

## **REDS II-INTERNATIONAL CHINA RISK FACTOR STUDY**

### **Questions relating to survey objectives**

The purpose of the interview questions is to collect donor profile data for comparing risk exposures between blood donors who test HBV/HCV positive (HBV/HCV cases) and HBV&HCV negative (controls). The responses will permit us to determine risk factors associated with HBV/HCV infection among volunteer blood donors in China. A case control study will yield interview data on HBV/HCV risk behaviors among donors that will be used; 1) to understand predominant risk behaviors associated with in HBV/HCV positive blood donation in China, for example: history of transfusion, having multiple heterosexual partners, and injection drug use (IDU), 2) the results may also lead to suggestions for modification to current operational donor screening questionnaire in ways that can decrease risk and improve blood safety. The questions for both cases and controls are identical.

Cases and controls will be mailed a Risk Factor Survey study packet which includes an informed consent document explaining the voluntary nature, the benefit and risk of this study, a Risk Factor Questionnaire and an envelope with paid postage for a donor to mail their completed questionnaire back to the blood center. The donor can also complete the survey at the study website. Donors are not asked to sign the consent form because of the anonymous design of this study. By sending back the completed questionnaire, a donor indicates his/her consent for this study.

### **Cover page- Study Data**

- **Date:** This question captures information on the administration of the questionnaire. The surveyed subject will fill out the date when the survey is taken.
- **Study identification number:** This will be completed by trained research staff. The study ID number will be used for de-identified administrative record keeping, such as linking interview responses to the HBV/HCV testing results and the donor/donation profile of the study subjects.

### **Body of the Questionnaire**

All the following questions in the questionnaire will be completed by study subject in privacy.

### **Demographic information**

**Objective:** The following questionnaire items are related to the general demographic information of the study subjects.

- Q1 When were you born?
- Q2 What is your gender?
- Q3 What is your place of birth?
- Q4 What is your ethnicity?
- Q5 What is your current occupation?
- Q6 What is the highest level of education you have received?
- Q7 What is your marital status?

### **Previous donation**

**Objective:** The following questionnaire items are used to obtain data related to the frequency of previous donation and the year and type of each blood donation. In China due to the unsanitary illegal blood collection in the early to middle 1990s, the history of plasma donation in the 1990s has been identified by several studies as a major risk factor for HCV infection. So these questions will capture information on the association between previous donation and HBV/HCV infection status.

- Q8 How many times have you donated blood?  
 Q8a Year and type of each blood donation (If you have donated blood more than 4 times, please list the most recent three)

### **Incentives and motivation**

**Objective:** To determine motivational factors that lead participants to donate blood. The following questions help understand the donor's intention to get HBV/HCV testing through blood donation (test seeking). Blood bank serology testing may be a magnet that attracts people wishing to be tested for HBV/HCV. We intend to ascertain donor's perceptions/confidence related to HBV/HCV serology performed by the blood bank as well whether the blood screening serology testing was contributing factor in donating.

- Q9 How much do you agree or disagree about phrases below:  
 Q9a It's important that I received blood test results from blood donation.  
 Q9b I think blood donation is a good, fast, anonymous way to get my blood test.  
 Q9c One of my reasons for donating blood is to find out if I have HIV and/or hepatitis infection.

### **Medical History**

**Objective:** To obtain data related to general medical history exposures that could lead to HBV/HCV transmission, including acupuncture, medical injection, medical surgery, cosmetic surgery, dental cleaning, dental surgery, endoscopies, both life time and exposure in the year before blood donation.

- Q10 Have you ever received acupuncture treatment?  
 Q10a In the 12 months before your most recent donation, did you have acupuncture?  
 Q11 In the 12 months before your most recent donation, did you have any injection (including intravenous and intramuscle injections)?  
 Q11a How many times did you have injection(s)?  
 Q12 Have you had any finger sticks?  
 Q12a In the 12 months before your most recent donation, did you have finger sticks?  
 Q13 Have you ever had in-patient medical surgery?  
 Q13a In the 12 months before your most recent donation, did you have in-patient medical surgery?  
 Q14 Have you ever had out-patient medical surgery?  
 Q14a In the 12 months before your most recent donation, did you have out-patient medical surgery?  
 Q15 Have you ever had cosmetic surgery (e.g. laser, eye/lip surgery, collagen injection, dermal abrasion)?  
 Q15a In the 12 months before your most recent donation, did you have cosmetic surgery?  
 Q17 Have you ever had any dental cleaning?  
 Q17a In the 12 months before your most recent donation, did you have dental cleaning?  
 Q18 Have you ever had any dental surgery, such as root canal treatment or tooth extraction?

- Q18a In the 12 months before your most recent donation, did you have dental surgeries?  
 Q19 Have you ever had any endoscopy (such as gastroscopy and colonoscopy)?  
 Q19a In the 12 months before your most recent donation, did you have endoscopies?  
 Q20 When you had acupuncture, finger sticks, or injections, were needles and syringes used disposable?

### **History of transfusion**

**Objective:** Due to the unsanitary illegal blood collection and transfusion practices in China in the early to middle 1990s, the history of blood transfusion in the 1990s has been identified by several studies as a major risk factor for HBV/HCV infection. So the following questions ask about the year and frequency of previous transfusion.

- Q16 Have you ever received a blood transfusion?  
 Q16a How many times did you have blood transfusions?  
 Q16b Year of your first time of blood transfusion?  
 Q16c Year of your last time of blood transfusion?

### **Previous deferral**

**Objective:** To ascertain if the blood donor has been deferred at the time of the blood donation and the reason for deferral. In China, the blood centers are building up the information system for deferred donors so next time when these donors come to donate, they will be automatically identified. These questions will be useful for understanding the effectiveness of deferral system and the donors' information of deferral.

- Q21 Have you ever been told that you are at risk for spreading diseases through your blood?  
 Q22 Have you ever been deferred as a blood donor?  
 Q22a For what reason were you deferred?

### **Previous diagnosis of hepatitis, HIV and STD**

**Objective:** Previous infection of other-type hepatitis, HIV and STD may be associated with HBV/HCV infection. The following questions ask about the donor's previous diagnosis of hepatitis, HIV and STD as well as the infectious status of their family members.

- Q23 Have you ever been previously diagnosed with hepatitis?  
 Q23a What type(s) of hepatitis did you have?  
 Q24 Have you ever been previously diagnosed with syphilis, gonorrhea, or any other sexually transmitted disease?  
 Q25 Have any of your family members had hepatitis?  
 Q26 Have any of your family members had HIV/AIDS?  
 Q27 Have you ever had household contact with someone with hepatitis or HIV/AIDS?  
 Q27a In the 12 months before your most recent donation, did you have household contact with someone with hepatitis or HIV/AIDS?

## Drug use

**Objective:** For the following questions we intend to evaluate the influence of illicit drug use on HBV / HCV infection. The questions include injected and non-injected illegal drugs use and frequency. To ascertain if illegal drugs use including sharing the drug delivery device, which could lead to disease transmission, we also ask the questions about sharing injected drug delivery device

- Q28 Have you ever used needles to shoot street drugs?
- Q28a How long have you shot drugs?
- Q28b How many times per month did you shoot drugs?
- Q28c Have you ever shared needles or syringes with others to inject street drugs?
- Q29 Have you ever used illegal oral or intranasal drugs without doctor's prescription?
- Q29a In the 12 months before your most recent donation, did you use illegal oral or intranasal drugs without doctor's prescription?

**Objective:** The following questions intent to identify illicit drug use among the donor's cohabitants lifetime and during the past 12 months, as well as among their family members

- Q30 Have you ever lived with a person with illegal injection?
- Q30a In the 12 months before your most recent donation, did you live with a person with illegal injection?
- Q31 Are any of your close friends or family members intravenous drug users?

## Sexual lifestyle

**Objective:** The following questionnaire items are used to obtain data related to 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 Chinese blood donors and whether this pattern may or may not be correlated to specific serologic markers. A better understanding of sexual risk factors for HBV and HCV may allow us to build more accurate questions to improve the donor qualification process. It may also help us to avoid potential discrimination and unnecessary loss of donors if the patterns of HBV/HCV transmission are not shown to be associated with sexual activity.

- Q32 Have you had 2 or more sexual partners of the opposite sex?
- Q32a How many heterosexual partners did you have?
- Q32b How often do you or your sex partner use a condom when you have sex with your heterosexual partner?
- Q33 (For male only) In your lifetime, have you ever had sex with another male?
- Q33a (For male only) How many times did you have sex with males?
- Q33b (For male only) How many male partners have you had sex with?
- Q33c (For male only) How often do you or your sex partner use a condom when you have sex with male partner?
- Q34 Have you ever paid or received money for having sex?
- Q34a How many times have you paid or received money for having sex?
- Q34b In the 12 months before your most recent donation, did you pay or receive money for having sex?

## Sexual partners

**Objective:** The following questions are related to known risks factors for blood borne disease in the donor's sexual partners in their lifetime.

- Q35 Have you ever had a sex partner that was an intravenous drug user?
- Q35a In the 12 months before your most recent donation, did you have a sex partner that was an intravenous drug user?
- Q36 In the past ten years, have you ever had a sex partner who had a positive test for syphilis, gonorrhea, or any other sexually transmitted disease?
- Q36a In the 12 months before your last donation, did you have a sex partner who had a positive test for syphilis, gonorrhea, or any other sexually transmitted disease?
- Q37 In the past ten years, have you ever had a sex partner who had been diagnosed with hepatitis or HIV/AIDS?
- Q37a In the 12 months before your most recent donation, did you have a sex partner who had been diagnosed with hepatitis or HIV/AIDS?
- Q38 In the past one year, have you had sexual contact with anyone who received blood transfusion?
- Q38a In the 12 months before your most recent donation, did you have sexual contact with anyone who received blood transfusion?

### **Work Place Exposures**

**Objective:** Donors who work in a health care profession or other social setting that could lead to exposure to blood or other body fluids could be at higher risk for HBV/HCV acquisition.

- Q39 Have you ever contacted with human blood and other human body fluids in your workplace?
- Q39a In the 12 months before your most recent donation, did you contact with human blood and other human body fluids in your workplace?

### **Other Potential Risk Factors**

**Objective:** To obtain data related to rare risk factors for HBV/HCV infection such as body piercing and tattoo, we ask about ever exposure and also exposure in the year before blood donation.

- Q40 Have you ever had a tattoo?
- Q40a In the 12 months before your most recent donation, did you have a tattoo?
- Q41 Have you ever had your ears or other body parts pierced?
- Q41a In the 12 months before your most recent donation, did you have your ears or other body parts pierced?

### **Notification and adherence**

**Objective:** The following questions are used to determine the notification service provided by the blood center and whether or not the donor is willing to adhere to the advice for further testing and health care. This helps us understand if the notification is effective.

- Q42 Did you receive notification from blood center about your infection status?
- Q42a Did you seek further testing or health care according to the instruction of the notification?
- Q42b Are you planning to seek further testing or health care according to the instruction of the notification?