
Promoting Informed Decisions About Cancer Screening in Communities and Healthcare Systems

Peter Briss, MD, MPH, Barbara Rimer, DrPH, Barbara Reilley, RN, PhD, Ralph C. Coates, PhD, Nancy C. Lee, MD, Patricia Mullen, PhD, Phaedra Corso, PhD, Angela B. Hutchinson, PhD, MPH, Robert Hiatt, MD, MPH, Jon Kerner, PhD, Prethibha George, MPH, Cornelia White, MPH, Nisha Gandhi, MPH, Mona Saraiya, MD, MPH, Rosalind Breslow, PhD, George Isham, MD, Steven M. Teutsch, MD, MPH, Alan R. Hinman, MD, MPH, Robert Lawrence, MD, MPH, Task Force on Community Preventive Services

Abstract: Individuals are increasingly involved in decisions about their health care. Shared decision making (SDM), an intervention in the clinical setting in which patients and providers collaborate in decision making, is an important approach for informing patients and involving them in their health care. However, SDM cannot bear the entire burden for informing and involving individuals. Population-oriented interventions to promote informed decision making (IDM) should also be explored.

This review provides a conceptual background for population-oriented interventions to promote informed decisions (IDM interventions), followed by a systematic review of studies of IDM interventions to promote cancer screening. This review specifically asked whether IDM interventions (1) promote understanding of cancer screening, (2) facilitate participation in decision making about cancer screening at a level that is comfortable for individuals; or (3) encourage individuals to make cancer-screening decisions that are consistent with their preferences and values.

Fifteen intervention arms met the intervention definition. They used small media, counseling, small-group education, provider-oriented strategies, or combinations of these to promote IDM. The interventions were generally consistent in improving individuals' knowledge about the disease, accuracy of risk perceptions, or knowledge and beliefs about the pros and cons of screening and treatment options. However, few studies evaluated whether these interventions resulted in individuals participating in decision making at a desirable level, or whether they led to decisions that were consistent with individuals' values and preferences.

More research is needed on how best to promote and facilitate individuals' participation in health care. Work is especially needed on how to facilitate participation at a level desired by individuals, how to promote decisions by patients that are consistent with their preferences and values, how to perform effective and cost-effective IDM interventions for healthcare systems and providers and in community settings (outside of clinical settings), and how to implement these interventions in diverse populations (such as populations that are older, nonwhite, or disadvantaged). Finally, work is needed on the presence and magnitude of barriers to and harms of IDM interventions and how they might be avoided. (Am J Prev Med 2004;26(1):67–80)

From the Epidemiology Program Office (Briss, Corso, Hutchinson, White), National Center for Chronic Disease Prevention and Health Promotion (Coates, Lee, Saraiya, Breslow), and National Center for Infectious Diseases (George), Centers for Disease Control and Prevention, Atlanta, Georgia; National Cancer Institute (Rimer, Hiatt, Kerner), National Institutes of Health, Bethesda, Maryland; School of Public Health, University of Texas-Houston (Mullen), Houston, Texas; Health Program Development (Reilley), Houston, Texas; California Department of Health Services (Gandhi), Sacramento, California; Merck & Co., Inc. (Teutsch), West Point, Pennsylvania;

Bloomberg School of Public Health, Johns Hopkins University (Lawrence), Baltimore, Maryland; Task Force for Child Survival and Development (Hinman), Atlanta, Georgia; and HealthPartners (Isham), Minneapolis, Minnesota

The names and affiliations of the Task Force members are listed at www.thecommunityguide.org.

Address correspondence and reprint requests to: Peter A. Briss, MD, MPH, Community Guide Branch, Centers for Disease Control and Prevention, 4770 Buford Highway, MS-K73, Atlanta GA 30341. E-mail: pbriss@cdc.gov.

Introduction

The growing interest in patient education, patient-provider communication, and patient satisfaction with healthcare decision making is reflected in *Healthy People 2010*,¹ the nation's health agenda (Table 1). Along with this growing interest, a number of trends are contributing to increased involvement of individuals in making decisions about their health care. These trends include a growing emphasis on informed choice by consumers; more patient involvement in healthcare decisions²; greater quality and availability of rigorous, state-of-the-science information on clinical options, including their pros and cons; increased understanding among both consumers and practitioners that many clinical decisions are not "one size fits all" and need to be sensitive to individual values³⁻⁵; and less paternalism in provider-patient interactions.^{6,7}

Some argue that information provided about screening tests and other healthcare procedures may be unbalanced and that better data should be provided about what a patient can expect, including any potential harms and limitations. On the other hand, direct marketing of healthcare products and services to consumers is increasingly common, and often takes place regardless of whether scientific consensus on effectiveness has been reached. Societal trends also support greater public involvement in interpreting scientific findings and developing science policy.⁸ In addition to these healthcare, marketing, and societal trends, the relationship between individual involvement in clinical decision making and healthcare quality has been addressed by the Institute of Medicine; the Institute's position is that quality health care should be patient centered—that is, respectful of and responsive to patient needs and values.⁹

The review team (the team) defined informed decision making (IDM) as occurring when an individual understands the nature of the disease or condition being addressed; understands the clinical service and

its likely consequences, including risks, limitations, benefits, alternatives, and uncertainties; has considered his or her preferences as appropriate; has participated in decision making at a personally desirable level; and either makes a decision consistent with his or her preferences and values or elects to defer a decision to a later time. Based on the work of the U.S. Preventive Services Task Force (USPSTF), the team defined shared decision making (SDM) as occurring when a patient and his or her healthcare provider(s), in the clinical setting, both express preferences and participate in making treatment decisions. The team defined an IDM intervention as any intervention in a community or healthcare system that promotes IDM. IDM interventions, including SDM in the clinical setting, are emerging concepts that may increase the involvement of individuals in decision making about their health care.

This confluence of national trends raises several questions addressed in this paper:

1. What are IDM and SDM, and how do they relate to one another?
2. Is there a need for IDM to complement SDM?
3. Can interventions effectively promote IDM and SDM?
4. What are the pros, cons, and tradeoffs involved in IDM and SDM interventions?
5. What is known about the use of IDM interventions for cancer-screening decisions?
6. What types of cancer-screening decisions could be addressed through IDM and SDM interventions?
7. What outcomes are likely to result from IDM or SDM interventions?
8. What additional research is needed?

To answer these questions, the team developed a conceptual framework for IDM and SDM interventions showing the relationship between these interventions and key outcomes (Figure 1). Using this framework, the team conducted a systematic literature review to assess

See
related
Commentary
on page 81.

Table 1. *Healthy People 2010* objectives relevant to informed decision-making interventions

Objective	Intervention
1-3 h	(Developmental) Increase the proportion of persons appropriately counseled about management of menopause (females aged 46-56 years).
3-10	Increase the proportion of physicians and dentists who counsel their at-risk patients about tobacco use cessation, physical activity, and cancer screening.
7-7	(Developmental) Increase the proportion of healthcare organizations that provide patient and family education.
7-8	(Developmental) Increase the proportion of patients who report that they are satisfied with the patient education they receive from their healthcare organization.
11-4	(Developmental) Increase the proportion of health-related World Wide Web sites that disclose information that can be used to assess the quality of the site.
11-6	(Developmental) Increase the proportion of persons who report that their healthcare providers have satisfactory communication skills.

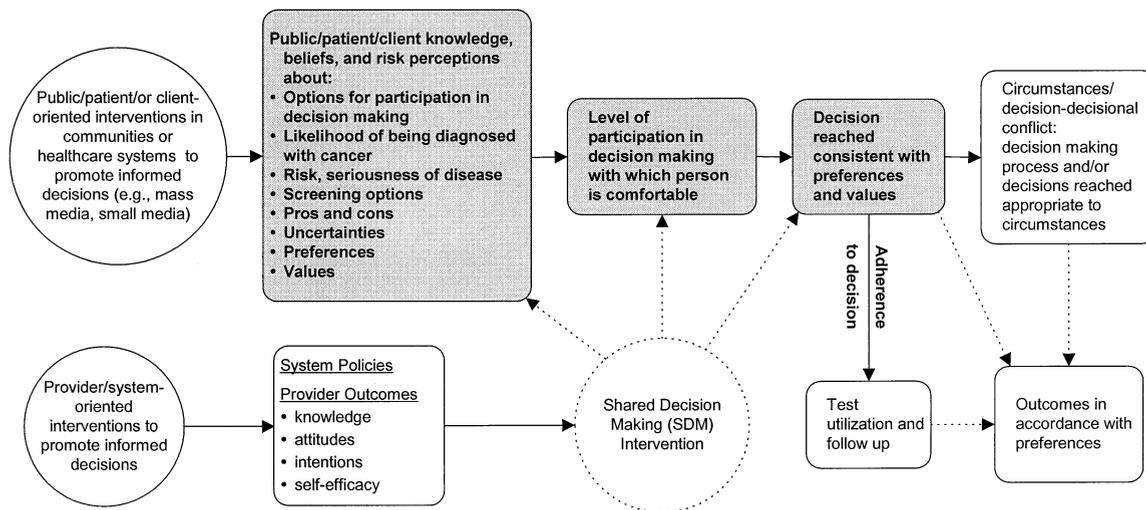


Figure 1. Analytic framework showing the relationship between interventions and postulated outcomes that guided the search for evidence in this review. Shaded boxes show outcomes used to support recommendations; solid lines indicate areas evaluated; dashed lines indicate areas not evaluated.

whether IDM interventions in one subject area—cancer screening—have been effective in achieving these outcomes. Development of the conceptual framework and the systematic literature review were conducted as part of the larger *Guide to Community Preventive Services* initiative (more at www.thecommunityguide.org); the framework and review provide the basis for conclusions by the Task Force on Community Preventive Services.

The systematic reviews in this report represent the work of the independent, nonfederal Task Force on Community Preventive Services (the Task Force). The Task Force is developing the *Guide to Community Preventive Services* (the *Community Guide*) with the support of the U.S. Department of Health and Human Services, in collaboration with public and private partners. The Centers for Disease Control and Prevention (CDC) provides staff support to the Task Force for development of the *Community Guide*. A special supplement to the *American Journal of Preventive Medicine*, “Introducing the *Guide to Community Preventive Services: Methods, First Recommendations, and Expert Commentary*,” published in January 2000,¹⁰ presented the background and the methods used in developing the *Community Guide* (articles are also available at www.thecommunityguide.org).

IDM and SDM: How Do They Relate to Each Other?

Various authors have different conceptions and nomenclature for IDM, SDM, and related interventions. In proposing nomenclature for this review, the team has benefited considerably from the work of others^{4,7,11–15} and has collaborated closely with the USPSTF.¹⁶ In addition, the development of IDM and SDM interventions is predicated on basic research, including decision analysis^{7,17–19} and risk communica-

tion.²⁰ The team incorporated ideas from such research when defining interventions, identifying potential outcomes, and addressing other conceptual issues.

Both SDM and IDM can result in informed decisions, and they are mutually supportive. Many professional societies and organizations recommend SDM in some form as a means of assisting individuals in making informed choices about their health care.

Additional interventions not conducted by providers can also promote IDM. The team’s definition of IDM interventions includes any intervention in a community or healthcare system that promotes IDM, including healthcare system interventions that facilitate SDM in the clinical setting. (Figure 2 illustrates the relationship

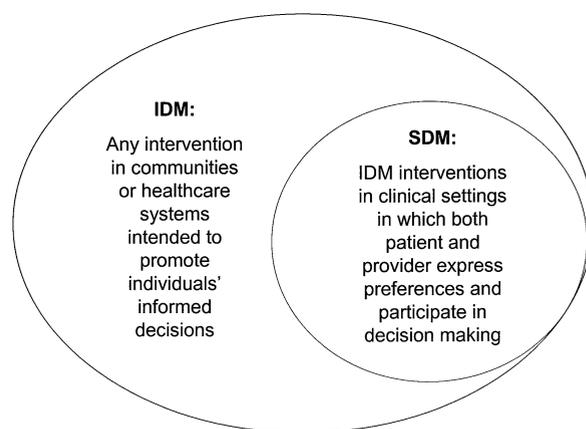


Figure 2. The relationship between informed decision making (IDM) and shared decision making (SDM). SDM interventions involve both patients and providers in which both parties provide information express preferences, and participate in decision making. SDM interventions are a subset of a larger universe of healthcare system and community interventions intended to promote informed decisions.

Table 2. Range of IDM interventions

All IDM interventions would

Contain evidence-based, balanced, understandable, appropriate, and succinct information on disease and the potential intervention including any applicable risks and benefits of prevention or treatment options

Encourage individuals to participate in values clarification and decision making consistent with their preferences

IDM interventions might differ in the following characteristics:*IDM interventions oriented to the public would be*

Conducted by providers, insurers, healthcare organizations, public health agencies, community groups, faith-based organizations, community organizations, cancer centers, academic medical centers, and other appropriate groups

Delivered by a range of channels including mass media, computers, counseling, and small group education

Tailored (i.e., created for the individual based on relevant information about that person)²⁴ or untailored

Targeted at public/individuals/patients themselves, family members, or both

IDM interventions oriented to clients or patients of healthcare systems would be

Conducted by healthcare systems

Targeted to clients, patients, and family members

IDM interventions oriented to providers or healthcare systems would

Be conducted by healthcare systems, communities, or both

Target healthcare providers, systems, or both

Educate providers on how and why to conduct SDM

Promote policies that encourage provider use of SDM (e.g., payment policies that pay for SDM, or development of nonphysician staff trained to conduct SDM)

IDM, informed decision making; SDM, shared decision making.

between IDM and SDM interventions.) IDM interventions can be delivered through a variety of channels, including mass media, small media, group education, and one-on-one education. New computer-based applications can provide interventions tailored to individuals. IDM interventions can be delivered to community members outside of healthcare systems,^{13,21–23} to clients of healthcare systems, or healthcare providers and systems. Table 2 illustrates the range of IDM interventions.

IDM interventions have a broader reach than SDM interventions in that they need not involve providers and are not limited to clinical settings. However, SDM interventions can be more comprehensive or more personalized than IDM interventions, because they take place in clinical settings and involve one-on-one interactions between providers and patients, mutual information sharing, and expressions of preferences.

Thus, SDM and IDM interventions are both important, reinforcing and building on one another. For individuals who want to participate in an SDM exchange, IDM can facilitate the process by providing basic information. However, SDM interventions may require lengthy discussions and may not be needed or appropriate for all individuals or all screening tests. For example, rather than engaging in SDM, some individuals may prefer to leave decision making to the healthcare provider.

IDM interventions include but are not limited to decision aids, which were defined (consistent with O'Connor et al.¹⁴) as interventions designed to help people make specific and deliberative choices among options (including electing not to have an intervention or deferring a decision). Decision aids provide people with specific information relevant to specific healthcare decisions.²⁵ At a minimum, they provide information

on the options and outcomes relevant to a person's health status. Decision aids usually also provide information on the disease or condition, costs associated with healthcare options, probabilities of outcomes tailored to personal health risk factors, and information on others' opinions. They can also facilitate a clarification of values and provide guidance or coaching in the decision-making process and in communicating with healthcare providers. Decision aids may also facilitate more active patient involvement in decision making.²⁵

IDM and SDM are increasingly used in helping patients evaluate options for therapy, such as options for cancer treatment. IDM and SDM are also increasingly recommended for providing information about preventive services. Topics recently addressed include hormone replacement therapy and various forms of cancer screening.¹⁴

This article addresses only IDM about clinical preventive services. Although IDM has some important parallels to community participation in public health program and policy development, it also has important differences. The arguments for greater public involvement in public health interventions and policy (e.g., laws, policies, and environmental change) are similar to those for greater individual involvement in clinical decisions (see section below on potential pros, cons, and tradeoffs involved in IDM and SDM). In addition, communities can help to ensure that IDM interventions are culturally appropriate and consistent with community priorities. However, there are also important differences between IDM and community involvement, including the types of problems addressed, the participants, the processes by which individuals and communities are involved, and the types of pros and cons considered as well as methods for their assessment.

Because of these differences, the team did not further address the concept of promoting increased community involvement in health policy decision making.

Is There a Need for IDM to Complement SDM?

The time demands of SDM could place a considerable burden on individual healthcare providers.^{19,26,27} Most patients have multiple needs and interests, but the average primary care visit is now approximately 15 minutes long.²⁸ Providing information about only one topic could easily take much of that time. Although providers must have a central role in informing, educating, and advising patients, as well as taking action when decisions are reached, time constraints in contemporary medical practice often keep them from providing everything required to support informed decisions. This may be particularly true for prevention topics, because many potential prevention options appropriate for a patient might not be the primary focus of a visit. Finally, not all providers have the skills and training to do a thorough job of facilitating SDM.

It appears increasingly feasible and desirable to complement SDM by providing information to interested individuals outside of the clinical encounter through a range of community-oriented or healthcare system-oriented approaches. Increased use of community approaches to promote IDM might result in more efficient provision of information and a reduced burden on individual healthcare providers, while preparing patients for a more active role in the clinical encounter. Similar efficiencies might be achieved by healthcare system approaches to promoting IDM, such as specialized referral centers within healthcare systems that focus on SDM or IDM. Further, community approaches to promoting IDM might increase the development of tools (e.g., decision aids) that can be shared, reducing the need for providers and healthcare systems to engage in the time-intensive process of developing their own tools. Finally, IDM may reach people who would not be reached by SDM: not all individuals have the access to health care and relationships with providers required for SDM, but IDM can conceivably be available to all individuals.

What Are the Potential Pros, Cons, and Tradeoffs Involved in IDM and SDM?

IDM and SDM may well involve a range of pros, cons, and tradeoffs. The following arguments support increased individual involvement in decision making.

Ethical considerations. It has been pointed out that IDM and SDM approaches are consistent with medical ethics. This line of thinking, exemplified by the patient empowerment movement, holds that people can and should have the right to make decisions about their

own health care, based on the ethical principle of autonomy.

Improved decision making. Increased patient involvement may improve the decision-making process as well as the “quality” of decisions reached. The more an individual is involved in making decisions, the greater the likelihood that the decisions reflect his or her needs, preferences, and values.

Improved outcomes. Increased patient participation in health care might help to improve patient satisfaction with the healthcare process and the decisions reached, patient adherence to a chosen course of action,¹³ and therefore to health outcomes.²⁹

Improved availability of high-quality, balanced health information. Although not all patients want to be involved in making clinical decisions,^{3,30} most individuals want more health information. Such information is increasingly available to and used directly by individuals, fueled in part by the growth of the Internet. In 2002, 53% of adults sought health-related information on the Internet, up from 27% in 1998.³¹ However, not all health-related information is of high quality. IDM interventions might help to increase patient access to accurate and balanced information, and could also help people to assess the quality of available health-related information.

Improved tailoring of health care to individuals. Many issues have no definite “right” answer and individual preferences must be considered to determine the best approach(es). Improved tailoring of care according to individual preferences might increase the chances of reaching outcomes that individuals desire most and reduce the chance of outcomes they desire least, and thus be an advantage even if average health outcomes did not change.

The following arguments oppose greater use of IDM and SDM.

Communicating complex information to the general population is difficult. Information must be credible and up to date, avoid excessive or contradictory messages, and be unbiased. An example of a potential bias is a framing effect, where the way information is presented influences the way it is interpreted.²⁵ Health information must be accessible to people with widely varying literacy and numeracy levels. Finally, more and better information is not always as powerful as underlying beliefs.³² Although these are important issues, the risk-communication and decision-analysis literatures provide insight into avoiding many of these problems.

Admitting uncertainty may be uncomfortable. Policymakers, clinicians, and patients may be uncomfortable

admitting their uncertainty about treatment options or considering individual preferences.

Some individuals may be unprepared to cope with uncertainty. Some have even argued that increased involvement of individuals in decision making may represent a failure of professional responsibilities. A prominent leader in healthcare quality summed it up as follows: "Today people talk about patient autonomy, but often it gets translated into patient abandonment."³³

More individual involvement in decision making could have negative social consequences. Attention to IDM could take time, energy, and resources that could be put to more effective and cost-effective uses. Further, IDM might decrease use of effective services or increase patient demand for unproven, expensive, or even harmful treatments. Because of these possible negative consequences of IDM, some would argue that patients would be better served by active promotion of services with known net benefit, dissuasion from services known to be ineffective, and development of more and better research on inadequately tested clinical procedures.

SDM is difficult to conduct effectively. Furthermore, many providers may not be adequately trained to do so.²⁵

Tension may exist between promoting effective clinical services on the one hand and respecting individual autonomy on the other. Patients should be informed of all their options, but too much patient autonomy could lead to a worsening of health outcomes. This article will not resolve that tension. Providers should continue to recommend, and healthcare systems fund, choices that have been shown to produce net community benefit. However, individuals should know what to expect (including limitations, risks, and potential harms) and should be encouraged to select among effective options consistent with their preferences and values. Some informed patients might elect to decline or defer effective cancer-screening tests. Contrary to the argument that autonomy translates into abandonment, it is perfectly acceptable for healthcare or health policy professionals to express a point of view about what is best for (or detrimental to) most people when evidence supports that perspective. In fact, SDM, as defined by the USPSTF, requires that providers express preferences and participate in decision making. According to that definition, SDM need not be value neutral.

Systematic Review of IDM and Cancer Screening: Rationale

As part of the *Guide to Community Preventive Services*, a systematic review of IDM for cancer screening was conducted to help further explore the extent to which IDM interventions have been tested in this area and

assess the extent to which the potential outcomes have been evaluated empirically. This inquiry was limited to IDM outside of the individual clinical encounter (i.e., excluding SDM) and to prevention and early detection (SDM is evaluated by the USPSTF elsewhere in this issue¹⁶).

IDM is relevant to many treatment and prevention topics; however, this review was limited to a single prevention area (i.e., cancer screening) because different prevention topics are likely to raise unique questions. For example, most benefits and potential harms of cancer screening accrue to the individual. In contrast, in many infectious disease areas, population-level benefits of prevention and treatment might occur. For example, immunizations might result in population immunity (which can protect unvaccinated as well as vaccinated people), and sexually transmitted disease screening and treatment might result in interruption of the disease transmission cycle. Either of these could provide considerable societal benefits that might not be recognized at the level of individual decision making.

What Is Known About IDM for Cancer-Screening Decisions?

IDM is increasingly advocated for many cancer-screening decisions, including whether to have a test at all, when to start and stop testing, at what intervals testing should occur, and which screening modality should be chosen.^{5,11-13} The purpose of this systematic review was to explore the extent to which IDM interventions have been tested and the potential outcomes empirically assessed. Although research on IDM in cancer treatment can inform IDM in cancer screening, this review was limited to the latter because people with diagnosed cancer differ in a variety of important ways from apparently healthy people who are facing decisions about screening.

What Types of Cancer-Screening Decisions Could Be Addressed Through IDM?

Tests of uncertain benefit. The effectiveness of some cancer-screening tests in improving health outcomes is unclear, either because evidence is insufficient to determine whether screening reduces mortality or improves quality of life, or the balance of benefits and harms is unknown or difficult to weigh. Nonetheless, providers and individuals are often compelled to consider such tests because of some combination of the following: (1) the screening test is highly publicized or widely available; (2) the test addresses a critical public health problem for which no good alternatives exist for prevention or treatment; and (3) public interest in the test is strong. At times, when publicity fails to fully inform the public about the potential risks and benefits

of a given screening test, IDM and SDM can help put potential risks and benefits in context.

Prostate-specific antigen (PSA) testing for prostate cancer is a relevant example. Prostate cancer is the most commonly diagnosed cancer in men other than non-melanoma skin cancer, and the PSA screening test is widely recommended and available. This has led to considerable public interest in the test. However, the effectiveness of PSA screening in reducing cancer morbidity and death is uncertain, and the diagnostic testing and treatment that follows PSA testing may involve important risks³⁴ of which individuals may not be aware. Moreover, some of the diagnostic testing may be unnecessary in that it results from a false-positive screening test or identifies a cancer that would never have become apparent during the individual's lifetime. As a result of these uncertainties, the balance of the benefits and harms of PSA screening is unclear. For individuals considering PSA screening, IDM can be an important aid to understanding the benefits, risks, and uncertainties of this screening method, and can help them make an informed choice. IDM might also be applicable to other high-profile cancer-screening issues such as spiral-computed tomography for lung cancer or pelvic ultrasound for ovarian cancer. The importance of IDM for cancer-screening tests of uncertain benefit is likely to increase as more and more cancer-screening tests become available.

Tests with proven benefit. Scientific studies have shown that some screening tests produce greater benefit than harm on a population basis. As a result, these tests are widely recommended. For example, the USPSTF recommends mammography every 1 to 2 years for women aged >40 years, because this screening test has been found to reduce breast cancer mortality.³⁵ Nonetheless, the magnitude of benefit is relatively small, there is a remaining scientific discussion about how conclusively the benefit has been proven, the test is inconvenient, and there is a moderately high rate of false-positive results requiring follow-up for which women should be prepared. For these reasons, balanced information on the benefits and harms to the public should be provided.

For a growing number of healthcare conditions, the individual must choose from two or more equally valid screening regimens. For example, the recommended interval for cervical cancer screening may be yearly or less frequently (e.g., every 2 or 3 years).³⁶ Colon cancer screening can be performed in a variety of ways (fecal occult blood testing, sigmoidoscopy, colonoscopy, or barium enema),³⁷ but the relative merits of each method vary, as do the values individuals place on these relative merits.^{5,37} An example of an Internet-based tool intended to promote IDM for colorectal cancer screening, including the pros and cons of different

screening options, can be found at www.med.unc.edu/medicine/edursrc/colon.htm.³⁸

What Outcomes Are Likely to Result from IDM or SDM Interventions?

The team postulated that individual- or community-oriented IDM interventions would change a number of important outcomes in the desired direction. These outcomes provide the basis for the findings of the Task Force on Community Preventive Services as part of the *Guide to Community Preventive Services*. The outcomes follow:

- Accuracy of individuals' knowledge, beliefs, and perceptions of risk about the disease or condition(s) being addressed and options for prevention or early detection, including risks, limitations, benefits, alternatives, and uncertainties of various options.
- Individuals' participation in decision making at the level desired for a particular decision at a point in time. This level could range from delegating decision making entirely to a provider after learning that greater participation is possible to making a unilateral decision once information has been obtained from a reliable source.
- Facilitation of decision making consistent with individual preferences and values, through improved knowledge and more accurate beliefs and perceptions combined with more active participation in the decision-making process.

To support recommendations, the Task Force would have required changes in all of these outcomes in the desired direction; for example, improved knowledge and risk perceptions without participation at a desired level would have been a step in the right direction but insufficient to demonstrate success.

The team also assessed whether interventions or policies oriented to providers or healthcare systems led to provider or system outcomes that, in turn, led to the individual outcomes discussed above. For example, the team assessed whether these interventions led to:

- Greater implementation of policies that promote and facilitate SDM (e.g., payment policies that increase time for or reimbursement to providers who participate in SDM, or hiring or training of additional nonphysician staff to help facilitate SDM).
- Improvement in provider knowledge and self-efficacy about, attitudes toward, and intentions to perform SDM.
- Improvement in provider participation in SDM.
- Improved outcomes for individuals as a result of desired changes in provider and system approaches.

Finally, additional outcomes were postulated that were of interest but would not provide a basis for a Task Force recommendation. For example, do IDM inter-

Table 3. Informed decision making: descriptive information about included reports

Description	n	Reference
Reports meeting inclusion criteria	11	13,23,38,41–50
Additional reports on an already included study	2	23,50
Qualifying reports	11	
Reports excluded, limited quality of execution	0	
Actual number of qualifying reports	11	13,23,38,41–50
Greatest suitability of design	11	
Reports with >1 independent intervention arm	3	13,41,42
Number of qualifying intervention arms	15	
Good quality	3	41,45,49
Fair quality	12	13,38,41–44,46,47,48,50
Intervention activities		
Small media alone		
Videos	3	41,42
Written materials	3	13,45,49
Tailored (i.e., customized for the individual)	1	13
Video with or without a brochure	1	46
One-on-one education alone	3	47,48
One-on-one education plus small media (written materials)	2	13,43
One-on-one education aided by computer-generated decision aids	1	44
Small-group education alone	1	42
Small-group education plus small media (video)	1	42
Small media (video) plus provider-oriented intervention	1	38

ventions lead to better adherence to decisions? Do they increase or decrease actual use of screening tests or rates of follow-up of abnormal tests? Do they improve the match between individual circumstances and decisions? Do they change individual levels of decisional conflict? Do they lead to enhanced satisfaction with either the decision-making process or the decisions reached? Do they improve health outcomes or improve the fit between the types of health outcomes achieved and individual preferences? Are there harms or unintended consequences of these programs? The relationship of all outcomes to the interventions and to each other is portrayed graphically in the conceptual framework (Figure 1).

The proposed outcomes on which recommendations would be based in this review (i.e., knowledge, participation, and consistency with values) differ from those typically identified in *Community Guide* reviews,³⁹ in that they are not health outcomes or established proxies for health outcomes. However, for this novel public health intervention, informed and participatory decisions consistent with preferences and values were considered to be of value regardless of whether they led to better health.

People who make decisions about health and public health programs vary in the extent to which they prefer to promote decisions consistent with individuals' values and preferences rather than other important social goals, such as improved population health or rational resource allocation. However, they usually have multiple and potentially conflicting goals when choosing programs. For example, goals may include providing treatments that produce the greatest likelihood of good

outcomes for the greatest number of individual patients, while considering the best available science, rational societal resource allocation, and organizational financial impact, as well as the need to respect individual autonomy. Decision makers must make tradeoffs among such competing goals when choosing clinical or public health interventions. This review seeks to clarify what is known about the likely outcomes of programs to promote IDM about cancer screening, so that decision makers can compare the results of these programs with other alternatives. For example, some interventions might lead to "more rational" decisions about prostate cancer screening that may or may not save lives. On the other hand, good conceptual grounds and some empirical evidence suggest that informed and involved individuals are more likely to adhere to treatment recommendations,^{13,29} and some evidence indicates that less-informed patients may have poorer outcomes. Better-informed patients may therefore have more autonomy and better health.

Methods

The general methods used to conduct systematic reviews for the *Community Guide* have been described in detail elsewhere.^{39,40} The specific methods for conducting this review, including intervention selection, outcome determinations, and search strategy, are presented in the Appendix.

Results

Effectiveness

Eleven reports met the inclusion criteria (Table 3).

Three of the reports^{13,41,42} provided data on more than one intervention arm. Therefore, a total of 15 independent intervention arms were identified for the review. Of the 15 included intervention arms, ten addressed prostate cancer screening,^{41-43,45-47,49,50} three addressed colorectal cancer screening,^{38,44,48} and two (in one report) addressed mammography screening.¹³

Only three of the intervention arms^{13,49} evaluated interventions implemented outside of clinical settings, and only one of the studies³⁸ included any intervention component oriented to providers or healthcare systems. Only one of the studies⁴⁴ reported results that could be mapped to all three outcomes on which recommendations would be based.

Thirteen of the studies^{13,41,42,44-50} (in eleven reports) measured patients' knowledge, beliefs, or perceptions about the risk or natural history of the disease, or about the performance of the preventive service. Although the measures were diverse, almost all reported increases in knowledge, increased accuracy of beliefs and perceptions, or both, relative to usual care. Some, but not all, of the more intensive interventions tended to produce larger effects. For example, addition of telephone counseling to tailored print materials resulted in larger improvements in knowledge than print materials alone.¹³ Similarly, small group education in combination with a video produced larger effects than either method used alone.⁴² On the other hand, a more intensive computer-assisted counseling intervention produced high self-reported understanding of screening options, but a less-intensive counseling intervention produced even higher self-reported understanding.⁴⁴

Three intervention arms from one report⁴² showed self-reported increases in preference for shared decision making; however, the report did not address whether increased screening actually occurred. Three studies^{38,43,49} reported some information on the effect of the intervention on the extent of individual or patient participation in decision making. All reported information based on single questions about whether patients had discussed screening with their doctor; although the three reports were consistent in reporting increases, the reports varied in reporting effect sizes or significance. Only a single study⁴⁴ reported on whether participation was consistent with expressed preferences for level of participation, showing that 42% of clients in both an intensive intervention group and a less-intensive intervention made decisions consistent with their pre-intervention preferences (i.e., primarily by patient, primarily by physician, or shared). None of the reviewed studies allowed for a comparative assessment of whether decisions reached were consistent with values or preferences; one study did provide information showing that only 19% of patients who received an intensive intervention actually chose a screening strategy at their next office visit that was consistent with the

most highly rated strategy identified by the patient during the intervention.⁴⁴

Results of the interventions on screening outcomes were mixed, but effect sizes were generally small. Of the studies of prostate cancer for which there is no consensus about whether screening provides a net benefit, eight^{41-43,45,49} allowed for calculation of percentage-point changes in testing and showed a median 8 percentage-point decrease (range 47 percentage-point decrease to 14 percentage-point increase). Two more prostate cancer studies^{46,47} showed statistically significant decreases in self-reported preferences for screening.

Of the five studies of colorectal cancer or breast cancer, where consensus is greater about the benefits of screening, four allowed calculation of proportions of patients accepting screening following the intervention^{13,38,44} and showed a median 6 percentage-point increase in screening (range 2 percentage-point decrease to 14 percentage-point increase). Only the 14 percentage-point increase was reported to be statistically significant. The other study⁴⁸ showed generally small and nonsignificant increases in intentions to be screened.

Other Positive or Negative Effects

The team considered whether the intervention might have negative effects on individuals or community members (e.g., confusion, frustration, positive or negative effects on other preventive care); healthcare systems or providers (e.g., effects on clinic efficiency); or whole communities (e.g., adverse effects of competing or contradictory clinical and community approaches). None of the reviewed studies provided empirical information about any of these postulated other effects.

Conclusions

According to *Community Guide* rules of evidence,³⁹ current evidence is insufficient to determine the effectiveness of IDM interventions for individuals in healthcare settings, for community members outside of healthcare settings, or for interventions targeted to healthcare systems and providers. Although there was generally consistent evidence that these interventions improved knowledge, beliefs, risk perceptions, or a combination of these (e.g., knowledge about the disease, the test or the consequences of the test, accuracy of risk perceptions, or accuracy of beliefs), there was little evidence about whether these interventions resulted in participation in decision making at a level desired by individuals, or whether the 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 of

healthcare systems or targeted to healthcare systems and providers.

Research Issues

Systematic reviews are useful both for developing recommendations and identifying important unanswered questions. Because evidence for these interventions was insufficient to determine effectiveness, numerous research issues remain. The research questions posed below can guide future research and be used by government agencies, foundations, healthcare systems, and others in their allocation of research funding and by academic and other research organizations in their selection of research priorities.

More work is needed on the effect of these interventions on all of the outcomes in the conceptual framework, especially on recommendation outcomes other than knowledge, beliefs, and perceptions of risk. Few studies reported individuals' participation in decision making, and only one of those reported whether participation was at a desired level. It is not possible to know from the published reports whether questions about this issue were not asked or whether current instruments are not sufficiently sensitive to discriminate different levels of patient interest in participation, causing investigators not to report the data. If the problem is the latter, more sensitive measures of patient desire for participation should be developed.

The medical decision-making field has given considerable attention to assessing patient preferences for health states—that is, the quality of life in a particular health situation. Health economists call these preferences “utilities” and use them, among other purposes, to inform cost-utility analyses. This research needs, however, to be extended to accurate and feasible ways to assess preferences in clinical encounters and to ensure that patient decisions are congruent with individual preferences and values.

Because most of the included studies in this review addressed prostate cancer, additional work on other cancer screening would be welcome. Additional studies are needed in community contexts outside of clinical settings. Similarly, studies are needed that focus on providers and healthcare systems to promote SDM instead of, or in addition to, directly targeting individuals. Studies with providers and in healthcare systems should measure provider and system outcomes, but should also measure the client outcomes that are the ultimate goal of these programs and policies.

Social and demographic variables have been shown to affect individuals' desire for involvement in healthcare decisions and may also affect the effectiveness of IDM interventions. To date, IDM seems to be more acceptable to younger and more educated patients.⁵¹ However, this may be a consequence both of how questions are asked and of patients' confidence. More

empirical work is needed in diverse populations, such as nonwhite, older, and medically underserved populations. Achieving IDM in such populations is a challenging but desirable goal.

Although the study designs and executions of available studies in this review were generally strong, some measurement issues need additional attention. Sensitive, appropriate measures are still needed of individual involvement in decision making⁷ and the match between decisions and preferences or values. In addition, work is needed on how best to elicit patient preferences and respond to them in nonthreatening, time-sensitive, and culturally appropriate ways.

Although much work has already been published in the risk communication literature about how to communicate complex information involving probabilities to individuals,⁵² additional work is still needed on appropriate and feasible ways of communicating technical information so that it is helpful and not overwhelming. Additional empirical work on people's information needs and preferences for level of involvement in decision making, how those needs and preferences might evolve over time, and how best to meet those needs and preferences would also be useful. Finally, more work is needed on whether IDM or SDM increases or decreases the use of effective services.

It is known that, at least for some diseases (e.g., breast cancer), individuals overestimate both the disease risks and the benefits of screening.⁵³ IDM could help patients achieve a more realistic perspective on risks and benefits. In particular, quantitative risk models, which clearly show patients the risks and benefits of screening in terms of their personal characteristics, would allow patients to take personal risk factors into account when making healthcare decisions.⁵⁴ Such techniques, which permit individualization of the risks and benefits, might help people to make better-informed decisions.

Summary and Discussion

The finding of this review—that available evidence is insufficient to recommend interventions to promote IDM—is not evidence that they do not achieve their objectives. IDM and SDM are important emerging trends, and additional studies of these interventions should be conducted. Limitations, costs, uncertainties, and tradeoffs should be studied empirically and should be considered when choosing interventions. However, hypothesized costs, barriers, or tradeoffs should not limit additional exploration of IDM.

As previously noted, the emphasis on greater patient involvement in making healthcare decisions is growing. Individuals often want more information about healthcare options and greater participation in decision making than is customarily provided. Healthcare systems are slowly increasing responsiveness to patient needs and values. This trend is likely to continue.

Individuals vary in the extent to which they want to participate in healthcare decision making.^{51,55} In the short run, participation could be facilitated for those who want it. In the long run, greater numbers of people could be encouraged to participate more fully in their health care. This is especially needed in older, less-educated, and minority populations, which have typically had less exposure to IDM principles and practices. Interventions that promote IDM might increase the demand for IDM in these populations.

Respect for individual choices does not mean that societal consequences should be ignored when formulating policy. For example, IDM principles may dictate that the public should have access to information on the benefits and drawbacks of spiral computerized tomography, but this does not necessarily mean that society should pay for the service until or unless scientific evidence that the service's benefits exceeded its harms is found. Because financial and other resources for IDM (including time) are limited, selecting the tests and topics for which IDM interventions will be developed will require priority setting.

Furthermore, every issue will not require the same depth of information. Adjusting the level of information to promote the aims of IDM without being overwhelming will require experience. Several criteria may make IDM interventions of higher priority, make the provision of more information appropriate, or both. These include the following:

1. High interest in the test(s) in the community or among individuals, especially if combined with one or more of the following factors:

Uncertainty about effectiveness

Uncertainty about balance of benefits and harms

Unavailability of balanced information (e.g., knowing the pros but not the cons of a particular screening test)

High complexity of tradeoffs

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 issues for IDM interventions are likely to meet several of these criteria (prostate cancer screening is a good example). Interventions addressing such issues will be in high demand. Other issues of interest might include those for which an apparent disparity between evidence of effectiveness and level of community interest exists (e.g., colorectal cancer screening).

Over time, communities, providers, and healthcare systems will probably be increasingly able to provide IDM. Infrastructure for undertaking these interventions (e.g., tested decision aids or high-quality data on

pros and cons) is likely to improve. The public sector might play a greater role in developing or supporting the development of materials, and might increase the availability of high-quality materials for supporting decisions that can be shared. Medical and public health training might incorporate training in relevant concepts and skills, and the comfort and skill level of healthcare providers and systems in engaging in and supporting SDM are likely to increase over time. Finally, healthcare systems will develop additional creative strategies to increase system supports for IDM.

Summary: Findings of the Task Force

This report addresses the area of informed decision making (IDM) as it relates to cancer screening, specifically whether IDM interventions (1) promote understanding of cancer screening; (2) facilitate participation in decision making about cancer screening at a level that is comfortable for individuals; or (3) encourage individuals to make cancer-screening decisions consistent with their preferences and values. IDM interventions have resulted in changes in people's beliefs and risk perceptions, but evidence is scant about many aspects of IDM, and more research is needed. If IDM is to occur outside the research context, more community-oriented approaches to promoting informed decisions will be needed and clinicians will need evidence-based tools that fit within the context of modern practice.

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Appendix

Methods

In the *Community Guide*, evidence is summarized on (1) the effectiveness of interventions; (2) the applicability of effectiveness data (i.e., the extent to which available effectiveness data might apply to diverse population segments and settings); (3) positive or negative effects of the intervention other than those assessed for the purpose of determining effectiveness, including positive or negative health and non-health outcomes; (4) economic impact; and (5) barriers to implementation of interventions. When evidence of the effectiveness of the intervention on a specific outcome is insufficient, information about applicability, economics, or barriers to implementation is not included unless there is an issue of particular interest.

The process used to review evidence systematically and translate that evidence into the conclusions reached in this article involved the following steps:

Forming a systematic review development team

Developing a conceptual approach to organizing, grouping, and selecting interventions

Selecting interventions to evaluate

Searching for and retrieving evidence

Assessing the quality of and abstracting information from each study

Assessing the quality of and drawing conclusions about the body of evidence of effectiveness

Translating the evidence of effectiveness into recommendations

Considering data on applicability, other effects, economic impact, and barriers to implementation

Identifying and summarizing research gaps

This section summarizes how these methods were used in developing the reviews of interventions to promote IDM. The reviews were produced by the systematic review development team and a multidisciplinary team of specialists and consultants representing a variety of perspectives on cancer prevention (see Acknowledgments section in main text).

Search for evidence. Electronic searches for literature were conducted in MEDLINE, National Library of Medicine's Bioethicsline, PsychINFO, and the Chronic Disease Prevention databases. Also reviewed were the references listed in all retrieved articles, as well as other key systematic reviews and review articles. In addition, we consulted with experts on the systematic review development team and elsewhere.

Only journal articles were included. To be included in the reviews, studies had the following characteristics:

Publication date of 1966 through 2002

Primary study rather than a guideline or review

Took place in a developed country or countries

Met the systematic review development team's definition of the intervention

Provided information on one or more outcomes related to the analytic framework

Compared a group exposed to the intervention with a group not exposed or less exposed (comparisons could be concurrent or in the same group over a period of time)

Some study results were published in more than one report, and some reports included information on more than one study. Studies were defined as "independent" if they differed importantly in terms of intervention activities, interveners, or population evaluated. "Important" differences were determined by consensus of the team. One study could provide data on any or all of the outcomes in the analytic framework. The search for evidence began in 1999 and continued through December 2002.

Abstraction and evaluation of studies. Two reviewers read each study that met the inclusion criteria, and used a standardized abstraction form to record information from the study.¹ Any disagreements between the reviewers were reconciled by consensus of the review team members.

Assessing the suitability of study design. Design suitability was assessed for every abstracted study.² The study design classifications, chosen to ensure consistency in the review process, sometimes differed from the classification or nomenclature used in the original studies. Studies with good or fair quality of execution, and any level of design suitability, were included in the body of evidence for the purpose of assessing effectiveness.

Assessing quality and summarizing the body of evidence of effectiveness. The quality of study execution was systematically assessed, using the methods and abstraction form developed for the *Community Guide*.^{1,2} Some studies had more than one separate intervention arm (i.e., distinct interventions that were compared with each other or a control or both). For the purposes of this review, distinct intervention arms were treated as independent interventions.

Criteria for assessing the strength of evidence on effectiveness in the *Community Guide* have been published elsewhere.² Generally, by *Community Guide* standards, the minimal number of studies considered sufficient to draw a conclusion about given intervention outcome is as follows:

One study of greatest design suitability and good execution and sufficient effect size, or

Three studies of greatest or moderate design suitability and good or fair execution with sufficient and consistent effect size, or

Five studies of greatest, moderate, or lowest design suitability and good or fair execution with sufficient and consistent effect size.

Information was abstracted from the studies about the outcomes of interest for each intervention evaluated. In some cases, we had to select among several possible effect measures for inclusion in the summary measures of effectiveness. When available, measures adjusted for potential confounders in multivariate analysis were included, rather than crude effect measures. When effect measures were evaluated at different follow-up points, the last available measure was used, both before and after the intervention, in calculating effect sizes. No studies were excluded from the evaluation strictly on the basis of an insufficient follow-up period.

For this review, results were summarized qualitatively. For individuals' uptake of screening, percentage-point changes in screening rates were abstracted or calculated, and the distribution of these percentage-point changes was summarized with a median and range. For most other outcomes in the

analytic framework, the number of available measures was limited or outcomes were measured in diverse ways. In such cases, it was decided that precise mathematical estimates of effect added little to decision making. (For example, we decided that “knowledge measures generally increased by 0.5 standard deviations” added little additional information beyond “knowledge measures generally increased.”)

In evaluating the body of evidence, size and consistency of reported effects were assessed and, to the extent possible, any inconsistencies were explained. Also assessed was whether the body of evidence contained common threats to validity that either weakened or strengthened the conclusions. The strength of the body of evidence was summarized on the basis of the number of available studies, the strength of their design and execution, and the size and consistency of reported effects, as described in detail elsewhere.²

It is critical to note that when we conclude that evidence is insufficient to determine the effectiveness of an intervention on a given outcome, it is meant that it is not yet known what effect, if any, the intervention has on that outcome. It is not a conclusion that the intervention has no effect on the outcome.

Other effects. The *Community Guide* review of IDM interventions systematically sought information on other important harms or side benefits of the intervention. Harms or side benefits were noted if they were mentioned in the studies reviewed.

Applicability of effectiveness data, economic evaluations, and barriers to implementation of interventions. Applicability, economic efficiency, or barriers to implementation of these interventions were not assessed because effectiveness was not

established. In general, *Community Guide* reviews assume that effectiveness should be demonstrated before more downstream issues (e.g., economic efficiency, barriers) are addressed.

Summarizing research gaps. Systematic reviews in the *Community Guide* identify existing information on which to base public health decisions about implementing interventions. An important additional benefit of these reviews is identification of areas in which information is lacking or of poor quality. To summarize these research gaps, we began by identifying remaining research questions for each evaluated intervention. Because evidence of effectiveness of these interventions was insufficient, remaining questions about only effectiveness and other effects were summarized. Applicability issues were summarized only if they affected the assessment of effectiveness.

For each category of evidence, issues that had emerged from the review were identified, based on the informed judgment of the team. Several factors influenced that judgment. Within each body of evidence, the team considered whether there were general methods issues that would improve future studies in that area.

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