

Improving FDA Health Communications with Older Women Regarding FDA-Regulated Products

Focus Group Preamble

Thank you for taking part in this focus group. I am [FACILITATOR NAME], and I will be starting today's discussion. This is [NAME], who will be taking notes on what we discuss.

As [RECRUITER] may have explained to you, we are here to learn about how you get health information on products the US Food and Drug Administration (also known as the FDA) oversees. The FDA is responsible for protecting the nation's health by ensuring that products like drugs, vaccines, medical devices, and food are safe, do what they are supposed to do, and that the companies making these products follow FDA regulations.

For today's discussion, we will be using the term "health information" to refer to messages that are meant to increase awareness or knowledge about two categories of FDA products, vaccines and prescription or over-the-counter drugs. Our goal is to learn the best ways FDA can provide you with the health information you are looking for.

There are two parts to today's discussion. During the first part, we want to learn how you find or receive health information, and what you do with this information. During the second part, we want to hear your opinions about different types of health messages regarding vaccines and drugs.

Your feedback is valuable to the FDA, and your opinions will help the FDA make their communication materials clearer and easier to read. This will help consumers like you make more informed healthcare decisions.

We will not discuss *your personal health*. Instead, we will focus on learning more about how you find and use health information.

Do you have any questions about what I've said so far? [*Answer any questions.*]

In a focus group, it's important to express yourself openly. There are no right or wrong answers. We simply want to know what you think.

I would like everyone to be a part of this conversation. You do not need to wait for me to call on you to talk, but only one person should speak at a time.

I want to remind you that your participation in this discussion is *voluntary* and you can choose *not* to respond to any question for any reason.

Also, we ask you to keep what we discuss today within this group and not share what we discussed with others who did not participate. This is to make everyone feel comfortable sharing their honest opinions with the group.

At this time, I will read the participant information sheet each of you has in front of you. This sheet describes this study and what you will be asked to do if you agree to participate.

[Give participants enough time to review the sheet. Answer any questions that may arise. Ask if there are any questions or things that need clarification.]

Do you give verbal consent to participate in this focus group?

[Confirm that participants provided verbal consent.]

We would like to record this discussion today as a back-up to make sure our notes are correct. What you say will *not* be linked to your name in any report, and the recording will be destroyed after we have analyzed the discussions. If at any time you do not want your comment to be recorded, please let [NAME] know and we will turn off the recorders while you are speaking.

Do I have your permission to record our discussion?

[Obtain a verbal agreement. If anyone does not want to be recorded – the focus group discussion will not be recorded.]

We will ask you to say your first name before speaking. If you would prefer not to identify yourself, you can use a different name. Since this discussion is being recorded, saying your name will help us identify who is speaking when we listen to the recording later on. The only people who will hear the tape or see the written record are the researchers working on this project.

Please silence your cell phones and other electronic devices. You might also notice that I may repeat or ask questions about some of the comments that you make throughout our discussion today. I will do this to ensure that we capture everything that is said and to confirm that I understand what you said.

Are there any questions before we get started?

[Answer any questions.]

Introduction

First, we'll go around the room and have each of you state your first name. If you do not wish to give your name, you can use a different name. When you introduce yourself, please tell us on whose behalf you typically seek health information i.e. for yourself only, plus one (spouse or partner), and/or someone you give care to like a parent, grandparent, child, or grandchild.

Health information seeking intentions and behaviors with respect to FDA-regulated products

For the first half of our discussion, I have some questions about how you look for information about either your own health or the health of someone you care for. As a reminder, for today's discussion, we will focus on prescription drugs, over-the-counter drugs (drugs you can buy at the drug or grocery store without a doctor's prescription), and vaccines.

Perhaps you have had a question about a prescription medication, an over-the-counter drug, or a flu vaccine. For example, you might have thought about how to take it, how to store it, what it might make you feel like, whether food and other drugs make it work better or worse, etc.

[If participants start talking about their health conditions, treatments, insurance, etc., steer the conversation back to the process of finding health information.]

1. When you had a question about a drug or vaccine, did you try to find information to answer your question? You don't need to talk about any particular health concern, but just whether you tried to find information about this concern.

Probe:

- If no, why not? (e.g., fears, time, not sure where to find information)
- If yes, why? (e.g., motivations; health-related goals; discussion with provider, family, friends)
- Would your responses differ depending on whether your question is about prescription drugs, over-the-counter drugs, or vaccines? If yes, please explain how it differs.

2. If you looked for information to answer your question, where you did look?

Probe:

- Sources of information: family, friends; physicians, pharmacists, other healthcare providers; pharmaceutical industries; patient support groups; medical societies; ministers, communities, senior centers; product website, the internet (if so, what site?), social media; journal articles; news; drug inserts; pamphlets/newsletters.
- Would your responses differ depending on if it is for prescription drugs? Over-the-counter drugs? Vaccines? If yes, please explain how it differs.
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- What sources of information do you trust or rely on the most? What makes them your trusted sources of information? What sources do you not trust and why?
- How often do you look for information on the FDA website? If you use the FDA website, do you find the information useful and easy to access? If not, why not?

3. Thinking about the types of information that you found on the FDA website, was this information useful (e.g., testimonials, data, where or who was providing the information (peer, provider, etc.))?

Probe:

- If yes, what made this information useful to you?
- If no, what could make this information more helpful?
- Would your responses differ depending on if it is for prescription drugs? Over-the-counter drugs? Vaccines? If yes, please explain how it differs.

Let's now consider a situation where you have gathered the health information you were looking for and you want to make a decision based on this information. For example, you may want to decide whether to start taking a prescription drug or whether to get a flu vaccine.

4. Assuming that you've learned about the different choices you can make to improve your health, what source of information is most helpful or influential to you in making a health-related decision among the following sources:

family, friends, physicians, pharmacists, other healthcare providers, pharmaceutical industries, patient support groups, medical societies, ministers, communities, senior centers, FDA website, product website, the internet, social media, journal articles, and news

Probe:

- What source(s) do you find most helpful?
- Would your responses differ depending on if the information is for prescription drugs? Over-the-counter drugs? Vaccines?

5. Have you ever looked for answers to a health question, but couldn't find enough information about the topic or what you found didn't really help you?

Probe:

- If yes, what was the reason for this? (e.g., information lacking or needed improvement, overwhelmed with too much information, don't know where and how to find this information)
- Did you end up making a decision about your health even though you wanted more information about the topic? If so, why or why not? If yes, how?

6. Have you ever looked for answers to a health question, and you found information that was too confusing to understand?

- If yes, what made you confused? (e.g., difficult to understand terms, overwhelmed with too much information,...etc.)

Older women's perceptions about FDA's health communication regarding FDA-regulated products

Now, for the second part of our discussion, I want to show you some examples of different ways health information can be shared with women like you. These examples include [*a pamphlet, a website page, or a podcast*].

After I show you each example, I'll ask you a few questions to get your opinions about each one. I won't ask you questions about the words, graphics, images, or colors. Instead, I'm interested in hearing what you think about the different ways of receiving information about drugs and vaccines.

[Note, if participants speak about content, message, or design, redirect discussion to type of communication as a way to receive health information.]

Let's take a look at the first [*type of communication*]. This is an example of [*type of communication, add in brief description*].

- For the pamphlet, hand a copy to each participant.
- For the website page, show an example of an FDA webpage on a projector screen.
- For the podcast, run a short FDA audio podcast (less than 2 minutes).

7. What are your thoughts about receiving health information in this [*type of communication*] format?

Probe:

- Does this [*type of communication*] appeal to you as a way to receive health information? If so, what makes it appealing? If not, what are the reasons (e.g., can't read well, need help to understand)?
- What would make [*type of communication*] more helpful when you are looking for health information (e.g., time, access to technology, balanced information on both benefits and risks, large font size, short, comprehensive, patient experience data, up-to-date)?
- Is this type of communication the best way to receive information about prescription drugs? Over-the-counter drugs? Vaccines? None of them? Why or why not?

8. Thinking about [*type of communication*] as a way to receive health information, would you recommend [*type of communication*] to others?

Probe:

- Whom would you recommend this to (e.g., age, gender, cultural groups)?
- What are some reasons why you would recommend this type of communication to others?
- What are the reasons why you would not recommend to this type of communication to others?

Repeat questions #7 and #8 for each type of communication.

9. Do you have a preference for one type of communication format over the others when you think of...

- Prescription drugs?
- Over-the-counter drugs?
- Vaccines?

10. What do you think about receiving FDA newsletters at regular intervals containing messages about drug- or vaccine-related health information?

Probe:

- Does a newsletter appeal to you as a way to receive health information? If so, what makes it appealing? If not, what are the reasons (e.g. annoying)?
- If it is appealing, how often do you like to receive these newsletters (e.g. weekly, monthly, custom?)

- Would your responses differ depending on if the information is for prescription drugs? Over-the-counter drugs? Vaccines? If yes, please explain how it differs.

11. Now, I'd like you to think about the papers that come packaged with a prescription or over-the-counter drug. These papers have information about the drug, how to use the drug safely, potential benefits and risks, and a phone number to report side effects. What are your thoughts about these papers?

Probe:

- Do you find these papers helpful?
- How would you improve on the design of these papers to make them more user-friendly? (e.g., language, format, content).

12. Please share your experience, if any, in finding health information on vaccines.

Probe:

- What are your feelings about this experience?
- What could have improved this experience for you?

13. Is there any other type of communication that you would prefer to receive from the FDA that we did not discuss today?

CLOSURE

Those were all the questions I had for you today. Before we end our discussion, is there anything else that you'd like to discuss related to the FDA's health communications to women like you?

[If ideas are mentioned, discuss them further. If not, continue to wrap up.]

If there's nothing further you'd like to discuss, I'd like to thank you for participating. We have learned a great deal from you and we appreciate your help with this important topic.

If you think of anything else you would like to share with us, please feel free to contact the [PI NAME] by email or phone [give email and phone number to contact]. You can also find this information on your information sheet [show participants where to find the PI email and phone number].

Thank you again for your time. We will hand a gift card to each of you in a minute.