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AWARD NUMBER: W81XWH-06-1-0182

TITLE: Internet-Based Education for Prostate Cancer Screening

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REPORT DATE: December 2009

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 1 December 2009		2. REPORT TYPE Final Addendum		3. DATES COVERED 31 Dec 2008 – 30 Nov 2009	
4. TITLE AND SUBTITLE Internet-Based Education for Prostate Cancer Screening				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-06-1-0182	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Kathryn L. Taylor, Ph.D. E-Mail: taylorkl@georgetown.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Georgetown University Washington, DC 20007				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
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 1,710 participants to the randomized trial. In the final year of funding, we will accrue the remaining 165 participants, continue to follow the enrolled participants, and conduct data analyses.					
15. SUBJECT TERMS Prostate Cancer Screening, Medical Decision Making, Education and Communication					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 12	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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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. The randomized trial has been ongoing for two years and we currently have accrued 1,710 participants with a 38% 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. One thousand four hundred thirty- seven one-month assessments have been completed (91% response rate), and four hundred four 12-month assessments have been completed (91% 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	731 (42%)	237 (31%)	742 (37%)	1,710 (38%)
One-Month Response Rates	659 (91%)	199(87%)	579 (91%)	1,437 (91%)
12-month Response Rates	265 (93%)	104 (85%)	35 (100%)	404 (91%)

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 this addition we have been able to accrue 742 MPP patients (37% 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 have added their data to the manuscript on physicians' attitudes and practices regarding prostate cancer screening.

Increase in Recruitment. Since the last report we began sending out 72 letters a week in order to reach our accrual goals. After seeing a substantial increase in the number of baseline interviews we were completing, we increased the number of letters to 96 each week (beginning in May 2009). Since that increase we have been averaging 25 completed baseline interviews a week. Since our report last year we have accrued 1,092 patients. If we continue accruing an average of 25 participants a week we anticipate reaching our accrual goal of 1875 by mid-January 2010.

Increase in Night and Weekend Call Shifts. Since our last report, our overall response rate has declined (41% to 38%) although our follow-up response rates have remained the same ~91%. In an effort to increase our ability to reach patients, we have recently increased the number of night and weekend call shifts. We suspect that a significant number of our participants work during the day and we are unable to reach them between normal business hours. Previously, we had 1-2 interviewers working 3 nights a week to make calls between 6pm and 8pm. We have now increased the number of interviewers to 2-3 working 3-4 nights a week. Additionally, we have increased the number of Saturday's we call a month and the

amount of time we call during the weekend shift. This increase will hopefully allow us to call participants at times that are more conducive to their schedules.

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. We are also planning to use 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 has become available in the two years since we have been accruing participants. Due to the economy and some of our participants being transient, we expect that by running their names through the Choice Point system it will result in new information. We then will be able to re-contact these participants whom we were never able to make contact with. 2) Our website was the recipient of the Award winning health education and promotion materials contest sponsored by the American Public Health Association annual meeting, November 2009. 3) We began working on analyzing the web-viewing behaviors of study participants assigned to this group. We recently submitted an abstract to the American Society of Preventive Oncology Annual Meeting to be held in March 2010. We plan to begin writing the manuscript for this data. 4) Since our last annual report, we submitted the development paper which describes the process we undertook to redesign the booklet and develop the website (currently under review).

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 ONGOING

- a. Eligible participants will be accessioned and the baseline interview will be administered by telephone. *This task is underway; we have accrued 1,710 men to the protocol to date. We plan to accrue an additional 165 participants. Based on our accrual rates to date, we expect that approximately 40% will come from the Georgetown site, 40% will come from the Medstar Physician Partners site, and 20% will come from the Washington Hospital Center site.*
- 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 GU and WHC. The Project Coordinator 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. MPP has agreed this same procedure will work well for them. As soon as we have 20 final interviews completed from this site we will begin this process.*
- e. Begin accessing patient information from the charts. *Underway.*

Task 2. 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.*

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.
- b. Annual reports will be written.
- c. A manuscript from the baseline interview will be written and submitted.

Task 4. Final analyses and manuscript preparation. NOT YET BEGUN

- a. Final analyses of data from interviews and medical record abstractions will be performed.
- b. A final report and manuscripts will be written and submitted.

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) Began conducting the one-year assessment.
- 5) 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. Physicians' Attitudes and Practices Regarding Prostate Cancer Screening. (under review for publication).
- 6) Submitted the manuscript for the development of the web- and print materials. 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. (2009). The Development of a Web- and a Print-Based Decision Aid for Prostate Cancer Screening. (under review for publication).
- 7) Recipient of materials contest award and presented material at the APHA annual meeting. Williams RM, Dorfman CS, Kassan EC, Red S, Dawson DL, Tuong W *et al.* Prostate Cancer Screening: Making the Best Choice. Public Health Education and Health Promotion. Award winning health education and promotion materials presentation. American Public Health Association annual meeting, November 2009.
- 8) Submitted abstract for the web-viewing data to the ASPO conference. Kassan, E.C., Williams, R.W., Kelly S.P., Penek, S., Barry, S.A., Fishman, M., Cole, C., Miller, E., Taylor, K.L. 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. (submitted abstract)
- 9) Poster accepted to the Metropolitan Washington Public Health Association annual meeting. Kassan, E.C., Williams, R.M., Kelly S.P., Taylor, K.L. Use of an Internet -based decision aid by men in an educational prostate cancer screening study. March 2009.
- 10) 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. We have submitted two manuscripts for publication; one which describes the development process of both the booklet and the website and one that assesses physicians' attitudes and practices regarding prostate cancer screening. Additionally, we have begun to look at the behaviors and use of our website in which we have recently submitted an abstract to be included in this year's poster session at the ASPO conference. We are working on preparing a manuscript on this data. Our website was selected as an award winning health education material and we presented our material at this year's annual meeting for APHA.

Plans

- 1) Continue accruing the remaining 165 participants needed to reach our accrual goals, 2) working to improve participation rates and the rate of accrual, and 3) 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
- 3) Abstract of web-viewing behaviors supplemental project
- 4) Presentation for award winning materials contest

A Pilot Study of Primary Care Physicians' Attitudes About the Shared Decision Making Process for Prostate Cancer Screening (under review)

Kimberly Davis, Ph.D., Lisa Haisfield, MA, Caroline Dorfman, BA, Elizabeth Parker, BA, Sara Red, BA, David Dawson, BA, Trent Jackson, MA, Paula Goldman, MA, Mary Fishman, MD, Carmela Cole, MD, Edward Miller, MD, Alex Krist, MD, MPH, and Kathryn L. Taylor, Ph.D

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.

The Development of Web- and Print-based Decision Aids for Prostate Cancer Screening Education (under review)

Caroline S. Dorfman, Randi M. Williams, Elisabeth C. Kassan, Sara N. Red,
David L. Dawson, William Tuong, Elizabeth R. Parker, Janet Ohene-Frempong, Kimberly M. Davis,
Alexander H. Krist, Steven H. Woolf, Marc D. Schwartz, Mary Fishman, Carmella Cole, and Kathryn L.
Taylor

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.

**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**

Kassan, E.C., Williams, R.W., Kelly S.P., Penek, S., Barry, S.A., Fishman, M., Cole, C., Miller, E.,
Taylor, K.L.

Background: There are currently no universally accepted recommendations for men regarding prostate cancer screening (PCS). Most medical organizations agree that men should engage in shared and/or informed decision making. Decision aids can help men make these decisions. Using tracking software and self-report, we examined men's use of an interactive, web-based decision aid for PCS within an ongoing randomized trial. **Method:** Participants (aged 45-70) were primary care patients at two academic hospitals and a community based practice. Mean age was 57 yrs (SD=7), 36% were AA, and 91% reported having Internet access. Following the baseline telephone interview, men were randomly assigned to the web (N=395), print (N=403) or usual care (N=439) arm and completed a subsequent interview 1-2 months later. The website covers the continuum from PCS to treatment, and includes an interactive values clarification tool (VCT), 8 video testimonials, and animated features. Prior to viewing the website, participants indicated whether they were 'pro' or 'con' screening. Using tracking software, we assessed the number of log-ins, time spent on website, use of the VCT, and use of video testimonials. **Results:** Within 2 mos of randomization, 190/395 (48%) logged on and completed the second interview. Compared to non-users, users were more likely to be white, married, employed, have a higher income, higher education, fewer comorbidities, and a cancer history (all $p < .05$). Users were largely 'pro' screening (84%), and rated the website as very/extremely helpful (83%) and the right length (60%). Based on the tracking software, the median number of logins was 2, 85% used the VCT, 95% used the video testimonials, and median time spent on the website was 35 min (range=0.5-119), with the most time spent in the Screening section (median=14 min). Comparing self-report to the tracking software, men overestimated their likelihood of logging on ($p=.000$), time spent using the website ($p=.000$) as well as use of the VCT ($p=.024$). **Conclusions:** These findings indicate both the feasibility and the limitations of conducting web-based PCS education. Additional data will be presented on men's use of specific website sections, stratified by demographic variables and baseline screening preference.