

PERINATAL ADHERENCE QUESTIONNAIRE MODULE 2
GENERAL REASONS FOR NON-ADHERENCE
NIAID PEDIATRIC AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					mmm	dd	yyyy		
Protocol Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	<input type="text"/>	<input type="text"/>	* Seq No.	<input type="text"/>	** Step No.	<input type="text"/>	Key Operator Code	<input type="text"/>

* Enter a "1" if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.

**Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

This module captures the general reasons for non-adherence linked to each drug taken. In this step, the interviewer will collect information on reasons why the subject may be having difficulty taking each agent.

QUESTIONS 1 AND 2 ARE TO BE COMPLETED BY THE STUDY NURSE:

1. Was the questionnaire completed at this visit? (1-Yes, 2-No)
If Yes, go to question 2.
If No, complete 'a.'

a. Indicate the reason the questionnaire was not completed:...
1-Subject refused
2-Subject missed clinic visit
3-There was not enough time
9-Other reason, specify

If Other, specify [30]: _____

2. Who responded to the questions?.....
1-Subject
9-Other, specify

If Other, specify [30]: _____

INSTRUCTIONS FOR COMPLETION OF DRUG SPECIFIC TABLE:

- Enter the drug code name of each antiretroviral drug that the subject is receiving in the space provided at the top of each column. Refer to page 3 for the list of most commonly used anti-HIV medications. Refer to Appendix 3 or the Drug Code Lookup Program at the DMC Web Site (<http://www.fstrf.org>) for any medications not listed.

Identification of Reasons for Non-Adherence:

READ the following paragraph to the subject or primary caregiver:

"Many people at one time or another have trouble with these medications. We would like to better understand the things that make giving medications hard for families. These are some of the reasons others have identified which have made it difficult to take [give] all of the HIV medicines."

Show and read the list of reasons to the subject or primary caregiver.

After the list is read, ask the following question for each drug (question 3 on page 2):

"Over the last two weeks, have any of the following been problems for you with _____ (drug name or characteristics) _____?"

If "Yes," enter the frequency code for each reason (a-n).

If "No," go to the next drug.

For data entry, use the tab key after the last entry on the page.



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Pt. No. * Seq. No. ** Step No. Date
mmm dd yyyy

DRUG SPECIFIC ADHERENCE DIFFICULTIES:

Frequency Codes

Use these codes to indicate the frequency with which each listed reason for non-adherence occurs. This needs to be done for each antiretroviral drug the subject is taking.

- 0-Never a problem
- 1-Hardly ever a problem
- 2-Frequent problem
- 3-Almost always a problem

Enter Drug Code and Name:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:
	Drug #1 Name [15]:	Drug #2 Name [15]:	Drug #3 Name [15]:	Drug #4 Name [15]:	Drug #5 Name [15]:
3. Problem identified? (1-Yes, 2-No)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reasons for Non-Adherence:

a. Can't get drug (drug store doesn't have supply):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Didn't refill; ran out:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Nausea, couldn't keep it down, difficulty swallowing, taste:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Forgot:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Side effects/toxicity:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Scheduling:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1. Interferes with lifestyle (work, meals, school, sleep)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Too busy with the baby	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Couldn't deal with it that day; didn't feel like taking it; needed a break:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Change in living situation:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Concerns about disclosure:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Sick with other illness:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Don't think I need it anymore:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Lack of family/social support:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Concerns about medication effects on baby:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n. Other, specify Specify [30]:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Language: English



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DRUG CODE REFERENCE

*Drug Codes and Names for Commonly Used Drugs.
Refer to Appendix 3 or the Drug Code Lookup Program at the
DMC Web Site (<http://www.fstrf.org>) for drugs not listed below.*

Anti-HIV Drugs for Protocol	
08180407	Abacavir/ABC/Ziagen/1592U89
08180025	Alovedine/CL-184824
08181205	Amprenavir/APV/Agenerase/141W94/VX-479
08181214	Atazanavir/ATV/BMS-232632
08180018	Ateviridine mesylate U-87201E
08180006	Azidouridine/AzdU/azido-2',3'-dideoxyuridine
08180021	AZT/ZDV/Zidovudine/Retrovir
08180032	CD4/RST4
08180412	Combivir (3TC/ZDV)
08180024	d4T/Stavudine/Zerit
08180414	DAPD/Amdoxovir/trimeric
08180020	ddC/Zalcitabine/HIVID
08180007	ddI/Didanosine/Videx
08180031	DLV/delavirdine mesylate/Rescriptor
08180804	Efavirenz/EFV/Sustiva/DMP266
08180411	Fluorouridine/935U83
08180415	FTC/coviracil/emtricitabine
08181218	GW433908
08180043	Indinavir/IDV/Crixivan 10920013
	Interleukin-2/IL-2
08180026	Lamivudine/3TC/Epivir
08181208	Lopinavir/Ritonavir (LPV/RTV)/Kaletra
	ABT-378/r
08180048	Loviride/Lotrene
08181204	Nelfinavir/NFV/Viracept
08180013	Nevirapine/NVP/Viramune
08181203	Ritonavir/RTV/Norvir
08181209	Saquinavir soft gel/FTV/Fortovase
08180030	Saquinavir (HGC)/SQV/Invirase/R031-8959
08188804	T-20/pentafuside/Enfuvirtide/ENF
08182002	TDF/Tenofovir/Tenofovir disoproxil fumarate/Viread
08180418	Trizivir (3TC/ABC/ZDV)
99999998	Blinded Study Drug
99999999	Drug Code Pending

