

**Cognitive Interview – Moderator’s Guide**  
**Project CONFER: Cognitive Interviews to Optimize the DFL (Task 1)**  
**August 2016**

**Goals:**

To obtain feedback about a model DFL from potential end users of OTC Naloxone through the administration of unstructured cognitive interviews with defined user segments.

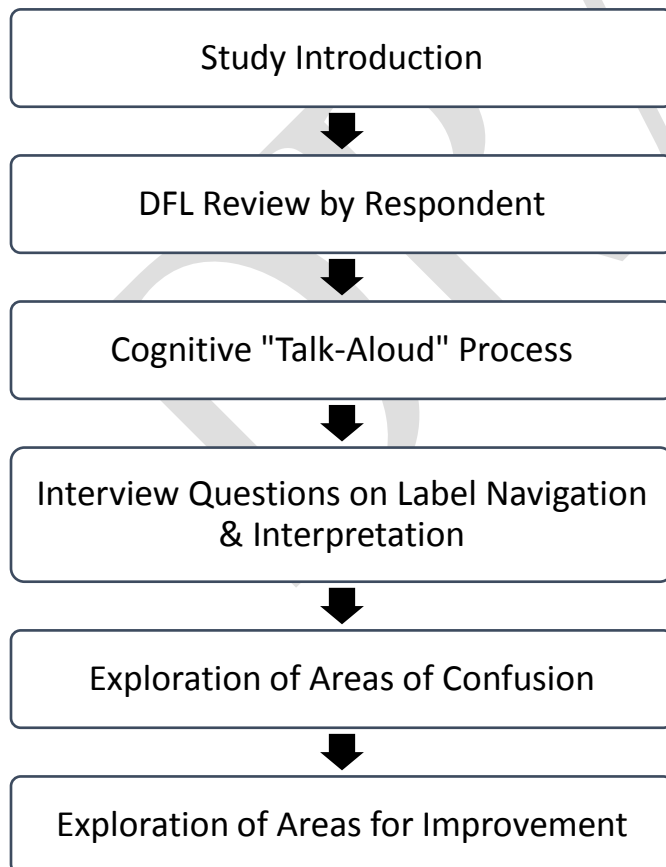
**User Groups:**

- Group 1: Prescription opioid users/associates (n=9)
- Group 2: Heroin users/associates (n=9)
- Group 3: Adolescent opioid or heroin users/associates (n=9)
- Group 4: All comers (nearly 100% low literacy, including pregnant women) (n=9)

**Key Topics:**

- Text (Perceptions about product use, key safety and risk messages)
- Pictograms (Interpretation, potential areas of confusion)
- Overall flow and content, usefulness, areas of confusion, input on improvements

**Interview Flow:**



**A. Introduction/Warm up****3 min*****Introduction***

Welcome and thank you for agreeing to participate today. We have asked you here today to talk about the label for drug that may become available over-the-counter, which means that no prescription will be needed.

***Ground Rules:***

- *Explain we are audio-recording and if the interview is being observed*
- *Explain there are no right or wrong answers, active part in the interview – asking in-depth questions, not just yes/no/ varying answers*
- *Explain that we need their honest input and feedback*
- *Explain the moderator does not work for the company who makes the drug or write the directions that they will look at*
- *Put respondent at ease about this topic and this drug*
  - *There are other people of all potential user groups included in interviews*
  - *We are not intending to sell or influence them; need their input.*
  - *We are not going to ask questions about their personal use of any drugs in this interview.*
- *Explain purpose: OTC products give different types of warnings and directions on the label and we need their help to make sure that this product can be used safely and appropriately - looking more for someone to help us assess the label*

**B. Respondent Review of the Draft Drug Facts Label****3 min*****Hand the respondent the DFL -***

“Here is a possible new label for this drug. Please take a few minutes and read the label. Take all the time that you need. Then we will talk more about it.”

**C. Purpose of Drug****1 min**

1. After reading the label, what do you think this drug is for?
  - a. How do you know that? [IF NEEDED: Can you point me to where you saw this information?]

**D. Talk-Aloud Cognitive Interview****8 min**

1. “Imagine you were in a situation where you had to use this product on a friend. Talk out loud and explain to me what you would do.”
  - a. Document verbatim responses
  - b. Document sequence
  - c. Document areas of stated or apparent confusion
  - d. Document areas that are incorrect and further explore.
2. **Explore incorrect responses:** “Thank you – you mentioned that you should do X or Y (cite incorrect responses) – tell me more about why you gave this response.”

**E. Label Navigation and Interpretation****24 min**

1. “Where did your eyes go first on this label? What did you see first?”
2. “Look at the Uses section. What is this telling you?”
3. “What is the Warnings section telling you?”
4. “Focus on #1 – What are the words telling you? What does the picture mean to you?”
5. “Focus on #2 – What are the words telling you? What does the picture mean to you?”
6. “Focus on #3 – What are the words telling you? What does the picture mean to you?”
7. “Focus on #4 – What are the words telling you? What does the picture mean to you?”
8. “Focus on #5 – What are the words telling you? What does the picture mean to you?”

**“Now I have some questions about some specific words or phrases on the label.”**

- “What does “temporary emergency” mean?”
- “What are the signs of opioid overdose?”
- “What are examples of opioids?”
- “Are opioids street drugs or prescription drugs?”
- “What are some examples of ‘prescription pain medicines’ that are opioids?”
- “Tell me about what you think “rub knuckles hard in the middle of the chest” means?”
- “When do you think you should call 911?”
- “How would you watch the time between doses (i.e. “watch 2-3 min”)?”

**F. Confusion****3 min**

1. “Was anything on the label confusing?” (Ask participant to point to area or verbalize)  
**Explore what was confusing.**

**G. Improvements****3 min**

1. “Is there anything they could improve or make better?”
2. **Explore:** “Do you have any other suggestions?”

**H. Wrap Up****3 min****Moderator: Check with back room for additional questions.**

1. Is there anything else you want to tell me about this labeling?

**Thank the respondent and end the interview.**