

CDC Evaluation of Emergency Use Fact Sheets Regarding Medical Countermeasures – Comprehension Evaluation/Message Testing:

**In-Depth Interview Discussion Guide
Version 11-19-2018**

IN-DEPTH INTERVIEW DISCUSSION GUIDE

Objective: Conduct in-depth, semi-structured interviews to assess how participants comprehend emergency fact sheets regarding medical countermeasures.

NOTES TO REVIEWER:

Question probes are *italicized*. These are suggestions for the interviewer to follow, and will be used or modified as deemed relevant and necessary in the natural flow of discussion.

Moderator instructions are highlighted in yellow.

Stimuli prompts are highlighted in blue.

Session Overview:

SECTION I: INTRODUCTION (5 min.)

The purpose in this section is for the moderator to explain the purpose of the project, review any ground rules or guidelines, and allow participant to ask any questions.

SECTION II: BACKGROUND INFORMATION (10 min.)

The purpose of this section is to ease into the conversation and gather relevant background information such as participants' experience with discussing medicines with their healthcare provider or factors that influence their decision to take medicine and medicine adherence.

SECTION III: STIMULI DISCUSSION (45 min.)

The purpose of this section is to provide a deep dive in participants' knowledge and comprehension, attitudes and beliefs, behaviors, and communication related to the fact sheets. Each participant will see 2 standard fact sheets. Should time allow, participants will see a redesigned fact sheet and provide feedback.

Public reporting burden of this collection of information is estimated to average 65 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 CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0572).

- Fact sheet 1: 20 minutes
- Fact sheet 2: 20 minutes
- Redesigned fact sheet: 5 minutes (time allowing)

CONCLUSION

If time permits, moderator will check with project team members and observers if they have additional questions (with participant on hold). If, yes moderator asks follow-up questions and then wraps up discussion and ensures that all of the participant's comments have been heard.

SECTION I: Introduction (5 minutes)

[Please refer to participant by FIRST NAME only.]

- My name is _____, and I'm part of an independent evaluation company called Fors Marsh Group. This means that I'm here to listen to you and what you have to tell me, and I have no stake in how you respond.
- We are partnering with the Centers for Disease Control and Prevention (CDC). The purpose of today's interview is to get your thoughts and reactions about the information presented to you.
- Your thoughts are very important to us, and your time today is appreciated.
- We will have about 60 minutes for our discussion.

As we begin, I want to review a few ground rules for our discussion.

- Your participation is voluntary and you have the right to withdraw your participation at any time during this interview.
- Most importantly, there are no 'right' or 'wrong' answers. We want to know your opinions and what you think about the things we will be discussing.
- Just a reminder, I do not work for the people who are sponsoring this project, so don't hold back from giving me your honest opinions.
- As we move through our discussions, please make sure to refrain from providing any personal information to us. This could be any information that would make it possible for someone to identify you such as your last name, address, phone number or any other personal information.
- Members of this project team are listening in to this interview and taking notes. This interview will also be audio recorded and the screen share recorded for data analysis and reporting. Only people who are

involved in the project will have access to this data. **I am going to go ahead and start the recording now. [START RECORDING]**

- And just to confirm, can you see my screen on your computer? It should say “Participant [READ PARTICIPANT ID #].” OK great, we won’t be using the computer just yet—I will let you know when we get to that part.
- Do you have any questions before we begin?

Okay, great. Let’s get started.

SECTION II: Background Information (10 Minutes)

I’d like to start by talking with you a little bit about your typical experience when you are prescribed medicines by a healthcare provider.

- When your healthcare provider prescribes you a medicine, what, if any, information do you typically want to know?
- Do you typically have conversations with your healthcare provider about that medicine?
 - [If participant needs more explanation] *Do you talk about possible side effects? Dosing information? General instructions for use?*
 - [If yes] *What kinds of conversations do you typically have? (Can touch on above probes) What type of information do you typically try to receive from your doctor when prescribed a medicine?*
 - *Do you ever follow up with your pharmacist for more specific instructions?*
- Do you typically read the instructions on your own once you receive your medicine from the pharmacy?
 - *Do you ever speak with your pharmacist about medicines?*
- If you wanted more information, how would you seek it?
- What helps you decide to take medicines? [Probe on specific mentioned factors]
- What do “benefits of a medicine” mean to you?
 - Do you typically consider the benefits of a particular medicine prior to taking it? If so, how?

- What about “risks of a medicine” what does that mean to you?
 - o What do risks of a disease mean to you

Great, thank you for that information. We’re now going to transition to start talking about specific medicine fact sheets that are implemented by the CDC in case of a public health emergency.

SECTION III: Stimuli Discussion (45 min.)

During a public health emergency involving serious disease or outbreaks, — for example, anthrax, botulism, smallpox, pandemic flu — there are medical products such as drugs and vaccines that can prevent or treat these types of diseases and threats. CDC has emergency “Fact Sheets for Recipients” for each medicine that state and local governments would provide to the affected people during an emergency.

Today, we would like to gather your feedback regarding information in these fact sheets to ensure that they are clear and easy to understand. Ultimately, this feedback will be used to help revise and improve these communications and may inform the development of similar fact sheets in the future, so we greatly appreciate your input.

To do this, I am going to ask that you use your computer. Are you looking at your computer now? OK, great. I am going to show you two examples of these fact sheets. The two I will share with you were selected at random, but are similar in nature to all of the emergency fact sheets that could be distributed.

[Share Fact Sheet Stimuli]

I’m going to give my mouse control over to you now. You should now be able to move your cursor around the screen. I’d like to ask you to read through the information in the fact sheet. As you read through, I’d like you to “think aloud” and share any thoughts or questions that come to mind as you are going along.

[Allow participant to walk through process, spending no longer than a few minutes - if taking longer than 3 minutes: I know you are probably still reading through everything, but for the sake of our time today, I would like to start asking by showing you a worksheet and have you walk me through how you would respond to each question.

[Share Comprehension Activity on screen and record answers.]

You still have control of the mouse, so feel free to scroll around as you're answering my questions. [Allow participant to be able to view fact sheet that is being referenced in the probing sections.]

All fact sheet-specific questions can be found after the Communication sub header.

Knowledge and Comprehension

- After reading through this fact sheet, do you understand why you are being offered this medicine/vaccine?
- Do you have enough information on deciding whether or not to take this medicine?
 - o *Why or why not?*
- Was there anything unclear or confusing in this fact sheet?
 - o Are there any words or phrases that were unclear or you were unsure about?
 - o [Probe into particular words, phrases, or concepts that they say are confusing] *How could we change this to be more clear?*
- Could you tell me what this medicine is used to treat as explained on this fact sheet? Where did you find this information?
 - o *Had you ever heard of the (epidemic/pandemic/outbreak/emergency) that this medicine is designated to prevent/treat?*
- After reading through this fact sheet, what are some of the signs or symptoms that would require use of this?
 - o *Where did you find this information?*
- What about who should and should not take this medicine/vaccine. Could you tell me who should be taking this medicine/vaccine?
 - o *What about who shouldn't be?*
 - o *Where did you find this information?*
- What are some common side effects that might be experienced after taking this medicine/vaccine?
 - o *What about serious side effects?*

Fact Sheet-Specific Questions

[Please see Appendix A]

Communication

- Now, thinking about the fact sheet overall, how do you feel about the way this information is presented? [Probe on look/feel, formatting]
 - How do you feel about the font size on this fact sheet?
 - What about the amount of white space in between the text?
- What is the tone of the fact sheet? [If needed: provide examples of tone, e.g., authoritative, scary, trustworthy]
- What do you think about this information coming from the CDC – is this a reliable source? How so?
- What information will you remember tomorrow about this fact sheet?
- What information did you think was the most relevant to you?
- Would you share information from this fact sheet with a family member or friend?
 - *Why or why not?*
 - [If yes] *What information would you share?*
- Is there anything you would change about this fact sheet to make it more clear? [Probe to elaborate]

Attitudes and Beliefs

- What do you think the risks of not taking the medicines are? Risks meaning the bad things that might happen to you if you do not take it. [If needed, describe this means the risks of the disease]
- What information did you see about benefits of the information? Benefits meaning the good things that might happen to you if you take this medicine.

- o [If yes] *Did you read the information? What caused you to read this information?*
- o [If no] *If you look on (page x). Please read the information in that section.*
 - *Is there a reason you didn't read this information before?*
- o *How important is this benefits information? More or less important than other sections?*
- *Do you think the benefits of using this medical countermeasure outweigh the risks associated with the emergency in this situation?*
 - o *For what reasons?*

Behaviors

- *If you were given this fact sheet, how likely are you to read it?*
- *If you were in this scenario and a local health official provided you with this fact sheet, what piece (or pieces) of information would stick out to you the most in reading this?*
- *What pieces of information, if any, would help you decide whether to take/get the medicine/vaccine described on this fact sheet?*
 - o *For what reasons?*
- *What piece of information, if any, would make you not want to take/get the medicine/vaccine described on this fact sheet?*
 - o *For what reasons?*
 - o *What, if anything, could be changed about this fact sheet to make you more likely to take this medicine in an emergency?*
- *How confident are you that you could take this medicine/vaccine as instructed?*
 - o [For caregivers] *How confident are you that you could assist (your child/the individual you take care of) in taking this medicine?*

Designed Fact Sheet [Time Allowing]

So, along those lines of editing these fact sheets to make the information more straightforward or easily digestible, I am now going to show you an example of a fact sheet that has been reformatted by a graphic design team. [Pull up reformatted fact sheet on screen]. [Repeat 'think aloud' process, rating and discussion questions for second fact sheet]

[Show Designed Fact Sheet]

Take a minute to scroll through this fact sheet. I'm now going to show you that same worksheet we looked at before and have you walk me through your answer choices. [Share rating questions on screen and record answers.]

What are your initial reactions to this sheet? [Probe around likes, dislikes.]

- Was anything on this fact sheet confusing or unclear?
- What parts of this fact sheet grabbed your attention the most?
- If you were given this fact sheet, how likely are you to read it?
- If you were given this fact sheet, how likely are you to take the medicine?
- How confident are you that you could take this medicine as instructed?
 - o [For caregivers] How confident are you that you could assist (your child/the individual you take care of) in taking this medicine?
- Does the format of this fact sheet make the information more or less clear? How so?
- Which fact sheet style do you prefer?

SECTION IV: Closing

[IF TIME PERMITS - PLEASE CHECK WITH EVALUATION TEAM/OBSERVERS FOR FOLLOW UP QUESTIONS.]

Thank you, this has been helpful. I am going to check quickly with my colleagues to see if there are any follow-up questions for you in the time we have remaining. I will be right back on the line.

[Put participant on hold]

MODERATOR TO ASK FOLLOW-UP QUESTIONS (if applicable)

[Thank participant]

Thank you very much for participating in this interview. I have enjoyed getting to know you, and appreciate your time and feedback. Is there anything that you would like to share that you didn't have the chance to share yet?

Appendix A: Fact Sheet-Specific Questions

1. Anthrax (AVA vaccine)

- How is the vaccine given/administered?
 - o *Is it clear that the preferred way to give the vaccine is as a shot under your skin? Any why?*
 - o *And is it also clear that the vaccine can also be given as a shot into your muscle?*
 - o *Does/what does that difference mean anything to you?*
- How many shots do you need and when do you need to return to get them?
 - o *What is the dose and amount of vaccine to get?*
 - o *Is it clear that you could receive 2 full doses every 2 weeks or 3 half-doses ever 2 weeks?*
 - o *Does/what does that difference mean anything to you?_*
- What about antibiotics - what is your understanding about antibiotics when used with vaccine?
 - o *What is the duration of antibiotics? Is it different for different people?*
- What does “Emergency Use Authorization” mean?
 - o The AVA vaccine for anthrax is FDA-approved; however, it is approved for different dosing schedules, so using the vaccine as described in the fact sheet has to be authorized by FDA during an emergency - is this clear from the fact sheet?

2. Anthrax (Amoxicillin)

- How many times a day and how long do you need to take this medicine?
- If your child or an older family member you’re taking care of cannot swallow pills, how would you give the medicine to your child?
 - o *Are the instructions clear on how to a) use the powder to make an oral suspension and b) opening the pill and mixing the contents with food?*
- What does “Emergency Use Authorization” mean?
 - o Amoxicillin is a medicine that is FDA-approved; however, using it to treat anthrax is not approved, so the medicine has to be authorized by FDA during an emergency - is this clear from the fact sheet?

3. Anthrax (Doxycycline)

- How many times a day and how long do you need to take the medicine?
- If your child or an older family member you're taking care of cannot swallow pills, how would you give the medicine to your child?
 - o *Are the instructions clear on how to use the powder to make an oral suspension?*
 - o *Are the instructions clear on how to crush the tablet and mix it with food?*
- Based on what is explained about the expiration date of the medicine, what do you think about taking medicine that has an expired date on the label?
 - o *Would you take the medicine since FDA is allowing its use based on scientific review?*
 - o *Would you give the medicine to your child since FDA is allowing its use based on scientific review?*

4. Botulism (Heptavalent Botulism Antitoxin)

- How is the medicine given to you?
 - o *Is the fact sheet clear that it is given intravenously (into your vein)?*

5. Burkholderia (Bactrim)

- How long do you need to take the medicine?
- How is the medicine given to you?
- What does "Emergency Use Authorization" mean?
 - o Bactrim is a medicine that is FDA-approved; however, using it to treat burkholderia is not approved, so the medicine has to be authorized by FDA during an emergency - is this clear from the fact sheet?

6. Burkholderia (Meropenem)

- How is the medicine given to you?
 - o *Is the fact sheet clear that it is given intravenously (into your vein)?*
- What does "Emergency Use Authorization" mean?
 - o Meropenem is a medicine that is FDA-approved; however, using it to treat burkholderia is not approved, so the medicine has to be authorized by FDA during an emergency - is this clear from the fact sheet?

7. Pandemic flu (Oseltamivir)

- How long do you need to take the medicine?
- If your child or an older family member you're taking care of cannot swallow pills, how would you give the medicine to your child?
- Based on what is explained about the expiration date of the medicine, what do you think about taking medicine that has an expired date on the label?
 - o *Would you take the medicine since FDA is allowing its use based on scientific review?*
 - o *Would you give the medicine to your child since FDA is allowing its use based on scientific review?*

8. Pandemic flu (Peramivir)

- How is the medicine given to you?
 - o *Is the fact sheet clear that it is given intravenously (into your vein)?*

9. Pandemic flu (IV Zanamivir)

- How is the medicine given to you?
 - o *Is the fact sheet clear that it is given intravenously (into your vein)?*
- What does "Emergency Use Authorization" mean?
 - o IV Zanamivir is not a medicine that is FDA-approved so the medicine has to be authorized by FDA during an emergency - is this clear from the fact sheet?

10. Plague (Ciprofloxacin)

- How long do you need to take the medicine?
- If your child or an older family member you're taking care of cannot swallow pills, how would you give the medicine to your child?
 - o *Are the instructions on using the powder to make an oral suspension clear?*
- Based on what is explained about the expiration date of the medicine, what do you think about taking medicine that has an expired date on the label?
 - o *Would you take the medicine since FDA is allowing its use based on scientific review?*
 - o *Would you give the medicine to your child since FDA is allowing its use based on scientific review?*

11. Radiation (Neupogen)

- How is the medicine given to you?
 - *Is the fact sheet clear that it is given as a shot under your skin?*
- How long do you need to take the medicine?
- Why do you need to get blood drawn?

12. Radiation (Radiogardase)

- How long do you need to take the medicine?
- If you had to give your child the medicine, how would you do so?
 - *Are the instructions on opening the pills and mixing with food clear?*
- What does “Emergency Use Authorization” mean?
 - Radiogardase is FDA-approved for patients 2 years and older, but it is not for children younger than 2 years of age, so the medicine has to be authorized by FDA during an emergency to treat young children – is this clear from the fact sheet?

13. Smallpox (ACAM2000 vaccine)

- Is the fact sheet clear on who should receive the vaccine? How so?
- Is the fact sheet clear on who should not receive the vaccine? How so?
- How is the vaccine given to you?
 - *Is the fact sheet clear that it is given as multiple punctures/pricks into the skin?*
- What are the possible serious side effects from receiving the vaccine?
- After getting the vaccine, how do you take care of the injection site?
 - Are the instructions clear on how to take care of your vaccination site and how to avoid spreading the vaccine virus to other parts of your body or to someone else?
- If you experience any serious side effects, then what should you do?
- What does a successful vaccination on your arm look like?

14. Smallpox (Tecovirimat)

- How long do you need to take the medicine?
- If you child cannot swallow pills, how would you give it to your child?
- Are the instructions clear on eating a hearty meal each time you take the medicine?

- Based on what is explained about the expiration date of the medicine, what do you think about taking medicine that has an expired date on the label?
 - o *Would you take the medicine since FDA is allowing its use based on scientific review?*
 - o *Would you give the medicine to your child since FDA is allowing its use based on scientific review?*

15. Tularemia (Gentamicin)

- How is the medicine given to you?
 - o *Is the fact sheet clear that it is given intravenously (into your vein)?*
- How long do you need to take the medicine?
- What does “Emergency Use Authorization” mean?
 - o Gentamicin is a medicine that is FDA-approved; however, using it to treat tularemia is not approved, so the medicine has to be authorized by FDA during an emergency – is this clear from the fact sheet?