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Cognitive Interview Guide: March 2023 Breast Implant Safety Communication

Color Key:

Purple – Section headings and titles

Black – Text for interviewer to read

Red – Interviewer instructions (not to be read aloud)

Green – Research questions (for interviewer's information, not to be read aloud)

Research Questions

1. What are the main message(s) that participants get from the Safety Communication?
2. What do participants recognize as the call to action?
3. What information do participants indicate is new to them?
4. How clear and understandable is the text to participants? What words or phrases are confusing, and what suggestions do participants offer for improving them?
5. What information do participants find useful? Not useful?
6. How helpful do participants say the Safety Communication is for facilitating patient-provider discussions?
7. Is there information that is missing or would be helpful to add?
8. How well do participants think the content is organized?
9. What other suggestions do participants have to improve the information?

Introduction

Hello, my name is [INSERT INTERVIEWER NAME]. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is conducting this study, which is sponsored by the U.S. Food and Drug Administration (or FDA), to see what people think about health information related to breast implants.

In a moment, I will give control of the screen to you so you can look at a document. After you look at the document, I will ask you some questions on your thoughts and feelings about the information. Any ideas you have are okay.

IF PARTICIPANT CANNOT USE SCREENSHARING, ASK IF OK TO SEND EMAIL TO PARTICIPANT. IF PARTICIPANT IS NOT ABLE TO RECEIVE OR SCREENSHARE AND VIEW THE DOCUMENT, RESCHEDULE INTERVIEW.

Informed Consent

Before we get started, there are a few things I want to go over. Your participation in this interview is voluntary, and you don't have to answer any questions you prefer not to. It is also okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means we will not share your name or contact information. The interview will take about 45 minutes and you will receive [\$50 (consumers) OR \$100 (Primary Care) OR \$150 (Oncology or Plastic surgery)] as a token of appreciation.

We would like to record this conversation to make sure we hear everything you say correctly. Please speak clearly and loudly. Also, please minimize background noise by finding a quiet location away from other people and distractions. If you haven't already, please silence your cell phone and other devices.

Only the research team working on this project will be able to listen to the recording and see our notes. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

IF FDA STAFF ARE ON THE PHONE: I also want you to know that a couple members of the FDA research team are listening to this interview so they can hear directly from you.

Any questions? Is it okay if I record the interview? **IF NO, TERMINATE.**

TURN ON RECORDER. The date and time is _____. Now that I am recording, I want to ask again, is it okay if I record this interview?

Background Questions

To start, I have a few general questions.

FOR CONSUMERS WHO HAVE/HAD BREAST IMPLANTS

You told us when you volunteered for this interview that you [currently have breast implants/ previously had breast implants]. Is this correct? **IF NO, TERMINATE.**

How long [have you had/ did you have] breast implants?

What conversations did you have with your doctor about breast implants before getting them?

- What conversations have you had with your doctor about your breast implants since getting them?

Where else have you gotten information about breast implants? **IF NEEDED:** From the manufacturer, from the news, or from somewhere else?

What risks or complications are you aware of with having breast implants?

- **IF CANCER/TUMORS,** Tell me more about that. Which type or types of cancer have you heard being a risk of breast implants? In which body parts or areas might this cancer be found?

Have you heard any recent news or updates about the risk of cancer from breast implants? **IF YES,** Where did you get this information?

What questions do you have about your breast implants?

FOR CONSUMERS CONSIDERING BREAST IMPLANTS

You told us when you volunteered for this interview that you have considered getting breast implants. Is this correct? **IF NO, TERMINATE.**

How long have you been thinking about getting breast implants?

What conversations have you had with your doctor about getting breast implants?

Where else have you gotten information about breast implants? **IF NEEDED:** From the manufacturer, from the news, or from somewhere else?

What factors are you considering in your decision whether or not to get breast implants?

- What risks or complications are you aware of with having breast implants?
 - o **IF CANCER/TUMORS,** Tell me more about that. Which type or types of cancer have you heard being a risk of breast implants? In which body parts or areas might this cancer be found?

Have you heard any recent news or updates about the risk of cancer from breast implants? **IF YES**, Where did you get this information?

What questions do you have about getting breast implants?

FOR PRIMARY CARE AND PLASTIC SURGERY HCPs

What advice do, or would, you give patients who are interested in getting breast implants? **IF NEEDED**, What risks or complications do you discuss with these patients?

- **IF CANCER**: What specifically do you tell patients about the risk of cancer? **IF NEEDED**, Which types of cancer? What symptoms do you tell them to look for?

What advice do, or would, you give patients who already have breast implants?

- **IF NEEDED**, What do you tell these patients to look for or be aware of? What do you tell patients about the lifespan of their breast implants?

What materials or resources about breast implants do you share with patients? **IF NEEDED**, For example, the labeling, a checklist, websites, or anything else.

- **IF WEBSITES**, Which ones?
- What types of information or materials would be helpful for you to have in talking with patients about breast implants?

How do you stay updated on new safety information related to breast implants?

- **IF WEBSITES**, Which ones?
- Have you heard any recent news or updates about the risk of cancer from breast implants? **IF YES**, Where did you get this information?

FOR ONCOLOGY HCPs

What advice do, or would, you give breast cancer patients who are interested in getting breast implants? **IF NEEDED**, What risks or complications do you discuss with these patients?

- **IF CANCER**: What specifically do you tell patients about the risk of cancer? **IF NEEDED**, Which types of cancer? What symptoms do you tell them to look for?

What advice do, or would, you give patients who come to you for treatment for lymphomas or other types of cancer linked to their breast implants?

How do you stay updated on new safety information related to breast implants?

- **IF WEBSITES**, Which ones?
- Have you heard any recent news or updates about the risk of cancer from breast implants? **IF YES**, Where did you get this information?

Safety Communication Page

FOR ALL PARTICIPANTS

Now I am going to share my screen with you. Do you see a page with the first word “[UPDATE](#)” in the title? This is a page on FDA’s website. Please take a few minutes to read it now **without clicking on anything**. I will give you control of the screen so you can review at your own pace. **[HAND CONTROL TO PARTICIPANT]** When you finish, I will ask you some questions about the information.

CHECK IN AFTER 3 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.

IF RESPONDENTS NAVIGATE AWAY, DIRECT THEM BACK TO THE PAGE.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.

NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:

- Any verbal reaction to statements in the information.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which statements evoked any of these reactions.

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES REVIEW.

GENERAL IMPRESSIONS

In your own words, what is the overall, main message of what you've just read?

- What is it asking you to do?
- Why do you think the FDA is telling you this information?

What do you like about this page and why?

What don't you like and why?

Is there too little or too much information and why?

- **IF TOO LITTLE**, What other information would you have liked to see? Where on the page should that information go?
- **IF TOO MUCH**, What information seems unnecessary?

CONTENT

IF CONSUMER:

- How easy or difficult is it to understand the information on this page?
 - o Are there any words or phrases that confuse you or that you aren't sure of? **IF NEEDED**, How could that be stated more clearly?
 - o What is your understanding of the word “capsule” that is used on this page?
- After reading this page, what new information have you learned?
 - o Based on this page, what is your understanding of the difference between Squamous Cell Carcinoma (or SCC) and Breast Implant-Associated Large

Cell Lymphoma (or BIA-ALCL)? Which of these would you say is the focus of this page? Why is the other referenced?

Let's take a closer look at the table about half way down the page.

- o What is this table showing you?
- o Are there any parts of this table that confuse you or that you aren't sure of? **IF NEEDED**, How could this table be changed to make it easier to understand?
- o Why do you think the FDA is sharing this summary of the 19 cases?

IF HCP:

Does anything you've read in this article come as a surprise to you? **IF YES**, Which parts and why?

ALL PARTICIPANTS

Does anything you've read on this web page concern you? Why is that?

What are your thoughts on the way this page is set up?

- Is the information presented in a way that makes sense to you? Why or why not?

IMPACT

IF CONSUMER, How useful is this page to you? Please respond on a scale of 1 to 5 where 1 is not at all useful and 5 is extremely useful.

- What makes you say **[PARTICIPANT'S SCALE NUMBER]**?
- Which parts are most useful to you?
- Which parts are the least useful to you?
- Is there information on this page that is NOT needed or can be removed? **IF YES**, What information and why do you think it is unnecessary?
- Would you share this page with your doctor? Why or why not?

IF HCP, How useful is this page to you in communicating with patients about breast implants? Please respond on a scale of 1 to 5 where 1 is not at all useful and 5 is extremely useful.

- What makes you say **[PARTICIPANT'S SCALE NUMBER]**?
- Which parts are most useful to you?
- Which parts are the least useful to you?
- Would you share this page with patients? Why or why not?

ALL PARTICIPANTS

What additional questions do you have after reading this page?

Now that we've discussed the information, how well do you think the title fits the main messages of this page? **IF NEEDED**, Would you change the title in any way, and why?

WRAP-UP

Do you have any other suggestions for improving the web page I shared with you today?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT RESPONDENT SEEMED CONFUSED ABOUT).

CLOSING

IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.

Those are all the questions I have for you. Is there anything else you would like the FDA to know about the web page or communicating about breast implants?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time. The company who scheduled your interview will provide you with your incentive.

STOP TAPE RECORDER.