

Abbreviated Donor History Questionnaire Study, 2005

**AABB
Donor History Task Force**

Study Manual

Introduction

In 2000, AABB commissioned the Donor History Task Force to develop a donor history questionnaire (DHQ) that would standardize screening of potential blood donors. The length, complexity and content of existing questionnaires was markedly different across blood collecting facilities making the donor screening process more elaborate and more confusing for donors than was necessary. The Task Force has attempted to enhance donor comprehension by developing a questionnaire that asks each point of information separately, rather than in multiple, complex questions, and has organized questions into a logical format based on the time frame to which the questions refer. This questionnaire has been designed to be fully self-administered. In 2004, FDA issued a draft “Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components” document indicating their acceptance of the new uniform Donor History Questionnaire (DHQ) for donor screening. Blood collecting facilities commenced implementation of the new questionnaire in 2004.

The Task Force has also developed an abbreviated DHQ (aDHQ) for frequent donors. The aDHQ has introduced two medical capture questions to replace many of the questions regarding donor medical problems and treatment. The aDHQ has not been accepted by FDA for use in donor screening. The goal of this study is to test how well these two medical capture questions identify relevant donor eligibility information when compared to questions on the new full-length DHQ that they are designed to replace. The results of the study will be submitted to FDA.

Specific Objectives:

- To determine whether or not the two medical capture questions identify deferrable risks as well as the full-length questionnaire.
- To compare responses to the two medical capture questions with responses to the relevant questions on the full-length questionnaire.
- To identify reasons for discrepancies between answers provided to the two medical capture questions and relevant questions on the full-length questionnaire, using cognitive interviews.

These objectives will be met by studying donors who are eligible to use the aDHQ and have a discordant result between the two capture questions on the aDHQ, and the questions on the DHQ that they are intended to replace (see definition of discordant result below). For donors with discordant results, follow-up cognitive interviews will be conducted using trained interviewers. Additional information will be collected to ensure that the donors in the study are representative of donors who would be using the aDHQ.

Study Sites

The study will be conducted in five blood centers: New York Blood Center, Hoxworth Blood Center, Gulf Coast Regional Blood Center, Mississippi Valley Regional Blood Center and ARC, Lewis & Clark Region.

Study Administration

The study will be administered through AABB in close communication with Center Coordinators at all participating blood centers.

Study Term

The study will begin in the summer of 2005.

Role of the Center Coordinator

The Center Coordinator will be responsible for implementation of this protocol at their Center. The steps in implementation will be carried out as described below, although minor details of the implementation will be tailored to the collection site structure of each Blood Center. The Study Administrator will assist in selection of appropriate collection sites at the various Centers. The Center Coordinator will oversee data collection in the collection sites, ensure that the protocol is implemented correctly and that all forms described in this manual are complete and correct, and are forwarded to the Study Administrator as described.

Sample Size

Each blood center will enroll 250 donors who meet the selection criteria outlined below. As there will be five blood centers participating in the study, the final sample size for this study will be 1,250 donors.

Definition of a Discordant Result

A discordant result has occurred when a donor's answer to the medical capture questions on the aDHQ is not congruent with answers to questions on the full-length questionnaire that the aDHQ questions should capture.

Medical capture questions on the aDHQ :

Since your last donation, have you

Had any new medical problems or diagnoses?

Had any new medical treatments?

should be compared with the following questions on the DHQ:

Are you

Currently taking an antibiotic?

Currently taking any other medication for an infection?

In the past 12 months have you

Had a blood transfusion?

Had a transplant such as organ, tissue, or bone marrow?

Had a graft such as bone or skin?

Had or been treated for syphilis or gonorrhea?

Have you EVER

- Had a positive test for the HIV/AIDS virus?
- Used clotting factor concentrates?
- Had hepatitis?
- Had malaria?
- Had Chagas' disease?
- Had babesiosis?
- Received a dura mater (or brain covering) graft?
- Had any type of cancer, including leukemia?
- Had any problems with your heart or lungs?
- Had a bleeding condition or a blood disease?

If the donor answered yes to any of these questions on the aDHQ or the DHQ, the donor should be assessed as usual to determine whether or not the response indicates a reason for deferral.

It is a discordant result :

If the donor answers No to the medical capture questions on the aDHQ, but answered Yes to any of the DHQ questions referred to above, regardless of whether the response constitutes a reason for deferral.

OR

If the donor answers Yes to either medical capture question on the aDHQ, but answered No to all of the DHQ questions referred to above regardless of whether the response constitutes a reason for deferral.

Also discordant

It is possible that the donor answers No to the medical capture questions and reports on the DHQ, by answering Yes to one of the questions listed above, a deferrable risk that should have been reported on their last donation. This is a discordant result.

It is not a discordant result:

If the donor answers No to the two medical capture questions on the aDHQ and answers No to all of the questions on the DHQ listed above and during your assessment the donor volunteers no information to the contrary.

OR

If the donor answers Yes to either medical capture question on the aDHQ and answers Yes to the corresponding DHQ question(s) indicating the same information on both questionnaires.

Donor Selection

In order to participate in the study, donors must have completed donor screening twice using the new full-length DHQ, with at least the second use having occurred within the last six months. Both whole blood and apheresis donors may participate in the study. Donors who meet the criteria will be offered enrollment, from selected collection sites, on a consecutive basis in order to minimize selection bias. The proportion of donors with each donation type will be agreed upon between the Center Coordinator and the Study Administrator, but at least 30 % should be whole blood donors. This is because it is very important that the final sample includes donors from the full range of the six-month interval since their last donation. An effort will be made to include donors with the longest possible interval since the last donation. It is expected that some mobile sites will be involved as well as fixed sites, although frequent donors are more likely to come to a fixed site than a mobile site.

Informed Consent

Prior to participating in the study, the study will be explained and donors will be asked to sign a consent form. Donors who do not wish to participate will not be pressured to agree to participate, and donors will be permitted to stop at any time and to refuse to answer any questions that are not part of the routine assessment for donor eligibility.

Follow-up Cognitive Interviews

Donors that are identified as having discordant results will be invited to participate in a follow-up interview to determine why the donor answered the two questionnaires differently. An interviewer who has completed training in cognitive interview techniques will carry out a semi-scripted interview specifically designed for this study. The interview should not take more than five to ten minutes. The interviewer will make an audio recording of the interview with the donor, which will later be transcribed.

If an interviewer is available at the collection site, the interview will be carried out in a private room with minimal noise in order to ensure a good quality recording of the interview, and in order to ensure that the donor's responses are confidential.

It is anticipated that most interviews will be conducted, via telephone, within three days of the questionnaires being answered. As the donor's ability to remember how they were thinking at the time of donation may be less over time, every effort will be made to ensure that the interviews are carried out as soon as possible within the three day interval.

Implementation Steps

The following are the steps that will be carried out in this order at each blood center. Each Center Coordinator will input details in a separate document entitled "Collection Site Instructions" so that instructions for the staff are specific to that center.

1. Assess the donor's eligibility to participate.
2. Explain the study to the donor and obtain informed consent to participate.
3. Assign a Study ID Number to all eligible donors. Track the number of donors who

- are eligible to participate and the number who have refused. Record the Study ID Number on the Donor Registration Sheet along with the last two donation dates.
4. The donor completes the aDHQ (identified by Study ID Number).
 5. The donor returns the aDHQ to the staff.
 6. Give the donor the DHQ and the Demographic Questionnaire and ask the donor to complete them. (Identify Demographic Questionnaire by Study ID Number).
 7. During the health assessment Blood Center staff will determine eligibility to donate. Determine whether the donor's responses to the questionnaires are discordant or not discordant (with the reason for discordance). Document this information on the DHQ/aDHQ Assessment Sheet.
 8. When donors with discordant responses are identified arrangements must be made for a cognitive interview. If a trained interviewer is available at the collection site the interview will take place following the donation process. When a trained interviewer is not available at the collection site ask the donor to provide a contact telephone number for the cognitive interview.
 9. Forward a copy of the aDHQ and DHQ to the interviewer if a cognitive interview is required.
 10. Collect and paper clip together all forms (aDHQ, Demographic Questionnaire, and Consent Form) for each donor.
 11. Complete the Collection Site Summary Sheet at the end of the day.
 12. Collect the Collection Site Summary Sheet, the DHQ/aDHQ Assessment Sheet and the Donor Registration Sheet at the end of the day.

Confidentiality

All information provided by the donor is confidential, and will not be traceable to the donor record unless information is identified that would affect the donor's eligibility to donate. The donor will be identified on all study materials by a Study ID Number for which a separate list is maintained to identify the donor. This list will be stored separate from the other study materials. All study materials will be maintained in a locked environment, and once data is recorded in an electronic format, it will be stored in a secure, password protected server. All data will be reported in aggregate form and details of Blood Centers' operations will not be reported.

Risks and Benefits

There are no known physical or emotional risks associated with this study beyond what would normally be encountered in donating blood. The potential benefit of participation is that the data collected in this study will help to assess the abbreviated donor health questionnaire. As frequent donors, the participants in the study may be contributing to the implementation of a shorter, more concise questionnaire for all frequent donors.

Data Management and Evaluation

The completed data forms will be forwarded to the Study Administrator. Data will be coded and recorded electronically. The cognitive interviews will be transcribed and the transcription will be forwarded to the National Center for Health Statistics, Centers for Disease Control and Prevention where the transcriptions will be analyzed and a report will be

written.

Final Comments

If a donor has a question or concern for which staff do not have the answer, or the donor feels the answer is not adequate, the donor should be encouraged to call 1-XXX-XXX-XXXX

Appendix:

Donor Registration Sheet

DHQ/aDHQ Assessment Sheet

Collection Site Summary Sheet

Consent Form

Demographic Questionnaire

Donor History Questionnaire (DHQ)

Abbreviated Donor History Questionnaire (aDHQ)