

Medical Countermeasures Message Testing

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Appendix B. Moderator's Guide

MCM Message Testing

Moderator's Guide

- I. Introduction (5 minutes; Σ = 5 minutes)**
- a. Moderator-Introduce self
 - b. Purpose and FDA sponsorship
 - Opportunity for participants questions and comments
 - Important to get feedback about health messages developed by the FDA
 - c. Recording and observers
 - No personal identifiers used in reporting
 - Microphones, mirrors, observers, and audio taping
 - d. Ground Rules
 - One at a time
 - Let's try to hear from everyone
 - No right or wrong answers
 - Won't hurt my feeling if you like or dislike the messages because I did not develop them so please be honest
 - e. Respondent introductions
 - First name
 - How long lived in area
 - A favorite hobby
- II. Scenario (25 minutes; Σ = 30 minutes)**
- a. *Today we will be talking about information you might receive following a serious emergency. It's better to be prepared than to go "off the cuff" in an emergency, and FDA wants to understand the kinds of information you want and need in an emergency so they know better how to provide that.*
 - b. *Today we will be working with some draft messages that might be issued in the event of an emergency related to medicines such as antibiotics that are used to treat people who have been exposed to dangerous or hazardous agents. These could be hazards such as anthrax, cyanide, or radioactive materials. First, I'll give you some information about a particular hazard. Then, I'll ask you what information you would want to know about the hazard and the available medicines used to treat them, called medical countermeasures. Next, we will look at some examples of messages you might receive. I'll ask you what about the messages you thought was well done, and what would benefit from change,*

and some related questions. There are three things I'd like you to keep in mind as we proceed:

- 1. Keep in mind the messages are only a sample of those that might be used in an emergency. There are many more messages – too many for one group to review in a reasonable amount of time. Please feel free to tell us other questions that occur to you so FDA can examine them, but remember you are not seeing all of the messages.*
- 2. Some things cannot be known now. For example, the availability of medicines in a specific location. These and other details would require more information specific to each situation.*
- 3. In the event of an emergency, there will be constant news coverage, many press conferences and interviews with public health officials, elected officials, and others. TV, radio, newspapers, the Internet and other sources will have lots and lots of coverage. You are likely to hear information repeated often.*

c. Before we get started, I would like to provide background information on the type of health emergency we will be talking about today

Listening to message about threat

First I would like you to listen to some information about a specific threat. Imagine you have just come home from work or running errands. You hear an emergency announcement that there has been an anthrax attack here in [Insert city]. Based on what we know now, authorities believe that people who were in the [Insert specific area] neighborhood before noon this morning may have been exposed/are at risk.

Play recording of message about threat.

Response to hearing message

1. What did you think when you heard the information? How did you feel?
2. What information was the most important to you?
3. Was there any information that was confusing or unclear?
4. Was this new information for you?
5. Please write on your sheet of paper, On a scale of 1-10 (1-low; 10-high), how dangerous do you perceive this threat? Now that everyone has had a chance to rate

- this threat, [name of participant] could you please tell me what was your rating and why? [go around the group]
6. What other questions would you have about [the threat]?

d. Questions regarding MCM information priorities

Now that we've talked a little about the threat we are going to move on to treatment. Suppose you or a family member has been exposed to [insert threat] and there is a treatment, what questions would you want to know about the treatment? Take a few minutes to write on your pad questions you would have about available treatments. Also, please rank the questions you wrote with 1 being the least important and 10 being the most important.

[NOTE: provide time for note-taking]

Now, let's talk a little bit about this experience. First, what questions do you have? What do you want or need to know about the treatment at this point?

[NOTE: go around and get one or two question from every respondent and write on flipchart]

Now, I would like to understand the relative importance of these questions. I'm going to give each of you a set of five colored dots. I want you to use these five dots as votes, placing them on the flip chart paper next to the questions that are most important for you. If a question is really important to you, you may place more than one dot by that question to indicate how important it is.

NOTE: Count dots and debrief results

Probes:

1. What would be your greatest concern in this situation? Why?
2. Is there any other information you would want to know during an event such as this?

III. Message Testing (Message Maps)

(35 minutes; Σ = 65 minutes)

FDA Compassion Statement -(Message Maps)

[Hand out message to each respondent.]

I would like you to read message as I read it out loud.

1. What was the main message?
2. What is your reaction to this message?

Probe:

- What did you like? Dislike?
3. Did you find this message credible?
 4. After reading this do you have any unanswered questions?

MCM Message Testing- (Message Maps)

[Hand out message to each respondent.]

*I would like you to read message as I read it out loud.
As you read the message, please:*

WRITTEN MESSAGE:

- *Underline phrases or sentences you think are important.*
 - *Circle phrases or sentences you think are unclear or confusing.*
1. What did you indicate as important?
 2. What did you indicate as unclear or confusing?
 - i. Were there any words used that were unusual or unfamiliar?
 - ii. What other words can be used in their place?
 3. What did the message ask you to do? (if applicable)
 4. How easy are these instructions for you to understand? (if applicable)
 5. How easy are these instructions for you to follow or do? (if applicable)
 - i. What, if anything, makes it difficult to follow?
 - ii. How might this be presented in an easier way?
 6. What action, if any, would this prompt you to take? (if applicable)

PROBES:

- Call recommended telephone number (if applicable)
 - Visit recommended website (if applicable)
 - Contact physician (if applicable)
 - Go to pharmacy or point of dispensing site (if applicable)
7. Is there anything you want to know that this message does not tell you?

[REPEAT FOR OTHER MESSAGES]

IV. Message Testing: Oral Suspension Instructions (15 minutes; Σ = 80 minutes)

Participants will review a document from FDA that instructs participants how to create an oral suspension for [INSERT MCM].

Messages to test:

Doxy:

<http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM131001.pdf>

KI:

<http://www.fda.gov/downloads/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/UCM318791.pdf>

Prussian Blue:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021626s007lbl.pdf

I would like you to read message as I read it out loud.

As you read the message, please:

WRITTEN MESSAGE:

- *Underline phrases or sentences you think are important.*
- *Circle phrases or sentences you think are unclear or confusing.*

1. How easy are these instructions for you to follow or do?
2. What did you indicate as important?
3. What did you indicate as unclear or confusing?
 - i. Were there any words used that were unusual or unfamiliar?
 - ii. What other words can be used in their place?
4. How easy are these instructions for you to understand?
 - i. What, if anything, makes it difficult to follow?
 - ii. How might this be presented in an easier way?
5. What action, if any, would this prompt you to take? (if applicable)

PROBES:

- Call recommended telephone number
 - Visit recommended website
 - Contact physician or other health care provider
6. Is there anything you want to know that this message does not tell you?

V. Sources

(5 minutes; Σ = 85 minutes)

Next I would like to ask you some questions about the sources of information that you use in an emergency.

1. Where do you get information about an emergency situation?

2. Where would you like to hear or see this message? Prompt: Local radio, local TV news, National TV news like CNN, social media, government website, local newspaper, brochure at doctor's office or pharmacy, etc.
3. Who would you like to be telling you this information? Prompt: A local newscaster; a celebrity; a local government official; a federal government official; a scientist, doctor, pharmacist or nurse; etc.
Why?
4. In this type of emergency where the treatment is a medicine, what type of information would you go to the FDA for/want FDA to provide?

VI. Wrap-Up

(5 minutes; Σ = 90 minutes)

1. Those are all of my questions for you.
2. Thank you.
3. I know thinking about this subject may have raised some questions. Provide participants with CDER's webpage (<http://www.fda.gov/Drugs/default.htm>) and phone number (1-855-543-3784). Also, provide participants with a CDC fact sheet about the threat discussed in the focus group