

Medical Countermeasures Cognitive Interview Guide

Color Key:

Purple – Section headings and titles

Black –Text for interviewer to read

Red – Interviewer instructions (not to be read aloud)

Green – Research questions (for interviewer's information, not to be read aloud)

Introduction

Hello, my name is **INTERVIEWER NAME**. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is working with the U.S. Food and Drug Administration, or FDA, to see what people think about information they might receive following a serious emergency. The FDA wants to understand the kinds of information you want and need in an emergency so they know better how to provide that. Please know this is NOT a real emergency, and that the information we will share with you today was developed for testing purposes only.

I just sent you an email with some material we will discuss during the interview. Do you have your email account open?

IF YES, CONFIRM PARTICIPANT RECEIVED EMAIL: Please wait to open the attachment until I tell you it is time to start. After you look at the material, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

IF NO: ASK PARTICIPANT TO OPEN EMAIL ACCOUNT. IF EMAIL IS NOT RECEIVED, USE ON-SCREEN VERSION. IF COMPUTER IS NOT AVAILABLE, RESCHEDULE INTERVIEW.

Informed Consent

Before we get started, there are a few things I need to tell you. This is a research project, and this interview is voluntary. That means that if you do not want to answer a specific question just tell me and I'll go to the next one. It is okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means that we will not share your name or information. Also, we will not link any information to your answers to figure out who you are. The interview will take about 45 minutes and you will receive \$5000SB as a token of appreciation. We would like to record this conversation if you are okay with that. The recording helps us make sure we hear everything you say correctly. Only the people who work on this research project will be able to listen to the recording and see our notes. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

IF FDA STAFF ARE ON THE PHONE: I also want you to know that a couple other people from the FDA who work on this research project are listening to this interview to take notes as we talk.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay with you if I record the interview?

TURN ON RECORDER. The date and time is _____. Now that I am recording, I want to ask again, is it okay if I record this interview?

Background Questions and Information Review

To start, I have a few questions.

IF FDA-Approved MCM:

Have you ever heard of anthrax?

- **IF YES**, What do you know about it? **IF NEEDED**: How serious is it? What are the symptoms? How does it spread?

We are going to be asking you about what you would think and how you would feel if a terrorist attack occurred in your area. There would be many public announcements on the radio, on television, and online about the attack.

Suppose that you live or work in the area where an anthrax attack occurred. Also suppose that you are hearing the following message about it on the radio. I am going to play the message for you now.

- This is an urgent health message from the Emergency Alert System. Please pay careful attention to this message to protect your health and that of others.
- Public health officials believe that the spores that cause anthrax disease may have been deliberately released into the air.
- Anthrax is a serious disease caused by spores from the anthrax bacteria, and those who come into contact with anthrax spores may become ill.
- Anthrax spores can be inhaled or they can land on food or water. They are so small that you may not be able to see, smell or taste them.
- It only takes a small amount of anthrax to infect a large number of people.
- If not treated, anthrax can cause death.
- Anthrax cannot be spread from person to person.
- Seek medical care immediately if you think you may have been exposed to anthrax even if you do not have symptoms.

How does this message make you feel?

How confident are you that you would know how to respond in the best way to protect yourself during this emergency? Please respond on a scale of 1 to 5 where 1 is not at all confident and 5 is very confident.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

How well do you think the government would handle this type of emergency? Please respond on a scale of 1 to 5 where 1 is very poorly and 5 is very well.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

IF No MCM OR EUA-Authorized MCM:

Have you ever heard of Marburg hemorrhagic fever?

- **IF YES**, What do you know about it? **IF NEEDED**: How serious is it? What are the symptoms? How does it spread?

We are going to be asking you about what you would think and how you would feel if a Marburg virus emergency was reported in your area. There would be many public announcements on the radio, on television, and online about the virus.

Suppose that you live or work in the area where the Marburg virus has been found. Also suppose that you are hearing the following message about it on the radio. I am going to play the message for you now.

- This is an urgent health message from the Emergency Alert System. Please pay careful attention to this message to protect your health and that of others.
- Public health officials are reporting a public emergency involving the Marburg virus.
- Marburg hemorrhagic fever is a serious illness caused by the Marburg virus that can cause death.
- This contagious illness is spread from person to person through contact with blood, saliva or other body fluids from an infected person, or through contaminated objects.
- Avoid close contact with people who may have been exposed to the virus.
- Seek medical care immediately if you think you may have been exposed to Marburg virus even if you do not have symptoms.

How does this message make you feel?

How confident are you that you would know how to respond in the best way to protect yourself during this emergency? Please respond on a scale of 1 to 5 where 1 is not at all confident and 5 is very confident.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

How well do you think the government would handle this type of emergency? Please respond on a scale of 1 to 5 where 1 is very poorly and 5 is very well.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

Now please open the email I sent you at the beginning of this interview.

The email contains an attachment of a draft message that might be used in the event of an emergency like the one we've described. As a reminder, this is NOT a real emergency, and the information was developed for testing purposes only.

Please take a few minutes read the message now. When you are done, I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

CHECK IN AFTER 3 MINUTES. ALLOW 2-3 MORE MINUTES IF NEEDED.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.

NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:

- Any verbal reaction to statements in the information.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which statements evoked any of these reactions.

RETROSPECTIVE GENERAL PROBES

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.
SHOW MATERIAL ON SCREEN AS NEEDED TO AID DISCUSSION.

RESEARCH QUESTIONS

Is the material clear and understandable?

What is the main message that participants get from the material?

Do participants understand the information about the available medicine or treatment?

Do participants recognize whether they need to seek treatment, symptoms of the disease, the side effects of the medicine, and (Marburg hemorrhagic fever only: reduce their risk of contracting the virus)?

What information do participants find useful? Not useful?

Does the order in which the question sections are presented seem logical?

Is the material effective in increasing the likelihood that participants would take an FDA-approved or EUA-authorized medical countermeasure?

Does the material provide participants confidence in their ability to manage the emergency?

Does the material provide participants confidence that the government will effectively handle the emergency and act in their best interest?

GENERAL IMPRESSIONS

First, how does this information make you feel compared to when you heard the radio announcement?

What other thoughts do you have about what you've just read?

What do you like about it?

What don't you like?

How easy or difficult is it to understand this information? Is there anything confusing or unclear?

Were there any words or phrases that confused you or that you weren't sure of?

DESIGN AND LAYOUT

Does the order of the information make sense?

- In what order would you put these sections so that the most important information is in the place where it should be? **IF NEEDED**, What section should come first?

Would you say the amount of information is too little, just right, or too much? What makes you say that? If too much, what would you remove and why? If not enough, what's missing?

CONTENT

Now let's talk a little more specifically about the information.

In your own words, what is the overall, main message that this information is trying to tell you?

- What is it asking you to do?

IF FDA-Approved MCM: What does this material say about how exposure to anthrax is treated? Does this material clearly explain how exposure to anthrax is treated?

- **IF YES**, What about this material makes you say it is clear?
- **IF NO**, Can you say more about what wasn't clear?

IF EUA-Authorized MCM: What does this material say about how exposure to the Marburg virus is treated? Does this material clearly explain how exposure to the Marburg virus is treated?

- **IF YES**, What about this material makes you say it is clear?
- **IF NO**, Can you say more about what wasn't clear?

IF No MCM: What does this material say about how exposure to the Marburg virus is treated? Does this material clearly explain how exposure to the Marburg virus is treated?

- **IF YES**, What about this material makes you say it is clear?
- **IF NO**, Can you say more about what wasn't clear?

What additional questions do you have after reading this material?

IMPACT

IF FDA-Approved MCM:

What did the information say about the kind of medicine recommended for people exposed to anthrax in this emergency? [Only after they've answered] How did that information help you?

How willing would you be to take the recommended medicine, minocycline hydrochloride, if exposed to anthrax during this emergency? Please respond on a scale of 1 to 5 where 1 is very unwilling and 5 is very willing.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you more willing to take minocycline hydrochloride? **IF NEEDED**: What other questions would you need to have answered to make you more willing to take minocycline hydrochloride?

[IF PARENT] How willing would you be to give the recommended medicine, minocycline hydrochloride, to your child/children if exposed to anthrax during this emergency? Please respond on a scale of 1 to 5 where 1 is very unwilling and 5 is very willing.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you more willing to give your child minocycline hydrochloride? **IF NEEDED**: What other questions would you need to have answered to make you more willing to give minocycline hydrochloride to your child/children?

After reading this material, how confident are you that you would know how to respond in the best way to protect yourself during this emergency? Please respond on a scale of 1 to 5 where 1 is not at all confident and 5 is very confident.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you feel better able to protect yourself or your family during this emergency? **IF NEEDED**: What other questions would you need to have answered to make you feel better able to protect yourself or your family during this emergency?

After reading this material, how well do you think the government would handle this type of emergency? Please respond on a scale of 1 to 5 where 1 is very poorly and 5 is very well.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you feel better about the government's ability to handle this type of emergency? **IF NEEDED**: What other questions would you need to have answered to make you feel better about government's ability to handle this type of emergency?

IF No MCM:

After reading this material, how confident are you that you would know how to respond in the best way to protect yourself during this emergency? Please respond on a scale of 1 to 5 where 1 is not at all confident and 5 is very confident.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you feel better able to protect yourself or your family during this emergency? **IF NEEDED:** What other questions would you need to have answered to make you feel better able to protect yourself or your family during this emergency?

After reading this material, how well do you think the government would handle this type of emergency? Please respond on a scale of 1 to 5 where 1 is very poorly and 5 is very well.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you feel better about the government's ability to handle this type of emergency? **IF NEEDED:** What other questions would you need to have answered to make you feel better about government's ability to handle this type of emergency?

IF EUA-Authorized MCM:

What did the information say about the kind of medicine recommended for people exposed to the Marburg virus in this emergency? [**Only after they've answered**] How did that information help you?

How willing would you be to take the recommended medicine, risanavir, if exposed to the Marburg virus during this emergency? Please respond on a scale of 1 to 5 where 1 is very unwilling and 5 is very willing.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you more willing to take risanavir? **IF NEEDED:** What other questions would you need to have answered to make you more willing to take risanavir?

[**IF PARENT**] How willing would you be to give the recommended medicine, risanavir, to your child/children if exposed to the Marburg virus during this emergency? Please respond on a scale of 1 to 5 where 1 is very unwilling and 5 is very willing.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you more willing to give your child risanavir? **IF NEEDED:** What other questions would you need to have answered to make you more willing to give risanavir to your child/children?

After reading this material, how confident are you that you would know how to respond in the best way to protect yourself during this emergency? Please respond on a scale of 1 to 5 where 1 is not at all confident and 5 is very confident.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?

- What could be added to this material to make you feel better able to protect yourself or your family during this emergency? IF NEEDED: What other questions would you need to have answered to make you feel better able to protect yourself or your family during this emergency?

After reading this material, how well do you think the government would handle this type of emergency? Please respond on a scale of 1 to 5 where 1 is very poorly and 5 is very well.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What could be added to this material to make you feel better about the government's ability to handle this type of emergency? IF NEEDED: What other questions would you need to have answered to make you feel better about government's ability to handle this type of emergency?

WRAP-UP

Do you have any other suggestions for improving this material?

- Is there any other information that is NOT needed or can be removed? **IF YES,** What information?
- Is there any other information that could be added? **IF YES,** What information?
- Is there any other information that could be stated more clearly? **IF YES,** What could be stated more clearly?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT R SEEMED CONFUSED ABOUT).

Closing

IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.

Those are all the questions I have for you. Is there anything we haven't talked about that you would like the FDA to know?

As a reminder, the information shared during this interview was NOT about a real public health emergency. It was developed for research purposes for this interview only.

IF FDA-Approved MCM: For more information about anthrax, visit www.cdc.gov/anthrax.

IF No MCM OR IF EUA-Authorized MCM: For more information about Marburg hemorrhagic fever, visit www.cdc.gov/vhf/marburg.

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.