Published in final edited form as:

Am J Health Promot. 2015 ; 29(6): 393–401. doi:10.4278/ajhp.130904-QUAL-463.

Perceptions of Prostate Cancer Screening Controversy and Informed Decision Making: Implications for Development of a Targeted Decision Aid for Unaffected Male First-Degree Relatives

Clement K. Gwede, PhD, MPH, RN^{1,2}, Stacy N. Davis, PhD, MPH¹, Shaenelle Wilson, MPH¹, Mitul Patel, BS¹, Susan T. Vadaparampil, PhD, MPH^{1,2}, Cathy D. Meade, PhD, RN^{1,2}, Brian M. Rivers, PhD, MPH^{1,2}, Daohai Yu, PhD^{1,2}, Javier Torres-Roca, MD^{1,2}, Randy Heysek, MD¹, Philippe E. Spiess, MD^{1,2}, Julio Pow-Sang, MD^{1,2}, and Paul Jacobsen, PhD^{1,2}

¹H. Lee Moffitt Cancer Center & Research Institute

²University of South Florida, College of Medicine, Dept of Oncologic Sciences

Abstract

Purpose—First-degree relatives (FDRs) of prostate cancer (PC) patients should consider multiple concurrent personal risk factors when engaging in informed decision making (IDM) about PC screening. This study assessed perceptions of IDM recommendations and risk-appropriate strategies for IDM among FDRs of varied race/ethnicity.

Design—A cross-sectional, qualitative

Setting—Study setting was a cancer center in southwest Florida.

Direct all correspondences to: Clement K. Gwede, PhD, MPH, RN, Moffitt Cancer Center, 12902 Magnolia Drive, MRC-CANCONT; Tampa, FL 33612, PHONE: 813-745-3052; FAX: 813-745-6525; clement.gwede@moffitt.org.

Co-Authors

Stacy N. Davis, PhD, MPH

stacy.davis@moffitt.org; 813-745-1461

Shaenelle Wilson, MPH

shinnyw@gmail.com; 813-745-4673

Mitul Patel, BS

MVP4688@gmail.com; 813-745-4673

Susan T. Vadaparampil, PhD, MPH

susan.vadaparampil@moffitt.org; 813-745-1997

Cathy D. Meade, PhD, RN

cathy.meade@moffitt.org; 813-745-6730

Brian M. Rivers, Ph.D., MPH

brian.rivers@moffitt.org; 813-745-6448

Daohai Yu, PhD

dyu@temple.edu; 813-745-4673

Javier Torres-Roca, MD

javier.torresroca@moffitt.org; 813-745-1824

Randy Heysek, MD

randy.heysek@moffitt.org; 813-745-8424

Philippe E. Spiess, MD

philippe.spiess@moffitt.org; 813-745-8343

Julio Pow-Sang, MD

julio.powsang@moffitt.org; 813-745-2226

Paul Jacobsen, Ph.D.

paul.jacobsen@moffitt.org; 813-745-38626

Financial disclosure: None

Participants—The study comprised 44 participants (24 PC patients and 20 unaffected FDRs).

Method—Focus groups and individual interviews were conducted and analyzed using content analysis and constant comparison methods.

Results—Patients and FDRs found the PC screening debate and IDM recommendations to be complex and counterintuitive. They overwhelmingly believed screening saves lives and does not have associated harms. There was a strongly expressed need to improve communication between patients and FDRs. A single decision aid that addresses the needs of all FDRs, rather than separating by race/ethnicity, was recommended as sufficient by study participants. These perspectives guided the development of an innovative decision aid that deconstructs the screening controversy and IDM processes into simpler concepts and provides step-by-step strategies for FDRs to engage in IDM.

Conclusion—Implementing IDM among FDRs is challenging because the IDM paradigm departs from historical messages promoting routine screening. These contradictions should be recognized and addressed for men to participate effectively in IDM. A randomized pilot study evaluating outcomes of the resulting decision aid is underway.

Keywords

Prostate Cancer; Informed Decision Making; Decision Aid; First-Degree Relatives; Family History; Health Promotion; Prevention Research. Manuscript format: research; Research purpose: descriptive; Study design: qualitative; Outcome measure: behavioral; Setting: clinical/healthcare; Health focus: social health; Strategy: education, skill building/behavior change, and culture change; Target population age: adults; Target population circumstances: race/ethnicity and male first-degree relatives

PURPOSE

Prostate cancer (PC) is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American men. An estimated 233,000 men will be diagnosed with PC, and approximately 29,480 men will die from the disease in 2014.¹ The strongest risk factors for PC are family history, older age, and African ancestry.¹ Incidence and mortality are both higher for black men compared with their white counterparts.¹ This disproportionate impact is even more pronounced when black men are compared to other racial/ethnic minority groups, such as Asian, Hispanic/Latino, and American Indian/Alaska Native men.¹ Unaffected men with a family history of PC have a higher risk of being diagnosed with PC compared with men without a family history.² PC risk doubles for first-degree relatives (FDRs), specifically the biologic siblings, sons, or parents of men with PC, and risk increases 3-fold when more than one FDR has PC.² PC risk is greater for sons compared with brothers of a PC patient, and for younger siblings (vs. older siblings).^{2–4}

Screening tests for PC are widely available and include the digital rectal exam and the prostate-specific antigen (PSA) test. However, routine screening for PC remains highly debated regarding the value and benefits of screening for asymptomatic men, including FDRs.^{5,6} Two landmark studies reported contradictory findings about the benefits of routine PC screening. A European study found limited evidence of survival benefits of annual PSA testing and treatment.⁵ The results of the U.S.-based Prostate Lung Colorectal Ovarian

Cancer trial did not provide support for the benefits of PC screening; specifically, PC mortality rates did not differ between annual screening and usual care.⁶ Therefore, arguments persist that widespread screening will lead to significant increased diagnosis of indolent disease (overdiagnosis) that may not cause harm (morbidity, such as symptoms; or mortality). In addition, finding indolent disease may result in unnecessary treatment and morbidity due to treatment complications.^{7,8}

Treatments for early-stage, localized PC include surgery (prostatectomy), external beam radiation therapy, prostate seed implant (brachytherapy), or combinations of these modalities with or without hormone therapy.⁹ Common complications of various treatment modalities include urinary incontinence and other bladder control problems, sexual impotence or erectile dysfunction, and rectal complications such as chronic diarrhea.⁹ Subsequently, the U.S. Preventive Services Task Force revised its 2008 PC screening recommendation from “insufficient evidence” to a definitive recommendation against routine screening.¹⁰ Recently, leading health policy organizations, such as the American Cancer Society and American Urological Association, have also changed their policies and no longer recommend routine PC screening.^{1,7} All leading health policy organizations now recommend that men, including those at highest risk, should be provided with information that discusses both the potential benefits and harms of routine PC screening to facilitate individual informed decisions about whether or not to undergo testing based on personal values and preferences.^{1,7,10}

However, contrary to policy organization recommendations, PC screening in primary care and community settings remains a routine practice.^{11–13} Given their higher risk status, men with a family history and other concurrent risk factors are faced with difficult decisions about routine screening for PC.⁵ This presents a dilemma impinging on the prevailing paradigm regarding informed decision making (IDM) against the practice of routine screening. Thus, research aimed at helping men with screening decisions (for or against) remains vitally important.¹⁴

There is growing evidence that patient decision aids are helpful in preparing men to make a decision about whether or not to be tested.^{15–21} Desirable outcomes of decision aids include increased awareness and knowledge of PC and screening, reduced uncertainty or decisional conflict about screening decisions, and satisfaction with screening decisions made.^{2,16,22} Decisional conflict is often characterized by personal uncertainty in choosing a definitive course of action (e.g., whether to be screened or not) among competing actions that involve risks and benefits, potential for regret, and possible challenges to personal values and preferences.²³ Decisional conflict may stem from inadequate knowledge, unclear values due to controversy, or dissatisfaction with decision or choice made (i.e., the feeling that an ineffective decision has been made). Patients who experience decisional conflict may seek more information to clarify, or may avoid making a decision altogether and simply maintain the status quo. Men who have decisional conflict may worry more about what to do regarding PC screening, or worry whether the decision they made is the right one for them.^{16,19} For example, because of their increased risk associated with family history and African ancestry, black FDRs may be more conflicted on whether or not to do routine asymptomatic screening.

Few studies have adequately examined the perspectives and preferences of men at increased risk due to family history or family history combined with African ancestry. Men with multiple risk factors were no more likely to screen than men with only one risk factor.² FDRs, who have the strongest risk compared with average-risk populations, must consider multiple concurrent personal risk factors (e.g., age, race/ethnicity, and family history) when engaging in structured PC screening IDM. Because black race/ethnicity is a risk factor for PC, the Centers for Disease Control and Prevention (CDC) developed a separate decision aid for African-Americans. Tailoring by race/ethnicity is thought to have a higher positive impact on behavior by incorporating surface-and deep-structure cultural and social contexts into the decision aid.^{24–26} However, there is a need to assess various strategies for addressing and incorporating culture into decision aids,²⁵ particularly for PC screening decision aids.

To our knowledge, no decision aid has been developed in the United States specifically for FDRs of PC patients (i.e. brothers and sons). Given this paucity of decision aids developed for and tested with FDRs, this study sought to qualitatively assess PC patients' and unaffected FDRs' understanding of the PC screening controversy, perceptions of IDM recommendations and risk-appropriate strategies for IDM among FDRs. A secondary objective was to assess whether patients and FDRs preferred a separate decision aid for black FDRs (given the increased PC risk for this group). Ultimately, the information gained would help identify the salient elements and specific messages to be included in a decision aid targeted specifically toward FDRs.

METHODS

Design

This paper reports qualitative data from the first part of a larger pilot study. The design of the larger pilot study included two phases involving: (1) formative qualitative methods (focus groups and individual interviews) to develop a decision aid with increased relevance to FDRs, and (2) a quantitative randomized pilot study to evaluate the targeted decision aid using a two-arm comparative design. Data analysis for the randomized pilot study is still in progress. The study received University of South Florida institutional review board approval. All participants provided written informed consent before participation.

Setting

This study was conducted at a National Cancer Institute-designated comprehensive cancer center in southwest Florida. PC patients were recruited from the clinical databases of the cancer center and support groups in the community, and they nominated their FDRs.

Participants

The formative qualitative phase included both PC patients and unaffected FDRs (regardless of PC screening status) to achieve a broad representation of perspectives on the barriers, harms, and benefits of screening. PC patients were recruited because they are critical in discussions of PC screening, diagnosis, and treatment experience with their FDRs, and hence could be an important partner in dissemination of the decision aids to their FDRs.

To be invited to participate in the study, eligible PC patients had to: (1) self-identify as non-Hispanic black or non-Hispanic white; (2) have completed definitive PC treatment; (3) reside in the tricity Tampa Bay area (Hillsborough, Pinellas, and Pasco Counties, Florida); (4) agree to attend a focus group; (5) speak, read and write in English; and (6) provide written informed consent. PC patients were asked to nominate at least one male FDR (son or brother) with no personal history of PC. Eligible FDRs had to: (1) self-identify as a non-Hispanic black or non-Hispanic white male between the ages of 40 and 70 years; (2) report no personal history of any cancer, excluding non-melanoma skin cancer; (3) speak, read, and write in English; (4) agree to participate in an individual telephone interview; and (5) provide written informed consent.

PC patients were identified via clinical databases, approached in waiting rooms, or approached while attending community support groups. Patients nominated potentially eligible FDRs using a well-documented methodology^{27,28} where PC patients were contacted by mail or telephone and requested to nominate their male FDRs and provide contact information to researchers. The researchers then contacted FDRs by telephone or mailed a letter introducing them to the study and asking them to call the study team if interested or to decline participation in the study. Individuals who expressed interest in participating were contacted by telephone to evaluate eligibility. Eligible FDRs were mailed a consent form and asked to sign and return the consent form by mail.

Data Collection

Four focus groups (patients only) were held at either the cancer center or in community locations, such as public libraries, in southwest Florida. The focus group and interview guides were developed based on key research questions and with input from our cultural advisors (two black and one white male)—all of whom were PC patients. The cultural advisors added their perspectives for recruitment, and they brought rich experiences about family communication about disease experience and sharing diagnosis, screening decisions, and treatment decisions and outcomes. The advisors provided feedback on the CDC decision guide and focus group guides, reviewed aggregated participant data, reviewed scripts for DVD development, and appeared in the resulting DVD. Two experienced male researchers (African-American and white) trained in qualitative research methods comoderated the focus groups. The moderators were matched by race of the focus group participants. That is, the white researcher was the lead moderator of the focus groups for white patients; whereas the black researcher was the lead moderator of the focus groups for black patients. Comoderators audio recorded each focus group and took handwritten notes.

Focus groups were separated by race, consisted of at least 5 participants, and lasted about 90 minutes. During each session, PC patients provided their views about PC screening, informed decision-making processes, and the content of information they believed should be communicated to FDRs. Patients were mailed and asked to review and compare the two existing CDC decision guides (brochures) before attending the focus group: the general population brochure “Prostate Cancer Screening: A decision guide,” and a race-targeted brochure entitled “Prostate Cancer Screening: A decision guide for African-Americans.”^{29,30} PC patients were asked to provide specific feedback on the strengths and

limitations of each section of the CDC decision guides with regard to potential use with their FDRs. We used the concept of thematic saturation—where saturation is the point when no new information or themes emerge—to determine how many focus groups were enough.^{31,32}

Because of the geographic distribution of FDRs, using focus groups for FDRs was not feasible. Instead all FDRs were interviewed individually via the telephone. Telephone interviews lasted on average 30 minutes. The interview included assessment of the FDRs' current perceptions of their information needs and outcomes of screening informed decision making, including how they feel about screening, how they weigh pros and cons, and what facts they felt they needed to make a decision. FDRs were also mailed both of the CDC decision guides, and were asked for their reactions to the existing content during their interview. In accordance with the literature suggesting that 6 to 12 interviews are enough to reach thematic saturation,³³ we sought to accrue 20 FDRs (10 in each racial category).

PC patient focus groups were separated by race to assess whether there was a need to develop two separate versions of the targeted decision aid (DVDs), consistent with the available versions of the CDC screening decision guides.^{29,30} A similar question about the need for a separate decision aid was asked in each FDR interview.

Analysis Strategies

All focus groups and interviews were audiotaped and transcribed verbatim by a professional transcriptionist. Data were analyzed using a combination of content analysis (of transcripts and handwritten notes) and the constant comparison method.^{34,35} A priori and emergent codes were used to develop the study codebook. The a priori codes were derived from the study research questions and emergent codes were added to the codebook as data analysis progressed. Four investigators within the study team, including the lead author, formed two paired teams for transcript coding. Each transcript was individually coded by a paired team of investigators and the coding results were compared within the team to ensure reliability (dependability). ATLAS.ti (version 5.2; Atlas.ti GmbH, Berlin, Germany) was used to manage and analyze the text from transcripts. The analyzed data and emergent themes were discussed with the research team and cultural advisors to ensure appropriate interpretation and consensus of the results. Data were analyzed separately for FDRs vs. PC patients with race (black vs. white) as a secondary stratification for both groups.

RESULTS

Participant Characteristics

A total of 44 men (24 PC patients and 20 FDRs) participated in this study. Characteristics of participants are summarized in Table 1. Four focus groups were conducted (two focus groups per racial group) with a total of 24 PC patients (14 black patients; 10 white patients). The median age was 63 years (range, 46–82 years). PC patients were within 5 years of completing definitive therapy with either prostatectomy (50%) or radiation therapy (50%). A total of 20 unaffected FDRs (9 black FDRs; 11 white FDRs) completed individual telephone interviews. The median age of FDRs was 59.5 years (range, 41–69). Seventeen FDRs (85%)

had previously been screened for PC (any test), whereas 3 (15%) had never been screened. Among FDRs, 30% had a father who had PC, 55% had a brother who had PC, and 15% had both a father and brother who had PC.

Qualitative Findings

We sought to discover how PC patients and their FDRs perceive the PC screening controversy and IDM recommendations in order to identify salient elements to be included in a decision aid targeted specifically toward FDRs. Focus groups and individual interviews helped to identify new content topics as well as clarify men's preferences for information and desired level of participation in IDM. Table 2 summarizes selected findings in four key areas that directly informed development of the targeted decision aid for FDRs including: (1) patients' and FDRs' perceptions of PC screening controversy and IDM; (2) perceived lack of disclosure or discussion of PC diagnosis; (3) FDRs' fear and avoidance of the topic of PC screening; and, (4) FDRs' receptivity to social influence by their affected relatives. There were no prominent differences by race/ethnicity across the targeted key areas, suggesting common perceptions for both racial groups. Therefore, pooled results for both races among patients and FDRs are summarized by theme below.

Patients' and FDRs' Perceptions of PC Screening Controversy and IDM—

Patients and FDRs found the PC screening debate and IDM recommendations to be complex and counterintuitive. There was strong resistance to IDM messages, with most participants in favor of promoting screening. They asserted that because PC was so common and could be detected early (through routine PSA and digital rectal exam screening), the screening debate and the IDM recommendation/paradigm did not make sense to them. Both patients and FDRs did not see apparent harms or risks associated with screening; hence, they placed a high importance on promoting screening instead of IDM, especially for a higher-risk group such as FDRs. These sentiments are embodied in the representative quotes below.

- “I mean, I think there's just too much confusion going on with this and that... it's lacking focus on...on the positive aspects of being checked.” (patient)
- “...I don't understand the controversy of why all of a sudden it's being brought up that doctors...don't agree with the test...that's how I was diagnosed...” (patient)
- “...I don't see any down sides to being screened, it's not invasive, it's simple...Yes it's uncomfortable and its awkward but you know, it takes all of 5 seconds.” (FDR)

Although patients and FDRs felt the CDC decision guides could stimulate discussions among patients, FDRs, and health care providers, they found the CDC decision guides to be complex and vague in their explanation of the controversy and call to action. Both groups, regardless of racial background, specifically preferred a clear, targeted message for FDRs urging them to “get screened” because of their higher risk of developing the disease.

- “The confusion and the ambiguity in the latter part...[of the CDC booklet]...I wouldn't want to take a chance of ‘dissuading’ him [my son]...; that is, the section that states, ‘Is screening right for you?’ I think it [CDC guide] should say that... “Screening is right for you.” (patient)

- "...You shouldn't be asking them the question...[whether screening is right for you]...they should be told [to get screened]." (patient)
- "...It [CDC guide] says the decision's up to you and your doctor...No, no we don't wanna tell him it's up to him and the doctor...We don't want that flexibility." (FDR)

Lack of Disclosure or Discussion of PC Diagnosis—All patients preferred to be directly involved in informing their FDRs about their diagnosis and to be the first to discuss screening with their FDRs. However, both groups shared frustration about lack of communication by patients with their unaffected male FDRs about the details and experiences associated with a PC diagnosis, treatment, and survivorship. This communication barrier thus deprives the unaffected FDRs of the necessary and meaningful awareness of the family history and possible PC risk. Both FDRs and patients expressed urgency and a need to address this communication barrier by providing patients with information that prompts and prepares them to talk to their FDRs.

- "My father had prostate cancer for probably about 5 years and none of us knew..." (patient)
- "I think that we all have a responsibility to talk to our brothers and our sons about it." (patient)
- "I think we as men don't share that much information between us, until my dad died of cancer...it was ten years before we found out...he kept [it] hidden from us." (FDR)

FDRs Fear and Avoidance of PC Screening—Patients and FDRs concurred on their perceptions that there is widespread fear and avoidance of discussing PC screening among FDRs. This fear emanates from the anticipated impact of PC diagnosis and treatment on sexual performance; hence many FDRs tend to avoid discussing the topic of PC or screening.

- "...A lot a young men hesitate because fear of how it might affect, you know, their manhood" (patient)
- "...You know prostate [cancer] starts impacting sexual activity perhaps and they don't want to get involved." (FDR)

Role of PC Patients in PC IDM—An emergent key finding was that FDRs are receptive to advice of their affected family member and find patients to be credible influences with regard to communications about PC and PC screening. Similarly, most patients were highly motivated to "protect" their FDRs through information sharing and education. These dynamics can be gleaned from the FDR sentiments below.

- "The survivors have the best opportunity to say I'm here today because I got tested." (FDR)
- "I think that the most credible information you have is when you get it from a brother [survivor]...whose opinion you value." (FDR)

Is a Separate Decision Aid Needed for the Black Population?—Both patients and FDRs (black and white) advocated for a single decision aid that highlights the importance of family history and the increased risk for the black population. Black participants in particular strongly supported a common decision aid stating that all of the important differences could be covered and still appeal to both groups. For example, the decision aid could provide disease statistics that highlight racial/ethnic differences as needed, could feature comments from both white and black individuals, and could draw on similarities about understandings/misunderstandings to enhance clear communication. Their sentiments are embodied in the following statements.

- “...I’m not sure why you’d need to have a separate document because the facts are the facts and decisions you have to make are the same...” (white patient)
- “...a lot [of] things change it but it doesn’t have anything to do with whether you’re Black or White or Purple...I think you need to explain why there’s a difference...” (black FDR)
- “...The front cover shows [of the CDC booklet], ya know, Black men, White men so it really doesn’t discriminate in essence, ya know, the disease affects all men...” (white FDR)

These findings informed and guided our decision to develop one common decision aid for both racial/ethnic groups. There was also overwhelming support to develop a DVD rather than a paper-based decision aid or any other type of electronic or social media. There was overwhelming support for this format by cultural advisors and participants to ensure the information is accessible to all strata of the population. In addition, the DVD content could be adapted easily in the future to accommodate other media formats, such as mobile apps and Websites, thus widely disseminating the message and extending its utility.

Infusion of Qualitative Findings in an FDR-Targeted Decision Aid

The findings from the focus groups and interviews informed the content of the targeted decision aid (DVD). Space limitations preclude full discussion of the DVD development process. In short, the decision aid was constructed to promote skills and confidence for FDRs to engage in IDM and discuss PC screening with health care providers.^{36,37} The content, tone and format of the decision aid were structured to address opportunities, concerns, and barriers to IDM identified in formative work. Table 2 highlights how each theme/barrier was addressed in the decision aid. Patients, FDRs, and physicians from the local area were featured in the DVD (vs. professional actors), thus increasing the likelihood that the audience could readily identify with the messengers and their IDM message. Key sections of the resulting DVD titled “Deciding about PC screening: A family matter” were:

- discussion and deconstruction of the PC screening debate to improve understanding of the controversy and arguments for or against routine screening; and
- step-by-step guidance for patients and FDRs on how to speak to their family members and their health care providers about PC in order to facilitate IDM about screening. These critical strategies were reinforced by statistics, and the testimony of physicians, patients, FDRs, and the narrator in the video.

A four-step approach to IDM represented by a 4-D mnemonic was also included. The 4-Ds include: (1) **Data**: gather as much information to facilitate discussions with your health care provider; (2) **Discuss**: talk to your health care provider and family members; (3) **Deliberate**: consider both the benefits and harms of routine screening; and (4) **Decide**: make a decision that is right for you.

Once a draft DVD was produced, learner verification was conducted with patients (n = 3) and FDRs (n = 9) who had not participated in formative interviews/focus groups, in order to assess the suitability of the new decision aid in terms of acceptability, attractiveness, understandability, persuasion, and self-efficacy.³⁸ All participants involved in the learner verification of the decision aid found the length and information appropriate, and easy to understand, and found that it simplified the screening controversy, simplified the potential harm and benefits of screening, and provided a clear step-by-step process for initiating discussions with health care providers and making an informed decision. All found the DVD to be a highly acceptable learning format.

CONCLUSION

Findings in this mixed qualitative methods study of PC patients and unaffected FDRs underscore the complexity of the PC screening controversy and challenges in implementing the consensus recommendation to promote IDM among a population at increased risk. Several barriers and opportunities to improve PC screening education and IDM were identified in this study. The barriers to IDM included lack of awareness and misunderstanding of PC screening debate and IDM, lack of communication between patients and their FDRs, FDRs' fear and avoidance of PC as a topic, lack of a step-by-step guide to simplify the IDM process, and limited strategies to help FDRs speak to health care providers about screening and IDM. On the other hand, findings suggest receptivity to a decision aid that helps patients share their experience and help their FDRs.

Our findings highlight several challenges in the prevailing paradigm of PC screening IDM and the recently revised position against routine PC screening by many leading health policy organizations. Many patients and FDRs found the IDM recommendations to be counterintuitive. It is clear that patients in this study are potentially biased toward a proscreening message. This is demonstrated by patients' strong preference for involvement in the process of preparing their own unaffected FDRs in directed PC screening to improve early detection. Patients urged other survivors to take an active role in discussing their family history of this disease and to educate their own male siblings and sons for the sole purpose of improving early detection of PC. When a patient's proscreening position is juxtaposed against a health policy recommendation in favor of IDM, challenges for achieving education and IDM in community settings are inherent. It remains to be seen whether patients can indeed operationally adhere to a balanced discussion of the pros and cons of PC screening per guidelines. For some men, the benefits of PC screening were a "no brainer" and the risks were obscure or nonexistent. The pragmatic role of patients as partners with the healthcare providers in efforts to promote (balanced) IDM among their own FDRs remains unclear and requires further research.

These challenges notwithstanding, our findings on the perspectives of both patients and FDRs were insightful and directly instrumental in the development of a targeted decision aid for PC screening for FDRs. The “take-home message” is two-fold: (1) patients need information to prompt and help them to discuss family history with their unaffected FDRs, and (2) FDRs who are aware of a family history of PC should initiate discussions with their health care providers about whether or not they should be screened for PC, taking into account their individual risk factors, personal values and preferences. Use of participatory approaches and involvement of patients and FDRs in this educational process was highly valued by the participants. Our decision aid includes the “voices” of patients speaking directly to other patients and FDRs to encourage dialogue and information sharing about PC diagnosis (family history) and experiences with this disease. The DVD also outlines both the potential immediate and downstream benefits and harms (pros and cons) that may result from either decision—to screen or not to screen. Thus, one of the goals of our decision aid was to deconstruct the controversy into easy-to-understand chunks of information (to improve comprehension) consistent with principles of low literacy education.^{38–40} As examples, we broke down the IDM process using a four-step approach (data, discuss, deliberate and decide), and illustrated the process through the lens and voices of patients, FDRs, and physicians. To further assess the utility of the decision aid, a quantitative evaluation is underway to test feasibility, impact, and outcomes in a randomized pilot study comparing the new enhanced decision aid (DVD) for FDRs vs. the CDC screening decision guides.

This was one of the first studies to assess the question of whether PC screening decision aids should be targeted by race/ethnicity. The argument for separate decision aids is fueled by the desire for racial-cultural tailoring of messages and dissemination channels.^{24,25} We did not find racial differences in perceptions and barriers to IDM; our data support the feasibility of a single decision aid targeted to both black and white FDRs. Thus, we developed one decision aid for both racial groups while attending to important surface structure cultural characteristics. The DVD purposely includes diversity with regard to both black/African-American and white patients, physicians and FDRs. Given the preliminary nature of our qualitative results, this question is being further assessed in a subsequent randomized pilot study with race/ethnicity as a stratification factor and two versions of the CDC decision guides.

There continues to be a paucity of research in this area. Only one pilot study (n = 22) of Australian men with a family history of PC reported positive evaluation of both a paper-based and an online interactive version of a screening decision aid²⁸; however, it is not clear whether the decision aid was developed specifically for FDRs. Further quantitative research is needed to evaluate the impact decision aids have on understanding screening controversy and skills for IDM among high-risk populations. Comparisons are also needed to assess whether the outcomes (of general decision aids vs. targeted decision aids for FDRs) differ in this high-risk population. Such comparative studies would contribute new knowledge to support or refute findings from studies with unaffected average-risk populations.^{22,41,42} In that regard, this study—which produced one of the first targeted decision aids for FDRs—takes the first step toward that goal.

Further research is needed to delineate practical and meaningful steps to study and communicate the harms and benefits of both IDM⁴³ and recommendations against PSA screening,^{44,45} and to evaluate whether either perspective addresses the persistent disparities in PC outcomes. In addition, a reasonable question that could be proposed and rigorously tested in future studies is, “Would a single PC screening decision aid for all men (with or without FDR status) be sufficient?” Although this question is being investigated partially in a pilot randomized study underway among only FDRs comparing a general decision aid (non-FDR) to our enhanced decision aid (FDR status), a future study could stratify men by FDR status (with or without family history). This line of research is important and stems from (1) the current study finding that a single decision aid (not separated by race/ethnicity) was recommended by participants, (2) the national consensus recommendation to promote IDM for all men, and (3) practicalities of disseminating one product and potential efficiencies regarding widespread adoption and use of a single decision aid in multiple settings (doctor offices, benefit plans, worksite health promotion programs, community screenings, etc.).

The findings of this study should be considered in light of certain limitations. First, this is a qualitative study which involved purposive and convenience sampling, and a relatively small sample (N = 44). Although this sample size is sufficient for general qualitative analyses, the study enrolled a limited number of men with lower SES, and was not intended to support rigorous quantitative statistical analyses. Furthermore, this sample size may not have been large enough to allow sufficient and exhaustive exploration of race-specific themes and preferences. As such, the question of “tailoring” by race needs to be further addressed in a future study. Overall, participants are not representative of the general population. For instance the educational and income levels for both patients and FDRs were relatively high. Thus, it is possible that some patients with limited education, income, or health literacy would desire a race-“tailored” decision aid. In addition, most FDRs had been screened previously for PC, and firmly held a proscreening or more favorable attitude toward screening. Inclusion of the perspectives of patients who chose active surveillance or those who had unfavorable treatment outcomes, or FDRs who chose not to be screened or had negative experiences with previous screening, may have produced different results. Despite these limitations, the article does have numerous strengths. This study used a qualitative approach, which allowed researchers to gain rich insights into the needs of patients and their FDRs. This was also the first study to address the unique IDM needs of unaffected male FDRs through the production of an FDR-targeted decision aid.

To the best of our knowledge, this is the first study to examine patients and their adult male FDRs’ perceptions of PC screening controversy and informed IDM processes in the context of the development of a decision aid for FDRs. The perspectives of patients and FDRs guided development of a decision aid that deconstructs the IDM message and screening controversy into simpler salient messages, provides step-by-step strategies for participating in IDM, and encourages information sharing within the patient/FDR family unit—features that are often lacking in existing decision aids.^{15,16,22} The findings from this study also led to the development of a single decision aid as recommended by study participants (PC patients and FDRs) regardless of race.

SO WHAT? Implications for Health Promotion Practitioners and Researcher What is already known on this topic?

There is considerable literature on IDM in cancer screening, including PC.^{15–19} However, most of the literature does not separate findings or outcomes by FDR status. Furthermore, this is, to our knowledge the first study to include perspectives of both patients and FDRs, and to integrate these perspectives into the development of a decision aid targeted specifically toward FDRs. The results of this study identify challenges in men's understanding and acceptance of the logic and basis for IDM recommendations.

What does this article add?

To our knowledge, this the first study in the United States to address the IDM needs of FDRs and to produce a decision aid targeted specifically toward them. This is also one of the first studies to assess whether PC screening decision aids should be separated by race/ethnicity. This study concluded that a single integrated decision aid suffices, but acknowledges this question should be further assessed in future larger randomized control trials.

What are the implications for health promotion practice or research?

Until the decision aid is tested for feasibility and efficacy, the primary message for practitioners and researchers is to attend to the informational needs of each man—being cognizant that the screening controversy and IDM may not be intuitively meaningful to FDRs. Some men may require detailed dialogue to address why IDM is important even for FDRs. The use of supplemental educational tools (decision aids) may help to further enrich these important discussions.

Acknowledgments

This publication was supported by Grant Number 1R21 CA125428, from the National Cancer Institute and its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National Cancer Institute.

Stacy Davis contribution to this study was also funded by a grant from NCI (R25 CA090314; Paul B. Jacobsen, Ph.D., Principal Investigator).

References

1. American Cancer Society. Cancer Facts & Figures 2014. Atlanta, Ga: American Cancer Society; 2014.
2. McDowell ME, Occhipinti S, Gardiner RA, et al. A review of prostate-specific antigen screening prevalence and risk perceptions for first-degree relatives of men with prostate cancer. *Eur J Cancer Care (Engl)*. 2009; 18:545–55. [PubMed: 19686273]
3. Roumier X, Azzouzi R, Valeri A, et al. Adherence to an annual PSA screening program over 3 years for brothers and sons of men with prostate cancer. *Eur Urol*. 2004; 45:280–285. author reply 5–6. [PubMed: 15036671]
4. Beebe-Dimmer JL, Wood DP Jr, Gruber SB, et al. Risk perception and concern among brothers of men with prostate carcinoma. *Cancer*. 2004; 100:1537–1544. [PubMed: 15042690]
5. Schroder FH, Hugosson J, Roobol MJ, et al. Screening and prostate-cancer mortality in a randomized European study. *N Engl J Med*. 2009; 360:1320–1328. [PubMed: 19297566]

6. Andriole GL, Crawford ED, Grubb RL III, et al. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med*. 2009; 360:1310–1319. [PubMed: 19297565]
7. American Urological Association. Early detection of prostate cancer: AUA Guideline. 2013. Available at: <http://www.auanet.org/education/guidelines/prostate-cancer-detection.cfm>
8. Strobe SA, Andriole GL. Prostate cancer screening: current status and future perspectives. *Nat Rev Urol*. 2010; 7:487–493. [PubMed: 20818326]
9. Wilt TJ, MacDonald R, Rutks I, et al. Systematic review: comparative effectiveness and harms of treatments for clinically localized prostate cancer. *Ann Intern Med*. 2008; 148:435–448. [PubMed: 18252677]
10. Screening for Prostate Cancer: U S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2012; 157:120–134. [PubMed: 22801674]
11. Vedela I, Putsa MTE, Monettea M, et al. The decision-making process in prostate cancer screening in many primary care with a prostate cancer-specific antigen: asystematic review. *J Geriatr Oncol*. 2011; 2:161–176.
12. Volk RJ, Linder SK, Kallen MA, et al. Primary care physicians' use of an informed decision-making process for prostate cancer screening. *Ann Fam Med*. 2013; 11:67–74. [PubMed: 23319508]
13. Goodwin JS, Tan A, Jaramillo E, Kuo YF. Prostate-specific antigen testing in men aged 40–64 years: impact of publication of clinical trials. *J Natl Cancer Inst*. 2013; 105:743–745. [PubMed: 23459245]
14. Ferrante JM, Shaw EK, Scott JG. Factors influencing men's Decisions Regarding Prostate Cancer Screening: A Qualitative Study. *J Community Health*. 2011; 36:839. [PubMed: 21336996]
15. Wolf AM, Wender RC, Etzioni RB, et al. American Cancer Society guideline for the early detection of prostate cancer: update 2010. *CA Cancer J Clin*. 2010; 60:70–98. [PubMed: 20200110]
16. Volk RJ, Hawley ST, Kneuper S, et al. Trials of decision aids for prostate cancer screening: a systematic review. *Am J Prev Med*. 2007; 33:428–434. [PubMed: 17950409]
17. Barratt AL, Stockler MR. Screening for prostate cancer: explaining new trial results and their implications to patients. *Med J Aust*. 2009; 191:226–229. [PubMed: 19705986]
18. Lepore SJ, Wolf RL, Basch CE, et al. Informed decision making about prostate cancer testing in predominantly immigrant black men: a randomized controlled trial. *Ann Behav Med*. 2012; 44:320–330. [PubMed: 22825933]
19. Stacey D, Bennett CL, Barry MJ, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2011:CD001431. [PubMed: 21975733]
20. Hersch J, Jansen J, Irwig L, et al. How do we achieve informed choice for women considering breast screening? *Prev Med*. 2011; 53:144–146. [PubMed: 21723312]
21. Shokar NK, Carlson CA, Weller SC. Informed decision making changes test preferences for colorectal cancer screening in a diverse population. *Ann Fam Med*. 2010; 8:141–150. [PubMed: 20212301]
22. Myers RE, Daskalakis C, Kunkel EJ, et al. Mediated decision support in prostate cancer screening: a randomized controlled trial of decision counseling. *Patient Educ Couns*. 2011; 83:240–246. [PubMed: 20619576]
23. LeBlanc A, Kenny DA, O'Connor AM, Legare F. Decisional conflict in patients and their physicians: a dyadic approach to shared decision making. *Med Decis Making*. 2009; 29:61–68. [PubMed: 19196706]
24. Hawkins RP, Kreuter M, Resnicow K, et al. Understanding tailoring in communicating about health. *Health Educ Res*. 2008; 23:454–466. [PubMed: 18349033]
25. Kreuter MW, McClure SM. The role of culture in health communication. *Annu Rev Public Health*. 2004; 25:439–455. [PubMed: 15015929]
26. Kreuter MW, Wray RJ. Tailored and targeted health communication: strategies for enhancing information relevance. *Am J Health Behav*. 2003; 27 (Suppl 3):S227–S232. [PubMed: 14672383]
27. Vadaparampil ST, Jacobsen PB, Kash K, et al. Factors predicting prostate specific antigen testing among first-degree relatives of prostate cancer patients. *Cancer Epidemiol Biomarkers & Prev*. 2004; 13:753–758.

28. Wakefield CE, Watts KJ, Meiser B, et al. Development and pilot testing of an online screening decision aid for men with a family history of prostate cancer. *Patient Educ Couns*. 2011; 83:64–72. [PubMed: 20580521]
29. CDC. Tools to Facilitate Shared Decision Making for Prostate Cancer Screening: “Prostate Cancer Screening: A Decision Guide for African Americans”. Centers for Disease Control and Prevention; 2002.
30. Center for Disease Control and Prevention. Tools to Facilitate Shared Decision Making for Prostate Cancer Screening: “Prostate Cancer Screening: A Decision Guide”. Centers for Disease Control and Prevention; 2002.
31. Morgan, DL. *Focus Groups as Qualitative Research*. 2. Thousand Oaks, Calif: Sage Publications; 1997.
32. Morgan, DL.; Krueger, RA. When to use focus groups and why. In: Morgan, DL., editor. *Successful Focus Groups: Advancing the State of the Art*. Thousand Oaks, Calif: Sage; 1993. p. 3-19.
33. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods*. 2006; 18:59–82.
34. Glaser BG. The constant comparison method of qualitative analysis. *Soc Probl*. 1965; 12:436–445.
35. Neuman, WL. *Social Research Methods: Qualitative and Quantitative Approaches*. 3. Boston, Mass: Allyn and Bacon; 1997.
36. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*. 2000; 15:259–267.
37. Nutbeam D. The evolving concept of health literacy. *Soc Sci Med*. 2008; 67:2072–2078.
38. Doak LG, Doak CC, Meade CD. Strategies to improve cancer education materials. *Oncol Nurs Forum*. 1996; 23:1305–1312. [PubMed: 8883075]
39. Doak CC, Doak LG, Friedell GH, Meade CD. Improving comprehension for cancer patients with low literacy skills: strategies for clinicians. *CA Cancer J Clin*. 1998; 48:151–162. [PubMed: 9594918]
40. Doak, CC.; Doak, LG.; Root, JH. *Teaching Patients With Low Literacy Skills*. Philadelphia, Pa: J.B. Lippincott; 1996.
41. Hoffman RM, Lewis CL, Pignone MP, et al. Decision-making processes for breast, colorectal, and prostate cancer screening: the DECISIONS survey. *Med Decis Making*. 2010; 30:53S–64S. [PubMed: 20881154]
42. Costanza ME, Luckmann RS, Rosal M, et al. Helping men make an informed decision about prostate cancer screening: a pilot study of telephone counseling. *Patient Educ Couns*. 2010; 82:193–200. [PubMed: 20554423]
43. Smith RA, Cokkinides V, Brooks D, et al. Cancer screening in the United States, 2010: a review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin*. 2010; 60:99–119. [PubMed: 20228384]
44. Brett AS, Ablin RJ. Prostate-cancer screening--What the U.S. Preventive Services Task Force Left Out. *N Engl J Med*. 2011; 365:1949–1951. [PubMed: 22029759]
45. U.S. Department Health and Human Services. Administration HRaS. *Approved Uniform Data System Changes for 2012 (PAL 2012–03)*. Washington DC: Government Printing Office; 2012.

Table 1

Demographic Characteristics of Prostate Cancer Patients and First-Degree Relatives (FDRs)*

	Patients (n = 24)		FDRs* (n = 20)
Age, y, Median (range)	63 (Range 46-82)		59.4 (Range 41–69)
Race, No. (%)			
White/non-Hispanic	10 (42)		11 (55)
Black/non-Hispanic	14 (58)		9 (45)
Employment status, No. (%)			
Employed for wages	15 (63)		11 (55)
Retired or other	9 (37)		9 (45)
Education, No. (%)			
High school or GED	4 (17)		5 (25)
Vocational/college or above	20 (83)		15 (75)
Household income, No. (%)			
*\$20,000–\$59,000	7 (29)		5 (25)
\$60,000 or more	15 (63)		15 (75)
Prefer not to answer	2 (8)		0
Treatment received, No. (%)			
Prostatectomy	12 (50)		n/a
			n/a
Radiation therapy	12 (50)		n/a
			n/a
Relative with prostate cancer, No. (%)			
Father	n/a	n/a	6 (30)
Brother	n/a	n/a	11 (55)
Both father and brother	n/a	n/a	3 (15)
Screening Status, No. (%)			
Ever Screened	n/a	n/a	17 (85)
Never been screened	n/a	n/a	3 (15)

*  n/a indicates not applicable.

Table 2

Table of Summary Selected Themes, Participant Quotes, and Examples of How Information Was Used in Decision Aid*

Selected Themes/Barriers	Patient/FDR Quotes	How Barrier Was Addressed in Decision Aid
Perceptions of PC screening controversy and IDM	Patient Quotes: “I mean, I think there’s just too much confusion going on with this and that... it’s lacking focus on...on the positive aspects of being checked.” “No, no, we don’t wanna tell him it’s up to him and the doctor... We don’t want that flexibility cause [if] it’s up to him, it’s like hey, don’t need it.” “So if you deemphasize the negatives, emphasize the positives then you might be more successful at getting people tested.” “Honestly, I don’t understand the controversy of why all of a sudden it’s being brought up that doctors actually some of em don’t really agree with the test...that’s how I was diagnosed...”	- Narrator introduces the four Ds—Data, Discuss, Deliberate, and Decision—steps in IDM that help FDRs gather information and resources to consider in decision making. - Physician testimony about potential risks and benefits (pros and cons) of screening and the importance of making an individual decision with input from a health care provider. - Narrator describes the sources of controversy through description of fast-growing PC vs. slow-growing PC. - A physician explains in detail the sources of controversy—citing both the motivation and arguments for routine screening, as well as the counterarguments against routine screening. Physician also gives the historical account of how guidelines have changed from promoting routine screening to (more recently) promotion of IDM and individualization of the screening decision.
	FDR Quotes: “...I don’t see any down sides to being screened, it’s not invasive, it’s simple... Yes it’s uncomfortable and it’s awkward but you know, it takes all of 5 seconds.” “To me screening, it’s harmless... it’s a no-brainer as far as I am concerned.” “... Whether you should or shouldn’t be tested, I don’t understand that. That doesn’t make any logical sense to me whatsoever.”	
Lack disclosure about PC diagnosis	Patient Quotes: “My father had prostate cancer for probably about 5 years and none of us knew...” “... He didn’t tell us so he shared it with his doctor so only his doctor knew and so we couldn’t factor that in as being a risk factor.” “I think that we all have a responsibility to talk to our brothers and our sons about it.”	- FDR and patient testimony regarding the importance of disclosure of diagnosis and sharing the experience around the various aspects of the disease. - Narrator describes the importance of patients educating family members about diagnosis.
	FDR Quotes: “... We just don’t talk about it...he told me straight away, but I’m figuring that it’s probably that my mother directed that.” “I think that we all have a responsibility to talk to our brothers and our sons about it.”	

Selected Themes/Barriers	Patient/FDR Quotes	How Barrier Was Addressed in Decision Aid
FDRs fear and avoidance of discussing PC screening	• "I think we as men don't share that much information between us, until my dad died of cancer...it was ten years before we found out...he kept [it] hidden from us." Patient Quotes: • "...A lot of young men hesitate because fear of how it might affect, you know, their manhood" • "The biggest obstacle for most men is they don't...they don't go to doctors." FDR Quotes: • "... You know prostate [cancer] starts impacting sexual activity perhaps and they don't want to get involved." • "I think its physician driven. You know, the physician brings it up we typically will not [bring it up]..."	• FDR urges other FDRs to discuss with providers their family history of PC and what this means for their own decisions about screening • Patient testimony addressing audience not to fear the subject and to take responsibility for the management of their health in collaboration with a number of health care providers. • Physician interview addresses the specific strategy to aid FDRs to initiate discussion with health care providers.
Role of PC survivors in PC IDM	Patient Quotes:"It's up to us, ya know, to help...to get the word out." FDR Quotes: • "The survivors have the best opportunity to say I'm here today because I got tested." • "I think that the most credible information you have is when you get it from a brother [survivor]...whose opinion you value."	• Narrator (voiceover) emphasizes role of PC patients encouraging FDRs to: (1) encouraging FDRs to discuss PC with health care provider and (2) promoting information seeking about PC and screening benefits and risks. • Patient encourages PC patients to openly discuss PC with family.

* FDR indicates first-degree relative; PC, prostate cancer; and IDM, informed decision making.