

**Moderator’s Guide  
Formative Interviews  
for Patient Medication Information Sheet  
Flesch-Kincaid Grade Level 6.2**

**Interview preparation notes:**

|                                 |              |
|---------------------------------|--------------|
| <b>First Name and Location:</b> | <b>Date:</b> |
|---------------------------------|--------------|

**Objective and Task**

**Objective:** To explore consumers’ reactions toward different prototypes of patient prescription drug information including information on the risks, benefits and safe use of the drug.

**Task Purpose:** To conduct formative testing with consumers to explore the contextual factors (i.e., reactions, usefulness, preferences, and understanding) related to sample FDA patient information sheet.

**Data Collection**

**Setting:** In-person interviews will take place in the RTI offices in DC, Raleigh and Atlanta and last approximately 60 minutes in length. A trained interviewer will lead the discussion. Interviews will be audio taped and transcribed.

**Consenting:** Written consent will be obtained at the beginning of the interview.

**Process:** The interview will comprise the following steps.

- 1. Welcome:**
  - a. **Welcome**—the interviewer will thank the participant for taking the time to participate and explain the purpose of the interview.
  - b. **Informed consent**—the interviewer will briefly review the consent form and obtain participant’s written consent.
  - c. **Warm-Up**—the interviewer will ask participant a few questions about their current medication use.
- 2. Formative Testing. We will use the following materials to collect participants insights – [FDA Sample Prototypes]**
- 3. Closing.** The interviewer will summarize the findings with the participant and ask for final thoughts.

## WELCOME

Thank you for taking the time to meet with me today. Your participation is very important. I'm \_\_\_\_\_ from RTI International, a nonprofit research organization. The purpose of this interview is to get your feedback on draft materials containing patient drug information. As part of our discussion today we'll be talking about what you like and don't like about the information as well as when and how you might want to receive the information. Your feedback is very important to us and will ultimately be used to help develop a final version of the materials. Our discussion will last about one hour.

[*Give participant informed consent form.*] Here are two copies of an informed consent form. Please take a moment to review it and if you agree to it, please sign one copy. The other copy is for you to keep for your records. It contains a telephone number you can call if you have any questions after our interview is over.

- The consent form states that you agreed to participate in an interview about patient prescription drug information.
- Your **identity and anything you personally say here will remain confidential** as permitted by law. Your name, address, and phone number will not be given to anyone, and no one will contact you after this interview is completed. When I write my report, I will not refer to you by name. We will look at the results of the interviews as a group, not individually.
- Your decision to take part in this research study is completely voluntary. You can refuse to answer any question during the study and you can stop participating at any time. If you decide to participate and later change your mind, you will not be contacted again or asked for further information.
- Most importantly, there are **no right or wrong answers**. We want to know your opinions and what you think about the materials.
- I would like to **audio record** our interview to ensure accuracy. I am going to take notes during our conversation, but I would like to go back and review our discussion to make sure that I have everything correct. Do I have your permission to audio record our interview today?
- Finally, do you have any questions before we begin?

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## **I. Subject's Preference for the Three Versions**

In this section of the interview, I am going to be asking you questions about three versions of the same patient medication patient information sheets (INTERVIEWER SHOWS THEM ALL THREE VERSIONS AT THE SAME TIME). Remember there are no right or wrong answers. Please take a couple of minutes to compare each of the versions.

1. Please tell me what you like or don't like about these versions.
2. Which one of the three versions do you like the most? Why?
3. Which one of the three versions do you like the least? Why?

Now I am going to be asking you a few questions about this version (INTERVIEWER SHOWS THEM THE VERSION THEY LIKED THE MOST IN TWO FONTS – SERIF AND SANS SERIF).

4. What differences, if any, do you see between the two versions?
  - a. [IF NOT MENTIONED] Did you notice the difference in the lettering of the two versions?
  - b. Which one of the fonts do you prefer? Why?

(INTERVIEWER THEN SHOWS THEM THEIR FAVORITE VERSION ROTATING WHO SEE THE DIRECTION FIRST AND WHO SEES THE WARNING FIRST)

5. What differences, if any, do you see between the two versions? [IF YES] What is the difference?
  - a. [IF NOT MENTIONED] Take a look at the "uses" section. Did you notice that the "direction for use" section was right after the "uses" section in this version but in this version "the important warning" section was right after the "uses" section?
  - b. Which version do you prefer? Why?

(NOTE TO INTERVIEWER - FOR REMAINING QUESTIONS USE THE VERSION THEY PREFERRED.)

## **II. Overall format of the version**

Now I want to ask you some questions about your general impressions of this patient information sheet:

6. Have you seen information like this before?
  - a. Where have you seen it?
  - b. How does this information compare to what you have seen before?
7. What do you think is the main point or purpose of this information sheet?
8. How well do you think that main point comes across?

9. You'll notice the patient information sheet is broken into several sections: (the uses, direction for use common side effects, etc.). How useful are these sections when thinking about taking a prescription medicine?
10. Are there any sections you think are missing?
  - a. [IF NO] Why?
  - b. What else would you would like to see in this patient information sheet?
  - c. What would you call that section?
  - d. What do you think about how the sections (the uses, direction for use, common side effects etc) in this patient information sheet are arranged?
    - i. Should the sections be arranged in different order?
    - ii. [IF YES] ,In what order would you like to see the sections arranged in the patient information sheet?
    - iii. Do you have other thoughts about the format or layout of this information?
    - iv. What are those?

### III. Questions about specific sections of the versions

Now, we are going to talk about the information in the different sections of this patient information sheet.

(INTERVIEWER WILL GIVE THEM THE VERSION THEY LIKED THE MOST IN THE FONT THEY PREFERRED)

Imagine you are given this patient information sheet when you fill your prescriptions at the drug store. I'd like you to read it now and let me know when you are done. Take as much time as you need.

(NOTE TO INTERVIEWER - GIVE THEM ENOUGH TIME TO READ THE PATIENT INFORMATION SHEET AND THEY SHOULD BE ALLOWED TO LOOK AT THE PATIENT INFORMATION SHEET WHILE ANSWERING THE QUESTIONS)

First, let's look at the title or headline (the name of the drug):

11. Some drugs have both generic and specific brand names. What comes to mind when I say the words "generic drug?"
12. How would you describe the difference between a generic drug and a brand name drug?
13. What would you say is the generic name for this drug?
14. Would you change anything about how the name of the drug is written?
  - a. [IF YES] How would you change it?

Now, let's look at the section called "uses".-

15. What do you think is the main point of this section?
16. What do you think of this information? (general impressions; assessment of confusion; unclear information)
  - a. Was anything confusing or unclear?

- b. Did you notice any unfamiliar or confusing words?
- c. Were there any phrases or words that particularly caught your attention?
  - i. What were those?
  - ii. Why did they stand out?
- d. What questions do you have after reading this section?
- e. After reading this information, do you think this kind of drug would be right for someone like you?
  - i. Why or why not?

17. Is there any other information you would like to see in this “uses” section?
- a. [IF YES] What?

Now let’s look at the section called, “directions for use”

18. What is the main point of this section?
19. What did you think about the information in this section?
20. How easy or difficult would it be for you to follow these directions?
- a. What would make them easy or difficult for you to follow?

Now let’s look at the section called, “important warnings: serious infections”:

21. What did you expect under this heading?
- a. What does this title mean to you?
    - i. Now that you know what we were looking for, what would have been a better title for this section?
22. What do you think of the information in this section? (general impressions; assessment of confusion; unclear information)
- a. Was anything confusing or unclear?
  - b. Did you notice any unfamiliar or confusing words?
  - c. What questions do you have after reading this section?
  - d. Were there any phrases or words that particularly caught your attention?
  - e. What were those?
  - f. Why did they stand out?
23. What did this section make you think about when you read it?
24. Is there any other information you would like to see in this “important warning” section?
- a. [IF YES] What?

Let’s look at the section called “tell your doctor”:

25. What does this title mean to you?
- a. Is this a good title for this section? (Why or why not)
  - b. [IF NO] What do you think is an appropriate title for this section?
26. What was the main point of this section?
27. What did you think about this section? (general impressions; assessment of confusion; unclear information)

- a. Was anything confusing or unclear?
- b. Did you notice any unfamiliar or confusing words?
- c. What questions do you have after reading this section?
- d. Were there any phrases or words that particularly caught your attention?
- e. What were those?
- f. Why did they stand out?
- g. Is there any other information you would like to see in this “Tell your doctor” section?
  - i. [IF YES] What?
- h. How likely would you be to tell your doctor if you had any of these symptoms after taking the medication – very likely, somewhat likely, or not at all likely?
  - i. Why or why not?
  - ii. What would make it easier to tell your doctor?

Let’s look at the section called, “call your doctor”:

- 28. What does this title mean to you?
  - a. Is this a good title for this section? (Why or why not)
  - b. [IF NO] What do you think is an appropriate title for this section?
- 29. What was the main point of this section?
- 30. What did you think about this information? (general impressions; assessment of confusion; unclear information)
  - a. Was anything confusing or unclear?
  - b. Did you notice any unfamiliar or confusing words?
  - c. What questions did you have after reading this section?
  - d. Were there any phrases or words that particularly caught your attention?
  - e. What were those? Why did they stand out?
  - f. Is there any other information you would like to see in this “call your doctor” section?
    - i. [IF YES] What?

Okay let’s look at one last section, the one called, “common side effects”:

- 31. What does the phrase “common side effects” mean to you?
- 32. Is this a good title for this section? (Why or why not)
  - a. [IF NO] What do you think is an appropriate title for this section?
- 33. What is the main point of this section?
- 34. What did you think of this section? (general impressions; assessment of confusion; unclear information)
  - a. Was anything confusing or unclear?
  - b. Did you notice any unfamiliar or confusing words?
  - c. What questions did you have after reading this section?
  - d. Were there any phrases or words that particularly caught your attention?
  - e. What were those?
  - f. Why did they stand out?
  - g. What did this section make you think about?

- h. If you had any of the common side effects that are listed on this medication information patient information sheet, how likely would you be to call the number listed or go to the website to report those side effects – very likely, somewhat likely, or not at all likely?
  - i. Why or why not?
  - ii. What would make it easier to report those side effects?
- i. Is there any other information you would like to see in this “common side effects” section?
  - i. [IF YES] What?

#### **IV. Additional thoughts about the Patient Information Sheet**

Since we have a few more minutes, we would like to get some additional information from you about this patient information sheet.

- 35. When would be the best time for you to get the information in this patient information sheet?
  - a. In the pharmacy or at your doctor’s office?
    - i. Where do you usually ask more questions?
- 36. How would you like to receive this patient information sheet?
  - a. In paper form or by e-mail?
    - i. If you got it in paper form, would you keep it?
    - ii. If you got it as an email, would you save that email?
- 37. If you were given the chance to make this patient information sheet better, what would you do?
- 38. Do you have any final thoughts to share about this patient information sheet?

#### **V. Closing**

Thank you for answering my questions. The information you provided will be very helpful in improving how patient drug information is presented in the future. In order to get an unbiased reaction to this information, it was necessary to use a fake brand of drug in this study. Rheutopia is not a real product and it is not available for use or sale. Please contact your healthcare provider for any questions about your health.