

WIHS ID#

START F22MEDS3

B2. Now I'm going to ask about any antiretroviral medications you may have taken since your (MONTH) study visit. In addition to all your prescribed medications, please include any antiretroviral medications you have taken as part of a research study, including those in which you may have been blinded to the study medication.

PROMPT: REVIEW QXQS FOR INSTRUCTIONS ON HOW TO COLLECT ARV DATA.

PROMPT: HAND PARTICIPANT ANTIRETROVIRAL PHOTO MEDICATION CARDS.

CHECK THE DRUG(S) THE PARTICIPANT HAS TAKEN FOR HIV SINCE HER LAST STUDY VISIT. FOR DRUGS NOT ON THE LIST, RECORD THE NAME UNDER "OTHER" AS STATED BY THE PARTICIPANT AND FILL IN THE CORRESPONDING THREE-DIGIT DRUG CODE FROM DRUG LIST 1.

a. Since your (MONTH) study visit, have you taken...

Combination Medications

- 262 ___ Atripla (Sustiva + Viread + Emtriva)
- 227 ___ Combivir (AZT + 3TC)
- 254 ___ Epzicom (Ziagen + Epivir)
- 240 ___ Trizivir (abacavir + AZT + 3TC)
- 253 ___ ***Truvada** (Viread + Emtriva)

Entry Inhibitors

- 233 ___ Fuzeon (T-20, enfuvirtide)
- 265 ___ Selzentry (maraviroc)

Nucleoside/Nucleotide RTIs

- 239 ___ ***Emtriva** (emtricitabine, FTC)
- 204 ___ ***Epivir** (lamivudine, 3-TC)
- 092 ___ Retrovir (AZT, zidovudine, ZDV)
- 147 ___ Videx / Videx EC (didanosine, ddI)
- 234 ___ ***Viread** (tenofovir)
- 159 ___ Zerit (stavudine, d4T)
- 218 ___ Ziagen (abacavir)

Integrase Inhibitors

- 264 ___ ISENTRESS (raltegravir, MK 0518)

Non-Nucleoside RTIs

- 255 ___ Intelence (etravirine, TMC 125)
- 194 ___ Rescriptor (delavirdine)
- 220 ___ Sustiva (efavirenz)
- 191 ___ Viramune (nevirapine)

Protease Inhibitors

- 238 ___ Aptivus (tipranavir)
- 212 ___ Crixivan (indinavir)
- 210 ___ Invirase (saquinavir)
- 217 ___ Kaletra (lopinavir + ritonavir)
- 249 ___ Lexiva (fosamprenavir)
- 211 ___ Norvir (ritonavir)
- 256 ___ Prezista (TMC-114, darunavir)
- 243 ___ Reyataz (atazanavir)
- 216 ___ Viracept (nelfinavir)

Other

- 207 ___ Droxia or Hydrea (hydroxyurea)
- ___ Other anti-viral(s) (from Drug List 1)

Specify name of "other" antiviral:
Specify name of "other" antiviral:

→ Drug Code: |_|_|_|_|

→ Drug Code: |_|_|_|_|

END F22MEDS3

PLEASE COMPLETE THE DOSAGE FORM IF PARTICIPANT REPORTS HAVING TAKEN ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT IN QUESTION B2a.

b. IF PARTICIPANT HAS NOT TAKEN ANY ANTIRETROVIRAL MEDICATION SINCE HER (MONTH) STUDY VISIT, CHECK HERE: |_|_| (B10)

c. ENTER THE TOTAL NUMBER OF ANTIRETROVIRAL MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION B2a: |_|_|

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B3. FROM VCS AND DSG, HAS PARTICIPANT STARTED ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT?

YES1
NO2 (B4)

a. Is this the first time you have taken any antiretroviral medications(s)?

YES1
NO2 (B4)

Why did you start taking antiretroviral medication(s) now? **CIRCLE YES FOR ALL THAT APPLY.**

	<u>YES</u>	<u>NO</u>
b. My viral load went up	1	2
c. My CD4 level went down	1	2
d. I was diagnosed with AIDS	1	2
e. I became sicker, although I wasn't diagnosed with AIDS	1	2
f. My doctor recommended I start since my last study visit	1	2
g. My doctor had previously recommended I start	1	2
h. I'm pregnant or intend to become pregnant	1	2
i. Other reason	1	2

SPECIFY: _____

B4. FROM VCS AND DSG, HAS PARTICIPANT CHANGED OR STOPPED ANY ANTIRETROVIRAL MEDICATIONS SINCE HER LAST STUDY VISIT?

YES1
NO2 (B7)

You have reported a change in the antiretroviral medications you are taking. We want to understand the reasons for this change, so please tell me which of these reasons contributed to the decision to change or stop your antiretroviral medicines:

	<u>YES</u>	<u>NO</u>
a. My provider changed/stopped my medicines and I don't know why	1	2
b. My medicines weren't working – my CD4 count was lower or my viral load was higher	1	2
c. My virus was resistant	1	2
d. I was not taking my medicines any way	1	2
e. I am pregnant, or I am trying to become pregnant, or I changed after giving birth.....	1	2
f. I was tired of taking the medicines	1	2
g. I could not pay for the medicines.....	1	2
h. My prescription ran out.....	1	2
i. My medicines were too complicated to take, or there were too many pills, or they were hard to swallow	1	2

	<u>YES</u>	<u>NO</u>
j. Family or friends wanted me to change/stop my medicines.....	1	2
k. I heard about better medicines on TV, the radio, in a magazine or the newspaper	1	2
l. I had side effects or the medicines made me sick.....	1	2 (m)
i. I got a skin rash or had skin problems.....	1	2
ii. I got headaches	1	2
iii. I had gastrointestinal problems (nausea, vomiting, diarrhea, cramping)	1	2
iv. My body shape or body fat changed	1	2
v. I became depressed, moody, or had trouble with sleep.....	1	2
vi. My blood count tests weren't normal (anemia, low blood, low white count).....	1	2
vii. My liver tests weren't normal	1	2
viii. My kidney tests weren't normal.....	1	2
ix. I developed diabetes or high blood sugar.....	1	2
x. My blood tests for lipids/fat/cholesterol became abnormal	1	2
xi. I became allergic or hypersensitive to a medication	1	2
xii. I had some kind of side effect, but do not know what kind	1	2
m. Any other reasons for changing/stopping medicines.....	1	2 (B7)

SPECIFY: _____

B7. a. In general, over the past six months, how often did you take your antiretrovirals as prescribed?

100% of the time.....	1 (SECTION C)
95-99% of the time.....	2
75-94% of the time.....	3
<75% of the time.....	4
I haven't taken any of my prescribed medications	5

b. **PROMPT: HAND PARTICIPANT RESPONSE CARD D1.**
 People skip or miss taking their medications for various reasons. Since your (MONTH) study visit, how often have you missed taking your antiretroviral medications because you...

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Often</u>
i. Simply forgot?	0.....	1.....	2.....	3
ii. Had a change in daily routine (e.g., vacation, holiday, non-workday)?	0.....	1.....	2.....	3
iii. Fell asleep or slept through dose time?.....	0.....	1.....	2.....	3
iv. Had too many pills to take?	0.....	1.....	2.....	3
v. Ran out of pills?.....	0.....	1.....	2.....	3
vi. Did not feel like taking any pills?.....	0.....	1.....	2.....	3
vii. Did not want others to notice you taking medications? ..	0.....	1.....	2.....	3
viii. Were on drugs or drank too much?.....	0.....	1.....	2.....	3
ix. Wanted to avoid side effects?	0.....	1.....	2.....	3
x. Felt like the drug was toxic or harmful?	0.....	1.....	2.....	3

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	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Often</u>
xi. Felt too sick to take medications?.....	0.....	1.....	2.....	3
xii. Felt too depressed to take medications?.....	0.....	1.....	2.....	3
xiii. Had difficulty following special instructions (e.g., take with meals or on empty stomach)?.....	0.....	1.....	2.....	3
xiv. Other reason?	0.....	1.....	2.....	3

SPECIFY: _____

PROMPT: GO TO SECTION C.

B10. PROMPT: HAND PARTICIPANT RESPONSE CARD D3.

What is your **main** reason for not taking any antiretroviral medications or treatments? **CIRCLE ONE ANSWER ONLY.**

- I am HIV negative.....1
- My CD4+ was too high / viral load too low2
- I feel too healthy3
- I am taking alternative treatments.....4
- I don't want side effects.....5
- They are too hard to swallow.....6
- My doctor did not prescribe them.....7
- I can't afford them / have no insurance coverage.....8
- I am concerned about resistance9
- I'm having a baby10
- Personal decision to wait11
- They didn't work for my friends.....12
- Liver problems14
- Any other reason.....13

SPECIFY: _____

SECTION C. OI MEDICATION HISTORY

START F22MEDS4

C1. PROMPT: HAND PARTICIPANT RESPONSE CARD D4.

a. Since your (MONTH) study visit, have you taken the following inhaled medication?

114 ___ Pentamidine (aerosolized)

i. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION
IN C1a SINCE HER (MONTH) STUDY VISIT, CHECK HERE: **(C1b)**

b. Since your (MONTH) study visit, have you taken any of the following injected or infused drugs?

091 ___ Foscarnet (Foscavir)

125 ___ Ganciclovir (DHPG, Cytovene IV)

232 ___ Nandrolone (Deca-durabolin)

157 ___ Medication to increase white blood cell count (G-CSF, GM-CSF, Neupogen)

117 ___ Medication to increase red blood cell count (Erythropoietin, Epogen, Procrit, EPO)

090 ___ ***Interferon alfa-2b** (Intron A) or **Interferon alfa-2a** (Roferon-A)

124 ___ Amphotericin B (Ampho B)

242 ___ ***Pegylated interferon** (PEGASYS, PEG-Intron, Peginterferon alfa-2a, Peginterferon alfa-2b)

i. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION
IN C1b SINCE HER (MONTH) STUDY VISIT, CHECK HERE: **(C1c)**

c. Since your (MONTH) study visit, have you used any of the following pills, liquids or creams?

112 ___ Bactrim (Septra, cotrimoxazole,
trimethoprim-sulfamethoxazole,
TMP/SMZ)

184 ___ Biaxin (clarithromycin)

153 ___ Cipro (ciprofloxacin)

113 ___ Dapsone

116 ___ Diflucan (fluconazole)

213 ___ ***Famvir** (famciclovir)

125 ___ Ganciclovir (Cytovene,
valganciclovir, Valcyte)

138 ___ INH (isoniazid)

154 ___ Lamprene (clofazimine)

190 ___ Mepron (atovaquone)

540 ___ Methadone

705 ___ Methyl-prednisolone (Medrol)

229 ___ Monistat (miconazole)

137 ___ Myambutol (ethambutol)

145 ___ Mycelex or Lotrimin (clotrimazole)

127 ___ Nizoral (ketoconazole)

144 ___ Nystatin (Mycostatin)

228 ___ Oxandrin (oxandrolone)

706 ___ Orapred

707 ___ Prednisolone (Prelone)

704 ___ Prednisone (Deltasone)

182 ___ PZA (pyrazinamide)

235 ___ ***Rebetron** (Ribavirin & Interferon alfa-2b)

093 ___ Rifabutin (mycobutin)

139 ___ Rifadin (rifampin)

169 ___ Sporanox (itraconazole)

230 ___ Terazol (terconazole)

198 ___ Valtrex (valacyclovir)

247 ___ Vfend (voriconazole)

152 ___ Zithromax (azithromycin)

146 ___ Zovirax (acyclovir)

i. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION
IN C1c SINCE HER (MONTH) STUDY VISIT, CHECK HERE: **(PROMPT)**

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PLEASE COMPLETE DRUG FORM 2 FOR EACH MEDICATION MARKED ABOVE IN QUESTION C1a – C1c. IF NO MEDICATIONS ARE MARKED, GO TO SECTION D.

- d. ENTER THE TOTAL NUMBER OF NON-ANTIRETROVIRAL MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTIONS C1a, C1b and C1c:

SECTION D. HEPATITIS MEDICATION HISTORY

START F22MEDS9

D1. PROMPT: HAND PARTICIPANT RESPONSE CARD D4a.

- a. Since your (MONTH) study visit, have you taken any of the following medications for Hepatitis B or C?

- 090 ___ Interferon alfa-2b (Intron A) or Interferon alfa-2a (Roferon-A)
- 242 ___ Pegylated interferon (PEGASYS or Peginterferon alfa-2a)
(PEG-Intron or Peginterferon alfa-2b)
- 058 ___ Ribavirin (Virazole, Rebetrol, Copegus)
- 235 ___ Rebetron (Ribavirin and interferon alfa-2b)
- 204 ___ Epivir (lamivudine, 3-TC)
- 234 ___ Viread (tenofovir, bis-POC-PMPA)
- 224 ___ Hespera (adefovir, Preveon, bis-POM PMPA, GS 840)
- 239 ___ Emtriva (emtricitabine, Coviracil, FTC)
- 708 ___ Infergen (Interferon alfacon-1)
- 213 ___ Famvir (famciclovir)
- 253 ___ Truvada (Viread + Emtriva)
- 709 ___ Baraclude (entecavir, BMS-200475)
- 710 ___ Tyzeka (telbivudine)

- b. IF PARTICIPANT HAS NOT TAKEN ANY MEDICATION IN D1a SINCE HER (MONTH) STUDY VISIT, CHECK HERE:

 (SECTION E)

END F22MEDS9

PLEASE COMPLETE DRUG FORM 3 FOR EACH MEDICATION MARKED ABOVE IN QUESTION D1a.

- c. ENTER THE TOTAL NUMBER OF HEPATITIS MEDICATIONS THE PARTICIPANT REPORTED TAKING IN QUESTION D1a:

SECTION E. OTHER PRESCRIPTION MEDICATION USE

E1. Since your (MONTH) study visit, have you received any of the following vaccinations?

		<u>YES</u>	<u>NO</u>	<u>DON'T KNOW</u>
a.	Hepatitis A	1	2	-8
b.	Hepatitis B	1	2	-8
c.	Pneumovax.....	1	2	-8
d.	Varicella (chicken pox)	1	2	-8
e.	Tetanus	1	2	-8
f.	HPV (human papillomavirus).....	1	2	-8

E2. In the past year, have you had a routine flu vaccine, either a shot in your arm or FluMist, which is sprayed into the nose? A flu vaccine is usually given in the fall and protects against influenza for the flu season.

YES.....1
 NO.....2 (E7)

b. Which did you have?

Flu shot.....1
 Nose spray.....2

c. When did you receive the flu vaccine?

M				Y					

E7. The word ‘flu’ is used for several illnesses. For example, people may say they have ‘stomach flu’ for gastrointestinal illnesses (vomiting and diarrhea) that are caused by viruses other than influenza. Our questions are about influenza flu. Common symptoms are fever and a dry, hacking cough. Influenza flu is different from a cold; however, it can be very difficult to tell flu from a cold. In general, flu symptoms are much worse and last longer than cold symptoms. In the past year, did you have an illness that you think was the ‘flu’ (but not stomach flu)?

YES.....1
 NO.....2 (E11)

b. When did you have your most serious case of the flu?

M				Y					

E8. Did you have any of the following symptoms when you had flu?

		<u>YES</u>	<u>NO</u>
a.	Fever	1	2
b.	Dry cough.....	1	2
c.	Sore throat.....	1	2
d.	Muscle aches.....	1	2
e.	Nausea, vomiting or diarrhea.....	1	2
f.	Headache.....	1	2

E11. PROMPT: HAND PARTICIPANT RESPONSE CARD D4h.

Since your (MONTH) study visit, have you taken any of the following hormone replacement therapies (hormones, estrogen, progesterone) for more than one month? These therapies could have been taken in the form of a pill, cream, or patch worn on the skin. Please do not include any hormones taken only to prevent pregnancy; we will discuss those later in the interview.

ESTROGEN: Premarin, Estrace, Estratab, Menest, Ogen, Cenestin, Estraderm, Climera, Menostar, Estrasorb

PROGESTERONE: Provera, Cycrin, Amen, Prometrium, Micronor, Nor-QD

COMBINATION ESTROGEN/PROGESTERONE: Premphase, Prempro, Combipatch

OTHER HRT: Tamoxifen, Raloxifene, testosterone patch or cream, Estratest (combination estrogen/testosterone), birth control pills, Norplant, Ortho Evra (birth control patch), NuvaRing (a vaginal ring containing hormone)

YES1
 NO2 **(E12a)**

a. INTERVIEWER: BASED ON PARTICIPANT RESPONSE IN E11, CODE BELOW THE TYPE OF HRT PARTICIPANT REPORTED ABOVE:

ESTROGEN1
 PROGESTERONE2
 COMBINATION3
 OTHER HRT4

SPECIFY: _____

b. What are the main reasons you are taking hormone replacement therapy? Is it for:

	<u>YES</u>	<u>NO</u>
i. Menopause related symptoms (the change, hot flashes, vaginal dryness, sweating).....1	1	2
ii. Depression, anxiety or emotional distress1	1	2
iii. Replacement after hysterectomy or removal of ovaries1	1	2
iv. Osteoporosis, or to prevent or treat bone loss.....1	1	2
v. Prevention of heart disease1	1	2
vi. Irregular menstrual periods (spotting)1	1	2
vii. Other reason1	1	2 (E12a)

SPECIFY: _____

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- E12a. Since your (MONTH) study visit, have you taken any medication for blood pressure or your heart, (such as Amiodarone, Quinidine, Verapamil, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4b. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12b. (Since your (MONTH) study visit), have you taken any medication to lower your cholesterol, triglyceride, or blood lipid level, (such as Lipitor, Pravachol, Zocor, etc.)? **SHOW PARTICIPANT RESONSE CARD D4c. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12c. (Since your (MONTH) study visit), have you taken any medication to lower your blood sugar, such as insulin injections or any oral medications? **SHOW PARTICIPANT RESPONSE CARD D4d. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12d. (Since your (MONTH) study visit), have you taken any medication to prevent or treat osteoporosis, (such as Fosamax, Evista, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4e. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12e. (Since your (MONTH) study visit), have you taken any medication for seizures, (such as Tegretol, Dilantin, Phenobarbital, Depakote, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4f. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12f. (Since your (MONTH) study visit), have you taken any medication for psychological conditions or depression, (such as Zyprexa, Zoloft, Celexa, etc.)? **SHOW PARTICIPANT RESPONSE CARD D4g. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12g. (Since your (MONTH) study visit), have you taken any medication for HIV lipodystrophy or body fat changes related to HIV, such as growth hormones or steroids? **SHOW PARTICIPANT RESPONSE CARD D4i. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12h. (Since your (MONTH) study visit), have you taken any medication for breathing or lung problems, (such as Singulair, monteleukast, Accolate, zafirlukast, Zyflo, zileutin, Theodur, theophylline, Slo-phyllin, Slo-bid, or Aerolate)? **SHOW PARTICIPANT RESPONSE CARD D4k. IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E12i. Since your (MONTH) study visit, have you taken any other **prescribed** medications **not** previously mentioned? **IF “YES,” RECORD MEDICATION IN QUESTION E13a.**
- E13. ENTER THE TOTAL NUMBER OF OTHER PRESCRIPTION MEDICATIONS THE PARTICIPANT REPORTS TAKING IN QUESTIONS E12a – E12i:

PROMPT: IF E13 = 0, SKIP TO QUESTION G3. IF E13 ≥ 1, LIST MEDICATIONS IN COLUMN “a” AND COMPLETE COLUMNS “b” AND “c” FOR EACH MEDICATION.

PROMPT: PHOTOCOPY PAGE 12 AND INSERT IF PARTICIPANT REPORTS USING MORE THAN 7 OTHER PRESCRIPTION MEDICATIONS.

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a. Specify Drug Name	b. Have you taken this in the past 5 days? YES NO	c. INTERVIEWER, RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.
Name of drug:	1 2	Self report..... 1 Participant brought written list to visit..... 2 Participant brought medication bottles to visit..... 3 Participant brought pharmacy record to visit 4 Record obtained directly from pharmacy 5 Other 6 SPECIFY: _____
Name of drug:	1 2	Self report..... 1 Participant brought written list to visit..... 2 Participant brought medication bottles to visit..... 3 Participant brought pharmacy record to visit 4 Record obtained directly from pharmacy 5 Other 6 SPECIFY: _____
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a. Specify Drug Name	b. Have you taken this in the past 5 days? YES NO	c. INTERVIEWER, RECORD HERE HOW USE OF THIS MEDICATION WAS REPORTED.
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END F22MEDS6

G3. TIME MODULE ENDED:

:

AM 1
PM 2