

Attachment 3.2 –Questionnaire: Description of each item, source, and goal for Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

REDS III-INTERNATIONAL HIV STUDY 2014

Questions relating to survey objectives

The purpose of the interview questions is to collect donor profile to determine risk factors associated with HIV infection among volunteer replacement participant in Brazil. A case The yield interview data on HIV risk behaviors among prospective donors will be used; 1) to understand predominant risk behaviors associated with in HIV positive blood donation in Brazil, for instance: male-to-male sex, having multiple heterosexual partners, and to a lesser extent injection drug use (IDU), 2) to suggest modifications to current operational donor screening questionnaire in ways that can decrease risk and improve blood safety.

Section A- Study Data

Objective: Section A will be completed by trained research staff. The following questionnaire items are related to the general profile of respondents (study subjects), and will be used for de-identified administrative record keeping, such as linking interview responses to the HIV strain type and potential drug-resistance profile of the infection, as well as for obtaining general demographic information from study subjects.

Q. A1-Subject ID

Q.A2.-Subject Blood bank ID

Q.A8. Study subject is able to read

The following questionnaire items are related to general technical profile of blood bank staff and time and place for the interview.

Q.A6.-Research Assistant Initials

Q.A3.-Blood collection site

Q.A4.-Month of interview

Q.A5.-Year of interview

Q.A5-Type of interview

Section B- Demographic data

Section B will be completed by the study subject with the assistance of the trained research staff. The will allow the subject to become familiar with listening to and/or reading the questions and the use of touch screen for answering questions.

Objective: to obtain demographic data for general risk stratification based on the background of the subjects.

Q.B1.What is your gender?

Q.B2.What is your birth year?

Q.B3.What is your birth month?

Q.B4.What is your birth day?

Q.B5a.What is your country of birth?

Q.B5b.Please specify your country of birth

Q.B6.What is your race ? (Check all that apply)

Q.B7.What is your current marital status?

Q.B8.If you are married or living with someone, is your spouse/cohabitating partner

Q.B9.-What level of education do you have?

Q.B10.-What is your occupation?

Section C- Previous donation and HIV testing

Section C and all remaining sections will be completed by study subject in privacy. The purpose of using a self-administered instrument is to ensure that potentially stigmatizing behaviors will be reported as honestly as possible without fear or concern that an interviewer would stand in judgment.

Objective: to obtain data related to whether a donor has donated blood before and if so the frequency of previous donation and knowledge of information regarding blood donor's eligibility. In Brazil doesn't exist the Disqualified Donor Directory (DDD), indeed, a person at risk, might donate blood in many blood banks.

Q.C1. Have you ever donated blood at another blood center?

Q.C2. How many times have you donated blood at another blood center?

Q.C3. At the time of your last donation, do you remember being given information about who should not donate blood?

Objective: to determine if the donor exhibits HIV testing behavior that would suggest knowledge of risk factors for HIV acquisition and indicated if the donor has actively sought HIV testing before.

Q.C4.-Other than blood donation, have you ever been tested for HIV?

Q.C5a.-What was the reason for the HIV test?

Q.C5b.-Please specify the other reason for test.

C6a.-Other than a blood center, where else have you been tested for HIV?

C7.-Excluding HIV testing conducted as part of blood donation, how many times have you been tested for HIV?

Section D - Incentives and Motivations for Donating

Objective: to determine if the donor exhibits altruistic behaviors in their daily life. We want to correlate their daily behavioral answers to access altruistic reason to donate blood. It is already known that donors use to give a socially acceptable response rather than the real reason to donate. There is a major difference between asking a donor whether altruism is a motivation factor and measuring the degree to which donors report engaging in other altruistic behaviours.

Q.D1. Have you helped carry a stranger's belongings?

Q.D2. Do you allow someone who is elderly or disabled to go ahead of you in a line?

Q.D3. Have you offered to help a handicap or elderly person across a street?

Q.D4.Do you give money to charity?

Objective: to determine motivational factors and its frequency, that leads participants to donate blood. We will built, based into those answers, three categories of motivational factors; Altruistic, Direct appeal and Self interest and also to correlate them into donors sub-groups, by frequency (first-time, repeated and lapsed); type (volunteers, and replacement); and at risk participant (test-seekers *versus* no test-seekers).

Q.D5a.- To anonymously help someone else who needs blood.

Q.D5b.- To help a friend or relative who is sick or needs blood.

Q.D5c.- In response to a campaign on TV or radio.

Q.D5d.- I received a telephone call or letter from the blood bank asking me to donate.

Q.D5e.- I think that it is important to give blood.

Q.D5f.-I wanted to get test results for my blood.

Q.D5g.-My blood type is in high demand.

Q.D5h.-I think that I am doing something important for society.

Q.D5i.-I may need blood myself someday.

Q.D5j.-I heard that blood donation is good for my health.

Q.D5k.-I like to know about my health and blood donation is a good way to find out.

Q.D5l.-Someone offered me money for donating.

Q.D5m. -Blood banks always need blood and so donating is the right thing to do.

Q.D5n.-Is there another reason that best explains why you came to donate?

Q.D5p.-What is the reason that best explains why you came to donate?

Objective: to determine if the donor was asked to donate. How engaged participant can influence the participants to donate, the social influence of it.

Q.D6.-Some people feel they must donate blood because family, friends, co-workers or other persons in an organization they know donate blood or encourage others to donate. Did this happen to you when you last donated blood?

Objective: to determine donors intention to get HIV test through blood donation, to ascertain donors intentions, hidden or not, to came to blood bank in order to get tested for HIV. Blood bank serology may play a magnet effect to the participant. We intend to ascertain donor's perceptions/confidence related to HIV serology performed by the blood bank as well whether the blood screening serology still stimulating at blood donor's, the magnet effect.

Q.D7.-Do you believe that the blood center uses better HIV tests than are available at other places?

Q.D8.-Did you donate blood because you wanted to be tested for HIV?

Q.D9a.-Please checks all the boxes for the factors that contributed to your decision to come to the blood center to be tested for HIV.

Q.D9b.-Please specify other reason

Objective: to ascertain donors intentions, hidden or not, to came to blood bank in order to get tested for Hepatitis or other test.

Q.D10.-Did you donate blood because you wanted to be tested for hepatitis?

Q.D11a.-Please checks all the boxes for the factors that contributed to your decision to come to the blood center to be tested for hepatitis.

Q.D11b.-Please specify other reason

Q.D12a.-Did you come to the blood center to be tested for some other reason?

Q.D12b.-Please specify other reason

Objective: to determine whether health staffs have or had influenced donors' to donate blood to get tested. Health professionals may play an important role leading person to donate blood in order to get tested.

Q. D13.-Did a health worker such as a doctor, nurse, or someone from a health department suggest that you go to the blood center for a blood test for HIV, hepatitis, or for some other reason?

Q.D14.-Please tell us who suggested you to come to the blood center

Objective: to determine respondents' knowledge about HIV, risk behaviors and window period for HIV.

D15.-You can donate blood if you have engaged in risk behaviors for HIV or AIDS because the blood center tests all blood and throw away any infected blood

D16.-You can donate blood even if you engage in risk behaviors for HIV or AIDS as long as you have a negative HIV test.

D17.-The blood test for HIV identifies everyone who is infected with the virus.

Section E - Sexual History

Sexual lifestyle, including, the number of sexual partners during the lifetime increases the odds of having a sexual transmitted disease, as well its spread. The sexual history will allow us to determine, the most prevalent sexual patterns for the Brazilian participant and whether this pattern may or may not be correlated to specific serologic markers. HIV pathway spread has moved from homosexual to heterosexual patterns, in many countries. A better understanding of this moving patterns may allow us to built more accurate questions to improve donors' qualification, in order to avoid discrimination and unnecessary donors lose.

In 2004 Brazilian policies allowed MSM to donate blood since the last sexual intercourse was occurred 12 month before the blood donation. The HIV prevalence in Brazil is 10 times higher than in USA and NAT test has not been performed at the blood donation yet. No data has been published since this new policies has been implemented.

Objective: to ascertain the respondent sexual self-perception orientation. In many Latino American cultures, for instance, men do not consider themselves as homosexual, as long as, they only have insertive anal sex or oral sex.

E1.-What do you consider yourself to be?

Objective: to ascertain the men sexual past history

E2.-(Ask of Men Only) How many different women have you had sex with since you first began having sex?

E3.-(Ask of Men Only) How many different men have you had sex with since you first began having sex?

Objective: to ascertain the women sexual past history

E2.-(Ask of Women Only) How many different men have you had sex with since you first began having sex?

Section F - Sexual partners risks

The following section is related to general risks factor for blood borne disease which the participants may had in their lifetime. Those questions will be useful in those cases that the respondents says ZERO or None sexual partner in the 12 months before blood donation. (Section G)

Objective: To determine the general risk factors for the participants partners, related to blood borne disease.

F1a.-To the best of your knowledge, have you ever had sex with anyone who was an intravenous drug user?

F1b.-In the year before your last donation, have you had sex with anyone who was an intravenous drug user?

F2a.-To the best of your knowledge, have you ever had sex with anyone who tested positive for HIV?

F2b.-In the year before your last donation, have you had sex with anyone who tested positive for HIV?

F3a.-To the best of your knowledge, if your partner tested positive for HIV, was he/she taking HIV medications?

F3b.-In the year before your last donation, if your partner tested positive for HIV, was he/she taking HIV medications?

F4a.-To the best of your knowledge, have you ever had sex with a man who has had sex with another man.

F4b.-In the year before your last donation, have you had sex with a man who has had sex with another man?

F5a.-To the best of your knowledge, have you ever had sex with anyone who received a blood transfusion?

F5b.-In the year before your last donation, have you had sex with anyone who received blood transfusion

F6a.-To the best of your knowledge, have you ever had sex with anyone who was a hemophiliac?

F6b.-In the year before your last donation, have you had sex with anyone who was a hemophiliac?

F7a.-To the best of your knowledge, have you ever had sex with anyone who has spent three or more nights in jail, prison, or a detention center

F7b.-In the year before your last donation, have you had sex with anyone who has spent three or more nights in jail, prison, or a detention center

F8a.-To the best of your knowledge, have you ever had sex with anyone who had a job that involved exposure to blood or other body fluids

F8b.-In the year before your last donation, have you had sex with anyone who had a job that involved exposure to blood or other body fluids.

Section G- Social Matrix

This questionnaire was designed to capture sexual information for 5 sexual partners in the 12 months before the last blood donation. The reasons for that are; most of blood borne disease and sexual transmitted disease can be diagnosed within less than 12 months period; in Brazil having up to 6 sexual partners is the current deferral parameter; in general persons tend to maintain a sexual pattern in their lifetime (MSM, bisexual, heterosexual) as well some other sexual particularities that are relevant to identify riskier behavior for sexual transmitted disease. We assume therefore, asking more than 5 sexual partners will not provide any supplemental information. We also intend to correlate the HIV incidence and prevalence among repeated, lapsed and first time participant. The following questions will guide future screening questionnaire efforts target to avoid at risk participant.

Objective: to ascertain the blood donor sexual history in the past 12 months before the last blood donation is necessary to determine, whether the number of sexual partners, sexual habits or behaviors would give a better parameter to prevent a riskier person from blood donation.

G1.-How many people did you have sex with in the 12 months before your blood donation?

Objective: some demographic data are necessary to ascertain the participant's network relationship and to correlate

G2, G19, G36, G53, G70.-What is Partner 1,2,3,4 and 5's gender?

G3, G20, G37, G54, G71.-How old is partner 1,2,3,4 and 5s?

G5, G22, G39, G56, G73.-How would you describe partner 1,2,3,4 and 5's race? **(Check all that apply)**

Objective: to ascertain the participant's relation network and relationship level among them. These questions were designed to evaluate whether the environment and social network have influence on sexual behavior activity.

G4, G21, G38, G55, G72. -What type of partner is partner 1,2,3,4, and 5?

G9, G26, G43, G60, G77. -Where did you first meet partner 1,2,3,4, and 5?

G10, G27, G44, G61, G78 - Specify where you met partner 1,2,3,4, and 5?

G7, G24, G41, G58, G75. - Is partner 1,2,3,4 and 5 a male who has had sex with other males?

G8, G25, G42, G59, G76. - What is partner 1,2,3,4 and 5's HIV status?

Objective: to ascertain other risk factors than sexual, related to HIV transmission.

G6, G23, G40, G57, G74. - Is partner 1,2,3,4 and 5 an injection drug user?

Objective: to access unprotected sexual behaviors and correlated it to specific serologic markers

G11, G28, G45, G62, and G79.-Number of times you had vaginal intercourse with partner 1,2,3,4 and 5 in past 12 months.

G12, G29, G46, G63, G 80.-When you had vaginal sex, how frequently did you use condoms?

G13, G30, G47, G64, G81.-Number of times you had anal intercourse with partner 1 in past 12 months.

G14, G31, G48, G65, G 82.-When you had anal sex, how frequently did you use condoms?

G15, G32, G49, G66, G83.-Number of times you had insertive anal intercourse with partner 1 in past 12 months.

G16, G33, G50, G67, G84.-When you had insertive anal sex, how frequently did you use condoms?

G17, G34, G51, G68, G85.-Number of times you had receptive anal intercourse with partner 1 in past 12 months.

G18, G35, G52, G69, G86.-When you had receptive anal sex, how frequently did you use condoms?

Section H - Alcohol and drug use

For the following section we intend to evaluate the influence of social lifestyle in terms of alcohol and drug use. We also intend to evaluate whether specific serologic markers are related to riskier behaviors.

Objective: to ascertain the alcohol use frequency and quantity a day.

H1.-How often do you drink beer, wine, liquor, or mixed drinks?

H2.-On average how many drinks do you have each time you drink? Number of drinks

Objective: to ascertain the non-injected illegal drugs use and frequency

H3.-Have you ever used any non-injected illegal drugs (drugs that are smoked, snorted or taken orally), examples include marijuana (as called, pot) , hashish, cocaine (as called, blow or crack), methamphetamines (as called, crystal), ecstasy (as called, "e"), mushrooms, and LSD?

H4.-When was the first year you used non-injected illegal drugs?

H5.-When was the last year you used non-injected illegal drugs?

Objective: to ascertain the illegal drugs use and frequency

H6.-If you have smoked or snorted illegal drugs, did you share pipes or straws with another person?

Objective: to ascertain the injected illegal drugs use and frequency

H7.-Have you ever used or shot up injection drugs (examples include heroin, cocaine, and amphetamines)?

H8.-When was the first year you used injected drugs?

H9.-When was the last year you used injected drugs?

Objective: to ascertain the non-prescript substance use and frequency

H10.-Have you ever injected any non-prescription substances including vitamins, anabolic steroids, or hormones?

H11.-Have you ever shared needles or syringes with another person to inject any non-prescriptions substance including vitamins, anabolic steroids, and hormones?

Section I Medical History

Objective: to obtain data related to HIV general medical history exposure.

I1.-Have you ever had a blood transfusion?

I2.-How many transfusion episodes have you had?

I3.-When was the first year you received a transfusion?

I4.-When was the last year you received a transfusion?

I5.-Have you ever had minor or major medical surgery, tooth extraction or another dental procedure?

I6.-In the year before your last blood donation, have you had minor or major medical surgery, tooth extraction, or another dental procedure?

I7.-Have you ever had endoscopy (a medical test where a flexible tube is used to look inside of your throat and digestive system) or colonoscopy (a medical test where tube is used to look inside your colon/large intestine)?

I8.-In the year before your last blood donation, have you had endoscopy or colonoscopy?

Section J- Other Potential Risk Factors

- J1.-Have you spent three or more nights in jail, prison, or a detention center?
- J2.-Have you had acupuncture treatments?
- J3.-How many times have you had acupuncture treatments?
- J4.-In the year before your last blood donation, have you had acupuncture treatments?
- J5.-How many tattoos do you have on your body?
- J6.-In the year before your last blood donation, have you had a new tattoo or had one re-applied?
- J7.-Where did you get your most recent tattoo?
- J8.-How many ear or body piercing do you have?
- J9.-In the year before your last blood donation, have you had new ear or body piercing?
- J10.-Where did you get your most recent piercing?
- J11.-Have you ever had a manicure or pedicure at a beauty salon or had a shave at a barbershop?
- J12.-How many times have you had manicures or pedicures or shaves at a barbershop?
- J13.-In the year before your last blood donation, have you had a manicure or pedicure or had a shave at a barber shop?
- J14.-How many people do you personally know who currently have AIDS or have died of AIDS?
- J15.-How many people do you personally know who do NOT have AIDS, but have tested positive for HIV, the virus that causes AIDS?

Section K - Work Place Exposures

- K1.-In your profession, do you take care of humans or have exposure to their bodily fluids?
- K2.-In your professional work have you ever had a needle stick injury (accidentally been stuck by a needle or other sharp instrument used for providing medical care to someone else)?
- K3.-In your professional work have you ever got someone else's blood, body fluids, or excrement splashed into your eyes, mouth or in an open skin lesion?

Section L - Exposure and Treatment

The following 5 additional questions that will be asked at the end of the interviews related on topics that are unique for HIV positive individuals (cases).

Objective: to ascertain the blood donor HIV knowledge and actual or past treatment. In Brazil HAART is a universal treatment to HIV and these questions will be useful to analyze drug resistance, cases with low viral load level, among others.

- L1.-Did you know your HIV status before donating?
- L2.-How do you think you may have become infected with HIV?
- L3/L4.-When do you think you may have been infected with HIV?(Month and year)
- L5.-Are you currently taking antiretroviral therapy?
- L6.-Have you taken antiretroviral therapy in the past?