Protocol

Medical Countermeasures Message Testing

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Background

For many hazards, medical countermeasures (MCM) —medicines —represent a lifeline to an affected public. However, many of these medical countermeasures are not widely used or available. Furthermore, these medicines may carry unique or undocumented risks. For this reason, it is imperative that the FDA communicate rapidly and effectively with the public during a hazard scenario so they can understand the risks and benefits associated with the medical countermeasures.

Using evidence-based risk communication theories and best practices, FDA's Communicating Risks and Benefits: An Evidence-Based User's Guide[i] and the Centers for Disease Control and Prevention's Crisis and Emergency Risk Communication [CDC-CERC] framework[ii], and Message Mapping techniques[iii], FDA worked with ORAU to develop messages about various medical countermeasures that could be used to treat a variety of biological, chemical and radiological terrorism threats.

To help ensure the quality of those messages, FDA wishes to test them with the public. The Oak Ridge Associated Universities (ORAU) is to provide assistance. This protocol sets forth the plan for message testing.

Goals:

- Determine the public's information priorities regarding various medical countermeasures in a public health emergency.
- Explore the attitudes, beliefs, understanding, and behavioral intentions of members of the public with respect to draft messages relating to various medical countermeasures used during a public health emergency.
- Obtain insight and recommendations for developing effective medical countermeasure messages and communication initiatives for public health emergencies.

Objectives:

- Prioritize the anticipated concerns[ii] of members of the public and their information needs related to medical countermeasures during a public health emergency.
- Evaluate the extent to which selected medical countermeasure messages are relevant, comprehensible, credible, and motivate desired actions.
- Expand the current understanding of the public's knowledge of terrorism threats[iii] and of medical countermeasures[iv,v] and identify gaps in that information.
- Determine the public's preferred sources and channels of information[vi] regarding medical countermeasures and their associated public health threats.

Selected Medical Countermeasures:

Given the intensity of the subject matter, it is not feasible to explore all messages for all threats and all available medical countermeasures. Some medical countermeasures (Doxycycline, Potassium Iodide (Thyroshield), and Prussian Blue) could be obtained by members of the public over the counter, or distributed through a point of dispensing (POD) operation. In both of these distribution methods, the affected public would take the medical countermeasure with limited direct supervision by medical and public health officials. Providing clear and consistent messaging related to these particular countermeasures is of critical importance. Narrowing the selection to three allows for optimal depth and substance of discussion in order to best evaluate public response to the guidance provided in the messages within the existing resources. Given medical countermeasures are not available for a number of possible public health threats (e.g. botulism), messages will also be tested for threats where no MCM is available.

Selected Messages:

ORAU and FDA will select and test message maps[iii] containing information believed to be of highest priority[i] to the public.

Selected Threats:

It is important to test the messages in the context of a scenario to help focus group participants identify information priorities and better communicate potential questions and information needs they may have. While the main focus of the research is to gather information on messages related to medical countermeasures, it will also be helpful to gather data on how well various threats are understood by the public, especially those threats without medical countermeasures. Some of the selected countermeasures could be used in more than one type of public health emergency. When testing messages for Doxycycline, the scenario provided to the participants will rotate among three biological agents, Anthrax, Plague, and Tularemia, that have been identified by the CDC, 2012 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy[vii] and the HHS Public Health Emergency Medical Countermeasures Strategy and Implementation Plan [viii]:. Messages for Potassium Iodide and Prussian Blue will be presented in the context of a radiation emergency. Ebola and Marburg and will be the threats used to test messages where no MCMs are available.

Target Audience

The target audience for this study are:

- General Public
- People with a high school diploma or less
- Racial and ethnic minorities

OMB Approval:
ORAU will work with FDA staff to submit a package under the generic clearance of the package entitled "Focus groups and in-depth interviews for the FDA CDER risk communications initiative (0910-0677)."

IRB Approval:
ORAU will submit a package to ORAU's Institutional Review Board. After that IRB approval is obtained, ORAU will work with FDA staff to submit a package for approval to FDA's Institutional Review Board, the Research Involving Human Subjects Committee (RIHSC).

Audience Segmentation and Screening
ORAU will provide technical assistance for all screening, recruiting, and testing activities. Screenings are to be conducted by a commercial market research facility, using professional screening personnel.

In each city, research facilities will work to provide a representation of participants that are reflective of their community. It is understood that with the small number of respondents per group, and the relatively small number of respondents per city, it may not be possible to have respondents representing all combinations of characteristics in one group.

For each city focus groups will be segmented by:

- low education
- race/ethnicity

The remaining groups will consist of respondents from the general public.

All participants will:

- Be at least 18 years of age, but under 80 years old
- Not have earned a graduate or postgraduate degree.
- Be comfortable conversing in English

No respondents or members of their immediate family will be employed in any of the following fields:

- Advertising
- Public relations
- Market research
- Media
- Health care

- Public Health
- Pharmaceutical Industry
- Biologists, chemists, health physicists or related fields involved with radiological, chemical or biological hazards.

Methodology:

Recruiting

ORAU will be responsible for identifying and undertaking all activities associated with recruiting participants. Recruiting will be conducted through the market research facilities at which sessions are to be conducted, under the supervision of ORAU. Variations from this protocol must be approved by ORAU.

Facilities will provide only the first name and qualifications for screening criteria. No personal identifiers (e.g., last name, last initial, address, completed screening instruments) are to be provided to ORAU or FDA.

Numbers of prospective respondents to be recruited are as follows:

- Recruit 10 prospective respondents per group anticipating 8 to participate
- 6 groups per city over 2 days (3 groups a day)
- 30 groups total
- Up to 300 prospective respondents total

Tentative Schedule

Day	Day of the Week	Date	Activity
1	Sunday	TBD	Travel to City 1
2	Monday	TBD	Data Collection, City 1
3	Tuesday	TBD	Data Collection, City 1
4	Wednesday	TBD	Travel to City 2
5	Thursday	TBD	Data Collection, City 2
6	Friday	TBD	Data Collection, City 2
7	Saturday	TBD	Travel to City 3
8	Sunday	TBD	Rest
9	Monday	TBD	Data Collection, City 3
10	Tuesday	TBD	Data Collection, City 3
11	Wednesday	TBD	Travel Home

Break			
9	Sunday	TBD	Travel to City 4
10	Monday	TBD	Data Collection, City 4
11	Tuesday	TBD	Data Collection, City 4
12	Wednesday	TBD	Travel to City 5
13	Thursday	TBD	Data Collection, City 5
14	Friday	TBD	Data Collection, City 5
15	Saturday	TBD	De-brief in City 5
16	Sunday	TBD	Return home

Any changes must be approved by ORAU and agreed to by FDA before they are made. (See Appendix A for Screener)

In each city, data are to be collected in one day with groups conducted as follows:

- 3:30 – 5:00 pm local time Group
- 5:00 – 6:00 Dinner Break
- 6:00 – 7:30 Group
- 8:00 – 9:30 Group

Thirty focus groups will be conducted in five major metropolitan areas. These cities have been determined based on the Department of Homeland Security's Urban Area Security Initiative (UASI) as areas most at risk for a terrorist event. ORAU suggests the following cities: Los Angeles, CA; New York, NY; Chicago, IL; Washington, D.C/Baltimore (National Capitol Region); and Atlanta, GA. Focus groups will be diverse in terms of gender, age, race, ethnicity, and education level.

	Number of Groups										Totals	
	City 1		City 2		City 3		City 4		City 5			
	Day 1	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Day 1**	**Day 2**	**Groups**	**Recruits**
Low education	1	⟳	1	⟳	1	⟳	1	⟳	1	⟳	5	50
Racial/ethnic minority	1	⟳	1	⟳	1	⟳	1	⟳	1	⟳	5	50
General public	1	3	1	3	1	3	1	3	1	3	20	200
Total											30	300

Thus, total number of respondents to be recruited will be:

Each focus group will have approximately eight[ix] participants and is expected to last about ninety minutes. Focus groups are to be conducted by a commercial market research firm, using the firm's facilities and a professional moderator who will facilitate. All sessions will be conducted in English. Participants will be screened for those comfortable conversing in English (See Appendix A for Screener and Appendix B for the Moderator's Guide).

Prior to participating in the study, each prospective respondent will receive an information sheet providing such information as sponsorship of the study, their rights as participants, risks and benefits in participating, and contacts for more information. Respondents' information and responses shall be held in a secure manner to the extent allowed by law. The information sheet will contain the elements of informed consent. Because this study presents no more than minimal risk, signatures for informed consent will not be required. Information Sheets are included in Appendix C.

ORAU personnel will address any questions the participants have regarding the study before the session begins.

Each group will provide feedback for one medical countermeasure for one public health threat. Medical countermeasures and threats will be rotated among the focus groups to provide comprehensive data for all selected threats, medical countermeasures, and messages.

Groups will follow the following general outline:

- Listen to audio recordings of messages about a particular public health threat.
- Gather Questions regarding MCM information priorities from participants.
- Provide feedback to the selected medical countermeasure message maps.
- Evaluate oral suspension instructions.
- Identification of preferred methods for receiving information.

The focus groups will be audio-recorded and transcripts will be prepared from these recordings. Facilities will provide two copies of audio recordings of each session. No videotaping is to be conducted. Interested observers may choose to attend focus groups in-person, or through a real-time online video streaming mechanism.

Prior to the completion of each session, the moderator will confer with FDA observers to determine the need for any further discussions and/or clarification from participants as time permits.

The possibility exists that some participants will find contemplation of such subject matter upsetting. Participants will also receive CDER's website [http://www.fda.gov/Drugs/default.htm] and phone number (1-855-543-3784) and email address (druginfo@fda.hhs.gov) at the end of each focus group.

(See Appendix D for Sample Messages & Appendix E for a Sample Rotation Schedule)

Handling of Data and Records

ORAU will maintain no identifiers connecting any data collected to any particular respondent; neither will it provide any personal identifiers to FDA or others. Firms which conduct recruiting and host sessions will be required to not provide personal identifiers to ORAU or FDA. All information related to recruiting will be shredded after the last day of research in each city.

Additionally, ORAU will:

- Retain one set of de-identified audio recordings, transcripts, and at least one copy of any report it produces
- Use the transcripts, audio recordings, and other data collected to prepare a draft interpretive report for the full set of focus groups. The report will also discuss any differences in regions. The raw data for this report will be the words, phrases, sentences, and non-verbal responses, and other observations of the attendees.

- Complete a draft (top-line results) of the Key Findings to be included in the Final Report within one month after the completion of the last focus group, and shall submit this draft report to FDA for review.
- Develop a draft Final Report for FDA review in an agreed-upon format summarizing the analysis of the focus group sessions, including the responses provided by participants and addressing the regions where the sessions were held, and making recommendations to FDA based on those findings; the report will contain no personal identifiers -- that is, information sufficient to determine the identity of any participant (e.g. first and last name, address). The draft Final Report must incorporate FDA comments on the Key Findings and other substantive issues.
- Deliver to FDA the updated version of the Final Report, which is to include the FDA comments received on the draft of the final report, one set of recordings, one set of transcripts, and a spreadsheet or other mutually agreed-upon format that contains the socio-demographic data by number, and the themes, language, categories, etc. identified during the analysis.
- Retain de-identified records and audio recordings for three years, then burn, shred, or otherwise destroy them.

Data Analysis

During the focus groups, the ORAU staff will take notes individually. Notes will include preliminary themes, concepts, and the staff member's individual thoughts and reflections of each focus group. Following each day of focus groups, the research team (ORAU staff and moderator) will debrief via conference call. In addition, the day after the completion of all the research, the ORAU staff will hold a debrief meeting (via conference call) with FDA to identify overall impressions, initial themes, concepts, and observations. Next, two ORAU staff members will develop a codebook based on initial readings from their transcripts and notes, and on discussions with FDA staff. Once the initial codebook is established, the 2 staff members will take a selection of responses from the transcripts (one focus group from each city) to code independently. Next, the intercoder reliability statistics will be calculated based on the selection of responses. If the kappa is not acceptable (less than .80), the staff members will discuss the codes and modify any problematic codes. Using the modified codebook, the staff members will take another selection from the transcripts to code independently and run the intercoder reliability statistics again. If the reliability statistics are not acceptable, the process will be repeated. Once the kappa is acceptable (greater than .80), the 2 staff members will each code half of the transcripts independently. Intercoder reliability statistics will be obtained. If the kappa is not acceptable, the 2 staff members will discuss discrepancies and modify the codebook if needed and update the transcript coding to reflect these modifications. Once the kappa is acceptable, the 2 staff members will independently code the remaining transcripts and run intercoder reliability statistics on each of the final codes.[ix-xii] As a result, each of the 2 primary staff members will have read and coded all of the transcripts.

Tentative Data Analysis Timeline

Analysis	Codebook	1 week
	Initial transcript analysis (1 each city)	1 week
	Review intercoder reliability (until ≥ 0.80) and revise codebook as needed	1-2 weeks
	Code remaining transcripts and run intercoder reliability	2-3 weeks
Draft Report		3-4 weeks (This includes ORAU internal review process)
Revise and Finalize Report		Anticipate 14 days following receipt of comments from FDA. (This includes ORAU internal review process)

References:

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[ii]CDCynergy. Biological attacks: communication challenges [online]. [cited 2013 Sept]. Available from URL: http://www.orau.gov/cdcynergy/erc/Content/activeinformation/essential_principles/EP-bt.htm

[iii]Environmental Protection Agency (US)[Covello, V.].(2007).Communicating Radiation Risks: Crisis Communication for Emergency Responders. United States Environmental Protection Agency, Office of Radiation and Indoor Air. EPA-402-F-07-008. July. Washington, DC.

[iv]Hughes JM and Gerberding JL. Anthrax Bioterrorism: Lessons Learned and Future Directions. Emerging Infectious Diseases; 2002. [cited 2013 Sept]. Available from URL: http://wwwnc.cdc.gov/eid/article/8/10/02-0466.htm.

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[viii]Centers for Disease Control and Prevention. Bioterrorism Agents/Diseases [online]. 2012. [cited 2013December]. Available from URL:. http://emergency.cdc.gov/agent/agentlist-category.asp#catdef

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[x]Boyatzis, R. E. 1998. *Transforming qualitative information: Thematic analysis and code development*. Thousand Oaks, CA: Sage.

[xi]Denzin, N. K., and Y. Lincoln. 1994. *Handbook of qualitative research*. Thousand Oaks, CA: Sage.

[xii]Weinberger, M., J. A. Ferguson, G. Westmoreland, L. A. Mamlin, D. S. Segar, G. J. Eckert, J. Y.Greene, D. K. Martin, and W. Tierney. 1998. Can raters consistently evaluate the content of focus groups? *Social Science and Medicine* 46:929–33.

[xiii]Hruschka DJ, Schwartz D, Cobb-St. John D, DeCaro E, Jenkins R & Carey JW (2004). Reliability in coding qualitative data: Lessons learned from HIV behavioral research. *Field Methods.* 16:3, 307-31.

Appendix A. Screening Instrument

FDA Study

Screening Instrument

Recruit

- 3 groups DAY 1
  - 3:30 – 5:00 Low Education Group
  - 5:00 – 6:00 Dinner Break
  - 6:00 – 7:30 Racial/Ethnic Minority Group
  - 8:00 – 9:30 General Public Group
- 3 groups DAY 2
  - 3:30 – 5:00 General Public Group
  - 5:00 – 6:00 Dinner Break
  - 6:00 – 7:30 General Public Group
  - 8:00 – 9:30 General Public Group
- Recruit 10 per group

Good evening. My name is _____ and I am calling from _____, a market research firm. Today we are talking with people as part of a study for the Food and Drug Administration (also known as FDA). We are not selling anything. We have a few brief questions that will take just two – three minutes of your time, and if you qualify and are interested, we will invite you to take part in a discussion group with other people in your area that will take place at a later date.

Assess and verify ability to speak and understand English. [Terminate screener as soon as recruiting staff realizes the person does not speak or understand English]

1. Have you participated in a focus group, intercept interview, telephone survey, and/or online survey in which you were asked your opinions regarding a product, a service, or advertising within the past six months?

01 Yes **[THANK AND TERMINATE]**
02 No

2. Do you, or does any member of your household or immediate family work:

01 For a market research company
02 For an advertising agency or public relations firm
03 In the media (TV/radio/newspapers/magazines)
04 As a healthcare professional (doctor, nurse, pharmacist, dietician, etc.)
05 Pharmaceutical Industry

[IF YES TO ANY, THANK AND TERMINATE]

3. Are you an/a:

- **Employee of U.S. Department of Health and Human Services**
- **Employee of state or local health department**
- **Employee of Department of Homeland Security**
- **Employee of state or local emergency management agency**
- **Biologists, chemists, health physicists or related fields involved with radiological, biological or chemical hazards**

IF YES TO ANY OF THE ABOVE, THANK AND TERMINATE

4. In which of the following categories does your age fall?

01 under 18 years of age **[THANK AND TERMINATE]**
02 18-24 years of age
03 25-34 years of age
04 35-44 years of age
05 45-54 years of age
06 55-64 years of age
07 65-74 years of age
08 75 -80
09 81 and older **[THANK AND TERMINATE]**

[DOCUMENT ON GRID]
[RECRUIT A MIX WITHIN EACH GROUP]
[RECRUIT SO THAT GROUPS TOGETHER ARE REFLECTIVE OF THE COMMUNITY]

5. What is the highest level of education you have completed?

01 Less than high school graduate/some high school **[POSSIBLE RECRUIT FOR LOW EDUCATION GROUP]**
02 High school graduate or completed GED **[POSSIBLE RECRUIT FOR LOW EDUCATION GROUP OR GENERAL PUBLIC GROUP]**
03 Some college or technical school **[POSSIBLE RECRUIT FOR GENERAL PUBLIC GROUP]**
04 Received four-year college degree **[POSSIBLE RECRUIT FOR GENERAL PUBLIC GROUP]**
05 Some graduate studies **[POSSIBLE RECRUIT FOR GENERAL PUBLIC GROUP]**
06 Received advanced certificate or degree **[THANK AND TERMINATE]**
07 Other: _____ **[THANK AND TERMINATE]**

[DOCUMENT ON GRID]
[RECRUIT ACROSS GROUPS A MIX REFLECTIVE OF THE COMMUNITY]

6. Do you have health insurance?

- YES
- NO
    - If no, do you have health coverage like Medicare, Medicaid, TriCare, etc?
        - YES (RECRUIT as having health insurance)
        - NO (RECRUIT as having no health insurance)

[DOCUMENT ON GRID]
[RECRUIT A MIX]

7. Gender
   01 Male
   02 Female

[DOCUMENT ON GRID]
[RECRUIT ABOUT A 50/50 MIX]

8. Are you Hispanic, Latino/a, or Spanish Origin?
   (One or more categories may be selected)

Categories
a. ____ No, not of Hispanic, Latino/a, or Spanish origin **(SKIP TO QUESTION 9)**
b. ____ Yes, Mexican, Mexican American, Chicano/a
c. ____ Yes, Puerto Rican
d. ____ Yes, Cuban
e. ____ Yes, Another Hispanic, Latino/a or Spanish origin

[DOCUMENT ON GRID]
[RECRUIT AT LEAST 3 FOR RACIAL/MINORITY GROUP]
[ALSO RECRUIT A MIX REFLECTIVE OF THE COMMUNITY FOR GENERAL PUBLIC GROUP AND LOW EDUCATION GROUP]

9. Please indicate your race or ethnic background.
   a. ____ White
b. ____ Black or African American **[RECRUIT AT LEAST 3 FOR RACIAL/MINORITY GROUP]**

OTHER **[RECRUIT AT LEAST 2 FROM THIS CATEGORY FOR RACIAL/MINORITY GROUP]**

c. ____ American Indian or Alaska Native
d. ____ Asian Indian
e. ____ Chinese
f. ____ Filipino
g. ____ Japanese
h. ____ Korean
i. ____ Vietnamese
j. ____ Other Asian
k. ____ Native Hawaiian

l. ____ Guamanian or Chamorro
m. ____ Samoan
n. ____ Other Pacific Islander

[DOCUMENT ON GRID]
[ALSO RECRUIT A MIX REFLECTIVE OF THE COMMUNITY FOR GENERAL PUBLIC GROUP AND LOW EDUCATION GROUP]

10. Do you have children (under the age of 18) living in your household?
    01 Yes
    02 No

[RECRUIT A MIX; DOCUMENT ON GRID]

That is all of my questions. You do qualify for our discussion group and we would like to invite you to join us on _____ at _____ PM. The discussion will last about 90 minutes; it will be recorded (audio only) to be sure we get all the information. Researchers will be observing the research project either in-person or remotely through live video streaming.
The session will not be video recorded. At the end of the discussion, we will offer you $XXX as a token of appreciation.
Are you willing to participate?
01 yes
02 no

Prior to the start of the group discussion, you will receive an information sheet with such information as sponsorship of the study and contacts for more information. If after we hang up, you have a question about this group discussion or decide you can't participate, please contact me at _____.

Name_____
Address_____
City/State/Zip_____
Day Number_____Night Number_____

Appendix B. Moderator's Guide

Moderator's Guide

I. Introduction (5 minutes; ∑= 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; ∑= 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*

<u>Listening to message about threat</u>

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; ∑= 65 minutes)

FDA Compassion Statement -(Message Maps)

[Hand out message to each respondent.]
I would I 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 l 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; ∑= 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 l 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; ∑= 85 minutes)

Next I would l 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; ∑= 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.

Appendix C. Participant Information Sheet

U. S. Department of Health and Human Services

Food and Drug Administration [FDA] Study

Information for Participants

Purpose of this group discussion

You are being asked to participate in a research study being conducted by the Food and Drug Administration (FDA), with the assistance of The Oak Ridge Associated Universities (ORAU). In the discussion, you will be asked your opinions and practices regarding some information about messages that might be provided to the public during an emergency. Your answers can help efforts to provide accurate, helpful information to the public during a public health emergency. The discussion will be recorded (audio only) to be sure we get all of your comments.

Procedures:

We have asked you to join a group discussion called a focus group .The discussion will take place in a professional research facility. During the discussion, you will be asked your opinions and practices regarding some information about messages that might be provided to the public during an emergency. The group will consist of approximately eight people. A trained person will lead the discussion group. The total time involved in the interview, including instructions, will be no more than 90 minutes.

Please remember that:

You choose to participate.
You are not required to answer the questions.
This session should last about 90 minutes.
The session will not be video recorded.
You will receive $XX as a token of appreciation for participating in the discussion.
You are free to leave at any time without penalty, and you will still receive the $XX as a token of appreciation.
Researchers will be observing the research project either in-person or remotely through a real-time online video streaming mechanism.

Risks

The risks of your participation are expected to be minimal. This means that the risks are not expected to be greater than the risks persons may normally find in their daily life.

Benefits

You may be better informed about a public health issue.
You may have a sense of satisfaction from contributing to a research study.
Your comments may help improve the information FDA provides to the public about the drug treatments used in public health emergencies.

We will keep the information you give us private to the extent allowed by law. Your name will not be used in the final report. No statement you make will be linked to you by name. Only members of the research staff

will be allowed to look at the records, which will not connect your name to any comments you have made. When we present this study or publish its results, your name or other facts that point to you will not be included.

Persons to Contact

If you have questions about this session, or taking part in it, you may call: Karen Carera at 404-291-2236 at ORAU.

If you need more information about your rights as a study participant, you may contact:
Oak Ridge Site-Wide Institutional Review Board, ORAU, Oak Ridge, TN 865- 576-1725 or ORSIRB@orau.org

Appendix D. Sample Messages

Radio Script for Anthrax

Announcer	• 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.
Announcer	• Public health officials believe that the spores that cause anthrax disease may have been deliberately released.
Announcer	• Anthrax is a serious disease caused by spores from the anthrax bacteria. • Those who come into contact with anthrax spores may become ill. Anthrax cannot be spread from person to person.
Announcer	• Inhalation anthrax is the most serious form and could be fatal. • Seek treatment immediately if you think you have been exposed to anthrax.
Announcer	• Antibiotics are the main FDA-approved treatment for anthrax. • If left untreated, anthrax can eventually cause death.
Announcer	• We have challenges ahead, and we are working to find out more about this outbreak. • Stay tuned to local television and radio broadcasts for important updates.

Compassion Statement

About FDA

- **FDA protects public health by assuring drugs are safe and effective.**
- **FDA staff includes pharmacists, doctors, nurses, and other health professionals.**
- **FDA also works with outside experts.**

FDA Compassion Statement

- **We recognize that [insert threat] is frightening.**
- **We want to share this science-based information with you.**
- **So you can make informed decisions for yourselves and your loved ones.**

The FDA compassion statement (above) will be tested in each focus group prior to introducing the MCM. Due to the limited time during each focus group (35 minutes for message section), we will be unable to test message maps in their entirety. Therefore, we recommend testing the following sections for medical countermeasures (MCM) messages: What is [insert MCM]?, Exposure, and Side effects (common side effects). If time permits, alternative sections for testing include: Special populations (general information regarding allergic reaction) and Quality. Rationale to determine which sections to test is based on principles from the CDC's Crisis and Emergency Risk Communication (CERC) model. In addition, we have learned from experience when you provide participants more than 3 to 4 stimuli their feedback becomes repetitive and/or they lose interest.

Doxycycline Message Map

Doxycycline (What Is Doxy?):

- Doxycycline (Doxy) is an antibiotic used to treat bacterial infections, like anthrax.
- FDA has approved Doxy to treat and protect people from anthrax.
- Doxy can lower your risk of getting anthrax or stopping anthrax from getting worse.

Other Names for Doxy:

- There are several brand names for Doxy.
- Some other names are Atridox, Doxy 100, Doxy 200, Doxy Lemmon, Doryx, Doxychel, Doxychel Hyclate, Doxycycline Hyclate, Monodox, Oracea, Periostat, Vibra-Tabs, or Vibramycin.

Other Treatments (If I Cannot Find Doxy What Should I Take?):

- Doxy is one of several antibiotic treatment options for anthrax.
- Others include ciprofloxacin, demeclocycline hydrochloride, levaquin, minocycline hydrochloride, penicillin g potassium, and penicillin g procaine.
- A health care professional will determine which antibiotic is appropriate.

Exposure (How Do I Know if I Need Doxy?):

If you *think* you were exposed to anthrax:

- Only people in [INSERT LOCATION] at [INSERT DATE AND TIME] may have been exposed to anthrax.
- Consult your health care professional if you think you have been exposed.
- Listen to [insert local media information here] for the latest information from local officials.

If you *have* been exposed to anthrax:

- Anthrax is a serious disease and treatment must begin within 24 to 48 hours.
- People in [INSERT LOCATION] at [INSERT DATE AND TIME] may have been exposed to anthrax.
- Consult a health care professional because you may have to take an antibiotic.

If you *have not* been exposed to anthrax:

- Only people in [INSERT LOCATION] at [INSERT DATE AND TIME] may have been exposed to anthrax.

- Taking antibiotics is unnecessary if you have not been exposed to anthrax.
- Continue to follow directions from local officials.

Obtaining Doxy (How Can I Get Doxy?):

- People in [INSERT LOCATION] at [INSERT DATE AND TIME] may need Doxy.
- See a health care professional for a prescription.
- Go to the nearest pharmacy to fill this prescription.
- If you do not have a health care professional, listen to local officials for information on how to get treatment.

Quality (How can I guarantee the quality of my prescription?):

- Go to the closest pharmacy to fill your prescription.
- Avoid using an online pharmacy to fill your prescription.
    - Anthrax is a serious disease and treatment must begin within 24 to 48 hours.
    - Online pharmacies may result in a delay in receiving the prescription.
    - Some online pharmacies may provide the incorrect medicine by giving you the wrong product or dose.
    - To learn more about online pharmacies, visit BeSafeRx: http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/buyingmedicinesovertheinternet/besaferxknowyouronlinepharmacy/default.htm
- If possible, avoid buying Doxy from another country.
    - Other countries approval procedures and manufacturing controls may vary from the United States.
    - FDA can only monitor the quality or identity products approved for sale in the United States.
    - There are other FDA-approved treatments available for Anthrax.

Dosage (What are the Dosing Instructions?):

- Carefully follow the dose of Doxy recommended by health officials.
- Some age and weight groups take different doses of Doxy.
- Follow the special dosing instructions for these groups:
    - Children who weigh between less than 30 pounds
    - Children who weigh between 30 pounds and 89 pounds
    - Children who weigh 89 pounds or more
    - Adults and children who cannot swallow pills
    - Adults

Formulation (What Forms Does Doxy Come in?):

- Doxy comes in two forms: tablets or liquid.
- A Doxy tablet is 100 milligrams (mg).
- Liquid Doxy (oral suspension) comes in a 60 milliliter (mL) bottle.
- Carefully follow the dose of Doxy recommended by health officials.

Special Populations (Who Should Be Careful About Taking Doxy?):

- Because of the serious nature of anthrax disease, health officials believe the benefits of taking Doxy outweigh the risks.
- People who are allergic to tetracyclines or any ingredients in Doxy should not take Doxy.
    - Examples of tetracycline group antibiotics include chlortetracycline, oxytetracycline, demeclocycline, methacycline, tetracycline, and minocycline.
    - Tell the health care professional about all of your allergies.
- Tell a health care professional if:
    - You have trouble swallowing pills.
    - You have ever had problems with your liver or kidneys.
    - You have frequent heartburn.
    - You have had a stroke or seizure.
    - You have any history of unusual bleeding or bruising.
- Doxy may not work as well when taken with some medicines.
    - Tell a health care professional about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal and dietary supplements.
- Some medications may not work as well when taken with Doxy.
    - Hormonal birth control may not work as well if you are taking Doxy.
    - Use other forms of birth control, like condoms, until you are finished with the entire course of Doxy.
    - Doxy may affect dosing of certain blood thinners or seizure medicines.

Can Pregnant Women Take Doxy?

- Tell a health care professional if you are pregnant, might be pregnant, or planning to become pregnant.
    - Doxy may cause stained baby teeth in children exposed to Doxy in the womb.
    - Doxy may lead to poor bone development in the fetus.
    - Doxy may cause severe liver disease in some pregnant women.
- Doxy is a Pregnancy Category D drug.
    - Doxy should only be used during pregnancy if the potential benefit justifies the potential risk.
    - Researchers have found evidence of human fetal risk from Pregnancy Category D drugs, like Doxy.
    - The potential benefits of these drugs may still be considered acceptable in certain high-risk situations.

Can Nursing Mothers Take Doxy?

- Tell a health care professional if you are breast-feeding or planning to breast-feed.
- Doxy passes into breast milk.
- You and a health care professional should decide whether you should take Doxy and breast-feed.

Can Elderly Patients take doxy?

- Elderly patients may take Doxy.
- Elderly patients should tell a health care professional about any health issues.
- Elderly patients should tell a health care professional about medications they are taking.

Can Children take doxy?

- Children under 8 years of age should only be given Doxy in an emergency when no alternatives are available.
- The Doxy dose for a child will depend on the child's body weight.
- Follow dosing instructions from a health care professional.

Side Effects (What Are the Side Effects of Taking Doxy?):

Common Side Effects of Doxy

- As with all drugs, there are possible side effects of taking Doxy.
- Health officials believe the benefits of taking Doxy after an anthrax attack outweigh the medicine's potential risks.
- Common side effects of Doxy include an upset stomach, vomiting, diarrhea, or vaginal yeast infection.
- Doxy may make skin very sensitive to the sun.
- If you experience problems with any of these side effects, tell a health care professional.

Less Common Side Effects of Doxy

- Less common side effects of Doxy include dark urine, yellowing of the eyes or skin, sore throat, fever, unusual bleeding or bruising, fatigue, or white patches in the mouth.
- If you experience problems with any of these side effects, notify a health care professional.

Allergic Reactions to Doxy

- Severe allergic reactions to Doxy are very rare.
- Signs of an allergic reaction include rash, hives, throat tightness, itching, fever, rapid heartbeat, trouble breathing, yellowing of the skin or eyes, or swelling of the tongue, hands, or feet.
- If any of these symptoms occur, call a health care professional immediately.

Side Effects to Doxy in Children

- Children taking Doxy should be monitored by a health care professional for side effects.
- Doxy may cause staining of the teeth in infants and children 8 years of age and younger.
    - Their teeth may become grayish in color.
    - This color does not go away.
- If your child experiences any of these side effects, tell a health care professional.

Storage (How Should I Store Doxy?):

100 mg Oral Tablet:

- Store Doxy in a cool, dry, and dark place between 68–77°F (20–25°C).
- Replace cap tightly after use.
- Keep Doxy out of the reach of children and pets.
- Throw away any unused Doxy when it is expired or no longer needed.
    - For information on how to safety dispose of any unused medication, visit http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/

ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm or contact the U.S. Food and Drug Administration at 1-888-INFO-FDA (1-888-463-6332).
    - Do not take any Doxy after the expiration date printed on the bottle.

Oral Suspension:

- Store Doxy in a cool, dry, and dark place at temperatures between 59–86°F (15–30°C).
- Do not freeze liquid Doxy.
- Replace cap tightly after use.
- Keep Doxy out of the reach of children and pets.
- Throw away any unused Doxy when it is expired or no longer needed.
    - For information on how to safety dispose of any unused medication, visit http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm or contact the U.S. Food and Drug Administration at 1-888-INFO-FDA (1-888-463-6332).
    - Do not take any Doxy after the expiration date printed on the bottle.

Appendix E. Sample Rotation Schedule

	City 1, Day 1	City 1, Day 2	City 2, Day 1	City 2, Day 2	City 3, Day 1	City 3, Day 2	City 4, Day 1	City 4, Day 2	City 5, Day 1	City 5, Day 2
Focus Group 1	Radioactive Iodine, KI	Anthrax, Doxy	Radioactive Thallium, PB	Marburg, No MCM	Anthrax, Doxy	Radioactive Iodine, KI	Marburg, No MCM	Radioactive Iodine, KI	Radioactive Cesium, PB	Tularemia, Doxy
Focus Group 2	Tularemia, Doxy	Radioactive Iodine, KI	Ebola, no MCM	Radioactive Thallium, PB	Radioactive Iodine, KI	Plague, Doxy	Radioactive Thallium, PB	Marburg, No MCM	Plague, Doxy	Radioactive Thallium, PB
Focus Group 3	Ebola, No MCM	Radioactive Cesium, PB	Tularemia, Doxy	Radioactive Iodine, KI	Radioactive Cesium, PB	Ebola, No MCM	Anthrax, Doxy	Radioactive Cesium, PB	Radioactive Iodine, KI	Ebola, no MCM

***FDA Compassion Statement will be tested in every focus group.**