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TITLE: Value-Based Decision-Making in Prostate Cancer Early Detection

PRINCIPAL INVESTIGATOR: Ronald Myers, Ph.D.

CONTRACTING ORGANIZATION: Thomas Jefferson University
Philadelphia, Pennsylvania  19107

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documentation.
Proponents of prostate cancer early detection argue that the combination of digital rectal examination and prostate-specific antigen testing is effective and that early detection leads to improved chances for survival. Others caution against routine screening because no mortality benefit has been shown in randomized trials and treatment of diagnosed prostate cancer can have serious side effects. Typically, patients who undergo testing are not aware of these uncertainties and do not participate in deciding whether to screen. We are conducting a prospective study with men 50-69 years of age to evaluate the efficacy of a counseling intervention designed to promote value-based decision-making. A baseline survey questionnaire will be administered to measure demographic, cognitive, and psychosocial characteristics. A Standard Intervention Group will receive a generic educational booklet about prostate cancer early detection. Enhanced Intervention Group men will receive a theory-based educational counseling session the booklet will be enhanced by an Analytic Hierarchy Process educational counseling session delivered by a nurse educator. The session will engage participants in a personally-tailored process of evaluating whether to have or not have an early detection exam. The behavioral outcome will be the proportion of men in each group who have an early detection exam during a six month follow up period. This outcome will be measured using data obtained via medical chart audit. Cognitive and psychosocial outcomes will be assessed using endpoint survey data.
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# TABLE OF CONTENTS

1. Front Cover .............................................................. 1.
3. Foreword ...................................................................... 3.
4. Table of Contents .......................................................... 4.
5. Introduction .................................................................... 5.
8. Reportable Outcomes ..................................................... 16.
10. References ..................................................................... 18.
11. Appendices .................................................................... 19.
INTRODUCTION

In 1997, there will be more than 334,000 new cases of prostate cancer and an estimated 41,800 deaths in the United States. Men who are asymptomatic for prostate cancer are usually diagnosed through a digital rectal examination (DRE) and prostate-specific antigen (PSA) test. Proponents of prostate cancer early detection argue that the combination of DRE and PSA testing is effective and that early detection leads to improved chances for survival. Others caution against routine screening because no mortality benefit has been shown in randomized trials and treatment of diagnosed prostate cancer can have serious side effects. Typically, patients who undergo DRE and PSA testing are not aware of these uncertainties and do not participate in deciding whether to have an early detection examination. This situation highlights the need for the development of new approaches to facilitate informed decision-making in this area. We propose to do a small-scale prospective study with a random sample (N=160) asymptomatic men 50 to 69 years of age to evaluate the efficacy of an educational counseling intervention that is designed to promote value-based decision-making about prostate cancer early detection. A Standard Intervention (SI) Group (N=80) will receive a generic informational booklet about prostate cancer early detection. For Enhanced Intervention (EI) Group men (N=80), the informational booklet will be enhanced by an Analytic Hierarchy Process (AHP) educational counseling session delivered by a nurse educator. The AHP-based session will engage study participants in a personally-tailored process of evaluating early detection behavioral alternatives (i.e., to have or not to have an early detection exam) that have multiple attributes or criteria. We will integrate preventive health behavior theory into the AHP by using the Transactional Model of Stress and Coping (TMSC). The behavioral outcome will be the proportion of men in each group who have an early detection exam during a six month follow up period. A medical chart audit will be used to measure this outcome. Other outcomes, including knowledge, need for cognition, stress, social support, and satisfaction, will be assessed via telephone survey.
Task 1. Development and Pre-testing of the Intervention

a. Development of Informational Booklet and Counseling Guide

A series of meetings were held at which the study team, which includes TJU personnel, the Health Promotion Council (HPC) of Southeastern Pennsylvania, and consultants from Villanova University, discussed and drafted materials to be used in the intervention. These materials, which include the educational booklet and counseling guide, are described below.

**Booklet – What You Need to Know About Checking for Prostate Cancer**

The study team drafted the educational booklet. The booklet will be sent to participants in the Control Group and Intervention Group. It will also be used by a health educator with participants in the Intervention Group. The booklet contains information that will be used to help make a reasoned judgment about having an early detection examination. The booklet:

♦ describes the prostate gland and its function
♦ mentions possible prostate-related problems, including prostate cancer;
♦ describes risk factors and symptoms of prostate cancer
♦ explains the components of a prostate cancer early detection examination
♦ reviews possible follow-up tests in the event of an abnormal early detection examination result
♦ summarizes treatment options for early and late prostate cancer.

In addition, the booklet acknowledges that medical opinions vary about whether or not men should have an exam and outlines a stepwise process, based in the Analytical Hierarchy Process (AHP), for making a decision about whether or not to have an early detection exam.

**Counseling Guide – Counseling Guide for Using an AHP-Based Session to Help Men Decide Whether to Undergo Prostate Cancer Screening**

The study team developed the counseling guide for use by a health educator. The guide will be used to engage study participants in an AHP-based decision-making process. This process is designed to prepare men to make a value-based decision about whether or not to have a prostate cancer early detection exam. The AHP-based counseling protocol:

♦ reviews the booklet content and clarifies the need for informed decision making
♦ models the suggested decision-making approach
♦ provides a framework for implementing the step-wise decision-making process.

During the counseling session, personal decision factors (e.g., worry about having prostate cancer, concern about costs associated with medical procedures) are elicited and prioritized. The direction (or valence) of the factor in terms of whether or not to have an exam is clarified. At this point, the order of importance of each factor is specified and the magnitude of importance of each factor is determined in relation to other factors. The magnitude of importance of each factor is also assessed in relation to the decision to have or not to have an exam. Comparison scores obtained at each step are entered into a computer spreadsheet program, which, at the end of the process is used to compute a decision orientation score. The decision orientation score is an indication of the strength of preference that the individual has expressed in relation to the decision to have or not have an exam.
This score is displayed both numerically and graphically on a summary page, along with a written interpretation. The counselor and participant then discuss the decision preference score and interpretation in order to ensure that the process for generating the information and score are understood. Then the patient is asked about his intentions.

b. Focus Group Pre-Testing of the Intervention

Focus Group Discussion Guide

A focus group discussion guide was developed by Thomas Jefferson University investigators, Villanova University consultants, community practice primary care physicians, Health Promotion Council Director of Health Literacy, and study consultants.

Focus Groups

Two focus groups were conducted: one with men who had not had a prostate cancer early detection examination (N=6) and one with men who had had a prostate cancer early detection examination (N=8). A baseline survey was completed by focus group participants before the session and an endpoint survey completed after the session. Results of these surveys are presented in Tables 2-4.

Focus group participants were asked to review information about perceptions of men who have and have not had a prostate cancer early detection examination and current guidelines on prostate cancer early detection. They were also asked to identify information that is needed to make a judgment about having an early detection examination and discuss the value of preparatory educational counseling about early detection, diagnostic follow-up and treatment. Intervention content will be shaped by specific information that will be elicited concerning the subjects' psychosocial representations related to prostate cancer, prostate cancer early detection, prostate cancer treatment and related outcomes, social support, delay, participation in decision-making, and satisfaction with care. In the focus groups, decision-making was considered as a psychosocial process that involves the individual-in-situation, his immediate and extended family, and social network.

Based on observation of the focus groups and the summary report produced by the Health Promotion Council, a number of themes were identified as being salient to the process of decision-making about whether or not to undergo screening for prostate cancer. A summary of themes identified in the focus groups is presented in Table 5. This information has been used to update the educational booklet and counseling session protocol.

c. Clinician, Population, and Patient Review of the Intervention

After drafts of the intervention materials were developed, they were reviewed by the study team.

d. Health Educator Training

A health educator will be responsible for delivering the intervention to study participants. Health educator training has been conducted by the Principal Investigator. Training has included the following: didactic sessions with role-playing demonstrations; videotaped practice in situations that simulate the actual encounter, with instructor feedback; initial and periodic evaluation of effectiveness and consistency of effort; and preparation for writing field notes.

e. Pre-testing of the Intervention

In addition to the review noted above, arrangements were made to pre-test the educational counseling process and counseling guide with a number of patients from JIMA. These pilot sessions are being conducted to work through any logistical problems and to gain a level of comfort with the intervention counseling process. The sessions will help to develop avenues of communication,
address barriers, and facilitate the elicitation of decision factors that are meaningful to the individual patient. Areas of focus for these sessions are 1) recruitment, 2) development of the participant profile, 3) logistics of the visit, 4) content of the educational session, and 5) issues, implications, and recommendations.

A group of 20 men were randomly selected from the JIMA patient population. Telephone contact has been made with 15 of these men who were invited to participate in a counseling session. To date, six of these men have agreed to participate. These sessions are currently being conducted.

Task 2. Implementation of the Intervention

Identification of Study Subjects

The Jefferson Internal Medicine Associates practice provided a list of eligible patients, that is, men who met the following criteria:

- are 50-69 years of age
- have visited the office within the previous two years
- have not had a prostate biopsy
- have not been diagnosed with prostate cancer

A total of 1,703 men were identified from patient records. From this file, a sample of 400 men was selected for chart review. This sample consisted of Caucasian American (N=280), African American (N=99), Asian (N=11), Hispanic (N=6), and Native American (N=4) men. The chart reviews are currently being completed.
Tables

Table 1  Chart Audit Results
Table 2  Summary of Findings from Focus Group Survey - Background Characteristics
Table 3  Summary of Findings from Focus Group Survey - Attitudinal Characteristics
Table 4  Summary of Findings from Focus Group Survey - Perceptions Re: the Booklet and Educational Counseling Session
Table 5  Summary of Themes Identified in the Focus Groups
### Table 1
Chart Audit Results
(N=75)

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40-59</td>
<td>35</td>
<td>47%</td>
</tr>
<tr>
<td></td>
<td>50-69</td>
<td>40</td>
<td>53%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>42</td>
<td>56%</td>
</tr>
<tr>
<td></td>
<td>White</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>6</td>
<td>8%</td>
</tr>
<tr>
<td></td>
<td>Blank</td>
<td>26</td>
<td>35%</td>
</tr>
<tr>
<td>Previous PSA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>28</td>
<td>37%</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>47</td>
<td>63%</td>
</tr>
<tr>
<td></td>
<td>Normal</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Abnormal</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Previous biopsy for abnormal PSA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>2</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>3</td>
<td>60%</td>
</tr>
</tbody>
</table>
Table 2: Summary of Findings from Focus Group Survey Background Characteristics (N=14)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>≥ 50</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>&lt; 50</td>
<td>6</td>
</tr>
<tr>
<td>Education</td>
<td>≥ College</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>&lt; College</td>
<td>3</td>
</tr>
<tr>
<td>Marital Status</td>
<td>Married</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Not Married</td>
<td>5</td>
</tr>
<tr>
<td>Family History</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>12</td>
</tr>
<tr>
<td>DRE in Past 12 Months</td>
<td>Yes</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>1</td>
</tr>
<tr>
<td>PSA in Past 12 Months</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>5</td>
</tr>
<tr>
<td>Survey Item</td>
<td>Response Category</td>
<td>Baseline N</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>------------</td>
</tr>
<tr>
<td>I am bothered that having a prostate cancer early detection exam might be physically uncomfortable.</td>
<td>Agree</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>8</td>
</tr>
<tr>
<td>I am afraid that having a prostate cancer early detection exam might show that I have a prostate problem.</td>
<td>Agree</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>1</td>
</tr>
<tr>
<td>I think that African American men are more likely to develop prostate cancer than white men are.</td>
<td>Agree</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>1</td>
</tr>
<tr>
<td>If I do not have any prostate problems, it is not necessary for me to have to prostate cancer early detection exam.</td>
<td>Agree</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>1</td>
</tr>
<tr>
<td>I believe that when prostate cancer is found at an early stage, it can be cured.</td>
<td>Agree</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>1</td>
</tr>
<tr>
<td>Being treated for prostate cancer when it is at an early stage is likely to increase my chances for living a longer life.</td>
<td>Agree</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>0</td>
</tr>
<tr>
<td>Being treated for prostate cancer when it is at an early stage is likely to increase my chances for living a healthier life.</td>
<td>Agree</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>1</td>
</tr>
<tr>
<td>I have all the information I need to decide whether or not to have a prostate cancer early detection exam.</td>
<td>Agree</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>1</td>
</tr>
<tr>
<td>I intend to have a prostate cancer early detection exam in the next six months.</td>
<td>Agree</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Missing</td>
<td>2</td>
</tr>
</tbody>
</table>
Table 4
Summary of Findings from Focus Group Survey
Perceptions Re: the Booklet and Educational Counseling Session (N=14)

| I thought the educational booklet was useful. | Somewhat to Very Much | 11  |
|                                             | Not at All, A Little  | 1   |
|                                             | Missing               | 2   |

| I thought the counseling session was useful. | Somewhat to Very Much | 11  |
|                                             | Not at All, A Little  | 1   |
|                                             | Missing               | 2   |
Table 5
Summary of Themes Identified in the Focus Groups

1. The Primary Care Physician.
   The primary care physician is a trusted source of information.
   The primary care physician office is a good place to deliver the educational counseling session.

   Schedule educational counseling appointments at convenient times.
   Eliminate or reduce costs associated with attending the educational counseling appointment.
   Gain support for the educational counseling process from local opinion leaders.

3. Pain and Embarrassment.
   Address the issue of embarrassment re: discussion of prostate matters with a female health educator.
   Address the issue of pain from the DRE.
   Address notion of DRE as invasive.

4. Frustration with Uncertainty.
   Uncertainty about the benefit of early detection is frustrating.
   Avoid emphasizing what is not known about prostate cancer and early detection.
   "What we don't know" is viewed as "There is nothing that can be done."

5. Focus on Clarification.
   Clarify potential impact of early detection on quantity of life (years of survival) and quality of (impotence, incontinence).
   Clarify the sequencing of medical procedures (i.e., early detection via DRE/PSA, diagnosis via ultrasound/biopsy, Treatment via observation, surgery, radiation, hormone therapy).

6. Increasing Understanding.
   Present information about risk in a more qualitative than quantitative way.

   Emphasize value of educational counseling in a way that does not imply that individual is in need of help.

   De-emphasize the "numeric" computation in counseling. Translate numbers into familiar concepts.

9. Involving Significant Others.
   Be cautious about involving significant others in the process of encouraging participation.
KEY RESEARCH ACCOMPLISHMENTS

1. Pre-tested booklet and counseling guide.

2. Produced booklet and counseling guide (final version).

3. Identified target population.

4. Defined procedures for implementing the study intervention and for gathering survey data (baseline and follow-up) and chart audit data.
REPORTABLE OUTCOMES

see Key Research Accomplishments
CONCLUSIONS

The progress we have made to date has laid a good foundation for the implementation and evaluation of the study intervention.
REFERENCES

No publications to date.
APPENDICES

1. Informational Booklet
2. Counseling Guide
Informational Booklet
Is Being Checked for Prostate Cancer a Good or Bad Idea?

You Have the Right to Know the Facts and Decide What to Do

Plain Talk for Men Who Have Not Had Prostate Cancer
Dear Friend,

Most men will have prostate problems as they grow older. We feel that men should know about the prostate, problems that can develop with this gland, and what is involved in being checked for Prostate cancer.

This booklet provides information you can use to help decide whether you want to be checked for Prostate cancer. For some men, making this decision is easy. For other men, the decision is not so easy. It is important for all men to make this decision.

Please look through the booklet. Talk to a health care professional. Discuss the decision with your partner, other family members, and friends. Let us know if we can help.

Best regards,

Some experts think it is a good idea to have a routine check-up for Prostate cancer. They say:

- “A check-up can find cancer early.”
- “There may be a better chance for a cure.”
- “Being checked can lower the chances that men will die from Prostate cancer.”

Other experts think it may not be a good idea to have a routine check-up for Prostate cancer. They say:

- “There is not enough proof yet that being checked will lower a man’s chances of dying from Prostate cancer.”
- “So far there is no way to tell the difference between a fast growing and a slow growing Prostate cancer. One may need treatment; the other may not.”
- “Men may be harmed by tests and treatments they may not need.”

This difference of opinion may make it hard to decide what to do. Information on the following pages can help you make up your mind.
Find Out About the Prostate

The prostate is a sex gland. It makes semen, the fluid that carries sperm. It is about the size of a walnut and is located in front of the rectum.

The prostate gland is shaped like a doughnut. The tube (urethra) that carries urine passes through it.

Know Who Is At Risk for Prostate Cancer

- **Men over age 50**

- **African American men over age 40**
  Researchers are trying to find out why they are at risk at a younger age.

- **Men who have blood relatives who have had Prostate cancer**
  For example, a father, grandfather, or brother.

A man can still develop Prostate cancer even if he doesn't fit into any of these groups.
Prostate Problems

Prostate Problems

Problems that are not cancer:

• Enlarged or Swollen Prostate
  This alone is not cancer.

• Infected or Inflamed Prostate
  This alone is not cancer.

Prostate cancer:

• Cells begin to grow too fast
• Cell growth is uncontrolled
• There may be no symptoms
• Cancer can be life threatening

Know the Signs of Prostate Problems

• Getting up often at night to pass urine
• Difficulty passing urine
• Pain or burning when passing urine
• Pain in the upper legs or lower back
• Blood in the urine.

Sometimes, these signs indicate problems that are not cancer. Sometimes, these signs indicate Prostate cancer. Men can have Prostate cancer without having any signs.
Find Out What is Involved in Checking for Prostate Cancer

Step 1: Having a Check-up
If you do decide to get checked, the first step involves a rectal exam and a blood test.

Rectal Exam
Using a gloved finger, the doctor can feel if the gland is hard or has lumps.

Blood Test
A medical lab will test a sample of your blood for something called PSA. (PSA is made by the prostate).

Step 2: Having Follow-up Tests
The second step is only for men who have abnormal check-up results. This involves an ultrasound and a biopsy.

Ultrasound
A small probe is placed in the rectum. This test uses sound waves to look at the prostate.

Biopsy
Very small pieces of tissue are removed from the prostate and looked at under the microscope.

Talk to your doctor about what your test results mean for you. Sometimes, a test may give a false result.

Most men will find they do not have cancer. Some will have early stage Prostate cancer. Some will have late stage Prostate cancer.
Find Out What Can Be Done to Treat Prostate Cancer

**Treating Early Prostate Cancer**

**Watchful Waiting**
No surgery or radiation is used. The doctor continues to check on the cancer.

**Surgery**
The prostate gland and some tissue around it are removed.

**Radiation**
X-Rays are used to kill cancer cells. Or, very small radioactive pellets (seeds) are put directly into the prostate to kill the cancer cells.

**Treating Late Prostate cancer**

**Medication**
Medicine can be used to stop the body from making the hormones that the cancer needs in order to grow.

**Surgery**
The testicles can be removed to stop the body from making the hormone that the cancer needs in order to grow.

**Chemotherapy**
This treatment uses drugs that can kill cancer cells.

**Treatment May Help and It Can Cause Problems**

Treatment may give some men a chance for a cure. It can also cause a man to have problems holding his urine (incontinence), and having an erection (impotence).

**Treatment May Make a Difference**

Late Prostate cancer is hard to cure. But, treatment may offer a man a chance to improve the quality and the length of his life.
Make Your Own Decision About Getting Checked

- Think about the information in this booklet.

- Ask a health care professional that you trust to answer any questions you have.

- Discuss your decision with someone who is close to you.

Your Opinion is Important

- Deciding about whether or not to have a Prostate cancer check-up is an important thing to do.

- The more you know, the better decision you will make.

- You should feel satisfied with whatever decision you make.
Production of this booklet was funded in part by Aetna U.S. Healthcare, the American Cancer Society Pennsylvania Division Inc. Southeast Region, The Department of Health of the Commonwealth of Pennsylvania, and the Department of Defense (PC970595).

The booklet was developed in collaboration with the Health Promotion Council of Southeastern Pennsylvania.
For some men, the decision is easy...

...for other men, the decision is not so easy.
Counseling Guide
Counseling Guide for Using an AHP- Based Session to Help Men Decide Whether to Undergo Prostate Cancer Screening

Part I. Providing Some Basic Information

1. Provide an introduction.

   a. Introduce yourself. Explain your role.

   Hi, Mr. ______. Thanks for coming in. Please have a seat. My name is ______. I am a Health Educator and I work at Thomas Jefferson University. Dr. ______ (their doctor's name) asked me to talk with you and people, like yourself, who have expressed a willingness to come in and be a part of this study. I'm going to explain everything to you and answer any questions that you have. After that, if you still want to help us out, the session tonight should last about an hour. OK?

   b. Explain the purpose of the study.

   Let me begin by telling you what we are trying to do. The study has to do with helping men make an informed decision on whether or not to get an exam for prostate cancer.

   Right now, many men get an exam simply because they are advised to do so. They don't get much information beforehand.

   Now, some doctors feel that men should get more information before they agree to get have an exam. This is because if the exam shows that a man does have a prostate problem, it's not always clear what should be done. They feel that if a man knows this beforehand, he may decide not to have the exam in the first place. Others may still decide to have an exam.

   We have developed a method for helping men to: first get some factual information on prostate cancer and on getting an exam, and then reach a decision. We have developed a step-by-step process that is designed to let each man figure out what kinds of things are most important to him.

   So, the purpose of the study is to find out if this method is useful in helping men to decide whether or not to have an exam. We need your help in finding
out if this particular way of making a decision is useful. What we learn is going to help other men.

This study is a joint effort between Thomas Jefferson University School of Medicine and selected doctors in the area. I am a part of that joint effort. - Do you have any questions about what we are trying to do?

c. **Describe how the session will proceed.**

OK. Let me show you how we're going to do this. There are three main steps:

1. First, we're going to review some information about prostate cancer, in general, and about getting an exam for prostate cancer, in particular. You will have this booklet [*show them*] and you can ask questions. You don't need to memorize anything.
2. Then, we will go through a step-by-step decision making process about getting a prostate exam. It's just a different way of thinking through things.
3. Finally, you will have a chance to review your decision to see if you feel OK with it.

Do you have any questions?

d. **Confirm the person's interest in participating**

So, to sum it up, we would like you to spend some time going through the process of 1) getting some information, 2) thinking about what is most important to you, and then 3) **using** that to come to a decision that **you** feel comfortable with.

By using this process, we hope to help you figure out if **having** the exam helps you achieve the things that are most important to you or if **not** having the exam best achieves this.

If you want to stop at any time, just let me know. At the end, we would also like your thoughts about the usefulness of this way of doing things.

After we finish talking with the men in this large study, a report will be written to let people know about what we learn. Our goal is to help other men. Your name will **not** be used in any report. Everything will be confidential. No one will try to talk you into anything, and I'll answer any questions you have as we go along.

Are you ready to get started?
2. Give information about the disease and about screening.
   a. Give the participant the prostate cancer booklet and review the information.

   Let's get started. Did you receive a pamphlet like this in the mail?
   IF YES: Did you get a chance to take a look at it? Let's go over it together.
   IF NO: That's no problem. Let's take a look at it now. We can go through it together.

   Now, I want to go over some information about prostate cancer and what's involved in actually having an exam for prostate cancer. [Go over the information in the pamphlet].

3. Point out the likelihood of increased uncertainty.

   I know some of this information may not be new for you. But some of it might be. Most people think that deciding whether or not to have a prostate exam should be an easy decision. After they get a little more information about the disease, the treatment and the exam, they then begin to have some real questions about just what to do.

   We have just pointed out to you that there are pros and cons about having the prostate exam done. Our goal is not to confuse you, but to give you a little more information than you might usually get. We want you to make a decision based on a lot of the information, not just a little.

   Again, this is not like some other diseases where the decision is clear cut – for example like it is with breast cancer or colon cancer. With those diseases, we can tell you, straight out, that people should definitely get tested. With prostate cancer, as we just saw (from the pamphlet and the counseling session) it's not that clear. This might be a little hard for people to accept, since most of us are used to being told clearly what to do – even if we decide not to do it.

   But, there is no right or wrong decision here. It's up to you. And now that you know some details about this disease and the exam, what we want to do is to help you think about what's most important to you. If you feel strongly about some things you will probably not have the exam done. If you feel more strongly about some other things, you probably will have the exam done. Either way, it's your own well-informed decision.

   These are the kinds of judgements that you'll get a chance to make for yourself. I'll walk you through the process and let you know if - based on what you say - you seem to be leaning towards having the exam or not having the exam.
Again, the purpose is **not** to force you to make one decision or another, but to use the information you now have about prostate testing and come to a decision that you feel comfortable with. What you decide is up to you, and it very well may be different than what somebody else decides. Different men make different decisions - and that's OK.

We'll go the process step by step together. When we're done, you can let me know what you think of it.

OK? Do you have any questions?

Are you ready to get started?

*If the client decides that he does not want to continue, enter his reason in location AL on the back of the Worksheet.*
Part II. Facilitating the Decision (Calculator Version)

1. Make the transition to this next part.

   So now, let's turn our attention to having a prostate exam. As we discussed before, there are pros and cons related to having a screening exam. These are the facts that we know to be true at this time:

   Testing can find early prostate cancer.
   
   There is no sure way to find out if a cancer that is detected early is a dangerous type.

   Experts who are in favor of early detection testing for prostate cancer say it gives the best chance for cure. Others feel that testing may lead to unnecessary harm.

   Some doctors say it hasn't been proven that these tests save lives. Others say treatment of early prostate cancer gives the best chance for avoiding death.

2. Elicit decision factors from the participant (who will choose 3 most important and list in rank order.

   So keeping these things in mind, we're going to start by looking at the things that are important to you and might influence what you decide to do.

   **Pro exam:** If you completed this sentence, ....?: [use worksheet]

   [If help is needed to elicit decision factors, use list] Here is a list of things that others believe might be important in helping make a decision about whether to have a prostate exam.

   Some of them may not apply to you. We're interested in what you think. It may be totally different from what others think. So, if there're any other things that you believe are important in making this decision, feel free to add them right here.

   [If he does, add them to the list, in the spaces provided].

   **Con exam:** If you completed this sentence, ....?: [use worksheet and use list if needed]

   [Enter the names of the 3 things in locations 2a, 2b and 2c of the worksheet].

   Fine. Let's go over each one so that I'm sure of what you mean. Tell me what this one means to you. [Go over each factor for clarification]. For example, you said that ________ [from location 2a was a factor]. Can we call this ________ [enter in location 2d]?

   [This needs to be repeated for locations 2b and 2c with shortened entries added to locations 2e and 2f, respectively.]
Now, let's take a look at your list of reasons and tell me which of these would be most likely to influence your decision not to have the exam.

[Enter the names of the 3 things in locations 2a, 2b and 3c of the worksheet].

Fine. Let's go over each one so that I'm sure of what you mean. Tell me what this one means to you. [Go over each factor for clarification]. For example, you said that _______ [from location 2a] was a factor. Can we call this ________ [enter in location 2d]?

[This needs to be repeated for locations 2b and 2c with shortened entries added to locations 2e and 2f, respectively.]

Now, let's look at all of these factors one by one. Would you tell me which one of these factors is most important to you? [Enter the short name of this factor in location 3a.]

Which of the remaining factors is 2nd most important to you? [Enter the short name of this factor in location 3b,]

[If there is more than one factor remaining]: Which of the remaining factors is 3rd most important to you? [enter the name of the 3rd factor in location 3c.]

So, ________ [location 3a] is the most important thing to you, ________ [location 3b] is the second most important thing to you, and ________ [location 3c] is the third most important thing to you -- right? [If not, go back and adjust, as necessary.]

3. Find out how each factor would affect his decision to have the exam or not have the exam and determine the Weights of Exam or No Exam.

What we want to do next is to see what each factor means to you in terms of having or not having the prostate exam and how strongly you feel in that direction:

a. You just said that ________ [from location 3a] was the most important factor. How much would that push you toward having the exam/not have the exam?

[Depending on the response, circle Exam or No Exam in location 4A and determine what portion of the factor weight should be assigned to Exam or No Exam. Write ________ (from location 4 on the comparison chart.)]

When thinking about ________ (from location 4), you said that ________ [circled Exam or No Exam choice from location 4A] would push you toward ________ [the choice circled from location 4A]. So, I'm writing ________
[circled choice] on the top left side of the chart. The length of the bars shows how much [factor] would push you toward [exam/no exam]. Circle the bar on left that best matches your feelings. If you prefer to use the words and not the bars themselves, that's OK too.

If the bar above "Completely dominates" is circled, enter a 9.9 in location 4a. If the bar above "A whole lot more important" is circled, enter a 1.9 in location 4b. If the bar above "A lot more important" is circled, enter a 1.7 in location 4c. If the bar above "Somewhat more important" is circled, enter a 1.5 in location 4d. If the bar above "A little bit more important" is circled, enter a 1.3 in location 4e. If the bar above "About the same importance" is circled, enter a 1 in location 4f.

The use of the 9.9 will most likely occur if the decision factor is defined in terms of either having or not having the exam. For example, suppose that the client believes that a decision factor is avoiding pain from the exam. Since pain is only incurred if an exam is taken, it is reasonable to give a 9.9 judgment to not having the exam.

b. Repeat for 2nd and 3rd choices. If only two factor are mentioned (after probing) then use 1.0 as factor weight for 3rd choice.

4. Determine the relative importance of one factor to the other.
We're making great progress. The last thing we're going to do is find out how important each factor is compared to one another.

Remember, this is just a different way of thinking about things. And, let me remind you, that the point is not to influence you to do one thing or another, but to go through a stepwise process so that the decision you make is one that you really feel OK with. All right?

a. What I'd like you to do is to look at the first two things: [from location 3]

[Show the comparison graphic.] Since you said that ________ [most important from location 3] is more important than ________ [2nd most important], I'm writing ________ [most from location 3] on the top left side of the chart and ________ [2nd from location 3] underneath. The length of the bars on the left show how much more important ________ [most] is compared to ________ [2nd]. Circle the bar on left that best matches your feelings about how much more important ________ [most] is compared to ________ [2nd]. If you prefer to use the words next to the bars and not the bars themselves, that's OK too.

[If the bar above "Completely dominates" is circled, enter a 9.9 in location 7a. If the bar above "A whole lot more important" is circled, enter a 1.9 in location 7b. If the bar above "A lot more important" is circled, enter a 1.7 in location 7c. If the bar above "Somewhat more important" is circled, enter a
1.5 in location 7d. If the bar above "A little bit more important" is circled, enter a 1.3 in location 7e. If the bar above "About the same importance" is circled, enter a 1 in location 7f.

[If "Completely dominates" is circled, explain that this implies that the most important factor is so important that the other two factors really have little influence on their decision. Confirm that this is the case. If not, allow him to change his judgment.]

b. Now, let's compare the second and the third thing: (from locations 5 and 6, respectively). [Show the graphic.]
Since you said that _____ [2\textsuperscript{nd}] is more important than _____ [3\textsuperscript{rd}], I'm writing _____ [2\textsuperscript{nd}] on the top left side of the chart and _____ [3\textsuperscript{rd}] under it. Circle the bar on left that best matches your feelings about how much more important _____ [2\textsuperscript{nd}] is compared to _____ [3\textsuperscript{rd}].

[As before, enter a 9.9, 1.9, 1.7, 1.5, 1.3, or 1 in location 8 a-f, depending on the response.]

c. Finally, let's compare the first thing with the third thing: (from locations 7 and 9, respectively). [Show the graphic.]
Since you said that _____ [from location 7] is more important than _____ [from location 9], I'm writing _____ [from location 7] on the top left side of the chart and _____ [from location 9] under it. Circle the bar on left that best matches your feelings about how much more important _____ [location 7] is compared to _____ [location 9].

5. Enter the data into the calculator

[Follow the instructions to run the program on the TI 86 calculator. Follow the directions displayed on the calculator screen to enter the information. Then transfer the calculator output information to the worksheet.]
Part IV. Making the Decision

[The first two columns in Table 1 provide ranges for the scores associated with AB. Looking down the first two columns in Table 1, the counselor finds the range that contains the score in AB. Reading across that row to the third column, the counselor identifies the "Direction of Your Preference." The counselor then checks the appropriate box in section 1 of the Preference Related to Prostate Cancer Early Detection Form. The counselor write the "Direction of Your Preference" (either Exam or No Exam) above the shaded bar on the left-hand side of section 2 of the Preference Related to Prostate Cancer Early Detection Form. The option not chosen is written above the right bar. If the Direction of Your Preference is "No Preference" then it makes no difference whether Exam or No Exam is written above the bar on the left-hand side. Reading across to the fourth column of Table 1, the counselor checks the appropriate box in section 2 corresponding to the "Strength of Your Preference" on the Preference Related to Prostate Cancer Early Detection Form.]

[The counselor then reads across the recommended row in Table 1 to the fifth column and identifies the letter under the "Shaded Region" heading. The counselor then shades the left-hand bar up to the indicated letter on the Preference Related to Prostate Cancer Early Detection Form.
If the assessment is "No Preference" then no shading is needed.]

[The Preference Related to Prostate Cancer Early Detection Form should now be shown and explained to the client.]

After taking all of your judgments into consideration, the results indicate that

__________________________ [from Strength of Your Preference on Preference Related to Prostate Cancer Early Detection Form].

Do you agree with this assessment? What do you plan to do?

[AFTER discussion, the counselor should write the planned course of action in location AE of the Final Worksheet and also check the appropriate box in section 3 of the Preference Related to Prostate Cancer Early Detection Form. If the planned course of action is different than the assessment the counselor should write a brief explanation in location AF on the back of the Final Worksheet.]

Debriefing: Ask participant to complete Satisfaction Survey.

Measure the clients satisfaction with the educational and decision process parts of the session. [Enter this feedback on the Survey form.]
Table 1: Direction and Strength of Client Preference

<table>
<thead>
<tr>
<th>AB is greater than or equal to</th>
<th>AB is less than</th>
<th>Direction of Client Preference</th>
<th>Strength of Client Preference</th>
<th>Shaded Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.667</td>
<td>1.000</td>
<td>Exam</td>
<td>Exam is completely preferred</td>
<td>A circle exam</td>
</tr>
<tr>
<td>0.643</td>
<td>0.667</td>
<td>Exam</td>
<td>Exam is a whole lot more preferred</td>
<td>B circle exam</td>
</tr>
<tr>
<td>0.616</td>
<td>0.643</td>
<td>Exam</td>
<td>Exam is a lot more preferred</td>
<td>C circle exam</td>
</tr>
<tr>
<td>0.583</td>
<td>0.616</td>
<td>Exam</td>
<td>Exam is somewhat more preferred</td>
<td>D circle exam</td>
</tr>
<tr>
<td>0.545</td>
<td>0.583</td>
<td>Exam</td>
<td>Exam is a little bit more preferred</td>
<td>E circle exam</td>
</tr>
<tr>
<td>0.455</td>
<td>0.545</td>
<td>No Preference</td>
<td>Exam and No Exam are about the same</td>
<td>F</td>
</tr>
<tr>
<td>0.417</td>
<td>0.455</td>
<td>No Exam</td>
<td>No Exam is a little bit more preferred</td>
<td>E circle no ex.</td>
</tr>
<tr>
<td>0.384</td>
<td>0.417</td>
<td>No Exam</td>
<td>No Exam is somewhat more preferred</td>
<td>D circle noex.</td>
</tr>
<tr>
<td>0.357</td>
<td>0.384</td>
<td>No Exam</td>
<td>No Exam is a lot more preferred</td>
<td>C circle no ex.</td>
</tr>
<tr>
<td>0.333</td>
<td>0.357</td>
<td>No Exam</td>
<td>No Exam is a whole lot more preferred</td>
<td>B circle no ex.</td>
</tr>
<tr>
<td>0.000</td>
<td>0.333</td>
<td>No Exam</td>
<td>No Exam is completely preferred</td>
<td>A circle noex.</td>
</tr>
</tbody>
</table>
**Final Worksheet**

**Definitions of Decision Factors**

A. 

B. 

C. 

**Short Names of Decision Factors and Which Decision Choice Each Prefers**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Factor</th>
<th>Factor</th>
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<tbody>
<tr>
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</tbody>
</table>

**Rank Criteria in Order of Importance:**

<table>
<thead>
<tr>
<th>Most Important</th>
<th>Second Most Important</th>
<th>Third Most Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>G</td>
<td>H</td>
<td>I</td>
</tr>
</tbody>
</table>

Exam No Exam Exam No Exam Exam No Exam

| Judgment: | | |
|-----------| | |
| M         | N | O |

**Comparisons:** Most vs. Second: Second vs. Third: Most vs. Third:

<table>
<thead>
<tr>
<th>P</th>
<th>Q</th>
<th>R</th>
</tr>
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</table>

**Factor Weights**

<table>
<thead>
<tr>
<th>Most Important</th>
<th>Second Most Important</th>
<th>Third Most Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>T</td>
<td>U</td>
</tr>
</tbody>
</table>

Exam Weights:

<table>
<thead>
<tr>
<th>V</th>
<th>W</th>
<th>X</th>
</tr>
</thead>
</table>

No Exam Weights:

<table>
<thead>
<tr>
<th>Y</th>
<th>Z</th>
<th>AA</th>
</tr>
</thead>
</table>

**Final Score:**

Exam: \( (S)*(V) + (T)*(W) + (U)*(X) \) 

No Exam: \( (S)*(Y) + (T)*(Z) + (U)*(AA) \)

Total: \( (AB) + (AC) \) [This must sum to 1]

**Planned Course of Action:**

AE
Final Worksheet (back of form)

Explaination of why planned course of action is different from assessment (if needed).

________________________________________

________________________________________

AF

Reason for not proceeding to the AHP counseling phase of the study (if needed).

________________________________________

AG