4550 Montgomery Avenue | Suite 700, North Tower | Bethesda, MD 20814 | 301.907.6977 | aabb.org

Association for the Advancement of Blood & Biotherapies

Association Bulletin #22-03

Date: September 8, 2022

To: AABB Members

From: Dana Devine, PhD – President
Debra BenAvram – Chief Executive Officer

Re: 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

Association Bulletins (Bulletin) provide a mechanism for publication of documents that have been approved by the Board of Directors for distribution to individual and institutional members, such as:

- Standards that were adopted after publication of the most recent edition of *Standards*.
- Statements of AABB policy intended for distribution to members.
- Guidance, recommendations, and reports that have been developed by AABB Committees or National Office staff for distribution to members.

This Bulletin was developed by AABB's Transfusion Transmitted Diseases (TTD) Committee and the Donor History Task Force (DHTF), including representatives from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

Summary

This Bulletin provides recommendations to update and replace the donor eligibility recommendations in AB #20-04 *The Impact on Blood Safety of Effective Antiretroviral Medications for HIV Prevention and Treatment* (now obsolete). The Bulletin reflects new information regarding the impact of donor use of long-acting, injectable cabotegravir (trade name Apretude) as pre-exposure prophylaxis (PrEP) approved by FDA in late December 2021. AABB encourages members to carefully review this new information on the long-acting pharmacokinetic properties of cabotegravir and considerations for donor testing described in this Bulletin. The donor eligibility recommendations in AB #20-04 remain unchanged and are included in this new Bulletin for individuals taking antiretroviral medications by mouth to 1) prevent sexual transmission of human immunodeficiency virus (HIV), known as PrEP or post-exposure prophylaxis (PEP) or 2) for treatment of HIV infection, known as antiretroviral therapy (ART). It is important to note that the need to assess risk for false-negative test results in individuals taking medications for HIV prevention and treatment extends to all donors and is not limited to specific subgroups.

AABB fully supports the CDC's Ending the HIV Epidemic in the U.S. campaign, including increased access to and use of PrEP medications to prevent HIV infection. AABB is committed to the continued safety of the blood supply and strongly believes that the health of each donor and patient must be protected. The recommendations in this Bulletin are intended to address the eligibility of donors using PrEP, PEP, and ART medications until the next version of the Donor History Questionnaire (DHQ), version 3.0, is reviewed and formally recognized by FDA. For this reason, this Bulletin provides recommendations that can be used with the current DHQ v2.1 system of documents to address the potential impact of PrEP for a period of months while the version 3.0 DHQ with PrEP, PEP, and ART is under review. For planning purposes, after the DHTF finalizes the version 3.0 system of documents, we anticipate the extensive review process within FDA will *take a minimum* of 3 months and possibly longer based on the large number of changes across multiple documents.

Important Information Emerges for the New Injectable PrEP Drug

Prior to FDA approval of injectable PrEP, AABB followed the evolving information on the long-acting properties of the drug while tracking new developments related to PrEP:

- The CDC began discussing a draft of the HIV PrEP Clinical Practice Guidelines, which included injectable PrEP in May 2021. AABB noted that one clinical trial was stopped early by the trial Data and Safety Monitoring Board because results demonstrated "*that long-acting injectable cabotegravir as PrEP is highly effective in preventing HIV acquisition in women*…", and noted a long pharmacokinetic tail phase.
- An update on injectable PrEP was presented to the TTD Committee. The drug remained in ongoing clinical trials.
- AABB identified new information stating, "False-negative results may occur in individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART), post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP)." This new information is provided under the "Limitation of the Test" in the package insert of the Bio-Rad Geenius HIV 1/2 Supplemental Assay [Number 7 on page 13].
- Cabotegravir (Apretude) received FDA approval on December 20, 2021. The package insert [page 8], described the "Long-Acting Properties and Potential Risks: Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). Healthcare providers should take the prolonged-release characteristics of cabotegravir into consideration…"
- Through a series of email communications with FDA's Center for Biologics Evaluation and Research (CBER), FDA supported AABB's understanding that:
    - *The long-acting properties of Apretude likely pose a greater risk for false-negative test results than the oral medications, due to delayed viral load detection/delayed seroconversion.*
    - *The available information suggests that a 3-month deferral is not an adequate deferral period for long-acting injectable cabotegravir (Apretude).*

    - *Based on the pharmacokinetics of injectable cabotegravir, it seems likely that suppressive levels may be present in the circulation for 12 months or more. Therefore, a longer deferral period may be necessary to allow time for seroconversion and viral load detection.*
- A TTD Work Group was formed in February 2022 to provide deferral recommendations to the DHTF for donor use of injectable PrEP. The Work Group considered a recent publication[1] describing the long-acting pharmacokinetic properties of the newly approved injectable PrEP and collaborated with national researchers and subject matter experts.

The TTD Work Group recommendations included the following considerations:

- By intention, long-acting cabotegravir demonstrates prolonged bioavailability and detectability in blood for extended periods, particularly for injected administration.[2-5]
- Injected cabotegravir tail-phase pharmacokinetic data also demonstrate a strong sex-effect, with clearance in females taking significantly longer than in males. For both males and females, published tail-phase elimination data extend out to 76 weeks (19 months) of observation following the last cabotegravir injection. At 76 weeks, cabotegravir was detectable above the lower limit of quantitation in 4 of 30 males (13%) and 27 of 64 females (42%).[1]
- These tail-phase cabotegravir data are of concern because of the direct implications for antiretroviral activity long after discontinuation of use and the ability to detect an incident HIV infection under these conditions.
- Although injected cabotegravir has been shown to be superior to daily oral emtricitabine and tenofovir PrEP to prevent HIV infection in controlled clinical trials, evaluation of HIV infections during open-label periods found an inability to detect HIV RNA in the presence of cabotegravir and evidence of blunted seroconversion and seroreversion, during post-study monitoring of injected cabotegravir participants. Package inserts for HIV RNA diagnostics and some HIV serological confirmation tests used for blood screening (Bio-Rad HIV Geenius) indicate these assays may fail to detect HIV infection resulting from the profound impact of cabotegravir on HIV disease progression dynamics.[6]
- Longitudinal data show the presence of detectable HIV infection using ultrasensitive research laboratory testing methods at time points in advance of HIV detection by standard serologic assays using FDA-approved HIV diagnostic tests.[7]

This Bulletin provides updated recommendations and mitigation strategies.

The Bulletin:

- Describes current evidence, risk, and the impact of the suppressive effects of antiretroviral medications on diagnostic and donor screening assays for HIV.
- Provides recommendations, in the absence of FDA guidance, for acceptable mitigation strategies for blood donor assessment, eligibility, and deferral for individuals taking oral PrEP and PEP medications, injectable PrEP medication, and ART as treatment for HIV.

- Provides recommendations based on available evidence for an extended donor deferral period for individuals who have received an injection or shot to prevent an HIV infection (cabotegravir/Apretude).
- Is accompanied by a Toolkit and Example Documents for Use with DHQ v2.1 that outlines an example of an acceptable approach for implementation of the recommendations in this Bulletin.

Historical Background - Donor Deferral for Use of PrEP and ART Taken by Mouth (oral)

The antiretroviral medications PrEP, PEP, and ART are critical components[8] of public health campaigns aimed at ending the global HIV epidemic and have been given prominent roles in the United States (US) HIV control strategy. The operative concept behind the high priority of PrEP and PEP as prevention[9] is the ability to stop an infection from occurring even if someone has been exposed to HIV. For ART as treatment, the concept of "undetectable equals untransmittable" or "U=U" for sexual transmission (also referred to as $U=U_{sex}$), meaning even if an infection is present the amount of virus is too low to be able to transmit the infection to a sexual partner, is an important public health message. This is well established[10,11] for sexual transmission from infected partners taking ART, where treated infections are characterized by viral control and thus small inocula of virus in body fluids. However, U=U does not apply to transfusion because of the intravenous route of exposure and the large volume of blood or blood products infused. As the availability of PrEP, PEP, and ART medications continues to expand, the potential infectivity of blood collections from individuals receiving ART for an established HIV infection or from those rare situations where individuals may have become infected because of not fully adhering to PrEP dosing has become an increasing concern. 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.

In December 2019 FDA issued the communication, Important Information for Potential Donors of Blood and Blood Products after a "recent study of the blood supply in the United States 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 ($U = U_{sex}$), this does not apply to transfusion transmission."

Current Evidence – The Impact of Antiretroviral Medications on Testing

There is clear evidence that receipt of ART can alter the detectability[11] of HIV infections by 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. 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,[12] there is evidence that the evolution of an

individual's detectability by diagnostic assays may be delayed, extending the test-negative window period in potential blood donors. The Central Laboratory of REDS-IV-P is conducting studies to evaluate the blood safety implications and approaches for advancing testing for screening donors with HIV infections who may be taking PrEP, PEP, and ART therapies. The purpose of this project is to characterize the altered dynamics of viremia and seroconversion, using donor screening and other modalities of HIV molecular and serologic assays, in HIV-infected individuals who initiated ART early after infection or were taking prophylaxis drugs. The goal is to understand the implications for blood services to detect HIV under these conditions.[13]

An article,[14] published in *Blood* in 2020 as part of the Transfusion Transmissible Infections Monitoring System in collaboration with the Division of HIV Prevention of the CDC, found that 15% of donors with confirmed HIV infection had antiretroviral medications in their blood at the time of donation and 0.6% of an anonymized sample of male, first-time donors from six large cities in the country who donated and were negative for all infectious disease marker testing, were taking PrEP at the time of donation. Additional studies are under way to continue to monitor for evidence of PrEP, PEP, and ART medications in blood donations collected in the US. Future research with primate studies may provide additional evidence about the infectivity of such donors.

Risk Mitigation

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

1. Three direct questions about receipt of these medications in the area for additional questions at the end of the AABB DHQ v2.1.
2. Information on PrEP, PEP, and ART medications to the Blood Donor Educational Material v2.1 provided to each donor.
3. PrEP and PEP for HIV prevention and ART to treat HIV infection, to the Medication Deferral List (MDL) v2.1.
4. A combination of these measures.

These recommendations take into consideration that a donor's attention to the Blood Donor Educational Material may be suboptimal,[15] 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"[16] rather than answering the specific question being posed. Recognizing this, in combination with the explicit message of "U = U" for sexual transmission with antiretroviral medication use, the addition of three direct questions (one for PrEP and PEP taken by mouth, one for PrEP received as an injection or shot, and one for ART) is thought to be the best strategy to minimize risk in the short and medium terms. Accordingly, the DHTF has developed a Toolkit and Example Documents for Use with DHQ v2.1 that is consistent with the recommendations of the TTD Committee. These materials have been designed for use as a system of documents to establish donor eligibility, consistent with

established practice, and to mitigate the potential impact of these medications on donor testing for HIV.

AABB Recommendations

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

1. Update the DHQ v2.1 and Related Materials:
   - Update the DHQ v2.1 by adding three questions to the area for additional questions to evaluate donor use of PrEP, PEP, and ART medications.
   - Add the appropriate language to the Blood Donor Educational Material v2.1 and MDL v2.1 to screen individuals for use of antiretroviral medications, known as PrEP, PEP, and ART.
   - Add the PrEP, PEP, and ART Flowcharts v2.1 consistent with DHQ numbering.

2. Medication deferral for individuals taking PrEP or PEP for HIV prevention and who have never tested positive for HIV:
   - HIV *uninfected* individuals taking PrEP and/or PEP by mouth should be deferred until 3 months after the last dose of antiretroviral medication.
   - HIV *uninfected* individuals who have received injectable PrEP (Apretude) should be deferred for 2 years after their last injection. This deferral period is addressed in more detail in the Question-and-Answer section.

3. Deferral for individuals taking ART medications for treatment of HIV infection (a positive HIV test):
   - Individuals taking ART medications are indefinitely deferred because ART is prescribed for treatment of an individual with an established HIV infection (a positive test for HIV).
   - This indefinite deferral for HIV (a positive test) is currently required by FDA recommendations and the current regulations at 21 CFR 610.41(c). This is the reason use of ART for treatment is not a 2-year medication deferral.
   - In addition to the risks identified by the MDL, the individual would be indefinitely deferred by the following questions intended to identify HIV risk:
     - "Have you ever had a positive test for the HIV/AIDS virus?"
     - "Have you ever taken any medication to treat an HIV infection?"

4. Policies and SOPs to address discrepant responses:
   - Policies and SOPs should include a process to resolve discrepant responses that makes it possible to:
     - Address donor confusion about use of PrEP, PEP, and/or ART medications.
     - More accurately determine donor eligibility.

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 modifications to the AABB DHQ v2.1 documents. Refer to current FDA guidance recognizing the DHQ v2.1 as acceptable for use.
- The FDA recognizes AABB DHQ v2.1 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 v2.1 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]

Questions and Answers

Additional information is provided in the Implementation Toolkit.

- **Which version of the Donor History Questionnaire will be revised to implement the changes recommended in this Bulletin?**
  The current AABB DHQ v2.1 and Related Materials should be revised to include this information and is the only DHQ formally recognized by FDA at this time.

- **Will there be a new version of the AABB DHQ with the PrEP and PEP information?**
  Yes. The DHTF has already incorporated the information from this Bulletin, along with other updates, into the next version of the DHQ (version 3.0), which will be submitted to FDA for formal review and acceptance in the very near future. Until FDA formally recognizes the new version 3.0 DHQ, blood centers can use these recommendations with DHQ v2.1 to address the potential impact of PrEP, PEP, and ART medications on donor testing for HIV.

- **Given that cabotegravir is a new drug, how did the committees decide that a deferral period of 24 months was more appropriate than 18 months?**
  The TTD Committee and the DHTF carefully reviewed the available data for this new medication. As described in AABB's Hot Topic Discussion on the impact of PrEP (Aug 18, 2022), published data demonstrates the presence of cabotegravir out to 76 weeks (19 months) following the last injection. Experts do not know what level of residual cabotegravir may act to modify HIV acquisition or detection after the last injection. Modeling with log-linear regression curves show the potential for the drug to remain in the plasma far longer than 19 months (Slide 1, below). The 75th percentile of the time to below the limit of quantitation, meaning the time to undetectable cabotegravir for 75% of all participants, was nearly 24 months for women and 16 months for men. The upper end of the range for persons with quantifiable concentrations of cabotegravir was over 4 years for women and nearly 3 years for men with the longer durations observed in individuals with a higher body mass index (Slide 2, below).

The uncertainty surrounding the persistence of the drug and its potential impact on HIV testing led to the 2-year deferral recommendation.

Slide 1 Hot Topic Discussion (courtesy of Brian Custer, PhD, MPH, Vitalant Research Institute)

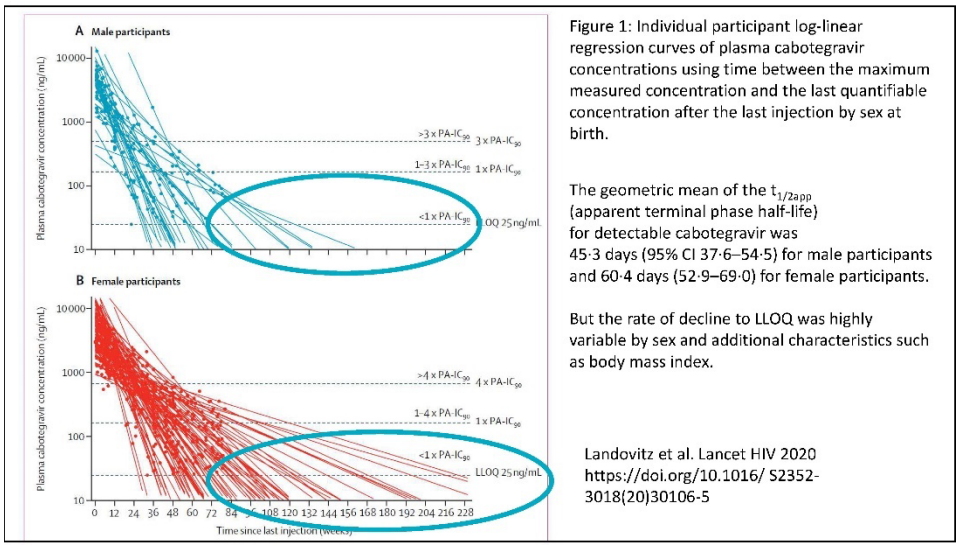


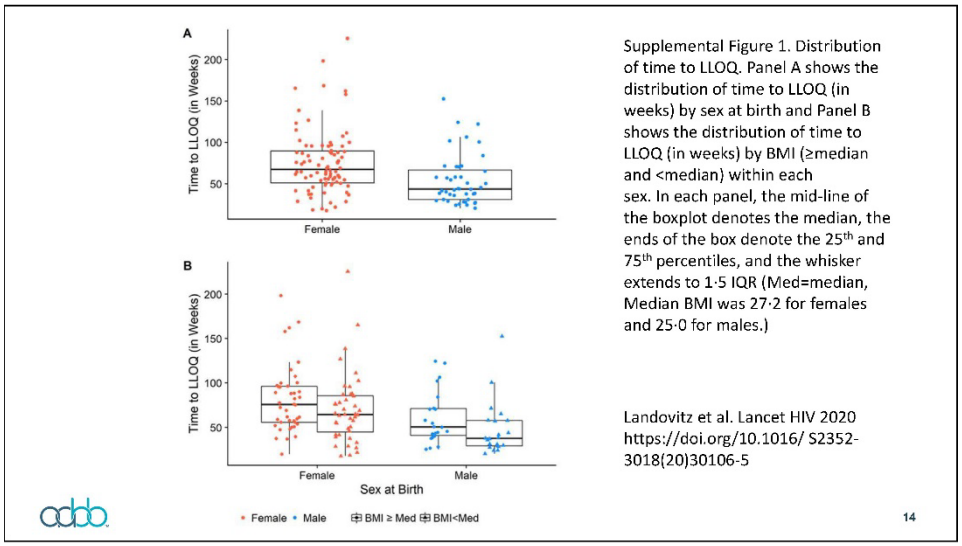
Figure 1: Individual participant log-linear regression curves of plasma cabotegravir concentrations using time between the maximum measured concentration and the last quantifiable concentration after the last injection by sex at birth.

The geometric mean of the $t_{1/2app}$ (apparent terminal phase half-life) for detectable cabotegravir was 45·3 days (95% CI 37·6–54·5) for male participants and 60·4 days (52·9–69·0) for female participants.

But the rate of decline to LLOQ was highly variable by sex and additional characteristics such as body mass index.

Landovitz et al. Lancet HIV 2020 https://doi.org/10.1016/ S2352-3018(20)30106-5

Slide 2 Hot Topic Discussion (courtesy of Brian Custer, PhD, MPH, Vitalant Research Institute)



Supplemental Figure 1. Distribution of time to LLOQ. Panel A shows the distribution of time to LLOQ (in weeks) by sex at birth and Panel B shows the distribution of time to LLOQ (in weeks) by BMI (≥median and <median) within each sex. In each panel, the mid-line of the boxplot denotes the median, the ends of the box denote the 25th and 75th percentiles, and the whisker extends to 1·5 IQR (Med=median, Median BMI was 27·2 for females and 25·0 for males.)

Landovitz et al. Lancet HIV 2020 https://doi.org/10.1016/ S2352-3018(20)30106-5

- **Are the PrEP and PEP medication deferrals related to HIV risk associated with sexual activity or groups at risk for HIV historically?**
  No, the medication deferrals are not related to risk posed by sexual activity, nor gender of sexual partners. The medication deferral is not related to MSM deferrals or other HIV risk deferrals.

  The medication deferral addresses the impact of the drug itself on HIV testing and the potential risk for false-negative HIV test results. The risk exists precisely because PrEP works so well by suppressing HIV to a level that it is undetectable

when tested. However, even when a blood donor screening test is unable to detect these low levels of virus, an infected person taking PrEP can unknowingly transmit HIV to a patient through a blood transfusion.

- **Are there examples to follow when updating the AABB DHQ v2.1 and other documents?**
  Yes. The materials found in the links below were developed by the DHTF to meet the recommendations of this Bulletin. Refer to the Toolkit and Example Documents for Use with DHQ v2.1 for additional information to support implementation.
  - Example DHQ v2.1 with PrEP, PEP, ART
  - Example Flowchart v2.1 with PrEP and PEP taken by mouth (oral) page 47
  - Example Alternative Flowchart v2.1 with PrEP and PEP taken by mouth (oral) page 48
  - Example Flowchart v2.1 with Injectable PrEP page 49
  - Example Flowchart v2.1 with ART page 50
  - Example MDL v2.1 with PrEP, PEP, ART
  - Example Blood Donor Educational Material v2.1 with PrEP, PEP, ART

- **What is the Alternative Flowchart?**
  - At the request of members, the Association 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 the Flowchart with PrEP and PEP taken by mouth (oral) page 47.

- **When should these changes be implemented?**
  The recommendations in this Bulletin should be implemented as defined in your facility's SOPs. This approach provides blood centers with adequate flexibility for effective implementation.
  - The AABB DHQ v2.1 and Related Materials provided in the Implementation Toolkit contain a "with Inj PrEP added" date that represents the month and year AABB released the example materials.
  - This date, used for version control purposes, 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 v2.1 if the changes are NOT less restrictive. This Bulletin recommends changes that are more restrictive.

- **How should I report these changes to FDA?**
  If implemented as recommended, the more restrictive 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 v2.1 and Related Materials?
The AABB DHQ v2.1 User Brochure describes change control and limitations on changes to the documents formally recognized by FDA.

- **Who should I contact if I have additional questions?**
The Implementation Toolkit provides critical details to support operations. Please don't hesitate to contact AABB Regulatory Affairs with questions at regulatory@aabb.org.

References and Resources

References

1. Landovitz RJ, Li S, Eron JJ, Jr., et al. Tail-phase safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in HIV-uninfected adults: A secondary analysis of the HPTN 077 trial. Lancet HIV 2020;7:e472-e81. doi: 10.1016/S2352-3018(20)30106-5. [Available at: https://pubmed.ncbi.nlm.nih.gov/32497491/.]
2. Patterson KB, Prince HA, Kraft E, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: Implications for prevention of HIV-1 transmission. Sci Transl Med 2011;3:112re4. doi: 10.1126/scitranslmed.3003174. [Available at: https://pubmed.ncbi.nlm.nih.gov/22158861/.]
3. Kearney BP, Flaherty JF, Shah J. Tenofovir disoproxil fumarate: Clinical pharmacology and pharmacokinetics. Clin Pharmacokinet 2004;43:595-612. doi: 10.2165/00003088-200443090-00003. [Available at: https://pubmed.ncbi.nlm.nih.gov/15217303/.]
4. Custodio JM, Fordyce M, Garner W, et al. Pharmacokinetics and safety of tenofovir alafenamide in HIV-uninfected subjects with severe renal impairment. Antimicrob Agents Chemother 2016;60:5135-40. doi: 10.1128/AAC.00005-16. [Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4997827/.]
5. Trezza C, Ford SL, Spreen W, et al. Formulation and pharmacology of long-acting cabotegravir. Curr Opin HIV AIDS 2015;10:239-45. doi: 10.1097/COH.0000000000000168. [Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5638427/.]
6. Marzinke MA, Grinsztejn B, Fogel JM, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. J Infect Dis 2021;224:1581-92. doi.org/10.1093/infdis/jiab152. [Available at: https://academic.oup.com/jid/article-abstract/224/9/1581/6178946?redirectedFrom=fulltext.]
7. Eshleman SH, Fogel JM, Piwowar-Manning, et al. Characterization of human immunodeficiency virus (HIV) infections in women who received injectable cabotegravir or tenofovir disoproxil fumarate/emtricitabine for HIV prevention: HPTN 084. J Infect Dis 2022;225(10):1741-9. doi: 10.1093/infdis/jiab576. PMID: 35301540; PMCID: PMC9113509. [Available at: https://academic.oup.com/jid/article-abstract/225/10/1741/6549543.]

8. 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. doi:10.1001/jama.2019.6587. [Available at: https://jamanetwork.com/journals/jama/fullarticle/2735345.]
9. 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 May 25, 2022).]
10. 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. doi:10.1001/jama.2019.2591. [Available at: https://jamanetwork.com/journals/jama/fullarticle/2735508.]
11. Keating S, Pilcher C, Busch M. Timing is everything: Shortcomings of current HIV diagnostics in the early treatment era (editorial). Clin Infect Dis 2016;63:562-4. doi: 10.1093/cid/ciw369. [Available at: https://pubmed.ncbi.nlm.nih.gov/27317798/.]
12. 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. doi: 10.1097/QAI.0000000000002186. [Available at: https://pubmed.ncbi.nlm.nih.gov/31714421/.]
13. Josephson CD, Glynn S, Mathew S, et al. The Recipient Epidemiology and Donor Evaluation Study-IV-Pediatric (REDS-IV-P): A research program striving to improve blood donor safety and optimize transfusion outcomes across the lifespan. Transfusion 2022;62(5):982-99. doi: 10.1111/trf.16869. [Available at: https://pubmed.ncbi.nlm.nih.gov/35441384/.]
14. Custer B, Quiner C, Haaland R, et al. HIV antiretroviral therapy and prevention use in US blood donors: A new blood safety concern. Blood 2020;136(11):1351-8. doi: 10.1182/blood.2020006890. [Available at: https://pubmed.ncbi.nlm.nih.gov/32645148/.]
15. Goldman M, Ram S, Yi Q, et al. The Canadian donor health assessment questionnaire: Can it be improved? Transfusion 2006;46;2169-75. doi: 10.1111/j.1537-2995.2006.01048.x. [Available at: https://pubmed.ncbi.nlm.nih.gov/17176331/.]
16. Willson S, Miller K, Seem D, et al. Cognitive evaluation of the AABB Uniform Donor History Questionnaire. Transfusion 2016;56;1662-7. doi: 10.1111/trf.13587. [Available at: https://pubmed.ncbi.nlm.nih.gov/27060456/.]

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 – August 2020

Centers for Disease Control and Prevention
HIV Risk and Prevention

NIH CLINICAL INFO.HIV.gov Glossary

HIV/AIDS Glossary

AABB

2022 Hot Topic Discussion Impact of injectable PrEP on donor testing and screening (22EL-766) – eCast, On-Demand

AABB Communication Tools

- PrEP/PEP Q&A Resource for Blood Collectors
- PrEP/PEP Q&A Resource for the Public
- Common Donor Deferrals

2021 Annual Meeting AM21-24: Hot topic: Men who have sex with men (MSM): Movement toward individual risk assessment

2020 Annual Meeting AM20-87: Keeping up with the Donor History Task Force: Major changes in blood donor screening

Blood Donor History Questionnaires v2.1 and Related Materials

The Feasibility of MSM Individual Risk Assessment Using the AABB DHQ – a 2018 Report of the DHTF