Malawi-Liverpool-Wellcome Clinical Research Programme
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Cognitive Interview Guide

Opening statements:

Thank you for taking time to speak with me. As you may remember, my name is _____. We have asked you to participate in this exercise because we are studying the feasibility of HIV self-testing in Malawi. For people to accurately and safely self-test, they should have clear instructions. We are aiming to develop clear instructions that can be used HIV self-testing. As discussed during the consent discussion, we will ask you to self-test using instructions we have developed. As you go through the process, we will ask you questions about your understanding of the instructions. This process is likely to take about one hour to complete. Feel free to let me know if you need a break at any time. You can also stop the interview if you do not want to continue the discussion. Before we begin do you have any questions?

Please take a look at the sheet that explains the instructions for self-testing.

A. General

- 1. What do you think of the layout of the instructions?
- 2. Do you understand where to start and which order of the instructions to follow?
- 3. What information is contained on the first page?
- 4. What information is contained on the second page?

B. Heading

- 5. What is your understanding of the instructions on the top left of the page (with the image of the cup and utensils)?
- 6. What is your understanding of the warning on the top left of the page (with the image of the triangle)?

C. Instruction number 1- characteristics of package

7. Please tell me in your own words what instruction number 1 is telling you to do.

Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer? Do you think another person would understand what is meant by "two pouches"?

D. Instruction number 2 - removal of tube from pouch

- 8. Please tell me in your own words what instruction number two is telling you to do.
 - Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?
- 9. Please go ahead and carry out the instruction as you understand it. [RECORD OBSERVATIONS]
- 10. How clear is the image? How clear is the instruction?
 - Probes: Do you think another person would understand what is meant by "tube"? Do you think another person would understand what is meant by "pouch containing the tube"?
- 11. How difficult was it to open the pouch?

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Probes: If it was difficult, what can be done to make it easier?

E. Instruction number 3 - opening of tube

12. Please tell me in your own words what instruction number three is telling you to do.

Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?

- 13. Please go ahead and carry out the instruction as you understand it. [RECORD OBSERVATIONS]
- 14. How clear is the image? How clear is the instruction?
- 15. How difficult was it to open the lid of the tube? Did any of the liquid spill as you opened it?

Probes: If it was difficult or if there were any problems, how could these be resolved? Do you think it is necessary to inform people that there is liquid inside the tube?

F. Instruction number 4 - sliding of tube into stand

16. Please tell me in your own words what instruction number four is telling you to do.

Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?

- 17. Please go ahead and carry out the instruction as you understand it. [RECORD OBSERVATIONS]
- 18. How clear is the image? How clear is the instruction?

Probes: Do you think another person would understand what is meant by "slide the tube into the stand"?

19. How difficult was it to slide the tube into the stand? Were there any problems identifying the stand? Did any liquid spill as you placed the open vial into the stand?

Probes: If it was difficult or if there were any problems, how could these be resolved?

G. Instruction number 5 - removal of test device from pouch

20. Please tell me in your own words what instruction number five is telling you to do.

Probes: Why might someone fail to understand this instruction? How could we modify the image or reword it to make it clearer?

- 21. Please go ahead and carry out the instruction as you understand it. [RECORD OBSERVATIONS]
- 22. How clear is the image? How clear is the instruction?

Probes: Do you think another person would understand what is meant by the "test device" and "flat pad"?

23. How difficult was it to open the pouch and remove the test device without touching the flat pad? Were there any problems identifying which part was the flat pad and which part was the results window? Did you understand what to do with the preservative?

Probes: If it was difficult or if there were any problems, how could these be resolved?

H. Instruction number 6 - collection of specimen

24. Please describe to me in your own words what instruction six is telling you to do.

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Probes: Do you think another person would be able to understand the instructions and do this correctly? How could we modify the image or reword it to make it clearer?

- 25. Please go ahead and carry out the instruction as you understand it. [RECORD OBSERVATIONS]
- 26. How clear is the image? How clear is the instruction?

Probes: Do you think another person would understand what is meant by the "press the flat pad against your gum" and "swab it along your upper gum/lower gum"?

27. How difficult was it to collect the specimen?

Probes: If it was difficult or if there were any problems, how could these be resolved?

I. Instruction number 7 - placement of test device

28. Please tell me in your own words what instruction number seven is telling you to do.

Probes: Do you think another person would be able to understand the instructions and do this correctly? How could we modify the image or reword it to make it clearer?

- 29. Please go ahead and carry out the instruction as you understand it. [RECORD OBSERVATIONS]
- 30. How clear is the image? How clear is the instruction?
- 31. How difficult was it to put the test device into the tube?

Probes: If it was difficult or if there were any problems, how could these be resolved?

Instruction number 8 - timing of test

32. Please tell me in your words what instruction number eight is telling you to do?

Probes: Do you think another person would be able to understand the instructions and do this correctly? How could we modify the image or reword it to make it clearer?

33. How clear is the image? How clear is the instruction?

Probes: What is the purpose of this instruction? How long must you wait before reading the test result? What may happen if you read your result early, or if you read your result after 40 minutes? What can be done if one does not have a watch?

J. Interpreting results - HIV negative

34. Please tell me in your own words what a negative result looks like.

Probes: Do you think another person would be able to understand the instructions and read their negative result correctly? How could we modify the image or reword it to make it clearer?

35. Please tell me in your own words what should be done if one tests HIV negative.

Probes: Do you think another person would be able to understand the instructions and read their negative result correctly? How could we modify the image or reword it to make it clearer?

K. Interpreting results - HIV positive

36. Please tell me in your own words what a positive result looks like.

Probes: Do you think another person would be able to understand the instructions and read their positive result correctly? How could we modify the image or reword it to make it clearer?

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37. Please tell me in your own words what should be done if one test HIV positive.

Probes: Do you think another person would be able to understand the instructions and read their positive result correctly? How could we modify the image or reword it to make it clearer?

L. Interpreting results - invalid

38. Please tell me in your own words what an invalid result looks like.

Probes: Do you think another person would be able to understand the instructions and read their invalid result correctly? How could we modify the image or reword it to make it clearer?

39. Please tell me in your own words what should be done if one gets an invalid result.

Probes: Do you think another person would be able to understand the instructions and read their invalid result correctly? How could we modify the image or reword it to make it clearer?

M. Interpreting own results

- 40. Please read your results. [RECORD OBSERVATIONS]
- 41. How clear are the images on how to interpret the results? How clear are the instructions on how to interpret the results?

Probes: Do you think another person would be able to interpret the results easily?

42. How difficult was it to interpret your results? Were you able to relate the appearance of your test to any of the pictures in the instructions?

Probes: If it was difficult or if there were any problems, how could these be resolved?

43. What was your test result? Do you feel confident that this result is correct?

Probes: Do you think another person would believe the result? Why? If no, what could be done so that people have confidence in the test result?

44. Is there any other information that you would like to have about what to do after taking the HIV self-test?

N. Test kit disposal

- 45. Please describe in your own words what to do with the test device and tube after the self-test?

 Probes: Do you think another person would be able to understand the instructions? How could we modify the image or reword it to make it clearer?
- 46. Please describe in your own words what to do with the remaining contents of the test kit after the self-test?

Probes: Do you think another person would be able to understand the instructions and read their positive result correctly? How could we modify the image or reword it to make it clearer?

47. How clear are the images on how to dispose the test kit? How clear are the instructions on how to dispose the test kit?

Probes: Do you think another person would be able to dispose the kit easily?

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O. Self-completed questionnaire

Now please take a look at the sheet that contains the questionnaire.

48. What do you understand regarding the information in the box on the top left of the page (with the phone number)?

Probes: Did you understand that there is no charge to you for calling this phone number? Did you understand that you can call this phone number with any questions, e.g. related to HIV or taking the test or post-test support?

- 47. What is your understanding of the instructions at the top of the page?
- 48. Please tell me in your own words what question number 1 and 2 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

49. Please tell me in your own words what question number 3 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

50. Please tell me in your own words what question number 4 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

51. Please tell me in your own words what question number 5 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

52. Please tell me in your own words what question number 6 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

53. Please tell me in your own words what question number 7 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

54. Please tell me in your own words what question number 8 is asking you to do.

Probes: Why might someone fail to understand this question? How could we modify the image or reword it to make it clearer?

P. General

55. What would you do if you had questions about how to perform the self-test correctly?

Probes: Who would you talk to and how would you contact them?

56. What would you do if you needed post-test counseling?

Probes: Where would you go?

57. What do you think about of the experience of self-testing?

Probes: How does this compare to your experience testing with a counsellor?

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58. Do you think that other people would be able to self-test accurately? Probes: Why do you say so?

59. What other suggestions would you have around improving the self-testing instructions?