

Search and Rescue Website 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 [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 get feedback from healthcare professionals about a website containing resources developed to assist prescribers tackle prescription opioid misuse, abuse, and addiction.

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

IF PARTICIPANT JOINS BY PHONE ONLY, ASK THEM TO OPEN THE WEBEX MEETING ON THEIR COMPUTER. IF PARTICIPANT IS NOT ABLE TO VIEW THEIR COMPUTER SCREEN, RESCHEDULE INTERVIEW.

Informed Consent

Before we get started, there are a few things I need to tell you. 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 that we will not share your name or contact information. The interview will take about 45 minutes and you will receive [\$100 (Primary care) OR \$150 (Specialists)] as a token of appreciation. We would like to record this conversation to make sure we hear everything you say correctly. 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 other members of the FDA research team are listening to this interview so they can hear directly from you.

Before we start, do you have any questions? Do you agree to be interviewed? Is it okay 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.

I have in my notes that you prescribe opioid analgesics for non-cancer pain about [number of times] per month on average. Is that accurate? **IF < 5 times/month, INELIGIBLE.**

Have you ever suspected that a patient might have a problem with prescription opioid misuse or abuse?

- **IF YES**, How did you handle that? What was the outcome? Is there anything you think might have helped prepare you for dealing with that situation?
- **IF NO**, If you suspected a patient might have a problem with prescription opioid misuse or abuse, what would you do? Is there anything you think might help prepare you for dealing with that situation?

What resources, if any, do you use when considering prescribing opioids for a new patient?

- What training, if any, have you completed related to opioids? **IF CME COURSES**, What about those CME courses was particularly helpful? Unhelpful?
- Do you use any other opioid-related guidelines? Which ones?
- How do you stay updated on changes being made to prescribing information on opioids?
- Are you aware of any websites or other online resources that provide prescribing information about opioids? **IF NEEDED**, Have you visited those sites? What were you looking for, and did you find it?

I am going to put a website on the screen now and hand control of the mouse to you. Please take a few minutes now to look at the homepage and the video **without clicking on any of the links that take you to different pages**. When you finish, I will ask you some questions about the site.

**CHECK IN AFTER 2 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.
REMIND RESPONDENTS TO WATCH THE HOMEPAGE VIDEO. IF RESPONDENTS NAVIGATE AWAY, DIRECT THEM BACK TO THE HOMEPAGE FOR NOW AND INFORM THEM THAT THEY WILL LOOK AT OTHER PAGES LATER.**

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.

RESEARCH QUESTIONS

What do participants understand to be the purpose of the website?

How intuitive do participants find navigation of the website to be?

Do participants indicate that any of the website's information is new to them?

Which resources provided on the website do participants find most useful and least useful?

What resources do participants recommend adding to the website?

What improvements do participants suggest for the website?

Will participants do anything as a result of visiting the website?

GENERAL IMPRESSIONS

Based on what you have seen, what is the purpose of this website?

What are your overall thoughts about what you see here on the homepage?

What do you like about it and why?

What don't you like and why?

How helpful is the video in explaining the purpose of this website? What makes you say that?

What do you think about the visual of the hand reaching down? How well does it go with the purpose of this website?

IF NEEDED (If this doesn't come up spontaneously under the previous questions):

What do you think is meant by Identify. Manage. Educate?

Does anything catch your attention? What do you want to click on first?

PRACTICE RESOURCES

[ASK PRIOR TO VIEWING] What would you expect to see if you clicked the Practice Resources link?

Please click the Practice Resources link and take a couple minutes to scroll through the content. I'd like you to get a general sense for what this page is providing by reading the short descriptions under each material. You are welcome to click on any of the materials, but know that my questions for you will be about this page generally, not about the specifics of any of the individual materials. **CHECK IN AFTER 2 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.**

How does what you see on this page compare with what you expected to see?

- Now that you've seen this page, how well does the name 'Practice Resources' describe its content? **IF NOT WELL OR POORLY**, What would you rename the link?

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

- Does separating the materials into the 4 sections make sense?
- How do the headings compare with the materials contained in each section? Would you change the names of any of the sections, and if so, which ones and how would you change them?
- Do you think any of these materials are intended to be shared with patients or are they just for physicians? **IF NEEDED**, Which ones are for patients?
- Would you change the order of any of the four sections?
- Would you move any of the materials into a different section?
- Which of the sections generally would be the most helpful to you and why? Least helpful and why?
- Are there any additional topic areas that you think should be included?

Of all the materials on this page, which ones do you think would be most helpful to you in your practice?

- How would you use these material(s) in your day-to-day work with patients?
- **IF "EDUCATE" MATERIALS NOT MENTIONED**, Would you provide any of the materials under the "Educate" header to your patients? Which ones, and why?

Of all the materials on this page, which do you think would be least helpful to you in your practice? Why is that?

- **IF “EDUCATE” MATERIALS NOT MENTIONED**, Are there any materials under the “Educate” header that you really can’t see yourself providing to patients? Which ones, and why?
- **IF NEEDED**, How much would the format of these materials, for example a PDF versus a weblink, affect your decision to provide them to patients? Do you prefer one format over another? Why?

What additional information, tools, or resources would be helpful to add? **IF NEEDED**, Would this additional information be a resource for you or your patients?

What opioid-related topics would be of interest to you for training or CME courses?

PATIENT MONITORING

[ASK PRIOR TO VIEWING] What would you expect to see if you clicked the Patient Monitoring link?

Please click the Patient Monitoring link at the top of the page and take a minute to scroll through the content. **CHECK IN AFTER 1 MINUTE. ALLOW 2-3 MORE MINUTES IF RESPONDENT CHOOSES TO WATCH THE VIDEO OR CLICK ON THEIR STATE PDMP SITE.**

DIRECT RESPONDENT BACK TO THE PATIENT MONITORING PAGE IF NEEDED. How does what you see on this page compare with what you expected to see?

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

- Would you change the order or placement of any of the information?

How helpful is this page in explaining state PDMPs generally? How well does this page describe your specific state’s Prescription Drug Monitoring Program/PDMP? Are there other terms your state uses to describe these programs, and if so what are they?

Are you registered for your state’s PDMP?

- **IF YES**, If you weren’t already registered, how helpful would this page have been in registering for your state’s PDMP? How often do you use your state’s PDMP? Will you use your state’s PDMP more consistently after visiting this website? Will you access your state’s PDMP through this website?
- **IF NO**, Were you not familiar with your state PDMP, or has something else prevented you from registering for it? Will you register for your state’s PDMP after visiting this website? How helpful is this page in registering for your state’s PDMP? Will you access your state’s PDMP through this website?

Can you think of any other information about state PDMPs that would be helpful to add?

OPIOID FACTS

[ASK PRIOR TO VIEWING] What would you expect to see if you clicked the Opioid Facts link?

Please click the Opioid Facts link at the top of the page and take a minute to scroll through the content. CHECK IN AFTER 1 MINUTE. ALLOW 1 MORE MINUTE IF NEEDED.

How does what you see on this page compare with what you expected to see?

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

- Would you change the order or placement of any of the information?

What do you think about the visuals on this page? How well do they go with each statistic? Would you suggest using any different visuals instead?

How helpful are the statistics provided on this page?

- How do you feel about some of these statistics being from 2018?

How helpful are the points outlined in the 'What Can You Do to Make a Difference' section?

What additional statistics or information would be helpful to add to this page?

IMPACT

Considering all pages on this website, what new information have you learned?

How helpful is this website in preparing you to handle a situation in which you suspect a patient might have a problem with prescription opioid misuse or abuse?

- Which page of the site was most helpful and why?

Will you do anything as a result of visiting this website? IF NEEDED, Share the link to this website with colleagues, seek out any additional training or resources, or something else?

- Why, or why not?

What would be a reason you would come back to this website? IF NEEDED, What information would most likely draw you back to this website?

What additional questions do you have after visiting this website?

WEBSITE WRAP-UP

Do you have any other suggestions for improving this website?

- How user friendly would you say this website is? Would you change or move anything to make it more intuitive?
- Is there any other information that is NOT needed or can be removed? **IF YES,** What information and why do you think it is unnecessary?
- 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 else you would like the FDA to know about this website or the resources included?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.

STOP TAPE RECORDER.