

Comprehensive Script 1

Note: *If the child is unaware of HIV serostatus, this interview should be conducted in his/her absence to prevent inadvertent disclosure.*

INSTRUCTIONS:

After the Comprehensive Script 1 has been administered three times, the Condensed Script 2 (shorter version) can be substituted at the discretion of the interviewer for subjects who appear to understand the purpose of the interview.

The Condensed Script 2 begins on page 3 of this document.

A. STEP ONE- Identification of Antiretroviral Medications:

READ the following paragraphs to the subject or primary caregiver:

“Most people with HIV have many different medicines to take at different times during the day. Many people find it hard to always remember to take [to give] their medicines. They get busy and forget to carry their medicines with them, or they get confused about the instructions and decide not to take [to give] them. Some people just decide it would be nice to have a day off.

We need to understand how people with HIV are really doing with their medicines. Please tell us what you are actually doing. Don't worry about telling us that you are not taking (giving) all the medicines. We need to know what is really happening, not what you think we want to hear.”

START QUESTIONING BY SAYING:

“The first thing we need to do is to make certain that we are both talking about the same medicines.

Medicines that directly fight HIV, the virus that causes AIDS, are called “antiretroviral drugs”. You may be on other medicines that are keeping you well. All the medicines you have been given are important. Right now we are only addressing the study drugs.

(Subject volunteers)

“Can you tell me what medicines you are supposed to be taking to fight HIV?”

Fill in ‘1’ in the Identification Code column for each antiretroviral medicine that is volunteered and identified by the subject.

To be “identified”, a subject can (1) name the drug; (2) list its characteristics (“the pill with the blue ring”) or (3) identify special adherence enhancing labeling (“the label with the blue stripes”).

As each antiretroviral medicine is identified, ask:

“How many times, not how many pills, how many times a day are you supposed to take _____ (drug name and characteristics) _____?”

Fill in the reported number of doses per 24 hour period in the Reported Doses column (column F) for each antiretroviral medicine volunteered and identified by the subject.

(Subject is prompted if not all medicines have been named.)

**SCRIPTS FOR
PEDIATRIC ADHERENCE QUESTIONNAIRE MODULE 1 - III (QL5003)
NIAID PEDIATRIC CLINICAL TRIALS GROUP**

When the subject is finished, ask:

“Are there any other medicines to fight HIV you are supposed to be taking?”

Fill in “2” in the Identification Code column for each antiretroviral medicine that requires this prompting and then is identified by the subject.

As each antiretroviral medicine is identified, ask:

“How many times, not how many pills, how many times a day are you supposed to take

_____ (drug name and characteristics) _____?”

Fill in the reported number of doses per 24 hour period in the Reported Doses column (column F) for each antiretroviral medicine volunteered and identified by the subject.

(Subject is specifically questioned about prescribed medications not reported at this point.)

When the subject is finished, ask:

“Are you supposed to be taking _____?”

If the subject needs to have the medicine identified and to be specifically questioned then remembers, fill in “3” on the Identification Code column. If the subject does not remember when the medicine is identified, code “4” on the Identification Code column for each antiretroviral medicine.

As each antiretroviral medicine is identified, ask:

“How many times, not how many pills, how many times a day are you supposed to take

_____ (drug name and characteristics) _____?”

Fill in the reported number of doses per 24 hour period in the Reported Doses column (column F) for each antiretroviral medicine volunteered and identified by the subject.

B. STEP TWO- Self-reported adherence behavior for specific time periods:**When the full antiretroviral regimen is accounted for, say, for each drug:**

“Now for (drug name and characteristics), it looks like this medicine needs to be taken _____ times each day.” (Refer to the prescribed number of times, not the number reported by the subject)

“Now think about yesterday. Of the _____ prescribed doses, how many did you miss?”

Record this number in column G.

“Now think about the day before that. That would have been _____. Of the _____ prescribed doses, how many did you miss?”

Record this number in column H.

“Go back just one more day. That would have been _____. Remember some of the things that happened 3 days ago? Of the _____ prescribed doses, how many did you miss?”

Record this number in column I.

GO TO THE NEXT LISTED MEDICATION AND REPEAT THE QUESTIONING PROCEDURE.

End of Comprehensive Script 1

Condensed Script 2

Note: *If the child is unaware of HIV serostatus, this interview should be conducted in his/her absence to prevent inadvertent disclosure.*

INSTRUCTIONS: Not to be used before the fourth adherence-measurement administration.

A. STEP ONE - Identification of Antiretroviral Medicines

Read the following paragraph to the subject or primary caregiver:

I'd like to ask you some questions, like we have done in past visits, to find out how you are doing with the antiretroviral medicines, the ones that fight HIV directly. Remember, we need to understand how people with HIV are really doing with their medicines. We know that taking these medicines is a big job. So please tell us what you are actually doing. Don't worry about telling us if you are not taking (giving) all the medicines. We need to know what is really happening, not what you think we want to hear.

(Subject volunteers)

"Can you tell me what medicines you are supposed to be taking to fight HIV?"

Fill in '1' in the Identification Code column for each antiretroviral medicine that is volunteered and identified by the subject.

To be "identified", a subject can (1) name the drug; (2) list its characteristics ("the pill with the blue ring") or (3) identify special adherence enhancing labeling ("the label with the blue stripes").

As each antiretroviral medicine is identified, ask:

"How many times, not how many pills, how many times a day are you supposed to take _____(drug name and characteristics) _____?"

Fill in the reported number of doses per 24 hour period in the Reported Doses column (column F) for each antiretroviral medicine volunteered and identified by the subject.

(Subject is prompted if not all medicines have been named.)

When the subject is finished, ask:

"Are there any other medicines to fight HIV you are supposed to be taking?"

Fill in "2" in the Identification Code column for each antiretroviral medicine that requires this prompting and then is identified by the subject.

As each antiretroviral medicine is identified, ask:

"How many times, not how many pills, how many times a day are you supposed to take _____(drug name and characteristics) _____?"

Fill in the reported number of doses per 24 hour period in the Reported Doses column (column F) for each antiretroviral medicine volunteered and identified by the subject.

(Subject is specifically questioned about prescribed medications not reported at this point.)

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When the subject is finished, ask:

“Are you supposed to be taking _____?”

If the subject needs to have the medicine identified and to be specifically questioned then remembers, fill in “3” on the Identification Code column. If the subject does not remember when the medicine is identified, code “4” on the Identification Code column for each antiretroviral medicine.

As each antiretroviral medicine is identified, ask:

“How many times, not how many pills, how many times a day are you supposed to take _____ (drug name and characteristics) _____?”

Fill in the reported number of doses per 24 hour period in the Reported Doses column (column F) for each antiretroviral medicine volunteered and identified by the subject.

B. STEP TWO- Self-reported adherence behavior for specific time periods:

When the full antiretroviral regimen is accounted for, say, for each drug:

“Now for (drug name and characteristics), it looks like this medicine needs to be taken _____ times each day.” (Refer to the prescribed number of times, not the number reported by the subject.)

“Now think about yesterday. Of the _____ prescribed doses, how many did you miss?”

Record this number in column G.

“Now think about the day before that. That would have been _____. Of the _____ prescribed doses, how many did you miss?”

Record this number in column H.

“Go back just one more day. That would have been _____. Remember some of the things that happened 3 days ago? Of the _____ prescribed doses, how many did you miss?”

Record this number in column I.

GO TO THE NEXT LISTED MEDICATION AND REPEAT THE QUESTIONING PROCEDURE.