User Brochure for the Full-Length Blood Donor History Questionnaire Version 4.0 and Accompanying Materials

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PURPOSE

The User Brochure for the Full-Length Blood Donor History Questionnaire (DHQ) Version 4.0 (v4.0) and Accompanying Materials is intended to provide instructions to guide blood collection establishments in the proper use of these documents which include the DHQ, the Blood Donor Educational Material, the Medication Deferral List (MDL), the Flowcharts, References, and this User Brochure. Consistent with our mission, AABB makes these blood donor screening documents available on the AABB website for access by the public, transfusion services, and all blood collection facilities, regardless of AABB membership or AABB accreditation. For the proper use of the Abbreviated Donor History Questionnaire (aDHQ) v4.0, refer to the aDHQ User Brochure posted on the Blood Donor History Questionnaire webpage. This User Brochure applies to blood donor screening only and AABB provides other donor screening documents on the AABB website.

INTRODUCTION

AABB's Donor History Task Force (DHTF) is comprised of professional member experts from the AABB community, including the Armed Services Blood Program, the American Red Cross, and America's Blood Centers, with support from Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and Canadian Blood Services representatives. The AABB Board of Directors issues charges to the DHTF regarding responsibilities to update and maintain the DHQ v4.0 and Accompanying Materials to be used as part of the screening process to establish donor eligibility. AABB submitted the DHQ v4.0 and Accompanying Materials to the FDA for formal review and acceptance. The FDA issued guidance (posted as Blood Guidances on FDA's website) to formally recognize the DHQ v4.0 and Accompanying Materials, as submitted, to be "an acceptable mechanism for collecting blood donor history information from donors of blood and blood components that is consistent with FDA requirements and recommendations."

FDA regulations in 21 CFR 630.10(b) require that the Blood Donor Educational Material be presented "in a manner designed to be understood by the donor." Blood collection establishments using these screening materials should be aware that these materials were tested on English-speaking donors and non-donor groups and due to practical limitations could not be tested in all possible settings, including with non-English-speaking donors.

It is important to note that the DHQ v4.0 and Accompanying Materials are designed, structured, and evaluated collectively for comprehension and effectiveness. Therefore, the DHQ and Accompanying Material are intended to be used together, as follows:

- The User Brochure and Flowcharts assist the donor historian performing the screening process to determine blood donor eligibility. The Flowcharts v4.0 are intended as a resource. Each facility has the option to revise the flowcharts or develop alternatives that are consistent with FDA requirements and recommendations, as described in the "Flowchart" section.
- The Blood Donor Educational Material and the Medication Deferral List (MDL) assist the donor in understanding the donation process, risk criteria for transmitting diseases to the transfusion recipient, recalling details of travel and medications taken, and other information necessary to protect the safety of both the donor and transfusion recipient.

BLOOD DONOR HISTORY QUESTIONNAIRE v4.0

DHQ Structure and Content: The DHTF developed the DHQ based on principles of cognitive psychology. The goal of this format is to facilitate donor understanding of questions and accurate recall of relevant risk activities in a streamlined process. This is achieved in the following ways:

- Donor eligibility is assessed using individual donor assessment questions posed to all donors consistent with FDA's policy updated in 2023 to remove male-specific and female-specific questions.
- The questions are grouped into common time frames in chronological order. The DHQ begins with questions about "today," moving to questions requiring recall from progressively longer periods of time, and finally asks "Have you ever…" The progression through time is intended to assist the donor in recalling information more accurately.
- The questions are designed to be easily understood by the donor. Compound questions are not used.
- This streamlined process uses capture questions to minimize the number of questions. This means a single question is designed to capture information on a broad topic and the donor historian asks additional questions designated in the flowchart. The additional questions are intended to further clarify the information necessary to assess donor eligibility.

Refer to the section on "Change Control and Limitations" for additional information and limitations on changes to the DHQ and Accompanying Materials.

Administering the DHQ: The DHQ must be administered consistent with FDA regulations in 21 CFR 630.10. More specifically, FDA regulations at 21 CFR 630.10(c) state, the DHQ must be administered on the day of donation and prior to collection.

Consistent with FDA regulations at 21 CFR 630.10(b), all donors must read the Blood Donor Educational Material and review the MDL prior to completing the DHQ. The materials:

- may be provided to the donor electronically for self-administration of the DHQ, either at the time of arrival at the collection site or prior to arrival,
  OR
- may be given to the donor as individual copies for use when completing the DHQ prior to arrival or upon arrival at the collection site,
  OR
- may be prominently displayed at the collection site for the donors' completing the DHQ on site.

All DHQ materials should remain available to the donor for reference throughout the screening process including while completing the DHQ. Additional information on these materials is provided in related sections.

The method of administration should follow the blood collection establishment's SOPs for donor screening. Blood collection establishments are reminded that donor screening is an interactive process involving open communication between the donor and donor historian regarding confidential information. Blood collection establishment SOPs must:

- Provide an opportunity for the donors to voice questions about the DHQ, the Blood Donor Educational Material, and the MDL, or concerns about the donation process.

- Require that donors be asked if they have further questions and if their questions have been answered. This can be incorporated into the donor eligibility process and/or put into the donor consent and does not require a specific question on the DHQ.
- Address the process to resolve discrepant donor responses to improve accuracy in donor assessment. (For example, AABB Association Bulletin #22-03 Updated Recommendations on Donor Deferral for Use of Antiretroviral Medications for HIV Prevention and Treatment including Long-Acting Injectable PrEP and the Impact on Blood Safety, page 6, recommends resolution of discrepant donor responses related to use of HIV medications to address confusion and defer appropriately)

Providing a setting to protect the donor's privacy is a critical component for an effective donor screening process [21 CFR 606.40(a)(1)]. The setting must be adequate to ensure the donor is able to complete the DHQ and discuss information in a confidential manner which is consistent with AABB's Standards for Blood Banks and Transfusion Services.

Self-Administration: The DHQ was designed for self-administration by the donor with review and follow-up by a trained donor historian. Donors can use a hard copy or computer assisted DHQ as provided in guidance. Donors should be encouraged to complete the entire DHQ to provide the most accurate eligibility determination. Complete information is preferred to ensure that multiple reasons for deferral are identified and documented. However, there will be circumstances in which the donor simply leaves prior to completing the DHQ. Blood collection establishment SOPs should define options for management of information received when the DHQ is not completed.

Other Methods of Administration: Alternatively, the DHQ may be administered by a donor historian. The goals and approach for this process remain the same with alternative methods.

Documentation: Information impacting donor eligibility should be accurately documented on the DHQ. If a donor is determined to be ineligible during the screening process, the reason for deferral should be documented in a designated area on the DHQ. Likewise, if a donor is determined to be eligible during follow-up questioning, an explanation for each question must be documented in sufficient detail in a designated area on the DHQ. The blood collection establishment's SOP should define the process to be used for documenting this information and inform the donor of the reason for deferral as required in 21 CFR 630.10(h) and 21 CFR 630.40. Here are two examples of adequate documentation:

> Example #1: A donor answers "Yes" to: "Are you currently taking an antibiotic?"
> Sample documentation: "Donor taking tetracycline daily for acne prophylaxis: OK per SOP."
> Basis for documentation: Medication identified and found acceptable.
>
> Example #2: A donor answers "Yes" to "In the past three years have you been outside the United States or Canada?"
> Sample documentation: "Donor traveled to Nayarit, Mexico; malaria endemic, 3-month deferral, date of departure from malaria area: 6 weeks ago, length of stay: two weeks."
> Basis for documentation: Location, date of departure, length of stay and required deferral are provided.

ACCOMPANYING MATERIALS

Blood Donor Educational Material: The Blood Donor Educational Material is read by the donor prior to donation and informs the donor by providing an overview of the donation process and includes information about:

- The importance of accurate and complete answers on the DHQ.
- The importance of protecting the donor using eligibility information, such as medications and health history, as well as protecting the transfusion recipient by identifying risks for infectious disease transmission from the donor to the transfusion recipient as result of travel and other risk activities.
- The importance of not donating when a risk factor is present.
- The various steps in the collection and testing of the donation.
- What happens after the donation process.

Medication Deferral List: Refer to the current MDL for relevant medications and time frames that must be reviewed. This list identifies medications taken within a specified time frame that must be considered when establishing donor eligibility. Medications on the list require donor deferral to protect the health and safety of the donor and/or transfusion recipient. The MDL posted on the AABB website may differ from the list formally recognized by the FDA. As updates are required, the DHTF will make changes to the MDL that will be announced in AABB publications prior to posting of the new version on the AABB website. Blood collection establishments may either replace their current MDL with the AABB update or modify their own materials. As stated by FDA at the time of acceptance, under 21 CFR 601.12(d), licensed blood establishments are required to report this minor change and its implementation date in their next annual report. Updates to the MDL should be implemented as defined in blood collection establishment SOPs and soon as reasonably possible.

Flowcharts: The User Brochure provides for the use of optional flowcharts to guide the donor historian through the screening process. These flowcharts are intended to serve as a resource, but use of the AABB DHQ v4.0 Flowcharts is NOT REQUIRED if the blood collection establishment has an equivalent method for evaluating donor responses to the screening questions that are consistent with FDA requirements and recommendations. Flowcharts may be revised by blood collection establishments to reflect local policy, provided deferrals are consistent with those required by FDA and AABB and are not less restrictive.

A flowchart has been designed for each question and contains the following information:

- Question: Question number and the question.
- Donor Eligibility: This section provides additional information to the donor historian on donor eligibility requirements for each question.
  Note: Optional field; additional relevant information relating to the donor question.
- Flow Chart: Each question is flow-charted using standard flow-charting symbols.
  Rectangle/Square - Statement
  Diamond - Question/decision point
  Oval - Action
  Arrow - Indicates direction on the flowchart

Each flowchart ends with an ARROW that indicates to “move to the next question”; however, it must be emphasized that donor eligibility decisions are based on the blood collection establishment’s SOPs. For some questions, a “yes” answer requires the donor be deferred. A required deferral is designated in the flow chart by the Action “Defer donor.” The donor historian may need to refer to the blood collection establishment’s SOP to determine if or when the donor

may be eligible to return. The blood collection establishment may elect to end the donor screening process at the time of deferral OR may continue with the remainder of the questions on the DHQ based on the SOP. For other questions, a "yes" answer may trigger a line of questioning to determine if the donor is eligible. The donor historian will refer to the blood collection establishment's SOP for follow-up questions to determine eligibility. This type of deferral is designated in the flow chart by the Action "Defer donor per SOP." For example, if a donor answers "yes" to the question "Are you currently taking an antibiotic?" blood collection establishment may ask additional questions to identify the name of antibiotic and specific indication for use by the donor. Some blood collection establishments may allow donation if a donor is taking antibiotics for certain indications, such as prophylaxis for acne, as defined in their SOP. Other establishments may elect to defer all donors taking antibiotics, regardless of the drug or its indication.

CHANGE CONTROL AND LIMITATIONS

Implementing more restrictive policies: An establishment can implement donor screening policies that are more restrictive than required by AABB and FDA based on the judgement of the establishment's medical director. Examples of implementing more restrictive policies include (1) placement additional of questions in the designated area, and (2) use of more restrictive deferral criteria for existing questions, such as a longer deferral period.

Adding Questions: The DHQ includes an area designated for additional questions at the end. This area for additional questions is used to:

- Implement more restrictive deferral policies.
- Implement new regulatory requirements – New questions that are necessary to comply with more restrictive requirements from FDA and/or AABB Standards can be added to the designated area.
- Implement Ebola screening questions – AABB's DHTF has developed donor screening questions to be added to the designated area during a period of widespread transmission of Ebola as determined by CDC and required in current FDA guidance.

Reformatting Materials: Blood collection establishments may use alternative formats for the DHQ and Accompanying Materials. Examples of such modifications include:

- Formatting the questions on the page in a single column, double columns, single page, double pages, etc.
- Placing duplicate numbers in front of the answer boxes or behind the answer boxes to ensure the proper box is used.
- Use of different font types, sizes, and colors.
- Use of shading to assist donors in staying "on-line" as they answer questions.
- Formatting the Blood Donor Educational Material and the MDL as needed to use as a brochure, handout, poster, or alternative presentation based on local needs, provided the order, content, and wording are unchanged for the FDA reviewed content.
- Adding additional medications to the MDL based on a more restrictive local policy, provided all other content on the original list remains unchanged. Additional medication deferrals should be added at the end of the list.

Limit on Changes to Documents Recognized by the FDA: The DHTF develops the DHQ and Accompanying Materials for formal review and acceptance by FDA. After the FDA issues guidance formally recognizing these materials as acceptable for use as an acceptable mechanism

for establishing donor eligibility, the materials are posted on AABB's website and may be used by any facility, regardless of AABB membership or AABB accreditation.

- The development of these documents by the DHTF and the request for FDA review submitted by AABB can remove the burden for FDA submission. Each facility that elects to use the FDA recognized DHQ and Accompanying Materials *as posted*, *without revision and in accordance with FDA guidance will not require additional FDA approval prior to implementation*.
- The FDA guidance may specify additional expectations and limitations for a blood collection establishment electing to revise the DHQ and Accompanying Materials which, following revision, are no longer recognized by FDA and require further action as described in the FDA Guidance. A DHQ with changes to the content, order, and language (other than as described in the **Adding Questions** and **Reformatting Materials** sections above), and/or the use of less restrictive criteria is no longer recognized by FDA and will require an FDA submission, as described in FDA Guidance.
- The current implementation limitations and FDA's expectations for revised documents can be found in FDA's Guidance formally recognizing the DHQ posted on the FDA Blood Guidance webpage https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances.

AABB's Revisions to the DHQ: At the time FDA issues new or revised requirements, the DHQ and Accompanying Materials will be revised by the DHTF to comply with new FDA requirements and/or AABB Standards. AABB will follow the process described earlier in this User Brochure to revise and submit *draft* documents to FDA for formal review *and acceptance.* Once the documents are *formally accepted* by the FDA, the newly revised DHQ and Accompanying Materials will be posted on the AABB website for implementation by any facility. Consistent with our mission, AABB makes these documents available for access by the public, hospitals, and all blood collection establishments, regardless of AABB membership or AABB accreditation. AABB provides notification of the changes and assistance with implementation in AABB publications. It is the responsibility of each blood collection establishment to revise forms, procedures, and processes to incorporate these revisions within the time specified by FDA.

GLOSSARY

The following terms are defined in the context of their use in the DHQ and Accompanying Materials.

Capture Question – A single question that covers a broad topic to simplify the process. When an affirmative answer is given, additional follow-up questions to elicit relevant information are asked by the donor historian.

Self-administered DHQ – A questionnaire that the donor completes on their own, followed by donor historian review with follow-up questions as necessary.

Types of Contact
Contact with Blood – (1) a needle stick or other sharps injury from an instrument that has been used on any individual or patient; (2) exposure to non-intact skin (e.g., skin that is chapped, abraded, or afflicted with dermatitis); (3) a human bite that breaks the skin; (4) exposure to eye, nose, or mouth i.e., the mucous membranes.

Sexual Contact – The meaning of the words "sexual contact with" and "sex" are identical, and apply to any of the following activities, whether or not a condom or other protection was used: (1) Vaginal sex (contact between penis and vagina); (2) Oral sex (mouth or tongue on someone's vagina, penis, or anus); (3) Anal sex (contact between penis and anus).

Close Contact with Smallpox Vaccination Site – Touching the vaccination site, including the bandages covering the vaccination site; touching/handling materials that might have come into contact with an unbandaged vaccination site including clothing, towels, and bedding.

Types of Donor Deferral

Indefinite Deferral – Prospective donor is unable to donate blood for someone else for an unspecified period of time due to current regulatory requirements. The indefinite deferral would no longer apply if regulatory requirements changed and the donor qualified for re-entry based on results of improved testing methods or a change in the impact of the relevant transfusion-transmitted infection, also referred to as an RTTI. Indefinitely deferred donors may be eligible to donate autologous blood.

Permanent Deferral – Prospective donor is deferred from donation with no possibility for re-entry. Some permanent deferrals may result from the testing performed on a previous donation. Permanently deferred donors may be eligible to donate autologous blood.

Temporary Deferral – Prospective donor is deferred from donation for a specified period of time. Temporarily deferred donors may be eligible to donate autologous blood.