

0059 02 JUN -4 10:35

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
(7001 2510 0002 5544 4004)
May 23, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 02-9687: Draft Guidance for Industry – Streamlining
The Donor Interview Process: Recommendations for Self-
Administered Questionnaires**

Dear Docket Officer:

Thank you for the opportunity to provide comments and suggestions concerning the Center for Biologics Evaluation and Research's draft guidance on recommendations for self-administered questionnaires. We wish to bring the following to your attention.

II Background

This section states FDA's commitment to improving the efficiency and effectiveness of the donation process and seeks to address the burdensome nature of the current donor questionnaire process, which is made so by the complicated nature of the questionnaire and the increasing demands the interview process places on limited resources.

These issues are not necessarily redressed by the guidance. A significant number of blood centers currently utilize self-administered questionnaires. The requirement for oral presentation of questions to new/infrequent donors will add to the donor's sense of burden as the time required for the process expands and will require additional resources to perform the process. In addition, unless FDA agrees that the donor's recollection can be used to establish the last donation date, the guidance will adversely impact any blood center without a computerized infrastructure at all collection sites since they will be forced to administer the questionnaire verbally to all donors.

02D-0080

CI

III (A) Recommendations for Manual Procedures

Item (3) states that the donor must be provided with a “confidential” setting for the completion of the questionnaire. Since this is a self-administered activity, please confirm that the guidance implies the donor must be in an environment that assures visual isolation (distance, screens, etc.) from other donors. Also confirm that it applies to both manual and computer-assisted options.

Item (4) indicates that blood centers must utilize direct oral or computer-assisted methodology for new or infrequent donors. The underlying premise implies there is some advantage to the verbal (audio-visual) presentation of questions to a specific subset of donors. Please restate your validated scientific evidence in support of this position. Verbal presentation (or the audio-visual equivalent) of questions is not a dialog with the donor nor could it be in the reality of the current blood donation environment. It becomes at best a sonorous recitation mediated by a human or computer. We support the position taken on this topic by the AABB Donor History Task Force (Attachment 1).

Item (5) implies a validation of the donor’s comprehension by using an essentially unvalidated secondary process. While steps to identify donor literacy are straightforward, assessing comprehension is a science beyond the scope of most blood establishments. The limitations of this position were explained, by experts, to FDA representatives who participated in the AABB Donor History Task Force. If the guidance implies a simple technique such as “What state/country/etc. do you live in?” where any correct answer other than a blank is acceptable, then please restate the guidance and its premise.

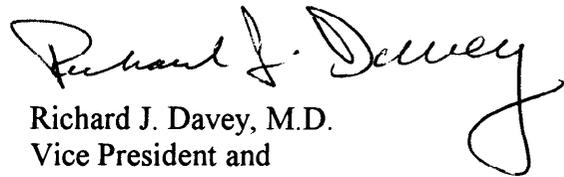
Item (8) states that blood centers must document all reason for deferral on the donor record. This process is straightforward with the self-administered questionnaire. However, please clarify the implication that in the case of oral questioning, if the donor presents a response at the beginning of the process that would lead to deferral, then all remaining questions must still be asked in order to determine if there are any other reasons for deferral? This position would be inconsistent with the goal of making the process more efficient.

III (C) Additional Recommendations for Computer-Assisted Interactive Programs

Item (2) appears to imply that even with a computer-assisted process where the donor interacts and responds on-line, the end point of the process requires the generation, review and sign-off on a hardcopy questionnaire essentially equivalent to the form used in a purely manual process. Please restate the guidance to clarify the following:

- Which is the official, permanent record? The hardcopy questionnaire signed by the donor and blood center staff. The computer record containing the donor's interactive responses? Both?
- If the interactive system fulfills the requirement for "electronic signature", is the generation of a hardcopy questionnaire still required?

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Davey". The signature is written in a cursive style with a large, sweeping flourish at the end.

Richard J. Davey, M.D.
Vice President and
Chief Medical Officer

cc: D. Kender, Ph.D.
D. Kessler
E. McQuail
M. Sparrow
E. Streun

ATTACHMENT 1

FINAL REPORT

Of The

**TASK FORCE TO REDESIGN
THE BLOOD DONOR SCREENING QUESTIONNAIRE**

**AMERICAN ASSOCIATION OF BLOOD BANKS
MARCH 2002**

1

information. A sample of subjects evaluated the abbreviated version in the NCHS interviewing process, and feedback is provided in the NCHS summary. This truly streamlined version is expected to be welcomed and well-received by those donors to whom usage criteria apply, and could make a major difference in the perception of the donation process for many current and prospective donors.

D. Donor Pre-screening Educational Materials [Tab 11]

The concept of providing donors with pre-screening educational materials was devised by the AABB in 1984¹¹, and the FDA has required it since 1990¹². The intent was to educate donors about HIV and AIDS with the goal of prompting self-deferral or at least questioning of blood center staff by those to whom such information might apply. Since then, the educational materials have played an increasingly significant role in familiarizing donors with other deferrable risks and the donation process. A Task Force review of educational materials from more than twenty blood centers, including the American Red Cross which uses standardized materials, showed considerable variation, however.

12
14

Because the educational materials constitute an informational tool with which donors are familiar, the Task Force is advocating that renewed emphasis be placed on them and that they be standardized. This Task Force-designed document emphasizes the importance of accuracy and honesty in responding to screening questions, has defined sexual contact, more clearly explained HIV and AIDS information, and detailed the donation process. In addition, because information contained in some previously AABB-generated questions is being transferred to the educational materials, the Task Force is recommending that the educational materials be standardized; blood centers would be permitted to add additional information, but not delete or rearrange the materials once approved by the FDA.

E. The User Brochure [Tab 12]

When approved by the FDA, the new donor screening instruments – the full-length and abbreviated versions and the educational materials – will represent a significant change for blood centers. In order to facilitate understanding and use of the new materials by blood centers and donor screeners, the Task Force has developed a “User Brochure.” This document details how the questionnaires should be administered, explains the concept of capture questions – already in use by blood centers – and offers suggested follow-up for affirmative responses to capture questions. Its flow-charted format, based on information-mapping models, is expected to provide ease of use and enable rapid adoption of the new screening materials.

Methods of Administration

The User Brochure addresses the manner in which the questionnaires should be administered. Simplification and donor comprehension have been a major goal of the project in order to maximize the quality of donor information and to facilitate the adoption of a self-administered questionnaire. The discussion that follows details the rationale of the Task Force for recommending that the questionnaires be self-administered by donors.

Self-Administered Questionnaires and Direct (Face-to-Face) Oral Questioning

*
↓

AABB blood center survey data [Tab 3] show that the direct oral questioning of donors who have already completed a written questionnaire has been cited by some centers as a source of

donor complaints. Currently, most non-American Red Cross (ARC) blood centers utilize a donor self-administered written questionnaire but are required to ask the HIV risk questions in face-to-face interviews¹³. Recently issued FDA questions regarding CJD/vCJD¹⁴ and xenotransplantation¹⁵ also recommend direct oral questioning. However, a precedent for allowing donor self-administration of a written questionnaire was established when the American Red Cross received FDA approval for such an approach, provided that the donors are given an opportunity to ask additional questions or seek clarification. This FDA-approved ARC method, which showed no apparent increase in infectious disease incidence or prevalence rates,¹⁶ has been in general use since 1998. To date, incidence and prevalence data have not shown a compromise in blood safety as a result of utilizing this alternative screening methodology.

The interest in using direct questioning of blood donors vs. Self-Administered Questionnaires (SAQs) for HIV risk questions originated in an early study that showed a statistically significant difference in overall deferrals and HIV risk deferrals in blood donors screened with direct questions. However, it was observed that, in general, first-time and occasional donors were more likely than frequent donors to pay attention to SAQs¹⁷. In a later study that compared blood donor interview modes, donors seemed more likely to provide HIV risk information in a face-to-face interview vs. a self-administered format. However, the observed overall decline in HIV seroprevalence was not statistically significant, had been observed prior to implementation of direct questioning, and was likely not attributable to direct questioning¹⁸. It is also likely that public awareness of HIV risk factors has increased in the decade since the first study was undertaken¹⁷, possibly diminishing or even negating the potential of direct questioning to identify individuals with risk.

Outside the blood donor screening arena, there is considerable evidence that people disclose less information of a personal nature - such as use of alcohol and illicit drugs, sexual behaviors, and mental health - in the presence of an interviewer. Examples include studies by Aquilino demonstrating greater likelihood to discuss a history of depression¹⁹ and admit to use of illegal drugs and alcohol in SAQs compared to other modalities²⁰; and Tourangeau et al, showing a significantly increased likelihood to report number of sexual partners, sexually transmitted diseases, and condom use in SAQs vs. face-to-face interviews²¹.

Input from Task Force and NCHS survey design experts also generally favors SAQs over face-to-face interviews for several reasons. Interviewers can introduce errors into the data collection process, some of which can be avoided by self-administration. For example, even well trained interviewers can start to anticipate responses to questions that have little response variation, and they may also introduce variety into question administration. In addition, respondents are more likely to focus on questions that they themselves read vs. those that are read to them.

Viewed alone or in concert, survey design literature and the experience of survey design experts suggest that any perceived advantage of direct questioning over SAQ in identifying risks among blood donors may no longer be as great as originally perceived. *It is particularly important and relevant to this discussion to note that the cognitive interviews performed by NCHS assumed a self-administered survey. This offers reassurance that a SAQ would "work" in a blood donor screening milieu.* Conversely, there is no guarantee that an interviewer-administered questionnaire would be as effective. For these reasons, the Task Force recommends in the User Brochure that the questionnaires be self-administered by blood donors, without the use of direct questioning by blood center staff. However, it does recommend that blood center staff be readily available to assist donors and provide clarification when needed. Blood centers that wish to continue using direct questioning will have that option.

↑
Blood centers that have implemented CASI will find that the capture-question approach, questionnaire format, and simplified questions of both the full-length and abbreviated questionnaires will be easily integrated into a computerized methodology. However, it should be noted that CASI is in its nascency, and only now is being implemented in a handful of blood centers. Non-CASI screening will continue to be used for the foreseeable future until CASI software is further refined and validation guidelines are more clearly delineated by regulatory and standard-setting agencies. Therefore, the User Brochure focuses primarily on self-administration of the questionnaire by donors.

VIII. The Blood Donor Screeners' Survey: Field Testing the New Materials [Tab 13]

The Task Force determined that the new screening and accessory materials should ultimately be evaluated by a cohort of blood center staff who perform eligibility screening of prospective donors. These individuals, referred to as blood donor historians or screeners, were selected to cover a range of experience, ages, and genders. Thirteen screeners from five blood centers reviewed the near-final educational materials, the full-length and abbreviated questionnaires, the medication deferral list, and the user brochure. Specific areas of interest to the Task Force were the format, ease of use, and understandability of the documents.

Using a survey developed by the NCHS, the participants were asked to respond on a rating scale to statements about each document. They were also asked to compare their current questionnaire to the full-length questionnaire. The data indicated strong support and enthusiasm for the new documents, suggesting that the Task Force had met its goals in producing materials that would be relatively easy to administer and would be well-received by donor screeners.

IX. Communicating with Constituents

As important as the redesign process, so has been the Task Force's effort to communicate their work, thinking, and progress. The process has been open, public, and widely publicized. The Task Force members have effectively engaged in bi-directional communication with their respective organizations. Documents have been given to the FDA for internal review, and FDA input on all issues has been consistently sought. Updates have been provided in the past year-and-a-half in numerous meetings sponsored by the AABB, ABC, ARC, PPTA, and the FDA. Most of these organizations have regularly provided information to their members in newsletters and other publications. In the past six months drafts of Task Force documents have been posted on the public section of the AABB Web site for review and comment by the public and AABB members. Finally, and perhaps most critical, the Task Force's approach and document drafts were reviewed by the FDA's Blood Products Advisory Committee (BPAC) in June 2001, and received BPAC endorsement.

X. Implementation

Following the FDA's review and approval of the redesigned screening products and processes, the AABB will disseminate the materials and information about usage to members through teleconferences, meetings, publications, and its Web site. Blood and plasma centers will be responsible for familiarizing themselves with the new documents and training their staff. The AABB will make its resources available to provide assistance as needed.

References

1. Technical Methods and Procedures. American Association of Blood Banks. Dallas TX. 1953:3-5.
2. Epstein JS. FDA/AABB Workshop on Streamlining the Blood Donor History Questionnaire. National Institutes of Health, Rockville, MD. October 16, 2000.
3. O'Callaghan S. Biological Product Deviation Reports: What Has Been the Industry Response and Problems? Fifth Annual FDA and the Changing Paradigm for Blood Regulation. New Orleans, LA. January 2002.
4. Kowalski A, Director, Electronic Blood Donor Record Department. Personal communication. February 2002.
5. AABB Weekly Report. July 2000 6(26).
6. Orton SL, Virvos VJ, Williams AE. Validation of selected donor-screening questions: structure, content, and comprehension. *Transfusion*. 2000;40:1407-1413.
7. Sanders S and Reinish J. Would you say you "had sex" if...? *Journal of the American Medical Association*. 1999;281(3):275-277.
8. Binson D and Catania JA. Respondents' understanding of the words used in sexual behavior questions. *Public Opinion Quarterly*. 1998;62:190-208.
9. Cognitive Testing of the NHANES Sexual Orientation Questions. Questionnaire Design Research Laboratory, National Center for Health Statistics. Interviews conducted October 18-December 8, 2001.
10. Callaghan E. The Abbreviated Donor Questionnaire. FDA/AABB Workshop on Streamlining the Blood Donor History Questionnaire. National Institutes of Health. Rockville, MD. October 16, 2000.
11. Standards for Blood Banks and Transfusion Services, 11th Ed. American Association of Blood Banks. Arlington, VA. 1984.
12. FDA Memorandum, February 5, 1990: Recommendations for the Prevention of HIV Transmission by Blood and Blood Products.
13. FDA Memorandum, April 23, 1992: Revised Recommendations for the Prevention of HIV Transmission by Blood and Blood Products.
14. FDA Guidance for Industry. January 9 2002. 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.
15. FDA Draft Guidance, February 1, 2002. Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts.
16. Letter from Brian McDonough (American Red Cross) to Kathryn Zoon, PhD (FDA). February 10, 1998 (FDA code number 98-0921).
17. Mayo DJ, Rose AM, Matchett SE, et al. Screening potential blood donors at risk for human immunodeficiency virus. *Transfusion*. 1991;31:466-477.
18. Johnson ES, Doll LS, Satten GA, et al. Direct oral questions to blood donors: the impact on screening for HIV. *Transfusion*. 1994;34:769-74.
19. Aquilino WS. Effects of interview mode on measuring depression in younger adults. *Journal of Official Statistics*. 1998;14(1):15-29.
20. Aquilino WS. Interview mode effects in surveys of drug and alcohol use: A field experiment. *Public Opinion Quarterly*. 1994;58:210-240.
21. Tourangeau R, Rasinski K, Jobe JB, et al. Sources of error in a survey on sexual behavior. *Journal of Official Statistics*. 1997;13(4):341-365.



4.63
MET
081
U.S. POSTAGE

^{E. STREET}
New York Blood Center
310 East 67 Street, New York, NY 10021

TO

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

00002554440

: HFA-305/ RM 1061

FDA
OF PCS: 1



025264516

RM:
HFA-305/ RM 1061

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT
OF THE RETURN ADDRESS. FOLD AT DOTTED LINE
CERTIFIED MAIL