

ATTACHMENT K

SSLA— IN-DEPTH TELEPHONE INTERVIEWS WITH INNOVATORS

SOCIETAL STAKEHOLDER LEVEL OF ANALYSIS (SSLA) INTERVIEW PROTOCOL FOR INNOVATORS

Description of the Protocol

The purpose of the in-depth stakeholder telephone interviews is to collect information on the three primary domains of interest—knowledge and skills, attitudes and beliefs, and behaviors and experiences—in an effort to understand what processes stakeholders use to engage in CER. The interviews will also follow up on issues raised in other data collection activities. We will collect this information from each *key* stakeholder group—those that are directly involved in CER decision-making or are CER users, including: (1) physicians, (2) consumers/patients, and (3) health care organizations. We will also collect this information from each *additional* stakeholder group—those that use and contribute to CER but are not directly involved in point-of-care decision making, including: (4) employer/payers, (5) researchers and (6) developers of innovation. This will allow us to examine differences in CER-relevant knowledge and skills, attitudes and opinions, and behaviors and experiences held by various stakeholder groups. We will use the data we collect from the telephone interviews to help answer SSLA evaluation questions as well as inform other levels of analysis. (Please see the stakeholder-specific section of the draft approach for more detail.)

The expectation is that we will conduct 8 to 10 interviews for each of the 6 stakeholder groups, for a total of up to 60 hour-long interviews.

For innovators, we will recruit from the three biggest representatives of health care intervention innovators: (1) PhRMA-drug manufacturers; (2) biologic agent manufacturers; and ADVAMED (device manufacturers).

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990- . The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer

The total burden of this interview protocol is 10 hours.

I. GENERAL INTRODUCTION (<5 minutes)

We appreciate you taking the time to speak with us today. Before we begin, let me introduce myself and tell you a little bit about the work we are conducting for the Office of the Assistant Secretary for Planning and Evaluation (ASPE), which is part of the Department of Health and Human Services. My name is _____, and I work for an independent policy research firm called Mathematica Policy Research (Mathematica). *[If note taker, introduce him/her as well.]*

We are helping ASPE learn more about what people know and think about comparative effectiveness research, which is often called CER for simplicity, and I will use this term, CER, during our discussion today as well. To do this, we are interviewing people from key stakeholder groups, including health care innovators, to hear about your opinions and experiences with CER. We obtained your name from [insert name of sampling frame]. Your participation today is voluntary and our discussion is private. We will combine your answers with those of others to develop a broad overview of perspectives regarding comparative effectiveness research.

The results of our discussion will be synthesized in a final report and only general themes that emerge from our discussions will be reported. We will not attribute specific comments or quotes to named individuals without permission and your individual answers will be kept private to the extent permitted by law. Only the Mathematica evaluation team will have access to individually identifiable information.

We expect this discussion to take about an hour.

Before we begin, do you have any questions?

II. BACKGROUND QUESTIONS (5 minutes)

First, I want to ask you a couple of background questions about the organization you work for.

1. What does your company primarily produce?
2. In what areas of health care is your organization involved?
3. Please describe your position within the company?

- What do you work on?
4. At a very high level, can you describe in about a minute or so, what sort of research or information gathering process does your company (or field) use to produce [INSERT GENERIC PRODUCT(S) NAME HERE]?

- Please describe

III. GENERAL KNOWLEDGE ABOUT CER (10-15 minutes)

Now, I would like to discuss comparative effectiveness research (CER).

A. Awareness/Understanding of CER

1. [Awareness]: Have you heard of comparative effectiveness research (CER) or patient-centered outcomes research?

- If yes, could you describe it in your own words? (And give an example?)

*[Give Interviewee the AHRQ 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.]*

2. [Awareness]: Different people interpret definitions differently. What would you say the definition I read for CER means, in your own words?
3. [Awareness]: Please describe some recent examples of CER
4. [Awareness]: Do the terms “comparative effectiveness research” and “patient-centered outcomes research” mean the same thing to you or do they mean something different?

- If they are different, is one more positive or negative than the other? Why do you think that?

B. Knowledge/Understanding of CER

[Knowledge] [Attitudes] I would also like to ask you about some specific aspects of comparative effectiveness research and how important these are for improving health care.

1. How important is it that this kind of research responds to the information needs of patients, providers, and other decision makers? Why or why not?

2. How important is it that this kind of research examines effectiveness of interventions for different types of patients? For example:
 - **Probe:** Should it examine effectiveness for different age groups? Why or why not?
 - **Probe:** Should it examine effectiveness for different ethnicities and races? Why or why not?
3. How important is it that this kind of research examines a range of interventions? For example:
 - **Probe:** Should it examine medications? Why or why not?
 - **Probe:** Should it examine procedures like surgical and screening procedures? Why or why not?
 - **Probe:** Should it examine medical and assistive devices and technologies? Why or why not?
 - **Probe:** Should it examine behavioral change strategies such as strategies to help patients monitor their own conditions? Why or why not?
4. How important is it that this kind of research examines a range of health-related outcomes (for example, looking at clinical outcomes but also patient satisfaction outcomes)? Why or why not?
5. Could you please rank these four aspects of comparative effectiveness research by how important they are to you (1= most important, 4=least important)?

IV. KNOWLEDGE, ATTITUDES, BEHAVIORS REGARDING ELEMENTS OF COMPARATIVE EFFECTIVENESS RESEARCH (15 – 20 minutes)

A. Methods

1. [Awareness]: Are you familiar with any methods for conducting comparative effectiveness research?
 - *If yes, which ones? Any new ones?*
[Give one or two examples: An example of CER methods includes:
 - 1)
 - And
 - 2)]
 - *If no, provide examples: Examples of two different kinds of methods used for this type of research are randomized controlled trials and an analysis of existing data from electronic databases.*
2. [Attitudes]: What are your thoughts about different methods being developed for conducting comparative effectiveness research? Why?

B. Databases for using CER

1. [Awareness]: Are you familiar with any large databases that can be used for conducting comparative effectiveness research?

- *If yes, which ones? Any new ones?*

[Give one or two examples: An example of CER databases includes:

1)

And

2)]

- *If no, provide examples: an example of CER databases include merging all payer claims or linking payer data with electronic health record information*

C. Use of CER findings in decision-making

1. [Behavior]: How long have you used information of comparative effectiveness in decision-making for your organization?
2. [Behavior]: How often do you use information of comparative effectiveness in decision-making for your organization?
3. [Behavior]: How do you use comparative effectiveness research to make decisions?

V. GENERAL ATTITUDE TOWARD CER (10-15 minutes)

[Attitude] Now that we have discussed the different elements and possible uses of comparative effectiveness research, I would like to ask you more generally about what you think of this type of research.

1. What are your thoughts on how CER might affect your industry? Can you give an example?
2. What are your thoughts on how CER might affect health care in the US?
3. What are your thoughts on how greater provider use of CER in clinical decision-making might affect health care in the US?
4. What are your thoughts on how greater patient use of CER in clinical decision-making might affect health care in the US?
5. What are your thoughts on how greater use of CER by health plans or other payers might affect health care in the US?

VI. WRAP UP (<5 minutes)

Are there any other thoughts about CER that you would like to add in the time we have left?

(Check with note taker to see if anything was missed or if s/he has follow-up questions)

Thanks for taking the time to speak with us. Your comments have been very helpful.