

Promoting Cancer Screening: Lessons Learned and Future Directions for Research and Practice

Supplement to Cancer

Informed Decision Making: What Is Its Role in Cancer Screening?

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Dr. Chan was supported by a K02 Independent Scientist Award from the Agency for Healthcare Research and Quality.

Dr. Rimer was supported in part by grants 5-P30-CA16086-28 and 1-R01-CA105786-01.

The authors thank Daniel Gregg and James Rosen for word processing and editorial assistance. They also thank the reviewers for helpful suggestions.

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Received April 22, 2004; revision received May 26, 2004; accepted May 26, 2004.

Interest in informed decision making (IDM) has grown in recent years. Greater patient involvement in decision making is consistent with recommendations to improve health care quality. This report provides an overview of IDM; clarifies the differences between IDM, shared decision making (SDM), and informed consent; and reviews the evidence to date about IDM for cancer screening. The authors also make recommendations for research. We define IDM as occurring when an individual understands the disease or condition being addressed and comprehends what the clinical service involves, including its benefits, risks, limitations, alternatives, and uncertainties; has considered his or her preferences and makes a decision consistent with them; and believes he or she has participated in decision making at the level desired. IDM interventions are used to facilitate informed decisions. The authors reviewed the evidence to date for IDM and cancer screening based primarily on published meta-analyses and a recent report for the Centers for Disease Control and Prevention's *Guide to Community Preventive Services*. IDM and SDM interventions, such as decision aids, result in improved knowledge, beliefs, risk perceptions, and combinations of these. Little or no evidence exists, however, regarding whether these interventions result in 1) participation in decision making at a level consistent with patient preferences or 2) effects on patient satisfaction with the decision-making process. These variables generally either were not assessed or were not reported in the articles reviewed. Results of interventions on uptake of screening were variable. After exposure to IDM/SDM interventions, most studies showed small decreases in prostate cancer screening, whereas four studies on breast and colorectal cancer screening showed small increases. Few data are available by which to evaluate current practices in cancer screening IDM. Patient participation in IDM should be facilitated for those who prefer it. More research is needed to assess the benefits of IDM/SDM interventions and to tailor interventions to individuals who are most likely to desire and benefit from them. There are many system barriers to IDM/SDM and few tools. More work is needed in this area as well. In addition, research is needed to learn how to incorporate IDM into ongoing clinical practice and to determine whether there are unintended negative consequences of IDM. *Cancer* 2004;101(5 Suppl):1214-28. © 2004 American Cancer Society.

KEYWORDS: informed decision making, cancer screening, shared decision making, evidence.

Not long ago, physicians told patients what to do, and patients were expected to comply. Patients who did not follow orders were labeled noncompliant. Thus, early research on screening for breast and cervical cancers focused on identifying reasons why women did or did not comply when initial mass mailings and other strategies failed to produce expected levels of screening uptake.¹⁻³ Over time, it

became clear that simply offering screening tests is insufficient for generating adequate response.

Society has changed, and the paternalistic model is no longer the dominant model in the United States for ideal physician-patient relationships.² That ideal—which, as this article demonstrates, has yet to be achieved—has evolved into one in which decision-making power is shared based on mutual participation and respect.⁴⁻⁷ A patient can make a choice with his or her physician or can choose to give decision-making authority to the physician or to another individual.⁷ Similarly, combinations of approaches can be used.

Interest in informed decision making (IDM) was catalyzed by several forces, including important controversies in medical and health care, the growing strength of advocacy organizations and movements, and the communications and informatics revolutions. In this report, we have reviewed these topics briefly.

One of the best examples of IDM-relevant controversies is hormone replacement therapy, for which IDM was recommended a decade ago to help women weigh its complex benefits and harms.^{8,9} For similar reasons, IDM also has been advocated for such topics as chemoprevention of breast cancer,¹⁰ aspirin prophylaxis for coronary artery disease,¹¹ and treatment for benign prostatic hyperplasia.¹² Controversies about screening for breast, prostate, cervical, colorectal, and other cancers have identified large areas of uncertainty, even for well-accepted screening tests, such as mammography, clinical breast examinations, and Papanicolaou (Pap) tests. Debates have arisen over whether and at what age women should get mammograms,¹³⁻¹⁵ the value of breast self-examinations (BSEs),¹⁰ how often women should get Pap tests,¹⁶ and whether there should be an upper age limit for these tests. Similarly, questions emerged regarding the choice of tests for colorectal cancer screening^{17,18} and whether the unproven benefits of prostate-specific antigen (PSA) testing for prostate cancer are offset by the known harms of treatment.¹⁹⁻²¹ Inherent in each of these debates is the tension between benefits and harms, questions about the information needed by individuals to make good decisions, and questions about the evidence required to justify population recommendations for screening.²²⁻²⁵

In many areas of health care, the role of advocacy organizations has increased, putting additional pressure on the health care system to help patients and consumers assess the appropriateness of recommended cancer screening tests. The result is an increasing call for patients to understand the risks and benefits of screening tests and to make informed decisions about them.

The communications and informatics revolutions have been major forces in empowering patients within a culture of consumerism, fostering patients' expectations that they can decide for themselves what is best and, thus, building demand for IDM. Vast amounts of health information are now available to millions of physicians, consumers, and patients through the Internet. Evidence shows that access to and use of this information are changing consumers' and patients' behavior.^{26,27} Kulkarni and Graham²⁸ noted that modern medicine is information-intensive. Clinicians regularly synthesize voluminous, growing literature and use the information both for decision making and for communicating with patients. The Internet also has enabled access to massive storehouses of information and the efficient dissemination of clinical practice guidelines to patients and providers alike. Clinical decision support tools also have proliferated.²⁸ These factors have helped to create both the demand for IDM and the development of accessible IDM tools.

Although IDM already had been applied to other topics in medicine, interest in IDM for cancer screening grew in the middle 1990s, particularly in the wake of widespread interest in and rapid uptake of PSA testing for prostate cancer. Groups that once held polarized stances on the appropriateness of such testing reached consensus on IDM as a patient-centered strategy²⁹ for addressing the complex consequences of screening (e.g., requirements for additional testing, with attendant costs; physical and psychological morbidity) in the absence of definitive evidence of efficacy.^{15,30-32} The role of IDM in breast cancer screening has received special attention because of a recognized need to help women quantify the benefits and probability of harms and to understand screening test options and their limitations.^{15,32} Recently, Jepson et al.³³ called for *informed uptake* regarding decisions about cervical cancer screening. This call undoubtedly will receive even more attention in the wake of changing guidelines for cervical cancer screening.¹⁶ Similarly, most relevant organizations now recommend regular colorectal cancer screening, but they also advocate IDM to help patients choose from among a range of acceptable screening tests with different risks, benefits, and preparation requirements.

Greater involvement of patients in clinical decision making is consistent with recent recommendations to improve health care quality. According to the Institute of Medicine, quality health care should be patient centered—that is, it should provide care that is respectful of and responsive to patient preferences, needs, and values, and it should ensure that patients' values guide all clinical decisions.³⁴

Patients often do not make informed decisions

about cancer screening.³⁵⁻³⁷ For example, they may place undue weight on potential benefits of screening while underestimating potential limitations.^{38,39} This weighting is especially important for screening tests like the PSA test, for which there is not clear evidence of a reduction in mortality. The clinical cascade triggered by PSA screening can lead to important negative consequences, such as incontinence or impotence. With breast cancer screening, numerous studies document the tendency of women to overestimate the benefits of mammography and to minimize potential risks and limitations (e.g., Chamot and Perneger⁴⁰). Similarly, a patient may not have weighed the advantages and disadvantages of all possible colorectal cancer screening tests before choosing one. Frequently, a mismatch occurs between the roles patients want to play in decision making about cancer screening tests and treatments.⁴¹ Those authors found that patients were most satisfied and least anxious when decisions about treatment were shared by physicians and patients.

Thus, it is both appropriate and important to examine the role of IDM in cancer screening. The sections below define IDM, describe IDM interventions, and examine the outcomes assessed, measures used, evidence, lessons learned, and research needs. We draw heavily on a recent evidence review that was conducted by Briss and colleagues⁴² for the *Guide to Community Preventive Services*.

What Is IDM?

IDM occurs when an individual understands the disease or condition being addressed and also comprehends what the clinical service involves, including its benefits, risks, limitations, alternatives, and uncertainties; has considered his or her own preferences, as appropriate; believes he or she has participated in decision making at a level that he or she desires; and makes a decision consistent with those preferences.⁴³ These elements represent the various *components* of an informed decision, and not the *steps* in the process. The latter include at least the following: 1) understanding the screening test, its risks, benefits, and alternatives; 2) understanding personal values and preferences; 3) weighing the pros and cons of the test; 4) clarifying decisional preferences; 5) finding additional information, if needed; and 6) deciding on an action plan. Providers frequently are involved in some or all of these steps, and the steps often occur over time. Shared decision making (SDM) connotes a process in which physicians and patients share in the decision-making process, which is conducted through one or more face-to-face encounters.

Commonly measured outcomes in studies of de-

cision making, especially those involving the use of decision aids, include patients' knowledge about their conditions and about the benefits, risks, and limitations of recommended management options; satisfaction with the process of decision making or the decision; perceived level of participation in the process of decision making or the decision; level of conflict about the treatment choice; and overall or disease-specific health status.⁴⁴ Delivery of the service (e.g., whether a PSA test was ordered or whether fecal occult blood tests [FOBTs] were returned) is another outcome, although it is not the direct objective of IDM. In general, similar or identical measures are used to assess both IDM and SDM interventions, although the processes would differ.

Cancer screening tests vary with regard to the strength of the evidence about their efficacy. Different decision-making processes may be needed for different levels of evidence. However, all decisions about cancer screening should be informed. When the evidence for the efficacy of a screening test is strong, and a test is recommended by expert bodies, such as the U.S. Preventive Services Task Force (USPSTF), physicians may be comfortable making strong recommendations, and little (not "no") discussion may be needed for most patients. This is consistent with the decision-making typology proposed by Whitney and colleagues.⁴⁵ Those authors argued that SDM is irrelevant when one optimal path exists. Although we urge that all patients should be educated and informed, we recognize that, given a shortage of physician time, most efforts should be devoted to those decisions that are more difficult. Some cancer screening tests will have less convincing evidence of effectiveness or will entail important harms and may require more extensive discussion. Individuals differ, and, ultimately, decision-making processes should be tailored to individual needs. Some patients may be willing to accept substantial risk even for modest benefits, whereas others are unwilling to accept any risk. At different ages, for individuals of different cultures, and for different procedures, the risks and benefits may be viewed differently. What is best for one patient may not be best for another.

IDM and SDM often are confused with informed consent. Both similarities and differences exist. In their review of the literature on informed consent, Beauchamp and Childress⁴⁶ noted two different senses of informed consent: One is defined within the legal framework of an individual's autonomous authorization of a medical intervention or participation in research; the other is defined more within standard procedures for obtaining valid consent from patients or participants prior to diagnostic, therapeutic, or re-

search procedures.⁴⁶ The legal, regulatory, philosophical, medical, and psychological literatures define informed consent by five components: 1) competence, 2) disclosure, 3) understanding, 4) voluntariness, and 5) consent.⁴⁶ IDM is not the same as informed consent, both because SDM and IDM may be more flexible in the amount of participation that a patient may choose (ranging from delegating decision making to a provider or someone else, to making a decision about what to do before seeing the physician) and because SDM and IDM are more focused on producing decisions consistent with patient preferences and values.⁴⁶ Recently, Whitney and colleagues⁴⁵ argued that the legal power of informed consent should not be merged with the moral authority of SDM. The ideal of having patients and physicians share in decision making does not displace informed consent, because not all informed consent processes must involve SDM. These definitions still are evolving.

IDM and SDM Interventions

We have defined an IDM intervention as any intervention in communities or health care systems to promote informed decisions, consistent with the definition used by the United States Task Force on Community Preventive Services. There are several types of IDM interventions.^{42,47–49} These include, but are not limited to, interpersonal counseling, tailored and untailored print materials, videotapes, audiotapes, scripted telephone counseling, computer programs, Web sites, and decision boards.^{50,51} Interventions can be delivered directly to individuals or through group education; provided by physicians and other health professionals; and delivered through computers or by mail, telephone, and other methods.^{36,49} The possibilities are nearly limitless, and new computer and communication technologies expand available choices. Inherent in IDM and SDM is an opportunity and even a mandate to individualize information for patients.

IDM interventions need not involve providers directly at the point of delivery of a decision-making intervention; nor must they be limited to clinical settings, although, ideally, they should embrace these foci. In fact, IDM interventions probably are not appropriate for individuals without access to health care (and SDM would not be possible at all). SDM interventions assume real-time, interactive, patient-provider discussions; mutual sharing of information; and expressions of patient preferences.⁴³ For some discussions, key family members may be present.

Conceptual Model for Cancer Screening IDM

The Centers for Disease Control and Prevention's *Guide to Community Preventive Services* report on IDM explains the conceptual model for the relation between IDM interventions and the hypothesized outcomes of reduced decisional conflict, satisfaction with decisions, and decisions in accord with preferences.⁴² Various interventions affect intermediate steps, such as benefits and preferences, which, in turn, lead to IDM or SDM and appropriate outcomes. For example, it is assumed that interventions directed at the public and at patients promote informed decisions by enhancing knowledge and beliefs and improving the accuracy of risk perceptions. This information leads to a level of participation in decision making that is consistent with an individual's values and preferences. Resulting decisions are consistent with these values and preferences and, ultimately, lead to a reduction in decisional conflict and overall satisfaction with decisions. Information needed to achieve IDM and SDM varies considerably. Variability may be due to clinical variables, such as risk factors, past medical therapy, clinical presentation, and social circumstances, and to personal values, such as utility, preferences, and life plans.

Decision aids are a promising type of intervention to promote IDM. Consistent with O'Connor et al.,⁴⁸ we have defined decision aids as interventions designed to help individuals make specific and deliberative choices among options (including the status quo) by providing (at a minimum) information on the options and outcomes relevant to an individual's health status. Decision aids usually include information on the disease/condition, probabilities (benefits and harms) of outcomes for each option (preferably tailored to personal risk factors), some form of values clarification exercise, and guidance or coaching in the process of decision making. Decision aids give individuals information that is relevant to specific health care decisions⁵² and also may help patients become more active participants in making decisions,⁵² although empirical evidence about this result is sparse (see below). Dolan⁵³ and Dolan and Frisina⁵⁴ used structured interviews and an analytic hierarchy process to guide patients through the IDM process as a variant on decision aids. Dolan reported that the process was well-received, and some outcomes were improved; however, participation did not increase decision making at a desired level.⁵⁵ More work is needed in this area.

For example, breast cancer screening decision aids explain the choices and supporting evidence for each available test (e.g., mammography, clinical

TABLE 1
How Informed Decision-Making Interventions Address Difficult Clinical Decisions and Clinical Limitations^a

Issues encountered with difficult clinical decisions	How IDM interventions address these issues
Physicians' time generally is constrained to short patient visits.	IDM interventions reduce time pressures on physicians during office visits by enabling patients to review information outside of the clinical encounter.
Physicians may not be conversant with all relevant data.	IDM interventions can provide state-of-the-science information that is accurate and balanced and that reduces the imperative for individual physicians to develop their own tools.
Guidelines (and embedded notions about preferences) may vary among specialty physician groups, individual physicians, and patients.	Decision aids may enable patients to choose from the full spectrum of recommended approaches.
Patients often report that they get information from physicians that is incomplete, not personally relevant, or difficult to understand.	IDM interventions provide more complete, state-of-the-science information in a variety of formats (e.g., expert commentary, documentary, and animation) that can be adapted to individual patients' needs, contexts, and situations.
Patients often receive information during a period of extreme stress, when they are least likely to retain it.	Decision aids may enable patients under duress to make informed decisions at another time when they are more receptive.
Guidelines may recommend what is best for patients as a group, but not what is best for individuals within that group with specific circumstances and wishes.	Decision aids and IDM interventions can be adapted to individual patients' needs, contexts and situations.

IDM: informed decision making.

^a Adapted from Marteau, Making the Right Choice, Network, 2002, p. 11.

breast examination, BSE), the potential benefits and limitations, costs, the importance of patient preferences, and other information relevant to the individual woman, often including her risk of breast cancer. Decision aids can incorporate Gail Model scores to help women assess the probability of benefits from screening with regard to their individual risks for breast cancer, as reported by Rimer and colleagues.³⁹ Lawrence et al.³² wrote that decision aids merge evidence from the *laboratories* of epidemiology, screening, therapy, prognosis, and decision-instrument technology and bring it to the *bedside* of consumer-based decisions. Table 1 summarizes some of the issues that decision aids and other IDM interventions address and how they address them. Decision aids can have different objectives, such as focusing on whether one should be screened (e.g., PSA testing), the age at which to start or stop screening (e.g., mammography), or (as in colorectal cancer screening) which of several possible test options is best.

IDM interventions can be directed at any of the following targets, alone or in combination: public, patients/clients, high-risk individuals, health providers, and health care systems. Although most IDM interventions have been designed for patients within health care systems, this is not a necessary limitation. McBride et al.⁵⁶ and Bastian et al.⁵⁷ demonstrated the effectiveness of a decision aid on hormone replacement therapy among a community sample of women ages 50–65 years.

Most decision aids and other IDM interventions have not had strong theoretic foundations. Some decision aids, however, have used theory to inform in-

tervention design and evaluation. Theories have included the precaution adoption model,⁵⁸ the transtheoretical or stages-of-change model,⁵⁹ and the Leventhal self-regulation model.⁶⁰

Types of IDM Outcomes

Studies have examined a broad range of positive and negative effects of IDM/SDM on decision-making processes and outcomes.^{30,49,61–65} Although decision aids and other interventions focus on diverse health care decisions, many have similar objectives, such as improved knowledge, more realistic expectations of health care outcomes, participation in decision making, satisfaction with the decision-making process, and reduced decisional conflict. Some investigators also have examined behavioral outcomes, such as use of cancer screening tests.³⁹ Ideally, a measure of IDM should capture several components (e.g., recognition of the risks, benefits, and alternatives of recommended actions). No gold standard measure exists, however, and different investigators have operationalized IDM in different ways. Moreover, we are aware of no studies that have examined the effect of IDM on health care providers or on the delivery of care in its broader context.

The *Guide to Community Preventive Services*⁴² team that was responsible for drafting a chapter on IDM agreed on the following potential outcomes, which are stated as questions. 1) Do group and/or patient/client-oriented interventions in health care systems and communities increase client knowledge and beliefs about screening options and their pros and cons; increase client knowledge about the risk/seri-

ousness of the disease; increase client knowledge of screening options as well as their pros and cons; increase the level of participation in the decision-making process; result in decisions that are more consistent with clients' values; allay client uncertainties about screening and reduce decisional conflict; reduce decisional conflict, if not immediately, in the longer term; increase client satisfaction with the decision-making process; cause any untoward consequences, such as anxiety, depression, or regrets; or result in client adherence to the decision reached by him or her? 2) Do provider-oriented interventions to promote informed decisions increase provider knowledge, beliefs, and self-efficacy regarding IDM; increase clinicians' practice of IDM processes with patients; and, if so, then do these result in improved outcomes? 3) Do system-oriented interventions to promote IDM increase adoption of policies to promote IDM (e.g., payment policies, visit times, use of nonclinician providers)? 4) do any of these interventions cause harm, in that they cause confusion or frustration among clients; divert limited time and energy from health issues of greater importance; cause patients to underuse screening tests for which there is agreement regarding benefit; cause confusion or frustration among providers; reduce clinical efficiency (e.g., due to time and disruption of patient care operations); cause adverse effects on communities of competing or contradictory clinical and community approaches; or cause increased litigation?

Lessons Learned about IDM

Sources of evidence.

We relied primarily on evidence reviews of IDM interventions supplemented by key articles, including one by Whelan et al.⁴⁹ that was commissioned by the Agency for Healthcare Research and Quality. Whelan et al. identified 39 IDM studies that assessed various decision aids. Six studies focused on prostate cancer screening, two studies focused on colorectal cancer screening, and one study focused on breast cancer screening. Jepson et al.³³ took a slightly different approach by focusing on informed uptake to screening. The only trials that met the criteria of Jepson et al. and addressed cancer screening were two prostate cancer studies. O'Connor et al.⁴⁸ identified 23 separate decision aids in 4 studies focused on prostate cancer screening, 2 studies focused on colorectal cancer screening, and none focused on breast cancer screening. Briss et al.⁴² found 13 reports that met inclusion criteria and reported on 11 independent studies. Three of those studies provided > 1 intervention, for a total of 15 independent intervention arms. Of those intervention arms, 10 dealt with prostate cancer

screening;^{20,31,66-70} 3 dealt with colorectal cancer screening;^{54,71,72} and 2 dealt with breast cancer screening.^{39,73} Different reviews counted studies somewhat differently, mainly because they used different inclusion and exclusion criteria or covered different periods. We performed additional literature searches to capture appropriate articles that were published since the last reviews. Table 2 lists the IDM/SDM studies on screening from O'Connor et al.,⁴⁸ Whelan et al.,⁴⁹ Briss et al.,⁴² and our updated review.

In the section below, we discuss lessons learned about intervention effects on the basis of the small universe of studies. Table 3 introduces the lessons learned.

Outcomes of IDM interventions.

Lesson 1: IDM interventions increase short-term improvements in knowledge, beliefs, and accuracy of cancer risk perceptions. The review of the *Guide to Community Preventive Services*⁷⁴ covered all interventions examined in this report except for Lawrence et al.,³² which was included by Whelan et al.⁴⁹ Fourteen of the intervention arms measured knowledge, beliefs, risk perceptions, and/or test use.^{20,31,39,54,66,68-70,72} Nearly all interventions increased knowledge, accuracy of beliefs and risk perceptions, or both. Much of the gain diminished over time, although only a minority of reports included follow-up \geq 12 months postintervention.^{39,75} Some studies still are underway.

More intervention usually is better, as other intervention reviews have shown. For example, the addition of tailored telephone counseling to tailored print materials resulted in larger improvements in knowledge compared with print materials alone.³⁹ Similarly, small-group education combined with a videotape produced larger effects compared with either method used alone.⁶⁹ More is not always better, however; a more intensive, computer-assisted counseling intervention produced high self-reported understanding of screening options, but a less intensive counseling intervention produced even greater self-reported understanding.⁵⁴

Lesson 2: There is insufficient evidence to conclude whether IDM interventions result in decisions consistent with patients' preferences. Three interventions from one report⁶⁹ showed self-reported increases in preferences of patients to share decisions with physicians; however, no data were provided to determine whether these preferences were acted on. Three studies that tested the effects of interventions on the extent of individual or patient participation in decision making showed increased patient control over decisions.^{67,69,71} Dolan and Frisina found a statistically significant reduction in decisional conflict among in-

TABLE 2
Informed Decision Making Screening Studies Used by Sources: All Cancers

Systematic review or other source (reference citation) ^a	Date of study/publication	Citation in this article
42, 48, and 49	1999	Davison BJ, Kirk P, Degner LF, Hassard TH. Information and patient participation in screening for prostate cancer. <i>Patient Educ Couns.</i> 1999;37:255-263. ⁶⁷
42	2002	Dolan JG, Frisina S. Randomized controlled trial of a patient decision aid for colorectal cancer screening. <i>Med Decis Making.</i> 2002;22:125-139. ⁵⁴
42 and 49	1996	Flood AB, Wennberg JE, Nease RF Jr., Fowler FJ Jr., Ding J, Hynes LM. The importance of patient preference in the decision to screen for prostate cancer. Prostate Patient Outcomes Research Team. <i>J Gen Intern Med.</i> 1996;11:342-349. ³¹
42	2001	Frosch DL, Kaplan RM, Felitti V. The evaluation of two methods to facilitate shared decision making for men considering the prostate-specific antigen test. <i>J Gen Intern Med.</i> 2001;16:391-398. ⁶⁹
49	2000	Lawrence VA, Streiner D, Hazuda HP, Naylor R, Levine M, Gafni A. A cross-cultural consumer-based decision aid for screening mammography. <i>Prev Med.</i> 2000;30:200-208. ³²
42, 48, and 49	2000	Pignone M, Harris R, Kinsinger L. Videotape-based decision aid for colon cancer screening. <i>Ann Intern Med.</i> 2000;133:761-769. ⁷¹
42	2001	Rimer BK, Halabi S, Skinner CS, et al. The short-term impact of tailored mammography decision-making interventions. <i>Patient Educ Couns.</i> 2001;43:269-285. ⁷³
42	2002	Rimer BK, Halabi S, Sugg Skinner C, et al. Effects of a mammography decision-making intervention at 12 and 24 months. <i>Am J Prev Med.</i> 2002;22:247-257. ³⁹
42, 48, and 49	2000	Schapiro MM, VanRuiswyk J. The effect of an illustrated pamphlet decision aid on the use of prostate cancer screening tests. <i>J Fam Pract.</i> 2000;49:418-424. ⁶⁸
42, 48, and 49	1999	Volk RJ, Cass AR, Spann SJ. A randomized controlled trial of shared decision making for prostate cancer screening. <i>Arch Fam Med.</i> 1999;8:333-340. ²⁰
42	2001	Wilt TJ, Paul J, Murdoch M, Nelson D, Nugent S, Rubins HB. Educating men about prostate cancer screening. A randomized trial of a mailed pamphlet. <i>Eff Clin Pract.</i> 2001;4:112-120. ⁷⁰
42, 48, and 49	1996	Wolf AM, Nasser JF, Schorling JB. The impact of informed consent on patient interest in prostate-specific antigen screening. <i>Arch Intern Med.</i> 1996;156:1333-1336. ⁶⁶
42	1998	Wolf AM, Schorling JB. Preferences of elderly men for prostate-specific antigen screening and the impact of informed consent. <i>J Gerontol.</i> 1998;53:M195-M200. ¹¹⁶
42, 48, and 49	2000	Wolf AM, Schorling JB. Does informed consent alter elderly patients' preferences for colorectal cancer screening? Results of a randomized trial. <i>J Gen Intern Med.</i> 2000;15:24-30. ⁷²

^a Review sources: Briss P, Rimer B, Reilley B, et al. Promoting informed decisions about cancer screening in communities and healthcare systems. *Am J Prev Med.* 2004;26:67-80.⁴² O'Connor AM, Stacey D, Rovner D, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2001;1:CD001431.⁴⁸ Whelan TM, O'Brien MA, Villasis-Keever M, et al. Impact of cancer-related decision aids. Evidence report/technology assessment number 46. Rockville: Agency for Healthcare Research and Quality, 2002. Available from URL: <http://www.ahrp.gov/clinic/evrptfiles.htm#canceraids> [accessed November 19, 2003].⁴⁹

dividuals who received a decision aid about colorectal cancer screening.⁵⁴ Although the reports described above were consistent in reporting increases in patients' preferences, they were variable in reporting effect sizes and significance levels. None reported whether increased patient control over decisions was consistent with individual levels of desired participation or resulted in choices consistent with values or preferences. Only a single study⁵⁴ reported whether participation was consistent with expressed preferences for level of participation. That study showed that, in both an intensive intervention group and a less intensive intervention group, 42% of respondents said that they participated in decision making in a manner consistent with preintervention preferences (i.e., primarily by patient, primarily by physician, or shared). Generally, there were no differences in patient satisfaction between the intervention and control

groups.⁷⁵ That finding is consistent with the high levels of health care satisfaction found in most surveys.

Lesson 3: The impact of IDM interventions on screening is modest; generally, IDM interventions have resulted in small decreases in prostate cancer testing and small increases in testing for breast and cervical cancers. Results of decision-making studies with cancer screening outcomes were mixed, but effect sizes generally were small. Of the IDM studies on prostate cancer (for which there is currently no consensus to screen), there was a median 8% decrease in PSA test use (range, from a 47% decrease to a 14% increase).^{31,67-69,71} Two studies^{20,66} showed statistically significant decreases in preferences for testing. Longer term (12-month) data showed that the differences reported in the Volk study between the intervention and control groups in this area were maintained.⁷⁵

TABLE 3
Lessons Learned Regarding Informed Decision Making: What Is Its Role in Cancer Screening?

Lesson 1	IDM interventions increase short-term improvements in knowledge, beliefs, and accuracy of cancer risk perceptions.
Lesson 2	There is insufficient evidence to conclude whether IDM interventions result in decisions that are consistent with patients' preferences.
Lesson 3	The impact of IDM interventions on screening is modest. IDM interventions generally have resulted in small decreases in prostate cancer testing and small increases in testing for breast and cervical cancers.
Lesson 4	IDM interventions are needed, especially for those cancer screening tests for which the evidence is uncertain or is very sensitive to patients' preferences.
Lesson 5	Numerous patient, provider, and system factors pose challenges to the optimal integration of IDM into health care decision making.
Lesson 6	In the short run, participation in IDM should be facilitated for those patients who want it. Greater numbers of individuals should be encouraged to participate more fully in their health care.
Lesson 7	Decision-making information can be provided to individuals outside clinical encounters. This not only may attenuate health disparities but may enhance the efficiency of patient-physician interactions.

IDM: informed decision making.

Interventions to improve decision making about prostate cancer screening are especially important. The PSA test is available widely and frequently is recommended and ordered by physicians. There is uncertainty about the effectiveness of screening to reduce prostate cancer morbidity or mortality, and the diagnostic testing and treatment that may follow PSA screening introduce important risks⁷⁶ of which individuals may not be aware. Unfortunately, we lack the diagnostic tools to confidently identify which cancers must be treated and which can be safely ignored. Uncertainties contribute to the difficulty of weighing the benefits and harms of PSA screening. For men who are faced with the decision, IDM can help to clarify the benefits, risks, and uncertainties of screening; identify and explore personal values; and facilitate informed choices. IDM also may be useful for other high-profile cancer screening issues, such as spiral-computed tomography screening for lung cancer or pelvic ultrasound examinations for ovarian cancer. The importance of IDM for cancer screening tests of uncertain benefit is likely to increase as more cancer screening tests become available and as advances in genetic science broaden both the availability of various tests and the downstream consequences of screening.

Of the studies on colorectal cancer or breast cancer screening, for which there is a consensus to screen,

four intervention arms measured the proportions of patients who reported being screened following intervention. These interventions showed a median 6 percentage point increase in screening (range, from a 2 percentage point decrease to a 14 percentage point increase).^{39,54,71} Only the 14% increase was statistically significant. The other study⁷² showed small and non-significant increases in intentions to be screened.

The most important outcome of IDM is whether patients make informed choices, and not which specific choices they make. Because this is a new field of study, the current lack of evidence is not surprising. Despite consistent evidence that interventions improved knowledge, beliefs, risk perceptions, or a combination of these, little or no evidence was found about whether the interventions resulted in participation in decision making at a level desired by individuals or whether interventions promoted decisions consistent with individual preferences and values. In addition, too few studies were available to determine the effectiveness of IDM interventions targeted to community members outside health care systems or targeted to health care systems and providers. IDM interventions appear to increase screening use of tests for which there is strong evidence, e.g., mammography, but decrease screening use of tests for which there is not a clear recommendation by evidence-based decision-making groups, e.g., prostate cancer screening. The benefits of IDM interventions are modest; no harms have been identified to date. There is no evidence to support a fear that often is heard in discussions about IDM—that such interventions will discourage screening.

When to use IDM.

The evidence reviewed in this article, although it is not definitive in its appraisal of the effectiveness of IDM, does provide insights into how IDM can be used most effectively in the context of such decisions. IDM is advocated increasingly and appropriately for a range of cancer screening decisions, including whether to have a test at all, when to start and stop testing, the intervals at which testing should occur, and which screening modality should be used.^{18,39,63,77,78} Lessons learned include the following:

Lesson 4: IDM interventions are needed, especially for those cancer screening tests for which the evidence is uncertain or is very sensitive to patients' preferences. The evidence presented above attests to the value of IDM for tests like PSA, for which evidence of a mortality benefit is not definitive and concerning which considerable controversy exists among health professionals. Moreover, when available information is too complex or too biased to clearly, fully, and fairly ex-

plain the potential risks and benefits of a given screening test, IDM and SDM can help put potential risks and benefits in context. The ability of IDM to improve knowledge, beliefs, and risk perceptions is demonstrated in the *Guide to Community Preventive Services* review.⁴²

Some screening tests are of greater benefit than harm on a population-wide basis and, thus, are recommended widely. For example, the USPSTF has concluded that the evidence about mammography now justifies recommending mammography every 1–2 years for women age > 40 years.⁷⁹ Nevertheless, several factors make clear the importance of providing balanced benefits/harms information to the public, even for this seemingly obvious case. There is scientific uncertainty about the strength of the evidence for most screening tests, and all screening tests have performance limitations (e.g., false-positive results). For mammography and other cancer screening tests, the appropriate age at which to cease recommending cancer screening tests for all individuals is a sensitive issue about which there are still too few data. Recent changes in guidelines for cervical cancer screening⁸⁰ undoubtedly will lead to questions from both patients and physicians about periodicity. Communicating to health professionals about cancer screening is challenging; communicating with patients about information, such as probability, risk, and potential benefits and limitations of tests, is both a science and an art—neither of which is well understood.

For a growing number of health care conditions, individuals must choose between two or more equally valid screening regimens that differ in their periodicity, benefits, and harms, and in the public's perceptions of benefits and harms—all further complicating the decision-making process. Reasonable and recommended intervals for cervical cancer screening may be yearly or less frequent, such as every 2 or 3 years.¹⁶ Colorectal cancer screening can be performed in a variety of ways (FOBT, sigmoidoscopy, colonoscopy, or barium enema),⁸¹ but the relative merits of each method vary, as do the values individuals place on these merits.^{18,81} Data also are evolving on the appropriate interval for colorectal cancer screening.⁸² An example of an Internet-based tool to promote IDM for colorectal cancer screening, including the pros and cons of different screening options, can be found at <http://www.med.unc.edu/wrkunits/2depts/medicine/edursrc/colon.htm>.

Patients should receive balanced information about what to expect from screening tests with proven benefits (including limitations, risks, and potential harms), and they should be encouraged to select from among effective options consistent with individual

preferences and values. This means that some informed patients will elect to decline or defer effective cancer screening tests that may be recommended by guidelines and/or by their personal physicians, what Forbes et al.⁸³ describe as *informed uptake*. IDM interventions may be of higher priority when one or more of the following criteria are met: 1) uncertainty about effectiveness, uncertainty about balance of benefits and harms, unavailability of balanced information (e.g., general knowledge of the pros but not the cons of a particular screening test), and/or high complexity of trade-off; and/or 2) low demand despite known effectiveness; 3) high variability in values or preferences; 4) high-stakes issues (e.g., more common or serious conditions; more costly, complex, or dangerous consequences of screening).

In the short term, high-priority topics for IDM interventions (e.g., prostate cancer screening) probably will meet several of these criteria, and interventions that address such issues will be in high demand. Over time, communities, providers, and health care systems increasingly may provide IDM even for lower priority issues. Infrastructure for undertaking these interventions (e.g., high-quality data on pros and cons of tested decision aids) is likely to improve, and the comfort and skill level of health care providers and systems both to engage in and to support IDM/SDM are likely to increase. Walsh and McPhee⁸⁴ have made useful recommendations regarding how to conduct SDM discussions.

Patient-related challenges.

Lesson 5: Numerous patient, provider, and system factors pose challenges to the optimal integration of IDM into health care decision making. Most (but not all) patients want to be informed about their illnesses and medical conditions,⁸⁵ and a significant proportion do not get all of the information they desire.^{86,87} The extent to which patients want to be involved actively in decision making about the options available to them, however, varies widely.^{44,50,88,89} In any situation, the optimal strategy is to adjust the level of patient participation to their preferences. Yet, the practical realities of today's health care settings make this goal difficult to achieve.

Patients may or may not use information provided to them as they make decisions,⁹⁰ and they may lack necessary information for IDM, even when they are provided with decision aids. Patients tend to overemphasize the potential benefits of screening and downplay the risks.^{39,73} Thornton and Dixon-Woods⁹¹ observed that today's risk-conscious patients may demand tests, even when no evidence of effectiveness exists. In addition, patients differ in the extent to

which they value or prefer IDM or SDM.^{41,50,92} Individuals exhibit cognitive, socioeconomic, cultural, and psychosocial differences in their needs for information and in how they respond to it. Several studies show that preferences for active roles in decision making vary according to a number of sociodemographic and disease-specific characteristics. Older age, male gender, and lower income are related inversely to a desire for active involvement in decision making.^{26,93} Myers found that African-American men were less knowledgeable than white men about prostate cancer screening and would benefit from preparatory information to help them make decisions.⁹⁴ Patients at all education levels may be at a disadvantage in understanding risk information, but those with a high school education or less are particularly challenged in this regard. Moreover, for some conditions and procedures, patients may be price-sensitive, and cost considerations may overwhelm other considerations, as shown by Pignone et al.¹⁷ with regard to colon cancer screening. Benbassat et al.⁹³ found that demographic and situational factors accounted for only about 20% of the variance in decision making, thus indicating that other important factors are yet to be understood. Sicker patients are less likely to prefer or choose IDM.^{88,95,96}

Most patients are unfamiliar with probabilistic thinking. Risk and uncertainty are complex, difficult concepts. Partly as a consequence of low levels of numeracy, patients generally have difficulty understanding risk information.^{40,97,98} Personalized risk information seems to lead to greater uptake of screening; however, this action is not necessarily evidence of IDM.⁹⁹ The best advice probably comes from a recent review of the data on breast cancer risk perception and surveillance: Risk information should be explained in a way that is tailored to the individual client's needs.¹⁰⁰

Research also shows that information provided as part of IDM may not have much effect on patients' strongly held beliefs.¹⁰¹ Patients may be reassured by IDM interventions; however, in some cases, their reassurance could be inappropriate.¹⁰² Strongly held beliefs about the value of screening are reinforced by the media. In-depth, qualitative interviews conducted among women, for example, showed little ambivalence about mammography.¹⁰³

Many patients expect physicians to take charge of clinical decisions and are uncomfortable with a more central role. This is especially true for cancer treatments. Patients may find the complexity of decisions overwhelming and worry about the regret they may experience if their decisions result in adverse outcomes. Screening tests may be a low-priority health

issue for some patients. Others may desire shared decisions but find their physicians unprepared or uncomfortable with this approach. In addition, physicians are less likely to offer a participatory decision-making style with certain patients, such as African Americans.¹⁰⁴

Few data are available to evaluate current practices regarding IDM. Most studies are retrospective and include small samples, usually from clinic populations. In one of the few population-based studies, Australian researchers used random-digit dialing to assess women's reported and preferred decision-making roles and preferences for information on screening tests. Mammography was the example test most women chose. At least in Australia, the overwhelming majority of women (94.6%) wanted to share test-related decision making with their physicians. Moreover, most women said they had not been given information about the possibility of side effects or of false-positive results.¹⁰⁵ Increasing evidence from the therapeutic arena shows that a balanced decision-making process shared by patients and physicians may be the optimal model for all patients. For example, Gattellari et al. reported that patients who said they had shared a decision-making role with their oncologists were most satisfied with the consultation, information, and support.⁴¹

Lesson 6: In the short run, participation in IDM should be facilitated for those patients who want it. Greater numbers of individuals should be encouraged to participate more fully in their health care.

Multiple models of IDM will be required to reflect patients' differing needs and preferences for information and participation. In addition, as noted by Nguyen,¹⁰⁶ McPhee¹⁰⁷ and colleagues,¹⁰⁷ decision-making styles exist in a cultural context. For some cultures, IDM/SDM may involve other family members in addition to the patient. For some health care situations, this may be true for patients of all cultures. A tendency to accept illness as part of one's destiny in life may cause some patients to reject IDM/SDM. More cross-cultural research is needed not only to gain a better understanding of the influence of culture, ethnicity, and other factors on decision making, but also to develop IDM/SDM models that, culturally, are sensitive and appropriate. Obviously, in the United States, IDM/SDM materials prepared in English are of limited value for non-English-speaking individuals.

Provider-related challenges.

Physicians vary in the extent to which they support IDM and SDM and how prepared they feel to advise patients in this new paradigm.⁵⁰ Time pressures and limited reimbursement in contemporary medical

practice have been cited as serious constraints.^{44,108} Although physicians worry about time constraints, and lack of time often is portrayed as a barrier, one recent review suggests that involving patients does not necessarily require more time.¹⁰⁹ However, more evidence is needed in this regard. Few evidence-based tools are available, and few physicians have been trained to facilitate either IDM or SDM. Moreover, the evidence suggests that physicians are not accurate in assessing patients' preferences.^{109,110} Many medical practices lack the resources to mail materials in advance of appointments or to create materials that are individualized to patients' needs and preferences, as discussed by Barry.⁴⁴ Practice personnel also are not prepared or do not have time to help patients find and use decision aids.

Much remains to be learned about IDM and SDM. Perhaps, ultimately, if IDM and SDM are to be realized, then clinicians must leverage resources beyond individual encounters, such as engaging other office personnel who are trained to deliver appropriate interventions; making use of continuity relationships (in primary care) to extend discussions over multiple office visits; and using decision aids, Web-based tools, and community resources to empower patients to practice IDM independent of providers. Reimbursement schemes also are necessary to compensate providers for offering these resources. Moreover, benchmarking systems, like the Health Plan Employer Data and Information Set, should consider including measures of decision making.

System-related challenges.

It is one thing to talk about paradigm shifts in decision making; it is yet another to provide the tools and systems to facilitate IDM/SDM.¹¹¹ We may have achieved the former, but we are far from the ideal regarding the latter. SDM interventions and, to a lesser extent, IDM interventions involve considerable opportunity costs. Without structural and process changes, such interventions are not inserted into organizations easily. Furthermore, the infrastructure for developing, delivering, and helping individuals understand and use SDM and IDM interventions is underdeveloped.

Lesson 7: Decision-making information can be provided to individuals outside clinical encounters; this not only may attenuate health disparities but may enhance the efficiency of patient-physician interactions. The increased use of community approaches to promote IDM may increase the development of tools (e.g., decision aids) that could be shared, reducing the need for providers and health care systems to engage in the time-intensive process of developing their own tools. The emergence of Web-based decision aids for

cancer screening enables the dialogue between provider and patient to reach beyond clinic walls, permitting patients/consumers to explore a broader spectrum of evidence-based resources and to integrate that information with advice from clinicians. Not all individuals have access to health care or relationships with providers that enable SDM, but it is realistic to expect that all individuals can achieve IDM for health care decisions that are important to them.

Research Agenda and Unresolved Questions

Many important questions about IDM/SDM remain unresolved.

Definition and specification.

1) To date, there is no accepted definition of either a "good decision" or IDM. Are the differences between IDM and SDM substantial? Can they be operationalized? 2) What are the appropriate objectives (outcomes) for IDM/SDM?

Methodologies.

1) Are there simple diagnostic measures that could be used to assess patient preferences for particular levels of involvement in decision making? There has been far too little research in this area. Arora et al. examined the utility of a stage-of-change type of measure to assess patient preferences for participating in decision making.¹¹² It was used successfully to discriminate among patients at different stages of readiness for participation. Encouraging both the development of validated measures and their use will be critical to advancing the field of cancer-related decision making. 2) What core measures are appropriate for assessment of IDM/SDM outcomes? Comparisons must be able to be made across studies. 3) What is the appropriate control group in a decision-aid study?

Decision aids.

1) What are the essential elements in decision aids?⁴⁸ 2) Are there types of tests, decisions, or individuals for whom IDM is inappropriate?⁴⁴ 3) Should IDM be used for screening tests for which evidence contraindicates population-based screening? 3) Barry⁴⁴ suggested that major questions should include how to avoid bias in decision aids, how much quantitative information should be presented and in what formats, and how decision aids can be incorporated into medical practice. 4) Are special interventions needed for populations that are older, have low incomes, have low levels of education, are ethnic minorities, or speak languages other than English? 5) Do combinations of IDM interventions produce greater effects than single IDM interventions? 6) Do decision aids have any negative

sequelae (e.g., increased patient anxiety or regret, diversion from more important health priorities)? One study showed that a decision aid on mammography increased knowledge and accurate risk perceptions significantly without increasing cancer-related worry.³⁹

The role of physicians and other providers in IDM.

1) What is the appropriate role for physicians or other providers? Is it ethical to deliver IDM interventions to patients who lack primary care providers? 2) How can clinicians most effectively help to guide patients to accurate, timely information on the Internet as a part of facilitating IDM? For example, meta-Web sites with rated and reviewed content are one starting point.²⁸ 3) How can e-communication be used to enhance IDM? Although electronic communication between patients and clinicians can help patients become more involved in their own care. To date, only a small proportion of physician practices have embraced it.

Effects on health systems and population health.

1) What are the effects of decision aids and other IDM/SDM interventions on medical practices and on physicians' time? Given the increasing number of topics for which SDM is recommended, how can the typical primary care physician incorporate multiple SDM discussions into health maintenance examinations? Is it realistic to expect physicians to conduct IDM discussions for tests that are well accepted by professional organizations? How can such interventions best be incorporated into practice? For example, Volk et al. recommended that patients view decision aids before visits to their provider.⁷⁵ 2) What should be the role of IDM/SDM in population health? Marteau and Kinmonth¹¹³ observed that the public health approach focuses on maximizing participation rather than on informed participation. Different representations and combinations of risk information may affect individual screening decisions. Is there a conflict between the traditional efforts to motivate individuals to be screened and what now is described as *informed uptake*? More research is needed in this area. 3) What are the effects of interventions oriented to providers and systems? 4) What are the economic effects of IDM interventions? What is their cost-effectiveness?

Conclusions

Some articles in this supplement describe 20 years or more of intervention research, but IDM is much newer; therefore, there are fewer lessons and more questions. Nevertheless, this is an important area as patients' choices become more complex, and they are faced with decisions among interventions that may be

weighted equally. Various forms of decision aids and other tailored health communications can be used to deliver information to patients. Patients show increased knowledge and improved risk perceptions as a result of exposure to IDM interventions. Outcomes in terms of screening behavior vary and seem to reflect a tendency to decline screening when the evidence is insufficient to justify population screening while perhaps encouraging screening tests for which the evidence is strong. These lessons are offered with caution, however, because the evidence base is extremely small.

The emphasis on IDM and SDM undoubtedly will grow as new screening technologies make it possible to find cancers earlier and earlier. Perhaps these technologies also will identify specific types of cancers in individuals with particular genetic mutations. This will require tailoring to provide the level of individualization needed to communicate with individuals about their specific screening needs.

IDM and SDM require interdisciplinary studies. For the most part, research on IDM/SDM has been atheoretical. More work is needed to advance theory. Theories should be drawn not only from medicine and health behavior but also from communication sciences and other disciplines that address risk communication.^{114,115}

Although we have yet to determine how best to promote IDM, it is a worthy goal. Many questions remain unanswered about how and when to provide IDM/SDM interventions and tools. There is tension, as noted by Chamot and Perneger,⁴⁰ between the goal of respecting individual autonomy and the goal of achieving greater public health effectiveness. We are only beginning to learn the lessons from this area and to apply them, as shown in this report. There can be little doubt, however, that the future will bring increased attention to IDM and SDM. It will be important to address the needs of diverse populations and age groups as we focus increasingly on this topic. It is critical that no populations be left behind when it comes to IDM.

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