## Shared Decision-Making About Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force

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In 1984, the Department of Health and Human Services established the U.S. Preventive Services Task Force (USPSTF) as an independent panel of nonfederal experts that would develop evidence-based recommendations on clinical preventive services based on systematic reviews of published research and explicit decision rules for translating science into practice policy. At that time, the central question was whether there was high-quality evidence showing that a preventive service improved health outcomes. Recommendations were graded according to a scheme adapted from the Canadian Task Force on the Periodic Health Examination, which focused on whether evidence existed to support performing the service as part of the periodic health examination (Figure 1A). Most preventive services had not been formally studied, and the USPSTF gave many "C" recommendations, indicating insufficient evidence was available to recommend for or against the service. Interventions such as mammography and hypertension screening, however, received "A" recommendations because formal studies showed that they improved health outcomes. Implicitly, clinicians were encouraged to promote preventive

services that had been shown to improve outcomes and give lower priority to those with unevaluated health effects.

In the years that followed, multiple studies of prevention appeared in the literature, enabling the USPSTF to recommend a larger number of preventive services. Because these studies included more precise data on the magnitude of potential benefits and harms than had previously been available, the USPSTF was faced with answering a new and more complex question: is the magnitude of potential benefit from a service sufficient to outweigh the magnitude of potential harm?

In time, the USPSTF encountered preventive services for which even this question could not be easily answered. The answers did not jump from the pages of clinical trials but instead depended on the value that individual patients assigned to the potential harms and benefits. Although in some cases the USPSTF was comfortable weighing those tradeoffs based on assumptions of how most patients would value the outcomes, increasingly the USPSTF recognized that patient preferences were

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C:	There is poor evidence regarding the inclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.					
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Poor = I, insufficient evidence to determine the net benefit of the service or to recommend for or against routinely providing the service.

too variable to reach a generic determination of what was best.

To reflect its growing recognition of the complexity of its decision-making, the USPSTF published a new framework for grading recommendations (Figure 1B).<sup>1</sup> This framework drew a distinction between the USPSTF's assessment of the quality of evidence and its subjective judgment about the degree to which benefits outweighed harms. Under this new scheme, the USPSTF assigned "C" recommendations to services thought to have small net benefit when averaged across the population. The USPSTF recognized, however, that the net benefit might be larger for population subgroups with special risk factors or for individual patients with personal preferences that differed from those of the panel. Given that recognition, the USPSTF decided not to make a generic recommendation for "C" services, but rather to highlight that all "C" decisions are "likely to be sensitive to individual patient preferences."1

Explicit language encouraging consideration and discussion of patient preferences also began creeping into the rationale for those "A" and "B" recommendations in which the USPSTF recognized large or moderate net benefit, but also a substantial potential for harm or a significant amount of uncertainty about which screening modality was best. For instance, in 2002, the USPSTF issued a "B" recommendation for mammography screening and also recommended a conversation with women to ensure a realistic understanding of the limited absolute benefit of screening in the face of potential harms.<sup>2</sup> Additionally, recommendations for colorectal cancer screening indicated that patients should be invited to participate in the process of determining which of the 4 available screening options was preferable.<sup>3</sup>

This trend toward recommending discussions to elicit patient preferences introduced some discomfort for the USPSTF. The USPSTF did not want to suggest that informing patients

about the benefits and harms was unnecessary for services in which discussions were not explicitly recommended; rather it envisioned a more systematic process for some services. Members of the Task Force disagreed about whether such discussions should be practiced for all preventive services or should be advocated for only certain services, such as those involving "close calls." Many Task Force members expressed concerns for the busy clinician who lacks the time to engage in extended discussions about every potential clinical preventive service that a patient might want. As confusion began to surround the question of whether "A" and "B" recommendations from the USPSTF meant that the preventive service was to be "performed" or "discussed," the panel decided to formulate some suggestions about how the clinician might approach discussions about screening and chemoprevention.

These USPSTF suggestions are summarized in this article, along with commentary on the current thinking and evidence regarding shared decision-making between patients and clinicians. Unlike conventional USPSTF reports, this document is neither a systematic evidence review nor a formal recommendation statement. The USPSTF comes to this topic not with its customary objective of evaluating effectiveness, but rather to articulate its finding that shared decision-making is a necessary tool for making recommendations to individual patients concerning interventions that have net benefit for some but not for others. This article is, therefore, a concept paper, intended to clarify how the USPSTF envisions the application of shared decision-making in the execution of preventive services recommendations.

The suggestions herein were derived from a non-systematic evidence review and an iterative dialogue between the authors of this paper and USPSTF members, experts, clinicians, and representatives from the Task Force on Community Preventive Services at the Centers for Disease Control and Prevention. These suggestions underscore the USPSTF's growing recognition that some recommendations need to be individualized according to patients' special circumstances and preferences.

## Patient-Clinician Interactions on Screening and Chemoprevention

The USPSTF does not endorse a specific style of patient interaction, but does have suggestions for clinicians on how to interact with patients for each of its 5 categories (A, B, C, D, I) of screening and chemoprevention recommendations.

The USPSTF encourages clinicians to inform patients about recommended services. Ideally, this means that clinicians track the "A" and "B" recommended preventive services for each patient, making sure that patients are informed that these services are recommended at given intervals. Many patients may already be informed about these services or accept them as a routine part of the medical exam (eg, screening for high blood pressure or obesity), making lengthy and frequent discussion unnecessary. It is prudent, however, for clinicians to be prepared to discuss the potential benefits and harms of these services if patients indicate an interest. For example, clinicians might sensibly prepare to respond to patients' concerns about the rates and consequences of false-negative Papanicolaou smears during cervical cancer screening.

For some "A" and "B" recommended services, clinicians may want to consider more discussion. For example, the USPSTF has recommended (A recommendation) that clinicians discuss aspirin chemoprevention with adults at increased risk for coronary heart disease and that adults not take aspirin prophylaxis without understanding the likelihood of specific benefits and harms.<sup>4</sup> Patients with different values might make different decisions about taking prophylactic aspirin, thus discussion of preferences is necessary. Similarly, the USPSTF has recommended (B recommendation) engaging women who are at high risk for invasive breast cancer and low risk for the adverse effects of chemoprevention in discussions to determine whether chemoprevention for breast cancer is appropriate.<sup>2</sup> This decision also cannot be made from existing evidence but depends on personal preferences.

A proactive approach to discussions may also be desirable for certain "C" and "I" recommended services, particularly if they have high visibility due to substantial media attention and may be on the patient's mind (eg, prostate cancer screening) or if they have the potential to substantially affect a given patient (eg, ovarian cancer screening in a woman who has multiple first-degree relatives with ovarian cancer). Given the demands of clinical practice, however, the USPSTF encourages clinicians to rely on clinical judgment when deciding which discussions of "C" and "I" recommendations to initiate and to consider decision aids or trained assistants to help provide information about these services. Community approaches such as those suggested by the Task Force on Community Preventive Services<sup>5</sup> may also be helpful to patients in understanding the trade-offs involved with "close call" or "uncertain" services.

Clinicians are generally under no obligation to initiate discussions of services with "D" recommendations; these are services that the USPSTF has found to be either of no benefit or potentially harmful. Nonetheless, clinicians should be prepared, with the help of decision aids and trained assistants, to explain why these services are discouraged. Clinicians should also consider a proactive discussion for services with high visibility or special importance for the individual, or for services for which new evidence has prompted withdrawal of previous recommendations. For instance, with recent evidence demonstrating the adverse effects of hormone replacement therapy (HRT) on the heart,<sup>6</sup> clinicians should consider raising the issue of the appropriateness of HRT with the many women who are currently receiving such chemoprevention. Clinicians may also want to proactively raise the issue of HRT with a woman who places special value on reducing the risk for bone fractures and wants to consider all options. In such circumstances, the woman should be fully informed of the tradeoffs between potential benefits and harms and of her unique situation that could dictate departure from recommended practice.

Whenever decisions about preventive services must be made, the USPSTF encourages informed

and joint decisions. This means that patients should be informed about preventive services before they are performed and that the patientclinician partnership is central to decision-making. The need for this is most clearly demonstrated for those "C" and "I" recommendations that require decision-making because of high visibility or special importance to the individual. For such "C" recommendations, in which the average net benefit is small (eg, osteoporosis screening in postmenopausal women under the age of 60 or aged 60-64 with no risk factors), patients may be aided not only by evidence-based information about the magnitude of benefit and its close tradeoff with potential harms, but also by clinician assistance in determining whether their individual risk profile and personal preferences make the net benefit positive or negative. Similarly, for "I" recommendations, in which the evidence is insufficient to recommend for or against screening (eg, prostate cancer screening), patients may sometimes need both discussion of the uncertainty that precludes a clear recommendation and clinician assistance in determining their preference for or against action in the face of uncertainty.

One important form of informed and joint decision-making is "shared decision-making," in which patients are involved to the extent that they desire as an active partner with the clinician in clarifying acceptable medical options and in choosing a preferred course of clinical care. Although available research shows mixed results about the effect of this type of decision-making on health outcomes, support for a patient-clinician partnership in decision-making comes from a combination of ethical and practical arguments, which are detailed below.

## What Is Shared Decision-Making?

Decision-making within a patient-clinician partnership has been alternately called "shared decision-making,"<sup>7–9</sup> "informed decision-making,"<sup>10–11</sup> "informed shared decision-making,"<sup>12</sup> "evidenceinformed patient choice,"<sup>13–14</sup> "patient-centeredness,"<sup>15</sup> "enhanced autonomy,"<sup>16</sup> "relationship-centered decision-making,"<sup>16</sup> "deliberative decision-making,"<sup>17</sup> "interpretive decision-making,"<sup>17</sup> and "mutual participation."<sup>18</sup> Whatever its name, decision-making within the patient-clinician partnership universally encompasses a process in which both the patient and clinician share information with each other, take steps to participate in the decision-making process, and agree on a course of action.

In some models, the process has clearly defined steps or competencies that have been identified through focus groups or literature reviews.9-16 In other models, the process is left to the discretion of the individual patient and clinician.7,8,17,18 Of those models that define specific steps, many acknowledge the patient's right to relinquish the decision to the clinician and proceed in a paternalistic model,7-10,12,13 several call for evidence-based presentations of information,<sup>10-14</sup> a few call for physicians to express their preferences,7,16,19,20 and a few call for an explicit check of patient understanding.9,10 One model acknowledges the practical limitations of medical practice,<sup>10</sup> proposing a hierarchy of decision complexity, with more complex decisions requiring a greater intensity of interaction than simple decisions.

Some confusion has surrounded the use of various terms for decision-making within the patient-clinician partnership, particularly the terms shared decisionmaking and informed decision-making. Researchers,<sup>7</sup> patients, and clinicians sometimes use the term informed decision-making to describe both independent decision-making by the patient and joint decision-making by the patient and clinician.

The USPSTF, in collaboration with the Task Force on Community Preventive Services,<sup>5</sup> defines *informed decision-making* (IDM) as an individual's overall process of gathering relevant health information from both his or her clinician and from other clinical and non-clinical sources, with or without independent clarification of values. The Task Force defines *shared decision-making* as a particular process of decision-making by the patient and clinician in which the patient: 1) understands the risk or seriousness of the disease or condition to be prevented; 2) understands the preventive service, including the risks, benefits, alternatives, and uncertainties; 3) has weighed his or her values regarding the potential benefits and harms associated with the service; and 4) has engaged in decision-making at a level at which he or she desires and feels comfortable. This process has the goal of an informed *and* joint decision. Thus, although the definition focuses primarily on evidence for patient involvement, the process necessarily requires clinicians to reveal their clinical reasoning and biases to facilitate a truly joint decision.

Shared decision-making differs significantly from decision-making under the doctrine of informed consent, which arose in the law in the mid-1970s. Although informed consent was an obvious forerunner of shared decision-making, its focus in practice was on clinician disclosure rather than on joint participation. Informed consent did mandate that patients actively express consent rather than just expressing agreement with, yielding to, or complying with proposed medical care.<sup>21</sup> Its success was measured, however, by clinician disclosures before risky procedures. These disclosures included a description of the proposed treatment, the alternatives to the proposed treatment, and the inherent risks of death and bodily injury, as well as any other information that a reasonable clinician would disclose or a reasonable patient would want to know in the same circumstance. Clinicians could forgo these disclosures if a patient did not want to be informed, if the procedure was simple with little risk, and, if (in the clinician's judgment) it was not in the patient's best interest to know.<sup>22</sup> Although patients' signatures signified their receipt of the information, little attention was given to ensuring active involvement in decision-making.23

Shared decision-making also differs from decision-making in consumerism, in which patients gather relevant information, which they obtain from their clinician and other sources (eg, the Internet), and independently determine which options they prefer. In this model, the clinician's role is not to serve as a partner in decision-making; rather it is to execute the selected intervention, without giving special attention to exploring the patient's understanding, values, or reasoning.

# Why Engage Patients in Shared Decision-Making?

Over the last few decades, interest in shared decision-making has been growing. In a recent report, a committee of the Institute of Medicine suggested that "a patient-provider partnership is needed to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they require to make decisions and participate in their own care."<sup>24</sup> To highlight the importance of this partnership, the committee identified creating a patient-provider partnership as 1 of the 6 principal aims of the 21st century health care system.

Shared decision-making can be recommended on multiple grounds. From an ethical perspective, it promotes patient autonomy, protecting the integrity of the patient as an independent and rational decision-maker capable of selfdetermination. From the interpersonal perspective, shared decision-making promotes trust in the patient-clinician relationship<sup>25</sup> and may enhance the confidence of patients to participate in their health care.<sup>26</sup> From an educational perspective, shared decision-making improves knowledge about screening and chemoprevention options, creates more realistic expectations about benefits and harms, and reduces the decisional conflict associated with feeling uninformed.27,28 From a utility perspective, the "best choice" for decisions involving close tradeoffs can only be made by incorporating the personal preferences of the patient.

From a health perspective, evidence that shared decision-making improves health outcomes is indirect and mixed. Systematic reviews of decision aids, which are based on the tenets of shared decision-making and provide patient education and values clarification, have shown no consistent demonstrable effect on health outcomes.<sup>27–32</sup> This result might have been anticipated because decision aids help patients choose among alternatives in which the balance of benefits and harms is a "close call," thereby creating an environment in which the net health benefit across a population of reasonable people who choose differently might approach zero.

Only a few studies<sup>33,34</sup> have measured adherence to a chosen course of action; such measurements could give further insight into the effects of decision aids and shared decision-making. Interventions that have provided patients with training in information-seeking and negotiation skills have resulted in improvements in symptoms and physiologic outcomes.<sup>26,35–38</sup> Importantly, these studies have targeted health conditions in which benefits generally outweigh harms for most individuals. Studies in which patients perceive that they negotiate a common plan with the clinician also show benefits in health outcomes,<sup>19</sup> as do studies in which patients perceive that they are active participants in decision-making (regardless of their preferred role).<sup>39-41</sup>

## Do Patients Want to Be Actively Engaged in Shared Decision-Making?

Patient willingness to participate is critical for shared decision-making. A recent review<sup>42</sup> reported mixed interest in participation (19%-68%), noting that patients who were younger and more highly educated showed greater interest. The authors offered possible explanations for mixed interest, including lack of a clear distinction between medical problem solving, which requires tasks for which patients are not qualified, and medical decision-making, which could be shared.<sup>43–44</sup> The authors also noted that patients may not realize that medicine is an inexact science, believing that their clinicians prescribed the only treatment available. Other reasons for lack of interest in participation include lack of understanding that there is a decision to be made, discomfort with a new role in decision-making, inexperience with clinicians employing this approach to decisions, steadfastness in preconceptions about the course of care,43 membership in an ethnic group that does not value patient autonomy,45,46 and fear of regret for decisions that turn out badly. Clinicians should address such concerns and misconceptions about participation in decision-making before assessing patients' desire to participate.

## Are Patients Able to Engage in Shared Decision-Making?

Even when patients are interested in shared decision-making, inability to understand medical concepts may limit their participation. For instance, multiple studies have demonstrated that some patients have difficulty understanding risk concepts,<sup>47–54</sup> which calls into question their ability to accurately weigh the benefits and harms of preventive services. Low functional literacy and numeracy, each of which affects approximately a quarter of the U.S. population,<sup>55</sup> exacerbate these difficulties. Low literacy has been repeatedly associated with reduced health knowledge and poor outcomes.<sup>56,57</sup>

Even patients who have good reading and numeric skills may find themselves at a loss in medical conversations. Clinicians frequently speak in a medical jargon that is inaccessible to patients. Clinicians also use ambiguous qualitative descriptions such as "some" or "likely," which patients may interpret differently than clinicians intended.<sup>58,59</sup> Furthermore, the normal constraints of short-term memory limit patients' ability to walk away from in-depth discussions remembering all key information.<sup>60</sup>

Fortunately, the number of resources available to address these problems is increasing.<sup>56,60,61</sup> These resources allow patients to privately consider complex medical information over time.<sup>29</sup> That said, it is unclear whether patients need to comprehend and remember large volumes of complex information to share decisions about screening and chemoprevention with their clinicians. The effectiveness of providing simple, focused information in concise formats to facilitate shared decision-making requires further study.

## What Are Barriers to Clinician Use of Shared Decision-Making?

Clinician interest is also of critical importance to shared decision-making, but few studies have expressly examined clinician interest in engaging patients in the decision-making process.<sup>42</sup> Many have observed, however, that clinicians currently face barriers that could potentially diminish initiation of shared decision-making.<sup>42,62</sup>

Even the most well-intentioned and conscientious clinicians have difficulty in engaging patients in all appropriate preventive care. With shortened office visits, primary care clinicians struggle against competing demands and opportunities to find the time for prevention.<sup>63–66</sup> Including patients in decision-making may aggravate these struggles, resulting in reduced or delayed action as patients consider their options. Alternately, shared decisionmaking may provide patients with skills that improve decision-making and motivation across other aspects of their health care,<sup>67</sup> freeing up more time for prevention. The long-term effects of shared decision-making on competing clinical demands are hard to estimate and ripe for study.

The potential financial costs of shared decisionmaking are also of concern. Lack of financial reimbursements is a disincentive to take the time to discuss topics such as breast or colon cancer screening. Additionally, the cost-effectiveness of such discussions has not been studied. We expect the cost-effectiveness of shared decision-making to be best for decisions that are highly sensitive to patient values.68 These decisions could be identified by formal decision analysis,69 but more likely correspond to decisions for which the USPSTF has felt uncomfortable making global recommendations. A hierarchical approach to shared decision-making (ie, using shared decision-making for some, but not all, decisions), as suggested in this article, might be expected to maximize the cost-effectiveness of shared decision-making for preventive services.

Even when clinicians have the necessary time and financial support for shared decision-making, additional barriers exist. Many clinicians lack training in the interviewing techniques needed to engage patients in decision-making.<sup>70</sup> The lack of accurate, organized scientific evidence about the benefits and harms of many preventive services leads to confusion about the potential benefits and harms of screening and chemoprevention services, making shared decision-making more complex. When organized evidence is available, providers are often uncertain about which decisions require patient participation and about how to communicate technical concepts to patients in simple language that is accurate, balanced, and understandable.

With these barriers, clinicians, regardless of their interest, may have difficulty engaging patients in shared decision-making. Although the potential of creative solutions to increase shared decision-making is uncertain, system-level changes may be worth exploring. Health plans could alter reimbursement to encourage time for shared decision-making. Delivery systems could modify visit schemes to facilitate group education or promote the use of nurses or case management teams to relieve the time burden for clinicians. Health plans and delivery systems could post shared decision-making materials on Web sites providing decision support to both patients and clinicians. Such interventions have been shown to improve the processes and outcomes of care in chronic illness71,72 and offer promise for surmounting barriers to informed and joint decisions.

## How Might Clinicians Facilitate Patient Participation in Decision-Making?

Although there are distinct barriers to shared decision-making about screening and chemoprevention, clinicians can facilitate this type of decision-making using the techniques described below.

## Know What It Takes to Make Informed and Joint Decisions

The length of discussions about screening and chemoprevention may vary according to the scientific evidence for that service; the health, preferences, and concerns of each patient; the decision-making style of each clinician; and the practical constraints of any office visit. The measure of an informed and joint decision, however, should not vary (Figure 2). A decision should be considered to be adequately informed if the patient 1) understands the risk or seriousness of the disease or condition to be prevented; 2) understands the preventive service, including the risks, benefits, alternatives, and uncertainties; and 3) has weighed his or her values regarding potential benefits and harms associated with the service. The decision should be considered jointly made if the patient and clinician participate as partners, each clarifying their knowledge and preferences for the decision.

In practice, patient participation in decisionmaking is on a continuum, ranging from no participation to complete control of the decision, and, although joint decision-making may be ideal, participation should be considered satisfactory when the patient has participated at a level at which he or she desires and feels comfortable.

To facilitate patient understanding about screening and chemoprevention, the USPSTF suggests that all clinicians be prepared to respond to patients' needs for balanced, unbiased, and evidence-based information to patients. To facilitate accurate weighing of patient preferences, clinicians should contrast the rationales used by patients who decide for screening or chemoprevention and those who decide against it. Clinicians should also encourage patients to consider their own values for the potential harms and benefits associated with the decision. Ideally, clinicians would help patients to identify and overcome social, financial, or other barriers that, if absent, would alter their decision.

### Set Reasonable Expectations

Patients are often eligible for more than 1 preventive service for which shared decision-making might be a useful adjunct. Performing shared decision-making for all such services in 1 office visit, however, is rarely feasible. Clinicians who have ongoing relationships with patients may stagger discussions across several office visits, focusing first on the issue that they and their patients mutually identify as the highest priority and deferring other discussions to a later date. The initial discussion can represent the first step in the shared decision-making process; patients can then be encouraged to review additional information at home and further consider their preferences before making a final decision at a future visit. Clinicians may also want to involve other staff in the shared decision-making process, allowing the clinician to focus on answering questions and

#### Figure 2. Characteristics of an Informed and Joint Decision

#### The patient must:

- 1. Understand the risk or seriousness of the disease or condition;
- 2. Understand the preventive service, including the risks, benefits, alternatives, and uncertainties;
- 3. Have weighed his or her values regarding the potential harms and benefits associated with the service;
- 4. Have engaged in decision-making at a level at which he or she desires and feels comfortable.

negotiating an agreement. Other staff could spend more time with the patient on education and decision support.

#### **Consider Decision Aids**

The USPSTF suggests that clinicians consider decision aids as a way of providing information in an efficient and tailored manner. Good decision aids, including pamphlets, computer programs, audioguided workbooks, videotapes, videodiscs, decision boards, and Web-based tools, can offer balanced, unbiased, and evidence-based information, in addition to values clarification,<sup>27</sup> and can be employed both within and outside the patient-clinician encounter to promote shared decision-making. As previously noted, these aids have been shown to extend participation in medical decision-making and enhance knowledge about the decision.<sup>29</sup> Several are now available at www.healthdialog.com73 or http://www.ohri.ca/programs/clinical\_epidemiology/ OHDEC/default.asp.74

#### Use Effective Strategies for Communicating Information

Even when relying on decision aids, clinicians may need to answer questions, help patients clarify their thinking, and negotiate a decision. This participation requires the use of effective strategies for communicating information.

Although few studies have examined how differences in the medium of information presentation affect outcomes, some studies<sup>27</sup> have shown that the information content significantly affects the outcomes of decisions. For instance, decision aids with detail, probabilities, examples, and personal guidance are more acceptable to patients than decision aids without these characteristics. Tailored communications, which provide information specific to the individual, may also be better remembered, read, and perceived as relevant and/or credible than non-tailored communications.<sup>75</sup>

Alternate presentations of the same information also yield different outcomes. For instance, the presentation of probabilities as relative risk reductions are more persuasive than presentations as absolute risk reductions; by contrast, presentations of probabilities as absolute risk reductions are more understandable.<sup>76</sup> Framing (eg, the chance of survival vs the chance of death) also influences choices.<sup>76</sup> Because clinicians may influence patient choices, ideally clinicians would make a special effort to be aware of effective communication strategies and would choose their words, as well as their nonverbal cues, carefully to avoid unintended effects on the patient.<sup>77</sup>

#### Consider a Systematic Approach

Because the evidence about shared decision-making is limited, and the patient-clinician partnership is complex, defining how any given interaction about screening and chemoprevention should transpire is impossible. A systematic approach, however, is likely to improve the quality of interactions and provide the foundation for systematic study of patientclinician interactions concerning screening and chemoprevention.

Figure 3 outlines 1 possible approach for patientclinician interactions. This approach approximates the 5 As framework (ask, advise, agree, assist, arrange),<sup>78</sup> which the USPSTF has supported for behavioral counseling interventions and which is consistent with its previous suggestions about how clinicians might interact with patients on screening



and chemoprevention recommendations. The approach leads clinicians through a stepped process of assessing patients' needs for preventive services, determining their desire to be involved in decisionmaking, conveying information on the disease and preventive services, eliciting patient values, negotiating a course of action, and delivering the preventive service. Importantly, it acknowledges the characteristics of an informed and joint decision and can be adopted for the "A," "B," "C," "D," and "I" recommendations of the USPSTF. Figure 4 provides an example of how one might apply this approach for an individual patient in clinical practice.

Although not highlighted in Figure 4, an important part of this systematic approach is clear documentation of the agenda setting and decisionmaking. Such documentation mitigates against lapses in follow-up when discussions span more than 1 visit and safeguards against the potential medico-legal consequences of subsequent detection of a potentially preventable disease when discussions are delayed. What constitutes adequate documentation is something the medical and legal communities need to further explore.

## Conclusions

The USPSTF places a high value on informed and joint decisions about screening and chemoprevention; such decisions are essential for making recommendations to individual patients concerning interventions that have net benefit for some patients, but not for others. One approach to encouraging informed and joint decisions is shared decision-making. Although the effect of this approach on health outcomes is uncertain, shared decision-making is supported by ethical,

#### Figure 4. Applying a Consistent Approach

#### A clinician approaches a 60-year-old male with diabetes and hypertension.

**ASSESS:** After ensuring that the patient is up-to-date on his management of diabetes and hypertension, the clinician determines that the patient is eligible for a few preventive services, including chemoprevention with aspirin and screening for colon cancer, each of which receives an "A" recommendation from the USPSTF. The patient additionally wants to discuss screening for prostate cancer, for which the USPSTF has given an "I" recommendation. The patient demonstrates a clear interest in being engaged in the decision-making process.

**ADVISE:** The clinician reviews the list of recommended services and advises the patient that several services warrant a shared decision-making discussion to enable him or her to make informed choices. The clinician and patient decide to address aspirin chemoprevention at this visit, arranging to return to the other topics at a follow-up visit to occur in 1 month. The clinician inquires about the patient's existing knowledge about coronary heart disease and the role of aspirin and determines that the patient is unfamiliar with the rationale and potential risks of aspirin use. The clinician displays a decision aid that uses the patient's 5-year risk of a cardiac event to present balanced, evidence-based information about the probability of benefit from aspirin, the risk of complications, and scientific uncertainties. The clinician recommends that the patient take a daily aspirin given the high potential for benefit compared to harm. The clinician additionally encourages the patient to review more details about this topic on a Web site.

**AGREE:** The patient telephones the clinician 1 week later after having reviewed the Web site, expresses concern about hemorrhagic stroke, and asks the clinician for guidance on whether it should influence his choice. The clinician explains the types of consequences that might arise from a hemorrhagic stroke, but again encourages the patient to take aspirin given the potential for benefit that outweighs the potential for harm. The patient responds that no amount of benefit in preventing heart disease is worth an increased chance of stroke. The clinician and patient agree to defer aspirin use for now, but the clinician makes a note to return to this at a future visit.

ASSIST: Not applicable since the patient wishes to defer chemoprevention.

**ARRANGE:** A decision is made to plan on addressing screening for colorectal cancer at the follow-up visit in 1 month. In preparation for this, the clinician provides the patient with an informational brochure. He also recommends reading on prostate cancer screening.

interpersonal, and educational considerations. Clinicians might, therefore, consider incorporating elements of shared decision-making into appropriate interactions with patients about screening and chemoprevention.

Future research should address the objective impact of this approach on relevant health outcomes, consider ways to improve the feasibility of this approach in current medical practice, and identify best practices in performing and teaching the shared decision-making process. Researchers should devote particular attention to measuring the effects of shared decision-making for value-sensitive decisions under each of 4 distinct circumstances: 1) when the benefits of a preventive service clearly outweigh the harms for the majority of the population; 2) when the harms of the service clearly outweigh the benefits for the majority of the population; 3) when the balance of harms and benefits is too close to call; and 4) when there is insufficient evidence to know the balance of harms and benefits. In the latter 2 settings, measurement should focus on whether shared decision-making improves adherence to and satisfaction with a chosen course of action. Researchers should be vigilant in measuring patients' desired and actual levels of participation in decision-making and should distinguish this clearly from their desired and actual levels of information receipt. To assess the feasibility of shared decision-making in clinical practice, researchers should continue to develop and evaluate novel practice- and system-level interventions. These should be tested not only for effectiveness, but also for cost-effectiveness and practicality both within and outside the clinical arena. Details about practical, effective interventions should be made available to clinicians, health systems, educators, and researchers alike.

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### References

- Harris RP, Helfand M, Woolf SH, et al. Current methods of the U.S. Preventive Services Task Force: a review of the process. *Am J Prev Med.* 2001;20:21–35.
- U.S. Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. *Ann Intern Med.* 2002;137:344–346.
- U.S. Preventive Services Task Force. Screening for colorectal cancer: recommendation and rationale. *Ann Intern Med.* 2002;137:129–131.
- U.S. Preventive Services Task Force. Aspirin for the primary prevention of cardiovascular events: recommendation and rationale. *Ann Intern Med.* 2002;136:157–160.

- Briss P, Rimer B, Reilly B, et al. Promoting informed decisions about cancer screening in communities and healthcare systems. *Am J Prev Med.* 2004; 2004:26(1):67–80.
- Grady D, Herrington D, Bittner V, et al. Cardiovascular disease outcomes during 6.8 years of hormone therapy: Heart and Estrogen/progestin Replacement Study follow-up (HERS II). *JAMA*. 2002;288:49–57.
- Charles C, Gafni A, Whelan T. Shared decisionmaking in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med.* 1997;44:681–692.
- Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med.* 1999;49:651–661.
- Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *Br J Gen Pract.* 2000;50:892–899.
- Braddock CH III, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*. 1999;282:2313–2320.
- Walter LC, Covinsky KE. Cancer screening in elderly patients: a framework for individualized decision making. *JAMA*. 2001;285:2750–2756.
- Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. *BMJ*. 1999;319:766–771.
- Holmes-Rovner M, Llewellyn-Thomas H, Entwistle V, Coulter A, O'Connor A, Rovner DR. Patient choice modules for summaries of clinical effectiveness: a proposal. *BMJ*. 2001;322:664–667.
- Entwistle VA, Sheldon TA, Sowden A, Watt IS. Evidence-informed patient choice. Practical issues of involving patients in decisions about health care technologies. *Int J Technol Assess Health Care*. 1998;14:212–225.
- 15. Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. *Soc Sci Med.* 2000;51:1087–1110.
- Quill TE, Brody H. Physician recommendations and patient autonomy: finding a balance between physician power and patient choice. *Ann Intern Med.* 1996;125:763–769.

- Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. *JAMA*. 1992;267:2221–2226.
- Szasz TS, Hollender MH. A contribution to the philosophy of medicine. The basic models of the doctor-patient relationship. *Arch Int Med.* 1956;97:585–592.
- Stewart M, Brown JB, Donner A, et al. The impact of patient-centered care on outcomes. *J Fam Pract.* 2000;49:796–804.
- 20. Stewart M. Towards a global definition of patient centred care. *BMJ*. 2001;322:444–445.
- Beauchamp T, Childress J. The principle of respect for autonomy. Principles of Biomedical Ethics. 3rd ed. New York, NY: Oxford University Press; 1989.
- 22. Annas GJ. Informed consent. *Ann Rev Med.* 1978;29:164–165.
- Sulmasy DP, Lehmann LS, Levine DM, Raden RR. Patients' perceptions of the quality of informed consent for common medical procedures. *J Clin Ethics.* 1994;5:189–194.
- Institute of Medicine. Envisioning the National Healthcare Quality Report. 2000. Washington, DC, National Academy of Sciences.
- Katz J. Physicians and patients: a history of silence. The silent world of doctor and patient. New York, NY: Free Press; 1984:1–29.
- Kaplan SH, Greenfield S, Ware JE Jr. Assessing the effects of physician-patient interactions on the outcomes of chronic disease. *Med Care*. 1989;27:S110–S127.
- O'Connor AM, Fiset V, DeGrasse C, et al. Decision aids for patients considering options affecting cancer outcomes: evidence of efficacy and policy implications. *J NCI Monogr.* 1999;67–80.
- Molenaar S, Sprangers MA, Postma-Schuit FC, et al. Feasibility and effects of decision aids. *Med Decis Making*. 2000;20:112–127.
- O'Connor AM, Stacey D, Rovner D, et al. Decision aids for patients facing health treatment or screening decisions. In Cochrane Library 3; 2001.
- O'Connor AM, Rostom A, Fiset V, et al. Decision aids for patients facing health treatment or screening decisions: systematic review. *BMJ*. 1999;319:731–734.

- Barry MJ. Health decision aids to facilitate shared decision making in office practice. *Ann Intern Med.* 2002;136:127–135.
- 32. Agency for Health Care Policy and Research. Consumer Health Informatics and Patient Decision-making. Rockville, MD, 1997.
- Man-Son-Hing M, Laupacis A, O'Conner AM, et al. A patient decision aid regarding antithrombotic therapy for stroke prevention in atrial fibrillation. *JAMA*. 1999;282:737–743.
- Rothert ML, Holmes-Rovner M, Rovner D, et al. An educational intervention as decision support for menopausal women. *Res Nurs Health*. 1997;20:377–387.
- Greenfield S, Kaplan SH, Ware JE Jr, Yano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med.* 1988;3:448–457.
- Rost KM, Flavin KS, Cole K, McGill JB. Change in metabolic control and functional status after hospitalization. Impact of patient activation intervention in diabetic patients. *Diabetes Care*. 1991;14:881–889.
- Oliver JW, Kravitz RL, Kaplan SH, Meyers FJ. Individualized patient education and coaching to improve pain control among cancer outpatients. *J Clin Oncol.* 2001;19:2206–2212.
- Greenfield S, Kaplan S, Ware JE Jr. Expanding patient involvement in care. Effects on patient outcomes. *Ann Intern Med.* 1985;102:520–528.
- Brody DS, Miller SM, Lerman CE, Smith DG, Lazaro CG, Blum MJ. The relationship between patients' satisfaction with their physicians and perceptions about interventions they desired and received. *Med Care*. 1989;27:1027–1035.
- Golin C, DiMatteo MR, Duan N, Leake B, Gelberg L. Impoverished diabetic patients whose doctors facilitate their participation in medical decision making are more satisfied with their care. *J Gen Intern Med.* 2002;17:857–866.
- Gattellari M, Butow PN, Tattersall MH. Sharing decisions in cancer care. *Soc Sci Med.* 2001;52:1865–1878.
- 42. Frosch DL, Kaplan RM. Shared decision making in clinical medicine: past research and future directions. *Am J Prev Med.* 1999;17:285–294.

- Deber RB, Kraetschmer N, Irvine J. What role do patients wish to play in treatment decision making? *Arch Intern Med.* 1996;156:1414–1420.
- Deber RB. Physicians in health care management: 7. The patient-physician partnership: changing roles and the desire for information. *Can Med Assoc J.* 1994;151:171–176.
- Blackhall LJ, Murphy ST, Frank G, Michel V, Azen S. Ethnicity and attitudes toward patient autonomy. *JAMA*. 1995;274:820–825.
- Carrese JA, Rhodes LA. Western bioethics on the Navajo reservation. Benefit or harm? *JAMA*. 1995;274:826–829.
- Schwartz LM, Woloshin S, Black WC, Welch HG. The role of numeracy in understanding the benefit of screening mammography. *Ann Intern Med.* 1997;127:966–972.
- Feldman-Stewart D, Kocovski N, McConnell BA, Brundage MD, Mackillop WJ. Perception of quantitative information for treatment decisions. *Med Decis Making*. 2000;20(2):228–238.
- Grimes DA, Snively GR. Patients' understanding of medical risks: implications for genetic counseling. *Obstet Gynecol.* 1999;93:910–914.
- Halpern D, Blackman S, Salzman B. Using statistical risk information to assess oral contraceptive safety. *Appl Cogn Psychol.* 1989;3:251–260.
- Woloshin S, Schwartz LM, Byram S, Fischhoff B, Welch HG. A new scale for assessing perceptions of chance: a validation study. *Med Decis Making*. 2000;20:298–307.
- 52. Lipkus IM, Samsa G, Rimer BK. General performance on a numeracy scale among highly educated samples. *Med Decis Making*. 2001;21:37–44.
- Hoffrage U, Gigerenzer G. Using natural frequencies to improve diagnostic inferences. *Acad Med.* 1998;73:538–540.
- Chase GA, Faden RR, Holtzman NA, et al. Assessment of risk by pregnant women: implications for genetic counseling and education. *Soc Biol.* 1986;33:57–64.
- 55. Kirsch I, Jungeblut A, Jenkins L, Kolstad A. Adult Literacy in America: A First Look at the Findings of the National Adult Literacy Survey. 93. Washington, DC, National Center for Education Statistics, US Department of Education, 1993.

- Sheridan SL, Pignone M. Numeracy and the medical student's ability to interpret data. *Eff Clin Pract.* 2002;5:35–40.
- 57. Williams MV, Baker DW, Parker RM, Nurss JR. Relationship of functional health literacy to patients' knowledge of their chronic disease. A study of patients with hypertension and diabetes. *Arch Intern Med.* 1998;158:166–172.
- 58. Bryant GD, Norman GR. Expressions of probability: words and numbers. *N Engl J Med.* 1980;302:411.
- Nakao MA, Axelrod S. Numbers are better than words. Verbal specifications of frequency have no place in medicine. *Am J Med.* 1983;74:1061–1065.
- 60. Doak CC, Doak LG, Root JH. Teaching Patients with Low Literacy. 2nd ed. Philadelphia, PA: J.B. Lippincott Co.; 1996.
- 61. Kefalides PT. Illiteracy: the silent barrier to health care. *Ann Intern Med.* 1999;130:333–336.
- 62. Coulter A. Partnerships with patients: the pros and cons of shared clinical decision-making. *J Health Serv Res Policy.* 1997;2:112–121.
- 63. Jaen CR, Stange KC, Nutting PA. Competing demands of primary care: a model for the delivery of clinical preventive services. *J Fam Pract.* 1994;38:166–171.
- Stange KC, Flocke SA, Goodwin MA. Opportunistic preventive services delivery. Are time limitations and patient satisfaction barriers? *J Fam Pract.* 1998;46:419–424.
- Stange KC, Flocke SA, Goodwin MA, Kelly RB, Zyzanski SJ. Direct observation of rates of preventive service delivery in community family practice. *Prev Med.* 2000;31:167–176.
- 66. Stange KC, Jaen CR, Flocke SA, Miller WL, Crabtree BF, Zyzanski SJ. The value of a family physician. *J Fam Pract.* 1998;46:363–368.
- 67. Roter DL. Patient participation in the patientprovider interaction: the effects of patient question asking on the quality of interaction, satisfaction and compliance. *Health Educ Monogr.* 1977;5:281–315.

- Ubel PA, Arnold RM. The unbearable rightness of bedside rationing. Physician duties in a climate of cost containment. *Arch Intern Med.* 1995;155:1837–1842.
- 69. Kassirer JP, Moskowitz AJ, Lau J, Pauker SG. Decision Analysis: a Progress Report. *Ann Intern Med.* 1987;106:275–291.
- Kaplan SH, Greenfield S, Gandek B, Rogers WH, Ware JE Jr. Characteristics of physicians with participatory decision-making styles. *Ann Intern Med.* 1996;124:497–504.
- Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: the chronic care model, Part 2. *JAMA*. 2002;288:1909–1914.
- Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA*. 2002;288:1775–1779.
- 73. Health Dialog. Support for decisions that matter most. Available at: www.healthdialog.com. Accessed October 2002.
- 74. Ottawa Health Research Institute. Patient decision aids. Available at: http://www.ohri.ca/programs/ clinical\_epidemiology/OHDEC/default.asp. Accessed October 2002.
- Skinner CS, Campbell MK, Rimer BK, Curry S, Prochaska JO. How effective is tailored print communication? *Ann Behav Med.* 1999;21:290–298.
- 76. Edwards A, Elwyn G, Covey J, Matthews E, Pill R. Presenting risk information—a review of the effects of 'framing' and other manipulations on patient outcomes. J Health Commun. 2001;6:61–82.
- 77. Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? *BMJ*. 1999;318:318–322.
- Whitlock EP, Orleans CT Pender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence-based approach. *Am J Prev Med.* 2002;22:267–284.

