

Terms and Phrases: Meaning Elicitation Survey Interview Guide: Consumers

Overview:

1. **Introduction & Consent** (5 minutes)
The interviewer will provide background information about the project and get consent to proceed.
2. **Discussion** (50 minutes)
 - Terms and phrases
3. **Closing** (5 minutes): Thank you and incentive information.

List of Terms and Phrases for Consumers

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| 1. Convenient | 17. Restores; rebuilds |
| 2. Straightforward/simple/easy to use | 18. Many/most/some/few; majority |
| 3. Prevent; vs. help prevent; vs. reduce the incidence | 19. Prescription drug promotion versus prescription drug advertising |
| 4. Proven to help; proven effective | 20. reaction; serious reaction; severe, life-threatening reaction |
| 5. Natural | 21. Endpoint |
| 6. Targeted; acts locally, targeted mechanism of action | 22. Pure; purity |
| 7. Powerful; potent | |
| 8. #1 prescribed | |
| 9. New (as in new product) | |
| 10. Novel/unique; first and only; works differently (as in novel MOA or unique properties) | |
| 11. FDA-approved | |
| 12. Off-label | |
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I. Introduction & Consent

INTERVIEWER: Hello and thank you for making time to talk with me today.

My name is [] and I work for RTI International, a not-for-profit research organization located in Research Triangle Park, North Carolina.

The Food and Drug Administration has contracted with RTI to conduct interviews with health care providers and consumers to better understand how people interpret words and phrases that are commonly used in prescription drug promotion.

Informed Consent

Before we begin, I would like to review a few items:

Consent Form. I understand that you reviewed the informed consent form when you scheduled your appointment. Just a few highlights...

- **Participation.** Your participation is voluntary and you can stop participating at any time. If at any time you are uncomfortable with any question, you can choose not to answer.
- **Privacy.** Your name and contact information will not be given to anyone else and no one will contact you after our discussion is over.
- **Audio Recording.** To make sure that we capture everything people say today, we are making an audio recording of this discussion, which will later be transcribed. We will provide the FDA with a transcription and audio recording of our discussion. However, your name and any identifying information about you will not be included nor associated with the project or the report in any way.
- **Observation.** Members of our study team, including staff from FDA, may listen to today's discussion so they can hear your thoughts directly from you.
- **Reporting.** As part of this study, we will write a report for the FDA summarizing what we learned from these interviews. We will not use your name or any identifying information in the report.

Do you have any questions before we begin?

Do I have your consent to participate? [get a verbal "yes" then continue]

II. Discussion

For our discussion today, I'm going to be reading some words and phrases to you. I will also show them on the screen (confirm that the participant can see the test screen).

1. Convenient

SCREEN 1: "Taking one dose a day of Drug A is **convenient**."

Probe: As used in this context, what does "convenient" mean to you?

Probe: What does the word "convenient" suggest about drug A?

2. Straightforward/simple/easy/easy to use

SCREEN 1: "Drug B is **straightforward** to use."

Probe: As used in this context, what does the phrase "straightforward" mean to you?

Probe: What do you think about drug B when you hear that it is "straightforward" to use?

SCREEN 2: "Drug C is **simple** to use."

Probe: As used in this context, what does the phrase "simple" mean to you?

Probe: What do you think about drug C when you hear that it is "simple" to use?

SCREEN 3: "Drug D is **easy** to use."

Probe: As used in this context, what does the phrase "easy" mean to you?

Probe: What do you think about drug D when you hear that it is "easy" to use?

SCREEN 4: "Straightforward"
"Simple"
"Easy to use"

Probe: Is there a difference between these three phrases when used to describe a drug? If so, what is the difference(s)?

3. Prevent vs. help prevent vs. reduce the incidence

SCREEN 1: "Drug E is shown to **prevent** severe asthma attacks."

Probe: As used in this context, what does "prevent" mean to you?

Probe: What does the word "prevent" suggest about drug E?

SCREEN 2: "...shown to **help prevent** severe asthma attacks."

Probe: As used in this context, what does “help prevent” mean to you?

Probe: Is there a difference in meaning between “prevent” and “help prevent” as used in these contexts? If so, what is the difference?

Probe: Would your thoughts about drug E change depending on which phrase is used? If so, how would your thoughts change?

SCREEN 3: *Statement 1:* “...shown to **help prevent** severe asthma attacks.”

Statement 2: “...shown to **reduce the incidence** of severe asthma attacks.”

Probe: Does the phrase “reduce the incidence...” change the meaning of this claim? If so, how does it change the meaning?

4. **Proven to help; proven effective**

SCREEN 1: “Drug F is **proven to help** reduce the risk of severe asthma attacks.”

Probe: As used in this context, what does “proven to help” mean to you?

Probe: What does the phrase “proven to help” suggest about drug F?

SCREEN 2: “**proven effective** at reducing the risk of severe asthma attacks.”

Probe: As used in this context, what does “proven effective” mean to you?

Probe: Is there a difference in meaning between “proven to help” and “proven effective” as used in these contexts? If so, what is the difference?

Probe: Would your thoughts about drug F change depending on which phrase is used? If so, how would your thoughts change?

5. **Natural**

SCREEN 1: “Drug G is a prescription medication that’s made from a **natural** ingredient: omega-3 fish oil.”

Probe: As used in this context, what does the word “natural” mean to you?

Probe: When you hear that a drug is made from a “natural” ingredient, what does that make you think? Is it more or less effective than other drugs? Safer or less safe? Why?

6. **Targeted; acts locally; targeted mechanism of action**

SCREEN 1: “Drug H helps prevent migraine by **targeting** and blocking calcitonin gene-related peptide (CGRP) receptors . . .”

Probe: As used in this context, what does the word “targeting” mean to you?

Probe: What do you think about drug H when you hear that it “targets” receptors?

SCREEN 2: “Drug I **acts locally** to help address migraine”

Probe: As used in this context, what does “acts locally” mean to you?

Probe: Is there a difference between a drug that provides “targeted therapy” vs. a drug that “acts locally”? If so, what is the difference?

SCREEN 3: “Drug J has a **targeted mechanism of action** to help address migraines.”

Probe: As used in this context, what does the phrase, “targeted mechanism of action” mean to you?

Probe: What do you think about drug J when you hear that it has a “targeted mechanism of action”?

7. Powerful; potent

SCREEN 1: “Drug K is a **powerful** single-tablet regimen with a high barrier to resistance.”

Probe: As used in this context, what does the word “powerful” mean to you?

Probe: What do you think about drug K when you hear it being described as “powerful”?

SCREEN 2: “Drug L is a **potent** single-table regimen with a high barrier to resistance.”

Probe: As used in this context, what does the word “potent” mean to you?

Probe: What do you think about drug L when you hear it being described as “potent”?

8. #1 prescribed

SCREEN 1: “Drug M is the **#1 prescribed** weight loss brand”

Probe: As used in this context, what does “#1 prescribed” mean to you?

Probe: What do you think about drug M when you hear it is the “#1 prescribed” brand?

Probe: Does hearing that the drug is the “#1 prescribed” brand make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

9. New (as in new product)

SCREEN 1: “Drug N is **new**”

Probe: What do you think of a drug that is described as “new”?

Probe: Does hearing that the drug is “new” make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

10. Novel/unique; first and only; works differently (as in novel MOA or unique properties)

SCREEN 1: “Drug O works **differently.**”

Probe: As used in this context, what does the phrase “works differently” mean to you?

Probe: What do you think about drug O when you hear that it “works differently”?

Probe: Does hearing that the drug “works differently” make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

SCREEN 2: “Drug P is the **first and only** drug to...”

Probe: As used in this context, what does the phrase “first and only” mean to you?

Probe: What do you think about drug P when you hear that it is the “first and only” drug...?

SCREEN 3: “Drug Q has a **novel** mechanism of action.”

Probe: As used in this context, what does the word “novel” mean to you?

Probe: What do you think about drug Q when you hear that it works in a “novel” way?

Probe: Does hearing that the drug works in a “novel” way make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

SCREEN 4: “Works differently”

“First and only”

“Novel”

Probe: Is there a difference between these three phrases when used to describe a drug? If so, what is the difference(s)?

Probe: Do you think one phrase suggests that a drug is more or less effective compared to a drug described with the other phrases? If so, which phrase(s) and how?

11. FDA-approved

SCREEN 1: “Drug R is a prescription drug available for the treatment of plaque psoriasis. Drug R is FDA approved.”

Probe: What do you think of a drug that is described as “FDA-approved”?

Probe: Does hearing that something is “FDA-approved” make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

12. Off-label

SCREEN 1: "Drug S is used **off-label**"

Probe: What does "off-label" mean to you in the context of prescription drugs?

Probe: If you hear that a drug is being prescribed "off-label" does that affect your opinion on whether the drug will work? If so, how?

Probe: If you hear that a drug is being prescribed "off-label" does that affect your opinion about the drug's safety?

Probe: Does hearing that a drug is prescribed "off-label" make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

13. Reverses

SCREEN 1: "Drug T **reverses** bone loss."

Probe: As used in this context, what does the word "reverses" mean to you?

Probe: What do you think about drug T when you hear that it "reverses" bone loss?

Probe: Does hearing that the drug "reverses" bone loss make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

14. Individual results may vary

SCREEN 1: "Cure means no virus found in the blood 3 months after treatment ends.
Individual results may vary."

Probe: As used in this context, what does the phrase "individual results may vary" mean to you?

Probe: What do you think about a drug when you hear that "individual results may vary"?

Probe: Would it impact your decision to ask your doctor about the drug? If so how, how would it impact your decision?

15. Significant (as in statistically significant)

SCREEN 1: "Compared with placebo, people taking drug U saw a slight decrease in respiratory symptoms. It is not certain if drug U was responsible for this decrease."

Probe: In your own words, what is this statement saying?

SCREEN 2: “Compared with placebo, people taking drug V saw a slight decrease in respiratory symptom score. This change was not **statistically significant.**”

Probe: What do you think of a treatment effect that is described as “not statistically significant”? One that is described as “statistically significant”?

Probe: What impact would it have on your decision to ask your doctor about drug V?

16. Manageable safety profile; established safety profile; well-studied safety profile; well-tolerated

SCREEN 1: *Statement 1:* Drug W offers a **manageable safety profile.**

Statement 2: Drug X offers an **established safety profile**

Statement 3: Drug Y offers a **well-studied safety profile.**

Statement 4: Drug Z is **well-tolerated.**

Probe: What do the phrases [READ PHRASES] mean to you in relation to prescription drugs? Do they all mean the same thing, or are there differences in what they mean? If so, how do they differ?

Probe: What do you think about a drug when you read that it has an “established safety profile”?

17. Restores; rebuilds

SCREEN 1: “Drug AA **restores** vaginal tissue.”

“Drug BB **rebuilds** vaginal tissue”

Probe: As used in this context, what does “restores” mean to you? What about “rebuilds”? Do the meanings of these words differ? If so, how do they differ?

Probe: What do you think about a drug when you hear that it “restores or rebuilds” vaginal tissue?

18. Many/most/some/few; majority

SCREEN 1: “For **many**, drug CC cuts the number of monthly migraine days in half... or more! ...with some people being migraine-free.”

Probe: As used in this context, what does “many” mean to you? How many (or what %) of people?

Probe: What do you think about drug CC when you hear that it works for “many” people?

SCREEN 2: “Many”

“Most”

“Some”

“Few”

“Majority”

Probe: Is there a difference between the phrases “many,” “most,” and “the majority”? If so, what is the difference? What about “some” and “few”?

19. Prescription drug promotion versus prescription drug advertising

SCREEN 1: Prescription drug promotion

Prescription drug advertising

Probe: What does the phrase “prescription drug promotion” mean to you? What about the phrase “prescription drug advertising”?

Probe: Is there a difference between the phrases “prescription drug promotion” and “prescription drug advertising”? If so, what is the difference?

20. Reaction; serious reaction; severe, life-threatening reaction

SCREEN 1: “Drug DD can cause reactions.”

Probe: As used in this context, what does the word “reactions” mean to you?

Probe: What do you think about drug DD when you hear that it can cause reactions?

SCREEN 2: “Drug EE can cause serious reactions.”

Probe: As used in this context, what does the phrase “serious reactions” mean to you?

Probe: What do you think about drug EE when you hear that it can have “serious reactions”?

SCREEN 3: “Drug FF can cause severe, life threatening reactions.”

Probe: As used in this context, what does the phrase “severe, life threatening” reactions mean to you?

Probe: What do you think about drug FF when you hear that it can have “severe, life threatening reactions”?

SCREEN 4: Reaction

Serious reaction

Severe, life threatening reaction

Probe: Is there a difference between a “reaction” and a “serious reaction”? If so, what is the difference?

Probe: Is there a difference between a “serious reaction” and a “severe, life threatening reaction”? If so, what is the difference?

21. Endpoint

SCREEN 1: “Drug GG’s effectiveness was based on clinical trial **endpoints**.”

Probe: What does the word “endpoint” mean to you when it is used in this context?

22. Pure

SCREEN 1: “Drug HH is a “**pure**” solution.”

Probe: As used in this context, what does the word “pure” mean to you?

Probe: What do you think about drug HH when you hear it being described as a “**pure**” solution?

Probe: Does hearing that the drug is a “pure” solution make you think it is safer or less safe than other drugs? More or less effective than other drugs? Why?

SCREEN 2: Drug II follows strict “**purity**” standards.

Probe: What do you think about Drug II when you hear that it follows strict “purity” standards.

Probe: What do “purity” standards means to you?

Probe: Does hearing that the drug is follows strict “purity” standards make you think it is safer or less safe than other drugs? More effective or less effective than other drugs? Why?

III. Conclusion

These are all of my questions. Is there anything else you would like to share before we wrap up?

To obtain the most objective responses, the drug names used as examples in this survey are not for real drugs.

Thank you for your time. You will receive a check for \$75 in the mail in approximately 4-6 weeks.