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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 618 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. Since our last annual report, we have submitted a manuscript for the physician study (currently under review) and we are working on submitting the development paper which describes the process we undertook to redesign the booklet and develop the website. The randomized trial has been ongoing for one year and we currently have accrued 618 participants with a 41% participation rate. We anticipated a 50% participation rate in our calculations of accrual feasibility and are working toward increasing the participation rate using number of measures, described in detail below. Four hundred-sixty three one-month assessments have been completed (92% response rate), and eleven 12-month assessments have been completed (92% response rate).

	Georgetown University, n (% response rate)	Washington Hospital Center, n (% response rate)	MedStar Physician Partners, n (% response rate)	Total, N (% response rate)
Baseline Response Rates	358 (47%)	184 (31%)	76 (48%)	618 (41%)
One-Month Response Rates	284 (92%)	145 (89%)	34 (100%)	463 (92%)
12-month Response Rates	11 (92%)	None due to date	None due to date	11 (92%)

Development of the Booklet. As noted in our report last year, our consultants, experts in prostate cancer screening (Steven Woolf, M.D., and Alex Krist, M.D.) and health communication (Janet Ohene-Frempong, M.S.), all suggested significant modifications to our existing print booklet. As a result, we spent three months holding meetings, rewriting the booklet, sending it to our consultants and research team members for edits, all in an iterative process. The development of the website could not occur simultaneously with the rewriting of the booklet, as the content of the print and website had to be consistent. As a result of these events, we were several months behind our intended schedule, but have been able to make up this time during this one year of accrual.

Website development. Once the booklet was close to its final version, development of the website began. We sent the revised booklet to our web developer (Triad Interactive) to incorporate all the changes we had made in the booklet into the website. Triad gave us several versions of the website to review throughout early 2007. Edits were made and the final website was tested and then completed in August 2007. The address of the website is www.prostatedecision.org and the Username is Guest and the Password is Guest1235.

Physician Study. Prior to beginning the PCSEd randomized trial, we conducted a cross-sectional survey of the primary care physicians at the two academic medical centers from which patients will be recruited for the randomized trial. The goal of this ancillary study was to examine the physicians' attitudes and practices regarding prostate cancer screening prior to the start of the trial. Understanding what factors may influence their discussions about the risks and benefits of PCa screening as well as practices and recommendations to their patients may aid in the interpretation of the findings from the trial. Additionally, we sought to determine the impact of physician rank (attending, resident, or intern) on screening knowledge and practice. Surveys assessed beliefs about prostate cancer screening, factors that influence screening practices, and preferences for shared decision making. Since our last report, we completed data analysis of the physician surveys and submitted the manuscript to a journal publication (See Appendix for the manuscript's abstract).

At the conclusion of the patient-based intervention study, we will reassess the primary care physicians using the same questionnaire. Since the two assessments will be completed several years apart, the information will only provide a snapshot of the two clinics, as the staff will likely change significantly during that time. We will also assess if physicians were aware of our study, with respect to whether patients discussed the intervention materials with them.

Addition of Third Recruitment Site. In an effort to increase our accrual and response rates, we added a third recruitment site to this study. Since June 2008 we have been working closely with the President of MedStar Physician Partners (MPP), Dr. Edward Miller, to include MPP as an additional site for recruitment. Dr. Miller agreed to serve as Site Principal Investigator and confirmed that he would be able to provide approximately 12,000 patients that are seen by the 49 doctors under MPP as potential study participants. We received approval from the DoD and Georgetown University's IRB to add MPP as a third site. Since that approval we have been able to accrue 76 MPP patients (48% response rate) to our trial.

In order to have the same data on the 49 physicians under MPP we also administered the one time survey and received 35 completed questionnaires (71% response rate). We will include their data in future analysis of the physician surveys.

Increase in Recruitment. As of October 1, 2008 we were sending out 90 letters every two weeks and on average accruing 18 participants out of the 90 patients invited to join the study. Based on these numbers we did a series of calculations to determine the number of participants we will need to accrue to reach our goal of 1,875 subjects. It was determined we needed to increase accrual of subjects by approximately 50%. In order to do that, on Friday, October 3, 2008 we began sending out 72 letters a week.

Study Year	N	Ss Accrued/2 Weeks	Ss Accrued/Week
11/2007 -11/2008	470	18	9
12/2008-11/2009	675 Total N = 1145	27	13.5
12/2009-11/2010	675 Total N = 1820	27	13.5
12/1/2010	55 Total N = 1875	27	13.5

Additional accomplishments during this grant year: 1) As noted in our last report, approximately 15-20% of the addresses and phone numbers that we were receiving from the study sites were incorrect. Since July 2008 we were able to activate an account with Choice Point. Choice Point is a company that utilizes various sources to obtain up to date information, including utility records and death records, to provide updated contact information. This procedure was approved by the DoD and Georgetown IRB and we have begun to use this service to help us locate the most up to date contact information for our study participants. 2) Since June 2008, we have hired one full time project coordinator and one full time research assistant to assist with accrual for this study. Thus, allowing us to increase the number of invitation letters we send out and the follow up calls we make in order to accrue participants who do not call in to our 800 number. We now have a total of 4.5 FTE telephone interviewers. 3) Finalized the questionnaire to be used at the 12-month assessment.

Below we have inserted Tasks 1-3 from the Statement of Work and indicated progress made on each item.

Task 1. Develop the educational website and booklet **COMPLETED**

Task 2. Conduct participant accrual **ONGOING**

- a. Eligible participants will be accessioned and the baseline interview will be administered by telephone. *This task is underway; we have accrued 618 men to the protocol.*
- b. Participants will be randomly assigned to arm and the intervention materials distributed.--*Underway*
- c. Data entry and quality control measures will be ongoing. *Underway.*
- 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 at WHC and we will obtain records as soon as 25 final telephone assessments are completed. At GU, they are currently in the midst of a transition of all medical records to a new EMR system. We will wait a few months until this process is complete before we begin receiving medical records for study participants. At MPP, we just began recruiting participants from this site.*
- e. Begin accessing patient information from the charts. *Not yet begun.*

Task 3. Conduct follow-up assessments: **ONGOING**

- a. The Time 1 assessment will be conducted and the interventions will be distributed to participants. *Underway.*
- b. The Time 2 interviews will be conducted at 1 month post intervention. *Underway.*
- c. The Time 3 interviews will be conducted at 12 months post intervention. *Underway.*

Key Research Accomplishments

- 1) Addition of third recruitment site.
- 2) Increase in invitation letters mailed and number of patients being recruited.
- 3) Utilization of Choice Point to assist in getting the most up to date information on our study participants for accrual and retention rates.
- 4) Increase in FTE telephone interviewers.

- 5) Finalized the one-year telephone assessment.
- 6) Submitted the manuscript for the physician study: Davis, K., Haisfield, L., Dorfman, C., Parker, E., Red, S., Dawson, D., Jackson, T., Goldman, P., Fishman, M., Cole, C., Alex Krist, Steven Woolf, Taylor, K. (Under review). Physicians' Attitudes and Practices Regarding Prostate Cancer Screening.
- 7) Completion of abstract for the development paper and the manuscript is in progress.
- 8) Randomized trial is underway.

Reportable Outcomes

- 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.

Conclusions –

We do not yet have findings that are relevant for the scientific field. However, our work to date is extremely important for the progress of the proposed study. The revised print booklet has many strengths that the previous version did not have, while maintaining its original strong points. It is better organized and easier to read, while maintaining a level of detail for those men who wish to delve deeper into the topic. The feasibility study we conducted last year demonstrated men's computer/Internet access, their willingness to participate in an Internet-based study, and our access to the primary care clinics where we propose to accrue participants. It also increased our awareness of the potential for difficulties that some men face when attempting to gain up-to-date health-related information from the Internet. This information has been extremely important in helping to guide the development of the website. At present, we are preparing one manuscript which describes the development process of both the booklet and the website.

Plans

- 1) Continue accruing participants, working to improve participation rates and the rate of accrual. In the past year, we have taken several steps to improve our participation rates. Many of these measures (e.g. Choice point, adding MPP) did not come into place until the summer. We have already begun to see the effects of these efforts and hope to see more in the coming months.
- 2) Submit the one manuscript described above.
- 3) Begin to obtain the medical records for patients who have completed the study.
- 4) Begin some preliminary analyses and consider a paper generated from the baseline data at that point.

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Appendix

- 1) Abstract of physician study manuscript
- 2) Abstract of development process manuscript

Physicians' Attitudes and Practices Regarding Prostate Cancer Screening. (Under review).

Davis, K., Haisfield, L., Dorfman, C., Parker, E., Red, S., Dawson, D., Jackson, T., Goldman, P., Fishman, M., Cole, C., Krist, A., Woolf, S., & Taylor, K.

Background: As the evidence to support the benefits of prostate cancer screening (PCS) is uncertain, physicians are often faced with difficult clinical situations regarding PCS. ***Objective:*** We sought to evaluate physician attitudes and practices regarding PCS by training level in two academic internal medicine practices. ***Participants:*** Physicians included attendings (N=16), residents (N=39), and interns (N=45). ***Measurements:*** Physicians were asked to complete a 26-item survey assessing physician demographics and PCS attitudes, knowledge, decision making preferences, and screening practices. ***Results:*** The overall response rate across both sites was 84%. The majority of respondents understood the limitations of PCS and endorsed informing patients about PCS prior to screening. As anticipated, respondents who believed that an annual PSA should be the standard of care, that high risk men should be screened, or who had concerns about malpractice, were more likely to report conducting annual screening. However, while only 25% of attendings supported an annual PSA for average risk men, two-thirds reported that they actually conducted annual screenings. The attitudes and practices of the residents and interns were congruent, not reflecting the dichotomy found among attendings. ***Conclusions:*** These data provide evidence of the difficult task that even experienced physicians have when confronting the issues surrounding PCS. Given the external pressures to provide screening, as well as the current recommendations to discuss the risks and benefits of PCS with patients, our results suggest that better tools and systems are required to help physicians improve the PCS decision making process.

The Development of Web- and Print-based Decision Aids for Prostate Cancer Screening Education

Taylor, K.L., Davis, K.M., Schwartz, M.D., Goldman, P.H., Dawson, D.L., Ohene-Frempong, J., Woolf, S.H., Krist, A., Fishman, M.B., Cole, C.A., Red, S., Parker, E., Dorfman, C., and Haisfield, L.

Background. Prostate Cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death. However, randomized trials have yet to demonstrate that, by screening asymptomatic men, early detection and treatment will reduce disease-related mortality. As a result, health education tools are needed to facilitate informed decision making about PCa screening. While 20 randomized controlled trials (RCTs) have evaluated PCa screening decision aids, many reported only modest increases in participants' knowledge after viewing the interventions and very few included an exercise to help men clarify their values and preferences about PCa screening. **Objective.** We sought to develop two new PCa patient decision aids, a booklet and an interactive website, incorporating a values clarification exercise into each. This paper describes the development of these tools. **Methods.** A systematic approach was used to develop both the print and web-based tools. The booklet was adapted from two previous iterations that have been evaluated in RCTs, and the website was created to closely match the booklet. Both tools were reviewed by members of our target audience, with 14 men participating in booklet focus groups and 14 men participating in usability testing for the website. During both the focus groups and usability testing participants provided feedback on their thoughts, likes, and dislikes with regards to the materials and their impression of the overall message of each decision aid. At each step in the development process members of the research team reviewed the feedback and made changes to the tools. When changes related to content, both the website and booklet were modified. **Future Research/Applications.** The booklet and interactive website are currently being evaluated. By addressing the limitations of previous PCa decision aids, we intended to create widely disseminable and relevant materials. These tools may be useful at the primary care level to improve PCa knowledge and help men make informed screening decisions, as well as encourage shared decision making between patients and physicians.