

Risk Communication Strategies for Medical Countermeasure Distribution

Draft Moderator Guide:

Introduction – 10 minutes

Hello, and thank you for taking the time to be here! My name is _____, and I work for ICF Macro and I am going to be leading our discussion today. I want to take a few minutes to tell you what you can expect over the next 1 ½ hours. After that, I will give you the chance to introduce yourselves and we can get into the discussion.

The topic for this discussion is communicating information about the safety of drugs or medical products that may be distributed to the public during an emergency. Our goal is to find the best format for a document that would effectively communicate the safety and efficacy of the drug or product. Your opinions are important and will help the Food and Drug Administration (FDA) develop these documents.

As the group leader, I am not part of FDA. I do not have a particular point of view regarding the topics or questions I will ask you. I am here to listen to your honest opinions about issues of concern and importance to you and to guide the discussion. There are no right or wrong answers to any of the questions.

The discussion here will be kept strictly confidential. We will not report your comments by name in any reports, and we ask that you respect one another's privacy in the same way.

[Briefly review the Informed Consent Process.]

Just as a reminder, we are taping the conversation so that we can have an accurate record of what is said. Please identify yourself by your first name only when speaking and try to speak clearly and one at a time.

We do have representatives from the FDA and from my organization with us today. They are in the observation room so they can take their own notes and hear the discussion for themselves.

I'd like to review a few groundrules to keep the discussion flowing:

- Speak one at a time with no side conversations
- I'll make sure that everyone has a chance to speak; You can help with this too
- Please treat everyone with respect

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- Finally, you don't always have to agree. It's very important for us to get a lot of different opinions.

Can everyone agree to these groundrules?

Do you have any questions before we get started?

I. Warmup/Introductions – 5 minutes

To begin, I would like to give you the chance to introduce yourselves to me and to each other.

1. Briefly tell us:

- Your first name
- How many people are in your household
- The ages of the children in your household

II. Where Do You Turn for Health Information – 5 minutes

The first few questions are about where you go for health information.

2. Where are you most likely to turn for information when you want to learn more about general health issues? Example: To learn more about health conditions you've heard about or medications you've heard about, but it is not an emergency or urgent situation for you.

Probes: (Ask only if not mentioned)

- Internet (can you provide examples of which websites)
- Physician
- Pharmacist
- Television (particular programs), radio
- Books (examples)
- Family members, friends
- (others)

3. Who in your family takes the most responsibility for keeping up with the family's health issues and needs? Example: The person most responsible for keeping up with immunizations, physician's visits, reading up on health issues, etc.

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III. Materials Testing – Understandability – 35 minutes

Let's move now into discussing a very specific type of health information. As we discussed during the introduction, we are most interested in how to communicate effectively, in writing, information about a particular drug or product that must be distributed to the general public during an emergency.

I am going to read some background information to you so you understand a little better what this is about. **Read the following background information to participants:**

Over the past 5-6 years, Federal and State governments worked together in preparation for public health emergencies similar to the Swine flu outbreak we had last spring. Part of that preparation is the Center for Disease Control and Prevention's stockpile of medical countermeasures such as drugs and medical products ready for distribution if national supply runs short during an emergency. States have plans to care for their constituents during emergencies that include distribution of the CDC stockpiled medical countermeasures. If an emergency is declared, the CDC will deliver to each State an allotment of the stockpile for distribution. State implementation plans vary from State to State. Some States will use existing methods and organizations to dispense the countermeasures and others will involve points of distribution (PODS) where the public will go to receive the medical countermeasures. If an emergency is declared and a State implements the plan, the public will be instructed to send a family representative to one of the PODS and pick up the countermeasure for the entire family. The PODS can be schools, neighborhood recreation centers, and similar type places that can accommodate large numbers of people at one time. States design PODs to keep large numbers of people moving and provide information about the situation as people move through the process. Healthcare professional will have limited time with the public to answer questions about the medication or medical product. The high volume of people moving through the POD during an emergency make it impractical for healthcare professionals to spend much time with each person moving through the line. Patients will receive facts sheets explaining the safety and efficacy of the countermeasure before leaving the POD. The information on the fact sheet is almost identical to the information a patient receives when picking up a prescription at a pharmacy.

To help you review the materials and answer the questions, I am going to describe for you a scenario and ask that you think about yourself in that situation.

Read the following scenario to participants:

Your State has just declared a public health emergency because of an accidental release of the anthrax germ, potentially exposing everyone in the Western half of the state to the risk of the disease. The State is now implementing its plan to distribute stockpiled medication to prevent infections, including anthrax disease. Through TV and radio announcement PSAs, you are instructed to send one family member to your neighborhood high school to pick up medication for your entire family. When you

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arrive, you find a very long line of people doing exactly the same thing and healthcare professionals distributing the medication along with a fact sheet explaining the safety and efficacy of Ciprofloxacin, the specific medication being given to everyone.

4. Please use the index cards and pen you have in front of you and, thinking about this scenario, quietly for yourself, write down the three most important things that you expect to find on the fact sheet that is handed to you with the medication.
 - **Go around the table and ask each person to identify the first thing they have on their lists – record on flipchart, noting the items that are repeated. Do the same with the second and third items on their lists – recording only the ones that are unique and noting the duplicates.**
 - **Collect the index cards.**

Distribute Fact Sheet and ask participants to review it.

5. What do you think is the most important information on the Fact Sheet? Did it immediately stand out to you?
6. Did the Fact Sheet meet your expectations? Yes or no - in what ways?
7. After reading the Fact Sheet, are you certain that you know what to do for each member of your family?
 - Are you clear about the dosing instructions for the medication?
 - Do you have additional questions about dosing instructions?
 - Do you have questions about who should not take the medication?
 - Do you have other questions about the medication?
8. Do you feel confident that you could do what is described in the Fact Sheet after reading it? What would make you feel confident?
9. Given that you would likely receive only brief information on a fact sheet, where are you most likely to turn for more information about anthrax and Ciprofloxacin if you had questions after reviewing it? Probes: (Ask only if not mentioned)
 - Internet (sites named in Fact Sheet and/or others)
 - Family physician
 - Other medical personnel
 - Public health personnel through telephone number provided in flyer

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- Pharmacist
- Television, radio
- Family members, friends
- (others)

IV. Materials Testing – Format and Layout – 25 minutes

This next set of questions focuses on the look and format of the Fact Sheet.

Distribute the tri-fold Brochure to Participants and ask them to focus on the format and layout, not content.

10. In comparing the two different formats, tri-fold and one page Fact Sheet, which format do you prefer and why? Please be specific.
11. Let's go back to information you said was most important to include in the document you would receive. **Return to the flipchart created above.**
What is most helpful to make these things stand out: boxes, color, highlighting?
12. For dosing information, would you prefer to have adult information separate from pediatric information? How do you prefer to have the dosing information written out? Are tables easier to understand than text?

Distribute the extended Fact Sheet (multi-page) to Participants and ask them to briefly scan it, perhaps looking only at the headings.

13. Having reviewed this document only briefly, did you identify any topics that you think would be essential to include in the one page Fact Sheet or Brochure that you would receive with the medication? What would that topic be?
14. How do you think this document with more extensive information could be useful to you in the scenario we've been talking about?
15. How do you think people should be able to obtain more extensive or detailed information?

V. False Close and Closure of Focus Group - 10

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Before we wrap things up, I am going to step into the observation room to ask if the observers have any questions they would like me to follow-up on. I will back in just a couple minutes.

Ask any remaining questions.

That wraps up the questions I have for you today. Do you have any questions for me before we wrap up? On behalf of the FDA and ICF Macro, I want to thank you for your interest and willingness to participate in this important research effort.