

Attachment 3.2 –Risk Factor Assessment: Description of each item, source, and goal for Characterization of risk of HIV and HIV outcomes in the Brazilian Sickle Cell Disease (SCD) population and comparison of SCD outcomes between HIV sero-positive and negative SCD patients

REDS III-INTERNATIONAL

SCD Study 2015

Questions relating to survey objectives

The purpose of the interview questions is to collect information regarding risk factors associated with HIV infection such as male-to-male sex, having multiple heterosexual partners, and injection drug use (IDU) among persons with sickle cell disease (SCD) and a comparison non-SCD population in Brazil. The interview data will be used to understand if the risks of HIV in patients with SCD are different than in a demographically comparable population without SCD.

The information collected to achieve objective 1 will include answers to an assessment designed to measure HIV risk behaviors. The assessment is based upon an instrument previously utilized and validated by the US Centers for Disease Control and Prevention (CDC) in its HIV surveillance at U.S. blood banks and has been modified for use in this Study’s Brazilian setting for the REDS study “Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil” (OMB control number 0925-0597). The assessment was further modified for the Brazilian SCD population with input from Brazilian physicians, nurses and research assistants familiar with the population

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 test results as well as for obtaining general demographic information from study subjects.

Q. A1-Subject ID

Q. A2.-Subject Blood bank ID

Q. A.3-Designation of case (SCD) or control (non-SCD)

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

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 or ethnicity ? (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?

Q.B11-What is the approximate monthly income of your family?

Section C- Previous 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 determine if the subject has been previously tested for HIV.

Q.C1.-(cases) Have you ever been tested for HIV for any reason other than the routine care of your sickle cell disease?

(controls) Have you ever been tested for HIV?

Q.C1a.-What was the reason for the HIV test?

Q.C1b-Please specify the other reason for test.

Q.C2- Have you had an HIV test at any other place outside the Hemocenter?

Q.C2a-What other place outside the Hemocenter did you have an HIV test? (Check all that apply)

Q.C2b-Please specify the other test site.

Section D - Sexual History

Sexual lifestyle, including the number of sexual partners during the lifetime and sex without a condom, increases the odds of having a sexual transmitted disease as well as its spread. Therefore, detailed questions regarding sexual history are necessary to adequately measure risk of HIV in the study population.

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.

Q.D1.-What do you consider yourself to be?

Objective: to ascertain the male sexual past history

Q.D2- How many people have you had sex with in your entire life?

Q.D3- How many people have you had sex with in the last 12 months?

Q.D4 -(Ask of Men Only) How many different women have you had sex with since you first began having sex?

Q.D5.-(Ask of Men Only) How old were you when you had sex with a woman for the first time?

Q.D6-(Ask of Men Only) How many different men have you had sex with since you first began having sex?

Q.D7--(Ask of Men Only) How old were you when you had sex with a man for the first time?

Objective: to ascertain the women sexual past history

Q.D8.-(Ask of Women Only) How many different men have you had sex with since you first began having sex?

Q.D9 -(Ask of Women Only) How old were you when you had sex with a man for the first time?

Q.D10 -(Ask of Women Only) How many different women have you had sex with since you first began having sex?

Q.D11 -(Ask of Women Only) How old were you when you had sex with a woman for the first time?

Objective: To ascertain condom use with different types of sexual contact

Q.D12 –How many times have you had vaginal sex in the past 12 months?

Q.D13 -When you had vaginal sex, how frequently did you use condoms?

Q.D14-How many times have had anal sex in the past 12 months?

Q.D15-When you had anal sex, how frequently did you use condoms?

Q.D16-How many times have you had insertive anal sex in the past 12 months?

Q.D17-When you had insertive anal sex, how frequently did you use condoms?

Q.D18-How many times have you had receptive anal sex in the past 12 months?

Q.D19-When you had receptive anal sex, how frequently did you use condoms?

Section E - Sexual partners risks

The following section is related to other risks factor for HIV which the participants may have had in their lifetime due to HIV risk factors present in their sexual partners.

Objective: To determine the general HIV risk factors for the participants partners.

Q.E1.-To the best of your knowledge, have you ever had sex with anyone who used injected drugs?

Q.E2.-To the best of your knowledge, have you ever had sex with anyone who tested positive for HIV?

Q.E3-To the best of your knowledge, have you ever had sex with a man who has had sex with another man?

Q.E4.To the best of your knowledge, have you ever had sex with anyone who received a blood transfusion?

Q.E5. To the best of your knowledge have you ever had sex with anyone who has hemophilia?

Section F- Alcohol and drug use

For the following section we intend to evaluate the influence of social lifestyle in terms of alcohol and drug use.

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

Q.F1.-How often do you drink beer, wine, liquor, or mixed drinks?

Q.F2.-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

Q.F3.-Have you ever used any non-injected illegal drugs. These are drugs that are smoked, snorted or taken by mouth. Some examples of non-injected illegal drugs include marijuana (also called, pot) , hashish, cocaine (also called blow or crack), methamphetamines (also called, crystal), ecstasy (also called, "e"), mushrooms, and LSD?

Q.F4. Please mark all non injected drugs that you have ever used (chose or one or more)

Q.F4a Please specify the other non injected drug that you have used

Q.F5. When was the first year you used non injected illegal drugs

Q.F6. When was the last year you used non-injected illegal drugs

Objective: to ascertain the illegal drugs use and frequency

Q.F7.-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

Q.F8.-Have you ever used or shot up injection drugs? This means using a needle to inject drugs into a vein. Examples include heroin, cocaine, and amphetamines?

Q.F9. Please mark all of the injected drugs you have used (choose one or more)

Q.F9a. Please specify the other injected drug you have used.

Q.F10.-When was the first year you used injected drugs?

Q.F11.-When was the last year you used injected drugs?

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

Q.F12.-Have you ever injected any non-prescription substances including vitamins, anabolic steroids, or hormones?

Q.F13.-Have you ever shared needles or syringes with another person to inject any non-prescriptions substance including drugs, vitamins, anabolic steroids or hormones?

Section G Medical History

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

QG.1.-Have you ever had a blood transfusion?

QG.2.-How many transfusion episodes have you had?

QG.3.-When was the first year you received a transfusion?

QG.4.-What is the name of the place (hospital, Hemocenter or clinic) where this first transfusion happened?

QG.5.-When was the last year you received a transfusion?

QG.6.-Have you ever had an organ or tissue transplant?

QG.7-Please mark the type of tissue or organ you had transplanted (choose one or more)

QG.7a-Please specify the other tissue/organ

QG.8-Have you ever had a surgery?

QG.8a. Please specify the surgery.

QG.9 Have you ever had a tooth extraction?

QG.10 Have you ever had a dental root treated or surgery in your mouth?

Section H- Other Potential Risk Factors

Q.H1 – Were you born to an HIV positive mother?

Q.H2 – Were you breastfed by an HIV positive person

Q.H3.-Have you spent three or more nights in jail, prison, or a detention center?

Q.H4.-Have you had acupuncture treatments?

Q.H5.-How many times have you had acupuncture treatments?

Q.H6.-How many tattoos do you have on your body?

Q.H7.-Where did you get your most recent tattoo?

Q.H8.-How many ear or body piercing do you have?

Q.H9.-Where did you get your most recent piercing?

Section I – Personal contact with persons with HIV/AIDS and Work Place Exposures

Objective: To ascertain other potential exposure to HIV

QI.1.-How many people do you personally know who currently have HIV?

QI.2-How many people do you personally know with sickle cell and HIV?

QI.3-Are you currently working?

QI.4.-In your profession, do you take care of humans or have exposure to their bodily fluids?

QI.5.-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)?

QI.6-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 J - Exposure and Treatment

The following additional questions will be asked ONLY for HIV sero positive cases enrolled in objective 2 of the study.

Objective: To ascertain the subject's HIV knowledge and actual or past treatment as well as treatment location. We assume the HIV clinical history would be included in the Hemocenter records as infectious disease specialists treat SCD patients for HIV. Question J.1 will confirm this and ensure we would not be missing HIV related data in the medical record. 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.

QJ.1.-What is the name of the HIV clinic where you are treated for your HIV?

QJ.2.-How do you think you may have become infected with HIV?

QJ3/4.-When do you think you may have been infected with HIV?(Month and year)

QJ.5.-Are you currently taking antiretroviral therapy?

QJ.6.-Have you taken antiretroviral therapy in the past?