Advancing Transfusion and Cellular Therapies Worldwide

Implementation of Version 2.1 Donor History Questionnaire and Related Materials TOOLKIT for AABB Members

Implementation of Version 2.1
Donor History Questionnaire and Related Materials [dated April 2020]
TOOLKIT for AABB Members

AABB created this DHQ Toolkit to walk you through the updated information in the Donor History Questionnaire Version 2.1 (DHQ v2.1) and Related Materials, dated April 2020, based on:

- ✓ FDA's formal acceptance in Guidance on May 5, 2020,
- ✓ Guidance documents listed in the References, and
- ✓ AABB's Association Bulletin #20-04.

BACKGROUND

- ❖ **To reduce the operational burden for implementation of multiple updates**, AABB coordinated the release of Association Bulletin #20-04, *The Impact on Blood Safety of Effective Antiretroviral Medications for HIV Prevention and Treatment*, to coincide with the FDA guidance recognizing the DHQ v2.1 and Related Materials.

- ❖ **FDA's priority for expedited review of the v2.1 documents**:
  - ✓ Was limited to recommendations to address the urgent need for blood during the Coronavirus Disease 2019 (COVID-19) pandemic.
  - ✓ Did not permit additional time necessary to review changes related to donor use of PrEP/PEP/ART – now captured in Association Bulletin #20-04.

- ❖ **At the request of AABB's membership**, the *draft* v2.1 documents submitted for FDA review were made available on the AABB website:
  - ✓ *for planning purposes only*, and
  - ✓ **as expected, these *draft* documents have been revised during the FDA review process.**

- ❖ **AABB accredited collection facilities** will use the v2.1 documents with PrEP/PEP/ART, consistent with Association Bulletin #20-04.

- ❖ **Highlighted documents are linked in this toolkit to make it easy to identify the specific changes in each document. Crosswalks also detail the changes:**
  - ✓ DHQ v2.0 Crosswalk to v2.1
  - ✓ aDHQ v2.0 Crosswalk to v2.1

CHECKLIST

_____ Read the following:

- ✓ Association Bulletin #20-04 for:
  - Background information on the decision to take action.
  - Complete details on deferrals related to donor use of PrEP/PEP/ART.
- ✓ The recommendations from FDA guidance documents in the reference section that are the basis for the updates in v2.1, dated April 2020.

_____ Read the User Brochure v2.1:

- ✓ AABB Full-Length DHQ User Brochure v2.1 and Abbreviated DHQ User Brochure v2.1
- ✓ Limitations and instructions for appropriate use, including adding questions, reformatting materials, etc.

Following your policies and procedures for implementing a new version of the DHQ:

_____ Implement the AABB DHQ v2.1 with PrEP/PEP/ART, refer to the highlighted document which shows all of the changes, including significant changes listed below:

- ✓ New deferral period of three months based on the HIV Guidance.
- ✓ New deferral criteria for transfusion in Ireland.
- ✓ New language in questions:
  - DHQ v2.1 Questions: 15-16-28-30-31-32-40 and additional questions for PrEP/PEP/ART
  - aDHQ v2.1 Questions: 9-10-24 and additional questions for PrEP/PEP/ART
- ✓ New approach to questions related to geographical risk deferrals:
  - vCJD countries of risk are included in the questions to simplify information for the donor.
  - The list of vCJD Countries of Risk is discontinued.
- ✓ Updates in screening questions based on FDA guidance [see References] related to:
  - Chagas disease – question removed based on the Chagas Guidance.
  - Babesiosis – question updated and subject to regional testing recommendations of the *Babesia* Guidance.
- ✓ Two additional PrEP/PEP/ART Questions at the end of the DHQ v2.1 and aDHQ v2.1:
  - PrEP/PEP: In the past **3 months,** have you taken any medication to prevent an HIV infection?
    ART: Have you **EVER** taken any medication to treat an HIV infection?
  - Number additional questions according to your policy for use of the "area for additional questions" at the end of the DHQ.

____ Use the AABB DHQ v2.1 Flowcharts **–** refer to the highlighted document which shows the changes below:

- ✓ Include changes to Donor Eligibility Statements and/or Flowcharts:
  - DHQ v2.1 Flowcharts: 15-16-23-24-28-29-30-31-32-36-39-40 and additional questions for PrEP/PEP/ART
  - aDHQv2.1 Flowcharts: 9-10-16-17-24-25 and additional questions for PrEP/PEP/ART

- ✓ Determine if your facility will opt to use the Alternative Flowchart to distinguish between PrEP vs PEP deferrals.

_____ Use the AABB Blood Donor Educational Material v2.1, refer to the highlighted document which shows the changes below related to:
- ✓ HIV risk,
- ✓ PrEP/PEP/ART use,
- ✓ A history of Ebola [required in 02/2017 Ebola Guidance]

This Blood Donor Educational Material is used with both the DHQ and the aDHQ.

_____ Use the AABB Medication Deferral List v2.1, refer to the highlighted document which shows the changes below:
- ✓ The addition of PrEP, PEP and ART medications,
- ✓ The addition of Rinvoq as recommended by FDA's Center for Drug Evaluation and Research.
- ✓ The removal of human growth hormone and bovine insulin based on the CJD/vCJD Guidance.
- ✓ Refer to the 32nd Edition AABB Standards for Blood Bank and Transfusion Services, with a delayed effective date of July 1, 2020, for information on implementing changes in the Medication Deferral List. [Reference Standards 5.4.1A]

This Medication Deferral List is used with both the DHQ and the aDHQ.

_____ Report the implementation of AABB's DHQ v2.1 and Related Materials, consistent with Section IV of the FDA guidance and reporting requirements of 21 CFR 601.12, as a:
- ✓ **Minor change** in the Annual Report [§601.12(d)] to FDA when implemented as accepted by FDA or with minor changes to the v2.1 documents, as described in recommendations 1-4 of Section IV, page 3.
- ✓ **Moderate change** if implemented using "a computer-assisted interactive interview procedure," which requires a CBE30 supplement [§601.12(c)], as described in recommendation 5 of Section IV, page 4. Refer to FDA's July 2003 guidance.
- ✓ **Major change** if implemented as a modified version of the FDA accepted DHQ v2.1 materials, which may require the submission of a PAS [§601.12(b)] for FDA approval prior to implementation of the major changes, as described in recommendation 6 of Section IV, page 4.

Recommendations in the following FDA guidance documents were incorporated into v2.1, dated April 2020:

- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry 4/2020

- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products - Guidance for Industry 4/2020

- Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Guidance for Industry 4/2020

- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry
  5/2019

- Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components
  12/2017

- Recommendations for Assessment of Blood Donor Eligibility, Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry
  1/2017