

ISSUE SUMMARY:

Revised AABB Uniform Donor History Questionnaire for Blood Donor Screening Blood Products Advisory Committee, 6/14/01

Background

Before each donation, potential blood and plasma donors are asked questions about their medical history and high-risk behavior. These questions help to determine if the donation process will be safe for the donor and if the donated products will be safe for the recipient. FDA has required or recommended that certain information be obtained about donors' health history in our regulations or guidance documents.

Historically, blood centers were responsible for developing their own questions. The first uniform questionnaire was developed by AABB in the 1950's. This questionnaire asked for responses to 21 information points. As the number of recognized diseases and other problems associated with blood transfusions increased, the number of questions and complexity of the questionnaire increased. Current questionnaires ask donors to provide responses to 70 information points. Most blood collecting facilities currently use a variation of the AABB Uniform Donor History Questionnaire (UDHQ) that is based upon selection criteria contained in the *AABB Standards for Blood Banks and Transfusion Services*. FDA reviews and approves each new version of the AABB UDHQ instrument. Blood collection facilities may use this approved instrument without prior approval by FDA if no changes are made to its content.

Both blood donors and collection center personnel have complained that the current questionnaire is in need of improvement for the following reasons:

- a) Completion of the questionnaire is resource intensive (e.g., time, personnel).
- b) The questions and questionnaire format are confusing to donors.
- c) A small, but significant proportion of donors fail to identify risks that should prevent donation

A multi-organizational Task Force was formed in early 2000 to evaluate and revise the AABB UDHQ in an effort to streamline the screening process and address the above concerns. FDA has 3 liaison members on this Task Force who provide regulatory advice, as needed. An update regarding the efforts of the Task Force was first brought to the BPAC on September 15, 2000. The Task Force has now produced a revised draft questionnaire, which includes a description of the rationale for changes that have been proposed. The instrument has also undergone preliminary evaluation for donor understanding by a series of focus groups.

It is the Task Force's intention to more fully assess the revised uniform questionnaire for donor comprehension before it is submitted to FDA for review and approval. At the current meeting, Dr. Joy Fridey, chair of the Task Force, will update BPAC on these developments and describe plans for additional studies of donor comprehension. FDA seeks the advice of BPAC on the overall direction of this initiative.

Charge to BPAC

At this time, FDA is asking the BPAC to review and comment on several selected aspects of the revised UDHQ. The following questions are intended as a basis for discussion:

1. Is the UDHQ Task Force using the most appropriate overall approach in revising the UDHQ donor-screening instrument, with respect to:
 - a. donor comprehension studies
 - b. identification of questions proposed for elimination
 - c. transfer of some question content to the written donor information materials

2. Are the following elements of the re-designed questionnaire instrument appropriate:
 - a. Use of "capture" questions to identify individuals who are candidates for more in-depth question re: travel, etc?
 - b. Need/process to ensure on-site reading/understanding of the questionnaire by donors?
 - c. Use of separate medication and medical condition lists that can be expanded at local medical director discretion?
 - d. Provision of a user manual for the donor screening process?

4. When the completed revised UDHQ is submitted for FDA review and approval, what criteria and endpoints should FDA use to review:
 - a. Content
 - b. Format
 - c. Attention/comprehension
 - d. Estimated impact of screening on donor and/or blood safety