Informed Decision Making About Prostate-Specific Antigen (PSA) Testing: Findings and Implications from Formative Testing of a Multimodal Intervention

Cindy S. Soloe, Lauren A. McCormack, Katherine Treiman, David Driscoll, and Shelly Harris

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Abstract

We created the You Decide multimodal intervention to provide men with the information, skills, and reinforcement needed to engage in informed decision making (IDM) related to prostate cancer screening. We developed intervention materials based on three rounds of formative research conducted with 145 members of the intended recipient audience through 10 focus groups and more than 50 individual in-depth interviews. This report documents key findings from our formative research that may apply to the development of other IDM interventions, especially those related to prostate cancer. Our findings underscored (1) the difficulty of promoting IDM for cancer screening given people’s high affinity for such screenings, and (2) the challenge of graphically communicating risk-related tradeoffs. We found that pretest participants had a preference for full-story narratives conveying personal experiences and interpersonal learning opportunities. Our formative research findings also supported the need to use plain language to address a range of health literacy levels. We describe our efforts to apply these formative research findings in our final intervention materials and discuss implications for future intervention research. Our findings underscore the importance of involving the intended audience in the process of developing intervention materials.
Introduction

Given the uncertain benefits of prostate-specific antigen (PSA) screening, the US Preventive Services Task Force (USPSTF) recommends that “men should be informed of the gaps in the evidence, and they should be assisted in considering their personal preferences” before making a decision about screening.1, 2 Many professional organizations have issued similar recommendations for patient involvement in PSA decision making.1, 2 These recommendations reflect increasing recognition of the importance of informed decision making (IDM) as patients take ever more active roles in making health care decisions.

We created the You Decide multimodal intervention to provide men with the information, skills, and reinforcement needed to engage in IDM related to prostate cancer screening. Final intervention materials were based on three rounds of formative research. This report documents key findings from our formative research and describes how these findings were applied to refine key messages and finalize the components of our intervention.

Prostate Cancer Screening

The benefits and possible harms of routine PSA screening for prostate cancer remain uncertain to clinicians and patients alike. The potential benefits of reduced morbidity and mortality must be weighed against the risks of false-positive test results, which may lead to more invasive diagnostic procedures, and significant side effects associated with treatment.3 In 2001–2002, the USPSTF reviewed the evidence on the relationship between PSA testing and prostate cancer mortality and concluded that the evidence is insufficient to recommend for or against routine PSA screening for prostate cancer.1, 3 In 2008, the USPSTF updated this recommendation stating that current evidence remains insufficient to assess the balance of benefits and harms of prostate cancer screening in men younger than age 75 years; however, the USPSTF recommends against screening for prostate cancer in men age 75 years or older.2 Despite these recommendations, PSA screening is widespread in the United States; three-quarters of men age 50 or older report having had a PSA test at some time in their lives.4 This screening rate is higher than that for colorectal cancer, for which efficacy of screening is well demonstrated.4, 5 Thus, a disconnect is apparent between men’s enthusiasm for prostate cancer screening and the lack of evidence supporting screening.6 Moreover, support for cancer screening overall is widespread in this country, with limited recognition of the risks associated with overtesting and overtreating patients.7

Informed Decision Making

Wider access to consumer health information, especially through the Internet, and greater recognition that in many cases clinical decisions appropriate for some people may not apply to others have both contributed to patients’ growing role in decision making.8-10 As articulated by the Task Force on Community Preventive Services,* IDM occurs when patients understand the nature of the disease or condition; understand the clinical service including benefits, risks, limitations, alternatives, and uncertainties; consider their own preferences and values; participate in decision making at the level they desire; and make decisions consistent with their own preferences and values.8 IDM is particularly important in the face of uncertainty or controversy about optimal screening and treatment choices. Further, individuals’ abilities to engage in IDM depends in part on their literacy and health literacy, which is the degree to which they can obtain, process, and understand the basic health information and services they need to make appropriate health care decisions.11-14

IDM Interventions

Studies of behavioral decision making, which examine the cognitive processes by which people perceive, structure, and evaluate alternative decisions, provide important guidance for the development of IDM interventions.15 People often have difficulty processing probabilistic risk information10; for example, they frequently overweigh small probabilities and underweigh large probabilities, and they also have trouble revising probability judgments in light of new information.15 In one study designed

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* The Task Force on Community Preventive Services is an independent, nongovernmental, volunteer body of public health and prevention experts, whose members are appointed by the Director of CDC.
to explore how patients interpret treatment benefits, Sheridan and colleagues\textsuperscript{16} found that patients who received risk presentations in the simplest formats still had difficulty comparing and calculating benefit information. This finding raises questions about how well patients can independently make informed medical decisions using written quantitative information.\textsuperscript{16} To address the issue of limited numeracy skills and to convey risk information in a way that is easy to understand, researchers recommend strategies that use visual representations, absolute numbers (rather than relative risk or conditional risks), and consistent denominators.\textsuperscript{17-19}

Message framing, which refers to presenting the same health information in different ways, also affects how people perceive risk and other health information and make decisions. Substantial research evidence indicates that the way information is framed, for example emphasizing the gains rather than the losses of a behavior, has an important influence on perceptions of risk and patient decisions.\textsuperscript{20-29} Specifically, studies find that loss-framed screening messages (stressing the risks of not being screened) are more effective in influencing screening uptake than are gain-framed messages (stressing the benefits of being screened).

**Theoretical Guidance**

Researchers can use several different theoretical constructs to inform the development and evaluation of IDM interventions.\textsuperscript{30,31} In drafting and finalizing the intervention, our team drew on social cognitive theory (SCT), which specifies personal factors relevant to any health decision such as behavioral capability, self-efficacy, and outcome expectations.\textsuperscript{32-35} SCT also defines social, institutional, and other environmental factors that influence behavior through interactions with individual-level factors (referred to as reciprocal determinism).

Table 1 provides an overview of how these constructs relate to IDM and how we applied them in the You Decide intervention. In the case of PSA screening, an important environmental factor is the general bias favoring screening in the United States.\textsuperscript{7} In designing our IDM intervention, we also drew on evidence from the behavioral decision making research about effective risk communication, values clarification, and message framing.
Table 1. Application of social cognitive theory constructs to informed decision making

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition</th>
<th>Implication for IDM Intervention</th>
<th>You Decide Intervention Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Capability</td>
<td>Knowledge and skills to perform a behavior&lt;sup&gt;a&lt;/sup&gt;</td>
<td>IDM requires that an individual understand the nature of the disease or condition being addressed; understand the likely consequences, including risks, limitations, benefits, alternatives, and uncertainties; consider his preferences; and participate in decision making at his preferred level.&lt;sup&gt;b&lt;/sup&gt;</td>
<td>• Key messages and intervention materials included information necessary for men to engage in IDM (e.g., information about the prostate, prostate cancer the PSA test, and possible outcomes of the PSA test).&lt;br&gt;• Intervention messages were repeated in multiple formats (print materials, video, verbal presentation) to promote uptake of knowledge.&lt;br&gt;• Intervention materials described (print materials) and demonstrated (verbal presentation and video) skills necessary to engage in IDM.</td>
</tr>
<tr>
<td>Self-Efficacy</td>
<td>Confidence in ability to perform a behavior&lt;sup&gt;a&lt;/sup&gt;</td>
<td>IDM requires that an individual participate in decision making at his preferred level and make decisions consistent with his own preferences and values.&lt;sup&gt;b&lt;/sup&gt;</td>
<td>• Key messages outlined behaviors needed to engage in IDM (e.g., “Men should decide whether they feel the PSA test is right for them and talk with their doctors.”).&lt;br&gt;• The intervention modeled the behaviors needed to engage in IDM through a video that showed a man discussing prostate cancer screening with his doctor during a routine visit.</td>
</tr>
<tr>
<td>Expectations</td>
<td>Anticipated outcomes of a behavior&lt;sup&gt;a&lt;/sup&gt;</td>
<td>IDM occurs when an individual understands the likely consequences of a decision, including risks, limitations, benefits, alternatives, and uncertainties.&lt;sup&gt;b&lt;/sup&gt;</td>
<td>• Key messages clarified that outcomes following PSA testing and prostate cancer treatment may be different from what men anticipate (e.g., “A problem with the PSA test is that it leads some men with slow-growing prostate cancer to get treatment that they don’t need. About half of all men who get treatment for prostate cancer will have permanent side effects.”).</td>
</tr>
<tr>
<td>Reciprocal Determinism</td>
<td>Interactions between an individual’s characteristics, behaviors, and the environment (e.g., social and institutional factors)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>IDM may be influenced by environmental factors such as social norms and perspectives of influential others (friends, family, health care providers).</td>
<td>• Interventions were implemented in a community setting and designed to be interactive such that men could hear the questions, concerns, and opinions of their peers.&lt;br&gt;• Intervention materials of the Men’s Health intervention aimed to address pro-screening attitudes by contrasting the uncertain benefits of prostate cancer screening with other screening and men’s health behaviors that are accepted as more effective.&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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<sup>c</sup> See page 5 for a description of the Men’s Health version of the You Decide intervention.

### Project Overview

#### Purpose of the Intervention

We designed the You Decide intervention to increase men’s knowledge about prostate cancer generally and PSA screening specifically, a precondition for IDM. In addition, the materials sought to enhance men’s skills and self-confidence in communicating with their health care providers about the PSA screening decision—specifically, to ask questions and express concerns. We also designed the intervention to influence men’s expectations about the outcomes of communicating with their provider, specifically to foster an expectation of participation in the PSA decision at the level they prefer. Finally, we sought to help men clarify their values about the spectrum of health care interventions (screening through treatment) for prostate cancer. Values clarification ensures that men go through a process of considering their values related to screening, possible follow-up diagnostic procedures, treatment, and side effects. Consideration of personal values and preferences is central to IDM.8
The Men’s Health framing was based on the findings from our previous study of PSA messages for Medicare beneficiaries. The Medicare study identified several challenges to promoting IDM, including men’s overestimates of the number of deaths from prostate cancer, their lack of awareness of the controversy regarding PSA screening, and physicians’ influence on screening behavior. Further, cognitive interviews with the Medicare study audience revealed cognitive dissonance associated with exposure to messages that did not promote screening but instead guided men to carefully consider the pros and cons of this cancer screening test; this complex message appeared to reduce knowledge uptake about the topic.

Intervention Implementation
We implemented the two versions of the You Decide intervention in separate communities: the Men’s Health version in Greensboro, North Carolina, and the PSA Only version in Wilmington, North Carolina. In both cities, the interventions were implemented through community-based organizations (e.g., men’s clubs, churches). We selected organizations in both low and high socioeconomic communities. Raleigh, North Carolina, served as a control community.

We chose to implement the intervention in community settings rather than medical settings to reach men who may not have reliable access to medical care and to provide health information in a trusted and comfortable environment. Previous literature suggests that presenting health information in a novel setting (e.g., community organization vs. medical clinic) may encourage participants to attend more closely to message content. Further, evidence suggests that black men in particular may prefer to receive PSA education in community settings because of their negative experiences with and distrust of the health care system.

The purpose of this research report is to describe key findings from three rounds of formative research and how these findings were applied in finalizing the intervention. The next section describes our pretesting methods.

Intervention Messages
We developed the intervention to focus on four key messages designed to support men in making informed decisions about PSA screening:

1. There are two types of prostate cancers: slow- and fast-growing.
2. A problem with the PSA test is that it leads some men with slow-growing prostate cancer to get treatment that they don’t need.
3. About half of all men who get treatment for prostate cancer will have permanent side effects.
4. Men should decide whether they feel the PSA test is right for them and talk with their doctors.

The messages reflect the clinical evidence available at the time we developed the interventions, namely, September 2004; the messages were intended to convey the significant medical uncertainty surrounding the benefits of PSA screening and early treatment and the limited predictive ability of both the PSA test and pathological specimens collected from prostate biopsy.

To date, no new studies have emerged to fundamentally change the USPSTF recommendation about the PSA test. Although two randomized controlled trials of prostate cancer screening—the National Cancer Institute Prostate, Lung, Colorectal and Ovarian Trial and the European Randomized Study of Screening for Prostate Cancer—are currently ongoing, neither study has yet released mortality data.

We developed and tested messages framing the PSA screening information in two versions: the Men’s Health version and the PSA Only version. In the Men’s Health framing, messages contrast the uncertain benefits of PSA screening with the well-documented benefits of testing for colon cancer, high blood pressure, and high cholesterol and the proven benefits of other health behaviors. In the PSA Only framing, messages presented the limitations of the PSA test but without comparison with other screening tests.
**Methods**

**Message and Materials Testing**

**Pretest Methods.** The study team conducted three rounds of pretesting to refine the intervention messages and materials to meet the cultural and literacy requirements of the intended recipient audience. We used focus groups, a well-known technique for exploring group perceptions in a moderated discussion,\(^4^0\) to test the physician presentation, poster, video, and logo. Focus groups provided an environment most like that in which we ultimately planned to implement the intervention and, thus, generated the most applicable findings. We pretested the print materials through one-on-one cognitive interviews, a method that allows for maximum communication about topics of interest during an interview.\(^4^1\) Through these in-depth discussions, we explored men’s understanding of and reactions to specific phrases, concepts, and graphics in the draft materials. We revised our intervention materials following each round of testing based on input gained from pretest participants.

Table 2 lists the topics covered during interviews and focus groups. In each of the three rounds of testing, we asked men to provide their reactions to and suggestions for improving the content of the intervention materials. Trained team members collected observational data during each session to capture additional information about men’s reactions to the messages and materials and their interactions during the discussions. In the final round of interviews, we evaluated the format of the print materials.

**Pretest Participants.** Collaborators at Area Health Education Centers (AHECs) in Greensboro and Wilmington, North Carolina, the intervention communities, assisted in identifying possible pretest participants. Study team members screened and recruited these participants by phone. We attempted to recruit an equal distribution of black and white men between the ages of 40 and 80 who lived in the two cities.

<table>
<thead>
<tr>
<th>Cognitive Interviews</th>
<th>Focus Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pretesting print materials</strong></td>
<td><strong>Pretesting presentation, video, poster, and logo</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>• Expectation of content based on the title and cover page</td>
<td></td>
</tr>
<tr>
<td>• General reactions to the materials (i.e., likes or dislikes)</td>
<td></td>
</tr>
<tr>
<td>• Reaction to level of detail provided</td>
<td></td>
</tr>
<tr>
<td>• Interpretation of specific phrases or passages of text</td>
<td></td>
</tr>
<tr>
<td>• Reactions to alternate phrasing of text</td>
<td></td>
</tr>
<tr>
<td>• Interpretation of graphics</td>
<td></td>
</tr>
<tr>
<td>• Description of main messages in their own words</td>
<td></td>
</tr>
<tr>
<td>• Whether the information was new to them</td>
<td></td>
</tr>
<tr>
<td>• Information they might add</td>
<td></td>
</tr>
<tr>
<td>• Perceived key take-home messages</td>
<td></td>
</tr>
<tr>
<td>• How likely they would be to pick up the materials if they saw them in a doctor’s office</td>
<td></td>
</tr>
<tr>
<td>• Trustworthiness of materials</td>
<td></td>
</tr>
<tr>
<td>• Potential impact of materials on health decisions in general and specific to PSA testing</td>
<td></td>
</tr>
<tr>
<td>• Perception of appropriate audience</td>
<td></td>
</tr>
<tr>
<td>• Reactions to draft logos</td>
<td></td>
</tr>
</tbody>
</table>
Pretesting was conducted with a total of 145 men: 93 in 10 focus groups and 52 in one-on-one cognitive interviews. Focus groups and interviews were conducted at AHEC facilities in Greensboro and Wilmington. Participants were reimbursed $40 for their time and effort. Participant characteristics are presented in Table 3. Participants ranged in age between 40 and 80 years; 58 percent were black; and they came from varied educational backgrounds (19 percent less than high school, 34 percent high school graduates, and 44 percent more than high school education). Participants rated their health as excellent/very good (30 percent), good (43 percent), or fair/poor (26 percent).

### Results

Throughout three rounds of formative testing, we consistently observed five major qualitative findings. In developing the final intervention materials, we were mindful of these findings and made appropriate revisions to various components of the materials. We summarize these five points below and discuss how we used them to revise the intervention strategy, messages, and materials.

**Finding 1: Messages that do not clearly support cancer screening were counterintuitive to most participants.**

Americans demonstrate a strong affinity for cancer screening,\(^7\) which creates a challenge for efforts to inform people about potential concerns related to the PSA test and other cancer screening tests for which the evidence basis is limited or uncertain. As a result, people tend to overemphasize potential benefits and downplay the risks of screening.\(^42\) In other words, if people believe that early detection is always beneficial, they may not be receptive to IDM because it does not fit within their existing perspective.\(^42\)

Pretest participants reported that the concept of IDM for PSA screening was challenging; they interpreted our key intervention messages as directing men to either get screened or not get screened vs. suggesting that men should decide for themselves whether to have a PSA test. As a result of this finding, which was consistent with findings from our previous research,\(^37\) we revised and retested our key messages to ensure that the emphasis on informed decision making was clear to the intended audience. The misunderstanding of the key messages was mitigated somewhat as the messages were revised over the three rounds of materials pretesting.

Although the number of men who recognized the IDM focus of our materials increased by the final round of materials testing, some respondents in the final round still perceived that the messages advocated testing. That is, some respondents indicated that they felt the purpose of the key intervention messages was to encourage men to get tested. Contrary to this reaction, a subset of respondents perceived the materials as suggesting that men should not get tested.

### Table 3. Demographic characteristics of pretest participants

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>Number (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>40–50</td>
<td>39 (28%)</td>
</tr>
<tr>
<td>51–60</td>
<td>38 (27%)</td>
</tr>
<tr>
<td>61–70</td>
<td>36 (26%)</td>
</tr>
<tr>
<td>71–80</td>
<td>26 (19%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>81 (58%)</td>
</tr>
<tr>
<td>White</td>
<td>58 (42%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>26 (19%)</td>
</tr>
<tr>
<td>High school</td>
<td>49 (34%)</td>
</tr>
<tr>
<td>More than high school</td>
<td>64 (44%)</td>
</tr>
<tr>
<td><strong>Health status</strong></td>
<td></td>
</tr>
<tr>
<td>Excellent/very good</td>
<td>42 (30%)</td>
</tr>
<tr>
<td>Good</td>
<td>59 (43%)</td>
</tr>
<tr>
<td>Fair/poor</td>
<td>36 (26%)</td>
</tr>
</tbody>
</table>
Finding 2: Pretest participants favored the physician presentation over other intervention components.

We conducted focus groups to pretest video clips, a scripted physician presentation, poster, and logo. During each focus group, a physician delivered the presentation and participants then had the opportunity to ask questions and explore points of interest in an interactive session.

During pretesting focus groups, we observed that the physician presentations and subsequent question-and-answer sessions engaged participants more than the other intervention components. This was particularly evident in participant discussions of the Men’s Health materials. For example, those who took part in cognitive interviews and reviewed only print materials were generally unable to describe differences in the proven benefits of the screening tests for colon and prostate cancers. In addition, these participants were unable to describe differences in the level of certainty regarding the screening recommendations for these two cancers. In contrast, men who received this information during a moderated focus group discussion from the physician presentation demonstrated a general understanding of how the recommendations for colon and prostate cancer screening differed.

In response to these findings, we incorporated a scripted physician presentation in the final intervention (see Table 4). The presentations were sufficiently flexible to allow physicians to respond to audience questions and cues and provide additional information as appropriate.

Finding 3: Developing graphics that effectively conveyed the complexities of the PSA screening decision was challenging.

We developed and tested several different graphics designed to convey difficult risk-related concepts associated with the key intervention messages listed on page 5. Graphics developed to convey these concepts are presented in Figure 1.

<table>
<thead>
<tr>
<th>Table 4. Key talking points of physician presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Men’s Health Message</strong></td>
</tr>
<tr>
<td>• We are here today to talk about some of the things that can affect men’s health and what you can do to try and stay as healthy as possible.</td>
</tr>
<tr>
<td>• We will discuss three health problems: heart disease and stroke, colon cancer, and prostate cancer; how common each problem is and what can be done about; and how sure we are about whether the treatment works or not.</td>
</tr>
<tr>
<td>• Heart attack and stroke are the most common health problems for men; keep risk factors for these problems low by getting blood pressure and cholesterol checked, controlling them when necessary, and stopping smoking.</td>
</tr>
<tr>
<td>• Colon cancer is less common, but testing and treatments are proven to reduce the chance of dying from colon cancer.</td>
</tr>
<tr>
<td>• Prostate cancer is less common, and doctors don’t really know how important testing can be.</td>
</tr>
<tr>
<td>• Think about the health information we’ve given you, decide what is right for you, and then talk with your doctor about your decision. Always discuss your health decisions with a doctor or health care team member who knows about your medical conditions.</td>
</tr>
</tbody>
</table>
As shown in Figure 1, we tried several different approaches to convey these ideas, using color, posture and demeanor of figures of men, directional arrows, settings, and other cues. Nevertheless, pretest participants indicated during cognitive interviews and focus groups that these graphics were not helpful in increasing their understanding of the concepts that the brochure text provided. As a result of this intensive examination of the graphics, we ultimately relied more on narrative rather than graphical explanation of the risk concepts.

Figure 1. Graphics tested and removed from brochures based on testing results

<table>
<thead>
<tr>
<th>Key Message(s)</th>
<th>Tested Graphics</th>
<th>Final Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are two types of prostate cancers—slow- and fast-growing. Most prostate cancers are slow-growing. About half of all men who get treatment for prostate cancer will have permanent side effects.</td>
<td><img src="image" alt="Figure 1" /></td>
<td>Doctors don’t know which treatment for early prostate cancer is best or if any of today’s treatments help men live longer. Doctors do know that about half of all men who get surgery or radiation treatment will have <strong>permanent</strong> side effects from that treatment.</td>
</tr>
<tr>
<td><strong>Tested in round 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Slow and Fast Growing Cancers</strong></td>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
</tr>
<tr>
<td>About half of all men who are treated for prostate cancer will have one of the bad effects from treatment. This includes those with slow growing cancers that men can live with for many years.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tested in round 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Slow growing cancer</strong></td>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
</tr>
<tr>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fast growing cancer</strong></td>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
</tr>
<tr>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>After treatment, you may...</strong></td>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
</tr>
<tr>
<td>have bad effects</td>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
</tr>
<tr>
<td>have no bad effects</td>
<td><img src="image" alt="Figure 2" /></td>
<td></td>
</tr>
<tr>
<td><strong>Tested in round 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Men with harmless prostate cancer</strong></td>
<td><img src="image" alt="Figure 3" /></td>
<td></td>
</tr>
<tr>
<td><img src="image" alt="Figure 3" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tested in round 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>A problem with the PSA test is that it leads some men with slow-growing prostate cancer to get treatment that they don’t need.</strong></td>
<td><img src="image" alt="Figure 3" /></td>
<td></td>
</tr>
<tr>
<td><img src="image" alt="Figure 3" /></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Many men think that the PSA is just a simple blood test. But once you have the test, it can lead you quickly on a path to major treatment that you may or may not want.</strong></td>
<td><img src="image" alt="Figure 3" /></td>
<td></td>
</tr>
</tbody>
</table>
Finding 4: Pretest participants preferred videos that presented the full story of men’s experience with the PSA test.

During our focus groups, we had pretest participants view and comment on video clips depicting men’s experiences with PSA testing. Early iterations of the videos included clips from taped interviews with actual patients discussing various aspects of their decisions and experiences related to PSA testing. During the focus groups, participants expressed a desire for longer narratives (rather than simply clips) that captured men’s full stories, from their initial decision about whether to be screened through their receipt of PSA results, follow-up, and outcomes after further diagnostics or treatment.

Based on these findings, we revised the videos to illustrate longer-term results of the PSA decision. To create videos that cohesively presented men’s stories from their testing decision through follow-up and 1 year past treatment, as suggested by our respondents, the team developed scripts based on the key messages and hired actors to deliver them.

The final videos demonstrate how four men approached the PSA decision, with one man modeling an interaction with a physician about the decision. Two characters (one black, one white) choose to be screened, and two (one black, one white) choose not to be screened. The videos then follow the men over a year and describe the outcomes of their decisions. Of the two men opting for screening, one man was diagnosed with prostate cancer and, 1 year later, is incontinent as a result of treatment. The other man was also diagnosed with prostate cancer and underwent treatment but experienced no treatment side effects.

Finding 5: Men wanted background information relevant to prostate cancer to make informed decisions about PSA screening.

We designed the intervention materials to provide the information necessary for men to make informed decisions about whether to get a PSA test, such as information about potential side effects and outcomes of prostate cancer treatment and complexities associated with PSA testing. However, pretest findings indicated that the original versions of the intervention materials did not include sufficient background information about the prostate gland (e.g., where it is located and its function) or prostate cancer.

Previous studies have found that while awareness of the PSA test is high, knowledge of key facts is low (that is, information about the prostate, prostate cancer, and specifics of the PSA test required for IDM). Consistent with these findings, many pretest respondents suggested that they would find it helpful if the materials included background information about the prostate and prostate cancer; in particular, they wanted information about what the prostate is, where it is located in the body, and what its function is. In response to this feedback, we adapted our materials to include information about the prostate; these adaptations included a definition of PSA, an explanation of the PSA test, and a diagram showing the location of the prostate in the body (see Figure 2).

Figure 2. Basic background information: prostate diagram for print materials

Cognitive interview respondents who reviewed iterations of materials with this information indicated that the additional information, especially the anatomical diagram, helped them to understand some of the issues related to prostate cancer, such as symptoms and possible side effects of treatment. By adding this information, we were ensuring that men had the tools necessary to engage in IDM, such as a basic understanding of the disease or condition in question. This finding underscores the need to understand and address the health literacy of an intended recipient audience so that materials can be designed to provide the information needed to make informed decisions.
Applying findings from our formative research and relevant theoretical constructs (see Table 1), we developed a final set of multimodal intervention materials to convey our messages. Final materials included an interactive presentation delivered by a physician, poster, video, take-home print materials, and a website. We intended the presentation of key messages through multiple formats to increase the potential for participants to be receptive to and to understand the messages so as to help overcome the limitations of a single delivery method. All materials included a common You Decide project logo to emphasize that they were part of a set of materials. The intervention components are described briefly below.

**Physician Presentation and Poster.** A scripted overview of the key intervention messages was delivered by a physician as part of the intervention presentation. The presentations were designed to cover specific talking points (see Table 4) and to last about 10 minutes; they were followed by a brief question-and-answer session.

Information supporting these key points appeared on a 4’ × 8’ poster that the physician used as a visual aid throughout the presentation. Each physician was trained to adhere to the presentation script to standardize its delivery. This delivery method was emphasized as a key component of the overall intervention based on our finding that pretest participants found the physician presentation and subsequent question-and-answer sessions to be more engaging than the other intervention components. In addition, pretest participants who received the intervention messages through a live interaction with a physician demonstrated greater retention of these messages than those who reviewed print materials alone.

**Video.** The final 20-minute video presented the stories of four men, two white and two black, each of whom described the decision-making process he went through when choosing whether to have a PSA test. Based on our finding that men preferred to view a full narrative of one man’s story vs. clips from lots of different men’s stories, these videos were designed to tell each man’s full story from the initial decision about whether to be screened through receipt of PSA results, follow-up, and outcomes after further diagnostics or treatment.

The men discussed why they made the choice that they did, the consequences of their choice (e.g., side effects among men who received treatment and whether they had follow-up procedures), and their thoughts about their decisions after some time had passed. The videos depicted men either alone or with a spouse in nonclinical settings (e.g., a home, a public park).

In addition to discussing the men's PSA decision, the Men's Health video also included the men's decisions about how best to reduce their risk for heart attack and stroke and about colorectal cancer screening. In each video, one man chose to have the PSA test and one chose not to be screened.

**Print Materials.** The final set of print materials included brochures, list pads, and a pocket card. The brochures were designed as eight-panel bifolds that presented the study key intervention messages through a combination of text and graphics. Figure 3 shows the covers of the brochures. Full copies of the brochures are provided in the appendix. The information in the brochures was also available online via the study website.
In developing the print materials, we tested several text and graphical iterations of statistical information about the risks and consequences of prostate cancer screening. Early iterations of the brochures included several graphics designed to convey difficult concepts presented through the key intervention messages. Specifically, we developed and tested graphics to convey the four key messages listed on page 5. Because we found that these graphics did not help pretesting participants understand our key messages, we ultimately relied more on narrative rather than graphical explanation of these concepts. As a result, the final brochures included a single graphic designed to depict the number of prostate cancers out of 10 likely to be fast- or slow-growing, coupled with supporting text (see Figure 4).

We designed the list pads (see Figure 5) as tools to encourage men to consider and list questions that they would like to discuss with their doctor at their next appointment. Several well-respected patient education resources recommended that patients write down questions before a doctor's visit to increase the likelihood of engaging their physician in discussion and getting their questions answered.43,46,47 Further,
when patients ask questions, they have better recall of discussions with their health care provider, and providers better understand their patients’ informational needs.\textsuperscript{49} The list pads for the PSA Only and Men’s Health interventions both included tips for men to consider when talking with the doctor (e.g., show your list of questions to the doctor when he or she first comes in the room) and provided space to write questions.

![Figure 5. Front and back of the Men’s Health and PSA Only list pads](image)

**Men’s Health: Staying Healthy Depends on Making Good Decisions**

1. First, get the facts. Check out the brochure and website, www.menshealthdecisions.org, that go along with this list.
2. Next, think about what you want.
   - How do you want to lower your risk factors for heart attack and stroke?
   - What test do you want to have to find colon cancer early?
   - Is the PSA test right for you or not?
   - Remember Joe and Frank? See the two-sided card.
3. Then, talk with your doctor. Tips:
   - Before your visit, make a list of any questions or concerns you have about your health. Use the other side of this sheet to write them down.
   - Tell your doctor up front that you want to slow down or to use simple words.
   - If you don’t understand, it’s okay to ask your doctor to slow down and to use simple words.

For more information: www.menshealthdecisions.org

![Figure 6. Front and back of the values clarification pocket card](image)

**Figure 6. Front and back of the values clarification pocket card**

**Men’s Health Choices Deciding About the PSA Test**

1. First, get the facts. Check out the brochure and website, www.a-decide.org, that go along with this list.
2. Next, think about what you want.
   - Is the PSA test right for you or not?
   - Remember Joe and Frank? See the two-sided card.
3. Then, talk with your doctor. Tips:
   - Before your visit, make a list of any questions or concerns you have about your health. Use the other side of this sheet to write them down.
   - Tell your doctor up front that you want to slow down or to use simple words.
   - If you don’t understand, it’s okay to ask your doctor to slow down and to use simple words.

For more information: www.a-decide.org

**Things to talk with my doctor about:**

- My main reason for coming to the doctor today: ________
- Other things on my mind are:
  1. ________
  2. ________
  3. ________
  4. How to reduce my risk of heart attack and stroke
  5. Which type of test to have to find colon cancer early
  6. Whether or not to get a PSA test

   *Doctor, I want to tell you how prostate cancer looks from where I stand. I am more like ________ (Frank or Joe).*

**If you are like JOE, you might be thinking like this:**

It’s important to me to know whether I have a cancer. I would want to be treated even if treatment may not get rid of my cancer and may cause side effects. I’m the kind of person who just wants to know. I think I’ll go ahead and get a PSA test.

**If you are like FRANK, you might be thinking like this:**

I am the kind of man who doesn’t want to go looking for things that don’t need to be found. Most prostate cancers are slow-growing, and doctors don’t know if treatment works. The treatments may leave me with side effects. I don’t think I’ll get a PSA test right now.
Discussion

We designed a multimodal community-based intervention to encourage men to engage in IDM about whether to have a PSA test. Findings from our study strongly support the need to conduct formative research in designing consumer messages and materials. The formative research process allowed us to assess the intended audience's receptivity to the main messages of the materials, assess their preferences for information channels and level of detail, and apply information about audience health literacy levels to inform the specific content of our messages and the format of our intervention components.

Our results suggest that it is quite difficult for men to understand that, in some cases, the decision to get screened for certain types of cancer is not straightforward. The predilection for screening appears to affect uptake of counterintuitive information about cancer screening (i.e., that PSA screening may not be the right decision for all men). In addition, our findings suggest that mode of delivery has important implications for increasing receptivity to counterintuitive health information. Men were more engaged when information was presented verbally in a live presentation or through personal accounts (i.e., video footage) rather than through print materials alone. Respondents' preference for the verbal presentation could have been influenced by the fact that the presenters were physicians and were, therefore, viewed as highly credible. We could not determine from this formative research whether the status of the presenter as a physician or another factor, such as the in-person interaction, was the primary influence behind participant receptivity. Regardless, participant responsiveness to the verbal presentation and question-and-answer sessions indicates that at least some opportunity for live interaction may be an important component in future health interventions, particularly for those with complex messages.

In our pretesting, we found that participants preferred hearing about how men like themselves worked through the decision of whether to have a PSA test and their thoughts and experiences following this decision. Although we initially created and tested videos with short clips of men's experiences with PSA decision making at different points in time, results from our formative research indicate that men had a preference for full narratives. Men indicated that full narratives were more helpful in guiding them through the complexities of the PSA decision process. By presenting full stories, our intervention videos may have allowed participants to engage more fully in social comparison with men like themselves, thereby informing their own decision-making process.

Our findings also highlighted the importance of understanding the intended audience's level of knowledge regarding the topic at hand. Consistent with prior research, our pretest respondents indicated a need for additional information about prostate cancer before they tried to process information about the complexities of PSA screening. We adapted our materials to include basic background information about prostate cancer and the PSA test and received positive feedback from respondents during subsequent testing of these revised materials. IDM presumes that those involved have a basic understanding of the disease or condition in question. Our findings underscore the need to understand and address the health literacy of the intended recipients; materials should be designed at an appropriate level and include the background information necessary for the recipients to engage in IDM.

Limitations of the Research

Our work has important implications for the development of materials for interventional studies in general and IDM research in particular. In interpreting the results, it is important to bear in mind that the study involved a convenience sample of respondents; thus, the findings cannot be generalized to other populations. However, the sample was of reasonable size and diversity for this type of formative research.
**Areas of Future Research**

Based on our findings, we believe the following areas will be productive for future research to inform interventional studies, especially those intended to promote IDM:

1. What are the most effective strategies for conveying counterintuitive messages about cancer screenings (that is, that screening is not always the right choice)?

2. What are the barriers to audiences’ understanding and acceptance of the IDM message (*You Decide*) and how can interventions address these barriers?

3. What are the most important characteristics of group presentations for IDM interventions (e.g., physician vs. other presenter, opportunity for interaction) and other intervention modalities?

4. How can graphics be most effectively used to convey complex health information and aid in decision making, particularly for audiences with limited health literacy and numeracy?

5. How can graphics and text be used in combination to promote understanding of complex health information?

**References**


## Appendix

<table>
<thead>
<tr>
<th>You Decide Men’s Health Brochure</th>
<th>19</th>
</tr>
</thead>
<tbody>
<tr>
<td>You Decide PSA Only Brochure</td>
<td>23</td>
</tr>
</tbody>
</table>
You Decide Men’s Health Brochure

Making Good Decisions Depends on Getting All the Facts

There are different decisions to be made. For:

- **Heart attack and stroke**—decide how you want to lower your risk factors.
- **Colon cancer**—decide which test to have.
- **Prostate cancer**—decide whether or not to get a PSA test.

<table>
<thead>
<tr>
<th>Men’s Health Choices</th>
<th>How much of a difference could this make in keeping me healthy?</th>
<th>How sure are doctors that it will reduce my chances of dying?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowering risk factors for heart attack and stroke</td>
<td>A lot</td>
<td>Very sure</td>
</tr>
<tr>
<td>Getting tested for colon cancer</td>
<td>Some</td>
<td>Very sure</td>
</tr>
<tr>
<td>Getting a PSA test</td>
<td>Some</td>
<td>Not very sure</td>
</tr>
</tbody>
</table>

Think about the health information we’ve given you, decide what is right for you, and then talk with your doctor about your decision. Always discuss your health decisions with a doctor or health care team member who knows about your medical conditions.

For more information go to www.menshealthdecisions.org.

Published: 9-10-04
Heart Attack and Stroke

More than 50 out of 100 men die from heart attack and stroke. Your chances of having a heart attack and stroke are higher if you have certain “risk factors.” Some risk factors—like age, sex, or family history of heart attack and stroke—can’t be changed. But other risk factors can be changed.

The following risk factors are ones you can change to lower your chance of heart attack and stroke:

1. High blood pressure. Get your blood pressure checked at least once yearly and get it treated if it’s high. There are many good treatments that control blood pressure without side effects.

2. High cholesterol. Get your cholesterol checked at least every 5 years, and treat it if it’s high. Today’s treatments are very safe and work well.

3. Smoking. If you smoke, talk to your doctor about how to quit. Doctors have proven ways to help people stop smoking.

4. Poor diet and lack of physical activity. Eat healthy foods like fruits, vegetables, whole grains, and fish. If you are overweight, cut back on the number of calories you eat. Also get 20 to 30 minutes of physical activity at least 4 days a week.

For some people, taking a baby aspirin every day can lower your chance of having a heart attack. You should talk to your doctor about whether this is a good idea for you.

Colon Cancer

Although it is not as common as heart attack and stroke, colon cancer is an important problem for middle-aged and older men. About 2 out of 100 men will die from colon cancer. Doctors don’t know yet what to tell people to do or not to do to keep them from getting colon cancer.

Doctors do know that tests to find colon cancer early can lower your chance of dying from it. These tests find both early cancer and polyps. Polyps are small bumps of skin on your colon that can sometimes turn into cancer.
Tests for colon cancer
Several tests can find polyps and even colon cancer early, when treatment is most effective. It’s a good idea to get one of these tests on a regular basis beginning at age 50. Some tests are better at finding cancer, but are more difficult for the patient. Other tests are easier, but need to be done more often.

1. Cards for blood in the stool. You take these cards home and smear them with your bowel movement. Then you send the card back to the doctor to check for hidden blood. If there is blood in your stool, you may need more tests. This test should be done every year.

2. Sigmoidoscopy (sig-moyd-ah-sco-pee). A doctor puts a small, flexible tube with a light in your rectum to look for small cancers or polyps. The tube goes about halfway into your colon. This test should be done every 5 years.

3. Colonoscopy (co-lawn-ah-sco-pee). This test is like the sigmoidoscopy except that the tube goes all the way into your colon. A colonoscopy can find more cancers, but you will need more time to prepare for the test and to recover from it. The test also takes longer. This test should be done every 10 years.

Prostate Cancer
Like colon cancer, prostate cancer is not as common a problem as heart attack and stroke. The number of men dying of prostate cancer each year is nearly the same as the number dying of colon cancer. About 3 out of 100 white men and 5 out of 100 African-American men will die of prostate cancer. Like colon cancer, doctors don’t know yet what to tell people to do or not to do to keep them from getting prostate cancer.

The Prostate Specific Antigen (PSA) test is a blood test that can help to find prostate cancer.

The PSA test has some problems.

- A small amount of PSA in the blood is normal. Higher amounts of PSA can come from prostate cancer or from having an enlarged prostate with no cancer (a condition that many men have after age 50). Most men with a high PSA don’t have prostate cancer—they have an enlarged prostate instead.

- Some men with a normal PSA test still have prostate cancer. Some prostate cancers don’t increase levels of PSA.

Many men think that the PSA is just a simple blood test. But once you have the test, it can lead you quickly on a path to major treatment that you may or may not want.
There Are Two Types of Prostate Cancer—Slow-growing and Fast-growing

The prostate changes as men get older. In some men, the prostate gets larger. Another change is that some normal parts of the prostate start to look like cancer. Even though they look like cancer, they don’t act like cancer—they don’t cause any problems. These are often called “slow-growing” prostate cancers. Men live long, normal lives with a slow-growing prostate cancer. It grows so slowly, if at all, that it does not become dangerous in a man’s lifetime.

Most prostate cancers are slow-growing. If you think of 10 men who have prostate cancer, at least 6 have slow-growing cancer. Only about 4 of these 10 men have the fast-growing type of prostate cancer.

How can we find prostate cancer early? What are its symptoms?

Early prostate cancer doesn’t have any symptoms—so that’s not a good way to find it. The best way would be if doctors could just find fast-growing prostate cancers and leave the slow-growing ones alone. But the PSA test finds both kinds of prostate cancers—slow- and fast-growing—and doctors can’t tell which one a man has.

Different Treatments for Prostate Cancer

If your PSA level is high, your doctor will probably send you to a specialist. The specialist will do a “biopsy” of your prostate (a biopsy is when they stick small needles in your prostate to take samples for more tests).

If the biopsy shows cancer—although it’s most likely the slow-growing kind—there is no way to tell. So doctors will want you to get treated. Common treatments are:

- surgery (radical prostatectomy)—a major operation that removes the entire prostate, and
- external radiation therapy—burning a part of the prostate by using radiation.

Doctors don’t know which treatment for early prostate cancer is best or if any of today’s treatments help men live longer. Doctors do know that about half of all men who get surgery or radiation treatment will have permanent side effects from that treatment, including problems having an erection (also called “impotence”) and problems holding their urine (also called “incontinence”).
Ask yourself:
How Do I Feel About the PSA Test?

What’s right for you depends on how you feel. Men who feel like Joe should have the PSA test. But other men who feel like Frank should not.

[JOE]: It’s important to me to know whether I have a cancer. I would want to be treated even if treatment may not get rid of my cancer and may cause side effects. I’m the kind of person who just wants to know. I think I’ll go ahead and get a PSA test.

[FRANK]: I am the kind of man who doesn’t want to go looking for things that don’t need to be found. Most prostate cancers are slow-growing, and doctors don’t know if treatment works. The treatments may leave me with side effects. I don’t think I’ll get a PSA test right now.

Think about the health information we’ve given you, decide what is right for you, and then talk with your doctor about your decision. Always discuss your health decisions with a doctor or health care team member who knows about your medical conditions.

For more information go to www.u-decide.org.

Published: 9-10-04
Men Should Decide Whether They Feel the PSA Test is Right for Them and Talk With Their Doctors

Many men think that the PSA is just a simple blood test. But once you have the test, it can lead you quickly on a path to major treatment that you may or may not want. If the biopsy shows you have prostate cancer—although it is most likely the slow-growing kind—there is no way to tell. So doctors will probably want you to get treated. Men say that it’s hard to say “no” to the doctors’ advice—even if they don’t want treatment.

**Prostate Specific Antigen (PSA) and the PSA Test**

The Prostate Specific Antigen (or PSA) test is a blood test that can help to find prostate cancer. PSA is a natural substance made by the prostate, a small gland that only men have. The prostate is located between the bladder (that holds your urine) and your penis. The urine tube (urethra) runs through the prostate.

The PSA test has some problems.

- A small amount of PSA in the blood is normal. Higher amounts of PSA can come from prostate cancer or from having an enlarged prostate with no cancer (a condition that many men have after age 50). Most men with a high PSA don’t have prostate cancer—they have an enlarged prostate instead.
- Some men with a normal PSA test still have prostate cancer because some prostate cancers don’t increase levels of PSA.

**There Are Two Types of Prostate Cancer—Slow-growing and Fast-growing**

The prostate changes as men get older. In some men, the prostate gets larger. Another change is that some normal parts of the prostate start to look like cancer. Even though they look like cancer, they don’t act like cancer—they don’t cause any problems. These are often called “slow-growing” prostate cancers. Men live long, normal lives with a slow-growing prostate cancer. It grows so slowly, if at all, that it does not become dangerous in a man’s lifetime.

**Most prostate cancers are slow-growing.** If you think of 10 men who have prostate cancer, at least 6 have slow-growing cancer. Only about 4 of these 10 men have the fast-growing type of prostate cancer.

**How can we find prostate cancer early? What are its symptoms?**

Early prostate cancer doesn’t have any symptoms—so that’s not a good way to find it. The best way would be if doctors could just find fast-growing prostate cancers and leave the slow-growing ones alone. But the PSA test finds both kinds of prostate cancers—slow- and fast-growing—and doctors can’t tell which one a man has.
Different Treatments for Prostate Cancer

If your PSA level is high, your doctor will probably send you to a specialist. The specialist will do a “biopsy” of your prostate (a biopsy is when they stick small needles in your prostate to take samples for more tests).

If the biopsy shows cancer, you will probably get treated. Common treatments are:

- **surgery** (radical prostatectomy)—a major operation that removes the entire prostate, and
- **external radiation therapy**—burning a part of the prostate by using radiation.

Some other treatments are used less often, like internal radiation therapy (brachytherapy), where a doctor performs surgery to place small radioactive pellets inside or near the cancer to destroy cancer cells. You may have also heard of “watchful waiting.” This is not a common treatment option except in men over age 70. It means checking the patient’s prostate cancer often and treating it only if it causes symptoms or shows signs of growing.

Treatment for Prostate Cancer Can Cause Permanent Side Effects

Doctors don’t know which treatment for early prostate cancer is best or if any of today’s treatments help men live longer.

Doctors do know that about half of all men who get surgery or radiation treatment will have permanent side effects from that treatment.

About half of men who get treatment for prostate cancer will have permanent side effects, including problems having an erection (also called “impotence”) and problems holding their urine (also called “incontinence”).

Because doctors can’t tell whether a prostate cancer is slow- or fast-growing, they treat almost everyone. This means that some men who only had a slow-growing prostate cancer will end up with side effects.

Deciding About the PSA Test

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Men say that it’s hard to say “no” to the doctors’ advice—even if they don’t want treatment.
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