

ATTACHMENT E

**SSLA—FOCUS GROUPS WITH MEMBERS OF THE GENERAL PUBLIC
IN TWO ROUNDS**

**Research Evaluation and Impact Assessment of American Reinvestment and Recovery Act
(ARRA) Comparative Effectiveness Research Portfolio**

**Societal-Stakeholder Level of Analysis
Focus Groups with the General Public**

Conducted by:

Mathematica Policy Research

for

**U.S. Department of Health and Human Services,
Assistant Secretary for Planning and Evaluation**

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The total burden for this protocol is 240 hours.

Health Information Focus Group

1. Introductions (10 minutes)

- a. Moderator Introduction: Moderator introduces himself/herself and explains purpose and procedures:
 - These focus groups are being conducted with members of the public.
 - The purpose is to learn how people make decisions about health care and use information to deal with health problems.
 - We will discuss how people deal with health issues, how familiar people are with certain health care terminology, and ideas for getting health information to the people who could use it.
 - My role as the moderator is to ask questions rather than participate in the discussion or answer questions. There are no right or wrong answers—I'd like to hear from everyone so at times I will make sure that everyone has a chance to say what they think.
 - Everything we discuss today is private to the people in this room and the study investigators. Your name will never be used or associated with any comments.
 - The group is being tape recorded. I'd like to collect your consent forms now.
- b. Respondent Introduction: Respondents introduce themselves giving first name, occupation, household composition, and years living in CITY.
- c. CITY – Quality of Life (Ice breaker)
 - (Show of hands) Is life in CITY getting better, staying about the same, or getting worse than it was a couple of years ago?
 - Positives (words and short phrases).
 - Negatives (words and short phrases).

2. Health Decision-Making Behaviors and Experiences (40 minutes)

- a. Try and think about the last time you had to make a decision about your health or the health of someone close to you. We don't want to talk about colds or the flu. Please think about health conditions that require ongoing care. Some examples include diabetes, depression, attention deficit disorder, chronic back pain, atrial fibrillation, coronary artery disease, prostate cancer, or other conditions.
 - (*Count show of hands*) Did you see a doctor or other health provider (like a nurse or physical therapist)?
 - If not, why not?
 - Were you able to solve the problem on your own? If so, where did you go for information?
 - (If YES) Before going to the doctor or other health care professional, did you know what your options for treatment were? Or did you have an idea of what treatment you wanted or needed?
 - If yes, how did you know? Where did you get your information?

- When you saw the doctor or other health care provider, did they talk to you about different options for treating the health problem? Did you think that the health problem was one for which there were different options for treatment?
 - IF NECESSARY: For example, if you had a broken arm, you might think that getting a cast is the only fix, but if you had high cholesterol, you might think that there is more than one way to deal with it.
- b. How did you decide how to deal with the health issue? (Unaided first, PROBE ONLY IF NECESSARY) Did you:
- try and get advice from friends or family members
 - look up information about the health condition or treatment options
 - trust the recommendation of the doctor
 - get a second opinion from another doctor
 - (After discussion, *count show of hands on how people decide*)
- c. (PROBE IF SAW DOCTOR OR HEALTH PROVIDER) How would you describe how you came to that decision with your doctor? Do you feel like your doctor told you what to do, you told your doctor what you wanted to do, or some combination of the two?
- d. If you looked up information, either instead of going to the doctor or before going to the doctor, where did you look for information?
- How did you determine what information is trustworthy?
 - How confident were you that the information you found was correct?
- e. On a scale from 1 to 10, how confident were you that you made the right decision about your health or the health of someone close to you, with 1 being not at all confident and 10 being completely confident? (*Go around the table for rating from each person*).
- What made you sure of your decision? What would have made you feel more confident of your decision?
 - IF NEEDED: What if cost was not a concern?

3. Attitudes and Beliefs about Health Decision-Making and CER (20 minutes)

- a. Let's say that you went to see your regular/family doctor for some specific chronic health problem (such as heart failure or diabetes).
- Would you expect the doctor to be familiar with the research on how different treatments compare to one another, and the benefits and harms of different treatment options?
 - Do you think more of this research would change the kind of care that you receive from the doctor? Why?
 - What are the positives of this kind of research (short words or phrases)?
 - Negatives (short words or phrases)?
 - IF NECESSARY: Do you think having more of this research would have any effect on the choices you or your doctor have to when deciding about a course of treatment?

- What do you think is the doctor's role in helping you make a decision about treatment?
IF NECESSARY:
 - Would you expect her to tell you what to do without describing all the options?
 - Would you want her to first describe all the options available to you, including the disadvantages of each option, and then tell you what to do?
 - Would you expect the doctor to give you a list of options and let you decide?
 - Would you expect her to describe the pros and cons of all the options available to you and then discuss them with you so you can make a decision together? Would you want her to use a decision aid to help you guide you through the decision-making process? (A decision aid shows evidence-based information about treatment options, the pros and cons of each option, and how your preferences and values may make certain options better suited to you.)

- b. Would you seek out for yourself the information on how different treatments compare to one another, and the benefits and harms of the treatment options? Why or why not?
 - How useful would the information be to you?
 - How would you feel if you found out that there are three or four different options for treating one condition?
 - How would you decide on which option is best for you?

- c. HANDOUT: Opinions. (Agree/disagree items on a handout. Participants fill it out then discuss each) Why did you say that?
 - More care is better care;
 - newer drugs are better than older drugs;
 - medical treatments that work the best usually cost the most;
 - medical treatments that cost the most usually work the best;
 - cost should never be a factor in deciding on the best treatment;
 - more research on how different treatments compare to one another is good for health care;

4. Knowledge and Attitudes Regarding Comparative Effectiveness Research (30 minutes)

- a. (*Count show of hands*) Have you ever heard the term comparative effectiveness research? How about patient-centered outcomes research?
 - (If YES) Where did you hear about it?
 - How would you define what it means?
 - What do you think is positive or negative about it?

(HANDOUT) Comparative effectiveness research is a type of health care research that compares the results of one approach for managing a health problem to the results of other approaches. Comparative effectiveness usually compares two or more types of treatment, such

as different drugs, for the same disease. Comparative effectiveness also can compare types of surgery or other kinds of medical procedures and tests.

- How would you explain in your own words what this means to a friend who hasn't heard this before?
 - After reading the definition, what do you think is positive about comparative effectiveness research? Do any negatives come to mind?
 - Are you familiar with any medical research on common health problems or perhaps on a health problem you may be especially concerned about? If yes, which ones?
 - Next I am going to read a few statements out loud. Some are true and some are false. For each one, please tell me if you think it is true or false and then we'll discuss it together.
 - Comparative effectiveness research includes only reviewing a range of health-related outcomes for the population as a whole instead of for specific patient populations (such as by age, sex, or race) [FALSE]
 - *(Count show of hands of people answering T/F). Why did you say that? What do you think this statement means?*
 - Comparative effectiveness research does NOT look at behavior change, like strategies to promote correct use of prescription medications by patients [FALSE]
 - *(Count show of hands of people answering T/F). Why did you say that? What do you think this statement means?*
 - Sometimes comparative effectiveness research will show that the most costly option is the best treatment. (T)
 - *(Count show of hands of people answering T/F). Why did you say that? What do you think this statement means?*
- b. Would you trust the information that comes from comparative effectiveness research? Why or why not?
- (IF NO, OR NEED MORE INFORMATION) What factors would make you more likely to trust the information?
 - What would you consider a reliable source? What more do you need to know about comparative effectiveness research before you would trust the information?
- c. Let's go back to the example of when you went to see your doctor or nurse for a specific chronic health problem like heart failure or diabetes. What if the information in the comparative effectiveness literature for this health problem was different than what your doctor recommended that you do? (IF NECESSARY: which would you trust more? Would you talk to your doctor? How would you decide which course of action to take?)
- d. Have you ever decided to take a different course of action than what your doctor recommended? Why or why not?
- e. VIGNETTE HANDOUT: Now let's turn to the handout. Please read the scenario in the handout and then we're going to discuss it as a group.
- Given this information, what would you do if you were faced with this decision? Why would you do that?

- What would you want to discuss with your doctor?
- How would you weigh out the pros and cons of each of the options?
- If you had to make this decision, what information would be useful to you in making a decision about treatment?
- Would you feel capable of using research evidence to help you choose a treatment option? (What information would you need to feel capable?)
- Why do you feel that way?
- What would make you feel more confident about using research evidence to help you choose a treatment option?
- What else would you need before making a decision?
- Who else would you consult, if anyone?
- Have you made similar decisions before (about different health conditions and treatments)?

5. Using Comparative Effectiveness Research (10 minutes)

- Are you familiar with any new tools for helping health care providers or patients use information that compares different treatment options to make decisions about health care?
 - If yes, which ones?
- What would be some effective ways of getting information about comparative effectiveness research to the people who could use it? (Unaided first, PROBE ONLY IF NECESSARY)
 - Fact sheet in the waiting room of the doctor's office
 - Doctor/Health provider should talk through options with patient
 - Doctor/Health provider should give written information to the consumer when talking about treatment options
 - Doctor/Health provider should provide computer-based information/tools in the office to help the consumer consider treatment options
 - Popular health websites should link to the relevant fact sheet
- Which source(s) would you actually use?
- Do you currently go to any websites for health information? Are there any patient advocacy groups you belong to or read up on? Do you recall any public service announcements on TV or in magazines (not including ads for specific drugs)?

6. Suggestion (if time allows) (5 minutes)

- Is there anything about comparative effectiveness research we haven't talked about today that you'd like to comment on?

CONSENT FORM FOR FOCUS GROUP PARTICIPANTS
HEALTH INFORMATION FOCUS GROUPS

During this focus group, you will discuss questions regarding how people deal with health issues, how people find health information, what sources of information they trust, and how they make decisions with their doctors. You will also discuss opinions about different types of health research.

Everything we discuss in the focus group is private to the extent allowed by law. We will never use your name in any reports.

No direct benefits are expected from participation in this study other than the opportunity to discuss issues that may be of interest to you. All participants are asked to agree to keep the identities of all participants private. Issues discussed in the focus group may be discussed elsewhere as long as they are discussed in a way that does not identify other participants in this group.

We do not anticipate any risks from participating in this study. If any question makes you uncomfortable, you may refuse to answer any question you do not wish to answer.

If you would like more information about this study please contact [NAME] at Mathematica Policy Research, at [NUMBER].

Please read the following statements and fill out the appropriate section.

- 1. Yes, I wish to participate in this study.** I understand that my responses will not be associated with me personally in any way. Data from the focus group session will be audio-taped and transcribed for the purpose of filling in notes. Any names or places that could be attributable to me personally will be omitted from any reports or findings based on the focus group discussion.

I understand that I may choose not to answer specific questions asked during my focus group discussion by simply stating, "Pass" or "I prefer not to answer."

Signature: _____

Date: _____

Printed Name: _____

- 2. No, I do not wish to participate in this study.**

Signature: _____

Date: _____

Printed Name: _____

HANDOUT: VIGNETTE

Jane is a 61-year old woman with a history of congestive heart failure. Congestive heart failure is a condition where the heart can't pump enough blood to meet the body's needs. To manage her condition, Jane regularly takes a diuretic, or water pill, that is supposed to control her heart failure and prevent fluid from collecting in her body.

However, Jane visits her doctor with a new concern. She is experiencing an increase in shortness of breath when she exerts herself—such as when she walks up stairs. She has also gained a little bit of weight recently, even though she hasn't changed how much she eats or exercises and is still taking her diuretic regularly.

Worried about these changes, Jane goes in for an examination with her doctor. After examining Jane, her doctor tells her that her shortness of breath is a symptom that her congestive heart failure is getting worse. Her doctor tells Jane that she has three treatment options

1. adjusting the dosage of her current treatment, which is a diuretic medicine
2. adding a new medication to her current medicines that would help her heart to not have to work as hard
3. having surgery to connect a special pacemaker to her heart to help her heart pump more efficiently.

Jane and her doctor discuss together how they are going to make a decision about treating her worsening congestive heart failure.

HANDOUT: OPINIONS

1. More care is better care.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

2. Newer drugs are better than older drugs.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

3. Medical treatments that work the best usually cost the most.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

4. Medical treatments that cost the most usually work the best.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

5. Cost should never be a factor in deciding on the best treatment.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

6. More research on how different treatments compare to one another is good for health care.

Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

HANDOUT: DEFINITION

Comparative effectiveness research is a type of health care research that compares the results of one approach for managing a health problem to the results of other approaches. Comparative effectiveness usually compares two or more types of treatment, such as different drugs, for the same disease. Comparative effectiveness also can compare types of surgery or other kinds of medical procedures and tests.