



Advancing Transfusion and
Cellular Therapies Worldwide

Association Bulletin #20-04

Date: May 5, 2020

To: AABB Members

From: Beth Shaz, MD – President
Debra BenAvram – Chief Executive Officer

Re: The Impact on Blood Safety of Effective Antiretroviral Medications for HIV Prevention and Treatment

Summary

This Association Bulletin was developed by the AABB Transfusion-Transmitted Diseases (TTD) Committee and the Donor History Task Force (DHTF), which include representatives from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The AABB Board of Directors has approved this bulletin to provide new information and recommendations regarding blood donor eligibility for individuals taking antiretroviral medications to prevent sexual transmission of human immunodeficiency virus (HIV), or for treatment of HIV infection.

AABB's Association Bulletins may include announcements of standards or requirements for accreditation, recommendations on emerging trends or best practices, and/or pertinent information. No new standards are proposed in this bulletin.

Recent publications¹ have raised concern that the risk of HIV transmission by blood transfusion may increase because of the growing use of antiretroviral medications taken as 1) therapy (ART) by individuals with an established HIV infection or 2) as pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) to prevent transmission of HIV infection in the face of perceived risk. This bulletin enumerates these concerns and recommends mitigation strategies. The bulletin also:

- Describes current evidence, risk, and the impact of the suppressive effects of antiretroviral medications on diagnostic and screening assays for HIV.
- Provides recommendations, in the absence of FDA guidance, for acceptable mitigation strategies for blood donor screening, eligibility, and deferral, including examples of the recommended additions to the AABB Donor History Questionnaire (DHQ) and related materials.

FDA issued the December 2019 communication, [Important Information for Potential Donors of Blood and Blood Products](#) (Attachment 1) after a “recent study of the blood supply in the United



Advancing Transfusion and
Cellular Therapies Worldwide

States (US) identified some HIV-positive blood donations from individuals who were taking antiretroviral drugs” and noted FDA’s concern “about the risk that such donations pose to the overall safety of the blood supply.” FDA cautioned that “antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient. Although undetectable still equals untransmissible for sexual transmission (U = Usex), this does not apply to transfusion transmission.”

Background

The antiretroviral medications PrEP, PEP, and ART are critical components² of public health campaigns aimed at ending the global HIV epidemic and have been given prominent roles in the US HIV control strategy. The operative concept behind the high priority of ART as prevention³ is the concept of “undetectable equals untransmittable” or “U = Usex” for sexual transmission. This is well established^{4,5} for sexual transmission from infected partners, which is characterized by relatively modest inocula of virus. There is, however, a dearth of evidence regarding the infectivity of blood collections from individuals receiving ART for established HIV infection or from those rare individuals who become infected despite prescription of PrEP. The viral burden and route of infection are different in the latter circumstances and the risks for transfusion-transmission, while likely small, are uncharacterized at this time.

Current evidence: The impact of antiretroviral medications on testing

There is clear evidence that receipt of ART can alter the performance⁵ of diagnostic and screening assays for HIV. The goal of treating HIV-infected individuals is suppression of circulating HIV RNA to levels undetectable by highly sensitive contemporary nucleic acid tests (NAT). This level of suppression can be achieved in the large majority of patients. There is further evidence that reactive serologic assays (antibody and antigen tests) can revert to negative with successful ART. Finally, when rare HIV infections occur during receipt of PrEP,⁶ there is concern that the evolution of an individual’s diagnostic assays may be delayed, extending the test-negative window period in potential blood donors.

When HIV antibody-positive, NAT-negative donors (so called “elite controllers”)⁷ in South Africa were studied, 76.1% were, in fact, receiving antiretroviral medications despite the study’s stated criteria for participation. In the US, in the non-donor setting, half of HIV-infected men who have sex with men and deny infection during a structured interview, have antiretroviral medications in their blood when tested.⁸

In a plenary abstract from the Transfusion-Transmissible Infectious Monitoring System at the 2019 AABB Annual Meeting, 15% of donors found to be HIV infected had antiretroviral medications in their blood and 0.6% of selected, fully qualified donors from selected locales had antiretroviral medications on unlinked testing.⁹ Future research with primate studies may provide additional evidence about the infectivity of such donors.



Advancing Transfusion and
Cellular Therapies Worldwide

Risk Mitigation

Until an evidence base is developed to evaluate concerns related to use of PrEP, PEP, and ART by blood donors, potential mitigation strategies, in addition to current blood donor education, risk screening, and in-vitro testing, include:

1. The addition of information on PrEP, PEP, and ART to the Blood Donor Educational Material provided to each donor.
2. The addition of two direct questions about receipt of these medications on the AABB DHQ to the area for additional questions at the end of the DHQ.
3. The addition of Truvada, Descovy, and other antiretroviral medications on the Medication Deferral List (MDL).
4. A combination of these measures.

After extended discussion of these issues at the 2018 AABB Annual Meeting workshop, “PrEP: Pre-exposure HIV Prophylaxis in the Donor Room” and at the April 2019 meeting of the TTD Committee, a combination of all three interventions was recommended to the DHTF. This recommendation recognizes that a donor’s attention to the Blood Donor Educational Material may be suboptimal,¹⁰ and that the MDL is currently long and complex. Further, it is critically important to recognize that when donors respond to screening questions, they may be answering questions based on their assumption that “my blood is safe”¹¹ rather than answering the specific question being posed. Recognizing this, in combination with the explicit message of “U = Usex” for sexual transmission with antiretroviral medication use, the addition of two direct questions (one for PrEP and PEP, and one for ART) is thought to be the best strategy to minimize risk in the short and medium terms. Accordingly, the DHTF developed predonation screening tools consistent with the recommendations of the TTD Committee.

AABB recommendations

AABB recommends the following actions to evaluate donor eligibility and mitigate risks related to use of PrEP, PEP, and ART by individuals donating blood:

1. Update the AABB DHQ and related materials
 - Add the appropriate language to the Blood Donor Educational Material and MDL to screen blood donors for use of antiretroviral medications, known as PrEP, PEP, and ART. Refer to Attachment 2, Implementation Section for details and examples of an acceptable approach.
2. Deferral of individuals taking PrEP or PEP (who have never tested positive for HIV):
 - HIV *uninfected* individuals taking PrEP and/or PEP should be deferred until 3 months after the last dose of antiretroviral medication, and after routine laboratory tests that accompany preventive therapies have been completed by the prescriber.



Advancing Transfusion and
Cellular Therapies Worldwide

- This comports with and is slightly more conservative than [recommendations from CDC](#) for the management of non-occupational HIV exposure using PEP. Under CDC's recommendations, such exposed persons receive 28 days of a three-drug antiretroviral medication regimen and are last retested at three months after exposure.
3. Deferral of individuals taking ART:
- Individuals taking ART are indefinitely deferred because ART is prescribed for treatment of an established HIV infection (positive test for HIV).
 - This deferral is currently required by FDA regulations at [21 CFR 610.41](#) and recommendations based on evidence of HIV infection.
 - It is expected that individuals with HIV infection would also be deferred based on responses to other donor screening questions regarding HIV risk.

Implementation

Steps 1-5 of the **Instructions for Implementation - Attachment 2** describe the example documents and suggested approach for implementation of the recommendations in this bulletin. Consistent with established practice, these materials have been designed for use as a system to mitigate risks related to blood donor use of PrEP, PEP, and ART.

Example documents

The revised documents necessary to implement this risk mitigation strategy were developed by the DHTF. The documents in **Attachments 3 through 8** serve as examples for updating the AABB DHQ and related materials. A description and details on the appropriate use of the documents listed below are found in **Instructions for Implementation – Attachment 2**:

- Example Flowchart for PrEP and PEP – Attachment 3
- Example Alternative Flowchart for PrEP and PEP – Attachment 4
- Example Flowchart for ART – Attachment 5
- Medication Deferral List for PrEP, PEP, ART – Attachment 6
- Blood Donor Educational Material for PrEP, PEP, ART – Attachment 7
- Question and Answers – Attachment 8

References and resources

References

1. Seed C, Yang H, Lee J. Blood safety implications of donors using HIV pre-exposure prophylaxis. *Vox Sang* 2017;112:473-76.
2. Owens D, Davidson K, Krist A, for the US Preventive Services Task Force. Screening for HIV infection: US Preventive Services Task Force Recommendation Statement. *JAMA* 2019;321(23):2326-36.



Advancing Transfusion and
Cellular Therapies Worldwide

3. Centers for Disease Control and Prevention. HIV treatment as prevention. Atlanta, GA: CDC, 2020 [Available at: <https://www.cdc.gov/hiv/risk/art/index.html> (accessed March 10, 2020).]
4. Chou R, Evans C, Hoverman A, et al. Preexposure prophylaxis for the prevention of HIV infection: Evidence report and systematic review for the US Preventive Services Task Force. *JAMA* 2019;321(22):2214-30.
5. Keating S, Pilcher C, Busch M. Timing is everything: Shortcomings of current HIV diagnostics in the early treatment era (editorial). *Clin Infect Dis* 2016;63:562-64.
6. Van Epps P, Wilson B. Incidence of HIV in a nationwide cohort receiving pre-exposure prophylaxis for HIV prevention. *J Acquir Immune Defic Syndr* 2019;82(5):427-30.
7. Sykes W, van den berg K, Jacobs G, et al. Discovery of “false elite controllers”: HIV antibody-positive RNA-negative blood donors found to be on antiretroviral treatment. *J Infect Dis* 2019;220:643-47.
8. Hoots B, Wejnert C, Martin A, et al. Undisclosed HIV infection among MSM in a behavioral surveillance study. *AIDS* 2019;33:913-18.
9. Custer B, Quiner C, Haaland R, et al. Detection of antiretroviral therapy use in US blood donors. *Transfusion* 2019;59(S3):9A.
10. Goldman M, Ram S, Yi Q, et al. The Canadian donor health assessment questionnaire: Can it be improved? *Transfusion* 2006;46:2169-75.
11. Willson S, Miller K, Seem D, et al. Cognitive evaluation of the AABB Uniform Donor History Questionnaire. *Transfusion* 2016;56:1662-7.

Other Resources

FDA

[Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use](#) – Final Rule May 22, 2015

[Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products](#) – April 2020

Centers for Disease Control and Prevention
[HIV Risk and Prevention](#)

US Department of Health and Human Services
[HIV/AIDS Glossary](#)

AABB

[Blood Donor History Questionnaires](#)

[The Feasibility of MSM Individual Risk Assessment Using the AABB DHQ](#)

Important Information for Potential Donors of Blood and Blood Products



Safety & Availability (Biologics)

[Biologic Product Security](#)

[Blood Safety & Availability](#)

[CBER-Regulated Products: Shortages and Discontinuations](#)

[Pandemics & Emerging Diseases](#)

[Tissue Safety & Availability](#)

[Vaccine Safety & Availability](#)

[HIV Home Test Kits](#)

[Recalls \(Biologics\)](#)

[Report a Problem to the Center for Biologics Evaluation & Research](#)

Individuals who have ever tested positive for HIV should not donate blood

Content current as of: 12/20/2019

Date: December 20, 2019

The Food and Drug Administration (FDA) would like to remind the public that individuals who have **ever** tested positive for HIV (the virus that causes AIDS) should not donate blood, because of the potential risk of transmitting HIV to others. This is consistent with FDA's [current policy on blood donation](#).

A recent study of the blood supply in the United States identified some HIV-positive blood donations from individuals who were taking antiretroviral drugs.¹ To date, there have been no reported cases of HIV transmission to transfusion recipients by blood donated by such individuals. However, FDA is concerned about the risk that such donations pose to the overall safety of the blood supply.

FDA-approved [antiretroviral drugs](#) are safe and effective and can reduce the HIV viral load of individuals to undetectable levels as determined by conventional testing. However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient. Although undetectable still equals untransmissible for sexual transmission ($U = U_{sex}$), this does not apply to transfusion transmission.

FDA's aim in providing this important advice is to ensure the continued high-level safety of the U.S. blood supply for everyone.

¹ Custer et al. Detection of antiretroviral therapy use in US blood donors. *Transfusion* 2019;59 Suppl S3, 9A.

[FDA Archive](#)

[Visitor Information](#)

[FOIA](#)

[About FDA](#)

[Website Policies / Privacy](#)

[HHS.gov](#)

[Accessibility](#)

[No FEAR Act](#)

[USA.gov](#)

Contact FDA



1-888-INFO-FDA (1-888-463-6332)

Instructions for Implementation – Attachment 2

The recommendations of this bulletin should be implemented as soon as feasible and as defined in your facility’s standard operating procedures (SOPs). This approach provides blood centers with documented change control while allowing the blood center adequate flexibility to develop SOPs and to consider operational issues and challenges:

- For document change control purposes, the AABB DHQ for PrEP, PEP, ART and related materials contain a revision date that represents the month and year AABB released the materials.
- The revision date is not intended to serve as an effective date.

Reference Standard 5.4.1A - Requirements for Allogeneic Donor Qualification in the 32nd edition of the *Standards for Blood Banks and Transfusion Services*:

- Becomes effective July 1, 2020.
- Requires the facility to use the current MDL within six months, which supports flexibility with implementation, as described above.

STEP 1: Update the DHQ

Add two questions to the area designated for additional questions found at the end of the DHQ

- Donor eligibility will be evaluated using two additional questions placed at end of the DHQ:

Use this area for additional questions	Yes	No
<i>EXAMPLE REVISIONS – number per your policy</i>		
xx. In the past 3 months , have you taken any medication to prevent an HIV infection?	<input type="checkbox"/>	<input type="checkbox"/>
xx. Have you EVER taken any medication to treat an HIV infection?	<input type="checkbox"/>	<input type="checkbox"/>

- **“In the past 3 months**, have you taken any medication to prevent an HIV infection?”
As described in the flowchart, the individual is deferred for 3 months from the date of the last dose of antiretroviral medication taken by an HIV *uninfected* person to prevent HIV infection.

- **“Have you EVER** taken any medication to treat an HIV infection?”
As described in the flowchart, an individual taking ART is indefinitely deferred because ART is prescribed for treatment of an established HIV infection (based on a positive test for HIV). A positive test for HIV is evidence of a relevant transfusion-transmitted infection and requires deferral under current FDA regulations and recommendations. [[21 CFR 610.41\(a\) and \(c\)](#) and [April 2020 HIV Risk guidance](#)]

STEP 2: Add Flowcharts

Use of these flowcharts is optional if the blood center develops and follows an equivalent method for evaluating responses to the AABB DHQ, as described in the AABB DHQ User

Instructions for Implementation – Attachment 2

Brochure. Flowcharts may be revised by blood centers to reflect local policy, provided deferrals are either consistent with or more restrictive than those required by AABB and FDA.

- **Add the PrEP and PEP flowchart** consistent with DHQ question numbering.
 - **Refer to Example Flowchart for PrEP and PEP – Attachment 3**
 - **Refer to Example Alternative Flowchart for PrEP and PEP – Attachment 4**
The alternative flowchart tracks deferral to differentiate between use of PrEP and PEP. Centers that do not wish to track these deferral details should use the flowchart in Attachment 3.
- **Add the ART flowchart** consistent with DHQ question numbering.
 - **Refer to Example Flowchart for ART – Attachment 5**
This flowchart assesses donor eligibility and includes deferral criteria for use of ART. An individual answering “Yes” to this question acknowledges the use of ART for treatment of HIV infection. For that reason, the individual would also be expected to be deferred by the Question “Have you ever had a positive test for the HIV/AIDS virus?” Policies and SOPs must address the process to resolve discrepant responses.

STEP 3: Update the MDL to include PrEP, PEP, and ART.

- **Refer to MDL PrEP, PEP, ART – Attachment 6**
The MDL has been updated to identify if the donor has:
 - Taken an antiretroviral medication to prevent HIV (PrEP and PEP) in the past 3 months.
 - Ever taken an antiretroviral medication for therapy (ART), to treat an established HIV infection.

STEP 4: Update the Blood Donor Educational Materials

- **Refer to Blood Donor Educational Material – Attachment 7**
The Blood Donor Educational Material has been updated by inserting new information regarding medications to treat or prevent HIV:
 - **Are taking any medication to prevent HIV infection. These medications may be known by you under the following names: PrEP, PEP, TRUVADA, or DESCOVY.**
 - **Have taken such a medication in the past 3 months.**
 - **Have EVER taken any medication to treat HIV infection.**

STEP 5: Reporting minor, more restrictive changes to the FDA:

- These are minor changes that must be reported to FDA in your annual report under [21 CFR 601.12\(d\)](#), noting the date the process was implemented and describing the

Instructions for Implementation – Attachment 2

modifications to the AABB DHQ documents. Refer to [current FDA guidance](#) recognizing the version 2.1 of the DHQ as acceptable for use.

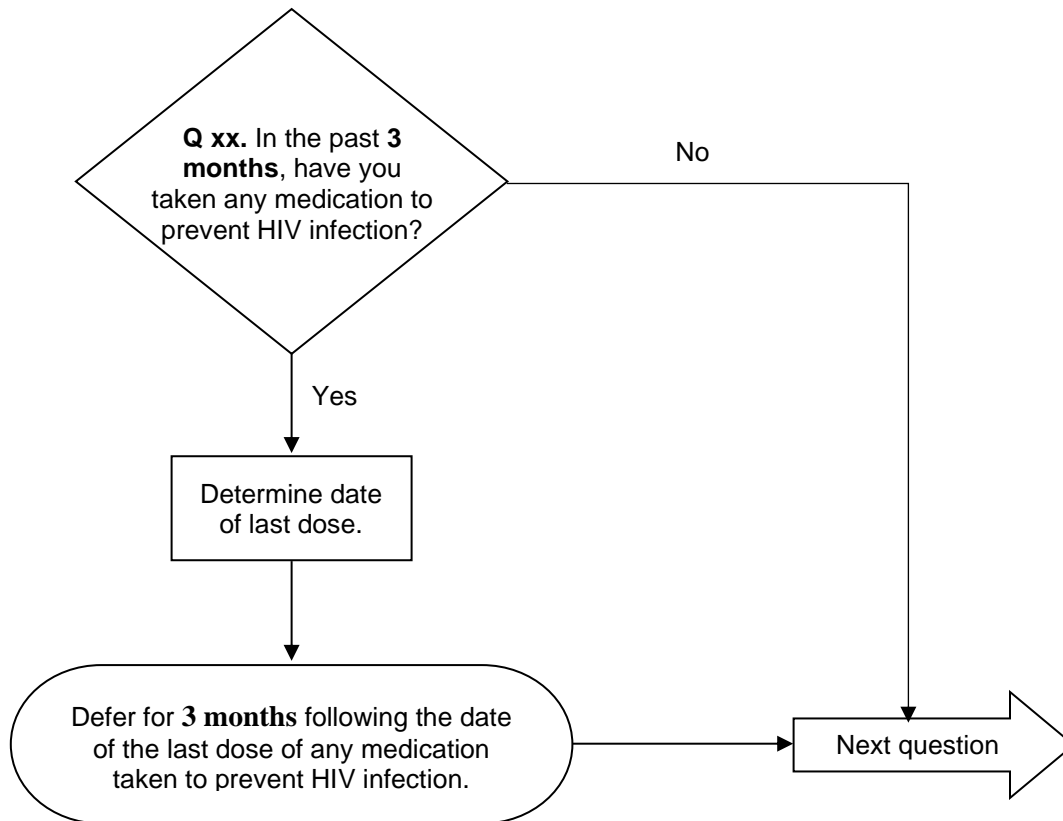
- The FDA recognizes AABB DHQ as acceptable for use as part of a system. The addition of questions is permitted in the area designated at the end of the AABB DHQ only if the changes are NOT less restrictive. In this bulletin, AABB is recommending changes that are more restrictive.
- The changes must be included in the Annual Report to FDA and do not require submission of a Prior Approval Supplement. [[21 CFR 601.12](#)]

Example: Flowchart for PrEP and PEP – Attachment 3

Question xx: In the past **3 months**, have you taken any medication to prevent HIV infection?

Donor Eligibility: A donor who has taken any medication to prevent HIV infection [also known as pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)] is deferred because it is possible that the presence of very low levels of virus may be undetectable when a donor taking this medication(s) is tested for HIV. The principle known as “Undetectable = Untransmittable” **does not apply to the potential risk to patients who receive transfusions.**

Version 2.1 Flowcharts can be found here: [DHQ](#), [aDHQ](#)



Resources:

TRUVADA® Official Site | See [Prescribing Information and Important Warnings](#)
<https://www.truvada.com/>

DESCOVY® Official Site | See [Prescribing Information and Important Warnings](#)
<https://www.descovy.com>

From the HHS/NIH “AIDSinfo” Website Glossary:

PrEP = “An HIV prevention method for people who are HIV negative and at high risk of HIV infection. Pre-exposure prophylaxis (PrEP) involves taking a specific combination of HIV medicines daily.”

PEP = “Short-term treatment started as soon as possible after high-risk exposure to an infectious agent, such as HIV ... The purpose of post-exposure prophylaxis (PEP) is to reduce the risk of infection.”

From the CDC’s MMWR Webpage: [Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016.](#)

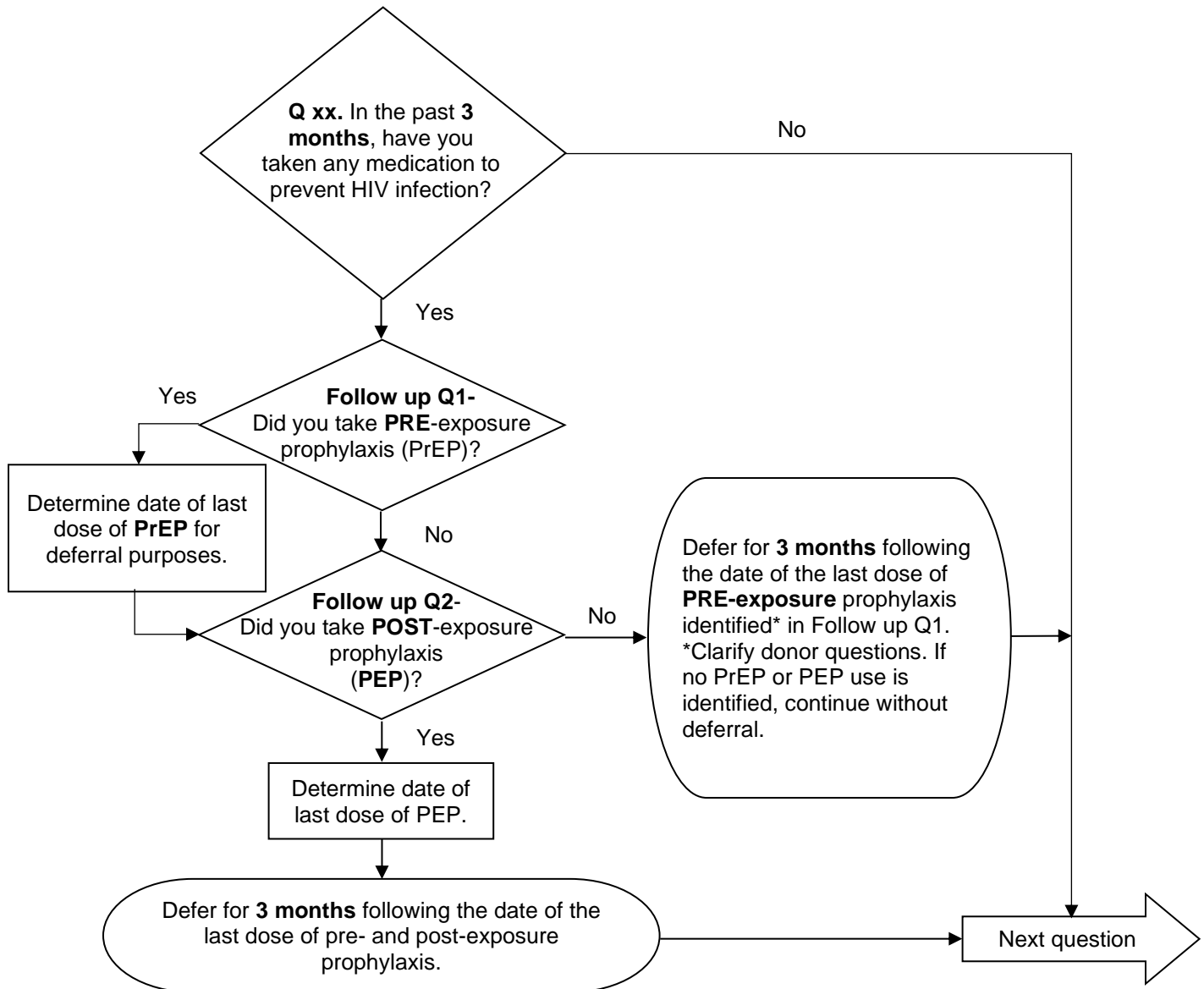
More information is available at <https://www.cdc.gov/hiv/basics/pep.html>

Example: Alternative Flowchart for PrEP and PEP – Attachment 4

Question xx: In the past **3 months**, have you taken any medication to prevent HIV infection?

Donor Eligibility: A donor who has taken any medication to prevent HIV infection [also known as pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)] is deferred because it is possible that the presence of very low levels of virus may be undetectable when a donor taking this medication(s) is tested for HIV. The principle known as “Undetectable = Untransmittable” **does not apply to the potential risk to patients who receive transfusions.**

Version 2.1 Flowcharts can be found here: [DHQ](#), [aDHQ](#)



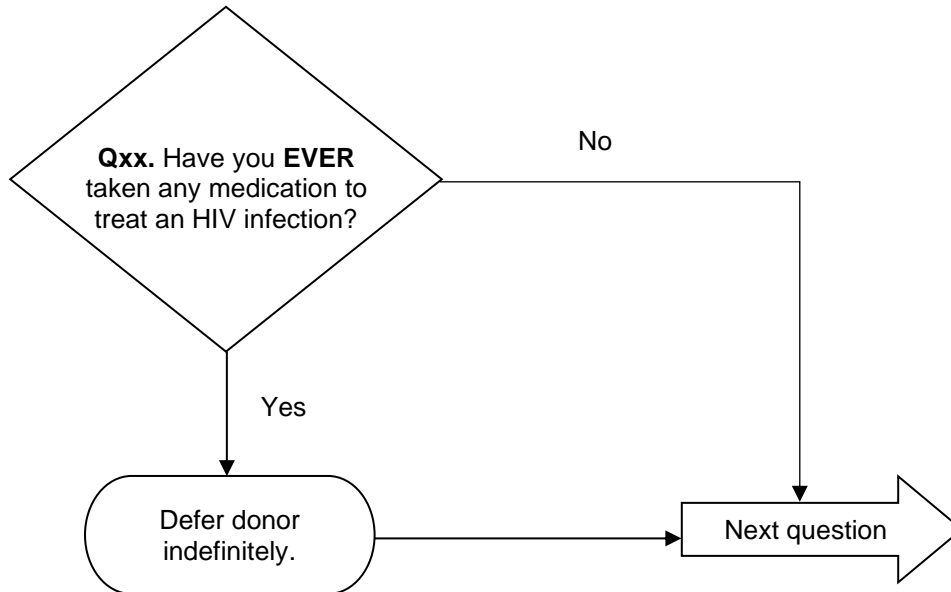
Refer to “Resources” at the bottom of Attachment 3 for links to Package Inserts, the HHS/NIH “AIDSinfo” Website, and the MMWR.

Example: Flowchart for ART – Attachment 5

Question xx: Have you **EVER** taken any medication to treat an HIV infection?

Donor Eligibility: An individual who has taken any medication to treat HIV (also known as antiretroviral therapy or ART medications) is indefinitely deferred. HIV infection requires an indefinite deferral, despite treatment with ART (see important information below from HHS/NIH) because the presence of very low levels of virus may be undetectable when a donor taking this medication(s) is tested for HIV. The principle known as “Undetectable = Untransmittable” **does not apply to the potential risk to patients who receive transfusions.**

Version 2.1 Flowcharts can be found here: [DHQ](#), [aDHQ](#)



From the [HHS/NIH "AIDSinfo" Website Glossary:](#)

"Drugs intended to treat HIV, commonly referred to as antiretroviral therapy (ART) for HIV may reduce a person's [viral load](#) (defined as the amount of HIV present in a blood sample) to an undetectable level. An [undetectable viral load](#) means that the level of HIV in the blood may be too low to be detected by testing.

Undetectable does not mean a person is cured. Some HIV, in the form of [latent HIV reservoirs](#), remains inside cells and in body tissues. Although ART can suppress HIV levels, ART cannot eliminate latent HIV reservoirs. For this reason, ART cannot cure HIV infection."

Medication Deferral List – Attachment 6

DO NOT STOP taking medications prescribed by your doctor in order to donate blood.

Donating while taking these drugs could have a negative effect on your health or on the health of the recipient of your blood.

PLEASE TELL US IF YOU:

ARE BEING TREATED WITH ANY OF THE FOLLOWING TYPES OF MEDICATIONS:	OR HAVE TAKEN:	WHICH IS ALSO CALLED:	ANYTIME IN THE LAST:
Antiplatelet agents (usually taken to prevent stroke or heart attack)	Feldene	piroxicam	2 Days
	Effient	prasugrel	3 Days
	Brilinta	ticagrelor	7 Days
	Plavix	clopidogrel	14 Days
	Ticlid	ticlopidine	
	Zontivity	vorapaxar	1 Month
Anticoagulants or “blood thinners” (usually taken to prevent blood clots in the legs and lungs and to prevent strokes)	Arixtra	fondaparinux	2 Days
	Eliquis	apixaban	
	Fragmin	dalteparin	
	Lovenox	enoxaparin	
	Pradaxa	dabigatran	
	Savaysa	edoxaban	
	Xarelto	rivaroxaban	
	Coumadin, Warfilone, Jantoven	warfarin	7 Days
Heparin, low-molecular-weight heparin			
Acne treatment	Accutane Amnesteem Absorica Claravis	Myorisan Sotret Zenatane isotretinoin	1 Month
Multiple myeloma	Thalomid	thalidomide	
Rheumatoid arthritis	Rinvoq	upadacitinib	
Hair loss remedy	Propecia	finasteride	
Prostate symptoms	Proscar Avodart Jalyn	finasteride dutasteride	
Immunosuppressant	Cellcept	mycophenolate mofetil	6 Weeks
HIV Prevention (PrEP and PEP)	Truvada, Descovy, Tivicay, Isentress	tenofovir, emtricitabine dolutegravir, raltegravir	3 Months
Basal cell skin cancer	Erivedge Odomzo	vismodegib sonidegib	24 Months
Relapsing multiple sclerosis	Aubagio	teriflunomide	
Rheumatoid arthritis	Arava	leflunomide	
Hepatitis exposure	Hepatitis B Immune Globulin	HBIG	12 months
Experimental Medication or Unlicensed (Experimental) Vaccine			
Psoriasis	Soriatane	acitretin	36 Months
	Tegison	etretinate	Ever
HIV treatment also known as antiretroviral therapy (ART)			

Medication Deferral List – Attachment 6

DO NOT STOP taking medications prescribed by your doctor in order to donate blood.

Some medications affect your eligibility as a blood donor for the following reasons:

Antiplatelet agents affect platelet function, so people taking these drugs should not donate platelets for the indicated time. You may still be able to donate whole blood or red blood cells by apheresis.

Anticoagulants or "blood thinners" are used to treat or prevent blood clots in the legs, lungs, or other parts of the body, and to prevent strokes. These medications affect the blood's ability to clot, which might cause excessive bruising or bleeding when you donate. You may still be able to donate whole blood or red blood cells by apheresis.

Isotretinoin, finasteride, dutasteride, acitretin, and etretinate can cause birth defects. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman.

Thalomid (thalidomide), Erivedge (vismodegib), Odomzo (sonidegib), Aubagio (teriflunomide), and Rinvoq (upadacitinib) may cause birth defects or the death of an unborn baby if transfused to a pregnant woman.

Cellcept (mycophenolate mofetil) and Arava (leflunomide) are immunosuppressants that may cause birth defects or the death of an unborn baby if transfused to a pregnant woman.

PrEP or pre-exposure prophylaxis involves taking a specific combination of medicines as a prevention method for people who are HIV negative and at high risk of HIV infection.

PEP or post-exposure prophylaxis is a short-term treatment started as soon as possible after a high-risk exposure to HIV to reduce the risk of infection.

ART or antiretroviral therapy is the daily use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection.

Hepatitis B Immune Globulin (HBIG) is an injected material used to prevent hepatitis B infection following a possible or known exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case; therefore, persons who have received HBIG must wait to donate blood.

Experimental medication or unlicensed (experimental) vaccine is usually associated with a research study, and the effect on the safety of transfused blood is unknown.

Blood Donor Educational Material – Attachment 7

READ THIS BEFORE YOU DONATE!

We know that you would not donate unless you think your blood is safe. However, in order for us to assess all risks that may affect you or a patient receiving a transfusion, it is essential that you answer each question completely and accurately. If you don't understand a question, ask the blood center staff. All information you provide is confidential.

To determine if you are eligible to donate, we will:

- Ask about your health and travel
- Ask about medicines you are taking or have taken
- Ask about your risk for infections that can be transmitted by blood – especially AIDS and viral hepatitis
- Take your blood pressure, temperature and pulse
- Take a blood sample to be sure your blood count is acceptable

Travel to or birth in other countries

Blood donor tests may not be available for some infections that are found only in certain countries. If you were born in, have lived in, or visited certain countries, you may not be eligible to donate.

If you are eligible to donate, we will:

- Clean your arm with an antiseptic. Tell us if you have any skin allergies
- Use a new, sterile, disposable needle to collect your blood

WHAT HAPPENS AFTER YOUR DONATION

To protect patients, your blood is tested for several types of hepatitis, HIV, syphilis, and other infections. If your blood tests positive it will not be given to a patient. There are times when your blood is not tested. If this occurs, you may not receive any notification. You will be notified about any positive test result which may disqualify you from donating in the future. The blood center will not release your test results without your written permission unless required by law (e.g. to the Health Department).

DONOR ELIGIBILITY – SPECIFIC INFORMATION

Certain diseases, such as AIDS and hepatitis, can be spread through sexual contact and enter your bloodstream. We will ask specific questions about sexual contact.

What do we mean by “sexual contact?”

The words “have sexual contact with” and “sex” are used in some of the questions we will ask you, and apply to any of the activities below, whether or not a condom or other protection was used:

- Vaginal sex (contact between penis and vagina)
- Oral sex (mouth or tongue on someone's vagina, penis, or anus)
- Anal sex (contact between penis and anus)

HIV/AIDS risk behaviors

HIV is the virus that causes AIDS. It is spread mainly by sexual contact with an infected person OR by sharing needles or syringes used by an infected person for injecting drugs.

Do not donate if you:

- Have ever had HIV/AIDS or have ever had a positive test for the HIV/AIDS virus
- Have used needles to take any drugs not prescribed by your doctor IN THE PAST 3 MONTHS
- Have taken money, drugs or other payment for sex IN THE PAST 3 MONTHS
- Have had sexual contact IN THE PAST 3 MONTHS with anyone who has ever had HIV/AIDS or has ever had a positive test for the HIV/AIDS virus, ever taken money, drugs or other payment for sex, or ever used needles to take any drugs not prescribed by their doctor
- Are a male who has had sexual contact with another male, IN THE PAST 3 MONTHS
- Are a female who has had sexual contact IN THE PAST 3 MONTHS with a male who has had sexual contact with another male IN THE PAST 3 MONTHS
- Have had syphilis or gonorrhea IN THE PAST 3 MONTHS
- Have been in juvenile detention, lockup, jail or prison for 72 or more consecutive hours IN THE PAST 12 MONTHS
- Have a history of Ebola virus infection or disease

Do not donate to get a test! If you think you may be at risk for HIV/AIDS or any other infection, do not donate simply to get a test. Ask us where you can be tested outside the blood center.

Do not donate if you have these symptoms which can be present before an HIV test turns positive:

- Fever
- Enlarged lymph glands
- Sore throat
- Rash

Your blood can transmit infections, including HIV/AIDS, even if you feel well and all your tests are normal. This is because even the best tests cannot detect the virus for a period of time after you are infected.

IMPORTANT NEW INFORMATION

DO NOT DONATE if you:

- **Are taking any medication to prevent HIV infection these medications may be known by you under the following names: PrEP, PEP, TRUVADA, or DESCOVY.**
- **Have taken such a medication in the past 3 months.**
- **Have EVER taken any medication to treat HIV infection.**

DO NOT donate if your donation might harm the patient who receives the transfusion.

THANK YOU FOR DONATING BLOOD TODAY!

(Donor Center Name)
(Telephone Number)

Questions and Answers – Attachment 8

- **What version AABB Donor History Questionnaire (DHQ) will be revised?**

The current AABB DHQ and related materials should be revised.

- **Will there be a new version of the AABB DHQ?**

- This Association Bulletin will apply to version 2.1 once accepted by FDA. Version 2.1 includes all new FDA recommendations issued in April 2020, and is currently under review with FDA as this bulletin is finalized.
- Changes captured in version 2.1 are limited to new FDA recommendations to enable FDA to expedite review making it possible to promptly implement changes that will increase the pool of eligible donors.
- As a result, FDA's expedited review timeline did not permit incorporating changes for PrEP, PEP and ART in the version 2.1 DHQ. The time necessary for such a full version review would delay implementation of new recommendations issued in response to the COVID-19 pandemic and its potential impact on the blood supply.

- **Are there examples to follow when updating the AABB DHQ and other documents?**

Yes. The materials found in **Attachments 3 through 7** were developed by the DHTF to meet the recommendations of this bulletin:

- **Example Flowchart for PrEP and PEP – Attachment 3**
- **Example Alternative Flowchart for PrEP and PEP – Attachment 4**
- **Example Flowchart for ART – Attachment 5**
- **MDL with PrEP, PEP, ART – Attachment 6**
- **Blood Donor Educational Material with PrEP, PEP, ART – Attachment 7**

- **What is the Alternative Flowchart?**

- At the request of members, AABB has developed an alternative flowchart for those who elect to track donor deferral specifically related to PrEP vs PEP.
- If your facility does not wish to track these details for deferral, use **Flowchart for PrEP and PEP – Attachment 3**.

- **When should these changes be implemented?**

As described in **Attachment 2, Instructions for Implementation**, “The recommendations of this bulletin should be implemented as soon as feasible and as defined in your facility's SOPs.” This approach provides blood centers with adequate flexibility for effective implementation.

- The AABB DHQ and related materials provided in this bulletin contain a revision date that represents the month and year AABB released the materials.
- The revision date is not intended to serve as an effective date.

- **Do these changes require a Prior Approval Supplement?**

No, under [21 CFR 601.12](#), a Prior Approval Supplement is not required for these minor changes. The addition of questions is permitted in the area designated at the end of the AABB DHQ if the changes are NOT less restrictive. This bulletin is recommending changes that are more restrictive.

- **How should I report these changes to the FDA?**

If implemented as recommended, the changes should be reported to FDA in your annual report as a minor change under [21 CFR 601.12\(d\)](#).

- **Where can I find additional information about implementing changes to the AABB DHQ and related materials?**

The AABB DHQ User Brochure describes change control and limitations on changes to the documents recognized by the FDA.

- **Who should I contact if I have additional questions?**

Please don't hesitate to contact AABB Regulatory Affairs with questions at regulatory@aabb.org.