

Attachments for 0925-0046-07

#7A Informed Decision-Making Screener

#7B Informed Decision-Making Protocol/Moderator Guide

#7F Participant Questionnaire

Attachment 7A: Informed Decision-Making Focus Groups
RECRUITMENT SCREENER

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized by The Public Health Service Act, Section 412 (42 USC 285 a-1). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. The information collected in this study will be held in professional confidence. Names and other identifiers will be separated from information provided and will not appear in any report of the study. Information provided will be combined for all study participants and report as statistical summaries.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-07). Do not return the completed form to this address.

Thank you for your interest in participating in a study sponsored by the National Cancer Institute (NCI) about how you make healthcare decisions.

We're organizing a focus group discussion in your area to learn more about how people make healthcare decisions with their doctors. I need to ask you a few questions to confirm that you are eligible to participate.

1. How old are you?

_____ {IF BETWEEN 55 AND 74 CONTINUE, OTHERWISE THANK AND END.
RECRUIT AT LEAST 2 MEN BETWEEN THE AGES OF 55 - 65 AND AT LEAST 4 MEN
BETWEEN THE AGES OF 66 -74}

2. Do you have or have you ever had prostate cancer?

- YES → THANK AND END
- NO

3. Have you heard of a PSA test?

- YES

NO → THANK AND END

4. Have you visited a doctor in the past year?

YES

NO → THANK AND END

5. Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOS, or government plans such as Medicare?

YES

NO → THANK AND END

6. Were you born in the United States?

YES

NO → THANK AND END

[NOTE WHETHER RESPONDENT'S ENGLISH IS UNDERSTANDABLE. IF NOT, THANK AND END]

IF ELIGIBLE:

7. Are you available to attend a session at **[LOCATION]** on **[DATE]** at **[XX] p.m.**?

YES

NO → THANK AND END

Thank you for answering all of my questions. I'd like to invite you to participate in a focus group session that will take about 1½ hours to complete. It will be held at **[LOCATION]** on **[DATE]** at **[XX] p.m.** You We will pay receive you \$100 for your time with us and we will provide you with refreshmentsfood.

In case you need to contact me for any reason, you can reach me at **[Phone Number]**.

Attachment 7B: PSA Decision-Making Focus Group Protocol/ Moderator Script

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0046-07). Do not return the completed form to this address.

A. INTRODUCTION (15 MINUTES)

A1. Welcome and Topic Introduction

Welcome! Thanks for coming. My name is <MODERATOR>, and I'm the moderator for today's group discussion which means that I will be asking you questions and guiding the discussion. Also with me is my colleague<CO-MODERATOR> who will be helping me with this session. We both work for Westat, a private research firm located in Rockville, Maryland. <DESCRIBE OTHERS SEATED IN ROOM AS NECESSARY.>

Today's discussion is part of a research study being conducted for the National Cancer Institute (NCI). We are interested in talking to you about the U.S. healthcare system in general and learning more about the healthcare decisions you make with your own doctor. This is one of six groups we will be conducting with men on this topic.

The discussion today will be approximately 1½ hours long. You were invited to participate in this discussion group because each of you has a doctor whom you have seen in the past year.

I want to thank each of you for coming today and for fitting this session into your schedule. How many of you have ever participated in a group discussion of this type, sometimes called a focus group before? There are a few things I'd like to go share with you about the group before we get started.

A2. Disclosures and Ground Rules

1. [IF APPLICABLE] Facility: Describe overhead mikes, mirrors, observers.
2. I would like to go over a few things that were covered in the consent form you signed earlier. The session is being audio-taped so I can write an accurate report, not about who said

what, but about *what* was said. Your contributions to our discussion will be anonymous, and your names will not appear in the summary report.

Your participation in the discussion group is voluntary. Identifying information about you will be kept confidential. The information you share today will be used only for the purposes of this research study and will not be shared with anyone who is not part of the research team.

- 3.** To help make our discussion more productive:
 - Please speak one at a time and try not to engage in any side conversations during the discussion. I want to hear what everyone has to say – either today or when I go back to listen to the audio files to write up my summary.
 - I want to hear from everyone, but not every person has to answer every question.
 - I want to hear a range of experiences, so if you have an opinion different from what most in the group are saying, please don't hesitate to speak up (there are no right or wrong answers).
- 4.** At any time you can excuse yourself to go to the restroom, or to get more food or beverages. I ask that only one person leaves the room at a time so we can keep the discussion going.
- 5.** Are there any questions about anything I've said so far?

A3. Participant Introductions and Rapport-building

Please introduce yourself to the group by telling us your first name and what you like to do in your free time. <Moderator: INTRODUCE SELF LAST.>

B. INFORMED DECISION-MAKING DISCUSSION (1 HOUR)

B1. Trust in Medical System [Research Question #4]: We are going to begin our discussion at a very broad level.

- 1.** Can each of you talk about your general feelings about going to the doctor?
[PROBES]:
 - How often do you go to a doctor?
 - Do you go for regular check-ups or do you wait until there's something wrong?
 - What do you think about when you're deciding if it's time to go to the doctor?

- 2.** Can each of you share a few thoughts about your level of trust in doctors, nurses, and their staff in general. [Note to moderator: We are not interested in issues related to insurance coverage]

[PROBES]:

- What makes you say that?
- What experiences have you had that make you more or less trustful of doctors and their staff?

- 3.** How do you think your feelings about trust in doctors and their staff affect how you make decisions?

[PROBE:]

- Can you describe some types of decisions you make (that you are comfortable sharing with the group)?

Anything else?

B2. Relationship with Doctor [Research Question #1]/ Balanced Information [Research Question #5]: How many of you have a regular doctor? [GET A SHOW OF HANDS]

If you have a regular doctor, think of that doctor when we talk about the next series of questions. If you do not have a regular doctor, think about some of the doctors you've seen recently or just one doctor you saw most recently.

- 1.** Can you talk about your relationship with this doctor or doctors?

[PROBES]:

- How would you describe the kind of communication you have?
- What about the quality of the relationship?
- How long have you been seeing your regular doctor or the doctors you are thinking about?

- 2.** What do you think about the quality of the advice he/she/they have given you?

PROBES]:

- Does the doctor generally seem to know what he/she is talking about?
- Has the doctor ever told you he/she was unsure about something?
- If a doctor ever did say he/she was unsure about something, what would you think of that?
- Have you ever heard that doctors and other experts sometimes disagree about a whether a test or treatment is helpful or not?

3. On a scale from 1 to 5, with 1 being bad and 5 being good, how would you rate the quality of advice your doctor's given you? [GET A COUNT]

4. When a decision about a medical test or procedure has to be made, how does that process usually go?

[PROBES]:

- Does the doctor ask how much information you want?
- Does the doctor discuss the pros and cons?
- Does the doctor discuss risks and benefits?
- Does the doctor use charts or other research?
- Does the doctor ask how much you want to be part of the decision?
- Does your doctor usually tell you what's the best thing to do or do you decide what to do together?
- Does your doctor ask your opinion about your care?
- Does your doctor give you a recommendation?
- How many of you have recently had to make a decision with a doctor? [Get show of hands]
- Can you describe how that decision was made?
- Before you made that decision, did you go home and find out more information about the topic (IF NEEDED: like searching the internet, talking to friends, reading books)? If so, why?
- Why did you take the doctor's recommendation rather than gathering more information about that test or procedure?

Anything else about this topic before we move on?

**B3. Prostate Specific Antigen (PSA) Test [Research Question #6]:
Now I'd like to discuss a particular medical test, called the PSA test.**

- 1.** When you were contacted by the recruiter, you told us that you were familiar with the PSA test. What do you know about the test?

[PROBES]:

- Where did you find out about it?
- What is your opinion about the test?
- Have you heard that experts disagree about the test? (If Yes) What have you heard?

- 2.** Before testing, did your doctor ever discuss the pros and cons of the PSA test with you?

- 3.** Now I'm going to shift gears a little bit. Do you know if the PSA test is covered by your insurance?

[PROBE]:

- If not, would this influence your decision as to whether or not to have the test? How so?

B4. Personal Allocation of Resources [Research Question #3]

- 1.** Continuing on the topic of the costs of medical tests and other medical procedures, can you think of times where knowing that you had to pay "money out of pocket" for a test or procedure might influence whether or not you decided to have it? How so?

MODERATOR NOTE: This question is asking about instances where the participant would have to pay for part or all of a test, not a standard co-pay, regardless of affordability. We do not want participants to talk about people without insurance.

B5. Zero-sum [Research Question #2]: Now we are going to ask you to think outside the box for a few minutes.

We've been talking about things that influence your health care decisions – talking with your doctor, getting information about the decision, and thinking how much a medical test might cost you. All of these things could affect what you do. Do you ask your doctor for a new test you've heard of, do you ever question a test your doctor suggests you have, and so on. All of this has been about you and your own personal doctor.

Now we want to talk about some other things that might influence those decisions. We all live in communities with other people who are making decisions about their health. Those people see the same doctors and go to the same hospitals. But, those doctors can only see so many people each day and those hospitals have only so many beds available. The next few questions will be about how those kinds of limited community resources could influence your health care decisions. We're interested in if you ever think about other people's needs when you make decisions about your own health care.

1. Can you think of time when considering other people's needs might be part of a medical decision you make? Can you think of time when a medical decision you make would affect others around you?

[IF PARTICIPANTS ASK "How would I know if it would affect others?", SAY]: What if you didn't know?"

[PROBES]:

- What would those situations be?

IF NEEDED: Let's think about the flu vaccine. Here's one scenario: *There were only a certain number of doses available; so if you, a healthy older adult got the vaccine, an elementary school age child in your community may not have been able to.* This is a situation where your decision affects other people in your community.

IF NEEDED: What if there was a terrible car accident involving multiple cars. Both you and another person involved in the crash had a rare blood type and needed transfusions, but there was only enough blood for one of you. What would you do?

- Would it make a difference if you knew the other person(s) or not?
- What possible consequences could your decisions have?
- Does thinking about healthcare that way affect how you would make a decision?

1. What if there were only \$1 million dollars to be spent on the health care for your entire community? Would you ever decide NOT to have a test or procedure so someone else could get it?

IF NEEDED: What if you needed a heart transplant, but knew that having the transplant would use up the vast majority of the health care money available for your community. How would you decide whether or not to have the transplant?

[PROBES]:

- How would you make that decision?
- Would you consult your doctor?

- Do you think that ultimately people should have the right to choose to have the heart transplant, regardless of the cost to the community?

Today we've discussed how you go about making medical decisions with your doctor. Are there any other areas related to making decisions with your doctor that we have not already discussed that you would like to bring up?

[IF NEEDED - SUMMARY OF PSA CONTROVERSY]: It is not clear if the benefits of screening for prostate cancer outweigh the potential harms caused by screening. According to the United States Preventative Services Task Force there is not enough good evidence showing that screening men using the PSA reduces death from prostate cancer. There is also concern that some men will get unnecessary invasive tests (such as a biopsy) or treatment for a prostate cancer that would never cause any problems, since the PSA can't tell how aggressive a cancer is.

C. CONCLUSION (15 MINUTES)

Those are all the questions I have for you today. Thanks so much for your help. Before we finish, I would like to check with the researchers from Westat and NCI behind the mirror to see if they have any additional questions.

Thank you!

HAND OUT MATERIALS ABOUT PROSTATE CANCER AND PSA TESTING.

Attachment 7E: Participant Questionnaire

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1. What is your age? ____

2. Are you Hispanic or Latino?
 - Yes
 - No

3. Which one or more of the following would you say is your race? Mark all that apply.
 - White
 - Black or African American
 - American Indian or Alaska Native
 - Asian
 - Native Hawaiian or Other Pacific Islander

4. What is the highest grade or level of schooling you completed?
 - Less than 8 years
 - 8 through 11 years
 - 12 years or completed high school
 - Post-high school training other than college (vocational or technical)
 - Some college
 - College graduate
 - Postgraduate

5. What is your current occupational status?

- Employed
- Unemployed
- Homemaker
- Student
- Retired
- Disabled
- Other, please specify _____

6. What is (or was) your occupation?

7. What is your marital status?

- Married
- Living as married
- Divorced
- Widowed
- Separated
- Single, never been married

8. Do you have a regular doctor that you see most often?

- Yes
- No

9. How long have you been seeing your regular doctor?

10. Have you ever lived outside of the United States?

Yes

No