

Opioid Packaging Cognitive Interview Guide

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)

Introduction

Hello, my name is **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 working with the U.S. Food and Drug Administration, or FDA, to see what people think about information related to a type of prescription medicine for treating pain. The FDA is interested in getting opinions about the information I am about to discuss with you.

You should have gotten [a packet in the mail/an email] for this study. Do you have the [packet we mailed to you with you/email we sent you available] right now?

IF YES, CONTINUE

IF NO BUT PACKET/EMAIL IS NEARBY/ACCESSIBLE, ALLOW PARTICIPANT TIME TO GET IT

IF NO AND NOT NEARBY, CONTINUE USING ON-SCREEN VERSION OR ASK IF IT'S OKAY TO EMAIL THE DOCUMENT TO RESPONDENTS

Please wait to open the [packet/attachment] until I tell you it is time to start. After you look at the [material inside the packet/attachment], I will ask you some questions about your thoughts and feelings about the information. Any ideas you have are okay.

Informed Consent

Before we get started, there are a few things I need to tell you. This is a research project, and this interview is voluntary. That means that if you do not want to answer a specific question just tell me and I'll go to the next one. 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 that we will not share your name or information. Also, we will not link any information to your answers to figure out who you are. The interview will take about 30 minutes and you will receive \$35 as a token of appreciation. We would like to record this conversation if you are okay with that. The recording helps us make sure we hear everything you say correctly. Only the people who work on this research 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 other people from the FDA who work on this research project are listening to this interview to take notes as we talk.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay with you if I record the interview?

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 and Information Review

To start, I have a few questions.

When you get prescription medicines, what types of written information typically come with it? Where do you find this written information? **IF NEEDED**, Staped to the pharmacy bag, inside a box, on the package, or somewhere else?

How often do you read any of the written information that you get with your prescription medicines? Please respond on a scale of 1 to 5 where 1 is never and 5 is always.

- **IF 1 (Never)**, Why don't you read any of this information? **IF NEEDED**, Is it because you are already familiar with your prescription medicines? Because you trust what your doctor has prescribed? Because the information is confusing? Some other reason?
- **IF 2-4**, What determines whether you will read this information? What information do you read or look for?
- **If 5 (Always)**, What information do you read or look for?

Have you heard about a type of prescription medicine to treat pain known as opioids?

- **IF YES**, What do you know about them? **IF NEEDED**, What are the good effects or benefits of taking an opioid medicine? What are the dangers or risks of taking an opioid medicine?

IF NOT TAKEN AN OPIOID IN PAST 3 YEARS

- If your doctor prescribed an opioid for you, would you be more likely, less likely, or just as likely to read the written information that you get with it compared to another prescription medicine? Why is that? What information would you read or look for?
- If your doctor prescribed an opioid for you, how would you store it?
- If you had an unused opioid medicine in your home, what would you do with it? **IF NEEDED**: Keep it in case you need it in the future, throw it away, or do something else with it?

IF TAKEN AN OPIOID IN PAST 6 MONTHS

- When your doctor prescribed an opioid for you, were you more likely, less likely, or just as likely to read the written information that you got with it compared to another prescription medicine? Why is that? What information would you read or look for?
- When your doctor prescribed an opioid for you, how did you store it?

- When your doctor prescribed an opioid for you, did you use it all? What did you do with any unused opioid medicine in your home? **IF NEEDED**: Kept it in case you need it in the future, threw it away, or did something else with it?

Randomly assign half of the participants to view Version 1 (“Taking too much of this medicine can cause death. Take as directed.”), and half to view Version 2 (“Take as directed. Taking too much of this medicine can cause death.”).

Now please open the [packet we sent you in the mail/email attachment]. Do you see a piece of paper that says “Lynaxin?” If you were prescribed an opioid, this information is what you might see on the package the opioid comes in. The drug name is made up, but the rest of the information is how a package from your pharmacy might look. Please take a few minutes to look at it now. When you are done, I have some questions for you about the information.

CHECK IN AFTER 2 MINUTES. ALLOW 2-3 MORE MINUTES IF NEEDED.
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.

RETROSPECTIVE GENERAL PROBES

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.
SHOW MATERIAL ON SCREEN AS NEEDED TO AID DISCUSSION.

RESEARCH QUESTIONS

Are the risks clear and understandable?

What is the main message that participants get from the material?

Do participants indicate that any of the material’s information is new to them?

Do participants find any of the warnings concerning?

What do participants understand from the information about how the medicine should be stored?

Is the disposal warning statement sufficient to encourage disposal of unused opioids. If not, what questions does it raise and how would participants get them answered?

How likely are participants to visit the website/type the website URL?

Do participants know to read the Medication Guide for more information?

GENERAL IMPRESSIONS

First, just tell me your overall thoughts about the information in the red box.

What do you like about it?

What don't you like?

How easy or difficult is it to understand the information inside the red box? Looking at each of the 5 warnings in the red box, is there anything confusing or unclear about any of them?

Were there any words or phrases that confused you or that you weren't sure of?

CONTENT

Now let's talk a little more specifically about the information.

In your own words, what is the overall, main message that this warning is trying to tell you?

- What is it asking you to do?

Does this warning clearly explain the dangers of this prescription medicine?

- **IF YES**, What about this material makes you say it is clear?
- **IF NO**, Can you say more about what wasn't clear?

Does the order of the 5 warning statements in the red box make sense?

- In what order would you put these statements so that the most important information is in the place where it should be? **IF NEEDED**, What statement should come first?

The first statements after the stop sign read [INSERT VERSION 1 OR VERSION 2 TEXT]. Are these two sentences in the order you would place them, or would you switch the order so that the second sentence comes first? Why is that?

- o **IF SWITCH**: If the order of these two sentences were switched, would you then change the order of any of the other information in the red box? **IF NEEDED**, In what order would you put these statements?

What does it mean to you when it says to store this medicine in a safe and secure place?

- Do you have any suggestions for a better way to explain how this opioid medicine should be stored?

After seeing this warning, what should you do with any unused medicine?

- Do you have any questions about the statement to “Dispose of unused medicine right away?” What are they?
 - o **IF YES**, How would you try to get answers to your questions about this statement?
- What does “right away” mean to you? **IF NEEDED**, When you stop taking the medicine? When you don’t expect to need it any longer? When it expires?
- Why do you think a web address is provided after the statement to “Dispose of unused medicine right away?” **IF NEEDED**, What would you expect to find on that website?
 - o Is it enough to say “Dispose of unused medicine right away” and provide a web address, or does more need to be said on this packaging? **IF NEEDED**, What else about the disposal of this opioid medicine needs to be said on the packaging?
- If your doctor prescribed an opioid for you and you saw this web address on the packaging, how likely are you to type the address into your internet browser and visit the website?
 - o What would make you more likely to visit the website?

Near the bottom of the red box it says to read the Medication Guide for additional information. Have you ever heard of a Medication Guide?

- **IF YES**, What kind of additional information does it include?
- **IF NO**, If you had to guess, what type of additional information do you think a Medication Guide might include?
- Where do you think you would get the Medication Guide?
 - o **IF UNSURE**, The statement says the Medication Guide is enclosed, which means it comes with the prescription opioid. Can you suggest a way to say that more clearly?

After looking at this packaging, what new information have you learned about opioid medicines?

Does anything you've read in this red box concern you? Why is that?

What additional questions do you have after reading this material?

IMPACT

How helpful is this packaging to you? Please respond on a scale of 1 to 5 where 1 is not at all helpful and 5 is extremely helpful.

- What makes you say {PARTICIPANT'S SCALE NUMBER}?
- Which parts of the material are of most interest to you?

Before seeing this packaging, you said you would store an opioid by [INSERT FROM BACKGROUND QUESTIONS]. Now that you've seen this packaging, how would you store this opioid medicine?

- **IF NO MORE SECURE**, It seems the material has not changed your mind about storing opioid medicines. Why is that?
- **IF MORE SECURE**, What about the material made you change your mind?

Before seeing this packaging, you said you would [KEEP, GET RID OF, SOMETHING ELSE] an unused opioid medicine in your home. Now that you've seen this packaging, what would you do with any of this unused medicine?

- **IF STILL KEEP**, It seems the packaging has not changed your mind about disposing of unused medicine. Why is that? What would the packaging need to say to encourage you to dispose of unused opioids?
- **IF CHANGE TO GET RID**, What about the material made you change your mind?

WRAP-UP

Do you have any other suggestions for improving this packaging?

- Is there any other information that is NOT needed or can be removed? **IF YES**, What information?
- Is there any other information that could be added? **IF YES**, What information?
- Is there any other information that could be stated more clearly? **IF YES**, What could be stated more clearly?

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 we haven't talked about that you would like to tell me?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.