This Toolkit provides compliance options to consider for implementation of FDA’s less restrictive recommendations of the August 2020 HIV Risk Guidance.
Toolkit: Compliance Options for Implementation of FDA’s August 2020 HIV Risk Guidance

AABB’s Donor History Task Force (the Task Force) has received several questions related to implementation of the less restrictive recommendations in FDA’s Aug 2020 HIV Risk Guidance. A table of change shows the shortened time frame for assessing risk posed by the donor’s sexual partner. On August 28, AABB announced the decision of the Task Force to achieve compliance with these less restrictive recommendations with the least burdensome approach, consistent with the v2.1 User Brochure for the DHQ. The approach ensures donor centers have flexible options to consider as they identify the compliance strategy that meets the unique needs of their establishment during this challenging pandemic period.

BACKGROUND
I. What changed in the FDA’s August 2020 HIV Guidance?
As shown in the table, FDA recommends a shortened 3-month time frame for assessment of risk posed by a donor’s sexual partner. The recommendations apply to risk posed by a sexual partner who has exchanged sex for money or drugs or engaged in non-prescription injection drug use in the past 3 months.

FDA changed the timeframe for risk posed by the donor’s sexual partner in the previous HIV Risk Guidance (April 2020) which stated:

4. Defer for 3 months from the most recent sexual contact, any individual who has a history of sex with a person who: has ever had a positive test for HIV, ever exchanged sex for money or drugs, or ever engaged in non-prescription injection drug use.

By replacing the phrase “has ever” with the 3-month time frame for the sexual partner’s risk in Section III. Recommendations, pages 8-9, to read:

B. Donor Deferral
We recommend that you defer as follows:

5. Defer for 3 months from the most recent sexual contact, an individual who has had sex with an individual who has exchanged sex for money or drugs in the past 3 months. If the individual has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.

6. Defer for 3 months from the most recent sexual contact, an individual who has had sex with an individual who has engaged in non-prescription injection drug use in the past 3 months. If the individual has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.

The recommendations also include a statement on donor requalification:

A donor deferred for any of the factors in section III.B. 2-12 of this guidance may be eligible to donate after the 3-month deferral period, provided the donor meets all other donor eligibility criteria.
II. The considerations for implementation options are illustrated in the following Q & A:

1) Are we required to update our DHQ now and how is this different because these are “less restrictive recommendations”?
No, but you must meet or exceed FDA’s requirements. You are not required to implement less stringent requirements, based on the following:

- An update to the DHQ is required when FDA’s new recommendations are more restrictive. In this case, FDA has shortened the deferral period to 3 months, which is less restrictive.
- The DHQ v2.1 with Questions 16 and 17 currently meet or exceed FDA’s new recommendations. This means centers are not required to implement these less stringent requirements to achieve compliance with FDA’s August 2020 Guidance.
- The User Brochure for v2.1 explains on page 5 that “Blood centers may implement more restrictive deferral policies than required by AABB and FDA.”

2) Will there be more changes to FDA’s recommendations in the future?
It is possible. FDA has demonstrated a commitment to remove unnecessary deferrals which “may help to address significant blood shortages that are occurring as a result of a current and ongoing public health emergency.” Here are additional considerations:

- This is the second update to the HIV risk recommendations since the pandemic began, and FDA has stated (on page 2 of the guidance) “within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with an updated guidance that incorporates any appropriate changes based on comments received on this guidance and the Agency’s experience with implementation.” This could require another update to the DHQ at that time.

- In response to Question 7 during the “Ask the FDA” session at AABB’s 2020 Annual Meeting, FDA also addressed future changes:
  **Question 7.** Does FDA plan to revise other recommendations and regulations to be consistent with the 3-month deferrals in the **August 2020 HIV Risk Guidance**, including for:
  - time spent in a correctional institute?
  - sexual contact or lived with a person who has hepatitis?
  - punctures and scars on the forearm that are indicative of IV drug use?

**FDA Response to Question 7:**
“We received public comments to the updated 2020 HIV guidance that addresses these current deferrals. We will review these comments and the available data in considering any future changes. As you know, the deferral for institutionalization for 72 hours or more in the past 12 months in a correct institution is required in 21 CFR 630.10(e)(1)(iv) and the requirement that a donor’s arms and forearms are free of punctures and scars indicative of injected drugs of abuse is in 21 CFR 630.10(f)(6)(ii). Therefore, regulation changes would be necessary to harmonize these deferrals with the behavioral deferrals in the 2020 HIV guidance. With respect to hepatitis deferrals we note that the requirement to defer donors who have had close contact with an individual who has viral hepatitis was eliminated when FDA published revised regulations for donor eligibility in May 2015. Instead, we added 21 CFR 630.10(e)(1)(v) to assess donors for intimate contact with risk for a relevant-transfusion transmitted infection.

The preamble to the **Final Rule** noted that the FDA accepted Donor History Questionnaires addressed the risk of transmission of HBV and HCV by including questions about the donor’s close contact with individuals with hepatitis. Similar to the other deferrals, we will consider the
public comments and available data in considering changes to this recommended deferral under 21 CFR 630.10(e)(1)(v).”

- IF AABB were to issue a new DHQ at this time, all donor centers would be required to implement the new version DHQ during the pandemic. This is would be required after FDA’s formal review and acceptance because DHQ v2.1 would no longer be recognized as acceptable by FDA.

3) When does AABB plan to release a new DHQ?
The next version, v3.0 of the DHQ, is expected to be submitted to FDA sometime in 2021 but the timing cannot be determined at this time.

- The precise timing of this decision will be made with the DHTF based on many factors, including the continued pandemic, and new FDA regulations and recommendations, as noted above (and certainly if they are more restrictive).
- This approach, using an effective compliance strategy without the operational burden of repeated changes to the DHQ, will achieve compliance with current donor screening requirements until v3.0 is finalized and submitted to FDA in 2021.

4) What are the options if we identify a large number of previously deferred donors and we decide we are able to implement the 3-month timeframe now to help our inventory?
Options 2 and 3, outlined below, provide a path for donor centers considering implementing the less restrictive deferral policy to “help address significant shortages,” with or without a change in the current DHQ.

Under Option 2, a center can update their Blood Establishment Computer System (BECS) with the shorter time frame for the risk posed by the donor’s sexual partner, now defined as in “the past 3 months” – without changing the questions on the DHQ. Option 2 is the least burdensome approach to remove unnecessary deferrals. Some centers may view Option 2 as the best approach during the pandemic to comply with FDA requirements without significant stress on resources and operations.

Option 3 is available to donor centers electing to submit a revised DHQ to FDA.

5) What are capture questions and how would they work with these new recommendations?
There are currently 25 capture questions used in DHQ v2.1. A capture question, as defined in the DHQ User Brochure, is “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.”
- When a donor responds “Yes” to these capture questions, the donor screener uses follow-up questions to establish the date of the last risk, and defer the donor based on that date.
- The EXAMPLE Flowcharts for current Questions 16 and 17 (Option #2, pages 6 and 7 of this Toolkit) demonstrate how the capture questions will effectively assess donor risk, consistent with other capture questions throughout the DHQ.
Options for Compliance with HIV Risk Guidance

**Option 1: Retain current DHQ v2.1 without changes in deferral policy because** DHQ v2.1 meets or exceeds the requirements in the August 2020 HIV Risk Guidance

- No changes are made to the questions on DHQ v2.1
- Previously deferred donors remain deferred without implementation of the new 3-month time frame.
- No changes in deferral policy are made to the BECS
- No FDA reporting is required

**Option 2: Retain current DHQ v2.1 with changes in deferral policy because** DHQ v2.1 meets or exceeds the requirements in the August 2020 HIV Risk Guidance

- No changes are made to the questions on DHQ v2.1
- Deferral policy is changed to address the risk posed by the sexual partner of the donor based on the sexual partner’s risk in the past 3 months (modifying the deferral for sexual contact with anyone who has ever exchanged sex for money or drugs, or ever engaged in non-prescription injection drug use.)
  - ✓ The DHQ v2.1 questions 16 and 17 are effective as capture questions that will lead to follow-up questions to further assess risk for HIV.
  - ✓ When a donor responds “yes” to these capture questions, the donor screener will use follow-up questions (Option 2: EXAMPLE Flowcharts for current Questions 16 and 17, pages 6 and 7 of the Toolkit) to determine:
    - ✓ the last date of donor’s contact with the sexual partner
    - ✓ the last date of contact the sexual partner was at risk for HIV
    - ✓ the donor eligibility based on the dates.
- Previously deferred donors may be eligible to donate again; “A donor deferred for any of the factors in section III.B. 2-12 of this guidance may be eligible to donate after the 3-month deferral period, provided the donor meets all other donor eligibility criteria.” (page 10, section III.C.1. of the guidance)
- Option 2: EXAMPLE Flowcharts for current DHQ Questions 16 and 17 (pages 6 and 7 of this Toolkit)
  - ✓ Include the reminder that the donor is deferred unless confident of the dates provided as stated by FDA: “If the individual has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.” AND “If the individual has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.”
  - ✓ As outlined in the DHQ v2.1 User Brochure, page 2, “Flowcharts are intended as a resource, and use of the flowcharts is not required. Flowcharts may be revised to reflect local policy as long as deferrals are not made less strict than those required by AABB and FDA.”
- BECS is updated with 3-month time frame for sexual partner’s risk
- SOPs and staff training
- No FDA reporting requirements. However, you may consider including updates made to the BECS in your Annual Report.

**Option 3: Develop new DHQ for FDA submission.** A donor center may elect to update their DHQ and their BECS now.
Deferral policy is changed to address the risk posed by the sexual partner of the donor based on the sexual partner’s risk in the past 3 months.

Update DHQ questions 16 and 17:
- EXAMPLE Question 16: “In the past 3 months, have you had sexual contact with a prostitute or anyone else who has taken money or drugs or other payment for sex in the past 3 months?”
- EXAMPLE Question 17: “In the past 3 months, have you had sexual contact with anyone who has used needles to take drugs or steroids, or anything not prescribed by their doctor in the past 3 months?”

Previously deferred donors may be eligible to donate again; “A donor deferred for any of the factors in section III.B. 2-12 of this guidance may be eligible to donate after the 3-month deferral period, provided the donor meets all other donor eligibility criteria.” (page 10, section III.C.1. of the guidance)

Flowcharts 16 and 17 are updated (Option 3: EXAMPLE Flowcharts for Updated DHQ Questions 16 and 17, pages 8 and 9 of this Toolkit)
- Include the reminder that the donor is deferred unless confident of the dates provided as stated by FDA: “If the individual has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.” AND “If the individual has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.”

BECs is updated with 3-month time frame for sexual partner’s risk

SOPs and staff training

Licensed facilities – submit a CBE as described in the section IV of the guidance, page 13: Licensed blood establishments must report changes to their approved application to FDA in accordance with 21 CFR 601.12.

1. Licensed blood establishments that revise their DHQs and accompanying materials must report the change to FDA in a Changes Being Effected (CBE) Supplement under 21 CFR 601.12(c)(5) (see 21 CFR 601.12(a)(3)). The blood and blood components collected using the change may be distributed immediately upon receipt of the supplement by FDA. Include the following information in your CBE Supplement:
   a. Form FDA 356h “Application to Market a New or Abbreviated New Drug, or Biologic for Human Use.”
   b. Cover letter describing the request and contents of the supplement.
   c. The DHQ and accompanying document(s). Please highlight the modifications.
Question 16: In the past 3 months, have you had sexual contact with a prostitute or anyone else who has ever taken money or drugs or other payment for sex?

Donor Eligibility: A person who has taken money, drugs, or other payment in exchange for sex in the past 3 months is at increased risk for transmitting HIV and other infectious diseases. For that reason, a donor who has had sexual contact with this person is also at increased risk for transmitting HIV and other infectious diseases, and is deferred for 3 months from the date of the last sexual contact.

FDA has stated that “If the donor has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.” HIV and other diseases may be transmitted through sexual contact.

Note: Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**OPTION 2: EXAMPLE FLOWCHART FOR CURRENT DHQ QUESTION 17**

**Question 17:** In the past 3 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?

**Donor Eligibility:** A person who has used needles, in the past 3 months, to take drugs, steroids, or anything not prescribed by their doctor is at increased risk for transmitting HIV and other infectious diseases. For this reason, a donor who has had sexual contact with this person is also at increased risk for transmitting HIV and other infectious diseases and are deferred for 3 months from the date of the last sexual contact. FDA has stated “If the donor has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.” HIV and other diseases may be transmitted through sexual contact.

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.

**Note:** The phrase "used needles" includes intravenous use, "skin popping" (injection under the skin), "mainlining" (arterial injection) and any other use of a needle to administer drugs, steroids or anything else not prescribed by their doctor for intravenous use.

![Diagram](image-url)
**OPTION 3: EXAMPLE FLOWCHART FOR UPDATED DHQ QUESTION 16**

**Question 16:** In the past 3 months, have you had sexual contact with a prostitute or anyone else who has taken money or drugs or other payment for sex in the past 3 months?  

**Donor Eligibility:** A person who has taken money, drugs, or other payment in exchange for sex in the past 3 months is at increased risk for transmitting HIV and other infectious diseases. For that reason, a donor who has had sexual contact with this person is also at increased risk for transmitting HIV and other infectious diseases, and is deferred for 3 months from the date of the last sexual contact.

FDA has stated that “If the donor has any uncertainty about when their sexual partner exchanged sex for money or drugs, defer the individual for 3 months from their most recent sexual contact.” HIV and other diseases may be transmitted through sexual contact.  

**Note:** Not all donors define "sex" or "sexual contact" in the same way. The donor must have read the Blood Donor Educational Material provided.
**OPTION 3: EXAMPLE FLOWCHART FOR UPDATED DHQ QUESTION 17**

**Question 17:** In the past 3 months, have you had sexual contact with anyone who has used needles to take drugs or steroids, or anything not prescribed by their doctor in the past 3 months?

**Donor Eligibility:** A person who has used needles, in the past 3 months, to take drugs, steroids, or anything not prescribed by their doctor is at increased risk for transmitting HIV and other infectious diseases. For this reason, a donor who has had sexual contact with this person is also at increased risk for transmitting HIV and other infectious diseases and are deferred for 3 months from the date of the last sexual contact. FDA has stated “If the donor has any uncertainty about when their sexual partner engaged in non-prescription injection drug use, defer the individual for 3 months from their most recent sexual contact.” HIV and other diseases may be transmitted through sexual contact.

**Note:** Not all donors define “sex” or “sexual contact” in the same way. The donor must have read the Blood Donor Educational Material provided.

**Note:** The phrase “used needles” includes intravenous use, “skin popping” (injection under the skin), “mainlining” (arterial injection) and any other use of a needle to administer drugs, steroids or anything else not prescribed by their doctor for intravenous use.

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**Flowchart**

1. **Question #17**
   - In the past 3 months, have you had sexual contact with anyone who has used needles to take drugs or steroids, or anything not prescribed by their doctor in the past 3 months?
     - **No**
     - **Yes**
       - **Determine the last date** the donor’s sexual partner used needles to take drugs or steroids, or anything not prescribed by their doctor.
         - **Was the last date your sexual partner used needles to take drugs or steroids, or anything not prescribed by their doctor greater than 3 months ago?**
           - **Yes**
             - Accept donor
           - **No, or do not know**
             - Defer donor for 3 months from the date of the most recent sexual contact
             - Next question