

PROMIS II-HIV

Concept Elicitation Interview Guide – Depressive Symptoms

(45 minutes)

Note to Interviewer: Please read or paraphrase the below interview script.

Introduction:

Before we start with the interview, I want to give you an idea of the overall goal of our study. This study is trying to improve health questionnaires that are used in clinics like this one. The first questionnaire that we are trying to improve is a depression questionnaire. We would like the depression questionnaire to have questions that are relevant to patients and useful for health care providers. Basically, we want to make sure that the questionnaires you fill out in the clinic ask questions that you would want your doctor or nurse or other health care provider to know about. And also that the questionnaire gives useful information about you to the clinics' health care providers so that they can give you better health care.

The purpose of this interview today is to find out from you and other patients at [name of clinic] in this clinic your experience with feeling sad or depressed to understand if patients who are HIV positive have different experiences than other patients. The first part of this meeting, I will be asking you questions about your experiences. The second part of the meeting, I will give you a depression questionnaire to fill out and will ask you to give me feedback about the questionnaire to see how we can improve the questions.

The meeting will take about 90 minutes of your time. I will use an audio recorder to record our conversation so that a transcript of our conversation can be made. In order to protect your identity please avoid using your name or any other person's name who you know.

Are you ready to begin the interview? Do you have any questions before we start?

Feeling sad or depressed is common for people living with HIV. We are trying to learn more about these feelings and how they affect patients, in order to improve how health care providers can give better care to patients experiencing these feelings.

General experiences:

- *Have you ever felt sad or depressed for a period of time?*
- *How long have you had experiences feeling sad or depressed?*
- *Has it been ongoing over time or just happens for short periods?*
- *Is there something in your life that causes you to feel sad or depressed?*

For these next questions let's just focus on your experiences with being depressed in the past six months or so.

In order to give you a better idea of the type of information we are looking for, I want to read for you a couple of depression questions that you may be familiar with from the computer assessment that you have taken in the clinic. **[READ THE PHQ 9 ITEMS BELOW]**

1. **Over the last 2 weeks, how often have you...** [NOTE TO INTERVIEWER: IF NEEDED, THESE CAN BE USED AS EXAMPLES OF THE LEVEL OF DETAIL WE ARE SEEKING, NOT AS INTERVIEW QUESTIONS HOWEVER]
 - a. Had little interest or pleasure in doing things?;
 - b. Felt bad about yourself, felt that you are a failure, or feel that you have let yourself or your family down?;
 - c. Had trouble concentrating on things such as reading the newspaper or watching television?;
 - d. Think that you would be better off dead or that you want to hurt yourself in some way?

Now, let's talk about your experiences with depression in the past 6 months or so.

- *Have you recently been experiencing feelings of being depressed or sad?*

What does being sad or depressed feel like for you?

- *What words come to mind when thinking about your own feelings of being depressed or sad?*
- *What words or phrases do you use to describe depression to family or friends in terms of symptoms or feelings?*
- *What emotions do you experience when you are depressed?*
- *How does your body feel when you are depressed?*
- *Do you experience physical sensations that are different than usual when you are depressed? If so, what?*
- *Can you tell me about the worst experience you have had with depression? How does it compare to other times that you have been depressed?*
- *Do your activities or behaviors change when you are depressed? If so, are there certain things you do that you didn't do before?*
- *Recently, have there been times when you feel really –a positive sense of well-being? If so, what are you feeling? What are you thinking? What are you doing to make this happen?*

How do you know when you are depressed?

- *How do you identify when you're depressed? How do you know you are a little depressed compared to extremely depressed?*

- When things are going well for you, what changes?

What do you think causes your feelings of depression?:

- *What causes you to feel sad or depressed? Think about a time when you felt sad or depressed. Can you tell me what you were feeling? Can you describe your thoughts? Can you describe how you were behaving or acting?*
- Is there something specific to being HIV positive that affects your feelings?
- Is there something specific to having a chronic disease like HIV that affects your feelings?

How does depression affect your life?:

- *What impact has depression had in your life? How does it affect your relationships?*
- *What are the biggest things that change when you are depressed? (If anything), what's lessened or taken away when you are depressed? (If anything), what emerges or increases when you are depressed?*
- *What keeps you going when you are going through difficult times?*

What's it like talking to your doctor about depression?:

- *What would you like to tell your doctor or clinician about your experience with depression? By this we mean to ask if there is something about depression symptoms that your doctor may not know about, may under-appreciate, or may frankly ignore.*
- *Do you feel there are aspects of your depression that your doctor not understand or ignore?*
- *Do you describe depression differently to loved ones than doctors?*
- *Consider the questions that we looked at at the start of the interview, these questions are meant to give information to the doctor about how you are feeling emotionally, is there something more that you want your doctor to know about your feelings of depression?*
- *Is there anything about your feelings about depression that you think we haven't covered?*

[CHECKLIST FOR INTERVIEWER: PLEASE REVIEW WITH PARTICIPANT ANY AREAS BELOW THAT MAY NOT HAVE BEEN DISCUSSED]

1. Do you experience any changes in your **FEELINGS OR MOOD** when you are depressed?
2. Do you experiences any changes in **HOW YOU THINK** when you are depressed?
3. Does your **BEHAVIOR** change when you are depressed?
4. Do you experience any **PHYSICAL SENSATIONS** or **CHANGES IN YOUR BODY** when you are depressed?

5. In the past, when you may have been depressed have you ever had **THOUGHTS OF KILLING YOURSELF OR DOING HARM TO YOURSELF?**

6. Imagine you are seeing a new doctor or social worker here at the clinic who knows nothing about your experience with depression. What would be the most important things you would like to **TELL THIS PERSON ABOUT YOUR DEPRESSION** so that he or she could help you?

PROMIS II-HIV

Concept Elicitation Interview Guide - Anxiety

(60 minutes)

Note to Interviewer: Please read or paraphrase the below interview script.

Introduction:

Before we start with the interview, I want to give you an idea of the overall goal of our study. This study is trying to improve health questionnaires that are used in clinics like this one. One of the first questionnaires that we are trying to improve is an anxiety questionnaire. We would like the anxiety questionnaire to have questions that are relevant to HIV patients and useful for health care providers. Basically, we want to make sure that the anxiety questionnaires you fill out ask questions that you would want your doctor or nurse or other health care provider to know about. And also that the anxiety questionnaire gives useful information about you to the clinics' health care providers so that they can give you better health care.

The purpose of this interview today is to find out from you and other patients at [name of clinic] who are HIV positive your experience with Anxiety. The first 10-15 minutes of this meeting, I will be asking you questions about your experiences with anxiety. The second part of the meeting, I will give you an anxiety questionnaire that we are trying to improve and ask you to answer the questions and then give me feedback about the questions. I will also ask you if you think there is missing information.

The meeting will take about 60 minutes of your time. I will be using an audio recorder during the meeting to capture our conversation. In order to protect your identity, please use an alias and not your real name.

Are you ready to begin the interview? Do you have any questions before we start?

Step 1: 10-15 minute discussion about anxiety experiences.

Feeling anxious is a common issue for people living with HIV. I would like to learn more about your experiences with anxiety in the past 6 months or so.

What words come to mind when thinking about your own feelings of being anxious?

Consider a time when you felt anxious. What was that like? Describe your thoughts and your behavior. What did it feel like?

Step 2. Anxiety Short form responses:

Now I would like you to complete a short anxiety questionnaire. Once you have completed the questions, I will go through how you answered each question and how the questions relate to your experiences with anxiety.

Interviewer: Hand 7-item PROMIS Anxiety short form to participant and ask them to fill out.

- “How did you answer question 1?” OR alternatively “I see you marked ‘sometimes’ for question 1, *I felt fearful*”
- “Can you tell me what your response (i.e. ‘rarely’, ‘all of the time’) means to you in relation to having anxiety?”
- Complete review of all 7 items.

In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
1 I felt fearful...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

Never Rarely Sometimes Often Always

2 I felt anxious...

₁ ₂ ₃ ₄ ₅

Notes:

Never Rarely Sometimes Often Always

3 I felt worried...

₁ ₂ ₃ ₄ ₅

Notes:

Never Rarely Sometimes Often Always

4 I felt it hard to focus on anything other than my anxiety...

₁ ₂ ₃ ₄ ₅

Notes:

Never Rarely Sometimes Often Always

5 I felt nervous ...

₁ ₂ ₃ ₄ ₅

Notes:

Never Rarely Sometimes Often Always

6 I felt uneasy ...

₁ ₂ ₃ ₄ ₅

Notes:

Never Rarely Sometimes Often Always

7 I felt tense ...

₁ ₂ ₃ ₄ ₅

Notes:

Step 3: Identify missing items:

The last step today is to find out from patients living with HIV what items or questions about anxiety are missing from the questionnaire. I would like to review the questions on the questionnaire that you said are issues for you.

- You mentioned that items [*read items where participant responded 'sometimes', 'often' or 'always'*] are all issues that you experience when you have anxiety. Is that correct?
- What other aspects of anxiety do you experience that are missing from this questionnaire?
- “From your experience what other things are important to anxiety that is not on the questionnaire that you think should be added to the short form?”
 - Possible probes:
 - Tell me more about that?
 - Can you think about any additional symptoms or feelings you have when you are anxious?
- In what way do you think the 7-items on this questionnaire provide enough information about your level of anxiety to your clinic provider?
- Anything else you would like to add before we end our meeting?

Thank you so much for all of the information you have shared with me today. We will be interviewing other participants and then review all of the information we have to create an anxiety questionnaire that is more relevant to patients and clinicians.

End meeting.

Note to interviewer:

Interviewer please review notes and transfer the patient responses and your notes onto to the “PROMIS II HIV Anxiety concept elicitation interview spreadsheet” and send spreadsheet & audio file to UW through Catalyst.

Questionnaire for Participant to fill out

Emotional Distress - Anxiety – Short Form 1

Please respond to each item by marking one box per row.

In the past 7 days...

		Never	Rarely	Sometimes	Often	Always
EDAIEX01	I felt fearful.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDAIEX02	I felt anxious.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDAIEX03	I felt worried.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDAIEX04	I found it hard to focus on anything other than my anxiety.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDAIEX05	I felt nervous.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDAIEX06	I felt uneasy.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDAIEX07	I felt tense.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Anxiety Questionnaire: Cognitive Interview
Review & Feedback by Participants
(45 minutes)

The purpose of this interview is to assess the wording and clarity of an anxiety questionnaire that has been used with diverse patient groups in different health clinics. We need to evaluate if it is relevant to patients with HIV. We are asking patients like you to help us improve this questionnaire. As you answer each question, please comment freely on the questions themselves, i.e., if any of the questions seem unclear. We welcome any feedback.

Of special interest to us is whether you feel there are essential aspects about your experience with anxiety and HIV that are missing from this questionnaire.

Interviewer Note:

Please have two copies of the PROMIS-1 anxiety 29-item questionnaire available.

MS Word document "Anxiety Bank Questionnaire 29 items"

Provide a copy to the participant and explain to the participant that for the first three questions on the questionnaire you will go over with the participant his/her understanding of each one. After the first three questions, please instruct the participant to go ahead and finish answering the questionnaire on their own. Please explain that when they are finished, you will review how they understood each question as modeled in the first three questions that you reviewed together with the participant.

ADMINISTER ANXIETY ITEMS

Now that you have completed the questionnaire, I will ask you some questions about areas where the questionnaire can be improved. Let's Begin...

Overall Comments:

- *Overall, how easy or difficult was this for you to complete the questionnaire? What was easy? What was difficult?*
- *Did you read the instructions? Were the instructions clear? Would you please tell me in your own words what the instructions mean?*

INTERVIEWER: REVIEW FOR EACH ITEM

Comprehension/ Understanding:

- *Was the wording clear? Was there a word that you focused on to answer this more than another?*
- *How did you interpret the question, what does it mean to you?*
- *What were you thinking of, recalling, or picturing when you answered this question?*
- *Do you have suggestions for how the question could be re-worded to make it clearer?*

Recall Period/Response options:

- *Is the time frame for the question reasonable? If not, what timeframe did you consider when completing these items? What specific days did you include (from what day to what day)?*
- *Did the response options make sense?*

Item Response Categories

Never
Rarely
Sometimes
Often
Always

- *How easy is it to tell the difference between each choice?*
- *How do you distinguish “sometimes” from “often?” Is “often” more or less frequent than “sometimes?”*

Missing Information/Comments:

- *During the first part of our meeting, you talked about [DOMAIN] in relation to being HIV positive. Now that you have looked over some of the items we have on our questionnaire...*
 - *What is missing from the questionnaire list that is relevant to your experience that you feel your health care provider should know about?*
 - *How do you think these questions could help your health care provider give you better medical care?*

-- Finally, are there any important issues missing from the questionnaire?

PROMIS II-HIV

Concept Elicitation Interview Guide - Fatigue

(45 minutes)

Note to Interviewer: Please read or paraphrase the below interview script.

Introduction:

Before we start with the interview, I want to give you an idea of the overall goal of our study. This study is trying to improve health questionnaires that are used in clinics like this one. One of the questionnaires that we are trying to improve is a questionnaire about fatigue.

We would like the fatigue questionnaire to have questions that are relevant to HIV patients and useful for health care providers. Basically, we want to make sure that the fatigue questionnaires you fill out ask questions that you would want your doctor or nurse or other health care provider to know about so they can give you the best health care possible.

When we use the word 'fatigue' we mean any feelings of tiredness to feeling completely worn out and lasting a long time.

The purpose of this interview today is to find out from you and other patients at [name of clinic] who are HIV positive your experience with Fatigue. The first 15-30 minutes of this meeting, I will be asking you questions about your experiences with fatigue. The second part of the meeting, I will give you a fatigue questionnaire that we are trying to improve and ask you to answer the questions and then give me feedback about the questions. I will also ask you if you think there is missing information.

The meeting will take a total of about 90 minutes of your time. I will be using an audio recorder during the meeting to capture our conversation. In order to protect your identity, please use an alias and not your real name.

Are you ready to begin the interview? Do you have any questions before we start?

Step 1: Semi-structured discussion about fatigue experiences.

I would like to learn more about your experiences with fatigue.

1. Please describe for me what being tired, worn out, or fatigued is like for you.
2. Consider a time when you felt tired, worn out, or fatigued. What was that like?
3. Would you say being tired, worn out, or fatigued affects your daily life? If so, how?
4. Would you say being tired, worn out, or fatigued affects your health? If so, how?

Step 2. Administer fatigue short form

Now I would like you to complete a short fatigue questionnaire. Once you have completed the questions, I will go through how you answered each question and how the questions relate to your experiences with fatigue.

Interviewer: Hand 8-item PROMIS Fatigue short form to participant and ask them to fill out.

End of Concept elicitation interview

Fatigue Questionnaire: Cognitive Interview
Review & Feedback by Participants
(45 minutes)

The purpose of this interview is to assess the wording and clarity of a fatigue questionnaire that has been used with diverse patient groups in different health clinics. We need to evaluate if it is relevant to patients with HIV. We are asking patients like you to help us improve this questionnaire.

Of special interest to us is whether you understand all of the questions and also if you feel there are essential aspects about your experience with fatigue and HIV that are missing from the questionnaire.

Interviewer Note:

Please have two copies of the PROMIS-1 fatigue questionnaire available.

MS Word document "Fatigue Bank Questionnaire"

Provide a copy to the participant and explain to the participant that you will interview him/her after s/he finishes the set of questions on each page. After the first page of questions, review their comprehension of each question.

ADMINISTER FATIGUE ITEMS

Let's Begin...Please answer the questions on the first page of the questionnaire. Once you have completed answering those questions we will review each one together.

INTERVIEWER: REVIEW FOR EACH ITEM

Comprehension/ Understanding:

- *Can you explain the meaning of this question/item in your own words?*
- *What were you thinking of, recalling, or picturing when you answered this question?*
- *What does [word] mean in this question?*
- *How easy is it to tell the difference between each choice?*
- *How do you distinguish "sometimes" from "often?" Is "often" more or less frequent than "sometimes?"*
- *Is this question clear to you? Is the wording clear to you? Was there a word that you focused on to answer this more than another?*
- *Do you have suggestions for how the question could be re-worded to make it clearer?*

Missing Information/Comments:

During the first part of our meeting, you talked about [DOMAIN] in relation to being HIV positive. Now that you have looked over some of the items we have on our questionnaire...

- *What is missing from the questionnaire list that is relevant to your experience that you feel your health care provider should know about?*

- *How do you think these questions could help your health care provider give you better medical care?*

-- Finally, are there any important issues missing from the questionnaire?

Step 2. Cognitive Interview of Fatigue Questionnaire (see Cognitive interview guide):

Now I would like you to complete a fatigue questionnaire. Once you have completed the questions, I will go through how you answered each question and how the questions relate to your experiences with fatigue.

**Interviewer: Give Fatigue questionnaire to participant and ask them to fill out.
 Note: Only ~32-items (approximate number of items) derived from 95 item PROMIS Fatigue item banks will be administered to participants.**

- Can you explain the meaning of this question/item in your own words?
- What were you thinking about when you answered this question?
- Can you tell me what your response (i.e. 'rarely', 'always') means to you in relation to feeling fatigue?
- How did you answer question 1? OR alternatively I see you marked 'sometimes' for question 1. How did you decide which category to pick?
- Complete review of all ~32 items (approximate number of items).

In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
1 I feel fatigued. <i>Notes:</i>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
2 To what degree did you have to force yourself to get up and do things because of your fatigue? <i>Notes:</i>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
3 To what degree did your fatigue make it difficult to start anything new? <i>Notes:</i>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
4 To what degree did your fatigue interfere with your physical functioning? <i>Notes:</i>	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
5 To what degree did you have trouble starting things because of your fatigue? <i>Notes:</i>	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

In the past 7 days...		Not at all	A little bit	Somewhat	Quite a bit	Very much
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6 How fatigued were you when your fatigue was at its worst? ₀ ₁ ₂ ₃ ₄

Notes:

7 How hard was it for you to carry on a conversation because of your fatigue? ₁ ₂ ₃ ₄ ₅

Notes:

In the past 7 days...		Never	Rarely	Sometimes	Often	Always
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8 How often did you feel run-down? ₁ ₂ ₃ ₄ ₅

Notes:

9 How often were you physically drained? ₁ ₂ ₃ ₄ ₅

Notes:

10 How often did you feel tired? ₁ ₂ ₃ ₄ ₅

Notes:

11 How often did your fatigue make you feel slowed down in your thinking? ₁ ₂ ₃ ₄ ₅

Notes:

12 How often did you find yourself getting tired easily? ₁ ₂ ₃ ₄ ₅

Notes:

In the past 7 days...		Never	Rarely	Sometimes	Often	Always
13	How often did you run out of energy?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
	<i>Notes:</i>					
14	How often did you have trouble finishing things because of your fatigue?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
	<i>Notes:</i>					
15	How often did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
	<i>Notes:</i>					
16	How often did your fatigue make it difficult to make decisions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
	<i>Notes:</i>					
17	How often did your fatigue make it difficult to organize your thoughts when doing things at home?	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
	<i>Notes:</i>					
18	How often did you have to push yourself to get things done because of your fatigue?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
	<i>Notes:</i>					
19	How often were you too tired to leave the house?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
	<i>Notes:</i>					

In the past 7 days...		Never	Rarely	Sometimes	Often	Always
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20 How often were you too tired to take a bath or shower? ₁ ₂ ₃ ₄ ₅

Notes:

21 How often did you have to limit your social activities because of your fatigue? ₁ ₂ ₃ ₄ ₅

Notes:

22 How often were you bothered by your fatigue? ₁ ₂ ₃ ₄ ₅

Notes:

23 How often did your fatigue interfere with your ability to engage in recreational activities? ₀ ₁ ₂ ₃ ₄

Notes:

24 How often did your fatigue interfere with your social activities? ₁ ₂ ₃ ₄ ₅

Notes:

During the past 7 days...		Not at all	A little bit	Somewhat	Quite a bit	Very much
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25 I have trouble starting things because I am tired... ₁ ₂ ₃ ₄ ₅

26 How much were you bothered by your fatigue on average?... ₁ ₂ ₃ ₄ ₅

27 How run-down did you feel on average?... ₁ ₂ ₃ ₄ ₅

During the past 7 days...		Not at all	A little bit	Somewhat	Quite a bit	Very much
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28 How fatigued were you on average?... ₁ ₂ ₃ ₄ ₅

In the past 7 days...	Never	Rarely	Sometimes	Often	Always
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29 How often did you experience extreme exhaustion?... ₀ ₁ ₂ ₃ ₄

30 How often did your fatigue limit you at work (include work at home)?... ₁ ₂ ₃ ₄ ₅

31 How often were you too tired to think clearly?... ₁ ₂ ₃ ₄ ₅

32 How often did you have enough energy to exercise strenuously?... ₁ ₂ ₃ ₄ ₅

Identify missing items:

The last step today is to find out from patients living with HIV what items or questions about fatigue are missing from the questionnaire. I would like to review the questions on the questionnaire that you said are issues for you.

- You mentioned that items [*read items where participant responded 'somewhat', 'quite a bit' or 'very much'*] are all issues that you experience when you feel fatigued. Is that correct?
- What other aspects of fatigue do you experience that are missing from this questionnaire?
- From your experience with fatigue what other things are important about fatigue that are not on the questionnaire that you think should be added?
 - Possible probes: Tell me more about that?
 - Can you think about any additional symptoms or feelings you have when you are fatigued?
- In what way do you think the items on this questionnaire provide enough information about your level of fatigue to your clinic provider?
- Anything else you would like to add before we end our meeting?

Thank you so much for all of the information you have shared with me today. We will be interviewing other participants and then review all of the information we have to create a fatigue questionnaire that is more relevant to patients and clinicians.

End meeting.

Note to interviewer:

Interviewer please review notes and transfer the patient responses and your notes onto to the "PROMIS II HIV Fatigue concept elicitation interview spreadsheet" and send spreadsheet & audio file to UW through Catalyst.

Concept Elicitation – Alcohol Use Interview Guide

Introduction (read or paraphrase to interviewee):

“You were asked to participate in this interview because in the clinic assessment you indicated that you drink alcohol.

Before we start with the interview, I want to give you an idea of the overall goal of our study. This study is trying to improve health questionnaires that are used in clinics like this one. One of the questionnaires that we are trying to improve is a questionnaire about drinking alcohol.

We would like the questionnaire to be relevant to patients with HIV and useful for health care providers. Basically, we want to make sure that the questionnaires you fill out ask questions that you would want your doctor or nurse or other health care provider to know about.

The purpose of this interview today is to find out from you and other patients at [name of clinic] who have HIV your experience with drinking alcohol. The first 15-30 minutes of this meeting, I will be asking you questions about your experiences with using alcohol.

In the second part of the meeting, I will give you a questionnaire that we are trying to improve and ask you to answer the questions and then give me feedback about the questions. I will also ask you if you think there is missing information.

The meeting will take about 90 minutes of your time. I will be using an audio recorder during the meeting to capture our conversation.

Are you ready to begin the interview? Do you have any questions before we start?”

Step 1: 15-30 minute discussion about drinking experience.

I would like to learn more about your experiences with drinking alcohol in the past year or so.

I will ask you about “drinks”, please keep in mind that a standard “drink” consists of:

(a) 12-ounces of beer,

(b) 8-ounces of malt liquor,

(c) 5-ounces of wine,

(d) 1.5-ounces or a “shot” of 80-proof distilled spirits or liquor (e.g., gin, rum, vodka, or whiskey).

1. What type of alcohol do you usually drink? PROBES: beer, mixed drinks, liquor, etc.
2. Are there places you usually go to drink or do you drink mainly at home? If you go places, where do you go?
3. Do you usually drink alone or with other people? If other people, who do you drink with? PROBES: friends, family, people at the bar.
4. What times of day do you usually drink?
5. How many days per week would you say you usually drink alcohol?
6. Would you say there's a usual amount that you drink when you are drinking alcohol? If so, how much is that?
7. Are there times when you find yourself wanting to drink but can't? What are these times like?
8. When are times you crave alcohol the most?
9. Are there certain situations or feelings that make you want to drink to excess?
10. When would you say you usually drink the most? During those times how much would you say you drink?
11. Are there times when you find yourself not wanting to drink but you do anyway? What are these times like? Why do you think you end up drinking during these times?
12. While you are drinking, what, if anything, do you do to avoid getting too drunk? PROBES: diluting drinks, pacing self, drinking water, eating something, avoid mixing, skipping rounds, having friends warn me.
13. Have there been times when you drank more alcohol than you planned to? How did you end up drinking more than you planned during these times?
14. What would you consider to be a normal amount of drinking? Drinks per day? Numbers of days drinking in a week? Why would you say that amount?
15. What would you consider to be heavy drinking? Drinks per day? Numbers of days drinking in a week? Why would you say that amount?
16. Why would you say you drink alcohol? What do you gain, if anything? What do you lose, if anything?
17. Overall, what do you think about your drinking? Would you say you drink too much or not? Would you say it's a problem for you?

ADMINISTER SHORT FORM NOW (NEXT PAGE):

Participant ID _____

Date of interview ____/____/____

Site Name (circle one): FHC UAB UCSD UW

	In the past 30 days....	Never	Rarely	Sometimes	Often	Almost Always
1.	I had trouble controlling my drinking	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
2.	It was difficult to get the thought of drinking out of my mind	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
3.	It was difficult for me to stop drinking after one or two drinks	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
4.	I spent too much time drinking	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
5.	I drank more than planned	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
6.	I drank too much	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
7.	I drank heavily at a single sitting	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

INTERVIEWER COPY

Alcohol use Questionnaire:

Review & Feedback by Participants

(45 minutes)

The purpose of this interview is to assess the wording and clarity of an alcohol use questionnaire that has been used with different patient groups and health clinics. We need to evaluate if it is relevant to patients with HIV. We are asking patients like you to help us improve this questionnaire. As you answer each question, please comment freely on the questions themselves, i.e., if any of the questions seem unclear. We welcome any feedback.

Of special interest to us is whether you feel there are essential aspects about your experience with alcohol use and HIV that are missing from this questionnaire.

Interviewer Note:

Please have a copy of the PROMIS-HIV Alcohol bank questionnaire available.

MS Word document "Alcohol Bank Questionnaire"

Provide a copy to the participant.

Please answer the first page of questions as if it was a real questionnaire. Then we will go over each question and I will ask you questions about each one. Do you have any questions? OK, Let's Begin...

INTERVIEWER COPY

Patient-Report Outcomes Measurement Information System (PROMIS)

Alcohol Domain-BLUE QUESTIONS (EVEN #s)

Interviewer, please ask for each question:

1. Can you tell me in your own words what the question/statement means to you?
2. What were you thinking of when you answered the question/statement?
3. Were there any words in the question/statement that were not clear? Could it be reworded?
4. How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost Always
1.(2) I finished several drinks fast to get a quick effect. ...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	1-2 drinks	3-4 drinks	5-6 drinks	7-10 drinks	More than 10 drinks
2.(4) On a typical day when I drank alcohol, I had...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
3.(6) I drank heavily at a single sitting...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
4.(8) I drank throughout the day...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>		Never	Rarely	Sometimes	Often	Almost always
5.(10)	I used alcohol and other drugs together, to get high...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>		Never	Rarely	Sometimes	Often	Almost always
6.(12)	I drank more than planned...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>		Never	Rarely	Sometimes	Often	Almost always
7.(14)	I felt that I should cut down on my drinking...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>		Never	Rarely	Sometimes	Often	Almost always
8.(16)	It was difficult for me to stop drinking after one or two drinks...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>		Never	Rarely	Sometimes	Often	Almost always
9.(18)	I had cravings for alcohol...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
10.(20) I had trouble stopping drinking when I wanted to...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
<i>Notes:</i>					

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
11.(22) I drank when I was alone...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
<i>Notes:</i>					

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
12.(24) I drank when I arrived at home...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
<i>Notes:</i>					

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
13.(26) I drank because someone made me angry...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
<i>Notes:</i>					

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
14.(28) I drank because I deserved it...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
<i>Notes:</i>					

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
15.(30) I drank because I felt tense...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
16.(32) I drank because I was nervous...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
17.(34) I drank because I was lonely...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
18.(36) I drank because I had physical pain...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

Missing Information/Comments:

- *What is missing from the questionnaire list that is relevant to your experience that you feel your health care provider should know about?*

INTERVIEWER COPY

Alcohol use Questionnaire:

Review & Feedback by Participants

(45 minutes)

The purpose of this interview is to assess the wording and clarity of an Alcohol use questionnaire that has been used with different patient groups and health clinics. We need to evaluate if it is relevant to patients with HIV. We are asking patients like you to help us improve this questionnaire. As you answer each question, please comment freely on the questions themselves, i.e., if any of the questions seem unclear. We welcome any feedback.

Of special interest to us is whether you feel there are essential aspects about your experience with Alcohol use and HIV that are missing from this questionnaire.

Interviewer Note:

Please have a copy of the PROMIS-HIV Alcohol bank questionnaire available.

MS Word document "Alcohol Bank Questionnaire"

Provide a copy to the participant.

Please answer the first page of questions as if it was a real questionnaire. Then we will go over each question and I will ask you questions about each one. Do you have any questions? OK, Let's Begin...

INTERVIEWER COPY

Patient-Report Outcomes Measurement Information System (PROMIS)

Alcohol Domain—Yellow Items (Odd# of 37)

Interviewer, please ask for each question:

1. Can you tell me in your own words what the question/statement means to you?
2. What were you thinking of when you answered the question/statement?
3. Were there any words in the question/statement that were not clear? Could it be reworded?
4. How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost Always
1.(1) I spent too much time drinking...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	1-2 times	3-5 times	6-10 times	More than 10 times
2.(3) I became drunk or intoxicated. ...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	1 time	2 times	3 times	4 or more times
3.(5) I spent a whole weekend drinking. ...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	1 time	2 times	3 times	4 or more times
4.(7) I drank too much...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>	1-2 drinks	3-4 drinks	5-6 drinks	7-10 drinks	More than 10 drinks
5.(9) The largest number of drinks that I had in a single day was...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	1-7 drinks	8-14 drinks	15-21 drinks	22-28 drinks	More than 28 drinks
6.(11) In a typical week, I drank...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
7.(13) I had an urge to continue drinking once I started...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
8.(15) I had trouble controlling my drinking...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
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9.(17) I had urges to drink...	□ ₁	□ ₂	□ ₃	□ ₄	□ ₅
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Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
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10.(19) I felt I needed help for my drinking...	□ ₁	□ ₂	□ ₃	□ ₄	□ ₅
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Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
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11.(21) It was difficult to get the thought of drinking out of my mind...	□ ₁	□ ₂	□ ₃	□ ₄	□ ₅
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Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
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12.(23) I drank because I had nothing to do...	□ ₁	□ ₂	□ ₃	□ ₄	□ ₅
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Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
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13.(25) I drank because I was angry with myself...	□ ₁	□ ₂	□ ₃	□ ₄	□ ₅
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Notes:

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
14.(27) I drank because I was irritable...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
15.(29) I drank because I was annoyed...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
16.(31) I drank at the end of a busy day...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
17.(33) I drank because I was sad...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

INTERVIEWER COPY

Interviewer, please ask for each question:

- Can you tell me in your own words what the question/statement means to you?
- What were you thinking of when you answered the question/statement?
- Were there any words in the question/statement that were not clear? Could it be reworded?
- How did you go about deciding on your answer?

<i>In the past 30 days...</i>	Never	Rarely	Sometimes	Often	Almost always
18.(35) I drank because I was depressed...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Notes:

19.(37) I drank because I was bored...	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
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Notes:

Missing Information/Comments:

- *What is missing from the questionnaire list that is relevant to your experience that you feel your health care provider should know about?*