AD_____

Award Number: DAMD17-02-1-0055

TITLE: Preferences and Utilities for Prostate Cancer Screening & Treatment: Assessment of the Underlying Decision Making Process

PRINCIPAL INVESTIGATOR: Deborah Watkins-Bruner, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

REPORT DATE: January 2004

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20040524 140

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	January 2004	Annual (1 Jan 2003 - 31 Dec 2003)

4. TITLE AND SUBTITLE
Preferences and Utilities for Prostate Cancer Screening & Treatment: Assessment of the Underlying Decision Making Process

5. FUNDING NUMBERS
DAMD17-02-1-0055

6. AUTHOR(S)
Deborah Watkins-Bruner, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

E-Mail: d_watkins-bruner@fccc.edu

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. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

The proposed study will evaluate two different populations, a community sample without prostate cancer, and a group of men diagnosed and treated for prostate cancer. The study is designed to evaluate the decision-making mechanism (i.e., risk attitude versus risk-perceptions) and processes (i.e., cognitive versus affective) that influence their preference for specific treatments (e.g., surgery and radiotherapy) and associated health states (i.e., sexual impotence and urinary incontinence). In order to assess risk-attitude versus risk-perception two variables must be considered, the point of reference of the subject (i.e. person with prostate cancer versus person without prostate cancer) and the way the treatment alternatives are communicated or framed (loss-framed message versus gain-framed message).

Understanding the decision making process driving preferences is important because it gives us information on how best to communicate or framed messages. It would also give us insight into how preferences may be manipulated and how different populations may have different preferences for the same treatment (e.g. surgery) or health state (e.g. impotence). Further, an analysis of how and what processes lead to group differences would assists in improved message framing, risk communications and possibly more relevant cost-utility analyses.

14. SUBJECT TERMS
Prostate cancer, decision making, TTO, utilities, risk perceptions

15. NUMBER OF PAGES
14

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

DAMD17-02-1-0055 (FCCC IRB # 01-026)

I. Investigator: Deborah Watkins Bruner, PhD

II. Title: Preferences and Utilities for Prostate Cancer Screening & Treatment: Assessment of the Underlying Decision Making Process

III. Grant Funding: DOD - DAMD17-02-1-0055 (27733)

IV. Project Summary:

A. Introduction:

The proposed study will evaluate two different populations, a community sample without prostate cancer, and a group of men diagnosed and treated for prostate cancer. The study is designed to evaluate the decision-making mechanism (i.e., risk-attitude versus risk-perceptions) and processes (i.e., cognitive versus affective) that influence their preferences for specific treatments (e.g., surgery and radiotherapy) and associated health states (i.e., sexual impotence and urinary incontinence). In order to assess risk-attitude versus risk-perception two variables must be considered, the point of reference of the subject (i.e. person with prostate cancer versus person without prostate cancer) and the way the treatment alternatives are communicated or framed (loss-framed message versus gain-framed message).

B. Body:

Objectives:

Aim 1: The proposed study will assess the mechanism (risk-attitude versus risk-perceptions) by which preferences are made for health outcomes.

Aim 2: The proposed study will asses potential mediators of risk attitude/perceptions, stated preferences and calculated utilities by assessing cognitive-affective factors individuals may weigh in making risky choices through the quantitative Risk Perceptions Questionnaire and the more qualitative Cognitive-Affective Mediating Units Questionnaire.

Aim 3: The proposed study will assess differences in risk-attitude/perceptions, cognitive-affective profile, stated preferences, and calculated utilities among the groups studied.

Methods:

Eligibility for this study includes men between 40 to 80 years of age. For the patient population, men diagnosed and treated for prostate cancer with either surgery or radiotherapy between 1 and 4 year prior to study are eligible. Patients are recruited with IRB approval and the permission of the participating physicians. The community sample is being recruited through a wide variety of methods including, most recently, radio and newspaper ads. The community sample will include men age 40 to 80 years of age and without prostate cancer.

C. Key Research Accomplishments:

1. List of untoward events that have occurred in the past year in connection with the project - None

2. Changes of Risk Factors(s) for patients (s) - None

3. Number of Participants Interviewed or seen since the last review - 90

4. Give number of additional participants needed in coming year – The total sample size for the study is 300, 150 patients with cancer and 150 community participants.

Year 1 (Actual) 2003		Year 2 (Projected) 2004		Year 3 (Projected) 2005	
Patients	Community	Patients	Community	Patients	Community
83	9	44	93	23	48
92		137		71	

5. Description of any changes in the protocol since date of last review - None

6. Clean copy of consent form (no stamp on consent form) - Please find attached two consent forms.

7. If protocol has been terminated, indicate reason and date, whether work was completed, and if not, why work was not completed - Protocol was not terminated.

D. Outcome of Study:

This study did not open to accrual until February 2003 after *lengthy* negotiations with the DOD Human Subject Research Review Board regarding recruitment. An amendment was submitted shortly there after to improve recruitment, which took further lengthy negotiations and was finally approved on July 25, 2003. Since February of this year we have accrued a total of 92 participants, which consists of 83 patients and 9 men in the control group. Most of the accrual has occurred

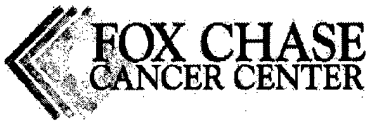
just since the amendment was approved in July which permitted advanced scheduling of patients, and has improved recruitment significantly and will continue throughout the remainder of the study recruitment period. Every possible effort has been made to increase the accrual of the control group. Accrual of participants through health fairs, newspaper advertisements, focus group meetings, talking to men at shopping malls, fire houses, police stations and also posting flyers and handing information regarding the study to patients' relatives at FCCC and our network sites has been tried but with little success. The radio advertisements finally began to air just as of December 1st 2003. The response has been overwhelming! In three weeks we have received over 85 phone calls and we have already scheduled 46 men (Control Group) to participate in the study over the next several weeks. Approximately 17 additional men have called in and need to be scheduled for an appointment. In between radio ads we will continue to recruit through the outreach activities mentioned above and to advertise in local newspapers. The next stretch of radio ads will run the months of February and March 2004.

E. Conclusions:

Radio advertisement seems to be a very effective media for recruitment of our control sample. Using the above-mentioned methods and strategies, accrual for the study seems achievable within the specified time frame.

F. References: None at this time.

G. Appendices: None at this time.



AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH APPROVED BY FOX CHASE CANCER CENTER [IRB]

IRB # 01-026

Study Tile: Preferences and Utilities for Prostate Cancer Screening & Treatment: Assessment of the Underlying Decision Making Process

Principal Investigator: Deborah Watkins Bruner, PhD

The Health Insurance Portability and Accountability Act of 1996 requires this form. Specifically the privacy regulations (HIPAA) permit the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved but the Fox Chase Cancer Center Institutional Review Board.

1. You authorize Fox Chase Cancer Center, your physician and/or administrative and/or clinical staff to use protected health information collected about **you and/or your family** for research purposes and/or disclose that protected health information to:

- The Principal Investigator, Dr. Deborah Watkins Bruner, and the Investigator's study team;
- The Fox Chase Cancer Center Institutional Review Board, the committee charged with overseeing research on human subjects;
- The Fox Chase Cancer Center Office for Data Management, which collects and stores study data.
- The Funding Agency, Department of Defense.

2. Specific description of the health information to be used and/or disclosed:

- Names;
- Addresses;
- Telephone numbers;
- Dates (i.e. births, deaths, diagnoses);
- Personal medical history;
- Family medical history;
- Tissue/blood/cells/DNA;

- Current and past cancer screening and lifestyle practices, medications, therapies, diagnostics tests, surgeries, and/or biopsies;
- Quality of life information;
- Current and past symptoms related to urination and sexual satisfaction;
- Any information collected in the Demographic form and/or other survey instruments completed during the course of the study.

3. This protected health information is being used and/or disclosed for the following purposes:
- To contact you during the study,
- As part of this research study and for the advancement of medicine and clinical care.

4. This authorization shall be in force and in effect **indefinitely**.

5. You understand that you have the right withdraw this authorization, in writing, at any time, by sending such written notification to **Dr. Deborah Watkins Bruner**, the Principal Investigator of this study. You understand that a revocation is not effective to the extent that your physician has relied on the use or disclosure of the protected health information.

6. You understand that if the person(s) who receives your health information is not a health care provider or health plan covered by federal privacy regulations, your health information could no longer be protected under this authorization.

7. Treatment by your physician will not be affected by whether or not you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. The use or disclosure requested under this authorization **will not** result in direct or indirect compensation to your physician from a third party.

_____ _____

Participant Signature Date

FOX CHASE CANCER CENTER

Consent Form for Second Interview
Preferences and Utilities for Prostate Cancer Screening and Treatment: Assessment of the Underlying Decision Making Process

You are among a subset of participants, randomly selected from the study we just described, being asked to take part in a second interview. The second interview will be very similar to the first one you are about to do with one slight difference. This sub-study also involves questions about different treatment options but in this interview we will give you a little more information to see if it makes a difference in your decisions. The importance of this study is to help health care professionals, who review health care policies for prostate cancer, know what types of treatments men prefer when making the decisions for treatment of prostate cancer. The nature of the study, the risks, inconveniences and other pertinent information are explained below. You are urged to discuss any questions you may have about this study with the staff members.

Why is the study being done?

The purpose of this study is similar to the first, to determine which treatment options men prefer most for prostate cancer. This part of the study is also being conducted to ask men who have had prostate cancer and men who do not have prostate cancer, their decisions about the options that are available for the treatment of prostate cancer. The outcome of this study will help men, who are faced with the decision of choosing a treatment for prostate cancer, know what other men preferred when faced with a similar decision. Also, this study is being conducted to help health care professionals, who examine health care policies for the treatment of prostate cancer, understand why men prefer certain treatments over others.

Procedures

You agree to participate in a second interview, one to two weeks following the first interview, where you will be asked which treatment for prostate cancer you prefer among a series of treatments. In choosing a treatment there will "potentially" be a different outcome for each state of health (i.e. impotence or urinary incontinence). The treatments that you choose will be referred to by name (surgery or radiation therapy), instead of by letter (A, B, C, etc as in the first interview) to observe whether this makes a difference in your choice of treatments. You will be shown pictures to help you understand the choices for treatments. The interview should take approximately 45 minutes to complete.

What is involved in the study?
You understand that when you return in one to two weeks for another 45-minute interview.

What are the risks for the study?
There are no known risks for participating in this study. Your participation in this study is completely voluntary. Some of the questions in the questionnaires and the interview may seem sensitive in nature. In the event that you feel anxious, uncomfortable or worried by some of the questions, you do not need to answer them. If you feel that you need to speak to someone regarding any emotional distress caused by answering some of these questions you may contact the Social Work Services Department at (215) 728-2668. You may withdraw from the program at any time without any consequences. You may refuse this second interview without affecting participation in the first part of this study.

Are there any benefits to taking part in the study?
As a participant in this study, the personal benefit to you would be the possibility of learning more about your attitudes and beliefs about prostate cancer. Your participation in this study may help other men who are diagnosed with prostate cancer make decisions about choosing a treatment. Also, you may help health care professionals, who review policies for the treatment of prostate cancer, understand why men prefer certain treatments for prostate cancer.

What about confidentiality?
None of the research information that you provide will ever be associated with your name. No information regarding this study that can be associated with your name will ever be published.

How will the data be stored and protected?
Your original interview answers will be stored in a locked cabinet indefinitely and will not be discarded after the study has ended. This study has been funded by a grant from the U.S. Army Medical Research and Material Command. Representatives from this division are eligible to review your research records as part of their responsibility to protect human subjects in research.

What are your rights as a participant?
Participation in this study is completely voluntary and you have the right to withdraw from the study at any time. You also understand that your medical care will, in no way, be affected by your participation or non-participation. You

understand that the interview is for research purposes only and will not become part of your permanent medical record or be revealed to any other sources. As a token of appreciation, you will receive $25.00 for participating in this study. You also understand that no additional compensation will be given for your participation in this study.

What if you have questions or need additional information about the study?
You are free to ask questions at any time about these procedures and to ask for additional information from the Project Manager, Sachin Kulkarni, M.S., or Research Study Principal Investigator, Deborah Watkins Bruner, RN, PhD, at (215) 728-2406, from 9 AM to 5 PM Monday through Friday.

If you have further questions or concerns about this research, you may contact W.Thomas London, MD, Chairman of the Institutional Review Board, at (215) 728-2518, from 9 AM to 5 PM Monday through Friday or by writing to Institutional Review Board, Fox Chase Cancer Center, 7701 Burholme Avenue, Philadelphia, PA 19111.

By signing below, you indicate that you have read this form, received acceptable answers to any questions, and willingly consent to participate.

_____ _____

(Print) Name of participant Date

_____ _____

Signature of participant Date

_____

Address (street, state, zip code)

_____ _____

Signature of health educator/research assistant Date

FOX CHASE CANCER CENTER
CONSENT FORM

Preferences and Utilities for Prostate Cancer Screening and Treatment: Assessment of the Underlying Decision Making Process

You are being asked to take part in a research study to evaluate which treatments men prefer most for prostate cancer. The study involves answering questions about different treatment options. This study will help health care professionals, who review health care policies for prostate cancer, know what types of treatments men prefer when making decisions for treatment of prostate cancer. The nature of the study, the risks, inconveniences and other important information are explained below. You are urged to discuss any questions you may have about this study with the staff members.

Why is the study being done?

The purpose of this study is to determine which treatment options men prefer most for prostate cancer. The study is being conducted to ask men who have had prostate cancer and men who do not have prostate cancer, their decisions about the options that are available for the treatment of prostate cancer. The outcome of this study will help men who are faced with the decision of choosing a treatment for prostate cancer know what treatments other men preferred when faced with a similar decision. This study is also being conducted to help health care professionals, who examine health care policies for the treatment of prostate cancer, understand why men prefer certain treatments.

Procedures

You agree to participate in an interview where you will be asked which treatment for prostate cancer you prefer among a series of treatments. In choosing a treatment there will "potentially" be a different outcome for each state of health (i.e. impotence or urinary incontinence). The treatments that you choose will be referred to by a letter (A, B, C, etc.) and not by the name of the treatment (i.e. surgery, radiation therapy, etc.). You will be shown pictures to help you understand the choices for treatments. The interview should take approximately 45 minutes to complete.

What is involved in the study?

You will be mailed three questionnaires for your review prior to your appointment. The questionnaires can be brought in with you to your appointment to be filled out at that time, or you may complete them at home at your convenience. If you decide

to complete the questionnaires at home, you will be provided with an addressed, stamped envelope to return the questionnaires to the program staff. The questionnaires include questions about your medical history, and other factors that may pertain to your beliefs about prostate cancer. If you have any questions regarding the questionnaires, you may ask any questions at the time of your appointment or call the program at (215) 728-2406 from 9 AM to 5 PM, Monday through Friday and speak with a health educator. The questionnaires should take about 45 minutes to complete.

What are the risks for the study?

There are no known risks for participating in this study. Your participation in this study is completely voluntary. Some of the questions in the questionnaires and the interview may seem sensitive in nature. In the event that you feel anxious, uncomfortable or worried by some of the questions, you do not need to answer them. If you feel that you need to speak to someone regarding any emotional distress caused by answering some of the questions you may contact the Social Work Services Department at (215) 728-2668. You may withdraw from the program at any time without any consequences.

Are there any benefits to taking part in the study?

As a participant in this study, the personal benefits to you would be the possibility of learning more about your attitudes and beliefs about prostate cancer. Your participation in this study may help other men diagnosed with prostate cancer make decisions about choosing a treatment. You may also help health care professionals, who review policies for the treatment of prostate cancer, understand why men prefer certain treatments for prostate cancer.

What about confidentiality?

You will be given a study number by which your questionnaire data will be coded and entered into the computer. None of the research information that you provide will ever be associated with your name. No information regarding this study that can be associated with your name will ever be published.

How will the data be stored and protected?

Your original questionnaires will be stored in a locked cabinet indefinitely and will not be discarded after the study has ended. This study has been funded by a grant from the U.S. Army Medical Research and Material Command. Representatives from this division are eligible to review your research records as part of their responsibility to protect human subjects in research.

What are your rights as a participant?

Participation in this study is completely voluntary and you have the right to withdraw from the study at any time. You also understand that your medical care will not be affected in any way by your participation or non-participation. The interview is for research purposes only and will not become part of your permanent medical record or be revealed to any other sources. As a token of appreciation, you will receive $25.00 for participating in this study. You also understand that no additional compensation will be given for your participation in this study.

What if you have questions or need additional information about the study?

You are free to ask questions at any time about these procedures and to ask for additional information from the Project Manager, Sachin Kulkarni, M.S., or Research Study Principal Investigator, Deborah Watkins Bruner, PhD, at (215) 728-2406, from 9 AM to 5 PM Monday through Friday.

If you have further questions or concerns about this research, you may contact W. Thomas London, MD, Chairman of the Institutional Review Board, at (215) 728-2518, from 9 AM to 5 PM Monday through Friday or by writing to Institutional Review Board, Fox Chase Cancer Center , 7701 Burholme Avenue, Philadelphia, PA 19111.

By signing below, you indicate that you have read this form, received acceptable answers to any questions, and willingly consent to participate.

_____ _____

(Print) Name of participant Date

_____ _____

Signature of participant Date

_____

Address (street, state, zip code)

_____ _____

Signature of health educator/research assistant Date