

DRAFT

Drug Safety Communications

Moderator's Guide

I. Introduction of Moderator and Informed Consent

- A. Independent consultant hired to moderate these discussions
- B. No vested interest in receiving any particular point of view

Have all had the opportunity to read and sign the informed consent notice? If you have not, please sign it now.

II. Ground Rules

- A. You have been asked here to offer your views and opinions; everyone's participation is important
- B. Audio/video/observers, and some observers are watching remotely through video conferencing
- C. Speak one at a time
- D. No side conversations
- E. No right or wrong answers
- F. It's OK to be critical. If you dislike something or disagree with something that's said, I want to hear about it.
- G. All answers are confidential, that is, they will not be associated with your name or any other personally identifiable information about you because we want you to feel free to speak your mind.

III. Introduction of Topic

Today we are here to discuss communications about your health, medicines, and safety concerns that come up with drugs that people are taking to treat an illness or to help improve their health. We want to hear your thoughts about the information you hear or read about problems with medicines and sources where you hear or read that information. We will also ask you to review some written materials about a drug and to answer questions about them.

It is important to note that there are no wrong answers. We want to know how you interpret and understand this kind of health information about medicines so that the U.S. Food and Drug Administration can improve how they communicate with the public about these issues. The Food and Drug Administration, also called FDA, is the official government agency that oversees drug safety.

I'd like to begin by getting to know all of you a little, and then I will go into further detail about what we are doing in this session.

IV. Participant Introductions

To begin, I'd like to have you go around the table and introduce yourselves. Please give me:

- a. your first name only
- b. how long you have lived in the area
- c. one personal interest

V. Exploratory (approximately 25 minutes)

Moderator: Tell participants that the group will discuss sources of drug information and their drug information seeking activities.

V.1 Knowledge, attitudes and beliefs related to [drug information challenges](#)

1. How important is it to get information about the drugs you are taking?
 - a. Probe: Why types of drug information are important for you to get? E.g. Instructions for use, storage information, safety information
 - b. Probe: Do you think it is important to understand the risks associated with a drug you take? Why/why not?
 - c. Probe: What do you think of when you think of risks associated with a medication?
 - d. Probe: What kinds of risks do you think it is important to know about?
2. How well do you feel like you understand the risks of the medicines you take?
 - a. Probe: What are some risks you are aware of with the drugs you are currently taking?
3. If you came across information about a new problem or risk with a drug you take, what would you do?
 - a. Probe: How would you determine what you should do with that information?
 - b. Probe: Once you know about a new problem risk, how would you determine whether you should act on that information?
 - c. Probe: When would you want to know about that new information? Would you want to know at the first possible time, even when information is early or incomplete and specific recommendations are not yet available, OR would you want to know later on, when more information is gathered and known about the safety issue, and recommendations are available that can help minimize risk?

V.2 Knowledge, attitudes and beliefs about [sources of drug safety information](#)

1. What are your primary sources for drug information? For information on risks and safety issues with the drug?

Moderator: Questions 2 – 4: skip if time is tight.

2. If you have a question or concern about a drug you are taking, where would you go for information?
 - a. Probe: Who would you talk to?
 - b. Probe: What sources might you read?
3. Why would you seek information from that source or person?
 - a. Probe on: qualifications of the source/person, detail in content, readability, etc.
4. What sources of drug information do you trust the most? Why?
 - a. Probe: What sources of information do you not trust? Why?
5. Would you seek drug information from any government agency? Why or why not? Look for information from the Food and Drug Administration/FDA specifically (As a reminder, I do not work for the FDA, and your responses are completely anonymous)? Why/why not?
 - a. Probe: What do you think is FDA's role with regard to drug information and safety issues?
 - b. Probe: What kind(s) of information do you think you could get from FDA?
 - c. Probe: How credible do you think FDA is as a source for drug safety, or drug risk information? Why? How much would you trust the information you receive about drug information and safety issues? Why?

V.3 Beliefs and behaviors associated with [seeking drug safety information](#)

1. How often, if ever, have you searched for information on drugs you are taking?
2. Why do you to search for drug information?
3. What drug information do you typically seek?
 - a. Probe: Have you ever sought information about possible risks of the drugs you take?
4. Where do you search for drug safety information or information on drug risks and benefits?
 - a. Probe: Do you search for other types of drug information in the same place or in a different place from drug safety and risk and benefit information?
5. Do you ever seek drug safety information directly from FDA? Why or why not?

- a. Probe: Are you familiar with FDA’s Drug Safety Communications?
6. Do you ever have difficulty finding drug information?
 - a. Probe: Typically, how hard is it to find the drug safety or risk and benefit information you are seeking?

VI. Evaluation Example 1 (approximately 55 minutes)

Provide information on the communications

Moderator: Say “In the next 2 sections of the focus group, we will ask you to respond to 2 different communications. These are examples of drug communications from FDA. We are interested in your thoughts and opinions on the communications.”

Show the online version of the original DSC example 1 on the screen. Say: “Imagine you have a medical condition and are being treated with the drug in this communication.”

VI.1 Impressions of Webpage

Moderator: Use this section for the DSC on the webpage. Might be first sometimes, might be the second DSC other times. If it is the second example, skip here and do this section with the second example.

1. Have you ever visited this webpage? [NOTE: This question and #s 2 and 3 should refer to the main DSC page, rather than to the page tied to the specific DSC. Main page: <http://www.fda.gov/Drugs/DrugSafety/ucm199082.htm>.
2. Why would you go to this webpage?
3. Based on its name -- Drug Safety Communications – what kind of information would you expect to see on this webpage? Why?
 - a. Probe: What information would you NOT expect to see on this webpage?
4. If you don’t see the information you are looking for, would you use the search box at the top of the page? (*Moderator point to search box*).
 - a. Probe: Did you even notice the search box?
 - b. Probe: What words would you type in the search box? Would you search by the name of a drug? By the disease or illness the drug treats?
 - c. Probe: Would it be helpful to you to be able to search on just the safety information and not on the entire FDA website?

Moderator: Now go to the specific page for the DSC being discussed in this focus group.

5. What is your initial impression of the webpage?

- a. What words would you use to describe the webpage?
 - b. What other things do you think would be helpful if this page included? Why?
6. Where on this web page would you go to look for information about the drug? What information would you want to find out?
- a. Probe: Did you notice these tabs? Would you click on any of them? Why/why not? What information would you expect to find under each tab? What makes you think that? Which tabs would you want to read? Why? Not read? Why?
 - b. Probe: Would you scroll down to see the rest of the page? Why/Why not?
 - c. Probe: What would you expect to see there?
 - d. Probe: What information is not there that should be?
7. Did you notice the “related information” section on the bottom of the page?
- a. Probe: What information would you expect to find there?
 - b. Probe: Do you think the information there is useful? Did you understand it?
 - c. Probe: What information would you want to see there? What information is missing?

Moderator: Hand out the original DSC printout. Say: “This handout I am giving you is a printout of the website we just looked at. Each separate page shows the information that appears under each tab on the webpage. Now that we have reviewed the online format of the communication, we are going to discuss the content of the communication more deeply. Please take few minutes to review the document and jot a few notes about the content. You may circle any information that you find useful or helpful, and also make a note about any words or information you do not understand.” Wait a few minutes (or until participants appear ready to move on) and begin questions.

VI.2 Knowledge, attitudes and beliefs on [communication understanding](#)

1. What do you think is the main purpose of this communication? What is the main point the FDA is trying to get across through this communication, i.e. the main piece of information you should know after reading this information?
2. What about the communication helps you understand the information?
 - a. Probe: Are there particular words in the communication that made it easier for you to understand the information?
 - b. Probe: Are there other elements that made it easier for you to understand the information?
3. What about the communication makes it hard to understand?
 - a. Probe: Are there particular words that made it hard for you to understand the information?
 - b. Probe: Are there other elements that made it hard for you to understand the information?

- c. Probe: What would you suggest to make it easier to understand the difficult things?
4. How informative is the title?
 - a. Probe: What's good about it? Bad about it?
 - b. Probe: If people have died as a result of the safety problem, should that be included in the title? Why/why not?
 - c. Probe: Should the disease the drug is used to treat be included in title? Why/why not?
 - d. Probe: How well does it summarize the main information contained in document?
5. Why do you think this information was released to the public?
 - a. Probe: When would be the best time to release this kind of information (e.g. as soon as a problem with the drug arises; at the point when the problems become serious enough to investigate; only when definitive information is known, etc.)?
6. Looking at the information contained on each of the tabs, did each section contain the information you expected to see there?
 - a. Probe: On the Safety Announcement tab/section? What does the information tell people who are likely to be affected to do?
 - b. What information is missing (e.g. questions to ask your health care professional about this safety issue or about the drug?) What information is not needed?
 - c. Probe: On the Facts About the Drug tab? What information is missing? What information is not needed?
 - d. Probe: On the Additional information for Consumers and Caregivers tab? What information is missing? What information is not needed?
 - e. Probe: On the additional information for health care professionals tab?
 - f. Probe: On the data summary tab?
7. How informative are the tab names?
 - a. Probe: What alternative words or phrases would better describe the content included on each of the tabs?

VI.3 Knowledge and beliefs on [relevance of the communication](#)

1. To whom is the communication targeted?
 - a. Probe: Are there particular groups of people who should pay more attention to the communication? Which one(s) and why?
2. If you were taking this drug, how would this information in this communication make you feel? Why?

3. If you were taking this drug, what would you do after reading this information? Why?
4. Is there any information in this communication that would make you stop taking this drug?
 - a. Probe: What is it (e.g. words, phrases, etc.) and why does it make you feel that way?
5. Based on this information included in this communication, does this drug seem safer for some people than for others?
 - a. Probe: For whom is it safer? For whom is it less safe?
 - b. Probe: What in the communications makes you feel that way?

VI.4 Knowledge, attitudes and beliefs about benefits and risks of the drug

1. How will this drug benefit the health of those who take it?
 - a. Probe: What in the communication led you to your decision?
 - b. Probe: What (else) would you like to know about the benefits of the drug?
2. If you were taking this medication, how would you describe the risk of taking this drug?
 - a. What words would you use to describe the seriousness of the **risk** (e.g. very low, low, medium, high, very high, etc.)?
 - b. What words would you use to describe the type of communication (e.g. update, alert, warning, etc.)?
 - c. What words would you use to describe the importance of this information is (e.g. typical, important, urgent, etc.)?
 - d. Are there other ways to identify the level of risk, e.g. through a series of images (like those used to describe pain) or colors (e.g. red, yellow, green)?
3. Let's say the safety issue with this drug included a risk rating, or some kind of indication (like a word, phrase or color at the top of the page) that shows the level of risk associated with this safety issue. What should that rating be? Why?
4. How would a rating help you determine whether this safety issue was something you needed to read/find out about?
5. Where would you expect to find that kind of risk rating on this communication?
 - a. Probe: What would you expect it to look like?

VI.5 Knowledge, attitudes and beliefs about the source information

1. How reliable is this information? What leads you to think that?
2. Do you trust the FDA as a source for this information? Why or why not?

VII. Evaluation Example 2 (approximately 30 minutes)

Moderator: Hand out the revised DSC printout. Say: “This handout I am giving you is a revised version of the communication we just looked at. Now that we have reviewed the original format of the communication, we are going to discuss the differences between the two versions. Please take a few minutes to review the document and jot a few notes. You may circle any information that you find useful or helpful, and also make a note about any information you do not understand.” Wait a few minutes (or until participants appear ready to move on) and begin questions.

VII.1 Attitudes and beliefs about the [comparison between the original and revised DSC](#)

1. How does this communication compare to the previous one in terms of your ability to understand the information? Why?
 - a. Probe: Is there information that you did not understand in one version but that you did understand in the other version? What information/which version?
2. Which version was easier to understand overall?
 - a. Probe: What words, phrases or elements of this communication made it easier to understand?
 - b. Probe: Which elements of the other communication helped make something clearer or easier to understand?
3. What elements of the second communication would you change to make it easier to understand?
4. How did the 2 titles compare?
 - a. Probe: Was one easier to understand than the other? Why?
5. Did one more clearly summarize the main point(s)? Why? Was it easier to identify the safety issue being presented on one or the other? Why?
 - a. Was one version better than the other at identifying who the safety issue is most likely to affect? Which one/why?
 - b. How did the headings compare? Did the headings in one or the other make it easier for you to identify the key information you needed?

Note: These questions would only be used with the revised testosterone DSC that contains the written and graphic versions of the numerical information:

6. This revised version of the communication contains some information describing in words and a graph that are supposed to help people better understand the risk of this safety issue.
7. What is the written information about the first study telling you?
 - a. Probe: Does that information help you to better understand this safety issue? Why/why not?

8. What is the graph telling you?
 - a. Probe: Did it help you understand the information? Why/why not?
9. What is the written information about the second study telling you?
 - a. Probe: Did it help you understand the information? Why/why not?
10. Would it have been helpful to you to have either the words or the graph included in the first DSC you saw? Why/why not?
11. Are there other ways to describe these numbers that would have been helpful to you?

These questions are for all DSCs

12. How does this communication compare to the previous one in terms of how easy it is to find the information you would look for? Why?
 - a. Probe: What elements of the communication made it easier or more difficult to find the information?
 - b. Probe: What elements of the communications would you change to make it easier to find the information?
 - c. Probe (*based on which DSC shown*): Which headings made it easier for you to identify the key information you needed? Why?
 - d. Probe: How did you feel about the bullets? How did you feel about the bolded information?
13. Does one version of the communication make the safety issue seem more or less serious than the other version? Why or why not?
14. Does one version of the communication make the drug seem more or less risky than the other version? Why or why not?
15. Does one communication seem more reliable than the other? Which one and why?
16. Does one communication seem more believable than the other? Which one and why?

VIII. Closing

Moderator: Check with observers for additional questions.

Thank participants for the discussion and dismiss them.