

Children's Cough and Cold Consumer Update

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 see what [people (parents/caregivers) OR healthcare professionals (Pediatric primary care)] think about health information related to medicines.

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 about 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.

Please wait to open the email attachment until I tell you it is time to start. After you look at the material inside the 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. 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 (parents/caregivers) OR \$100 (Pediatric primary care)] 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 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?

Research Questions

1. What is the main message that participants get from the material?
2. Do participants understand from the material that there is a difference between OTC and homeopathic products?
3. Are the recommendations clear to participants for children's homeopathic cough and cold products? For children's OTC cough and cold products?
4. Are the risks clear and understandable?
5. What do participants recognize as the call to action?
6. Do participants indicate that any of the material's information is new to them?
7. Do participants find any of the warnings concerning?
8. What information do participants find useful? Not useful?
9. For pediatrician participants, how useful of a tool is the material for communicating with parents/caregivers?
10. How well do participants think the visuals match the messages?
11. Is there information that is missing or that would be helpful to add?
12. How likely are parent/caregiver participants to give children under 4 homeopathic or OTC cough and cold products after reading?
13. How likely are pediatrician participants to recommend for children under 4 homeopathic or OTC cough and cold products after reading?

Background Questions

To start, I have a few general questions.

FOR PARENTS/CAREGIVERS

You told us when you volunteered for this interview that you have at least one child younger than 4 years old living in your household (**IF GRANDPARENT**, or that you watch regularly in your own home). Is this correct? **IF NO, TERMINATE**. Have you ever treated this child for a cough or cold?

- o **IF YES**, How did you treat this child's cough or cold?
 - o Did you give this child any cough and cold medicines or other products purchased over-the-counter without a prescription?
 - **IF YES**, Which ones, and for what purpose? Were any of these homeopathic products (**IF NOT SURE, explain we will discuss these later**)? Which ones?
 - How did you decide which over-the-counter medicines or products to treat this child's cough or cold with?
 - **IF NO**, How did you decide to not treat this child's cold with any over-the-counter medicines or other products?
 - **IF NEEDED FOR EITHER YES OR NO:**
 - Did you talk with this child's pediatrician or another healthcare professional about treating this child's cough or cold? Why or why not? **IF YES**, What advice did you receive?
 - Did you read any product labels? Why or why not? **IF YES**, What information were you looking for on the labels?
 - What risks are you aware of with using over-the-counter products to treat this child's cough or cold?
- o **IF NEEDED**, Other than any prescription or over-the-counter medicines or products, how else did you treat this child's cough or cold?
- o **IF NO**, If this child were to catch a cough or cold, how would you treat it? How would you decide whether or not to treat this child's cough or cold with any over-the-counter medicines or products? **IF NEEDED:**
 - o Would you talk with this child's pediatrician or another healthcare professional? Why or why not?
 - o Would you read any product labels? Why or why not? **IF YES**, What information would you be looking for?

- What risks are you aware of with using over-the-counter products to treat this child's cough or cold?
- **IF NEEDED**, Other than any prescription or over-the-counter medicines or products, how else would you treat this child's cough or cold?

What have you heard about homeopathic products? (**"NOTHING," "DON'T KNOW," AND "NOT SURE" ARE ALL ACCEPTABLE RESPONSES FOR THIS SECTION**)

- o What reasons have you heard for taking homeopathic products? What do you think are the benefits of using them?
- o Are homeopathic products the same or different from other over-the-counter medicines? How so? What about in terms of their safety and effectiveness?
- o What have you heard about giving homeopathic cough and cold products to children younger than 4 years old? What risks have you heard about?

FOR PEDIATRICIANS

What advice do you give parents of young children who have a cough or cold?

- o What do you tell parents of young children about giving cough and cold medicines purchased over-the-counter? What risks do you discuss with parents?
- o How does a child's age factor into your recommendations? At what age would you recommend that parents use over-the-counter medicines to treat their child's cold?
 - Which cough and cold products do you recommend parents give to children younger than 4 years old? Why?
 - Which cough and cold products do you recommend parents avoid giving to children younger than 4 years old? Why?

What advice do you give parents of young children about homeopathic products?

- o What do you tell parents are the benefits of using them? What risks of homeopathic products do you discuss with parents?
- o Have you ever recommended homeopathic cough and cold products for any child younger than 4 years old? Which ones have you recommended, and for what purpose?
- o How are homeopathic products different from other over-the-counter medicines? How are they the same? What about in terms of their safety and effectiveness?

IF NEEDED, Other than any prescription or over-the-counter medicines or products, how else do you recommend parents treat coughs and colds of children younger than 4 years old?

Now I am going to share my screen with you. Do you see a document titled “[INSERT CONSUMER UPDATE TITLE]?” This is a draft Consumer Update article that might appear on FDA’s website. Please take a few minutes to read it now. 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 2 MINUTES. ALLOW 1 MORE MINUTE 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.

GENERAL IMPRESSIONS

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

IF PARENT/CAREGIVER

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

IF PEDIATRICIAN

- What is it asking parents and caregivers to do?
- Why do you think FDA is telling parents and caregivers this information?

What are your overall thoughts about this article?

What do you like about it and why?

What don’t you like and why?

Is there too little or too much information and why?

IF PARENT/CAREGIVER, How easy or difficult is it to understand the information?

IF PARENT/CAREGIVER, Are there any words or phrases that confuse you or that you aren’t sure of?

Is there any information that could be stated more clearly? **IF YES,** What could be stated more clearly?

CONTENT

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

IF PARENT/CAREGIVER, After reading this article, what new information have you learned about treating children's coughs and colds?

IF PEDIATRICIAN, Does anything you've read in this article come as a surprise to you?

IF YES, What parts?

BOTH GROUPS:

- Based on this article, what is the minimum age for treating coughs and colds with over-the-counter medicines?
 - If FDA recommends over-the-counter cough and cold products not be used for children under 2 years of age, why do you think manufacturers say not to use these products in children under 4 years of age?
- Based on this article, what is the minimum age for treating coughs and colds with homeopathic products?

Based on this article, what is your understanding of the difference between over-the-counter medicines and homeopathic products?

- [Assuming side-by-side image of OTC and homeopathic products] What do you think about the visuals in this article? How well do they go with the content? Would you suggest using any different visuals instead?
- **IF PARENT/CAREGIVER**, The next time you are in the pharmacy, do you think you'd be able to tell over-the-counter medicines and homeopathic products apart from each other? **IF NOT**, What could be included in this article to help you tell the difference?

Are the risks of treating children with homeopathic cough and cold products clear and understandable? **IF YES**, What makes you say they are clear? **IF NO**, Can you say more about what isn't clear?

Are the risks of treating children with over-the-counter cough and cold products clear and understandable? **IF YES**, What makes you say they are clear? **IF NO**, Can you say more about what isn't clear?

- **IF PARENT/CAREGIVER**, Were you aware of all the other options for treating coughs and colds in young children without medications? **IF NO**, Which ones were new to you?
- **IF PEDIATRICIAN**, The article lists other options for treating coughs and colds in young children without medications. Are any options missing from this list? **IF YES**, What options would you add?

How trustworthy is the information in this article? What makes you say that? What could be done to increase trust in this information?

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

IF PARENT/CAREGIVER, What additional questions do you have after reading this article?

IF PEDIATRICIAN, What information is missing or would be helpful to discourage parents from treating children younger than 4 years old with these products? Why would this information be helpful?

IMPACT

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

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

IF PEDIATRICIAN, How useful would this article be to you in communicating to parents about treating children's coughs and colds? Please respond on a scale of 1 to 5 where 1 is not at all useful and 5 is extremely useful.

- o What makes you say {PARTICIPANT'S SCALE NUMBER}?
- o Which parts of the article are most useful to you?
- o Would you share this article with parents? Why or why not?

IF PARENT/CAREGIVER, Now that you've read this article:

- What situations, if any, might you break with the recommendation and treat your child under 4 years old with over-the-counter cough and cold medicines? How likely are you to break with the recommendation? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.
 - o What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What situations, if any, might you break with the recommendation and treat your child under 4 years old with homeopathic cough and cold products? How likely are you to break with recommendation? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.
 - o What makes you say {PARTICIPANT'S SCALE NUMBER}?

IF PEDIATRICIAN, Now that you've read this article:

- What situations, if any, might you break with the recommendation and advise parents to treat children under 4 years old with over-the-counter cough and cold medicines? How likely are you to advise parents to break with the recommendation? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.
 - o What makes you say {PARTICIPANT'S SCALE NUMBER}?
- What situations, if any, might you break with the recommendation and advise parents to treat children under 4 years old with homeopathic cough and cold products? How likely are you to advise parents to break with the recommendation? Please respond on a scale of 1 to 5 where 1 is very unlikely and 5 is very likely.
 - o What makes you say {PARTICIPANT'S SCALE NUMBER}?

WRAP-UP

Do you have any other suggestions for improving this article?

- Is there any 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 article or communicating about treating children's coughs and colds?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.
STOP TAPE RECORDER.