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Revision History

Version No.	Effective date	Reason for change
1.1.2	27 Dec 2018	Minor formatting updates
1.1.3	29 Jan 2019	Minor formatting updates
1.2.1	30 Jan 2019	Updates around format of ODK form and addition of new drop-down menus for some questions

I.   PURPOSE. To give instructions for doing the community control questionnaire. The SOP can be taken into the field. However, this SOP is designed to be a secondary source of information to the questionnaire itself (done on ODK).

II.   RATIONALE. We intend to find the incidence of fever in the catchment area of the study and also to conduct complementary social science work.

III.   SUPPLIES AND MATERIALS

1. Hard copy of the community control information sheet

2. Hard copy of the informed consent form

3. Participant ID stickers

4. Blood collection tubes

5. Pharyngeal swabs

6. Stamp for thumb print

7. This SOP

8. Tablet with ODK pre-loaded with questionnaire form

9. Antibiotic library

IV.   TARGET AUDIENCE

10. Investigators

11. Study co-ordinators

12. Field teams

V.   DEFINITIONS

13. **'Community control' or just 'control':** In this SOP, 'community control' or 'control' means the individual who has been selected to be in the study. They have been selected because they have similar basic information to someone participating in another part of the study. We are interested in comparing data about these two individuals.

14. **Respondent:** In this SOP, 'respondent' means the individual who is answering the questionnaire. For adults and adolescents, the control will be usually be the respondent. However, with younger children, the respondent will be the parent or guardian.

15. **Open Data Kit:** In this SOP, 'Open Data Kit' (from now on, **ODK**) is the data collection tool installed on the tablets to run the questionnaire. In this SOP, there are many direct quotes from ODK that you will find on the tablet. These are in ***bold italics***.

16. **Antibiotic Library**: In this SOP, 'antibiotic library' means the collection of antibiotics available within the catchment area of community controls.

VI.   PROCEDURES

A.   Before Going into the Field

17. Get hold of the information that you will need to locate the community controls

(see **SOP F.12 for finding community controls**).

18. Run through a check list to make sure that you have all of the supplies and materials needed to conduct the questionnaire.

19. Make sure the tablet is fully charged and functioning beforehand.

20. Head out into the field and locate selected community control(s).

B.   At the Home of Control

21. Greetings and pleasantries.

22. Conduct the informed consent process using the information sheets and consent forms (See **SOP F.02 for conducting informed consent**).

23. Discuss with the participant whether they would prefer to have their samples taken before, or after, you conduct the questionnaire

24. Find a suitable space in which to perform the questionnaire. Ideally, find a table at which both you and the respondent can sit. If not, aim to create an interview setting in which you are not standing over the respondent, but rather sitting or standing at an equal level. This is important because you do not want to make the respondent think you are in a position of power. You will also need to make sure that there is a surface available on which to do the pile sorting exercises.

25. Inform the respondent that, if they are ready, you can begin the questionnaire.

26. Remind them that their participation is voluntary and they can withdraw at any point. Ask them whether they have any questions before you begin.

A sample introductory statement would go as follows (Not in ODK):

"Now that we have finished the consent form, we will now begin the questionnaire. During the questionnaire, we will ask you about the illnesses that you experience frequently in your household and about the medicines you use to treat them. We will also do some exercises in which we will ask you to sort medicines into different piles. Don't forget, your decision to take part is voluntary and you are free to withdraw your participation at any time".

*Do you have any questions before we start?***"**

C.   Open and Prepare ODK

27. On the tablet, open "ODK collect"

28. Select "Fill Blank Form"

29. Select the current version of the control questionnaire

30. You will now see the questionnaire on the tablet. Only one question will appear on each page. Instructions for each question are provided below. The instructions below are in the exact order that they will appear on the tablet. For more general queries and possible responses, see **section VII**.

31. In this SOP, direct quotes from ODK are in ***bold italics***.

32. Some questions will not let you move on to the next one until you have given an answer. Also, the questionnaire adapts to previous answers. That is, your answers to some questions will affect the next question and the responses that can be given.

33. Once a question has been answered, move onto the next question by clicking 'right' (or swiping left). You can return to a previous question at any point (for instance, if a respondent changes their mind about the answer to a question). To return to a previous question, click left (or swipe right) until you get to the question you need. Note however that any changes to the form might affect the following answers, which will mean you have to fill them in again.

C.   **Introduction to the Form (No Input from Respondent Needed)**

34. Say to the respondent that you must firstly fill in some information on the tablet that will not require any information from them.

35. When you open the form in ODK, you will be presented with a series of questions and instructions. These include questions about:

- Country
- Health worker name
- Date and time of the interview
- The matched control's ID number
- The GPS co-ordinates of the matched control
- Basic information about the control
- Check that you have competed all steps of the consent process

36. Answer the question(s) on each page and then click left (swipe right) to get to the next page.

D.   **Section 1: Demographics**

37. When you get to '***Section 1: Demographics***', inform the respondent that you will now ask some basic information about <the control> (and about the respondent, if a different person to the control)

38. You will be presented with a series of demographic questions about the control (and respondent, if different to control). These include questions about:

- Age and date of birth
- Gender
- Self-reported ethnicity
- Details about respondent if not the same person as the control

39. Answer the question(s) on each page and then click left (swipe right) to get to the next page

E.   **Section 2: Illnesses and Medicines**

40. Thank the respondent for the information they have given. Inform them that you will now ask them about common illnesses experienced in their household.

Introduction in ODK:

Thank you for the information you have provided for us so far. We would now like to ask you about the illnesses that people in your household experience frequently and the medicines you use to treat them. The reason that we are asking about this is that most of what we know about illness and medicines comes from doctors. We want to learn more about what people think about illnesses and the use of medicines. We also wish to find out what medicines people have difficulty getting. There are no right or wrong answers. We are interested in your opinions and experiences.

41. You should ask the following questions exactly as they are written in ODK. If they have any difficulty understanding the questions see section IV.

42. ***What illnesses do people in your household frequently experience?***

Our aim in asking this this question is to find out about illnesses such as coughs, colds, stomach aches and fevers. However, do not offer any examples to respondents. Let them interpret the question in their own way. If the respondent has difficulty understanding, see section IV below.

There is drop-down list of the most common illnesses. Please do not read the drop-down list out to participants, but rather wait for the respondent to answer the question and select the appropriate responses. You can select multiple. There is an option at the bottom of the list called 'other'. If the participant says an illness that is not on the list, please select 'other' and then write down the illness in the open text box provided.

43. ***What are the most common medicines that you use in your household?***

Our aim is to find out which medicines people use to treat common illnesses (illnesses such as those mentioned in response to the previous question). But do not offer the respondents with any examples. Allow them interpret the question in their own way. If the respondent has difficulty understanding the question, see section IV below.

There is drop-down list of the most common medicines. Please do not read the drop-down list out to participants, but rather wait for the respondent to answer the question and select the appropriate responses. You can select multiple. There is an option at the bottom of the list called 'other'. If the participant says a medicine that is not on the list, please select 'other' and then write down the illness in the open text box provided.

44. ***How often are you able to get the medicines that your household needs? Please tell us which one of the following options best describes your answer: Always, most of the time, some of the time, rarely, never.***

You will be given five options: 'Always', 'most of the time', 'some of the time', 'rarely', 'never'. The respondent might feel that they are unsure of where to draw the line between two answers (e.g. between some of the time and most of the time). In this case, just tell them to say the answer that first pops into their head. Reassure them that their answer does not have to be precise.

F.   Section 3: Pile sorting exercises

45. Thank the respondent for their answers. Say to them that you would now like to do a series of exercises using the bag of medicines you have with you. At this point, present the antibiotic library and place it on the table (or alternative surface).

Phrasing in ODK:

"We would now like to continue asking you about medicines. To do this, we would like to show you some medicines that we have brought with us".

(Present them the antibiotic library)

"Doctors often call these kinds of medicine 'antibiotics'. We would like to do some exercises with you, where we will ask you to sort these medicines into different piles. The exercises are not to test your knowledge, but to find out whether you have seen any of these before and which you have used. The reason that we are doing the exercises is that it helps to actually show you these medicines to help you remember which ones you have seen. As you will see, the exercises do not take very long. If you are OK to continue, we will begin".

46. Gently empty the bag of antibiotics onto the table or another surface. Spread the antibiotics out so that the respondent can see all of them.

47. Get ready any boxes that you are using to help sort the 'piles'.

48. The exercises are designed to be a simple as possible, and each exercise involves asking the respondent to pick out antibiotics based on various criteria. There are five exercises in total (four in this section, one in the final section). The number of antibiotics used during the exercises will get much less after the first one, as you will see. Instructions for each exercise are given below.
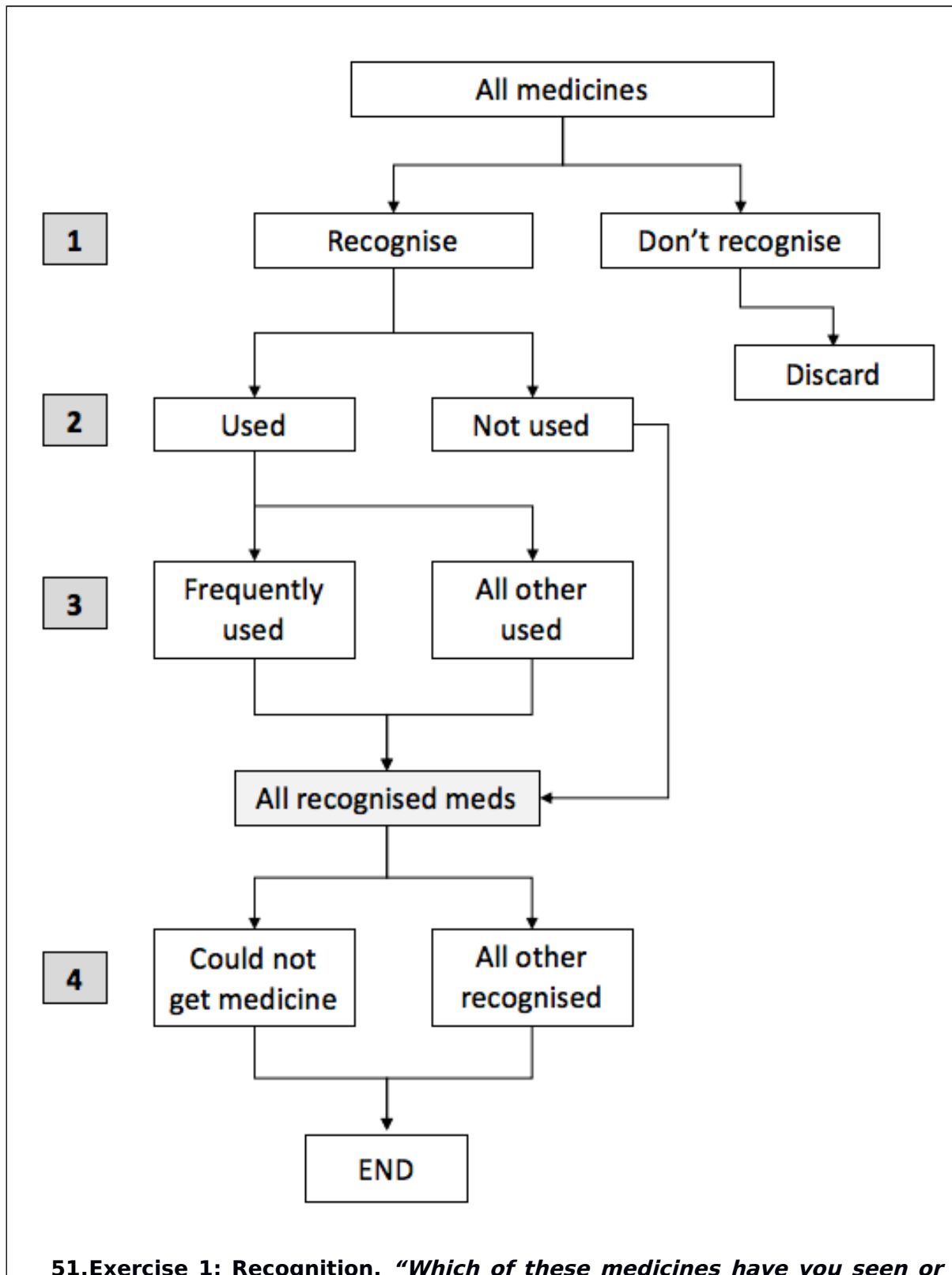
49. Each antibiotic in the library has a number between 1 and X that you will see on the packaging. This number can be used to quickly find the antibiotic in a list in ODK for each exercise. It is much quicker and more accurate to find the antibiotic in ODK using this number, rather than using the antibiotic name. For

this reason, please do use the numbering system.

50. The diagram below shows how the exercises flow to help you see how the process works. This diagram includes the number of the exercise down the left-hand side:

51.Exercise 1: Recognition. *"Which of these medicines have you seen or*

heard of before? Please pick out the ones that you have seen or heard of before and put them into one pile".

The purpose of this first exercise is to find out which antibiotics the respondent recognises. Encourage the respondent to take as much time as they need. Invite them to closely look at each antibiotic one by one. They are welcome to take the antibiotics out of their packaging (except blister packs), to read the packages and leaflets, and to smell them.

It is likely that there will be more unrecognised medicines than recognised ones. This is to be expected.

Look at the list of antibiotics in ODK. You will see that there are two columns for each antibiotic: "I recognise this medicine" and "I do not recognise this medicine". Only one of the two can be selected. Currently, all medicines will have "I do not recognise this medicine" selected. For each of the antibiotics in the pile made by the respondent, use the number on the packaging to find the antibiotic in the list and select 'I recognise this medicine'.

Remove the remaining pile of unrecognised medicines (they're now gone for good). Put them back in the bag that you brought them in. They are no longer needed. We are only interested in recognised medicines.

52. **Exercise 2: Medicines Used**. Once exercise 1 has been done and you have put the unrecognised medicines away, spread the recognised medicines out in front of the respondent. Then say:

    "Thank you. We would now like you to pick out the medicines that you have ever used before in your household. Please place them together in a pile".

    If the respondent does not understand, try phrasing the question another way: "Are there any medicines here (gesture to the recognised medicines) that you, or anyone in your household, have ever used before?"

    Look at the list of antibiotics in ODK. You will see that there are two columns for each antibiotic: "We have used this medicine" and "Medicine is recognised". Only one of the two can be selected. Currently, all medicines will have "Medicine is recognised" selected. For each of the antibiotics in the pile created by the respondent, use the number on the packaging to find the antibiotic in the list and select 'We have used this medicine'.

53. **Exercise 3: Frequently Used.** Put the unused medicines to one side. They are not needed for this exercise. Place remaining (used) medicines in front of the respondent. Then ask:

    "We would now like you to pick out the medicines that you use frequently when someone in your household is sick. Please place them together in a pile".

If the respondent is unsure of what counts as 'frequently', ask the respondent to interpret it in their own way. Reassure them that this does not have to be precise.

Look at the list of antibiotics in ODK. You will see that there are two columns for each antibiotic: "We use this medicine frequently in our household" and "we have used this medicine". Only one of the two can be selected. Currently, all medicines will have "We have used this medicine" selected. For each of the antibiotics in the pile created by the respondent, use the number on the packaging to find the antibiotic in the list and select 'We use this medicine frequently in our household'.

54. **Exercise 3b. For each medicine selected in exercise 3 (frequently used), a question will appear on the tablet:**

    "What do you use <this medicine> for in your household?"

    We are interested in finding out what people use antibiotics for in their household. Place the relevant medicine in front of the participant, and encourage the participant to list all the things that they use the medicine for in their household.

    There is a drop-down list to choose responses from. Please do not read the drop-down list out to participants, but rather wait for the respondent to answer the question and select the appropriate responses. You can select multiple. There is an option at the bottom of the list called 'other'. If the participant says an illness/complaint that is not on the list, please write down the illness/complaint in the open text box provided.

55. **Exercise 4: Used in the Last Month.** Put the frequently used medicines back together with the rest of the used medicines. Place all used medicines in front of the participant. Then ask:

    "We would now like you to pick out any medicines that you have used in your household in the last month. Please place them together in a pile"

    Here we are interested in whether any medicines have been used in the last month. However, this does not have to be precise. The respondent does not have to be 100% certain whether a medicine was used in the last 30 days. This is just to the best of their knowledge. Reassure the respondent of this if they express concern.

    To help the respondent, it might be best to tell them the date and month it is at the time of the interview, and then ask them to think back to the same date in the previous month. Use your judgement to decide how best to communicate 'in the last month' to the respondent.

    Look at the list of antibiotics in ODK. You will see that there are

two columns for each antibiotic: "We used this medicine in the last 30 days" and "we have used this medicine". Only one of the two can be selected. Currently, all medicines will have "We have used this medicine" selected. For each of the antibiotics in the pile created by the respondent, use the number on the packaging to find the antibiotic in the list and select 'We have used this medicine in the last 30 days'

56. **Exercise 5: Accessibility**. Bring back all recognised medicines and spread them out in front of the respondent. Then say:

    "We would now like you to pick out any medicines that you or a member of your household have been prescribed before but you could not get the medicine. To say this another way, for each medicine here, has there ever been a time when someone in your household has been prescribed the medicine but you could not actually get it? Please place them together in a pile.".

    Here we want to find if respondents have had difficulty accessing any medicines that they have been prescribed. If they express any confusion about what you mean by the term "prescribed", inform them that this means that a health worker has found that they need the medicine. The health worker might also have written this on paper for them to take to a pharmacy or dispensary to get the medicine.

    Look at the list of antibiotics in ODK. There are two columns for each antibiotic: "This medicine was unavailable" and "Medicine is recognised". Only one of the two can be selected. Currently, all medicines will have "Medicine is recognised" selected. For each of the antibiotics in the pile created by the respondent, use the number on the packaging to find the antibiotic in the list and select "This medicine was unavailable".

57. After the pile sorting exercises are complete, thank the respondent for taking the time to do these exercises. Assure them that they did very well and that the information is highly useful.

58. **Keep the pile of recognised medicines together** (it will be needed briefly in the next section).

G.   **Section 4: Last fever episode**

59. Reassure the respondent that this is the last section of the questionnaire. This final section involves asking them about the last time that <the control> had a fever.

    Phrasing in ODK:

Thank you for helping us with the medicines exercises. The final topic we would like to ask you about is the last time that <the control> had a fever. The reason we are asking about the last time <the control> had a fever is that we would like to find out about how often people get a fever in <study

site>. We also wish to find out what people do to get better when they get a fever.

60. **When was the last time that <the control> had a fever?**

You will see three options: 'In the last six months', 'more than six months ago', and 'never had a fever'. You will only be able to select one of these. Select the right one.

The respondent might feel that they are unsure of whether the last fever was 'in the last six months' or 'more than six months ago'. In this case, just tell them to give their best guess. Reassure them that their answer does not have to be exact.

The respondent might ask what a fever is. In this case, you may offer an example of the symptoms when someone has a fever. Inform them that a fever is an 'unusually hot body' that is often experienced by hot and cold flushes. If the respondent still does not understand what a fever is, reassure them that this is OK and select 'never had a fever'.

61. **How did you know that it was a fever?**

Our aim in asking this question is to find out how people come to call something a fever.

It is possible that the respondent will ask you to clarify the question. For instance, they might be unsure whether we want to hear about experiences of feeling feverish, or whether we want to hear about what the doctor told them. Do not attempt to clarify the question. Rather, ask them to interpret the question in their own way. There are no right or wrong answers. We are interested in *their* opinions and experiences.

There is drop-down list. Please do not read the drop-down list out to participants, but rather wait for the respondent to answer the question and select the appropriate responses. You can select multiple. There is an option at the bottom of the list called 'other'. If the participant says something that is not on the list, please select 'other' and then write down the response in the open text box provided.

62. **What do you think caused the fever?**

Here we are interested in how respondents view what causes people to get fevers. If they have difficulty understanding what you mean, try phrasing the question another way: "When <the control> last had a fever, why do you think you/they got sick?"

The respondent may say that only a health worker would know this. If they express any doubt or confusion about the question, reassure them that we are interested in what *they* think might have caused the fever. Reassure them that there are no right or wrong answers.

You will see an open text box. Manually enter the respondent's answer using the

exact words that they use (or as best as you possibly can).

63. Did you use any of these medicines [point to the antibiotic library] during the fever?

We wish to find out whether the control used an antibiotic during the last fever episode. However, because we do not wish to assume that the respondent is familiar with the term 'antibiotic', point towards the recognised medicines to show what you mean. You will have two options in ODK: Yes and no. Select the correct response. If the respondent cannot remember, select 'no'.

64. Can you pick out the medicines that you used? Please place them together in a pile

You will be shown this question only if the respondent says "yes" to the previous one. If the respondent cannot remember, then skip this question by clicking to the right. If they think they can remember, present them the pile of recognised medicines and ask them to pick out any medicines used during the fever.

You will be shown a list of all recognised medicines. If the respondent is able to pick out the antibiotic(s) that were used last, select them (using the numbers on the packaging). You are able to select multiple antibiotics if necessary.

65. Where did you get the medicine(s) from?

You will be shown this question only if the respondent said "yes" when they were asked if they used an antibiotic during the fever. It does not matter if they were actually able to pick out the medicine(s) in response to the previous question. They might still remember where they got the medicine from, even if they do not know exactly what it was.

You will be presented with a drop-down list of possible places where they might have got the medicine from. These include:

- Other household member
- Friend or neighbor
- Traditional/faith healer
- Informal drug vendor
- Retail Pharmacy
- Other shop selling medicines
- Public clinic
- Public hospital
- Private health facility
- Other (please specify – free text box provided)
- Don't know

Do not read this list to the respondent. Rather, let them answer the question and classify their response. There are two columns for each possible antibiotic source: "Mentioned" and "Not mentioned". Currently, all of the options will have "Not mentioned" selected. For all of the option mentioned by the respondent,

select "mentioned". You can select multiple if necessary.

If the respondent mentions something that is not on the list, select "other" and then briefly describe their response in the free text box provided. If the respondent either doesn't know or can't remember, select "don't know".

H.   Finalising form and Leaving

66. Before you finalise the form, you will be asked to confirm that you have:

- Completed the sample collection
- Completed the HIV test (if needed)

67. Mark the form as finalised.

68. Thank the respondent and ask if he/she has any questions for you about the questionnaire or about the blood that you have taken.

69. Conclude as follows (not in ODK):

"Thank you for your patience and for your help; we truly appreciate this. We will be in touch should anything come up for which we might need your views on, and we will be available should you need to contact us for any reason related to this questionnaire. Thanks again for everything, have a good day/good evening."

VIII. Possible queries and responses

70. Does not understand a question

- If the person does not understand a question, repeat the question to them slowly. The same goes for any of the response options.
- The question and the response options can be repeated as many times as is necessary. Use the advice in the sections above as best you can. However, if it becomes clear that the respondent does not understand, then reassure the respondent that they are going very well and move on to the next question.

71. Does not understand a drug pile sorting exercise

- If the person does not understand any or all of the pile sorting exercises, take time to re-explain the exercise(s) to them. If necessary, re-explain the entire process (see point 58).
- It may be helpful show how they might arrange the piles to help explain. If you do, make sure you select medicines randomly (so don't select medicines that you think they are more likely to recognise). Also, be careful to return the piles to how they were arranged before your example.
- The exercise(s) can be re-explained as many times as is necessary. But if it is clear that the respondent does not understand, then move on to the next pile sorting exercise. If they still do not understand the whole process, then reassure the respondent that they are doing very well and

move on to section H, 'last fever episode'.

72. Does not wish to answer a question

- Inform the respondent that all the questions are entirely voluntary. Say to them that it is important for us to hear your views. But assure them that if they are not comfortable, you will move on to the next question. See below if they do not wish to continue the questionnaire.

73. Does not wish to continue with the questionnaire

- Inform the person that participation is entirely voluntary. Say that they are being asked to complete the questionnaire because we are interested in people's perceptions of common illnesses and the medicines used to treat them. If the person still does not want to participate, stop the interview and thank the person for their time.

74. Is concerned that others will see their responses

- Reassure the respondent that all of his/her responses will be kept confidential by the research team. Explain that names will be replaced by a study number so that the questionnaires are completely confidential.

FIEBRE

Febrile Illness Evaluation in a Broad Range of Endemicities

DOCUMENTATION: FIEBRE protocol (version 3.0, 31 Oct 2018) section 7.5