Theories of Behavioral Research?**

We determined whether the study measured the patient’s knowledge, attitude, perceived normative pressure, self-efficacy, preference clarification, and intent regarding the cancer and cancer screening test in question. Here, preference is different from values in that “preference” is defined as an actual preference for a certain option.

3) **Does the Study Address the Impact of the Decision Aid on the Patient Behavior in Question?**

We determined whether the decision aid increased or decreased patient uptake of the particular cancer screening test, and whether it was by subjective (eg, patient self-report) or objective (eg, chart review) report. We also determined whether the completed cancer screening test was the option that the patient had originally chosen at the time of the decision aid use.

4) **Does the Study Address the Effect of the Decision Aid on the Subsequent Discussion Between the Patient and His/Her Clinician?**

We determined whether the study addressed the subsequent discussion between the patient and his/her clinician (ie, shared decision-making) and whether it was affected by use of the decision aid. We also determined
whether there was concordance between the patient and the clinician (ie, whether they agreed on a particular cancer screening test option). In addition, we determined whether any other factors after the patient/clinician encounter (eg, family members, media) were considered as having influenced the patient’s screening behavior.

5) Does the Decision Aid Appear to Be Applicable in Real-World Practice?
We determined the feasibility of applying the decision aid in real-world practice through the study’s setting and patient selection, and whether the decision aid was stand-alone or done in conjunction with other clinical activities. We also determined whether the study addressed the ability of the decision aid to be used in repeat screening and whether cost analysis was performed.

Determination of Outcomes
For the outcomes, only those outcomes based on intention to treat were considered when the intention-to-treat numbers were available. In addition, when the P value was available, only those outcomes that were statistically significant at P < .05 were considered to be meaningfully different. Outcomes were compared between groups for the studies that were randomized or factorial in design. Outcomes were compared before and after the intervention for those studies with a preintervention/postintervention design.

Specific Areas Addressed Based on the 5 Questions
The 2 evaluators independently read each publication to determine each of the following areas: 1) primary author and year; 2) target cancer for screening; 3) cancer screening options addressed; 4) target population and characteristics (eg, patient, clinician, or both); 5) study design; 6) setting (eg, community or academic); 7) follow-up duration; 8) content of the decision aid (theoretical framework, provision of information, risks and benefits, values clarification exercise, guidance on decision-making and communication, provision of a no-screening option, and discussion of when to stop screening); 9) patient outcomes assessed for the decision aid (knowledge, attitude, subjective norm, self-efficacy, preference clarification, intention, and screening behavior) as well as whether it was a self-report or an observational review; 10) patient/clinician outcomes assessed for the decision aid (shared decision-making and concordance); and 11) practice outcomes assessed for the decision aid (postvisit factors [eg, effect of media, family, and friends], incorporation of the decision aid into practice [eg, meaningful use], effect of the decision aid on repeated screening, and cost analysis).

The evaluators met as a group to review their classifications, discussed any disagreements, and arrived at a consensus of opinion for all studies.

Results
Seventy-nine studies were identified that evaluated 73 decision aids meeting the criteria outlined above. Only 2 decision aids dealt with cervical cancer screening. Eighteen decision aids dealt with breast cancer screening, 9 of which concerned mammography for the general population and 9 of which concerned genetic testing for those considered to be at high risk of breast cancer based on family history and other information. Twenty-one decision aids dealt with colorectal cancer screening; 29 dealt with prostate cancer screening; 2 decision aids dealt with both colorectal and prostate cancer screening; and one decision aid dealt with all 4 cancer screenings: breast, cervical, colorectal, and prostate.

Characteristics of the Identified Studies
Table 1 summarizes the characteristics of the identified studies. For breast and prostate cancer screening, options were a single test, namely mammography or genetic testing (BRCA) and prostate-specific antigen, respectively. The breast self-examination and clinical breast examination in one decision aid on mammography screening were not considered options but rather came as a set with the mammogram. Similarly, digital rectal examination and prostate-specific antigen testing in 12 of the 29 decision aids on prostate cancer screening were not options but were considered as a set.

The 2 decision aids on cervical cancer screening also dealt with a single test: cervical cytology (Papanicolaou test). Decision aids for colorectal cancer screening were the only ones that considered choosing among multiple screening test options. In these cases, the options varied from just one (4 of 21 decision aids) to 2 (4 decision aids) to 3 or more (13 decision aids). One study explicitly compared a 2-option decision aid, namely stool blood test and colonoscopy, with a 5-option decision aid with options that included stool blood test, flexible sigmoidoscopy, stool blood test and flexible sigmoidoscopy, barium enema, and colonoscopy. Of note, the newer screening tests of magnetic resonance imaging for women at high risk of breast cancer, human papillomavirus testing for cervical cancer screening, and computed tomography colonography and stool DNA testing for colorectal cancer screening have not yet been incorporated into the published decision aids.
| STUDY* | SCREENING OPTIONS | TARGET POPULATION* | DESIGN | SETTING | FOLLOW-UP DURATION |
|--------|-------------------|--------------------|--------|---------|-------------------|
| Kadison 199814 | BSE, CBE, MMG | Women aged 22-75 y | Longitudinal uncontrolled study: interactive voice-response risk assessment (initially: n=343; follow-up: n=189) | 2 companies in United States | 8 mo |
| Street 199815 | MMG | Women aged 40-75 y | RCT: computer-based multimedia DA (n=54) vs print DA (n=54) | 2 primary care clinics in United States | Immediate |
| Lawrence 200016 | MMG | Women aged 49-89 y | One-time uncontrolled intervention: print DA (n=103) | One medical school, one primary care clinic, and one community center in United States | Immediate |
| Valdez 200117 | MMG | Hispanic women aged ≥40 y | Parallel-group randomized experimental design (pre vs post): computer kiosk-based DA (n=269) | 5 clinics and one community-based organization in United States | 4 mo |
| Rimer 200118 and Rimer 200219 | MMG | Women aged 40-44 y and 50-54 y | 3-arm RCT: tailored print newsletter plus telephone counseling (n=339) vs tailored print newsletter (n=374) vs usual care (n=378) | One state-based health insurance membership in United States | 24 mo |
| Lewis 200320 | MMG | Women aged 35-49 y | 3-arm RCT: positive video (n=64) vs neutral video (n=54) vs negative video (n=60) | University-based general medicine clinic in United States | Immediate |
| Mathieu 200721 | MMG | Women aged 70-71 y | RCT: print DA (n=367) vs usual care (n=367) | Communities in Australia | 1 mo |
| Vernon 200822 | MMG | Women aged ≥52 y | 3-arm RCT: tailored print plus targeted print intervention (n=1803) vs targeted print intervention only (n=1857) vs usual care (n=1840) | National veteran registry in United States | 2 y |
| Mathieu 201023 | MMG | Women aged 38-45 y | RCT: immediate Web-based DA (n=189) vs delayed Web-based DA (n=223) | Online recruitment in Australia | Immediate |
| Kadison 199814 | BRCA testing | Women aged 18-75 y with family history of breast or ovarian cancer | 3-arm RCT: print DA plus counseling (n=122) vs usual care (n=114) vs waiting list control (n=164) | 2 cancer centers in United States | 1 mo |
| Green 200125 | BRCA testing | Women aged 19-59 y with family history of breast cancer | 3-arm RCT: interactive, multimedia CD-ROM DA plus counseling (n=29) vs counseling alone (n=105) | One federal research facility in United States | Immediate |
| Schwartz 200126 | BRCA testing | Ashkenazi Jewish women aged 18-83 y | RCT: print DA (n=191) vs usual care (n=190) | Religious organization in United States | 1 mo |
| Green 200427 and Green 200528 | BRCA testing | Women aged 24-77 y with personal or family history of breast cancer | RCT: interactive, multimedia CD-ROM DA plus counseling alone (n=105) vs counseling alone (n=105) | 5 university hospitals and one community hospital in United States | 6 mo |
| Miller 200529 | BRCA testing | Women aged ≥18 y | RCT: print DA vs usual care (total n=279) | One federal research facility in United States | 6 mo |
| Wang 200530 | BRCA testing | Women aged 22-76 y | 2 × 2 factorial design: CD-ROM DA plus counselor feedback (n=50) vs CD-ROM DA only (n=50) vs counselor feedback only (n=49) vs usual care (n=49) | One university-based cancer clinic in United States | Immediate |
| Wakefield 200831 | BRCA testing | Women aged ≥18 y with family history of breast cancer | RCT: print DA (n=73) vs control pamphlet (n=72) | 5 cancer clinics in Australia | 6 mo |
| Wakefield 200832 | BRCA testing | Women aged ≥18 y with family history of breast cancer | RCT: detailed print DA (n=73) vs control pamphlet (n=75) | 5 cancer clinics in Australia | 6 mo |
| Gray 200933 | BRCA testing | Women aged 18-70 y with personal or family history of breast or ovarian cancer | 3-arm RCT: Web site with risk information on BRCA testing attributed to experts (n=98) vs not attributed (n=93) vs no risk information (n=89) | 1 university-based research facility in United States | Immediate |
| Kadison 199814 | Cervical cytology | Women aged 20-64 y | RCT: leaflet with risks and uncertainties (n=153) vs standard leaflet (n=145) | 3 general practices in United Kingdom | Immediate |
| Park 200534 | Cervical cytology | Women of unknown ages | Nonequivalent, control group, posttest only design: DA (n=48) vs usual care (n=48) | One church in Korea | Immediate |
**TABLE 1. (Continued)**

| STUDY* | SCREENING OPTIONS | TARGET POPULATION\(b\) | DESIGN | SETTING | FOLLOW-UP DURATION |
|--------|-------------------|--------------------------|--------|---------|-------------------|
| Pignone 200017 | SBT, FS, SBT plus FS | Men and women aged 50-75 y | RCT: video DA (n=125) vs usual care (n=124) | 3 community primary care practices in United States | 3-6 mo |
| Wolf & Schorling 200015 | SBT, SBT plus FS | Men and women ≥65 y | 3-arm RCT: absolute risk script (n=130) vs relative risk script (n=130) vs control script (n=133) | 4 general internal medicine practices (one university and 3 community) in United States | Immediate |
| Dolan & Frisina 200216 | SBT, FS, SBT plus FS, BE, COL | Men and women aged 50-83 y | RCT: print DA (n=50) vs usual care (n=47) | One community and one university-based internal medicine clinic in United States | Immediate |
| Lewis 200844 | FS | Men and women aged 50-74 y | RCT: educational video (n=459) plus mailing vs no video (n=488) | 5 primary care practices in United States | 6 mo |
| Jerant 200738 | SBT, FS, COL | Men and women aged ≥50 y | RCT: tailored multimedia computer program (n=24) vs nontailored program (n=25) | 6 community family practices in United States | Immediate |
| Myers 200739 | SBT, SBT plus FS | Men and women aged 50-74 y | 4-arm RCT: tailored print plus telephone counseling (n=386) vs tailored print (n=386) vs nontailored print (n=387) vs usual care (n=387) | One university-based family practice in United States | 24 mo |
| Ruffin 200240 | SBT, SBT plus FS, BE, COL | Men and women aged 50-70 y who were never screened for CRC | RCT: Interactive Web site (n=87) vs standard Web site (n=87) | 3 communities (urban, suburban, and rural) in United States | 24 wk |
| Griffith 200841 | SBT, SBT plus FS, BE, COL (SBT, COL in 2-option) | Men and women aged 48-75 y | RCT: 5-option DVD DA (n=25) vs 2-option DVD DA (n=37) | One university-based research facility in United States | Immediate |
| Griffith 200842 | SBT, SBT plus FS, BE, COL | Men and women aged 50-85 y | RCT: 5-option plus no-screening option video DA (n=57) vs 5-option video DA (n=48) | 3 communities in United States | Immediate |
| Katsumura 200843 | SBT, COL | Men and women aged 40-59 y | RCT: Internet-based information plus risk information (n=150) vs Internet-based information only (n=159) | 1 Internet community in Japan | Immediate |
| Lewis 200844 | SBT, FS, COL | Men and women aged 50-75 y | RCT: mailed print DA (n=137) plus waiting list control (n=100) | University-based general medicine clinic in United States | 5 mo |
| Trenena 200845 | SBT | Men and women aged 50-74 y | RCT print DA (n=157) vs government guidelines (n=157) | 6 community family practices in Australia | 1 mo |
| Makoul 200946 | SBT, FS, COL | Hispanic men and women aged 50-80 y | Pretest/posttest design: computer kiosk DA (n=270) | 2 community clinics in United States | Immediate |
| Marne 200947 | COL | Men and women with family history of CRC | 3-arm RCT: tailored print plus telephone counseling (n=112) vs tailored print (n=161) vs standard print (n=139) | 26 medical centers in United States | 6 mo |
| Lewis 201048 | SBT, COL | Men and women aged 75-95 y | One-time uncontrolled intervention: print DA (n=46) | One senior center in United States | Immediate |
| Smith 201049 | SBT | Men and women with low educational attainment, aged 55-64 y | 3-arm RCT: print and DVD DA plus question prompt list (n=196) vs print and DVD DA only (n=188) vs standard information (n=188) | Community in Australia | 3 mo |
| Miller 201150 | SBT, FS, COL | Men and women aged 50-74 y | RCT: Web-based DA (n=132) vs usual care (n=132) | One community internal medicine clinic in United States | 24 wk |
| Pignone 201151 | SBT, SBT plus FS, BE, COL | Men and women aged 52-80 y | Clustered RCT: DVD/VHS DA (n=211) plus academic detailing of practices vs usual care (n=232) | 32 primary care practices participating in a single health insurance plan in United States | 12 mo |
| Schroy 201152 | SBT, SBT plus FS, BE, COL | Men and women aged 50-75 y | 3-arm RCT: DVD DA plus personalized risk assessment (n=223) vs DVD DA (n=212) vs usual care (n=231) | One university-based internal medicine clinic and one community health center in United States | Immediate |
| Steckelberg 201153 | SBT, COL | Men and women aged 50-75 y | RCT: print DA with risk information (n=795) vs print standard information (n=792) | Health insurance membership in Germany | 6 mo |
| Vernon 201154 | SBT, FS, BE, COL | Men and women aged 50-70 y | 3-arm RCT: tailored Web site (n=413) vs nontailored Web site (n=398) vs usual care (n=413) | One university-based clinic in United States | 24 mo |
| STUDY | SCREENING OPTIONS | TARGET POPULATION | DESIGN | SETTING | FOLLOW-UP DURATION |
|-------|-------------------|-------------------|--------|---------|-------------------|
| Flood 199655 | PSA | Men aged ≥50 y | RCT: educational videotape (n=184) vs control videotape (n=188) | One university hospital in United States (free screening program and clinic) | Immediate |
| Wolf 199656 and Wolf & Schorling 199857 | PSA | Men aged ≥50 y | RCT: scripted DA (n=103) vs usual care (n=102) | 4 university-affiliated primary care practices in United States | Immediate |
| Volk 199962 and Volk 200363 | PSA | Men aged 45-70 y | RCT: video DA before physician visit | One university-based clinic in United States | 1 y |
| Myers 199958 | PSA, DRE | Men aged 40-70 y | RCT: print information plus tailored information (n=192) vs print information only (n=221) | One university-based clinic in United States | 1 y |
| Wolf 199656 | PSA | Men aged 40-75 y | RCT: print DA plus survey (n=135) | One Veterans Administration clinic in United States | 2 wk |
| Watson & Van Ruiswyk 200056 | PSA | Men aged 40-70 y | RCT: print DA with detailed risk description (n=122) vs print information without (n=135) | One Veterans Administration primary care clinic in United States | 1 y |
| Frosch 200162 | PSA | Men aged ≥50 y | 2×2 factorial design: shared decision-making video plus discussion on risks and benefits (n=42) vs video only (n=46) vs discussion only (n=45) vs usual care (n=43) | One community hospital in United States | Immediate |
| Ruthman & Ferrans 200466 | PSA | Men aged 50-70 y | 2×2 factorial design: video DA vs usual care (n=195) | One Veterans Administration clinic in United States | 1 y |
| Gattellari & Ward 200568 | PSA | Men aged 45-69 y | RCT: Web-based DA (n=114) vs video DA (n=112) | One community hospital in United States | Immediate |
| Partin 200469 and Partin 200670 | PSA | Men aged ≥50 y | RCT: video DA before physician visit (n=80) vs information booklet 2 wk after physician visit (n=80) | One university-based family medicine clinic | Immediate |
| Partin 200671 | PSA | Men aged 50-70 y | RCT: video DA (n=103) vs video DA (n=102) | 4 Veterans Administration clinics in United States | Immediate |
| Watson 200657 | PSA | Men aged 40-75 y | RCT: print DA plus survey (n=980) vs usual care (n=980) | 11 general practices in United Kingdom | Immediate |
| Kripalani 200773 | PSA | Men aged 45-70 y | RCT: print DA (n=101) vs usual care (n=101) | One community hospital in United States | Immediate |
| Krist 200774 | PSA | Men aged 50-70 y | 3-arm RCT: video DA (n=140) vs print DA (n=140) vs conventional leaflet (n=140) | One large community in Australia | ≥7 d |
| Myers 200559 | PSA, DRE | African American men aged 40-69 y | RCT: print DA plus educational session (n=121) vs print DA only (n=121) | 3 community primary care practices in United States | 6-11 mo |
| Partin 200470 and Partin 200670 | PSA | Men aged ≥50 y | RCT: video DA (n=308) vs print DA (n=295) vs usual care (n=290) | 4 Veterans Administration clinics in United States | 1 y |
| Watson 200657 | PSA | Men aged 40-75 y | RCT: print DA plus survey (n=980) vs usual care (n=980) | 11 general practices in United Kingdom | Immediate |
| Kripalani 200773 | PSA, DRE | Men aged 45-70 y | RCT: detailed educational print (n=101) vs simple educational print (n=101) vs usual care (n=101) | One academic teaching hospital in United States | Immediate |
| Krist 200774 | PSA | Men aged 50-70 y | RCT: Web-based DA (n=226) vs print DA (n=196) vs usual care (n=76) | One community family practice in United States | 2 wk |
| Ellison 200871 | PSA, DRE | African American men aged 40-65 y | RCT: Web-based DA tailored to family history of prostate cancer (n=46) vs Web-based nontailored DA (n=41) | One annual Mason convention in United States | Immediate |
| Ilic 200872 | PSA | Men never screened for prostate cancer, aged >45 y | 3-arm RCT: Web-based education (n=56) vs video-based education (n=55) vs print-based education (n=50) | 5 states in Australia | 1 wk |
| Stephens 200877 | PSA, DRE | African American men aged 40-70 y and non-African American men aged 50-70 y | Solomon 4-group design: pretax plus print DA plus post-DA process measures plus posttest (n=50) vs DA booklet plus post-DA process measures plus posttest (n=50) vs pretax plus posttest (n=50) vs posttest only (n=50) | 10 urban professional research facilities in United States | Immediate |
| Volk 200878 | PSA, DRE | African American men aged 40-70 y, non-African American men aged 50-70 y | RCT: computer-based interactive DA (n=224) vs print DA plus CD (n=226) | 2 primary care clinics in United States | 2 wk |
| Weinrich 200879 | PSA, DRE | African American men aged 40-70 y, white men aged 50-70 y | Postintervention, quasi-experimental design: enhanced DA (print DA plus physician and peer pictures and statements; n=120) vs print DA only (n=110) | 4 urban communities in United States | Immediate |
Interestingly, most decision aids used on prostate cancer screening (19 of 29 decision aids) did not incorporate a theoretical framework. A few had adopted a formative approach (eg, interviews, focus groups, and expert feedback; 24 of 73 decision aids). However, others seemed to have moved relatively quickly from literature and expert review to the creation of the tool and pretesting.

Variation was seen in the methods of values clarification, in which the patient actively engages in a process where his or her values regarding the screening test(s) are clarified. The patient had to be actively involved in such an exercise, such as writing out the pros and cons (in cases of paper-based decision aids) or clicking on choices (in the case of Web-based and other interactive decision aids). Fewer than one-half of the decision aids used these exercises (27 of 73 decision aids).

Neither of the 2 decision aids that addressed cervical cancer screening incorporated them.

Variation was also seen in the methods of providing guidance for making decisions and communicating with the clinician. Some were simply a statement of recommendation to speak to a clinician.
### TABLE 2. Content of Decision Aids

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION EXERCISE | GUIDANCE ON DECISION-MAKING AND COMMUNICATION | ADDRESSES OPTION OF NO SCREENING | ADDRESSES WHEN TO STOP SCREENING |
|--------|------------------------|-----------------------------|---------------------------|-------------------|-------------------------------|-------------------------------------------------|---------------------------------|---------------------------------|
| Kadison 1998\(^14\) | None | Literature review, peer-review, pretest | Yes | No | No | Yes | No | No |
| Street 1998\(^15\) | Transtheoretical model, elaboration likelihood model | Pilot test | Yes | No | No | No | No | No |
| Lawrence 2000\(^16\) | None | Content development by multidisciplinary team and lay women; reliability and validity testing | Yes | Yes | No | No | No | No |
| Valdez 2001\(^17\) | Social learning theory | Expert consultation, key informant interviews, focus groups | Yes | No | No | Yes | No | No |
| Rimer 2001\(^18\) and Rimer 2002\(^19\) | Transtheoretical model, precaution adoption process model | Tailored messages based on baseline survey findings | Yes | Yes | Yes | Yes | Yes | No |
| Lewis 2003\(^20\) | None | Literature review, pretest | Yes | Yes | No | No | Yes | No |
| Mathieu 2007\(^21\) | Ottawa Decision Support Framework | Markov model, pilot test | Yes | Yes | Yes | Yes | Yes | Yes |
| Vernon 2008\(^22\) | Transtheoretical model, Health Belief Model, Social Cognitive Theory, Theory of Planned Behavior | Targeted focus groups Tailored: tailored messages based on baseline survey findings | Yes | Yes | Yes | Yes | No | No |
| Mathieu 2010\(^23\) | Ottawa Decision Support Framework | Markov model, pilot test | Yes | Yes | Yes | Yes | Yes | No |

### Breast cancer mammography screening (n=9)

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION EXERCISE | GUIDANCE ON DECISION-MAKING AND COMMUNICATION | ADDRESSES OPTION OF NO SCREENING | ADDRESSES WHEN TO STOP SCREENING |
|--------|------------------------|-----------------------------|---------------------------|-------------------|-------------------------------|-------------------------------------------------|---------------------------------|---------------------------------|
| Lerman 1999\(^24\) | Behavioral models of decision-making | Structural protocol | Yes | Yes | No | No | Yes | No |
| Green 2001\(^25\) | None | Provides same information as the genetic counselors | Yes | Yes | Yes | Yes | Yes | No |
| Schwartz 2001\(^26\) | None | NA | Yes | Yes | No | No | Yes | No |
| Green 2004\(^27\) and Green 2005\(^28\) | None | Provides same information as the genetic counselors | Yes | Yes | Yes | Yes | Yes | No |
| Miller 2005\(^29\) | Cognitive-social health processing model | Formative evaluation: interviews, focus groups | Yes | Yes | No | Yes | Yes | No |
| Wang 2005\(^30\) | None | Collaboration between content experts and health-related media experts | Yes | Yes | No | Yes | Yes | No |
| Wakefield 2008\(^31\) | Ottawa Decision Support Framework | Content analysis, pilot test | Yes | Yes | Yes | Yes | Yes | No |
| Wakefield 2008\(^32\) | Ottawa Decision Support Framework | Content analysis, pilot test | Yes | Yes | Yes | Yes | Yes | No |
| Gray 2009\(^33\) | Social Cognitive Theory | Literature review, expert consultation, pretest | Yes | Yes | No | Yes | No | No |

### Breast cancer genetic testing (n=9)

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION EXERCISE | GUIDANCE ON DECISION-MAKING AND COMMUNICATION | ADDRESSES OPTION OF NO SCREENING | ADDRESSES WHEN TO STOP SCREENING |
|--------|------------------------|-----------------------------|---------------------------|-------------------|-------------------------------|-------------------------------------------------|---------------------------------|---------------------------------|
| Adab 2003\(^12\) | None | Added information on risks and uncertainties to the National Health Service Cervical Screening Programme leaflet | Yes | Yes | No | No | No | No |

### Cervical cancer screening (n=2)

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION EXERCISE | GUIDANCE ON DECISION-MAKING AND COMMUNICATION | ADDRESSES OPTION OF NO SCREENING | ADDRESSES WHEN TO STOP SCREENING |
|--------|------------------------|-----------------------------|---------------------------|-------------------|-------------------------------|-------------------------------------------------|---------------------------------|---------------------------------|
| Park 2005\(^13\) | Health Belief Model, Theory of Reasoned Action, self-efficacy theory | Developed from focus groups | Yes | Yes | No | No | No | No |

### Colorectal cancer screening (n=21)

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION EXERCISE | GUIDANCE ON DECISION-MAKING AND COMMUNICATION | ADDRESSES OPTION OF NO SCREENING | ADDRESSES WHEN TO STOP SCREENING |
|--------|------------------------|-----------------------------|---------------------------|-------------------|-------------------------------|-------------------------------------------------|---------------------------------|---------------------------------|
| Pignone 2000\(^14\) | Transtheoretical model | Patient preference checking, focus groups | Yes | Yes | No | Yes | No | No |
| Wolf & Schorling 2000\(^15\) | None | Physician panel, pilot testing | Yes | Yes | No | No | Yes | No |
### TABLE 2. (Continued)

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION |
|--------|------------------------|----------------------------|--------------------------|--------------------|----------------------|
| Dolan & Frisina 200236 | Analytic hierarchy process | Structured interviews, feasibility testing | Yes | Yes | Yes |
| Zapka 200437 | PRECEDE/PROCEED model, Social Cognitive Theory | Literature review | Yes | Yes | No |
| Jerant 200738 | Transtheoretical model | Personally tailored feedback messages | Yes | Yes | Yes |
| Myers 200739 | Preventive health model | Tailored messages based on baseline survey findings | Yes | Yes | No |
| Ruffin 200740 | Elaboration likelihood model | Developed empirically from 10 focus groups and 30 patient interviews | Yes | Yes | Yes |
| Griffith 200841 | Transtheoretical model | Previous DA, literature review, usability testing | Yes | Yes | No |
| Griffith 200842 | Transtheoretical model | Previous DA, literature review, focus groups, expert/patient review | Yes | Yes | No |
| Katsumura 200843 | Analytic hierarchy process | Construction of decision model | Yes | Yes | Yes |
| Lewis 200844 | None: DA standard | Literature review, patient focus groups, patient and expert review | Yes | Yes | Yes |
| Trevena 200845 | Theory of Planned Behavior | Incorporated research-derived expert and lay beliefs | Yes | Yes | Yes |
| Makoul 200946 | Extended parallel process model | Patient interviews and focus groups, usability testing | Yes | Yes | No |
| Manne 200947 | Health Belief Model, transtheoretical model, dual-process theory | Construction of tailored messages | Yes | Yes | No |
| Lewis 201048 | Ottawa Decision Support Framework | Literature review, patient interviews, cognitive testing | Yes | Yes | Yes |
| Smith 201049 | None | Specific design for adults with low literacy skills using plain language and basic design, focus groups | Yes | Yes | Yes |
| Miller 201150 | Transtheoretical model | Previous DA, literature review, usability testing | Yes | Yes | Yes |
| Pignone 201151 | Transtheoretical model | Previous DA, literature review, usability testing | Yes | Yes | Yes |
| Schroy 201152 | Ottawa Decision Support Framework | Literature review, existing DA review, expert opinion, focus groups, usability testing | Yes | Yes | Yes |
| Steckelberg 201153 | United Kingdom Medical Research Council framework for complex intervention | Literature review, focus groups, expert review | Yes | Yes | Yes |
| Vernon 201154 | Transtheoretical model | Intervention mapping, incorporating theory and empiric evidence | Yes | Yes | Yes |

**Prostate cancer screening (n=29)**

| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION |
|--------|------------------------|----------------------------|--------------------------|--------------------|----------------------|
| Flood 199655 | None | Literature review, patient focus groups, patient and expert review | Yes | Yes | Yes |
| Wolf 199656 and Wolf & Schirling 199857 | None | Physician panel review, pilot testing | Yes | Yes | Yes |
| Myers 199958 | Preventive health model | Tailored messages based on baseline survey findings | Yes | Yes | Yes |
| Schapira & VanRuiswyk 200059 | Health Belief Model | Focus groups | Yes | Yes | No |
| Frosh 200160 | None | Literature review, patient focus groups, patient and expert review | Yes | Yes | Yes |
| Wilt 200161 | None | Expert review, content validity check, readability pretesting | Yes | Yes | Yes |
| Volk 199962 and Volk 200363 | None | Literature review, patient focus groups, patient and expert review | Yes | Yes | Yes |
| STUDY* | THEORETICAL FRAMEWORK | DESCRIPTION OF DEVELOPMENT | PROVISION OF INFORMATION | RISKS AND BENEFITS | VALUES CLARIFICATION EXERCISE | GUIDANCE ON DECISION-MAKING AND COMMUNICATION | ADDRESSES OPTION OF NO SCREENING | ADDRESSES WHEN TO STOP SCREENING |
|--------|----------------------|-----------------------------|---------------------------|-------------------|--------------------------------|-----------------------------------------------|---------------------------------|---------------------------------|
| Frosch 2003 | None | Conversion of a video DA (Frosch 2001) to Web-based DA | Yes | Yes | No | Yes | Yes | No |
| Gattellari & Ward 2003 | None | Literature review, pilot testing | Yes | Yes | Yes | Yes | Yes | No |
| Ruthman & Ferrans 2004 | None | Literature review, patient focus groups, patient and expert review | Yes | Yes | No | No | Yes | No |
| Sheridan 2004 | None | Literature review, cognitive interviewing and feedback | Yes | Yes | No | No | Yes | No |
| Gattellari & Ward 2005 | None | Literature review, pilot testing | Yes | Yes | Yes | Yes | Yes | No |
| Myers 2005 | Preventive health model | Tailored messages based on baseline survey findings | Yes | Yes | Yes | Yes | Yes | No |
| Partin 2004 & Partin 2006 | Social Cognitive Theory | Literature review, patient focus groups, patient and expert review | Yes | Yes | No | Yes | Yes | No |
| Watson 2006 | None | Expert review, field testing | Yes | Yes | No | Yes | Yes | No |
| Kralainen 2007 | None | Multidisciplinary team design, pilot testing | Yes | Yes | No | Yes | Yes | No |
| Krist 2007 | None | Expert review | Yes | Yes | No | No | No | No |
| Ellison 2008 | None | Based on Cochrane Review definition of DA | Yes | Yes | No | No | Yes | No |
| Ilc 2008 | None | NA | Yes | Yes | No | No | Yes | No |
| Stephens 2008 | Prostate cancer screening decisional conflict model | Created by the Centers for Disease Control and Prevention | Yes | Yes | No | Yes | Yes | No |
| Volk 2008 | None | Integration of didactic soap opera episodes with interactive learning modules | Yes | Yes | Yes | No | Yes | No |
| Weinrich 2008 | Social learning theory | Previous research findings, community feedback | Yes | Yes | No | Yes | Yes | No |
| Frosch 2009 & Bhatnagar 2009 | Chronic disease model | Literature review, health care professional feedback, patient usability testing | Yes | Yes | Yes | No | Yes | No |
| Allen 2009 | Ottawa Decision Support Framework | Expert opinion and published research findings | Yes | Yes | Yes | Yes | Yes | No |
| Allen 2010 | Ottawa Decision Support Framework | Expert opinion, International Patient Decision Aid Standards, focus groups, usability testing | Yes | Yes | Yes | Yes | Yes | No |
| Joseph-Williams 2010 | None | Expert review, field testing | Yes | Yes | Yes | Yes | Yes | No |
| Rubel 2010 | None | Created by the Centers for Disease Control and Prevention | Yes | Yes | No | No | Yes | No |
| van Vugt 2010 | None | Based on screening results of 6288 men | Yes | Yes | No | No | Yes | No |
| Capik & Gozum 2012 | Health Belief Model | Literature review | Yes | No | No | Yes | No | No |

Multiple cancer screening (n=3)

| Study | Theoretical Framework | Description of Development | Provision of Information | Risks and Benefits | Values Clarification Exercise | Guidance on Decision-Making and Communication | Addresses Option of No Screening | Addresses When to Stop Screening |
|--------|----------------------|-----------------------------|---------------------------|-------------------|--------------------------------|-----------------------------------------------|---------------------------------|---------------------------------|
| Frosch 2008 | None | Literature review, patient focus groups, patient and expert review | Yes | Yes | No | Yes | Yes (for prostate cancer screening) | No |
| Brackett 2010 | None | Literature review, patient focus groups, patient and expert review | Yes | Yes | No | Yes | Yes (for prostate cancer screening) | No |
| Krist 2012 | None | Efficacy, adoption and dissemination trials | Yes | Yes | No | Yes | Yes (for prostate cancer screening) | No |

NA indicates not addressed; PRECEDE/PROCEED, Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation/Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development; DA, decision aid.

*Listed in ascending order by the year of publication for each cancer.
Others provided a list of questions to ask the clinician\(^{17,49,84}\), some of these provided a list customized to the specific patient.\(^{22,31,82}\) Other studies attempted to facilitate communication through practice-based interventions, such as having the patient use the decision aid immediately before or during genetic counseling\(^{40-42}\), or providing color codes in the chart to let the clinicians know of the patient’s readiness for colorectal cancer screening.\(^{34,41,50,51}\) In all, 43 of 73 decision aids, including all 3 decision aids on multiple cancer screening,\(^{49,88-90}\) provided the guidance on communicating with clinicians. Neither of the 2 decision aids on cervical cancer screening did so.\(^{12,13}\)

Regarding provision of a “no screening” option, all decision aids involving breast cancer genetic testing\(^{24-33}\), and all but 2 decision aids involving prostate cancer screening (including those targeting multiple cancers)\(^{55-73,75-86,88-90}\) provided such an option. This is understandable since the choice in these cases is to undergo the screening test or not. This option was also available in 4 of 9 breast cancer mammography screening\(^{18-21,23}\) and 6 of 21 colorectal cancer screening decision aids.\(^{35,36,42,48,49,53}\) Neither of the 2 cervical cancer screening decision aids provided it.\(^{12,13}\) Of all the decision aids, only one on mammography screening\(^{21}\) and one on prostate cancer screening\(^{56,57}\) dealt with the question of when to stop screening.

### Patient Outcomes Assessed for the Decision Aids

Knowledge was assessed in a majority of the decision aids (52 of 73 decision aids) (Table 3).\(^{12-90}\) Twelve decision aids had no effect on knowledge.\(^{15,20,29,38,41,42,47,64,70,71,76,78,87}\) Attitude was assessed in 35 of 73 decision aids. There was no impact on attitude in 4 breast cancer mammography decision aids.\(^{15,18,20,23}\) Of the 7 breast cancer genetic testing studies, one showed an increase\(^{26}\) and 2 showed a decrease in perceived personal risk.\(^{24,27,28}\) One showed a decrease in positive belief,\(^{33}\) and one showed a decrease in worry.\(^{30}\) The remaining 2 demonstrated no difference.\(^{11,32}\) One decision aid on cervical cancer screening showed decreased perception of procedural and cognitive barriers and increased perceived benefit of the Papanicolaou test.\(^{13}\) Of the 8 colorectal cancer screening decision aids for which attitude was measured,\(^{38,42,43,45,47,49,53,54}\) there was little impact. Studies including a “no screening” option resulted in less clarity concerning perceived benefits\(^{42}\) and a less positive attitude overall toward colorectal cancer screening.\(^{49}\)

The 14 prostate cancer screening decision aids in which the attitude was measured, all but one of which contained a “no screening” option, showed overall a more negative attitude toward prostate cancer screening.\(^{59-61,65,68,72,76,77,80-82,84-87}\) Subjective norm, or perceived social pressure to engage or not to engage in a behavior, was addressed in just 5 of 73 decision aids.\(^{31,32,47,54,88}\) All but one of them (subjective norm was found to decrease with one decision aid on multiple cancer screenings)\(^{46}\) showed no effect. Self-efficacy was addressed in 10 of 73 decision aids. It was increased in 5 decision aids,\(^{13,38,54,65,82}\) decreased in 2,\(^{60,88}\) and not different in 3 decision aids.\(^{45,65,83}\)

Preference clarification was assessed in 31 of 73 decision aids.\(^{16,21,23,31-33,36,40-43,45,48-50,52,53,55,60,61,64,65,68,74,76-78,80-84}\) In 19 of these, preference clarification was assessed through decreased decisional conflict, greater values clarity (eg, a subscale of the decisional conflict scale), or greater informed choice (a combination of knowledge, values clarity, and intent).\(^{21,23,31,32,36,41,42,45,48,49,53,74-84}\)

Intention was measured in 40 of 73 decision aids. Nine decision aids led to an increased intention to get screened; 7 of these concerned colorectal cancer screening,\(^{34,38,46,48,50,52,54}\) and one each dealt with cervical cancer screening.\(^{13}\) and prostate cancer screening.\(^{36}\) A decreased intention to undergo screening was noted in 13 decision aids: 8 of these dealt with prostate cancer screening,\(^{55-57,60,62,63,66,70,71,80,81,84}\), 2 with breast cancer genetic testing\(^{29,33}\), and one each concerned mammographic screening,\(^{13}\) cervical cancer screening,\(^{23}\) and multiple cancer screening.\(^{88}\) No difference in intention was noted in 18 decision aids.\(^{21,24-28,35,41,42,45,47,65,67,68,72,76,82,83,87}\)

### Screening Behavior

Screening behavior was assessed in 36 of 73 decision aids. Thirteen decision aids led to an increase in screening (7 colorectal cancer screening decision aids,\(^{34,39,40,44,47,50,51}\) 3 prostate cancer screening decision aids\(^{58,73,87}\) and 2 mammography decision aids,\(^{14,17}\) and one cervical cancer screening decision aid\(^{13}\) ), while 5 decision aids led to a decrease (3 prostate cancer screening,\(^{55,62,63,84}\) one breast cancer genetic testing,\(^{30}\) and one colorectal cancer screening decision aid\(^{49}\) ). Eighteen decision aids showed no difference in screening.

### Patient/Clinician and Practice Outcomes Assessed for the Decision Aid

Many of the studies on decision aids did not address any of the issues related to shared decision-making, concordance, postvisit factors, incorporation into practice, impact of the decision aid, and cost analysis. Eighteen of 73 decision aids were assessed for their effect on shared decision-making. No trend toward an increased degree of shared decision-making was noted in these 18 studies. All studies used patient self-report and did not use observational measures, such as audiorecorded data, to assess shared decision-making. Of note, none of the decision aids on mammography or cervical cancer screening addressed shared decision-making as a measure.\(^{12-23}\) Concordance, or whether the patient and clinician agreed on a particular cancer screening test option, was addressed in just 5 of 73 decision aids.\(^{31,32,40,52,68}\) It was high in the 2 decision aids on breast cancer genetic testing,\(^{35,32}\) but only
| STUDY* | KNOWLEDGE | ATTITUDE | SUBJECTIVE NORM | SELF-EFFICACY | PREFERENCE CLARIFICATION | INTENTION | SCREENING BEHAVIOR |
|--------|-----------|----------|----------------|--------------|--------------------------|-----------|-------------------|
| Kadison 199814 | NA | NA | NA | NA | NA | NA | Self-report: increased BSE and CBE, but MMG not increased |
| Street 199815 | No difference | No difference in personal importance or anxiety | NA | NA | NA | NA | |
| Lawrence 200016 | NA | NA | NA | NA | NA | NA | Less preference for MMG, weaker feeling toward their own decision regarding MMG |
| Valdez 200117 | NA | NA | NA | NA | NA | NA | Self-report: 51% had completed or scheduled MMG |
| Rimer 200118 and Rimer 200219 | Increased for tailored print and telephone counseling vs usual care; not increased for tailored print vs usual care | Increased risk perception | NA | NA | NA | NA | Self-report: no difference |
| Lewis 200320 | No difference | No change or difference in perception of benefits and harms | NA | NA | NA | NA | |
| Mathieu 200721 | Increased | NA | NA | NA | Greater values for clarity and informed choice | No difference | Self-report: no difference |
| Vernon 200822 | NA | NA | NA | NA | NA | NA | Self-report: no difference |
| Mathieu 201023 | Increased | No difference in perceived benefits and harms or anxiety | NA | NA | No difference in informed choice | Decreased | NA |
| Breast cancer genetic testing (n=9) | | | | | | | |
| Lerman 199724 | Increased | Decreased perceived personal risk; increased perceived limitations; no difference in perceived benefits | NA | NA | NA | No difference | |
| Green 200125 | Increased | NA | NA | NA | No difference | NA | |
| Schwartz 200126 | Increased | No difference in perceived benefits; increased perceived risk | NA | NA | NA | No difference | |
| Green 200427 and Green 200528 | Increased in low-risk group; no difference in high-risk group | Greater decrease in absolute risk perception in low-risk group; no difference in high-risk group; no difference in decrease in relative risk perception; greater decrease in anxiety | NA | NA | NA | No difference | Self-report: no difference |
| Miller 200529 | No difference | NA | NA | NA | NA | Decreased in average-risk group, increased in high-risk group | NA | |
| Wang 200530 | Increased | Worry declined | NA | NA | NA | NA | Chart audit: decreased |
| Wakefield 200831 | Increased | No difference in distress (eg, intrusive and avoidant thoughts, anxiety, depression) | No difference in perceived family involvement in decision-making | NA | No difference in Decisional Conflict Scale except for Informed subscale (more informed); no difference in informed choice or decisional regret | NA | Self-report: no difference |
| Wakefield 200832 | Increased | No difference in distress (eg, intrusive and avoidant thoughts, anxiety, depression) | No difference in perceived family involvement in decision-making | NA | No difference in Decisional Conflict Scale except for Informed subscale (more informed) and Clear Values subscale (clearer values); no difference in informed choice or decisional regret | NA | Self-report: no difference |
| Gray 200933 | NA | Decrease in positive beliefs; no difference in trust in Internet testing or belief that Internet testing is wise | NA | NA | Increased preference for clinic testing rather than direct-to-consumer testing | Decreased | NA |
TABLE 3. (Continued)

| STUDY | KNOWLEDGE | ATTITUDE | SUBJECTIVE NORM | SELF-EFFICACY | PREFERENCE CLARIFICATION | INTENTION | SCREENING BEHAVIOR |
|-------|-----------|----------|-----------------|---------------|--------------------------|-----------|-------------------|
| Adab 2003 | NA | NA | NA | NA | NA | Decreased | NA |
| Park 2005 | Increased | Decreased perception of procedural barriers and cognitive barriers; increased perceived benefit of Pap test; no difference in perceived susceptibility and seriousness | NA | Increased | NA | Increased | Self-report: increased |
| Cervical cancer screening (n=2) |
| | | | | | | | |
| | | | | | | | |
| Pignone 2000 | NA | NA | NA | NA | NA | Increased | Chart review: screening ordering and completion increased |
| Wolf & Schorling 2000 | Increased | NA | NA | NA | NA | No difference | NA |
| Dolan & Frisina 2002 | NA | NA | NA | NA | Decisional conflict decreased | NA | Chart review: no difference |
| Zapka 2004 | NA | NA | NA | NA | NA | No | Self-report: no difference |
| Jerant 2007 | No difference | No difference in perceived benefits and barriers | NA | Increased | NA | Increased | NA |
| Myers 2007 | NA | NA | NA | NA | NA | NA | Review of chart, billing, laboratory database: increased |
| Ruffin 2007 | NA | NA | NA | NA | Increased | NA | Self-report: increased |
| | | | | | | | |
| | | | | | | | |
| Giffith 2008 | No difference | NA | NA | NA | No difference in decisional conflict and satisfaction | No difference | NA |
| Giffith 2008 | No difference | Less clarity regarding benefits and downsides with DA that included a “no screen” option | NA | NA | Less clarity concerning help in making a decision with DA that included a “no screen” option | No difference | NA |
| Katsumura 2008 | NA | Higher priority to “avoiding disadvantage” in information + risk group | NA | NA | Less preference for COL | NA | NA |
| Lewis 2008 | NA | NA | NA | NA | NA | NA | Chart review: increased |
| Trevena 2008 | Increased | No difference in anxiety | NA | No difference in perceived behavioral control | Increase in decisions that were informed and had clear values | No difference | Self-report: no difference |
| Makoul 2009 | Increased | NA | NA | NA | NA | Increased | NA |
| Manne 2009 | Not a mediator | Not mediators: perceived risk, severity, preventability | Not mediators: physician and family support | NA | NA | Partial mediator: decisional balance | Self-report with clinician confirmation: increased |
| Lewis 2010 | Increased | NA | NA | NA | Decisional conflict decreased | Increased | NA |
| Miller 2011 | Increased | Less positive; no difference in worry about CRC | NA | NA | Increased informed choice; decreased decisional conflict; no difference in decisional satisfaction or confidence | NA | Laboratory database: decreased |
| Schroy 2011 | Increased | NA | NA | No difference between 2 DA groups | Increased | NA |
| Steckelberg 2011 | Increased | Less positive | NA | NA | Increased informed choice | NA | Self-report: no difference |
| Vernon 2011 | Increased | Increased pros; decreased cons; no difference in worry | No difference in social influence | Increased | NA | Increased | Self-report: no difference |
| STUDY** | KNOWLEDGE | ATTITUDE | SUBJECTIVE NORM | SELF-EFFICACY | PREFERENCE CLARIFICATION | INTENTION | SCREENING BEHAVIOR |
|---------|-----------|----------|----------------|--------------|--------------------------|-----------|-------------------|
| Prostate cancer screening (n=29) | | | | | | | |
| Flood 1996**<sup>55</sup> | Increased | NA | NA | NA | Greater preference for conservative treatment | Decreased | Chart review: decreased |
| Wolf 1996* and Wolf & Schorling 1998*<sup>56,57</sup> | NA | NA | NA | NA | NA | Decreased | NA |
| Myers 1999*<sup>58</sup> | NA | NA | NA | NA | NA | Review of chart and billing data: increased screening adherence |
| Schapira & Van Ruiswyk 2000<sup>59</sup> | Increased | Decrease in perceived benefit | NA | NA | NA | NA | Chart review: no difference |
| Frosch 2001*<sup>60</sup> | Increased | Less concern about prostate cancer | NA | Less confidence about their decision | Greater preference for conservative treatment | Decreased | NA |
| Wilt 2001<sup>61</sup> | Increased | No difference in screening belief | NA | NA | No difference in preference for conservative treatment | NA | Laboratory database: no difference |
| Volk 1999*<sup>62</sup> and Volk 2003*<sup>63</sup> | Increased at 2 wk and at 1 y | NA | NA | NA | NA | Decreased | Self-report: decreased |
| Frosch 2003<sup>64</sup> | No difference | NA | NA | NA | Less preference for conservative treatment | NA | NA |
|Gattellari & Ward 2003*<sup>65</sup> | Increased | No difference in worry about dying of prostate cancer | NA | More likely to report ability of making informed choice | No difference in overall decisional uncertainty | No difference | NA |
| Ruthman & Ferrans 2004*<sup>66</sup> | Increased | NA | NA | NA | NA | Less likely to prefer PSA screening | NA |
| Sheridan 2004<sup>67</sup> | Increased | NA | NA | NA | NA | No change in interest in prostate cancer screening | NA |
| Gattellari & Ward 2005*<sup>68</sup> | Increased in print DA vs video DA and leaflet | No difference in worry about developing prostate cancer | NA | No difference in perceived ability to make informed choice | No difference in overall decisional uncertainty; less interest in PSA screening | No difference | NA |
| Myers 2005*<sup>69</sup> | NA | NA | NA | NA | NA | Chart review: no difference |
| Partin 2004<sup>70</sup> and Partin 2006<sup>71</sup> | No difference | NA | NA | NA | NA | Decreased | Chart review: no difference |
| Watson 2006*<sup>72</sup> | Increased | More negative attitude toward PSA screening | NA | NA | NA | No difference | NA |
| Kripalani 2007*<sup>73</sup> | NA | NA | NA | NA | NA | Chart review: increased PSA ordering |
| Krist 2007*<sup>74</sup> | Increased | NA | NA | NA | No difference in Decisional Conflict Scale | NA | Self-report and clinician report: no difference |
| Ellison 2008*<sup>75</sup> | Increased | NA | NA | NA | NA | NA |
| Ilic 2008*<sup>76</sup> | No difference | No difference in anxiety | NA | NA | No difference in decisional conflict | No difference | NA |
| Stephens 2008*<sup>77</sup> | Increased | Increased risk perception | NA | NA | Feeling more informed, to have clearer values, and to make more effective decision | NA | NA |
| Volk 2008*<sup>78</sup> | No difference | NA | NA | NA | Decreased decisional conflict | NA | NA |
| Weinrich 2008*<sup>79</sup> | Increased | NA | NA | NA | NA | Chart review: no difference |
| Frosch 2008*<sup>80</sup> and Bhatnagar 2009*<sup>81</sup> | Increased for DA but not chronic disease trajectory | No difference in concern | NA | NA | Greater decrease in decisional conflict; no difference in preference for conservative treatment | Greater decrease in DA-only and chronic disease trajectory-only groups to get PSA screening but not combined vs control | NA |
modest in the 2 decision aids concerning colorectal cancer screening.40,52 The single decision aid study on prostate cancer screening that addressed concordance noted that it was affected by the format of the decision aid.68

Only 2 of 73 decision aid studies, both dealing with breast cancer genetic testing, considered postvisit factors as potential mediators of screening behavior.31,32 In both studies, a patient’s sharing of received materials with family was assessed, with one study noting an increase31 and the other noting no difference.32 None of the decision aids was assessed for the effect of media, the referral process for testing, or other factors that may have also affected screening. Eleven of 73 decision aids were also assessed for incorporation into practice: 5 on breast cancer genetic testing,25,29-32 4 on colorectal cancer screening,34,41,50,51 and 2 on multiple cancer screening.89,90 The studies generally attempted to link a clinician visit with the decision aid through timing30 or modifications to the patient’s chart.31,41,50 Four studies specifically dealt with how to incorporate the decision aid into usual practice.32,51,89,90 Only 4 of 73 decision aids were evaluated for their cost of administration,22,44,54,70,71 which varied considerably: $2 per decision aid intervention administered for prostate cancer screening,70,71 $53 per participant for colorectal cancer screening,54 $94 per additional patient screened for colorectal cancer,44 or $1116 or more per additional patient screened for breast cancer.22

**Discussion**

Only 73 decision aids were found to have published data using our search strategies. This is a rather modest number given the many recommendations to use such tools.91,92 Most decision aids were evaluated with a sound research design, such as randomized controlled, 2 × 2 factorial, and Solomon 4-group designs. The use of a theoretical framework and the description of how the decision aid was developed were more variable. Our finding that just 41 of 73 decision aids (56%) used a theoretical framework is better than the findings from the review by Durand et al, in which 17 of 50 studies (34%) were shown to have used a theoretical framework in the development of decision aids for screening and treatment.93 However, the difference is likely due to the inclusion of other diseases and treatments in their review. When the studies in the review by Durand et al are limited

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**TABLE 3. (Continued)**

| STUDY* | KNOWLEDGE | ATTITUDE | SUBJECTIVE NORM | SELF-EFFICACY | PREFERENCE CLARIFICATION | INTENTION | SCREENING BEHAVIOR |
|--------|-----------|----------|----------------|--------------|---------------------------|-----------|-------------------|
| Allen 200981 | Increased | No difference in risk perception | NA | Increased | Decreased decisional conflict | No change in decisional stage | NA |
| Allen 201081 | Increased | NA | NA | No difference | No difference in decisional conflict; no change in decisional consistency (match between values and preference for screening) | Increased decisional stage; no change in desire for screening | NA |
| Joseph-Williams 201081 | Increased | More negative attitude toward PSA screening; no difference in anxiety | NA | NA | Decreased decisional conflict | Decreased | Chart review: decreased |
| Rubel 201085 | Increased | No difference in positive or negative schema; no difference in risk perception | NA | NA | NA | NA | NA |
| van Vugt 201086 | Increased | Decreased in perceived risk; more negative attitude toward PSA test | NA | NA | NA | Increased | NA |
| Capik & Gozum 201287 | No difference | Increased susceptibility; decreased barrier; no change in benefit or seriousness | NA | NA | NA | No change | Self-report: increased |

Multiple cancer screening (n = 3)

| Frosch 200888 | Increased | No difference | Decreased | Decreased | NA | Decreased | NA |
| Brackett 201089 | NA | NA | NA | NA | NA | NA | NA |
| Krist 201290 | NA | NA | NA | NA | NA | NA | Self-report: no difference in individual cancer screenings; increased for overall delivery of preventive services |

NA, not addressed; BSE, breast self-examination; CBE, clinical breast examination; MMG, mammography; Pap, Papanicolaou; DA, decision aid; COL, colonoscopy; CRC, colorectal cancer; PSA, prostate-specific antigen.

*Listed in ascending order by the year of publication for each cancer.
to decision aids on cancer screening, 8 of 15 studies (53%) used a theoretical framework, a figure similar to ours. Having a theoretical framework is important to determine how and why a particular decision aid is effective, since it is from this framework that the measurable outcomes are derived. The presence of a framework, however, did not necessarily mean that the development of the decision aid was well described. In particular, fewer than one-third of the studies contained enough information for the reviewers to be able to determine that a formative approach had been adopted.

The reviewed decision aids uniformly provided information about the cancer and screening tests and the benefits and risks of each screening option. In contrast, just over one-third of the decision aids provided explicit values clarification exercises. Values clarification may be explicit in that patient actions are required through an exercise, such as writing down pros and cons, answering surveys to create tailored messages, and an analytical hierarchy process. It could also be implicit, such as when comparing the options in a table. It is currently unclear whether the explicit method is superior to the implicit method, although there is emerging evidence that the former may be better. With regard to guidance on making decisions and communicating with the clinician, only a few decision aids were found to provide recommendations that were tailored to the patient. This may be better provided as part of a practice-based intervention, in which the decision aid is just one of the interventions, rather than attempting to put everything into a stand-alone tool.

Other than the decision aids on breast cancer genetic testing and prostate cancer screening, in which the decision in question is whether to be screened, few studies provided the option of “no screening.” For the established decision aids on cancer screening to be effective (e.g., cervical cancer screening, colorectal cancer screening), the issue of whether to include the option of no testing may be a delicate balance between patient autonomy and beneficence. Interestingly, of the 6 colorectal cancer screening decision aids in which this option was included, only one showed a clear decrease in screening uptake. This may have occurred because the decision aid in question provided a choice of getting a stool blood test versus not getting one, whereas in the other 5 studies, the “no screening” option was listed along with 2 or more screening options. Thus, the study by Smith et al. is similar to the studies of decision aids on breast cancer genetic testing and prostate cancer screening, which have been shown to decrease the test uptake. It is of interest to note that the decision aid that specifically addressed how the inclusion of a “no screening” option along with multiple screening options for colorectal cancer affected patient intent showed no difference, but also indicated that the patients presented with a “no screening” option felt less clarity in making a decision.

Few studies included information on when to stop screening. For breast cancer genetic testing, this is understandable, since it is a one-time test. For others, recommendations concerning at what age to stop screening did not become available until the recent guidelines. In addition, since most studies focused on a single decision-making event and not multiple decisions over time, and typically had a cap on the maximum age for inclusion, the issue may not have been relevant. From the perspective of incorporating a decision aid into daily practice, it may be more feasible to have a separate discussion on when to stop screening prompted through a clinician reminder system.

Other than knowledge, there was little consistency in the patient attributes measured as outcomes in the studies. The attributes in the Health Belief Model (e.g., perceived benefit, perceived risk) were used most frequently when assessing the positive or negative attitudes toward screening. Subjective norm and self-efficacy were rarely measured. These measures would be important in determining the contribution of the decision aids to the decision autonomy of the patients after their use. For example, patients who perceive greater social pressure (either through their family, peers, or clinician) may still be affected by others’ advice after using the decision aid.

Preference clarification was most commonly assessed by the Decisional Conflict Scale. This scale includes subscales of “Informed” and “Values Clarity,” which may be particularly relevant when measuring the effects of decision aids. Some studies have adopted an informed choice measurement, which is believed to be a better measure of decision quality and combines the scores of knowledge, values clarity, and intent or behavior. This measurement may be increasingly adopted in the future studies on decision aids.

Just approximately one-half of the studies actually measured screening uptake as an outcome. Of these, greater than one-half were by patient self-report after a variable period of time. This may be problematic, since patients tend to overreport screening behavior. Other studies used patient intention rather than screening uptake as the final outcome, which has an even lower correlation with actual behavior than self-report. Of note, 10 of 73 decision aids had neither intention nor behavior as their outcome.

There is little justification not to measure one or both of these outcomes at this time.

Few studies have actually addressed patient/clinician communication subsequent to use of a decision aid. Since the decision aids are purported to improve shared decision-making, it is surprising that there are few objective data to support such claims. The studies that did measure some component of shared decision-making based their measurements on patient self-report. Unfortunately, they are not considered to be sufficiently objective
measures compared with third-observer instruments such as the OPTION measurement tool, Decision Support Assessment Tool, or the Informed and Shared Decision Making instrument. The use of these measures would require recording of the patient/clinician encounter, which would also make them available for qualitative and mixed-methods analyses, thereby enriching the findings. Intriguing questions that may be answered through these processes include: How is patient/physician communication affected by the use of decision aids? Is sharing decision-making between the patient and physician always positively impacted by decision aids? Are there instances in which patient activation by decision aids may be deleterious (eg, patient strongly inclined to use stool blood test for colorectal cancer screening but the physician strongly recommends colonoscopy; frustrated, the patient decides not to get screened)?

Even rarer than the measurement of shared decision-making was the measurement of concordance. Since shared decision-making allows for a decision to be deferred when an agreement is not met, it would be important to assess whether the decision aid led to an increase in agreement between the patient and the clinician. Current cancer screening literature, particularly that regarding colorectal cancer screening, reveals a potential negative impact on shared decision-making as the clinicians increasingly prefer colonoscopy as the test of choice, to the exclusion of screening literature, particularly that regarding colorectal cancer screening, reveals a potential negative impact on shared decision-making as the clinicians increasingly prefer colonoscopy to the exclusion of the clinicians always positively impacted by decision aids? Are there instances in which patient activation by decision aids may be deleterious (eg, patient strongly inclined to use stool blood test for colorectal cancer screening but the physician strongly recommends colonoscopy; frustrated, the patient decides not to get screened)?

The study settings and populations in which the decision aids were used were sufficiently variable. Thus, these decision aids would likely lead to similar results in other settings. More problematic was that the decision aids tended to be stand-alone and not integrated into the daily practice routine. This would likely limit their practical use. When intention-to-treat analysis is adopted, many studies show a very small to negligible effect by the decision aids, due to the low usage by patients. In addition, studies have shown that although clinicians like the concept of decision aids, they actually rarely use them in settings that are conducive to shared decision-making and where publicly accessible decision aids are available. Unless the decision aids incorporate risk assessment and tailor their values clarification exercises accordingly (eg, moving from multiple options in average-risk patients to recommending colonoscopy in patients at increased risk in colorectal cancer screening), or a reminder system exists that could link patients to decision aids based on their profile, clinicians may perceive the decision aids to be too cumbersome. These barriers may not be overcome unless a more comprehensive, practice-based approach is adopted. An excellent example of using a practice-based approach in a real-world setting is a recent publication from a large health system in Washington State. Their organizational effort to implement decision aids for patients facing hip and knee arthritis and joint replacement surgery was associated with 26% fewer hip replacement surgeries, 38% fewer knee replacements, and 12% to 21% lower costs over 6 months. Currently, only one study has attempted an improvement in cancer screening through practice-wide intervention, including the use of decision aids.

**What Can Practicing Physicians Do?**

First, physicians need to accept that cancer screening has elements that are sensitive to patient preferences and choice. Second, it would be helpful for physicians to know how to access useful decision aids. An example is the repository of decision aids available from the Ottawa Hospital Research Institute in Ontario, Canada. Their Web site (decisionaid.ohri.ca/AZlist.html) contains links to high-quality decision aids in various topics, including screening for all of the cancers discussed in this review. Third, many organizations offer free information to patients in a way that may still provide them with desired information on how the cancer screening tests work and their risks and benefits. An example would be the American Cancer Society Web site (cancer.org), which provides the latest information on screening for breast, cervical, colorectal, and prostate cancers, among others. The barrier is how and when one uses these existing tools in the course of a busy day. It will likely be either before or after the physician visit, thus unloading time and effort from the visit itself. Fourth, the state-of-the-art interactive decision aid may not be feasible in a real-world practice setting at this time. This reality may be reflected in the fact that many of even the more recent studies use print rather than Web-based decision aids.

With the increasing use of electronic medical records linked to patient portals, as well as advances in mobile telephones and their applications, decision aids that are accessible and easily understandable may become more available in a timely manner to patients in the near future. The features used to evaluate the studies in this review would serve as an excellent checklist for physicians to use when examining such tools.

**Limitations**

First, despite an exhaustive attempt to identify all published English language studies on this topic, due to the
differences in current indexing practices in and among the electronic databases, we cannot ensure that we have examined all of the published English language works in this subject area. Some studies were published in abstract form only and could not be included due to a lack of detail. Second, there are likely to be unpublished studies relevant to this area. It is unknown if the results of these studies would sway the assessment given that most unpublished studies contain negative findings. Third, the published data lacked significant details regarding how the decision aids work. We searched for relevant articles on their development and accessed the original tools if available, but this was possible in only a minority of the cases. It may be that some decision aids actually possess the features that we had concluded were lacking. Fourth, the published data lacked detailed information on how the decision aids were developed and how the outcomes measures were determined. Because of this, we did not rigidly apply the International Patient Decision Aids Standards (IPDAS) criteria to the decision aids. Of note, IPDAS is an internationally recognized scoring system of decision aid quality. It measures the quality of the decision aids in 10 dimensions, including information provided, description of probabilities, and availability of decision guidance. It is increasingly influential in determining how decision aids should be developed. Finally, our approach to evaluating these studies highlights the vast array of complex data that need to be gathered and analyzed to adequately address the topics that were considered. For many investigators, collecting such a quantity and diversity of data may have been beyond their funding, resources, or skill set. It also may not be well reviewed at study review sections that place a priority on focused research questions. In addition, many investigators’ research teams lack expertise in certain areas not addressed. The collection of adequate data also may create too much of a burden on the study participants, which would limit accrual and follow-up. Thus, the ideal scenario would be a series of studies expanding the focus and further refining the intervention, which we did not find.

Unique Features of Our Review

Many high-quality reviews are available on decision aids. Our review is unique because it focused on cancer screening and measurable outcomes based on a theoretical framework. In particular, this review elucidated that few decision aids on cancer screening actually evaluated their effect on a patient’s entire decision-making process, including shared decision-making and reaching concordance with their clinician. Our review indicated areas in which further research is needed, as we detail below. Among the most important would be having a theoretical framework so that appropriate outcomes are measured, an objective assessment of shared decision-making, and attention to applicability in other settings.

Suggestions for Future Research

1) A strong theoretical framework should support the decision aid and guide its development as well as measurement outcomes. There should be a clear correlation between the theoretical framework and the measured outcomes.

2) There should be more studies that critically compare explicit versus implicit values clarification.

3) An objective measure of screening uptake (eg, paper chart review, extraction of electronic health record data) should be adopted to assess the effectiveness of the decision aid.

4) Shared decision-making between the patient and the clinician should be recorded and objectively measured by validated tools.

5) Other potential mediators that temporally occur after the patient’s decision aid use, such as media and family influence, should be considered.

6) How decision aids would fare as a meaningful part of primary care practice should be assessed through their better integration into practice and a broader, practice-based approach to measure their effectiveness.

7) To address applicability in real-world settings, studies should continue to be performed in heterogeneous community practice settings, using practice-based research networks.

8) Long-term effectiveness and viability should be addressed, including the effect on repeated screening and cost-effectiveness and cost-benefit analyses.

9) With the advent of more options in breast and cervical cancer screening and the need for even better informed and shared decision-making in prostate cancer screening with the advent of conflicting guidelines, there are even more opportunities for decision aids to be useful in the setting of cancer screening.

Conclusions

Decision aids are here to stay. Although much research needs to be done to determine what really makes for an effective decision aid, practical applications are already occurring. Many decision aids are now available free of charge. Clinicians are encouraged to explore them, select those that fit best with their current understanding of the topic in question, and apply them to their practice workflow in a creative way.
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