

Attachment 2B

Objective 3 - Clinical Follow up Questionnaire

**Incident HIV/Hepatitis B Virus infections in South African blood donors:
Behavioral risk factors, genotypes and biological characterization of early infection**

OMB Number: 0925-XXXX Expiration Date:

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This section of the form is to be completed by the research assistant or other research staff.

A1. Subject ID (*Internal study number to be assigned by Study Management System*)

A2. Subject Donor Number (*Number that will link with donor's Meditech info*)

A3. Location of Study Visit. (*Blood collection site neumonic (clinic site code). The neumonic can be mapped back to Branch, Zone or Province – this will have to be coded during analysis phase*)

A4. Date of Study Visit (DD/MM/YYYY)

A5. Research Staff Initials: _____

CURRENT MEDICAL STATUS

B1. Since your last visit for participation in this study have you gone to your doctor or sought medical care at a clinic or hospital?

0 No **Skip to B2**

1 Yes

97 Don't Know

98 Refuse to Answer

B1a. If yes, what was the reason for seeking medical care? _____

B2. Since your last visit for participation in this study have you gone to a traditional healer?

0 No **Skip to B3**

1 Yes

97 Don't Know

98 Refuse to Answer

B2a. If yes, what was the reason for seeing the traditional healer? _____

B3. Since your last study visit have you had a cold, flu, or any other infection?

0 No **Skip to B4**

1 Yes

97 Don't Know

98 Refuse to Answer

B3a. If yes, what symptoms did you have? Please list all the symptoms you can think of such as headache, fever, body pain, chills, vomiting, diarrhea, or any other symptom that you may have had. _____

B4. Since your last study visit have you started taking antiretroviral medicines, also known as ARVs?

- 0 No **Skip to B6**
- 1 Yes
- 97 Don't Know
- 98 Refuse to Answer

B4a. What are the names of the antiretroviral (ARV) medicines you are currently taking? _____

To help trigger your memory, please look at the placard with pictures of medicines and then place a check mark in the box next to the medications that look like the ones you are taking:

Place √ if taking this medication	Medication
	AZT – Zidovudine
	ddI – Didanosine
	3TC – Lamivudine
	D4T – Stavudine
	ABC – Abacavir
	TDF – Tenofovir
	FTC - Emtricitabine
	IDV - Indinavir
	NVP – Nevirapine
	EFV – Efavirenz
	ETV - Etravirine
	ATV – Atazanavir
	LPV/r – Lopinavir/Ritonavir
	RAL - Raltegravir
	SQV - Saquinavir
	OTH – Other not pictured

B5. If yes, have you had any side effects from taking your current antiretroviral (ARV) medicines?

- 0 No
- 1 Yes
- 97 Don't Know
- 98 Refuse to Answer

B5a. If yes, what side effects did you have? Please list all the side effect you can think of, such as nausea, loss of appetite, vomiting, diarrhea, or any other symptom that you may have had. ___

B5b. Did you miss taking some or all of the doses of your current antiretroviral (ARV) medicines because of the side effects you experienced?

- 0 No
- 1 Yes
- 97 Don't Know
- 98 Refuse to Answer

B6. Are you currently taking anything else for your health such as vitamins, herbs, supplements or natural medicines?

- 0 No
- 1 Yes
- 97 Don't Know
- 98 Refuse to Answer

B6a. If yes, please list the name(s) of each vitamin, herb, supplement you are taking? ___ ___ ___

B7. Since your last study visit have you started taking traditional medicines that were recommended or provided by a traditional healer?

- 0 No
- 1 Yes
- 97 Don't Know
- 98 Refuse to Answer

B7a. If yes, please list the names of traditional medicines you are taking? _____

B7b. If yes, have you had any side effects from taking these traditional medicines?

- 0 No
- 1 Yes
- 97 Don't Know
- 98 Refuse to Answer

B7c. If yes, what side effects did you have? Please list all the side effect you can think of, such as nausea, loss of appetite, vomiting, diarrhea, or any other symptom that you may have had. _____

B8. (Ask of Women Only) Are you currently pregnant?

- 0 No
- 1 Yes
- 96 Not applicable, never been pregnant
- 97 Don't Know
- 98 Refuse to Answer

Thank you for taking the time to complete this questionnaire. Please return this questionnaire to the research staff. If you have any questions or concerns, please talk to the research assistant or nurse. You can also contact the medical director at our blood bank.

Placard Showing Antiretroviral Therapy Pictures

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aidsmap

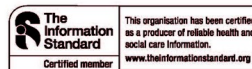
Antiretroviral drug chart

Generic name	Trade name	Formulation	Standard adult dose	Pills/day	Major side-effects	Food restrictions
Nucleoside reverse transcriptase inhibitors (NRTIs)						
3TC, lamivudine	<i>Epivir</i>	150* and 300mg tablets	150mg twice a day or 300mg once a day	2 1	Common: Nausea, vomiting, diarrhoea, headache, abdominal pain, hair loss, fever, insomnia (difficulty sleeping), rash, tiredness, runny nose, joint pain Rare: Lactic acidosis, liver damage	Take with or without food
Abacavir	<i>Ziagen</i>	300mg tablet	300mg twice a day or 600mg once a day	2	Common: Rash, nausea, vomiting, diarrhoea, fever, headache, tiredness, muscle pain, loss of appetite, fever Rare: Hypersensitivity reaction, lactic acidosis	Take with or without food
AZT, zidovudine	<i>Retrovir</i>	100 and 250mg* capsules	250mg twice a day	2	Common: Nausea, vomiting, fatigue, headache, dizziness, weakness, muscle pain, loss of appetite, fever Rare: Blood disorders, lipodystrophy, lactic acidosis	Take with or without food
d4T, stavudine	<i>Zenit</i>	20, 30 and 40mg* capsules	People over 60kg: 40mg twice a day People under 60kg: 30mg twice a day	2	Common: Lipodystrophy, peripheral neuropathy, nausea, diarrhoea, abdominal pain, heartburn, dizziness, tiredness, rash, itching Rare: Pancreatitis, lactic acidosis	Take with or without food
ddI, didanosine	<i>VidexEC</i>	125, 200, 250 and 400mg* capsules	People over 60kg: 400mg once a day or 200mg twice a day People under 60kg: 250mg once a day or 125mg twice a day	1 or 2	Common: Peripheral neuropathy, nausea, vomiting, diarrhoea, abdominal pain, heartburn, dizziness, tiredness, rash, itching Rare: Pancreatitis, lactic acidosis	Take at least two hours after and two hours before eating or drinking anything except water
FTC, emtricitabine	<i>Emtriva</i>	200mg capsule	200mg once a day	1	Common: Nausea, diarrhoea, headache, raised kinase levels, skin darkening in children Rare: Lactic acidosis, liver damage	Take with or without food
Nucleoside reverse transcriptase inhibitor (NRTI)						
Tenofovir	<i>Viread</i>	300mg tablet	300mg once a day	1	Common: Nausea, vomiting, diarrhoea, dizziness, low blood phosphate levels, weakness, rash, headache, stomach pains, fatigue, bloating, flatulence Rare: Kidney problems, bone thinning	Take with food
NRTI / NRTI fixed-dose combinations						
3TC / AZT	<i>Combivir</i>	tablet comprising 150mg 3TC and 300mg AZT	One tablet twice a day	2	See 3TC and AZT	Take with or without food
3TC / abacavir / AZT	<i>Trisivir</i>	tablet comprising 150mg 3TC, 300mg abacavir and 300mg AZT	One tablet twice a day	2	See 3TC, abacavir and AZT	Take with or without food
3TC / abacavir	<i>Kivona (EU)</i>	tablet comprising 300mg 3TC and 600mg abacavir	One tablet once a day	1	See 3TC and abacavir	Take with or without food
FTC / tenofovir	<i>Truvada</i>	tablet comprising 200mg FTC and 300mg tenofovir	One tablet once a day	1	See FTC and tenofovir	Take with food
NRTI / NRTI / NRTI fixed-dose combinations						
FTC / tenofovir / efavirenz	<i>Atipla</i>	tablet comprising 600mg efavirenz, 200mg FTC and 300mg tenofovir	One tablet once a day	1	See FTC, tenofovir and efavirenz	Take on an empty stomach, preferably at bedtime
FTC / rilpivirine / tenofovir	<i>Exelera</i>	tablet comprising 200mg FTC, 25mg rilpivirine and 300mg tenofovir	One tablet once a day	1	See FTC, rilpivirine and tenofovir	Take with a meal
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)						
Efavirenz	<i>Sustiva</i> <i>Stocrin</i>	600mg tablet* and 200mg capsule	600mg once a day	1 or 3	Common: Rash, dizziness, sleep disturbance, abnormal dreams, impaired concentration, nausea, vomiting, headache, tiredness, diarrhoea, anxiety, depression Rare: Psychosis, severe rash, liver problems	Take on an empty stomach, preferably at bedtime
Etravirine	<i>Intencef</i>	100 and 200mg* tablet	200mg twice daily	2 or 4	Common: Rash, peripheral neuropathy Rare: Severe rash (Stevens Johnson syndrome)	Take with food
Nevirapine	<i>Nvirapine</i>	200mg tablet	200mg once a day for two weeks then 200mg twice a day	2	Common: Liver toxicity, allergic reaction, rash, nausea, headache, fatigue, stomach pain, diarrhoea Rare: Severe rash (Stevens Johnson syndrome)	Take with or without food
Nevirapine	<i>Nvirapine prolonged-release</i>	400mg tablet	400mg once a day after introductory period on non-extended-release nevirapine	1	Common: Liver toxicity, allergic reaction, rash, nausea, headache, fatigue, stomach pain, diarrhoea Rare: Severe rash (Stevens Johnson syndrome)	Take with or without food
Rilpivirine	<i>Edurant</i>	25mg tablet	25mg once a day	1	Common: Insomnia (difficulty sleeping), headache, rash, mood changes, depression Rare: At doses above 25mg may cause a disturbance to the heart rhythm	Take with a meal
Protease inhibitors						
Atazanavir	<i>Atripla</i>	150, 200 and 300mg* capsule	300mg with 100mg ritonavir once a day or 400mg with 100mg ritonavir once a day with efavirenz or nevirapine	2 or 3 §	Common: Nausea, diarrhoea, rash, stomach ache, headache, insomnia (difficulty sleeping), vomiting, hyperbilirubinaemia, lipodystrophy, liver toxicity, diabetes, heartburn, jaundice Rare: Kidney stones, abnormal liver function, changes in heart rhythm	Take with food
Darunavir	<i>Prezista</i>	400 and 600mg* tablet	600mg with 100mg ritonavir twice a day or 800mg with 100mg ritonavir once a day	3 or 4 §	Common: Diarrhoea, nausea, rash, stomach pain, vomiting, headache, lipodystrophy, liver toxicity, diabetes, fever, abnormal liver function, changes in heart rhythm Rare: Changes in heart rhythm	Take with food
Fosamprenavir	<i>Telzir</i>	700mg tablet	700mg with 100mg ritonavir twice a day	4 §	Common: Raised lipids, nausea, vomiting, diarrhoea, rash, abdominal pain, headache, dizziness, tiredness, tingling around the mouth, changes in liver and pancreas function, lipodystrophy, liver toxicity, diabetes Rare: Severe rash, changes in heart rhythm	Take with or without food
Indinavir	<i>Crixivan</i>	100, 200 and 400mg* capsules	800mg three times a day	6	Common: Kidney stones, abdominal pain, lipodystrophy, nausea, vomiting, heartburn, diarrhoea, rash, headache, dizziness, dry skin and mouth, tiredness, insomnia (difficulty sleeping), liver toxicity, diabetes Rare: Liver abnormalities, changes in heart rhythm	Take one hour before or two hours after food or take with a light, low-fat snack
Lopinavir / ritonavir	<i>Kaletra</i>	Tablet comprising 200mg lopinavir and 50mg ritonavir	Two tablets twice a day or four tablets once a day	4	Common: Lipodystrophy, raised liver enzymes, nausea, vomiting, diarrhoea, abdominal pain, weakness, heartburn, headache, raised lipids, liver toxicity, diabetes Rare: Changes in heart rhythm	Take with or without food
Ritonavir	<i>Norvir</i>	100mg capsule and 100mg tablet*	Full dose: 600mg twice a day To 'boost' other PIs: 100 - 200mg once or twice a day	12 1 to 4	Common (at full dose): Raised lipid and liver enzymes, nausea, vomiting, diarrhoea, abdominal pain, headache, weakness, numbness around the mouth, bad taste in mouth, lipodystrophy, liver toxicity, diabetes Common (at low dose): Raised lipid levels Rare: Changes in heart rhythm	Take with food to avoid nausea
Saquinavir	<i>Inviso</i>	200mg capsule and 500mg tablet*	1000mg with 100mg ritonavir twice a day	6 §	Common: Lipodystrophy, nausea, vomiting, diarrhoea, rash, tiredness, raised liver enzymes and lipids, liver toxicity, diabetes Rare: Changes in heart rhythm	Take within two hours of food
Tipranavir	<i>Aptivus</i>	250mg capsule	500mg with 200mg ritonavir twice a day	8 §	Common: Nausea, diarrhoea, vomiting, abdominal pain, tiredness, headache, fever, liver abnormalities, rash, lipodystrophy, liver toxicity, diabetes, lipid increases, flatulence Rare: Bleeding in brain, changes in heart rhythm	Take with food
Fusion inhibitor						
T-20, enfuvirtide	<i>Fuzon</i>	Powder reconstituted in water	Injection of 90mg under the skin twice a day	-	Common: Injec-tion-site reaction, respiratory tract infections, peripheral neuropathy, weight loss	No food restrictions
CCR5 inhibitor						
Maraviroc	<i>Celsentri</i>	150*, 300mg tablets	300mg twice a day or 150mg twice a day with all ritonavir-boosted PIs except tipranavir or 600mg twice a day with efavirenz or etravirine	2 to 4	Common: Nausea, diarrhoea, fatigue, headache	Take with or without food
Integrase inhibitor						
Raltegravir	<i>Ireness</i>	400mg tablet	400mg twice a day	2	Common: Headache, insomnia (difficulty sleeping) Rare: Severe rash, hypersensitivity reaction	Take with or without food

*Formulation(s) shown. § Includes ritonavir capsule(s)

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