

ISSUE SUMMARY:

Should First Time Donors be Permitted to Use a Self-Administered Medical/Behavioral History Questionnaire?

Blood Products Advisory Committee, September 12, 2002

Background:

Before each donation, potential donors of Whole Blood and blood components, including Source Plasma, are asked questions about their medical history to ensure that the donors are in good health and to identify high-risk behaviors that might indicate risk for a blood-borne infection. These questions are intended to protect the health of the donor and to ensure the safety, purity, and potency of the donated products. Much of the content of current donor health history questions is derived from FDA regulations and guidance documents. Other questions have been added by industry, particularly in areas where FDA has not taken a position on the public health benefit of a donor question. FDA has not standardized the design, wording, or administration mode of the donor questionnaire. However, in practice, many of the recent donor questions recommended in FDA guidance documents have been discussed at advisory committee meetings and subsequently adopted verbatim by industry. As discussed at the September 15, 2000, June 14, 2001, and June 13, 2002 meetings of the Blood Products Advisory Committee, FDA has participated in the AABB Task Force to Redesign the Blood Donor Questionnaire. Through this multidisciplinary Task Force, the current donor questions have been systematically reviewed and question modifications were evaluated by cognitive studies of potential blood donors (via self-administration) to optimize comprehension. The revised UDHQ questionnaire has been submitted to FDA and is currently under formal review. The Task Force's intent is for the new UDHQ questionnaire to be self-administered to all donors.

Historically, blood centers have administered the health history questions to donors either by face-to-face interview with blood center staff, donor self-administration, or a combination of the two methods. In the early 1990s, published studies demonstrated higher rates of donor deferral for AIDS-related risk behaviors following face-to-face interview with blood center staff compared to self-administration (1,2). Based on these data, FDA made its current recommendation that the AIDS-related risk questions be administered orally to all donors (3). Beginning in 1998, some licensed blood establishments sought and were granted FDA approval for donor self-administration of the complete health history and behavioral questionnaire based upon submitted data. In this circumstance, blood center staff usually review the completed questionnaire before the donor is allowed to donate.

Issue:

Recent additions to the donor questionnaire include questions that necessarily contain complex scientific terminology (e.g. Chagas', Babesiosis, Creutzfeld-Jacob diseases). Some questions also require respondents to calculate time periods regarding possible travel exposures (vCJ-D, malaria). FDA believes that there is evidence that some at-risk

donors misunderstand the donor screening questionnaire. For example, it is well-documented that donors who are found positive for known infectious disease markers frequently have risk factors that should have resulted in their deferral prior to donation. Furthermore, the travel exposure questions have generated a marked increase in biological deviation reports to FDA indicating that blood banks are receiving post donation information that the donor should have been deferred.

FDA recommended that the new questions related to possible dietary BSE exposure be administered orally to first time donors due to their inherent complexity (4). In subsequent draft guidance (5), FDA also proposed oral administration of all medical/behavioral questions to first-time donors to help ensure that barriers of limited literacy, attention and comprehension do not compromise the donor qualification process. In this draft Guidance, FDA also proposed accepting the use of a computer-assisted self-administered interview with an audio component for all donors (Audio-CASI). Published reports describe audio-CASI as an effective mode of questionnaire administration for capturing sensitive interview information.

Because scientific opinions differ regarding the appropriateness of a self-administered questionnaire for all donors, the FDA is bringing this question to the BPAC for consideration. Presentations at the meeting will include a summary of the current literature pertaining to the collection of sensitive information. There will also be an overview presentation on different levels of literacy in the US, and the relationship of literacy and education to the collection of accurate medical information.

Following discussion, the BPAC will be asked to vote on the following questions:

- 1. Based on the information presented, should the current draft guidance on self-administration of the donor questionnaire be modified to allow first time donors to routinely self-administer the entire donor questionnaire? Yes/No**
- 2. If no, what portions of the donor questionnaire are appropriate for self-administration by first time donors?**
 - a. Routine medical history questions Yes/No**
 - b. HIV/AIDS high risk questions Yes/No**
 - c. Complex medical or travel questions Yes/No**
- 3. Does the Committee recommend that audio-CASI is a suitable mechanism for self-administration of the donor questionnaire to all donors? Yes/No**

References:

1. Mayo DJ, Rose AM, Matchett SE, et al. Screening potential blood donors at risk for Human Immunodeficiency Virus. *Transfusion* 1991 31(5) 466- 474,

2. Johnson ES, Doll LS, Satten GA, et al. Direct oral questions to blood donors: the impact on screening for Human Immunodeficiency Virus. *Transfusion* 1994; 34 (9): 769-774.
3. FDA guidance for industry, “Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products”, April 23, 1992
4. FDA guidance for industry: “Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products”, January 9, 2002.
5. FDA draft guidance, “Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires”, April 19, 2002.