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14. ABSTRACT Prostate cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death. However, screening asymptomatic men remains controversial, as early diagnosis and treatment of PCa has not yet demonstrated reduced disease-related mortality in a randomized trial. The goal of the current study is to develop and assess widely accessible, easily disseminable methods to assist men in making informed decisions about PCa screening. We will compare the efficacy of a new web-based, interactive decision support approach to our existing print-based PCa screening decision tool, among a diverse sample of male primary care patients. Abundant evidence documents the expanding role of the Internet in increasing access to and understanding of health information and the need for systematic evaluations of Internet-based interventions. The print- and web-based interventions have been completed and we have accrued 1,893 participants to the randomized trial.					
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INTRODUCTION

Prostate cancer (PCa) screening is controversial, as early diagnosis and treatment of PCa has not yet demonstrated reduced disease-related mortality in a randomized trial.^{1,2} The primary question is whether PCa screening results in overdiagnosis, the detection and treatment of disease that would not otherwise result in increased morbidity or mortality. The Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial³ is designed to address this question, but results will not be available for at least 10 years. At present, the lack of evidence for effectiveness and the resulting controversy have not deterred PCa screening, as the practice of screening asymptomatic men is increasing in the U.S.⁴⁻⁶ Most men who undergo PCa screening are not making fully-informed decisions, as they are unaware of the controversy and believe that the medical community unequivocally accepts the benefits of screening.⁷⁻⁹ This issue is not unique to PCa as the difficulty of making medical decisions prior to the availability of definitive outcome data has been a long-standing issue in cancer screening.^{10,11} Importantly, this issue is likely to become increasingly significant as screening technology advances more rapidly than our ability to validate it.¹¹⁻¹⁵ Thus, widely applicable approaches to health education are needed in order to facilitate informed decision making about the growing number of unproven treatment and screening technologies.¹⁶⁻¹⁷ The goal of the current study is to develop and assess a widely accessible and disseminable method to assist men in making informed decisions about PCa screening.

Specific Aims: 1) Evaluate the impact of the delivery method (Web vs. Print vs. Usual Care) on the key patient outcome variables of knowledge, decisional satisfaction, health-related quality of life (HRQL), and the screening decision. 2) Assess factors that moderate the interventions' impact on the primary outcomes, including commitment to screening (defined by screening history and decisional balance), computer literacy, and age. In exploratory analyses, we will evaluate baseline factors that are related to use of the website by tracking the topics accessed and the amount of information reviewed. Study Design: In Phase I (months 1-6), we will develop an interactive, Internet-based, patient information and decision aid. In Phase II (months 7-60), we will evaluate the impact of this decision aid in a randomized controlled trial with male primary care patients aged 45-70 (N = 600). Trial arms include: 1) print-based information and decision aid (Print), 2) web-based information plus interactive decision aid (Web), and 3) usual care (UC). Subjects will complete outcome assessments at baseline, 1- and 12-months post-baseline. Relevance: This research has the potential to make several significant and innovative contributions: 1) the development and evaluation of a widely-disseminable method of educating a heterogeneous group of patients about a controversial topic, which can be adapted for other similarly contentious issues, 2) a determination of whether Web based materials are a feasible method of patient education for this age cohort, compared to print materials, 3) a determination of who among the target population benefits the most from a web-based intervention, and 4) the information required to streamline and target future web-based educational interventions.

BODY

We have completed all tasks included in Phase I of this study. Additionally, we have analyzed the data and prepared manuscripts that describe the development work that went into the first Phase of this project (see abstracts below and complete manuscripts attached). The randomized trial has been ongoing for three years and we reached our accrual goal of 1,893 participants with a 39% participation rate. We anticipated a 50% participation rate in our calculations of accrual feasibility and we made several efforts to increase the participation rate during the course of recruitment. However, this participation rate is very similar to other web-based studies¹⁸⁻²⁰. All one-month assessments have been completed (N = 1,680; 89% retention rate), and 1,235 12-month assessments have been completed (87% retention rate). We have 380 more 12-month assessments to complete.

	Georgetown University, n (% response rate)	Washington Hospital Center, n (% response rate)	MedStar Physician Partners, n (% response rate)	Total, N (% response rate)
Baseline Response Rates	779 (44%)	241 (32%)	873 (38%)	1893 (39%)
One-Month Response Rates	704 (90%)	202 (84%)	774 (89%)	1680 (89%)
12-month Response Rates (ongoing)	617 (91%)	152 (71%)	466 (87%)	1235 (87%)

We have completed three published or in press manuscripts. The goals, results, and conclusions for each are summarized below. The complete version of the manuscripts are attached.

Physician Study. Davis, K., Haisfield, L., Dorfman, C., Krist, A., Taylor, K. (in press). Physicians' Attitudes About the Shared Decision Making Process for Prostate Cancer Screening. Family Medicine.

Background: Shared decision making (SDM) for prostate cancer screening is recommended for physicians and patients due to the uncertainty regarding the risks and benefits associated with the currently available screening tests. **Method:** We assessed primary care physicians' self-report of their attitudes and specific factors that may influence the SDM process, including physicians' level of training and practice setting. Participants included academic clinicians (N = 16) and interns/residents (N = 84) at two academic medical centers, and community clinicians (N = 35) from community-based practices. Physicians completed a 26-item survey that assessed attitudes about the SDM process for prostate cancer screening. **Results:** More physicians endorsed SDM (47.4%) or the patient deciding (35.6%), while few physicians reported that they wanted to decide for their patients whether they should be screened. However, 54.8% endorsed an annual PSA as the standard of care. Most felt that decisions should be based on full disclosure of the risks and benefits of testing (93.3) and few believed that the sensitivity and specificity of the PSA was adequate (36.6%). Across all physicians, lack of time, competing health demands, malpractice fears and patient interest were all commonly cited as potential factors that influence the SDM process. Compared to academic clinicians and interns/residents, community clinicians were more likely to endorse annual screening, to be concerned about malpractice, and to agree that the sensitivity and specificity of the PSA is acceptable (all ps < .001). **Conclusions:** The current findings demonstrate the difficulty physicians' face given the support of SDM and prostate cancer screening as the standard of care. Our results suggest that practice setting, level of training and a host of other factors may influence these differences. Further research is needed to replicate these preliminary findings regarding the SDM process for prostate cancer.

Web Viewing Study: Men's Utilization of an Internet-based Decision Aid for Prostate Cancer Screening (in press). Kassan, EC, Williams, RM, Kelly SP, Barry, SA, Penek, S, Fishman, MB, Cole, CA, Miller, EM & Taylor, KL.

Objective: Medical organizations recommend informed decision making before undergoing prostate cancer screening (PCS). We conducted a detailed evaluation of men's utilization of an interactive, web-based PCS decision aid. **Method:** Participants (N=531) were 57 years old (SD=6.8), 37% were African-American, and 92% had Internet access. Men completed two telephone interviews, pre- and one-month post-website availability. **Results:** One-half of the sample (N=256) accessed the website. Multivariate analysis revealed that users were more likely than non-users to be white (OR=2.37, CI 1.6-3.6), previously screened (OR = 2.13, CI 1.07-4.26), have Internet access (OR=3.66, CI 1.15-11.58), and to report daily Internet use (OR=2.58, CI 1.47-4.55). Agreement between self-reported and actual website use was moderate (kappa=0.67). Tracking software revealed M=1.3 (SD=0.5) log-ons and a median of 38 minutes per log-on. Eighty-four percent utilized the values clarification tool (VCT) and over 50% viewed each video testimonial. Baseline screening preference was associated with VCT responses and website feedback. **Conclusions:** This study revealed that, beyond the

digital divide, website use depended on more than Internet access. Further, electronic tracking of website utilization demonstrated the overestimation of self-reported use, the high utilization of interactive features, and the impact of baseline screening preference on men's response to the website.

Development Paper: Dorfman, C., Williams, R.M., Kassan, E.C., Red, S.N., Dawson, D.L., Tuong, W., Parker, E.R., Ohene-Frempong, J., Davis, K.M., Krist, A.H., Woolf, S.H., Schwartz, M.D., Fishman, M., Cole, C., and Taylor, K.L. (2010). The Development of a Web- and a Print-Based Decision Aid for Prostate Cancer Screening. *BMC Medical Informatics and Decision Making*, 10:12.

Background. Whether early detection and treatment of prostate cancer (PCa) will reduce disease-related mortality remains uncertain. As a result, tools are needed to facilitate informed decision making. While there have been several decision aids (DAs) developed and tested, very few have included an exercise to help men clarify their values and preferences about PCa screening. Further, only one DA has utilized an interactive web-based format, which allows for an expansion and customization of the material. We describe the development of two DAs, a booklet and an interactive website, each with a values clarification component and designed for use in diverse settings.

Methods. We conducted two feasibility studies to assess men's (45-70 years) Internet access and their willingness to use a web- vs. a print-based tool. The booklet was adapted from two previous versions evaluated in randomized controlled trials (RCTs) and the website was created to closely match the content of the revised booklet. Usability testing was conducted to obtain feedback regarding draft versions of the materials. The tools were also reviewed by a plain language expert and the interdisciplinary research team. Feedback on the content and presentation led to iterative modifications of the tools.

Results. The feasibility studies confirmed that the Internet was a viable medium, as the majority of men used a computer, had access to the Internet, and Internet use increased over time. Feedback from the usability testing on the length, presentation, and content of the materials was incorporated into the final versions of the booklet and website. Both the feasibility studies and the usability testing highlighted the need to address men's informed decision making regarding screening.

Conclusions. Informed decision making for PCa screening is crucial at present and may be important for some time, particularly if a definitive recommendation either for or against screening does not emerge from ongoing prostate cancer screening trials. We have detailed our efforts at developing print- and web-based DAs to assist men in determining how to best meet their PCa screening preferences. Following completion of our ongoing RCT designed to test these materials, our goal will be to develop a dissemination project for the more effective tool.

Accomplishments during this grant year: 1) As noted in our last report, we used the Choice Point system to run the names of all participants who were coded as could not reach (after 10 call attempts), whose number was disconnected, or whose invitation letter was returned due to a bad address to see if any new information had become available in the two years since we had been accruing participants. We were successful in obtaining new contact information and we recruited 40 participants in our last month of accrual helping us to achieve our goal of 1,893 participants. 2) We submitted a manuscript which is currently in the revise and resubmit phase describing the web-viewing behaviors of study participants assigned to this group. 3) Since our last annual report, the development paper which describes the process we undertook to redesign the booklet and develop the website was published (see the manuscript abstract in the Appendix). 4) Recently, Dr. Taylor was invited to present preliminary findings from the trial at the American Association for Cancer Research (see Appendix for presentation abstract). 5) Since the last report, we have also submitted two additional abstracts for this project. The first abstract was submitted to the Department of Defense's IMPACT meeting in which we described the short-term impact of our intervention on the primary outcomes of interest. The second abstract was submitted to the Society of Behavioral Medicine, which examined the impact the intervention had on screening preferences and actual screening behavior.

Below we have inserted the ongoing tasks from the original Statement of Work and indicated progress made on each item.

Task 1. Conduct participant accrual COMPLETED

- a. Eligible participants will be accessioned and the baseline interview will be administered by telephone. *This task is completed; we accrued 1,893 men to the protocol.*
- b. Participants will be randomly assigned to arm and the intervention materials distributed.--
Completed
- c. Data entry and quality control measures will be ongoing. *Completed.*
- d. The medical record abstract form will be finalized and the research assistant trained to obtain screening information from patient charts. *This task is underway. The research staff for this study sends 20 patient names at a time to the respective sites so that the staff at the sites can provide the patient's screening information from their medical records. To date, we have collected 663 medical records. .*

Task 2. Conduct follow-up assessments: ONGOING

- a. The Time 1 assessment will be conducted and the interventions will be distributed to participants. *Completed.*
- b. The Time 2 interviews will be conducted at 1 month post intervention. *Completed.*
- c. The Time 3 interviews will be conducted at 12 months post intervention. *Underway. To date, we have completed 1,235 time 3 interviews and there are 380 participants remaining to be contacted for the final assessment. We anticipate being completed with these remaining follow-ups by March 2011.*

Task 3. Preliminary data analyses and baseline manuscript. ONGOING

- a. Preliminary statistical analyses of data obtained from interviews and medical records will be performed periodically. *We have conducted preliminary analyses of the short-term impact of our interventions and have submitted these findings to 2 upcoming conferences and have presented the findings at the AACR meeting in November.*
- b. Annual reports will be written.
- c. A manuscript from the baseline interview will be written and submitted. *We are currently preparing a manuscript of the baseline and one-month outcomes for this project and plan to submit the paper in the coming months.*

Task 4. Final analyses and manuscript preparation. UNDERWAY

- a. Final analyses of data from interviews and medical record abstractions will be performed. *Although the final analysis of this data has not yet begun, we have checked and cleaned all data to date. The only remaining data to be cleaned will be the 380 final follow-up interviews we complete in the next few months. Once those are done, we will be ready to begin the final analyses for this project.*
- b. A final report and manuscripts will be written and submitted. *The NCI grant that also funds this project will be in a no cost extension for the following year and will cover the completion of this work.*

Key Research Accomplishments

- 1) Revised Print Booklet (included in last year's annual report)
- 2) Website: The address of the website is www.prostatedecision.org and the Username is Guest and the Password is Guest1235.

Reportable Outcomes : Please see PDFs of the 3 papers attached.

Davis, K., Haisfield, L., Dorfman, C., Krist, A., Taylor, K. (in press). Physicians' Attitudes About the Shared Decision Making Process for Prostate Cancer Screening. Family Medicine.

Dorfman, C., Williams, R.M., Kassan, E.C., Red, S.N., Dawson, D.L., Tuong, W., Parker, E.R., Ohene-Frempong, J., Davis, K.M., Krist, A.H., Woolf, S.H., Schwartz, M.D., Fishman, M., Cole, C., and Taylor, K.L. (2010). The Development of a Web- and a Print-Based Decision Aid for Prostate Cancer Screening. BMC Medical Informatics and Decision Making, 10:12.

Kassan, EC, Williams, RM, Kelly SP, Penek, S, Barry, SA, Fishman, MB, Cole, CA, Miller, EM, Taylor, KL. (in press). Primary care patients' use of an Internet-based prostate cancer screening decision aid: Characteristics of users vs. non-users and comparisons of electronic tracking vs self-reported website use. In press. Journal of Health Communication.

Taylor, K., Williams, RM, Davis, KM, Schwartz, MD, . Barry, SA, Penek, S, Luta, G, & Kelly, S. (2010). Decision making in prostate cancer screening. AACR Frontiers in Cancer Prevention Research, Philadelphia, PA, November 2010.

Taylor, K., Williams, RM, Davis, KM, Schwartz, MD, Barry, SA, Penek, S, & Luta, G, Kelly, S. (2010). Preferred and Actual Screening Outcomes from an RCT of Web and Print-Based Decision Aids on Prostate Cancer Screening. Submitted for Presentation at the annual meeting of the Society of Behavioral Medicine, Washington, DC, April 2011.

Taylor, K.L., Williams, RM, Davis, KM, Schwartz, MD, Barry, SA, Penek, S, Kelly, KP, Fishman, MB, Cole, CA Miller, E. (2011). Prostate Cancer Screening Education Study: A Randomized Controlled Trial. Accepted for presentation at the DoD IMPaCT: Innovative Minds in Prostate Cancer Today Conference March 2011, Orlando, FL.

Conclusions

Based on our preliminary analyses, we have found that our intervention materials (booklet and website) were effective in increasing knowledge and decreasing decisional conflict in comparison to the usual care participants. Additionally, participants' immediate screening preferences were reduced by the materials. However, men's long-term screening preference, self-reported screening, and actual screening were not impacted. Based on these promising results, we have submitted two abstracts and presented our findings at the recent AACR conference. In addition to these data, since our last report, the physician study paper, the web-viewing paper, and the development process of the materials paper have been accepted.

Plans

1) Continue completing the remaining 380 final follow-up assessments needed to complete data collection for this study 2) work on the manuscript describing the preliminary analyses, and 3) continue to clean and check the data so that we will be ready to begin final analyses as soon as the data collection period is over. 4) As our data indicate that the website and print booklet are equally effective at increasing knowledge and reducing decisional conflict, the next step will be to determine the most efficient way of distributing this information. We plan to write a grant proposal in order to conduct the next phase of this research, a dissemination study of the website and/or print booklet. We plan to submit proposal this in the next several months.

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Appendix

- 1) Complete physician study manuscript (in press)
- 2) Complete web-viewing manuscript (in press)
- 3) Development process paper (published)
- 4) Presentation abstract from AACR annual meeting
- 5) Abstract of the primary outcomes accepted to the DoD Impact meeting
- 6) Abstract of the preferred and actual screening outcomes submitted to the SBM meeting

Taylor, K., Williams, RM, Davis, KM, Schwartz, MD, Barry, SA, Penek, S, Luta, G, & Kelly, S. (2010). Decision making in prostate cancer screening.

Background: Prostate cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death. However, screening asymptomatic men remains controversial, as early diagnosis and treatment of PCa has not yet been definitively demonstrated to reduce disease-related mortality in a randomized trial. The primary question is whether PCa screening results in overdiagnosis, the detection and treatment of disease that would not otherwise result in increased morbidity or mortality. Ongoing trials are addressing this question, but the final results will not be available for several years. Further, if the trials do not provide a definitive recommendation for or against screening, the question will persist.

The difficulty of making medical decisions prior to the availability of definitive outcome data has been a long-standing issue in cancer screening and is likely to become increasingly important as screening technology advances more rapidly than our ability to validate it. Thus, widely applicable approaches to health education are needed in order to facilitate informed decision making about the growing number of unproven treatment and screening technologies, of which PCa screening is a prime example. Despite the PCa screening controversy, the practice of screening asymptomatic men is increasing in the U.S. and men are increasingly committed to screening. Most men who undergo PCa screening are unaware of the controversy and believe that the medical community unequivocally accepts the benefits of screening. One approach to improving informed consent for PCa screening is the development, evaluation and dissemination of patient education materials and decision aids.

Abundant evidence documents the expanding role of the Internet in increasing access to and understanding of health information. . However, systematic evaluations of Internet-based interventions are needed to address questions regarding the accessibility and efficacy of this mode of health education, particularly among older adults, persons without a college education, and minority participants. We conducted a randomized clinical trial to test the effectiveness of widely accessible and disseminable methods to assist men in making informed decisions about PCa screening . The goal of this research program is neither to encourage nor discourage PCa screening, but instead is designed to assist patients in making an informed decision until the definitive data on screening effectiveness are available.

Method: This study included male outpatients aged 45 to 70 from two Washington DC area hospitals and an outpatient group practice (N = 1,893). Trial arms included: 1) print-based information and a decision aid (Print; N = 630), 2) web-based information plus an interactive decision aid (Web; N = 631), and 3) usual care (UC; N = 632). Subjects completed outcome assessments at baseline, one- and 13-months post-baseline. The primary outcomes of interest were knowledge, decisional conflict, decisional satisfaction, health-related quality of life, screening preferences, screening intentions and screening behavior.

Results: Participants were a mean age of 57, 40% were African American, and 70% had been screened for PCa within 12 months prior to the baseline assessment. We assessed the short-term (one-month) impact of the educational interventions on knowledge, decisional conflict, and decisional satisfaction. Multivariate analyses revealed a significant improvement in knowledge for the Print and Web groups at the one-month assessment in comparison to the UC group ($F(2,1630) = 119.4, p = .000$). Regarding decisional conflict, the Web (OR = .449 (.341, .591)) and Print (OR = .464 (.352, .611)) arms were less likely than the UC group to report high decisional conflict at the one-month follow-up. There was no significant impact on satisfaction with the screening decision between the three study groups. We will also present findings on the short-term impact of the interventions on screening preferences and screening intentions, as well as the long-term (13-months) impact on prostate cancer screening behavior.

Conclusions: Both the Print- and Web-based tools significantly impacted short-term outcomes by increasing knowledge and reducing decisional conflict relative to the UC arm. However, contrary to prediction, there were no group differences in decisional satisfaction. This was likely due to a ceiling effect, as all groups reported a very high level of decisional satisfaction at both assessments.

We have developed and tested two methods of patient education that are easily disseminable in real-world settings. These methods are effective and could improve clinical care by providing an easily adaptable way to provide patients with the information needed to assist them in making an informed decision about PCa screening. The next step of this research is to conduct a dissemination trial to determine the most cost-effective method of educating large groups of men about PCa screening so that they may make the best screening decision for themselves, until there is a definitive recommendation either for or against screening.

DoD Impact Meeting, March 2011:
Prostate Cancer Screening Education Study: A Randomized Controlled Trial
Proposal Number PC051100, Award Number W81XWH-06-1-0182

Kathryn L. Taylor, Ph.D., Randi M. Williams, MPH, Kimberly M. Davis, PhD, Marc D. Schwartz, PhD, George Luta, PhD, Samantha A. Barry, BA, Sofiya Penek, BA, Scott P. Kelly, MS, Mary B. Fishman, MD, Carmella A. Cole, MD, Edward M. Miller, MD

Background and objectives: Prostate cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death. However, the utility of screening asymptomatic men remains unclear, as it has not yet been definitively demonstrated that it reduces disease-related mortality. The difficulty of making medical decisions prior to the availability of definitive outcome data has been a long-standing issue in cancer screening and is likely to become increasingly important as technology advances more rapidly than our ability to validate it. Thus, widely applicable approaches to health education are needed in order to facilitate informed decision making about the growing number of unproven screening technologies. The purpose of this study was to test the effectiveness of widely accessible and disseminable methods to assist men in making informed decisions about PCa screening (PCS). This abstract describes the preliminary outcomes of this trial.

Method: This study included male outpatients aged 45 to 70 from two Washington DC area hospitals and an outpatient group practice (N = 1,893). Trial arms included: 1) print-based information and decision aid (Print; n = 630), 2) web-based information plus interactive decision aid (Web; n = 631), and 3) usual care (UC; n = 632). Subjects completed outcome assessments at baseline, one- and 13-months post-baseline. The primary outcomes of interest were knowledge, decisional conflict, decisional satisfaction, health-related quality of life, screening preferences, and screening behavior.

Results: Participants were a mean age of 56.9 (SD = 6.8), 40% were African American, and 69.5% had been screened for PCa within 12 months prior to the baseline assessment. In this analysis, we assessed the short-term (one-month) impact of the educational interventions on knowledge, decisional conflict, and decisional satisfaction. The multivariate analyses revealed a significant improvement in knowledge for the Print and Web groups at the one-month assessment in comparison to the UC group ($F(2,1630) = 119.4, p = .000$). Regarding decisional conflict, the Web (OR = .449 (.341, .591)) and Print (OR = .464 (.352, .611)) arms were less likely than the UC group (reference category) to report high decisional conflict at the one-month follow-up. There was no significant difference in satisfaction with the screening decision between the three study groups. We will also present the long-term (13-months) impact of the interventions on the actual PCS choice.

Conclusions: In this preliminary analysis, both the Print- and Web-based tools significantly impacted short-term outcomes by increasing knowledge and reducing decisional conflict relative to the UC arm. However, contrary to prediction, there were no group differences in decisional satisfaction. All groups reported a very high level of decisional satisfaction.

Impact Statement: We have developed and tested two methods of patient education that are easily disseminable in real-world settings. Based on our initial findings, these methods are effective and could improve clinical care by providing an easily adaptable way to provide patients with the information needed to assist them in making an informed decision about PCS. The next step in this research will be to conduct a dissemination trial to assess the uptake of these materials and the most cost-effective method of educating large groups of men about PCS.

Society of Behavioral Medicine Abstract (April 2011)

RCT of Web- and Print-Based Decision Aids for Prostate Cancer Screening: Actual and Preferred Screening Outcomes

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Background: Screening asymptomatic men for prostate cancer (PCa) remains controversial, as early diagnosis and treatment has not yet been definitively demonstrated to reduce disease-related mortality. We have assessed the impact of print- and web-based decision aids (DA) on knowledge, screening preference, self-reported screening, and screening verified by medical records. **Method:** Men were aged 45-70 from three Washington DC outpatient practices (N = 1,893). Trial arms were: 1) print information + DA (Print; N=630), 2) web information + interactive DA (Web; N=631), and 3) usual care (UC; N=632). Subjects completed telephone assessments at baseline (T0), one-month (T1; N = 1680; 89%) and 13-months (T2; N = 1067; 86%; T2 data collection ongoing) post-baseline. **Results:** Subjects were 57 yrs (SD = 6.8), 40% were AA, and 70% were screened for PCa in the year prior to the T0. Multivariate analyses revealed a significant improvement in knowledge for the Print and Web arms relative to UC at the T1 ($F(2,1630) = 119.4, p < .001$) and at the T2 ($p < .001$). Men's preference to be screened declined from T0 to T1 in the Print and Web arms relative to UC ($X^2(N=1672) = 14.2, p < .01$). However, this finding was not significant at the T2 assessment ($p > .70$). Similarly, neither T2 self-reported screening ($p > .20$) nor T2 actual screening ($p > .20$) were associated with trial arm. **Conclusions:** Men's immediate and long-term PCa knowledge was significantly improved by both of the DAs, and their immediate screening preference was also reduced by the DAs. However, men's long-term screening preference, self-reported screening, and actual screening were not impacted. Improving men's understanding of the limitations of PCa screening does not appear to influence their long-term screening preferences or behavior. This may be associated with having undergone routine, annual screening, as well as men's need to 'do something' about PCa, regardless of the available evidence.

RESEARCH ARTICLE

Open Access

The development of a web- and a print-based decision aid for prostate cancer screening

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Abstract

Background: Whether early detection and treatment of prostate cancer (PCa) will reduce disease-related mortality remains uncertain. As a result, tools are needed to facilitate informed decision making. While there have been several decision aids (DAs) developed and tested, very few have included an exercise to help men clarify their values and preferences about PCa screening. Further, only one DA has utilized an interactive web-based format, which allows for an expansion and customization of the material. We describe the development of two DAs, a booklet and an interactive website, each with a values clarification component and designed for use in diverse settings.

Methods: We conducted two feasibility studies to assess men's (45-70 years) Internet access and their willingness to use a web- vs. a print-based tool. The booklet was adapted from two previous versions evaluated in randomized controlled trials (RCTs) and the website was created to closely match the content of the revised booklet. Usability testing was conducted to obtain feedback regarding draft versions of the materials. The tools were also reviewed by a plain language expert and the interdisciplinary research team. Feedback on the content and presentation led to iterative modifications of the tools.

Results: The feasibility studies confirmed that the Internet was a viable medium, as the majority of men used a computer, had access to the Internet, and Internet use increased over time. Feedback from the usability testing on the length, presentation, and content of the materials was incorporated into the final versions of the booklet and website. Both the feasibility studies and the usability testing highlighted the need to address men's informed decision making regarding screening.

Conclusions: Informed decision making for PCa screening is crucial at present and may be important for some time, particularly if a definitive recommendation either for or against screening does not emerge from ongoing prostate cancer screening trials. We have detailed our efforts at developing print- and web-based DAs to assist men in determining how to best meet their PCa screening preferences. Following completion of our ongoing RCT designed to test these materials, our goal will be to develop a dissemination project for the more effective tool.

Trial Registration: NCT00623090

Background

Prostate cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death [1,2]. While research has shown that PCa screening can find cancer at its earliest stages, it is uncertain whether early detection and treatment of PCa

leads to a reduction in disease-related mortality [3,4]. Preliminary results from two large randomized controlled cancer screening trials (RCTs) have recently been published [5,6]. While one trial found a 20% reduction in death from PCa as a result of screening [6], findings from the other trial showed no significant reduction in disease-related mortality [5]. Given these inconclusive results, the uncertainties regarding screening continue. The final mortality results from these trials will not be available for several years.

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The challenge of making medical decisions prior to the availability of definitive outcome data has been a long-standing issue in cancer screening [7-9] that is likely to become increasingly important as advances in screening technology outpace our ability to validate effectiveness [10-14]. Currently, there is no national standard of care with regard to PCa screening and national medical organizations differ in their screening recommendations [15-21]. However, most recommend that men learn about the pros and cons of PCa screening in order to reach an informed decision [16-19,21]. Thus, widely applicable and easily disseminable approaches to health education are needed [22].

Informed decision making occurs when individuals understand the benefits, risks, alternatives and uncertainties surrounding a medical condition or procedure and are able to use this information in conjunction with their preferences to make a decision that is consistent with those preferences [23]. One approach to promoting informed decisions for PCa screening is the use of patient education materials and decision aids (DAs). The goals of DAs are to foster informed health decisions by: 1) providing facts about the condition and procedures; 2) helping patients to clarify personal preferences and values; and 3) encouraging discussions with medical professionals to guide health decisions that match these preferences [24]. DAs are considered particularly useful when efficacy is unclear, outcomes are uncertain, and/or subjective judgments about benefits and risks are required [24]. Cancer screening-related DAs are particularly important because they have been found to increase cancer-related knowledge without increasing anxiety [25].

Increasingly, cancer screening decision tools have begun to utilize the Internet [26-31]. Despite the digital divide and differences in Internet use among different age and racial groups [32], the percentage of Americans who use the Internet is continuing to grow [33,34]. Internet users who access medical or health information have also increased between 2001 and 2007, from 66% to 76% for those aged 50 to 64 and from 60% to 71% for those over 65 [32]. These trends suggest that the Internet has vast potential as a widely accessible approach to delivering decision support materials for PCa screening.

The most recent systematic review of DAs for PCa screening was published in 2007, which presented the findings of 12 RCTs [35]. While we did not conduct our own systematic review, we used the same Medline search criteria used in Volk's review ('prostate cancer' and 'decision making') to locate RCTs published since the review, between January 2007 and June 2009. We located an additional six trials [27-29,36-38], and thus there have been a total of 18 published RCTs evaluating

materials designed to improve informed decision making regarding PCa screening [26-29,36-49]. These trials have assessed print, verbal, Internet, video and interactive computer-based PCa screening DAs. We have provided a summary of these 18 published RCTs (see Additional File 1). Quasi-experimental studies [50-54], abstracts, and studies evaluating DAs designed to increase PCa screening were excluded from our summary. Of the 16 trials that assessed knowledge, all reported a significant improvement. However, inconsistencies were seen among the trials with respect to changes in decisional conflict, screening behavior, intent to screen, and active participation in the screening decision (see Additional File 1).

Although these were well-conducted trials, there were several limitations in the development and evaluation of these DAs. First, only 5 of the 18 studies [27,38,40-42] included a values clarification component to assist men in integrating the information and elucidating their preferences about PCa screening. This may explain why most studies reported only a modest improvement in participants' knowledge, or modest reductions in decisional conflict [27-29,37,40,41,43-46,48]. Second, of the 4 web-based DAs, only one [27] utilized an interactive format, while the other studies with web-based interventions did not exploit the strengths of this medium [26,28,29]. Third, while one web-based tool utilized a tracking mechanism to monitor whether participants viewed the website [27], that study did not determine whether the amount of time spent and topics accessed on the site impacted outcome measures. Fourth, several of the studies reporting pre- and post-intervention evaluations had a brief follow up period of less than 1 month, thereby limiting the understanding of the long-term impact of the interventions on screening behavior and other outcomes [28,38,40,41,43,44]. Finally, only 4 of the RCTs included a substantial number of African American (AA) men, who are at greatest risk for PCa [36,38,42,45].

Our goal was to extend these prior studies by developing two new patient DAs, a booklet and an interactive web-based tool, that could be utilized in a variety of settings. We sought to create widely disseminable and relevant materials that would improve PCa knowledge and assist a heterogeneous population of men in making informed screening decisions. We incorporated a values clarification component into each DA, which is intended to help individuals determine their personal preferences and beliefs about PCa screening and to make informed choices in accordance with those preferences. We are currently conducting a three arm RCT (including a usual care arm) to assess the efficacy of these tools among a diverse sample of men accrued from primary care clinics. This paper describes the development and

content of these two DAs, including a description of our prior feasibility studies and randomized trials, each of which contributed to the evolution of these tools.

Methods

Development of Decision Aids

The development of the booklet and website was guided by two print booklets we had previously created and evaluated (Studies 1 and 2). Further, we conducted two feasibility studies and usability testing to confirm the viability of developing and testing a web-based decision tool (Study 3). All studies were approved by the Georgetown University/Medstar Oncology Institutional Review Board.

Study 1- *The Right Decision is Yours: A Guide to Prostate Cancer Check-ups*

Our initial version of the booklet was developed in collaboration with the Most Worshipful Prince Hall Grand Lodge of the District of Columbia (Masons) and was targeted to AA men and their spouses [55]. We conducted eight focus groups (N = 44) with AA men between the ages of 40 and 70 to determine the target population's informational needs and to guide the content and format of the booklet. We conducted two additional focus groups with internists, family physicians, and urologists to obtain input about factual information to include in the booklet.

Thematic analyses of transcripts of the lay focus groups, along with input from the physicians and guidelines of the Centers for Disease Control and Prevention for the development of educational materials (i.e., clear presentation, logical sequence, ease in understanding, and interesting, familiar, realistic, positive images) aided in the creation of pilot materials [55,56]. We modified the pilot materials based on iterative feedback from focus groups, members of the Prince Hall Masons, and the entire project team.

The end product, completed in May 2000, was a 16-page educational booklet entitled *The Right Decision is Yours: A Guide to Prostate Cancer Check-ups* and targeted specifically to AA men [55,57]. We found that the print intervention increased knowledge and reduced decisional conflict when compared to videotape and control conditions, and that screening behavior was not associated with either of the interventions [45].

Study 2- *Prostate Cancer Screening: Making an Informed Decision*

In our next study, we revised the above booklet to target men of all ethnic and racial backgrounds. The additions to the content were adapted from a Centers for Disease Control and Prevention educational tool [58] and provided information about the leading causes of death among men, the accuracy of the prostate-specific

antigen (PSA) test, and the treatment decisions that need to be considered when PCa is diagnosed.

Additionally, we included a 10-item values clarification component (adapted from Gattellari and Ward, 2003) [40] to help participants weigh the relative benefits and risks of screening. The balance sheet consisted of five items that addressed the benefits of screening (e.g., "I am worried about PCa and screening may give me peace of mind") and five items that addressed the limitations of screening (e.g., "I do not want to risk finding out I have cancer when it may never bother me"). Participants were asked to consider each item and indicate those 'that sound like you.' The purpose of the exercise was to provide men with a descriptive rather than a prescriptive summary of the screening objectives that were important to them. Their response patterns suggested whether they were leaning toward or away from getting screened.

We conducted 8 usability testing sessions with 3-4 men per session (total N = 29; 74% AA, 22% White, and 4% of Caribbean/West Indian descent; age 40-70). The majority of participants were recruited from fliers posted at Georgetown University Hospital (GUH), Howard University Hospital, the National Prostate Cancer Coalition, and the local fire department. Participants provided feedback on the style and method of presentation of the information to ensure that the booklet addressed relevant topics and that the uncertainty surrounding screening was addressed in a balanced manner. Further, participants gave their opinion of the values clarification component and suggested ways to improve the balance sheet.

Based on the usability testing findings and research team recommendations, a plain language specialist was consulted to ensure that the DA did not exceed an 8th grade reading level. The end product, a 24 page booklet entitled *Prostate Cancer Screening: Making an Informed Decision*, was completed in July, 2004. We evaluated the booklet in a RCT among men who were registered to undergo free screening [59], comparing this booklet to the PSA question and answer fact sheet developed by the National Cancer Institute [60]. Similar to Study 1, exposure to the DA resulted in a significant increase in knowledge and a decrease in decisional conflict but no change in screening behavior.

Study 3- *Prostate Cancer Screening: Making the Best Choice Overview* The development of our final set of materials was conducted in several steps. We conducted two studies to assess the feasibility of an Internet-based PCa screening decision tool. Next, we drafted both the new booklet and the website based on the materials described in Studies 1 and 2. Finally, we conducted usability testing to obtain feedback on our draft materials.

Feasibility Studies We sought to gain an understanding of our target population's access to and knowledge of the Internet. To do this, we conducted two feasibility studies with men accrued from the primary care clinics at two Washington, DC teaching hospitals, GUH and the Washington Hospital Center (WHC), the accrual sites for the target population in the ongoing RCT. GUH and WHC serve different populations with regard to race/ethnicity and socioeconomic backgrounds. GUH serves a racially diverse and middle to upper-middle class patient population, while WHC serves a largely AA patient population of predominately lower- to middle-class socioeconomic status.

We conducted feasibility studies with patients from both hospitals to determine how our materials should be tailored in order to meet the needs of each group. The feasibility studies were conducted 18 months apart to examine how Internet access and use changed among this population of men over time (January 2005 and June 2006). For each study, men between the ages of 45 and 70 without a previous diagnosis of PCa were accrued from the waiting rooms of the primary care clinics at GUH and WHC. Participants completed a brief survey that contained questions about sociodemographic information, PCa screening knowledge, and typical Internet use (see Table 1 for the sample description) (See Additional file 2). In the second study, we added the Newest Vital Sign component, a measure of medical literacy, to the questionnaire (See Additional file 3) [61].

Development of the Booklet and the Website The study team and consultants first drafted a new version of the booklet. The primary differences from the prior booklet included both substantive changes (e.g., additional information on screening recommendations, different methods of PSA measurement, and additional figures and statistics) as well as improved readability (e.g., layout changes, improved wording, adding text boxes to highlight main points, greater use of bulleted text, reordering of topics). At each step in the development process, members of our research team, including primary care physicians and researchers specializing in PCa screening education, reviewed and modified drafts of the booklet.

After finalizing the content of the new booklet, we began working with the web developers to design the website prototype. We provided them with both the draft form of the booklet and a list of website features to include or avoid, based on our review of several existing health websites. We sought to create a universally functional site by accommodating varying web-browsers (e.g., Internet Explorer, Safari), using Adobe Flash™ in the user interface, and using open source development tools to facilitate flexible site maintenance and support. The time required to load pages made the website

unsuitable for dial-up connections. However, the results of the second feasibility study confirmed widespread access to high-speed Internet, and we anticipated even greater broadband use after the completion of the randomized trial.

The booklet and website were edited by a plain language expert who provided guidance on the presentation of the information, including the use of parallel sentence construction, bolded headers and sub-headers to alert readers to changes in topic, the use of bulleted text and tabs on the right edge of the pages, and the inclusion of a detailed glossary that defined medical terms often misunderstood by laypersons. The presentation of content on the website was designed to improve its appeal to persons who may not be regular web-users. We omitted sections of text to increase readability and wrote the materials in the conditional tense to prevent the reader from misinterpreting the information. Importantly, we acknowledged men's uncertainty surrounding screening in an effort to help them consider information that conflicted with their prior beliefs. Both the booklet and the website were written at or below an 8th grade reading level based on the Fleish-Kincaid grade level formula [62].

The development of these materials was also guided by criteria from the International Patient Decision Aid Standards (IPDAS) Collaboration, a worldwide group of health-care practitioners and researchers who have developed standards for DAs [63]. IPDAS standards help researchers create DAs to prepare patients to have conversations with their physicians about medical tests and procedures [64].

Booklet Usability testing We recruited participants (N = 14) from GUH and WHC primary care clinic waiting rooms, from fliers placed in surrounding neighborhoods, and from a General Education Development center to ensure inclusion of men with limited literacy. Men were eligible if they were 45-70 years old and had not had PCa. Participants reviewed the booklet in our research offices (N = 6), as well as the clinic waiting room (N = 7) and their own home (with follow-up to discuss his feedback; N = 1) in order to accommodate their schedules.

At the start of each session, one to two members of the research team held a brief discussion with participants regarding their prior experiences with screening to ensure that no one had had unusual experiences that would impact their feedback. Participants then individually reviewed the booklet and completed a brief questionnaire concerning their opinions of the DA, their overall health, and demographic information (See Additional file 4). Moderators noted participants' recommendations for modifications to the text, graphs, figures, and their impressions of the overall message of the DA.

Table 1 Feasibility Study 1, January 2005

	GUH (N = 34)	WHC (N = 21)	Total (N = 55)
Age (N = 55)	M = 55.4 SD = 8.2	M = 53.7 SD = 6.7	M = 54.7 SD = 7.6
Race/Ethnicity #			
White (N = 19)	50%	10.5%	35.8%
African American (N = 30)	38.2%	89.5%	56.6%
Other (N = 4)	11.8%	0	7.5%
Education			
< HS grad (N = 14)	20.6%	33.3%	25.5%
Voc/trade or some college (N = 12)	14.7%	33.3%	21.8%
College Graduate (N = 7)	20.6%	0	12.7%
Graduate work/degree (N = 22)	44.1%	33.3%	40.0%
Marital Status			
Married (N = 37)	70.6%	61.9%	67.3%
Other (N = 18)	29.4%	38.1%	32.7%
Internet access at home/work			
Yes (N = 41)	82.4%	61.9%	74.5%
No (N = 14)	17.6%	38.1%	25.5%
Home/Work Computer Internet Usage (among those with access at home/work)			
Few times yr/few times month (N = 7)	7.1%	38.5%	17.1%
Once/twice a wk (N = 5)	14.3%	7.7%	12.2%
Daily (N = 29)	78.6%	53.8%	70.7%
Receiving Health Related Information #			
Prefers Internet (N = 23)	47.1%	36.8%	43.4%
Prefers Booklet (N = 30)	52.9%	63.2%	56.6%
Willingness to Read Prostate Cancer Info on the Internet #			
Definitely/Probably would (N = 42)	76.5%	84.2%	79.3%
Definitely/Probably would not (N = 11)	23.5%	15.8%	20.7%
Awareness of Disagreement in Medical Community Regarding Whether to Screen for PrCa			
Unaware of disagreement (N = 45)	82.4%	81.0%	81.8%
Aware of disagreement (N = 4)	2.9%	14.3%	7.3%
Not Sure (N = 6)	14.7%	4.8%	10.9%

N = 2 subjects with missing data

GUH = Georgetown University Hospital, WHC = Washington Hospital Center

Our intention was not to conduct traditional qualitative analyses, as we had previously done in Study 1 [55]. The majority of the content was decided upon from the previous versions of our materials and through updates gained from the CDC [58]. We conducted the usability testing to assess men's reactions to the presentation of the materials. The usability testing concluded with a brief questionnaire that inquired about men's opinions of the materials and demographic information.

Website Usability testing Participants for the usability testing were again recruited from GUH and WHC primary care clinics. Usability testing of the website involved the same recruitment method and protocol described above for the booklet usability testing. However, all but one session was conducted in our research offices. Following the consent process, we provided an explanation of the rationale for the website and then asked participants to individually review the proposed

website content. As in the booklet usability testing, website usability testing sessions were not recorded. However, one to three members of the research team observed each participant during the review process to look for navigation and usability issues and take note of verbal comments made by participants. The meetings ended with an informal discussion and a questionnaire to assess participants' thoughts, likes, and dislikes of the materials (See Additional file 5).

Results

Feasibility Studies

Sample

For the initial feasibility study (January 2005), 55/58 (95%) men agreed to participate. The mean age of participants was 54.7 (SD = 7.6), with a little over half of the men reporting that they were AA (Table 1).

The second feasibility study (June 2006) had a participation rate of 83% (99/119). The sociodemographic characteristics of these participants were virtually identical to that of the first feasibility study (see Table 2), with a mean age of participants of 54.6 (SD = 7.4) and just over half AA.

Results

Responses to the first feasibility study indicated that, regarding PCa screening knowledge, 97.1% of men at GUH and 85.7% at WHC endorsed the belief that 'experts agree that all men should be tested for PCa.' This suggested a lack of understanding of the uncertainties surrounding screening. Overall, the majority of men with Internet access at home or work reported accessing the Internet a few times a week or daily (82.9%). Further, 79.3% of all men indicated they would 'probably' or 'definitely' read information about PCa on the Internet. We did not compare the two sites for statistically significant differences as the goal was simply to describe the men present at each site.

In the second feasibility study, a majority of men reported having Internet access at home or work (70.7%), and just over half reported preferring to receive health related information on the Internet (53.8%). The mean total score for the Newest Vital Sign scale was 3.9 (SD = 2.0) at GUH and 1.9 (SD = 1.8) at WHC. Scores on the Newest Vital Sign scale range from 0 to 6, with fewer than four correct answers indicating the possibility of limited literacy.

The feasibility studies identified the need for educational tools to improve men's knowledge of the uncertainties surrounding PCa screening. Responses to the Internet access and use questions confirmed that the Internet was a feasible medium for a widely accessible PCa screening educational tool. Although these were not representative samples, the data suggest that a majority of men had access to the Internet, and this

access was sustained over time. These results further supported and gave us confidence in our decision to create a website that used a broadband Internet connection (as opposed to a dial-up connection) in order to deliver more complex interactive and video features. Participants' scores on the Newest Vital Sign reinforced the need for a plain language specialist in developing text for the website and the booklet.

Booklet Usability testing

Sample

The mean age of participants (N = 14) was 53.8 (SD = 7.8). Half of the men were unemployed or retired and 71.4% were AA. Additional demographic information for these participants is presented in Table 3. Given the overlap between the groups of men who reviewed the booklet and the website (N = 6 reviewed both), we did not assess the potential differences between the two groups.

Results

Responses to the questionnaire are presented in Table 3. Half of the men reviewing the booklet indicated that it had about the right amount of information and was about the right length, but a substantial minority reported that it contained more information than they would have liked (42.8%) or was too long (35.7%). Despite our efforts to provide balanced information, a majority of men (71.5%) said that the overall message of the booklet was that they should probably or definitely get screened for PCa. Many participants indicated that they were unaware of the uncertainty surrounding PCa screening. This suggested that a single discussion of the uncertainty was not enough to impact men's understandings of this complex topic.

In general, men were positive about the booklet, but many provided suggestions for information they would like to have added (Table 4); the content and layout of the booklet were revised accordingly. For example, the values clarification component presented in the Study 2 booklet, containing a non-prescriptive balance sheet, was simplified based on feedback from usability testing participants (see Figure 1). Participants were asked to select which of 10 statements 'sound like you,' with five highlighting the benefits of screening and five highlighting limitations. Participants' responses were intended to indicate whether they leaned toward or away from screening. Because many men found the original questions to be complex, we tested multiple versions of the questions.

Table 5 summarizes the booklet content and discusses the similarities and differences between the booklet and the web-based DA. We maintained consistency between the content of the booklet and website but note differences related to the interactive features of the web-based tool.

Table 2 Feasibility Study 2, June 2006

	GUH (N = 50)	WHC (N = 49)	Total (N = 99)
Age (N = 98) #	M = 53.9 SD = 7.5	M = 55.2 SD = 7.3	M = 54.6 SD = 7.4
Race/Ethnicity †			
White (N = 35)	52.0%	20.0%	36.8%
African American (N = 48)	28.0%	75.6%	50.5%
Other (N = 12)	20.0%	4.4%	12.6%
Education			
< HS grad (N = 25)	10.0%	40.8%	25.3%
Voc/trade/some college (N = 19)	10.0%	28.6%	19.2%
College Graduate (N = 18)	26.0%	10.2%	18.2%
Graduate work/degree (N = 37)	54.0%	20.4%	37.4%
Marital Status *			
Married (N = 53)	78.0%	29.8%	54.6%
Other (N = 44)	22.0%	70.2%	45.4%
Internet access at home/work			
Yes (N = 70)	92.0%	49.0%	70.7%
No (N = 29)	8.0%	51.0%	29.3%
Home/Work Computer Internet Usage (among those with access at home/work)			
Never/Rarely (N = 1)	0.0%	4.2%	1.4%
Few times per year/few per month (N = 4)	2.2%	12.5%	5.7%
Once a week/several times a week (N = 14)	17.4	25.0%	20.0%
Daily (N = 51)	80.4%	58.3%	72.9%
Receiving Health Related Information •			
Prefers Internet (N = 45)	66.0%	30.4%	48.4%
Prefers Booklet (N = 43)	25.5%	67.4%	46.2%
No preference (N = 5)	8.5%	2.2%	5.4%
Willingness to go to another location if no access to high-speed Internet connection? *‡			
Yes (N = 16)	33.3%	45.2%	43.2%
No/Not sure (N = 21)	66.7%	54.8%	56.8%
Newest Vital Sign (NVS) ^ (N = 99)	M = 3.9 SD = 2.0	M = 1.9 SD = 1.8	M = 2.9 SD = 2.2

#N = 1 subject with missing data

† N = 4 subjects with missing data

* N = 2 subjects with missing data

• N = 6 subjects with missing data

‡ Includes participants with slow-speed Internet access and no Internet access

^ Scores on the NVS range from 0 to 6, with fewer than four correct answers indicating the possibility of limited literacy

GUH = Georgetown University Hospital, WHC = Washington Hospital Center

Website Usability testing

Sample

Overall, 14 men reviewed the website, six of whom had previously reviewed the booklet. The mean age of participants was 54.0 (SD = 7.2). Despite the small sample size, half of the participants were AA and half were

employed. Additional demographic information for these participants is presented in Table 3.

Results

Based on the questionnaire data, one-half (50%) of the men said the site provided about the right amount of information and 42.9% said it was about the right

Table 3 Evaluation Data from Usability testing (Study 3)†

	Booklet N = 14	Web N = 14
Age	M = 53.8 SD = 7.8	M = 54.0 SD = 7.2
Race		
White	28.6%	50.0%
African American	71.4%	50.0%
Education		
<HS grad	21.4%	35.7%
Some college	42.9%	21.4%
College Graduate	14.3%	0.0%
Graduate work/degree	21.4%	42.9%
Marital Status		
Married/living as married	50.0%	35.7%
Not married	50.0%	64.2%
Employment Status		
Not employed/Retired	50.0%	50.0%
Employed	41.9%	50.0%
Health Insurance		
Yes	92.9%	78.6%
How often Screened		
3-6 months	7.1%	14.3%
Annually	50.0%	42.9%
Every 2 years	0.0%	0.0%
Don't know/Missing	42.9%	42.9%
Prior Abnormal Screening Result		
Yes	7.1%	7.1%
Amount of Information Provided		
Much/A little less info than wanted	7.1%	21.4%
About Right	50.0%	50.0%
A little more/a lot more info than wanted	42.8%	21.4%
Length of booklet/website		
Much too long/a little too long	35.7%	50.0%
About right	50.0%	42.9%
Wanted a little/much longer	14.2%	7.1%
Clarity		
Everything/most things clear	85.7%	92.9%
Some Clear	7.1%	7.1%
Many unclear	0.0%	0.0%
Missing data	7.2%	
Overall Message		
Definitely/Probably not screen	14.3%	14.3%
Neither	14.3%	35.7%
Definitely/Probably Screen	71.5%	42.8%

† No significance testing was conducted due to overlap between groups (6 men participating in web usability testing also participated in booklet usability testing)

length. Despite our efforts to ensure a balanced presentation of the issues, only 35.7% indicated that the website's overall message neither favored nor opposed PCa screening. Although far short of our goals, this was an improvement over our prior decision tools and over the current booklet (see Table 3). Anecdotal information

suggested that this viewpoint may be most prevalent among men who were screened regularly, as they may have taken note of the benefits of screening more so than the limitations. Table 4 describes revisions made to the website based on usability testing feedback. Changes related to content were made to both the website and booklet.

A primary concern during website development was whether men with little or no computer experience could successfully use the site. Based on difficulties experienced by three participants with little to no computer experience, several necessary modifications were made to the site to make it more user-friendly (Table 4). Difficulties in site navigation would have been overlooked if only computer savvy men had been sampled. While some men initially had trouble using the website, they were all ultimately able to successfully navigate the site and understand its content after viewing printed instructions.

Based on usability testing and recommendations from the research team, the web developers created several iterations of the website before a release candidate was created, approved, and launched. The website required 30-50 minutes to review and had a literacy level that did not exceed an eighth grade reading level. Importantly, the website aimed to present information in a balanced manner, neither encouraging nor discouraging screening. The web developers continue to provide ongoing technical support to ensure that team members and study participants do not encounter difficulties using the website.

Table 5 also provides details on the nine topic areas presented in the website as well as the booklet, including content features, similarities and differences with regard to the presentation of information, as well as a description of how general features differ between the two formats (e.g., audio vs. text, graphics). The final versions of the booklet and website, entitled *Prostate Cancer Screening: Making the Best Choice*, were completed in October 2007. The remainder of the Results section is devoted to the description of specific interactive features of the website.

Components of the Website

The interactive features of the website enabled an expansion and customization of the material. For example, web-users could access additional external information (e.g., the resource page included links to the homepages of national organizations that provide more information on PCa screening and treatments) or could use the table of contents to easily navigate to other sections of interest.

The website was made more accessible to men with limited literacy by presenting the majority of the text via voice over. Audio was available for approximately 70%

Table 4 Feedback and Subsequent Changes from Usability testing (Study 3)

Concern	Solution
Booklet Usability testing	
Questions about age- and race- adjusted PSA	- Sections added with this material
Complex material	- Plain language consultant was used - Changed in text based on comments from men - Used bullet points and short sentences
Complex DA questions	- Multiple versions of the DA questions were created and tested
Website Usability testing	
Little experience using the Internet	- Instructions and a troubleshooting packet provided to user - Instructions provided on the website
Complex material	- Used less text on each screen - Increased use of bullet points - Audio summarized what is on the page for the participant - New "vocabulary" words have a hyperlink to a pop-up with their definition
Figure of prostate looks "cartoon-like"	- Changed figure and other graphics to look more realistic
Some men commented that they would like to see audio on the pop-ups.	- Web developers and researchers decided that this would be too distracting; this suggestion was not implemented. - Audio was put on all main pages for consistency.

Below are issues to think about when making a decision about screening.

First, read the following sentences and check Yes or No for each one, depending on whether the sentence sounds like you or not. Then, look at all the sentences that you checked yes. See whether you lean more toward getting screened, or more toward not getting screened.

Men who have made these statements often decide to get screened.	Does this sound like you?	
	YES	NO
Getting screened will give me peace of mind about prostate cancer.		
Even though prostate cancer may never cause me any problems, I prefer to get screened so that I know whether I have prostate cancer.		
Getting screened will help me feel like I am doing everything I can do for my health.		
I understand that screening has not yet been proven to save lives. Even so, I prefer to get screened because I think it is better to be 'safe than sorry'.		
If I am screened and then diagnosed with prostate cancer, I will need to either accept living with untreated cancer or accept the side effects of treatment. Even so, I prefer to get screened because these potential consequences are worth the possibility of a longer life.		



Men who have made these statements often decide NOT to get screened.	Does this sound like you?	
	YES	NO
Since prostate cancer may never cause me any problems, I think I am better off <i>not</i> getting screened.		
Future research may demonstrate that getting screened helps men live longer. But, because we do not yet know for certain whether prostate cancer screening saves lives, I prefer to not get screened at this time.		
Screening may give an abnormal result when cancer is not present. It may also give a normal result when cancer is present. Therefore, I will wait until the screening test is more accurate before I get tested.		
Screening can cause a false positive result that leads to an unnecessary prostate biopsy. Therefore, I prefer to not get tested until the screening test is more accurate.		
If I am screened and then diagnosed with prostate cancer, I will need to either accept living with untreated cancer OR accept the side effects of treatment. These potential consequences would not be worth the possibility of a longer life. Therefore, I prefer to not be screened at this time.		

Adapted from Gattellari, M. & Ward, J.E. (2003).

Figure 1 Booklet Values Clarification Component (Adapted from Gattellari & Ward (2003)[40].

Table 5 Comparison of the Booklet and Web-based Educational Tools (Study 3)

Section	Summary of Content	Features/Differences between Booklet and Web
Title page & introduction	- Why you should read the material - Includes table of contents	- The website included a tutorial on how to use the program and its interactive features, such as video testimonials, pop-outs, and animated diagrams. - The website required participants to answer a question regarding their current beliefs about screening before they began reviewing the website. This question was followed by 2 tailored video testimonials. - The booklet table of contents was located on the second page, and the booklet included section tabs along the edges of the pages for easy access to specific topics. - The website table of contents was presented along the left side of each screen and allowed participants to select where to begin.
Know the basics about the prostate gland	- What is the prostate, types of prostate problems	- The first values clarification question was presented on the website.
Understand why there is no right or wrong choice about prostate cancer screening	- Definition of screening, description of screening tests, screening recommendations from national organizations - Information about whether screening will help men	- Two values clarification questions were presented on the website. - Two video testimonials were presented on the website.
Learn the facts about prostate cancer screening	- Steps involved in screening - Screening accuracy - Is screening right for you	- Four values clarification questions were presented on the website. - The website provided pop-out boxes with additional information about PSA testing (i.e. PSA velocity, race- and age- adjusted PSA, free vs. attached PSA). - The booklet had a tree branch diagram describing screening accuracy, while the website had an animated diagram with text and audio. - The booklet provided testimonial quotes from men who believed that screening was helpful and who questioned whether getting screened was helpful.
Facts you should know if prostate cancer is found—treatment issues	- Deciding whether to treat prostate cancer: the risks of engaging in watchful waiting and the risks of treating the cancer. - Information about Gleason Score, PIN, and over treatment - Treatment decisions and factors to consider - Types of active Treatment - Information about late stage prostate cancer - Side effects of treatment	- Three values clarification questions were presented on the website. - Two video testimonials were presented on the website. - The website included pop-outs discussing the side effects of active treatment for prostate cancer.
Steps you can take to make the best choice about whether to be screened for prostate cancer	- Know your risk factors: age, history, race, diet - Learn the symptoms - Talk with your doctor about screening—includes questions to consider when discussing screening with your doctor	- The website provided pop-outs with statistics about risk factors, symptoms, etc. (provided charts and graphs). - The booklet provided a space where men could write in questions they would like to ask their doctor about prostate cancer screening. - The website allowed for men to print out the questions to ask their doctor that have been provided and urged men to write down any additional questions they had.
Values Clarification Exercise	- Instructions for how to complete the worksheet	- The booklet presented the worksheet questions on two pages, separating statements from men who decided to get screened from men who have decided not to get screened.

Table 5: Comparison of the Booklet and Web-based Educational Tools (Study 3) (Continued)

	- The worksheet—includes 10 questions to determine if men are leaning towards or away from screening	- The website allowed men to review and change their answers to questions, and to view a results page with a balance beam diagram. The balance diagram showed participants if they leaned toward screening or against screening. Men could print a summary of their responses. - Values clarification questions were asked throughout the site and were located in sections corresponding to the content of the question.
Learn more about prostate cancer	- Charts and graphs about ways to measure PSA, disease incidence and mortality, concerns about active treatment for older men, and side effects from treatment	- The information that was seen in pop-ups earlier in the website was also available again at this point in the website, but the information was available in the booklet for the first time.
Additional sources for information about screening	- Glossary - References - Contact information for organizations	- The website provided hyperlinks to the websites of organizations that could provide men with further information about prostate cancer.
General features	- Audio vs. text - Pop outs vs. text boxes - Graphics - Testimonials	- Only the website allowed for audio. - The website featured pop-out boxes, while the booklet had text boxes highlighting important information. - There were more visual features and graphics on the website than on the booklet, due to the nature of the website's design. - The website presented 8 video testimonials, while the booklet presented 2 testimonial quotations.

of the text, and 80% of the audio matched the text verbatim. Users could deactivate the audio if they preferred to only read text.

The website included eight testimonials, prepresented as video clips of men speaking about their screening decision, whereas the booklet included written quotations from two men (one pro, one con). The videos enabled users to view the emotional reactions and facial expressions of the different actors as they relayed personal stories about PCa screening. We utilized actors that represented a racially diverse group of men in an effort to help make the information more relevant and understandable [31]. Of the eight video testimonials presented, 3 of the actors were AA, two were white, one was Asian, one was Native American, and one was Hispanic.

The interactive nature of the website insured that users were exposed to a perspective about PCa screening that differed from their own, in an effort to address the presence of a confirmation bias [65]. To do this, users indicated their history of screening, which was assessed upon entry into the website. The first two video testimonials were tailored so that a user who was leaning *toward* screening first viewed two testimonials of men who chose *not* to get screened, and vice versa for men leaning against screening. In subsequent sections of the website, the remaining six testimonials (3 pro, 3 con) were presented back to back so that

everyone viewed all 3 pairs. The race of the actors varied so that the pro and con messages were delivered by actors of different races.

The 10-item values clarification component described above for the booklet was also included on the website in an interactive format (Figure 2). Individual items were presented at the end of different content sections and users were prompted to respond: 'sounds like me,' 'does not sound like me' or 'not sure yet.' Questions that men skipped as they navigated through the site were automatically entered as 'not sure yet.' The questions were displayed again at the end of the website to provide men with an opportunity to change the response. Responses to all items were then depicted on a balance scale to help men determine if they leaned toward or away from getting screened. Finally, users always received a prompt to review the values clarification tool upon exiting the website; thus, it was seen by all men, even those who did not review the entire website.

The web-based format also allowed for animation and graphics to draw attention to key points and direct the user through the website. For example, a graphic of 100 men that illustrated the accuracy of the PSA test changed colors to distinguish subgroups from the whole and was accompanied by a voiceover that explained the figure (Figure 3). The booklet, however, provided a single tree diagram to depict the same statistics (Figure 4).

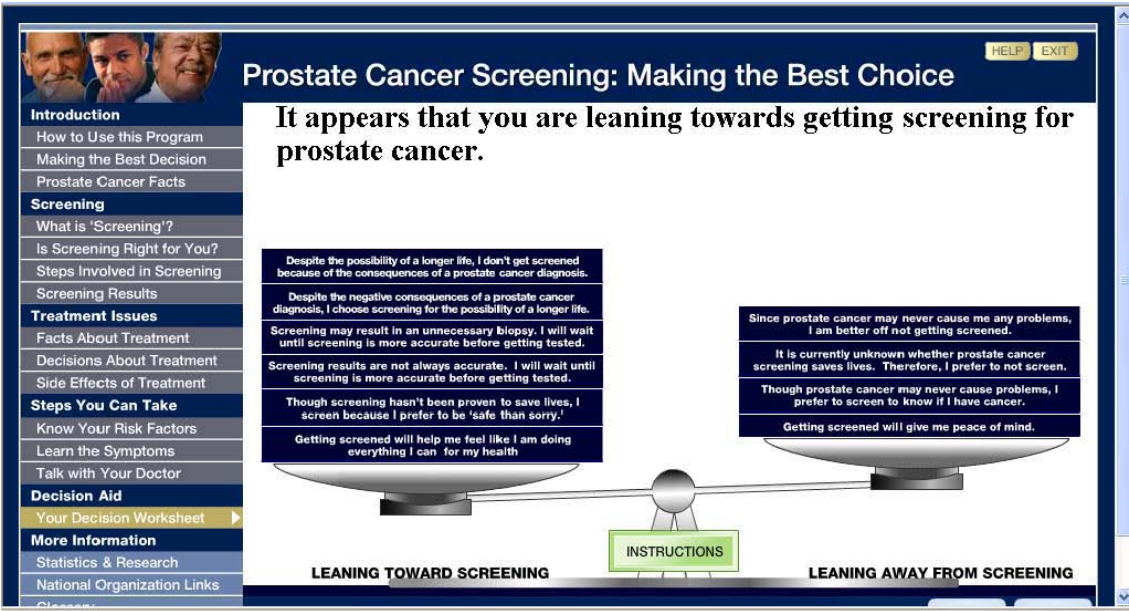


Figure 2 Website Values Clarification Component (Adapted from Gattellari & Ward (2003))[40].

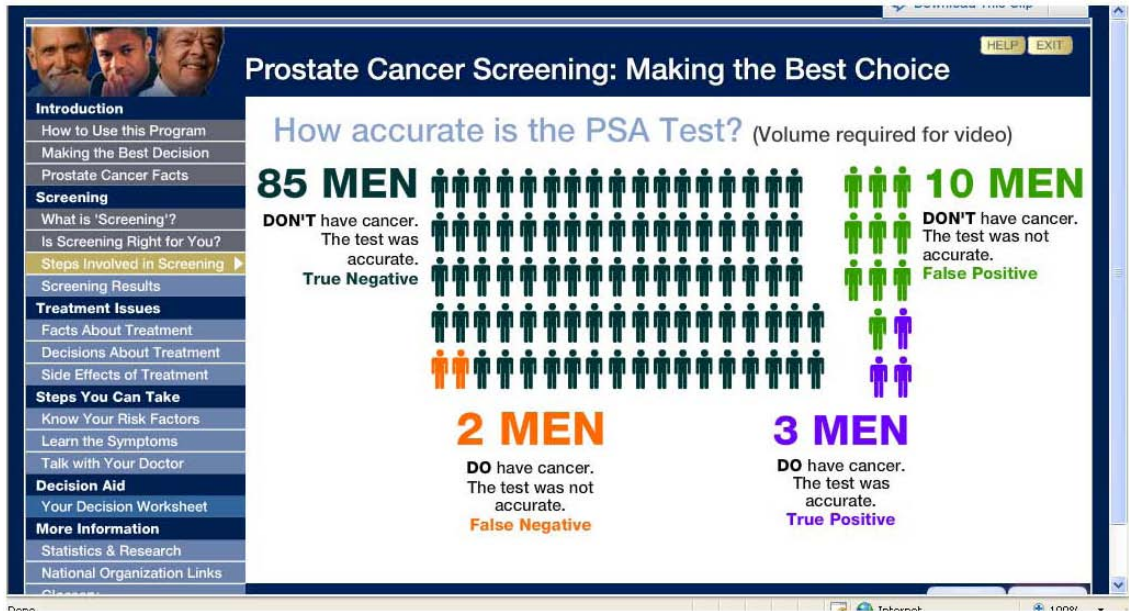


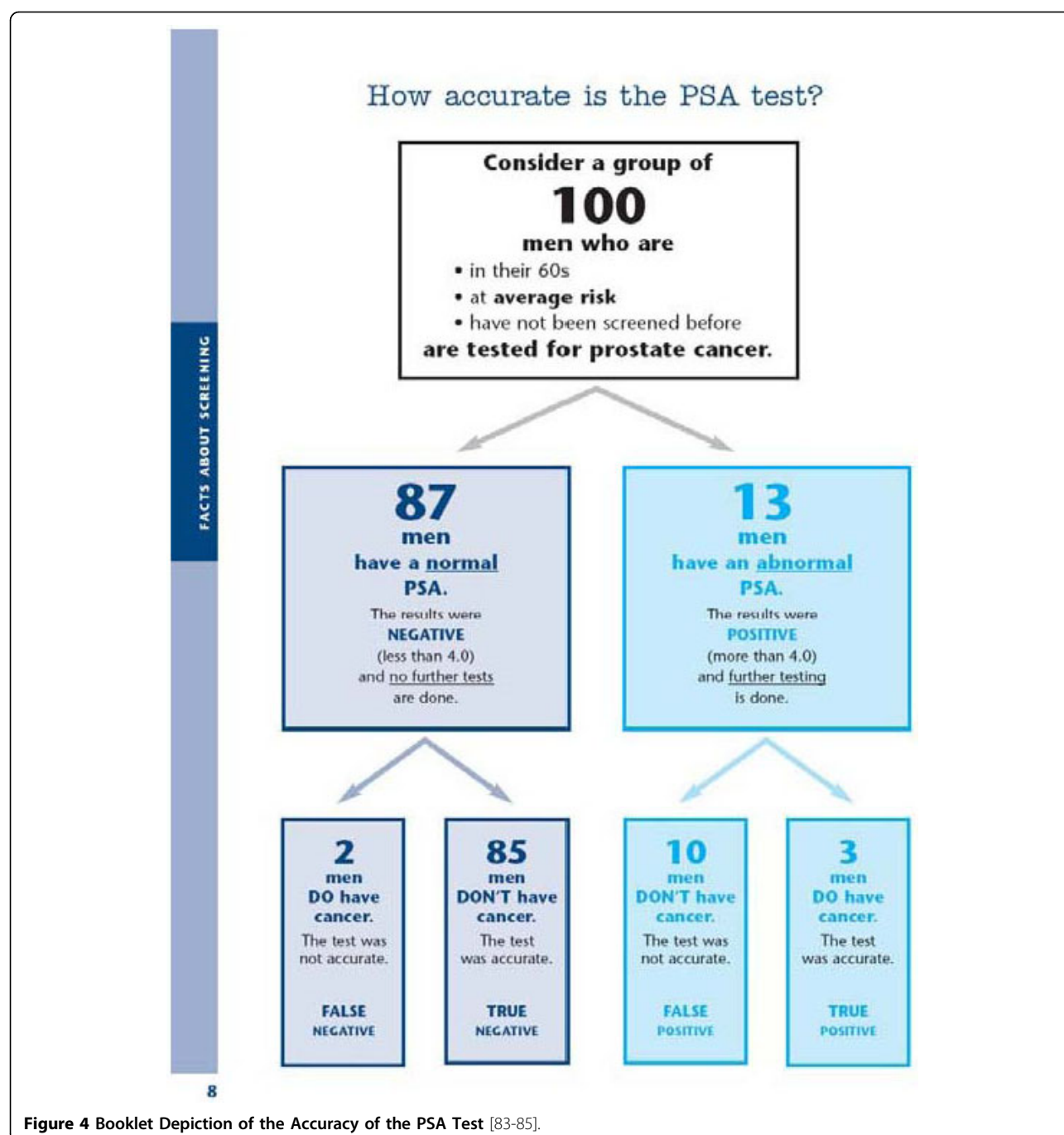
Figure 3 Website Screenshot of Animation Depicting the Accuracy of the PSA Test [83-85].

Finally, the website is capable of tracking men’s use of the materials and provides data on the behaviors of visitors. Data stored in a password protected Structured Query Language database provides records of the time spent visiting the website, time spent in each section, and responses to the DA queries. Upon completion of the RCT, this information will help determine whether initial screening preferences and usage patterns are associated with knowledge acquisition, decisional conflict,

baseline screening preference, and subsequent screening decisions.

Discussion

There is considerable interest in assisting men with PCa screening decisions, as evidenced by the 18 RCTs conducted to assess the efficacy of DAs. We sought to address several limitations of the previous studies with the development of two disseminable tools with



extensive formative evaluations: a print booklet and an interactive website. The booklet and the website offer the identical content, while the website also includes an interactive values clarification component, video testimonials, and tracking software to assess men's utilization of the website. The website recently received the 2009 American Public Health Association's award for Public Health Education Materials [66]. Our ongoing RCT will examine the impact of the website and booklet

on PCa screening knowledge, decisional conflict, satisfaction with decision, health-related quality of life and screening behaviors. The trial will be completed in 2011.

Our new materials offer several improvements over prior DAs. Given the persistent problem created by the digital divide, regarding both limited access and preferentially attracting Internet-savvy users, we designed features of the website to appeal to more diverse groups. Our formative work and prior randomized trials

included a large number of AA participants as well as participants from diverse socioeconomic backgrounds, which provided insights to design materials for these groups. For example, our DAs maintained a maximum of an 8th grade reading level, information was provided in plain language, and a glossary defined terms used throughout the website and booklet. Further, we incorporated visuals, graphs and charts, all of which have been suggested as methods for increasing comprehension among low-literacy groups [31].

In addition to making the materials appealing and understandable to diverse groups of men, we also assessed the extent of web access within our target sample. We found that over an 18-month period, web usage among lower socioeconomic men had increased. These results are consonant with some findings from the Pew Foundation [67], although other studies have reported slower growth among low SES and minority groups [68]. Our ongoing trial will provide more definitive evidence regarding the impact of web- vs. print-based media for PCa screening education, as well as the extent to which we managed to bridge the digital divide. The testing of these DAs among minorities and low literacy participants will provide an important opportunity to validate effectiveness in this population, which tends to be less informed about screening options and less engaged in decision-making [69,70].

To our knowledge, ours is the second study to describe an *interactive* web-based tool designed to educate men about PCa screening [27], and the first to utilize tracking software to compare website utilization patterns with patient outcomes. Potential advantages of using web-based materials include the relatively low cost of updating information and the increased capability of tailoring and interactivity, which may assist in the acquisition and integration of knowledge. For example, by tailoring the presentation of the first two video testimonials in response to the user's baseline screening preference, we have insured that men consider counter-arguments to help balance their perspective. Also, the interactive nature of the web-based values clarification exercise was designed to actively engage participants and enhance the integration of knowledge. This was intended to help men make a decision that corresponds more closely with their own values and screening preferences, decrease decisional conflict, and increase decisional satisfaction.

Over the course of the development of these DAs, we have encountered several important issues that may be useful to others who are creating similar tools. First, there was a tradeoff between providing detailed information vs. risking that the materials would require more time than men would be willing to devote to them. Despite our best efforts to be concise, between 35%

(booklet) and 50% (website) of the usability testing participants thought the materials were too long. As we did not want to exclude any pertinent information, it is possible that the length of our materials may deter some men from reading all of the text. However, with both the booklet and the website, we expect that men will selectively access sections of interest by using the Table of Contents.

Secondly, when we conducted our web usability testing, we provided a step-by-step instruction sheet for using the website. Men reported that the instructions were very helpful, particularly for those with less computer experience. Due to these findings, as well as what we know about the disparities between SES groups and Internet use, we have included the instruction sheet in the current randomized trial to ensure that men with less experience using the Internet will be able to successfully access and use our materials.

Finally, it was challenging to develop a DA that addressed the uncertainty of a screening test for men who had been undergoing regular screening *and* who were completely unaware of the uncertainty. The balancing act was to validate what men already knew while also providing information that was both counterintuitive and contrary to their previous impression. We worked to present the materials in an evenhanded fashion; however, results from the usability testing suggested that only a minority of men thought the booklet (14%) and website (36%) neither endorsed nor opposed screening. These findings highlight the fact that it may take more than a single exposure to materials such as ours for patients to grasp a message that is both complex and counter to one's current understanding and practices. While our usability testing provided critical information during the development process and our sample size was comparable to other studies involving usability testing [71,72], a larger sample may have provided the feedback necessary to more effectively present the uncertainty and the message of neither endorsing nor opposing screening.

Conclusion

Despite the uncertainty surrounding PCa screening, most primary care physicians routinely order the PSA test for men over 50, and some engage in unsupported practices, such as screening patients over age 75 and referring such men for biopsies when PSA values are elevated [73-75]. Due to the logistic constraints they face [76], many physicians administer PCa screening with little opportunity to discuss the test beforehand [77]. However, evidence indicates that many men would prefer to make a shared PCa screening decision in conjunction with their physicians [78-81]. Consequently, access to an effective DA in the primary care setting

may promote shared decisions among large numbers of men in the decisive period before testing occurs. In 2005, 80% of males had at least one visit with an ambulatory care physician [82], suggesting that an intervention implemented in this setting could have a widespread impact.

Providing assistance for informed decision making for PCa screening may be important for some time, particularly if a definitive recommendation either for or against screening does not emerge from the ongoing screening trials. We have detailed our efforts at developing print- and interactive web-based DAs to assist men in determining whether they prefer to be screened or not. Given that technological advances in medical screening tests will continue to occur faster than clinical translational research can keep pace, we hope that insights from the development of our decision tools will be applicable as other screening dilemmas arise.

Additional file 1: Appendix A. Outcomes of Randomized Controlled Trials of Prostate Cancer Screening Decision Aids
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6947-10-12-S1.DOC]

Additional file 2: Supp File 2. Pilot Screening and Internet Usage Questionnaire-Feasibility Study 1 - January 2005
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6947-10-12-S2.PDF]

Additional file 3: Supp File 3. Pilot Screening and Internet Usage Questionnaire-Feasibility Study 2 - June 2006
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6947-10-12-S3.PDF]

Additional file 4: Supp File 4. Booklet Usability Testing Questionnaire
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6947-10-12-S4.PDF]

Additional file 5: Supp File 5. Website Usability Testing Questionnaire
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6947-10-12-S5.PDF]

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Authors' contributions

CD took the lead role in the writing and editing of the manuscript, as well as in usability testing recruitment. RW administered the questionnaires for the first feasibility study and participated in drafting the manuscript. EK participated in drafting the manuscript and in data analysis. SR participated in drafting the manuscript, conducting usability testing, and data analysis. DD recruited participants, conducted usability testing, and participated in data analysis. WT participated in drafting the manuscript. EP recruited participants, conducted usability testing, and participated in data analysis. J O-F was the plain language consultant during the iterative development process and provided multiple edits to both the layout and the wording of the text. KD, AK, SW, and MS participated in drafting the manuscript and reviewing and editing the materials during the iterative process. MF provided access to the primary care clinic in which men were recruited for the feasibility studies and usability testing, as well as drafting the manuscript and reviewing the materials during the iterative process. CC provided access to the primary care clinic in which men were recruited for the feasibility studies and usability testing, as well as drafting the manuscript and reviewing the materials during the iterative process. KLT conceived the project, is the Principal Investigator of the NCI and DoD grants which have funded this project, edited and reviewed the materials during the iterative process, and participated in writing the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Running Head: Internet-based Aid for Prostate Cancer Screening

Men's Utilization of an Internet-based Decision Aid for Prostate Cancer Screening

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Abstract

Objective: Most medical organizations recommend informed decision making before undergoing prostate cancer screening (PCS). We conducted a detailed evaluation of men's utilization of an interactive, web-based PCS decision aid.

Method: Participants (N=531) were 57 years old (SD=6.8), 37% were African-American, and 92% had Internet access. Men completed two telephone interviews, pre- and one-month post-website availability.

Results: One-half of the sample (N=256) accessed the website. Multivariate analysis revealed that users were more likely than non-users to be white (OR=2.37, CI 1.6-3.6), previously screened (OR = 2.13, CI 1.07-4.26), have Internet access (OR=3.66, CI 1.15-11.58), and to report daily Internet use (OR=2.58, CI 1.47–4.55). Agreement between self-reported and actual website use was moderate (kappa=0.67). Tracking software revealed M=1.3 (SD=0.5) log-ons and a median of 38 minutes per log-on. Eighty-four percent utilized the values clarification tool (VCT) and over 50% viewed each video testimonial. Baseline screening preference was associated with VCT responses and website feedback.

Conclusions: This study revealed that, beyond the digital divide, website use depended on more than Internet access. Further, electronic tracking of website utilization demonstrated the overestimation of self-reported use, the high utilization of interactive features, and the impact of baseline screening preference on men's response to the website.

Introduction

Prostate cancer (PCa) is the most common visceral cancer among men in the United States and it is the second most common cause of male cancer-related death (American Cancer Society, 2010a). In an effort to reduce prostate cancer mortality, PCa screening has become widespread in the US (Ross, Berkowitz, & Ekwueme, 2008). However, though prostate cancer screening (PCS) has been shown to detect early-stage cancers, it has not definitively been proven to reduce cancer-related mortality (Andriole et al., 2009; Schroder et al., 2009). Due to the lack of consistent findings, there are no universally accepted recommendations regarding PCS. Consequently, most organizations recommend that men engage in informed decision making before undergoing PCS at the age of 50 (American Cancer Society, 2010b; American College of Physicians, 1997; American Medical Association, 2000; American Urological Association Education and Research, Inc., 2009; U.S. Preventive Services Task Force (USPSTF), 2008). For men who are at high risk for PCa, which include African-American men and men who have a first degree relative diagnosed with PCa prior to age 65, it is recommended to begin screening and discussions about screening at age 40 (American Urological Association Education and Research, Inc., 2009; National Comprehensive Cancer Network, 2010) or 45 (American Cancer Society, 2010b).

Decision aids (DAs) are designed to help individuals make an informed decision about which diagnostic or treatment option is most suitable for them. DAs often provide the user with both detailed information and a tool to help users sort out their preferred choice (O'Connor et al., 2005). While DAs have been presented in many formats (O'Brien et al., 2009), the use of electronic DAs is on the rise, including both computer- and Internet-based (Allen et al., 2010; Evans et al., 2010; Frosch, Kaplan, & Felitti, 2003; Frosch, Bhatnagar, Tally, Hamori, & Kaplan, 2008; Ilic, Egberts, McKenzie, Risbridger, & Green, 2008; Krist, Woolf, Johnson, & Kerns,

2007; Ruffin, Feters, & Jimbo, 2007; Thomson & Hoffman-Goetz, 2007; Wakefield et al., 2010). Volk and colleagues (2007) conducted a systematic review of PCS DAs and found that overall, DAs increased knowledge, reduced conflict, and increased an active role in the decision making process (Volk et al., 2007). However, a limited number of the studies using an internet- or electronic-based format were available for inclusion in the review.

Recent trends suggest that the Internet has vast potential as a widely accessible approach for delivering health-related information, including information related to PCS. In 2009, approximately 74% of Americans used the Internet at least occasionally (PEW Internet & American Life Project, 2009a) and 63.5% of households had broadband (high-speed) Internet access (National Telecommunications and Information Administration & U.S. Department of Commerce, 2010). Internet users are typically younger, white, have a higher income, and have more education than non-users (PEW Internet & American Life Project, 2010a). Regarding race/ethnicity differences, Internet use is higher among white, Non-Hispanic (80%) and Hispanic, English Speaking (82%) individuals, compared to Black, Non-Hispanic (71%) individuals (PEW Internet & American Life Project, 2010c). However, these race/ethnicity data are not available stratified by age and gender, and thus we do not know exactly how it may apply to our target audience (i.e., males over 50).

Despite the sociodemographic differences in Internet use, the percentage of Americans who use the Internet has grown significantly in the past decade (PEW Internet & American Life Project, 2010b). Furthermore, the number of adult Internet users who access medical or health-related information has also increased between 2000 and 2009, from 54% to 83% (PEW Internet & American Life Project, 2009b; PEW Internet & American Life Project, 2010b). From 2000-2007, use of the Internet for health-related information also increased among middle-aged and older adults: from 58% to 76% for those aged 50-64, and from 46% to 71% for those over 65

(PEW Internet & American Life Project, 2010b).

There have been seven published randomized controlled trials (RCTs) that have utilized a computer- or web-based DA to help men make an informed decision about PCS (Allen et al., 2010; Evans et al., 2010; Frosch et al., 2003; Frosch et al., 2008; Ilic et al., 2008; Krist et al., 2007; Volk et al., 2008). These studies achieved the intended outcomes of increased PCa knowledge, decreased decisional conflict, and increased active participation in PCS decisions. However, only one of these reports provided a detailed examination of the ways in which study participants utilized the DAs (e.g., time spent on the site, number of content pages accessed, number of interactive elements used; (Joseph-Williams et al., 2010), while a second study reported the percentage of participants who viewed the entire website (54%) and the percentage who viewed any of the website (60.5%; (Frosch et al., 2003).

Web use in other health-related areas has been monitored in more depth, including: HIV/AIDS (Boberg et al., 1995; Brennan, 1993; Flatley-Brennan, 1998; Gustafson et al., 1994; Pingree et al., 1993; Temesgen, Knappe-Langworthy, St Marie, Smith, & Dierkhising, 2006), diabetes (Gerber, Solomon, Shaffer, Quinn, & Lipton, 2007; Glasgow, Boles, McKay, Feil, & Barrera, Jr., 2003; McKay, Glasgow, Feil, Boles, & Barrera, Jr., 2002), Alzheimer's caregivers (Brennan, Moore, & Smyth, 1991; Brennan, 1993), and depression/anxiety (Christensen, Griffiths, & Korten, 2002; Clarke et al., 2005). Research has shown that breast cancer patients are more apt to use an interactive website for social-networking purposes than as an educational resource (Gustafson et al., 1993; Gustafson et al., 2001; McTavish et al., 1994). Other information-based websites have assessed whether the usage statistics have impacted behavioral outcomes such as smoking cessation (Cobb, Graham, Bock, Papandonatos, & Abrams, 2005; Danaher, Boles, Akers, Gordon, & Severson, 2006; Feil, Noell, Lichtenstein, Boles, & McKay, 2003; Lenert et al., 2003; Severson, Gordon, Danaher, & Akers, 2008; Strecher et al., 2008;

Wang & Etter, 2004), use of genetic testing (McBride et al., 2009; O'Neill et al., 2008), diabetes self-care (Glasgow et al., 2003; McKay et al., 2002; Tate, Jackvony, & Wing, 2003; Wangberg, 2008), depressive symptoms in HIV patients (Lai, Larson, Rockoff, & Bakken, 2008), weight loss (Tate, Wing, & Winett, 2001), exercise (Leslie, Marshall, Owen, & Bauman, 2005), and avoidance of general health-risk behaviors (Bosworth, Gustafson, & Hawkins, 1994). However, there has been a lack of consistency in describing and measuring website use (Danaher & Seeley, 2009), which has made it difficult to compare web-use behaviors across studies.

DAs are most useful when there is no clear best option for a medical decision. Despite the development of web-based DAs for PCS, only one small study has conducted a detailed assessment of how men use these materials (Joseph-Williams et al., 2010). This information may be useful not only for the design of future web-based tools, but also for determining the impact that website components have on the primary outcomes of interest. Further, most of the studies that have assessed web behaviors in detail were among patients with an existing health condition and were utilized to make a treatment decision. Little is known about how generally healthy individuals utilize web-based tools. This is important given the likelihood that healthy persons may be less motivated to educate themselves about disease screening, and therefore may spend less time on a website, and possibly may be less likely to access the website at all. Further, usage statistics available from web-based studies of patients may have little bearing on healthy persons who are learning about screening.

We sought to address these gaps in the literature by conducting a detailed analysis of the characteristics of website users vs. non-users, assessing whether certain topics were accessed more often than others, comparing self-reported use to actual use of the website, as well as examining whether baseline screening preferences impacted men's use of the website. This information is essential for understanding the mechanisms by which DAs impact decisions, for

highlighting the components men are most likely to use, and to determine whether web-use patterns predict outcomes.

Method

Overview

We are conducting a three-arm randomized controlled trial (RCT) of two decision aids for prostate cancer screening (web vs. print) vs. a usual care arm. The primary outcomes of the trial are PCa knowledge, decisional conflict, decisional satisfaction, and the actual screening decision. The current paper includes data from the web-arm only, and subsequent papers will present the results of the RCT once the one-year follow-up interviews are complete.

Subjects

Eligibility criteria for the RCT included: 1) men between the ages of 45-70, 2) no history of PCa, 3) English speaking, 4) ability to provide meaningful consent, and 5) outpatients at one of three accrual sites: Georgetown University Hospital (GUH), the Washington Hospital Center (WHC) or MedStar Physician Partners (MPP). Inclusion in this study was not based on having an upcoming appointment, but only on having had an appointment at one of these sites within 24 months of enrollment.

We invited 5984 men to participate in the RCT: 557 were ineligible (e.g., deceased, diagnosed with PCa, or outside the age range) and 601 had incorrect contact information. Of the remaining 4826 eligible men, 1269 (26.3%) were unreachable by mail or phone after 10+ call attempts (passive decliners), 1664 (34.5%) declined to participate (active decliners), and 1893 (39.2%) agreed to participate. When comparing decliners (active and passive) to participants, there was no difference in the percentage of African-Americans in each group (44%; $p > .20$) and the average age was the same in each group (mean = 56 years; $p > .20$). Among active decliners, reasons for declining included: too busy (31.4%), not interested (48.9%), too sick (3.7%), family member refusal (8.7%), questions too personal (2.1%), and other (5.4%).

Participants were randomly assigned to the print (N = 630), usual care (N = 632) or web-arm (N = 631). For the current paper, we included only the web-arm participants who had completed both the baseline (T0) and the one-month follow-up (T1) assessments (N = 535; 85.2%). The 96 subjects who did not complete the T1 interview did differ from the 535 completers. Non-completers were: older, less educated, more likely to be non-white, more likely to be from WHC, lower income, less likely to be insured, less likely to have been screened in the past, less likely to have been screened in the past year, less likely to prefer the Internet as the delivery method of health information, and less likely to have Internet access (all p 's < .05). There were no significant differences on marital status, having a regular doctor, employment, ethnicity, family history of PCa, personal cancer history, comorbidities, or having had a previous discussion with their doctor about PCS (all p 's > .05). We excluded four participants whose tracking data indicated they logged on but who self-reported they did not log on, as we suspected that a family member, rather than the participant, may have accessed the website. Thus, the total sample included in the analyses was N = 531. See Figure 1 for details of the accrual process.

Procedure

We mailed invitation letters and followed up with phone calls to men between October 2007 and January 2010. Interviewers described the study, obtained verbal consent, conducted the 20-25 minute baseline telephone interview, and then randomized participants to one of the 3 study groups. Web-arm participants received the written consent form and a stamped envelope for its return, the website address, a secure, unique user ID and password, instructions for using the website, and were asked to review the website within two to three weeks. Participants were also asked to not share their user ID and password in an effort to prevent contamination between study groups or use of the website by family members. Men then completed the T1 telephone interview, on average, 36 days after the T0 (range 21-74, SD = 9.1).

Participants in each arm of the study received a \$10 supermarket gift card and were entered into a lottery for a chance to win either \$100 or \$200 after completing the T1 interview. Logging on to the website was not required to receive the incentives. This study was approved by the Georgetown University/Medstar Oncology Institutional Review Board.

Website Description

Detailed information about the development, content, and usability testing of the website is described elsewhere (Dorfman et al., 2010). Briefly, the materials were designed to provide balanced information about the benefits and limitations of PCa screening. The content of the website and booklet is identical, covering the continuum from screening to treatment. The website is written at or below an 8th grade reading level, based on the Fleish-Kincaid grade level formula (Friedman & Hoffman-Goetz, 2006). Included on the website is a table of contents that allows navigation to sections of interest in a non-linear fashion, use of a voiceover to present the majority of the text, pop-up definitions of 77 PCa-related words, 8 video testimonials, a values clarification tool (VCT), as well as animation and graphics to draw attention to key points and help direct users through the website (See Figure 2: Screenshot of the Website). The website was created using Adobe Flash, Javascript, and HTML.

Informational Sections: Six informational sections are included, each with 3-4 subsections. A combination of voiceovers, text, figures, and graphics are used to provide detailed information regarding each topic. The *Introduction* section includes a basic tutorial of how to use the website and information about the prostate and prostate cancer. The *Screening* section provides users with detailed information about the types of PCa screening exams and what different screening results may indicate. The *Treatment Issues* section gives facts about the different treatments for PCa, including the risks and possible side effects. The *Steps You Can Take* section provides information about PCa risk factors and encourages a discussion with a

doctor about screening. The *Values Clarification Tool* section shows users their screening preference, based on their responses to the VCT items (described in detail below). Lastly, the section entitled *More Information* provides a list of related references, links to various cancer-related and general health-related organizations, and a glossary of terms.

Measures

Self-report Measures Obtained from Telephone Interviews

Demographic, medical, screening information. At the T0 interview, we assessed demographic information including date of birth, marital status, level of education, employment status, ethnicity/race, and income. Medical and screening information included having a regular doctor, health insurance status, personal history of cancer, family history of PCa, comorbidities, ever discussing PCS with a doctor, ever undergoing PCS, and having been screened in the last 12 months.

Computer access information. At the T0 interview, we assessed Internet access, high-speed Internet access, and frequency of Internet use (for both general and health-related purposes).

Preference for delivery method. At the T0 interview, participants indicated their preference for receiving health-related information: on the Internet, as a booklet, or no preference.

Website use and feedback. At the T1 interview, men reported their estimated number of logins and total time spent on the study website, as well as feedback regarding the length, helpfulness, clarity, and overall message of the website (see Table 5 for response options). Participants also indicated whether the website made them nervous or fearful about PCS, if it influenced their PCS decision, and if it made them think of new questions for their doctor.

Measures Obtained from the Website Tracking Database

The data used to track men's website utilization were stored in a password protected Structured Query Language database. Using customized web tracking software that was invisible to the user, patient logins were uniquely tracked, which captured a variety of user data on every screen visited. This allowed us to assess patient viewing habits, such as total and average time spent on the website, responses to the VCT items, and use of video testimonials.

Website use. *Users* were defined as participants who logged on at least once for a minimum of one minute (Gustafson et al., 1994). The login must have occurred prior to the T1 assessment and men must have also self-reported that they logged on. *Non-users* were participants who, based on tracking software, did not log on, regardless of self-report. A *login* was defined as each participant's unique visit from a start time to an end time.

Prostate cancer screening preference. PCS preference was determined by participants' response to a statement presented immediately after logging on to the website, which assessed men's prior screening behavior and personal PCS preference. Participants responded to the statement, "Since you became eligible to be screened for PCa, would you say that..." (1) 'I strongly believe in getting screened. I have been screened every year since I became eligible,' (2) 'I believe in getting screened. I have been screened most years, but not every year since I became eligible,' (3) 'I am not completely certain about getting screened for prostate cancer. I have been screened some years (but not most years) since I became eligible,' and (4) 'I am unsure about prostate cancer screening. I have either never been screened or have been screened very rarely since I became eligible.' (Although the ACS modified their PCS recommendations (American Cancer Society, 2010b), during the accrual phase of this study, the ACS encouraged providers to discuss the pros and cons of screening and to offer prostate cancer tests annually beginning at 50 for average risk men and earlier for high risk men). Due to skewed responses on this item, we collapsed the four items to two: Men who were certain about screening (#1 and #2 above), and

men who were less certain about screening (#3 and #4 above).

Values Clarification Tool (VCT) use. We adapted a 10-item VCT (Gattellari & Ward, 2003) to help participants weigh the relative benefits and risks of screening. This tool presented individual items throughout each section of the website, half of which addressed the benefits of screening (e.g., “I am worried about PCa and screening may give me peace of mind”), and half of which addressed the limitations of screening (e.g., “I do not want to risk finding out I have cancer when it may never bother me”). The following question was presented immediately after each VCT item: ‘Does this statement sound like you?’ and users clicked on ‘yes’, ‘no’, or ‘not sure yet.’ Items that men skipped as they navigated through the website were automatically entered as ‘not sure yet.’ All items were displayed again at the end of the website to provide an opportunity to review and change one’s responses. Users received a final prompt to review the VCT prior to exiting the website.

We defined a user of the VCT as someone who answered all 10 of the items. We created a summary score by classifying pro screening responses as +1, con screening responses as -1, and a neutral response (not sure yet) as 0. Thus, the total score for a participant could range from -10 to 10. This summary score was used to classify participants’ overall screening preference after having used the website: a positive score indicated a pro screening response, while a negative score indicated a con screening response. Responses to all items were then shown on a balance scale to visually depict men’s PCS preference, along with a statement indicating that the participant was ‘leaning toward’ or ‘leaning away from’ getting screened. Finally, we assessed the number of answers that were changed over the course of website use and the overall screening preference. Screening preference items were considered changed when users 1) went back to a page and changed their selected answer, or 2) changed their answers on the final page of the website when they were given the opportunity to review all of their responses.

Video Testimonial Use. In the development of the testimonials, we adhered to the International Patient Decision Aid Standard (IPDAS) (O'Connor et al., 2005) criterion that the stories represent a range of positive and negative experiences. Eight video testimonials, ranging in length from 25 to 60 seconds, provided users with insights into why some men may or may not choose to be screened. The first two video testimonials were tailored, based on the user's screening preference that he indicated just after logging on (see description above). A user who was leaning *toward* screening first viewed two testimonials of men who chose *not* to get screened, and vice versa for men leaning *against* screening. This was done to ensure that men were exposed to the alternate viewpoint about screening, in an effort to address the tendency to concentrate on information that validates one's existing beliefs (i.e., confirmation bias; (Chapman & Sonnenberg, 2000)). In the remaining sections of the website, pairs of a pro and a con video were presented to illustrate the benefits and limitations of screening, undergoing a biopsy, and treatment. We report the percentage of participants who viewed each testimonial in its entirety.

Data Analysis

We conducted descriptive analyses to assess the distribution of all variables and bivariate analyses (chi squares and t-tests) to assess the similarities and differences between users and non-users of the website on demographic and computer access variables. A logistic regression model was then conducted to determine the variables that independently predicted website use. Among website users, we evaluated the time spent on the website using the electronic tracking data. Bivariate analyses were conducted to assess whether men's baseline PCS preference was associated with time spent on the website, website feedback, use of the VCT, and testimonial use. We used SPSS Version 17.0 for data analyses.

Results

Characteristics of Website Users vs. Non-Users

Table 1 presents the differences between website users and non-users. Compared to non-users, users were more likely to be married, white, highly educated, previously screened, screened in the past 12 months, and to have a higher income, a regular doctor, a personal history of cancer, and less likely to be from the WHC site (all p 's < .05; see Table 1). Users were also more likely to prefer receiving health-related information on the Internet, to have Internet access, and to use the Internet on a daily basis (all p 's < .01; see Table 2). Including these participant characteristics that were significantly associated with web use, we conducted a logistic regression to determine the independent predictors of use (see Table 3). Education was used to represent socioeconomic status, as it was highly correlated with income ($r = .545$, $p = .000$) and 5% of participants were missing income information. The logistic regression indicated that men who were white, were previously screened, and used the Internet on a daily basis were more than twice as likely to use the website, and men who had Internet access were over three times as likely to use the website (see Table 3). The other variables in the model were not significantly related to website use.

Website Use

Approximately one-half of the sample ($N = 256$; 48.6%) logged on to the website prior to the T1 assessment, although 342 participants (64.0%) self-reported that they viewed it during this time. The kappa agreement between the tracking software and self-reported website use was .67. Among non-users ($N = 275$), the most frequent reasons for non-use included a lack of time (47.6%) and not having access or it was inconvenient to access the Internet (39%). The tracking software revealed that users spent a median of 38.7 minutes (range=1.2-198.0) on the website, while the median for self-reported use was 45.0 minutes (range=10.0-240.0). The difference between self-reported and actual time spent on the website was significant ($t(255) = 23.37$, p

<.001). The tracking software revealed that users logged on to the website a mean of 1.3 times (SD= 0.5; range = 1-3) prior to the T1 interview. Few participants logged on to the website following the T1 interview (N = 18).

We found that men spent the most time on the *Screening* section (median = 13.6 minutes), followed by the *Treatment Issues* section (median = 11.1 minutes, see Table 4). This was expected, as these sections contained the most number of pages. However, there was little difference in the amount of time spent per section when the pages per section were taken into account: men spent a median of 21 to 36 seconds per page across the different sections (Table 4). The majority of users viewed each of the sections of the website, with more than 84% viewing the 4 content-based sections and the DA (see Table 4). Certainty about screening measured at website entry was not associated with the amount of time spent on any of the website's sections or with time spent on the entire website (all p 's > .30; data not shown).

At the T1 telephone assessment, participants provided feedback about the website: 83% reported that the website was very/extremely helpful and 72% reported that it was unbiased (i.e., neither encouraged nor discouraged screening), although 35% indicated it was too long (see Table 5). We stratified men's feedback by screening preference and found similar responses regarding men's evaluation and use of the website. However, men who were less certain about wanting to be screened were more likely to report that the website made them feel nervous/fearful about PCS ($p < .05$), that it made them think of questions for their doctor ($p < .01$), and that the website influenced their screening decision ($p < .01$; see Table 5).

Use of the Values Clarification Tool (VCT)

Overall, 254 (99.2%) users answered at least one of the ten VCT items and 215 (84.0%) answered all ten items. Of the 254 users who answered at least one item, 67 (26.4%) changed one or more of their responses over the course of their website use (Mean = 2 changed responses;

SD=1.5). Answers were changed in both directions, from pro to con screening and from con to pro screening, with no clear trend regarding their initial screening preference. Of those who answered all 10 of the VCT items, 205 (95.3%) responded in favor of screening overall, defined as having a positive score summed across the ten items. Participants' initial PCS preference was associated with their responses to the VCT items, such that men who were certain about getting screened were more favorable towards screening on the VCT items ($M = 8.4$, $SD = 3.1$), compared to men who were less certain about screening ($M = 6.7$, $SD = 4.5$; $t(213) = 2.71$, $p \leq .05$).

Video Testimonial Use

Between 50-74% of all users viewed each video testimonial (see Table 6). The greatest number of users viewed the first set of testimonials (tailored to provide the viewpoint that opposed men's baseline screening preference) and the percent of men who viewed the remaining testimonials declined slightly. There were no statistically significant associations between participants' PCS preference and their testimonial use (all p 's $> .05$).

Discussion

Due to the lack of conclusive evidence regarding the utility of PCS, medical organizations recommend that men go through an informed decision process prior to undergoing PCS (American Cancer Society, 2010b; American College of Physicians, 1997; American Medical Association, 2000; American Urological Association Education and Research, Inc., 2009; U.S. Preventive Services Task Force (USPSTF), 2008). DAs are designed to assist individuals when there is no clear choice for a diagnostic or treatment decision (O'Connor et al., 2005). In recent years, several web-based DAs have been designed and evaluated on knowledge and decisional conflict outcomes (Frosch et al., 2003; Frosch et al., 2008; Ilic et al., 2008; Krist et al., 2007; Volk et al., 2008). However, to date, little research has been conducted to understand what components of these tools are being utilized by men. This paper represents a

detailed assessment of user characteristics, how participants used a decision aid for PCS, and the impact of men's baseline screening preference on their use of and response to the DA.

Although over 90% of all study participants (users and non-users combined) had Internet access, only one-half logged onto the website. A similar percentage has been found in several earlier web-based studies (Christensen et al., 2002; Leslie et al., 2005; O'Neill et al., 2008) . In order for a web-based DA to have a greater impact on the target audience, we need to understand and address the factors that limit its use, beyond issues of Internet access. We found that users of our web-based DA were similar to typical computer and Internet users, as they were more likely to be white, to have Internet access, and to be daily Internet users (PEW Internet & American Life Project, 2010a). Thus, in addition to having access to the Internet, being a daily Internet user also made it more likely that a participant would use the website. Our results also extended the current literature regarding the characteristics of PCS website users, as we found that users were more likely to have a history of PCS. Individuals who have utilized screening in the past may be more likely to seek health-related information, including Internet-based tools. However, we did not find a significant impact of age on website use, which has previously contributed to the digital divide. This may be due to the truncated age range in this study, or it may be due to the increasing willingness of older adults to use the Internet for health-related information. As the number of older adults who use the Internet for health information continues to rise, this will become a progressively useful medium to provide health education.

In addition to reporting predictors of use, we detailed the ways in which men utilized the DA. We found that users spent a median of 38 minutes on the website and logged-on just over one time. Men spent a similar amount of time in each of the informational sections, although there was a slight decline in the number of men accessing the information featured later in the website, despite the non-linear design. This result suggests the importance of placing the most

important content at the beginning of the website (Danaher & Seeley, 2009). Similarly, the majority of users viewed the first set of testimonials, but there was a decline in videos watched after the initial pair. Despite this decline, about one-half of the sample did view each of the remaining videos. Users were also likely to complete the VCT items, with 84% answering all 10 items, suggesting that this interactive component succeeded in capturing the attention of most users. Perhaps requiring the user to respond in some way generates more engagement than simply reading or listening to the information (Danaher et al., 2006).

A novel aspect of this study was the assessment of whether men's baseline certainty regarding their screening preference was associated with their perceptions of and use of the website. We found that certainty about screening did not impact the way that men perceived the website (e.g., its helpfulness in understanding the pros and cons of PCS, opinions about the site's length, or the overall message of the website), the amount of time spent on different sections of the website, or on types of information viewed, such as the video testimonials or use of the VCT. Not surprisingly, those who were *more* certain about screening indicated a more positive view of screening on their VCT responses, compared to men who were less certain about screening. Additionally, men who were *less* certain about wanting to be screened reported that the website made them feel more nervous about PCS, that it influenced their screening decision, and that it made them think of more questions to ask their doctor. These results suggest that men's predisposition toward screening may impact their perceptions of the material presented, as men who were less certain about screening reported that the website had a greater impact on their thoughts about the screening decision. Men who are more certain about wanting to be screened may require additional educational strategies to help them understand the limitations of screening, as they may be less able to consider the alternative viewpoint.

Study limitations should be noted when interpreting these results. First, the overall study

participation rate of 39% limited the representativeness of the sample. However, this participation rate is comparable to similar web-based studies (Frosch et al., 2003; Krist et al., 2007; Volk et al., 2008), indicating that much more work is needed to improve participation rates in these studies. Although we had a very good retention rate at the one-month assessment (85%), a second limitation is that non-completers of the T1 were different from completers with respect to several demographic and computer access variables, underscoring the digital divide and limiting the representativeness of the sample. These same difficulties with retention have been found in other studies (Frosch et al., 2003; Frosch et al., 2008; Volk et al., 2008). However, as the digital divide goes beyond having Internet access, future research needs to address whether it is possible to engage non-users or whether non-users simply prefer other forms of health education. Finally, while we intentionally placed the most relevant information towards the beginning of our website, future research needs to assess ways of making the content that is presented later more engaging to insure users receive the most information from decision aids.

This study has made several important contributions. First, we found that website use was not only a function of access to the Internet, but was also predicted by frequency of use and screening history. These results suggest that users of web-based health information are very comfortable using the Internet and have a prior interest in the topic. Second, we determined that men tended to over-report both whether they logged on and the actual time spent on the website, suggesting that self-report should not be used as a stand alone measure of use. Third, we reported that an interactive feature of the website was utilized by the majority of men, suggesting that interactive features may be an important way to engage users throughout a website. Fourth, despite the non-linear design of this website, users were somewhat less likely to access later pages, suggesting the importance of placement of the information considered to be most important. Finally, we showed that men's certainty regarding screening impacted their use of and

response to the website, suggesting the importance of incorporating participants' baseline conceptions about the target decision into the website design.

We have described in detail the ways in which men used a web-based DA for PCS. The information garnered from this study has significant implications for future research and development of web-based educational DAs. Particular attention should be devoted to methods to include those who are less likely to use the Internet to obtain PCS information. Future research is needed to better understand how to encourage those less likely to use the Internet in order to increase the potential benefit of this contemporary approach to health education.

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Table 1. Demographic, Medical, and Screening Characteristics
of Users vs. Non-Users (N =531)

	All (N=531)	Users (N = 256)	Non-Users (N=275)
Age Mean (SD) (Range 45-70)	57.3 (6.8)	57.6 (6.9)	57.0 (6.6)
	N (%)	N (%)	N (%)
Education (% with college degree or more) ⁺ **	311 (58.8)	175 (68.4)	136 (49.8)
Married/Marriage like relationship ⁺ * (% yes)	373 (70.4)	192 (75.0)	181 (66.1)
Race **			
White	315 (59.3)	189 (73.8)	126 (45.8)
African American	197 (37.1)	56 (21.9)	141 (51.3)
Other	19 (3.6)	11 (4.3)	8 (2.9)
Hispanic (% yes) ⁺	12 (2.3)	5 (2.0)	7 (2.6)
Site **			
GUMC	231 (43.5)	120 (46.9)	111 (40.4)
WHC	57 (10.7)	14 (5.5)	43 (15.6)
MPP	243 (45.8)	122 (47.7)	121 (44.0)
Employment (% full- or part-time)	368 (69.3)	187 (73.0)	181 (65.8)
Annual Income (% >100K) ⁺ **	230 (48.8)	137 (57.1)	93 (40.3)
Regular doctor (% yes) *	503 (94.7)	248 (96.9)	255 (92.7)
Insurance (% yes)	523 (98.5)	254 (99.2)	269 (97.8)
Comorbidities (% with 2 or more) ⁺	193 (36.4)	83 (32.4)	110 (40.1)
Personal Hx of Cancer (% yes) *	79 (14.9)	49 (19.1)	30 (10.9)
Family Hx of PCa (% yes) ⁺	126 (24.5)	63 (25.3)	63 (23.8)
Ever discussed PCS with doctor (% yes)	394 (74.2)	192 (75.0)	202 (73.5)
Ever screened for PCa (% yes) ⁺ *	477 (89.8)	241 (94.1)	236 (85.8)
Screened in past 12 mos. (% yes)*	346 (65.2)	185 (76.8)	161 (68.2)

* < .05

** < .01

⁺ Percentages do not add to 100 due to missing data.

Table 2. Computer Access of Users vs. Non-Users (N=531)

	All (N=531)	Users (N = 256)	Non-Users (N=275)
	N (%)	N (%)	N (%)
Health-Related Information Delivery Preference (% Internet) **	200 (37.7)	112 (43.8)	88 (32.0)
Internet Access (% yes) **	486 (91.5)	252 (98.4)	234 (85.1)
High Speed Access (% yes) ⁺	462 (96.5)	245 (97.6)	217 (95.2)
Daily Use (% yes) **	384 (79.0)	223 (88.5)	161 (68.8)
Frequency of Internet Use to Obtain Health-Related Information (% few times month/week) ⁺	178 (38.9)	92 (36.9)	86 (41.3)

* < .05

** < .01

⁺ Percentages do not add to 100 due to missing data.

Table 3. Logistic Regression Predicting Website Use (N = 531)

Demographic and Computer Access Variables	Website Use	
	OR	95% CI
Marital Status (ref= not married)	0.91	0.58, 1.42
Regular Doctor (ref=no)	2.13	0.86, 5.26
Education (ref=some college or less)	1.04	0.66, 1.62
Race (ref=non White) **	2.37	1.56, 3.59
Personal History of Cancer (ref=no)	1.69	0.97, 2.94
Ever Screened for PCa (ref=no) *	2.13	1.07, 4.26
Site (ref=WHC)		
GUH Site	0.96	0.43, 2.12
MPP Site	1.06	0.48, 2.32
Delivery Preference (ref = preferred web)		
Preferred Print-based Health-Related Information	0.93	0.60, 1.43
No Preference for Print or Web-based Health-Related Info.	1.06	0.58, 1.95
Internet Access (ref=no) *	3.66	1.15, 11.58
Daily Use (ref=no)**	2.58	1.47, 4.55

* < .05

** < .01

Table 4. Time Spent Using the Website (N=256)

Section	N	% Ever Viewed	Median time (minutes)	Page count per section	Median time per page per section (seconds)	Median # of page hits	Median # of page hits per section
Introduction	256	100.00%	6.05	16	22.8	16	1.2
Screening	243	94.92%	13.62	31	26.4	31	1.1
Treatment Issues	223	87.11%	11.11	19	34.8	19	1.1
Steps You Can Take	217	84.77%	3.90	11	21.0	11	1.1
Values Clarification Tool	216	84.38%	2.38	4	24.0	4	1.1
More Information	80	31.25%	1.62	4	36.0	3	0.8
TOTAL TIME (median)	256	100.00%	33.94	86	25.2	86	1.0

Table 5 User Feedback (N=256)

	All Users (N=256)	PCS Preference – Web: Pro N = 206 (80.5%)	PCS Preference – Web: Con N = 50 (19.5%)
How helpful was the information on the website, in terms of helping you to understand the pros and cons of PCS?			
Not/somewhat helpful	44 (17.2)	36 (17.5)	8 (16.0)
Very/extremely helpful	212 (82.8)	170 (82.5)	42 (84.0)
Did you have any trouble reading or understanding the website?			
Yes	7 (2.7)	5 (2.4)	2 (4.0)
No	249 (97.3)	201 (97.6)	48 (96.0)
How many pages did you view?			
Few/some pages	9 (3.5)	5 (2.4)	4 (8.0)
Most/all pages	247 (96.5)	201 (97.6)	46 (92.0)
How would you rate the length of the website? ⁺			
Much/a little too short	8 (3.2)	7 (3.4)	1 (2.1)
Just right	157 (62.1)	123 (60.0)	34 (70.8)
Much/a little too long	88 (34.8)	75 (36.6)	13 (27.1)
Do you think the overall message of the website suggested... ⁺			
Men should get screened	54 (21.3)	41 (20.1)	13 (26.0)
Men should not get screened	17 (6.7)	14 (6.9)	3 (6.0)
Neither	183 (72.0)	149 (73.0)	34 (68.0)
Did the website make you nervous/fearful about PCS? **			
Yes	25 (9.8)	16 (7.8)	9 (18.0)
No	231 (90.2)	190 (92.2)	41 (82.0)
Do you think the website influenced your decision about whether to be screened or not for PCa? ⁺ **			
Not at all	151 (59.2)	138 (67.3)	13 (26.0)
A little/somewhat	61 (23.9)	43 (21.0)	18 (36.0)
Very much/quite a bit	43 (16.9)	24 (11.7)	19 (38.0)
Did the website make you think of new questions to ask your doctor? **			
Yes	128 (50.0)	93 (45.1)	35 (70.0)
No	128 (50.0)	113 (54.9)	15 (30.0)

* < .05

** < .01

⁺ Percentages do not add to 100 due to missing data.

Table 6. Testimonial Use (N=256)

	All Users N = 256	PCS Preference – Web: Pro N = 206 (80.5%)	PCS Preference – Web: Con N =50 (19.5%)
Video 1:* Promoting Informed Decision Making (Con Screening)	--	133 (64.6)	--
Video 2:* Long Term Consequences of Screening (Con Screening)	--	153 (74.3)	--
Video 1:* Promoting Informed Decision Making (Pro Screening)	--	--	29 (58.0)
Video 2:* Long Term Consequences of Screening (Pro Screening)	--	--	31 (62.0)
Video 3: Elevated Screening Results followed by a Negative Biopsy (Pro Screening)	151 (59.0)	122 (59.2)	29 (58.0)
Video 4: Elevated Screening Results followed by a Negative Biopsy (Con Screening)	152 (59.4)	124 (60.2)	28 (56.0)
Video 5: Selecting Watchful Waiting as the Treatment Strategy (Pro Screening)	136 (53.1)	113 (54.9)	23 (46.0)
Video 6: Selecting Watchful Waiting as the Treatment Strategy (Con Screening)	132 (51.6)	111 (53.9)	21 (42.0)
Video 7: Selecting Active Treatment as Treatment Strategy (Pro Screening)	129 (50.4)	109 (52.9)	20 (40.0)
Video 8: Selecting Active Treatment as Treatment Strategy (Con Screening)	133 (52.0)	107 (51.9)	26 (52.0)

*Men who responded to the PCS preference question at website entry as certain about their choice to be screened received the two ‘Con Screening’ video testimonials. Men who responded as uncertain about screening received the two ‘Pro Screening’ video testimonials. All users had access to the remaining six testimonials.

Figure 1. Accrual Flowchart

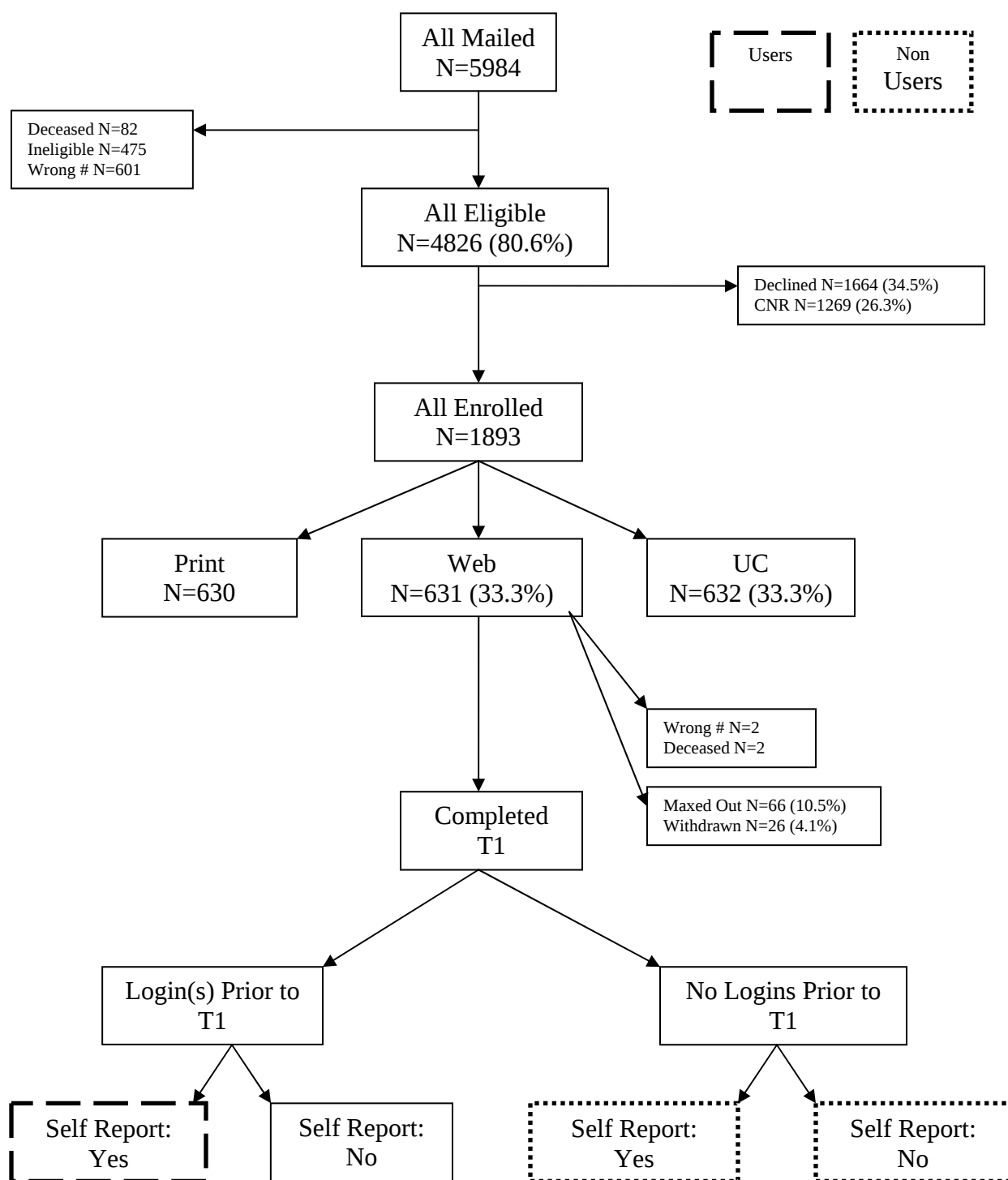
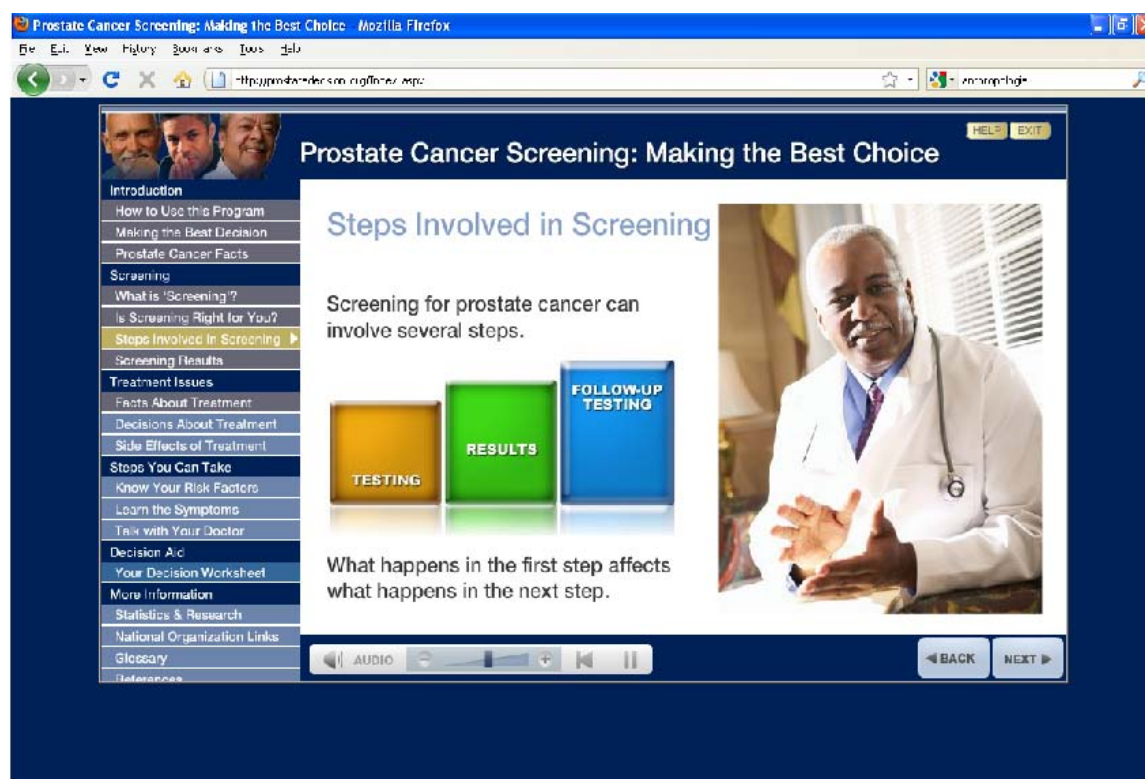


Figure 2. Screenshot of Website



Physicians' Attitudes About Shared Decision Making for Prostate Cancer Screening

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ABSTRACT

Physicians' Attitudes About Shared Decision Making for Prostate Cancer Screening

Background and Objectives: Shared decision making (SDM) for prostate cancer screening (PCS) is recommended for physicians and patients due to the uncertainty regarding the risks and benefits of screening. **Methods:** We assessed primary care physicians' attitudes and specific factors that may influence the SDM process, including level of training and practice setting. Participants included academic clinicians (N = 16), interns/residents (N = 84) and community clinicians (N = 35). Physicians completed a 26-item survey that assessed attitudes about the SDM process for PCS. **Results:** More physicians endorsed SDM (47.4%) or the patient deciding (35.6%), while few physicians wanted to decide for their patients about screening. However, 54.8% endorsed an annual PSA as the standard of care. Most felt that decisions should be based on full disclosure of the risks and benefits of testing (93.3%) and few believed that the sensitivity and specificity of the PSA was adequate (36.6%). Across all physicians, lack of time, competing health demands, malpractice fears and patient interest were all commonly cited as potential factors that influence the SDM process. Compared to academic clinicians and interns/residents, community clinicians were more likely to endorse annual screening, to be concerned about malpractice, and to agree that PSA sensitivity and specificity are acceptable (all $p < .001$). **Conclusions:** Our findings demonstrate physician, patient and systemic factors regarding the PCS decision. Further effort is needed to overcome the barriers of engaging patients in SDM if we want to truly promote effective SDM for PCS, as espoused by national guidelines.

INTRODUCTION

Shared decision making (SDM) for prostate cancer screening (PCS) is recommended for physicians and patients due to the uncertainty associated with currently available screening tests. Differing findings from the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial¹ and the European Randomized Study of Screening for Prostate Cancer (ERSPC)² highlight the fact that there is still insufficient evidence to recommend for or against PCS. While there is no national standard with regard to the SDM process, all medical organizations recommend that physicians should engage in SDM to help patients make an informed decision.³⁻⁶ This involves discussions of the pros and cons of screening to improve patients' understanding of the potential risks and benefits.³⁻¹¹ However, uncertainties surrounding the risks and benefits associated with screening, the enthusiasm of the public about screening,¹² and several patient, physician and systemic factors appear to reinforce the desire to screen, making the SDM process complex for both men and their doctors.^{13,14}

Some of the patient factors that may affect SDM include language barriers, comorbidities, health literacy, and patient demand.¹⁵⁻¹⁷ Physician factors include beliefs/attitudes about screening,¹⁷⁻²¹ personal and professional experience with prostate cancer/screening,^{20,22,23} and level of training.^{24,25} Systemic factors include lack of reimbursement for screening discussions, malpractice risk,^{7,26-28} lack of readily available patient decision aids, insufficient training in SDM strategies,^{18,29} and practice setting.²⁵ All of these factors may add complexities to the SDM process.

There have only been a few studies that assessed level of training or practice setting as factors which may impact the SDM process,^{24,25} therefore their role remains unclear. In preparation for our randomized trial of a PCS decision aid targeted to primary care patients,³⁰ we

assessed attitudes and factors that influenced the SDM process for the primary care providers (PCPs) from the participating practices.

METHODS

Participants

Three groups of PCPs were surveyed from two academic and one community based practice: 1) academic clinicians, 2) interns/residents and 3) community clinicians. Academic clinicians and interns/residents in the Divisions of General Internal Medicine at Georgetown University Hospital (GUH) and the Washington Hospital Center (WHC) completed the survey between May-July 2007. Community-based physicians in MedStar Physician Partners (MPP) completed the survey between September-December 2008. Medical students, non-primary care residents/interns, and non-physician healthcare providers were excluded.

Procedures for Survey Administration

We approached participants according to the recommendations of the three site co-investigators. The division chiefs of Internal Medicine at GUH and WHC distributed the study descriptions, surveys and consent forms to their respective PCPs. At GUH, interns/residents were recruited during six pre-clinic and noon conferences over three months. At WHC, interns/residents were recruited at clinic meetings on five consecutive days during one week. We mailed the MPP community clinicians an introductory letter, study description, consent form, survey, and a return self-addressed stamped envelope. This study was approved by the Georgetown/MedStar Oncology Institutional Review Board.

Survey Instrument

We developed a 26-item survey based on questions from recent physician surveys^{25,26} that addressed: 1) physician characteristics, 2) physician attitudes about screening, and 3)

physicians' report of the SDM process for PCS (See Appendix). Physicians were also asked whether they had experienced any adverse outcomes due to screening. Male physicians were asked whether they personally had had an elevated prostate specific antigen (PSA) or been diagnosed with prostate cancer. The survey required 5 to 10 minutes.

The demographic characteristics assessed included age, gender, race, ethnicity, level of training and years since medical school graduation. The five attitude items assessed physicians' beliefs about the standard of care for screening asymptomatic men over 50, malpractice liability, sensitivity of the PSA, routine screening of high risk men, and whether screening decisions should be based on the full disclosure of available information. These items had a 5-point response scale (Strongly Agree to Strongly Disagree).

Next, we asked physicians several questions about systemic, patient, and physician-related factors that may influence their discussions about PCS. Response categories were Never/Rarely, Sometimes, Often and Almost Always. Next, physicians indicated their preferred SDM style (see Appendix 1, question 10). The five response choices ranged from: physicians make the final decision, to patients make the final decision, and included a middle response of physicians and patients share the responsibility for deciding about screening.³¹ For the analyses, we collapsed the 5-point scale into a 3-point scale given the limited numbers in the two extreme categories. Physicians were also asked whether a decision aid would assist them in discussions about the risks and benefits of screening before, during, or after an office visit (Definitely, Possibly, Possibly Not, or Definitely Not). Finally, physicians were asked how frequently patient race, family history, co-morbid illnesses, patient preferences, and concern about malpractice influenced their screening practices: (Never/Rarely, Sometimes, Often and Almost Always).

Data Analytic Strategy

Data were entered and analyzed using SPSS version 17.0. Descriptive statistics were examined to assess overall beliefs and differences by practice setting and level of training. There were no demographic differences between the GUH and WHC clinicians or interns/residents, therefore we collapsed these two groups across sites. Thus, the analyses describe our sample and compares GUH/WHC interns/residents, GUH/WHC academic clinicians, and MPP community clinicians regarding their attitudes and the SDM process for PCS.

RESULTS

Descriptive Information

At GUH, 81 academic clinicians and interns/residents were approached, of which 4 were ineligible, resulting in 77 eligible participants. Of these, 54 (70.1%) completed and returned the surveys (GUH interns/residents = 44 and academic clinicians = 10). At WHC, 47 eligible participants were approached, of which 46 (97.9%) completed and returned the surveys (WHC interns/residents = 40 and academic clinicians = 6). At MPP, 50 community clinicians were approached and 35 (70%) eligible surveys were completed and returned. The final sample included 16 academic clinicians, 35 community clinicians and 84 interns/residents.

In Table 1, we present the demographic characteristics of the three groups. The mean ages were 29.9 years, 41.6 years and 48.6 years for interns/residents, academic clinicians and community clinicians, respectively. The only significant demographic differences between the groups included age and years since medical school graduation ($p < .001$). The community clinicians were significantly older than the academic clinicians, and had completed medical school earlier ($M = 22$ years ago vs. $M = 15$ years ago). No physicians reported adverse events, and only one male physician reported having had an elevated PSA.

Attitudes about the SDM process

Most physicians preferred SDM (47.4%) or the patient deciding (35.6%), while few preferred making the final decision for their patients about being screened. In Table 2, we present the percentage of all physicians who Agreed/Strongly Agreed with five attitudes about the SDM process and PCS. While a majority of all physicians endorsed SDM, 54.8% of all physicians also endorsed an annual PSA as the standard of care for men over 50. Most physicians felt that decisions should be based on full disclosure of the risks and benefits of testing (93.3%) and that high risk men should be routinely screened (90.3%). While overall few believed that the specificity and sensitivity of the PSA was adequate (36.6%), one-half (49.6%) believed providers face malpractice liability if a PSA is not performed and cancer is later detected.

Regarding SDM, most physicians in each group preferred a SDM style (academic clinicians = 50.0%, community clinicians = 48.5%, and interns/residents = 48.2%) or having the patient decide being screened 43.8%, 33.3% and 36.1%, respectively. Few physicians preferred to make the final decision for their patients (community clinicians = 18.2%, interns/residents = 15.7%, and academic clinicians = 6.3%). There was not a significant difference across the physician groups ($p > 0.20$).

Of interest were the significant differences by practice setting and level of training. There were significant differences by practice setting and level of training of physicians who agreed that asymptomatic men over 50 should be screened annually ($p < 0.001$). All academic clinicians and virtually all interns/residents endorsed the belief that decisions to be screened should be based on full disclosure of information about the diagnosis and treatment of early stage disease, compared to community clinicians ($p < 0.01$; Table 2). More community clinicians

agreed that the PSA has acceptable sensitivity and specificity compared to their academic counterparts and interns/residents ($p < 0.001$). Similarly, community clinicians reported the greatest concern about malpractice liability compared to academic clinicians and interns/residents ($p < 0.001$). There were no significant differences between the groups regarding their endorsement of routine screening for high risk men ($p > .20$).

Systemic, patient, and physician factors that impact the SDM process

Physicians indicated how frequently certain systemic, patient, and physician factors influenced the SDM process (Table 3). Across all physicians, lack of time (80.5%), competing health priorities (95.5%) and patient interest (69.9%) were all highly endorsed factors that influence the SDM process. Additionally, the complexity of screening (47.0%) and patients being well informed (51.9%) were endorsed by almost half of all physicians.

Of the systemic factors, physicians only differed on lack of reimbursement for the discussion. Almost 40% of community clinicians compared to 11% of interns/residents and 18.8% of academic clinicians endorsed lack of reimbursement as a factor that influenced their discussions ($p < 0.01$). Regarding patient factors, there were no significant differences between physician groups regarding patient interest ($p > 0.20$) or language as a barrier ($p > 0.20$). However, the more experienced academic and community clinicians were more likely to report that their patients were well informed about screening compared to interns/residents ($p < 0.01$). Finally, regarding physician factors, there were no differences across the three physician groups regarding whether SDM discussions would discourage patients from being screened. Community clinicians were more likely to endorse the belief that such a discussion would not influence whether he/she ordered the test, compared to academic clinicians and interns/residents ($p < .05$). Interns/residents were more likely to endorse their lack of knowledge about the risks

and benefits of screening than either academic or community clinicians ($p < 0.01$). Finally, significantly more interns/residents (96.4%) than academic (75.0%) or community clinicians (73.5%) indicated that decision aids used *during* the office visit would be useful ($p < 0.01$).

DISCUSSION

In this pilot study of PCP's attitudes about the SDM process for PCS, we identified several physician, patient and systemic factors that influence physicians to engage patients in SDM for PCS. Over 80% of physicians preferred to engage patients in SDM or let patients make the final decision and virtually all physicians reported that the decision to be screened should be based on full disclosure of what is known about the diagnosis and treatment of early stage prostate cancer. However, more than half of physicians reported that yearly screening should be the standard of care. Compared to academic clinicians, the majority of community clinicians (80%)--the setting where the majority of Americans receive healthcare--endorsed routine screening. Additionally, community clinicians indicated that the PSA had adequate sensitivity and specificity, and believed that they were also medically liable if they did not perform the test.

The physician factors we and other researchers observe may partially explain current screening practices, despite reported physician beliefs.³² Inconsistent with current evidence of the benefits of screening, American men are more likely to be screened for prostate than for colorectal cancer.³³ Most providers do not discuss PCS with patients, rather they paternalistically order a PSA as part of routine care.¹⁵ In fact many patients are acutely aware of the harms of prostate cancer and that the PSA can detect disease early, yet many lack important information about the harms of testing and the uncertainty about whether testing improves morbidity or mortality.¹³ As a result, many patients may initially want to be screened, but if fully informed

may elect to defer screening. However, there are many individual and systemic factors that positively reinforce physicians to conduct screening.

Patient and systemic factors that influenced the SDM process included competing health priorities, time constraints, patient interest, malpractice concerns, and the complexity of screening. In the present sample, these factors were commonly cited by all physicians as possible barriers to the SDM process. For example, acute patient complaints take precedence when patients see their PCPs and patient interest in screening must also be considered. Added to these factors was the concern about malpractice liability especially for community clinicians, further reinforcing PCS.²⁸ Failure to diagnose prostate cancer is well documented as a legal concern for physicians, but there are no known lawsuits regarding screening or overdiagnosis. Interestingly, most providers did not endorse lack of reimbursement, yet they did cite time constraints as a barrier. This is of interest because if SDM were reimbursed, then providers would be given time for such discussions and the current guidelines would be followed. However, in the current healthcare environment, reimbursement exists only for the PSA or the DRE but not SDM. At present, the concern about malpractice and the time constraints associated with SDM appear to be the most likely factors contributing to the contradiction between physicians' belief in SDM and their screening practices. Additionally, physicians and patients alike have difficulty appreciating that screening has drawbacks as well as benefits, and therefore discussions between physicians and patients are needed to determine what is most important for each individual.

In our sample, level of training and practice setting also emerged as important. Academic clinicians were least likely to endorse routine yearly screening, followed by clinicians in training and community clinicians. Consistent with Dunn et al. (2001), the three groups reported that time

constraints, the complexity of screening and competing demands were common barriers.¹⁵ However, clinicians in training felt less comfortable with their knowledge about the risks and benefits of screening and felt that their patients were less informed about screening than the other two groups; conversely, community clinicians felt greater concern for malpractice. Despite these feelings of discomfort, prior studies have demonstrated that patients report that clinicians in training engage patients as well as academic and community clinicians in the SDM process.²⁴ In our study, clinicians in training expressed a greater endorsement of the usefulness of a decision aid *during* the office visit. This may be to compensate for their lack of knowledge or may suggest an increased receptivity to using decision aids. Additional information is needed to better understand what tools will help physicians and when they will be most useful.

Several limitations need to be considered when interpreting these preliminary results. The small sample size, particularly among academic clinicians, limited our ability to make firm conclusions about group differences. Second, participants were drawn from two affiliated academic hospitals in Washington, DC and an affiliated community-based practice group of PCPs, potentially limiting the generalizability of the findings. A third limitation was that the data were based on physician self-report rather than observation of SDM processes or medical record review of screening practices.

CONCLUSIONS

In summary, these pilot data provide evidence of the multiple challenges that physicians face when assisting their patients in the SDM process for PCS. This is demonstrated by their endorsement of SDM on the one hand and the support of annual PSA testing for men over 50 on the other hand. Given the pressure to provide screening and the current recommendations to discuss the risks and benefits of screening, our results suggest that ongoing physician training

regarding these discussions with patients could be beneficial to the SDM process. Additional efforts are warranted to further examine the barriers to engaging patients in SDM for prostate cancer.

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Table 1: Physician Characteristics

Characteristics		Interns/ Residents (N=84)		Academic Clinicians (N=16)		Community Clinicians (N=35)		Total (N=135)	
Age	Mean (SD)***	29.9 (3.2)		41.6 (8.1)		48.6 (9.6)		36.1 (10.3)	
Male	N (%)	42 (50.0)		6 (37.5)		16 (45.7)		64 (47.4)	
Race	N (%)								
	White	46 (54.8)		12 (75.0)		21 (60.0)		79 (58.5)	
	Black	8 (9.5)		1 (6.2)		4 (11.4)		13 (9.6)	
	Asian/Pacific Islander	22 (26.2)		3 (18.8)		8 (22.9)		33 (24.4)	
	Native American	1 (1.2)		0 (0.0)		0 (0.0)		1 (0.7)	
	Other	4 (4.8)		0 (0.0)		2 (5.7)		6 (4.4)	
	Missing	3 (3.6)		0 (0.0)		0 (0.0)		3 (2.2)	
Ethnicity	N (%)								
	Hispanic	4 (4.8)		0 (0.0)		2 (5.7)		6 (4.4)	
	Non-Hispanic	72 (85.7)		13 (81.3)		23 (65.7)		108 (80.0)	
	Missing	8 (9.5)		3 (18.8)		10 (28.6)		21 (15.6)	
Level of Training	N (%)								
	Attending	--		16 (100.0)		35 (100.0)		51 (37.8)	
	Resident	45 (53.6)		--		--		45 (33.3)	
	Intern	39 (46.4)		--		--		39 (28.9)	
Yrs since Graduated from Medical School	Mean (SD)***	3.1 (3.3)		15.4 (7.8)		22.0 (9.7)		9.5 (10.4)	

***p < .001

Table 2: Percentage of Physicians Who Agreed or Strongly Agreed with Specific Attitudes about PCS

Beliefs about Prostate Cancer Screening	Interns/ Residents (N=84)	Academic Clinicians (N=16)	Community Clinicians (N=35)	All Physicians (N=135)
Yearly PSA test for asymptomatic men over 50 should be standard of care. **	50.0	25.0	80.0	54.8
High risk men (African-American men and men with a 1 st degree relative with PCa) should be routinely screened with a PSA test. #	86.7	87.5	100.0	90.3
Patients' decisions to be screened should be based on full disclosure of what is known about the diagnosis and treatment of early PCa. *	96.4	100.0	82.9	93.3
Providers face malpractice liability if a PSA test is not performed and prostate cancer is later detected. **	34.5	62.5	80.0	49.6
PSA has acceptable sensitivity and specificity, and positive predictive value as a screening test. **	27.4	20.0	65.7	36.6

* $p < .05$; ** $p < .001$; # $p < .10$

Note. PCS: prostate cancer screening; PSA: prostate specific antigen; PCa: prostate cancer.

Table 3: Factors that Influenced SDM Discussions¹

Factors Influencing Discussions	Interns/ Residents (N = 84)	Academic Clinicians (N = 16)	Community Clinicians (N = 35)	All Physicians (N =135)
Systemic Factors				
Lack of Time	78.3%	87.5	82.4	80.5
Complexity of Screening	42.2	53.3	55.9	47.0
Competing priorities/A need to focus on patients' current complaints/disease	97.6	93.8	90.9	95.5
Lack of reimbursement for discussion**	11.0	18.8	38.2	18.9
Patient Factors				
Level of patient interest in this topic	67.5	75.0	73.5	69.9
A language barrier between myself and my patients	34.9	37.5	35.3	35.3
The patients I see are already well informed about this topic**	39.8	75.0	70.6	51.9
Physician Factors				
My belief that a discussion would not influence whether I order the test*	21.7	6.3	39.4	24.2
My personal lack of knowledge about the benefits and risks of prostate cancer screening **	42.2	6.3	23.5	33.1
The concern that this discussion might discourage my patients from being screened	21.7	12.5	26.5	21.8

* $p < .05$; ** $p < .01$;

¹ Percentages reflect those who responded sometimes, often, or almost always.