

ABBREVIATED BLOOD DHQ (aDHQ) v4.0 USER BROCHURE

User Brochure for the Abbreviated Blood Donor History Questionnaire (aDHQ) Version 4.0 and Accompanying Materials

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User Brochure for the Abbreviated Blood Donor History Questionnaire Version 4.0 and Accompanying Materials

PURPOSE

The User Brochure for the Abbreviated Blood Donor History Questionnaire (aDHQ) 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 aDHQ, 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 Donor History Questionnaire (DHQ) v4.0, refer to the DHQ User Brochure posted on the [Donor History Questionnaire webpage](#). This User Brochure applies to the (abbreviated) 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 aDHQ v4.0 and Accompanying Materials to be used as part of the screening process to establish blood donor eligibility. AABB submitted the aDHQ v4.0 and Accompanying Materials to the Food and Drug Administration (FDA) for formal review and acceptance. The FDA issued guidance (posted as [Blood Guidances](#) on FDA's website) to formally recognize the aDHQ 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 donor 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 both the DHQ v4.0 and Accompanying Materials and aDHQ and Accompanying Materials are designed, structured, and evaluated collectively for comprehension and effectiveness. Use of the aDHQ is limited to qualified frequent donors with no changes to their eligibility. The list of questions is consistent with the DHQ but abbreviated to replace multiple questions with a single question designed to detect a change in eligibility. This is discussed in more detail in the section "**Criteria for using the aDHQ.**" Therefore, the aDHQ and Accompanying Materials 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

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recipient, recalling details of travel and medications taken, and other information necessary to protect the safety of both the donor and transfusion recipient.

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Criteria for using the aDHQ: A returning blood donor is eligible to use the aDHQ v4.0 when the frequent donor criteria are met AND the blood center has a system in place to identify donors that meet the criteria for use of the aDHQ. The blood center should have a method to inform the donor of the last donation date to assist the donor with the appropriate timeframe to answer questions beginning “Since your last donation...”

A frequent donor qualified to use the aDHQ is defined as a person who:

- has previously donated two times using the DHQ, with;
- one of those two donations occurring within the previous six months.

A frequent donor who is qualified to use the aDHQ and is then deferred, is eligible to use the aDHQ on the next donation if:

- The deferral was based on a physical finding (such as hemoglobin, temperature, pulse, blood pressure, platelet count), OR
- The deferral period was less than 6 months, AND
- The frequent donor attempts to donate again within 6 months of the last successful donation.

A returning donor who was qualified to use the aDHQ is required to use the DHQ for two successful donations before returning to the aDHQ (within 6 months of the last successful donation) if:

- The donor is deferred for 6 months or greater.
- The donor does not return to donate within 6 months.

For these purposes, “successful donation” means a donor is determined to be eligible to donate without regard to the success of the collection process.

Blood centers are not required to use the aDHQ. A donor who is eligible to use the aDHQ can use the DHQ without any adverse impact on the process or product suitability. However, use of the aDHQ by a donor who does not meet the criteria is not acceptable. The blood center’s standard operating procedures (SOPs) must identify actions to be taken, when an aDHQ is used by a donor who did not meet the criteria for use. This is to ensure that all components of the collection are quarantined until the donor eligibility questions are answered, the donor is determined to be eligible to donate as required in [21 CFR 630.10](#) and [21 CFR 630.15](#), and the products are suitable for use. Consistent with existing requirements, a biological product deviation report must be submitted to the FDA if any component of the improper collection was distributed prior to establishing the donor’s eligibility.

aDHQ Structure and Content: The DHTF developed the aDHQ 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 timeframes in chronological order. The aDHQ 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.

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- 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.
- The list of questions on the aDHQ is consistent with those on the DHQ. When possible, the aDHQ uses a single, broad question that is adequate based on the criteria for use by a frequent donor. For example, the single question “Since your last donation, have you had any new medical treatments?” on the aDHQ replaces several related questions on the DHQ. Frequent donors using the aDHQ are able to provide the same information in less time with fewer questions to answer.

Refer to the section on “Change Control and Limitations” for additional information and limitations on changes to the aDHQ and Accompanying Materials.

Administering the aDHQ: The aDHQ must be administered consistent with FDA regulations in [21 CFR 630.10](#). More specifically, FDA regulations at [21 CFR 630.10\(c\)](#) state, the aDHQ 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 aDHQ. The materials:

- may be provided to the donor electronically for self-administration of the aDHQ, 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 aDHQ prior to arrival or upon arrival at the collection site.
OR
- may be prominently displayed at the collection site for the donors’ completing the aDHQ on site.

All aDHQ materials should remain available to the donor for reference throughout the screening process including while completing the aDHQ. 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 aDHQ, 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 aDHQ.
- Address the process to resolve discrepant donor responses to improve accuracy in donor risk 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).

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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 aDHQ and discuss information in a confidential manner which is consistent with AABB's Standards for Blood Banks and Transfusion Services.

Self-Administration: The aDHQ 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 aDHQ as provided in guidance. Donors should be encouraged to complete the entire aDHQ 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 aDHQ. Blood collection establishment SOPs should define options for management of information received when the aDHQ is not completed.

Other Methods of Administration: Alternatively, the aDHQ 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 aDHQ. 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 aDHQ. 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 aDHQ. 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](#), as shown in the following example:

Example: A donor answers "yes" to "Since your last donation, 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 aDHQ.
- 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 a 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 relevant timeframes 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

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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 the use of the AABB aDHQ 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.
- Flowchart: 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 aDHQ 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 flowchart by the Action “Defer donor per SOP.” For example, if a donor answers “yes” to the question “In the past 3 months, have you had a tattoo?”, a blood collection establishment may ask additional questions to identify whether the tattoo was applied by a state regulated entity with sterile needles and non-reused ink. Some blood collection establishments may allow donation, as defined in their SOP. Other establishments may elect to defer all donors who have had a tattoo in the past 3 months.

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 of additional questions in the designated area, and (2) use of more restrictive deferral criteria for existing questions, such as a longer deferral period.

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Adding Questions: The aDHQ 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 aDHQ 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 aDHQ 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 aDHQ 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 aDHQ and Accompanying Materials which, following revision, are no longer recognized by FDA and require further action as described in the FDA Guidance. An aDHQ 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 aDHQ posted on the FDA Blood Guidance webpage <https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances>.

AABB’s Revisions to the aDHQ: At the time FDA issues new or revised requirements, the aDHQ 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 aDHQ and Accompanying Materials will be posted on the AABB website for implementation by any facility. Consistent with our mission, AABB makes these

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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 aDHQ 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 aDHQ– 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 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.