

Issue Summary
Blood Products Advisory Committee Meeting
March 17, 2005
Gaithersburg, MD

Topic III: Study Design for an Abbreviated Uniform Donor History Questionnaire

Issue: The Donor History Task Force sponsored by the AABB has proposed an abbreviated Donor History Questionnaire as an alternative to asking a qualified subset of repeat donors to complete a full-length donor history questionnaire at each donation. FDA seeks the advice of the Committee on whether the study design and sample size proposed by the Task Force will test how well two proposed capture questions identify relevant donor eligibility information.

Background

Before each donation, potential donors are asked questions about their medical history and high-risk behavior. FDA has required or recommended that certain health history information be obtained to help determine if the donation process will be safe for the donor, and the donated product safe for the recipient.

The first uniform questionnaire was developed by AABB in the 1950s. As the number of infectious diseases and other problems associated with blood transfusions has increased, the number of questions and complexity of the questionnaire has also increased, resulting in numerous modifications of the questionnaire. Both blood donors and collection center personnel complain that the questionnaire is burdensome, resource intensive, the battery of questions is potentially confusing to donors.

In 2000, the Donor History Task Force was convened to evaluate, revise and streamline the AABB uniform donor questionnaire, in an effort to address these concerns. The task force evaluated pre-existing and new questions for donor comprehension and accuracy of responses, using focus group studies and one-on-one cognitive interviews. This resulted in a revised and redesigned full-length Donor History Questionnaire. The Task Force also developed a user brochure including glossary, flow charts and references; a Medical Deferral List; Blood Donor Education Materials; and a proposed abbreviated Donor History Questionnaire. On April 23, 2004, FDA published “Draft Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components”, accepting the full-length questionnaire and other associated materials, but not the abbreviated questionnaire.

Discussion

The current accepted full-length Donor History Questionnaire developed by the DH Task Force contains 17 questions about medications and medical events. In the abbreviated questionnaire originally proposed by the Task Force, these questions were consolidated into one medical history capture question: “Since your last donation, have you had any new medical problems, diagnosis, or treatments, including vaccinations?” This capture

question was administered to four test subjects during one-on-one cognitive interviews, to determine if it was an adequate substitute for the specific medical questions. One of the four subjects did not provide information about experiencing a significant medical event. While this question was tested on a limited sample, it did not elicit information in 25% of the subjects. More importantly, it did not elicit information from the only subject with a significant medical event.

In response to FDA's concern, the original compound capture question was revised and the current proposed abbreviated questionnaire now contains 2 medical capture questions: "Since your last donation have you had any new medical problems or diagnoses?" and "Since your last donation have you had any new medical treatments?"

The DH Task Force is proposing to conduct a cross-over study designed to test how well the two capture questions identify relevant donor eligibility information in repeat donors.

The specific objectives are:

- ?? To determine whether or not the two capture questions identify deferrable risks as well as the full-length questionnaire.
- ?? To compare responses to the two capture questions with responses to the 17 questions that are in the full-length questionnaire.
- ?? To identify reasons for discrepancies between the capture questions and the full-length questionnaire using one-on-one cognitive interviews.

Repeat donors eligible to participate in the study will have completed the full-length DHQ at least twice, with the second completion having occurred in the 6 months prior to study enrollment.

FDA supports measures that will improve the predictive value of the donor screening process and increase its efficiency. An abbreviated donor screening questionnaire is likely to reduce the time needed for donor screening and, theoretically, may offer improved predictive value due to increased donor attention focused on fewer questions. At the same time, FDA believes that the donor interview process is a key element of continued blood safety and believes that broad use of an abbreviated questionnaire format must be based upon reasonable assurance of predictive value that is at least equivalent to currently approved procedures.

Based upon the questionnaire and study design proposals, (to be presented by a representative of the Donor History Task Force) we are asking for BPAC to discuss the information presented and address the following questions.

Questions for the Committee

1. Does the committee agree that the proposed study design (exclusive of sample size) is adequate to reasonably demonstrate equivalence (or lack of equivalence) between the two capture questions on the abbreviated questionnaire, and the 17 specific questions on the full-length questionnaire?
2. If yes, does the committee agree that the proposed sample size is adequate?
3. If no, what alternate study design and/or sample size does the committee propose would be adequate?