

**Blood Products Advisory Committee Meeting
FDA White Oak Campus, Silver Spring, MD
March 20-21, 2019**

Topic III: Blood Donation Policies Regarding Men Who Have Sex with Men (MSM)

Issue: FDA asks the Blood Products Advisory Committee (BPAC) to consider the blood donation and deferral policies regarding men who have sex with men (MSM), examine the current scientific data on HIV and MSM, and identify additional information that could support alternative procedures to FDA's current MSM donor deferral policy that would maintain the safety of the blood supply.

The BPAC will hear presentations on the current epidemiology of HIV and risk groups in the United States (U.S.); global developments in MSM deferral policies and measures to reduce the risk of transfusion-transmitted HIV; data from the Transfusion-Transmitted Infection Monitoring System (TTIMS) for the incidence and prevalence of HIV among current blood donations; a proposal to study a questionnaire for individual HIV risk assessment among MSM; and a proposal from a blood establishment for accepting MSM donors with concurrent use of an FDA-approved pathogen reduction device for apheresis platelet components.

I. Background:

A. Current MSM deferral policy to reduce HIV transmission by blood products

FDA is responsible for protecting the public health by ensuring the safety of the blood supply, which depends on the implementation of donor screening measures that are based on the available scientific evidence. In 2015, FDA changed the indefinite deferral for MSM, first introduced in 1985, to a 12-month deferral from the most recent sexual contact with another man (for detailed regulatory history, refer to Ref. 1). The decision was based on a multiagency collaboration within HHS, additional HHS-sponsored research studies, as well as the experience in other countries.

To summarize, between 1997 and 2010, FDA held several public meetings, including workshops and advisory committee meetings, to review the available evidence and to discuss its blood donor deferral policies aimed at preventing transmission of HIV through blood components. In September 2010, the Assistant Secretary of Health charged an Intra-agency Blood, Organ and Tissue Safety (BOTS) Working Group comprised of representatives from FDA, Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), HHS Office of Civil Rights, and the Office of the Assistant Secretary for Health (OASH), to explore the feasibility of a data- and science-driven policy change. By mid-2014, results from the studies that the BOTS Working Group had recommended were available,

including an operational assessment demonstrating a negligible risk of quarantine release errors (Refs. 2,3), studies of blood donors' understanding and adherence to the predonation donor history questionnaire, opinions among MSM about the deferrals and reasons for noncompliance, the risk factors among HIV-reactive deferred blood donors, and the feasibility of a surveillance program among blood centers (Refs. 4-7). The change to a 12-month deferral was also supported by the experience and data from other countries that had similarly changed their MSM policies, most notably, Australia, discussed in greater detail in section I.B., below (Ref. 8).

In September 2015, FDA and NHLBI launched the Transfusion-Transmitted Infections Monitoring System (TTIMS) in collaboration with four blood centers (American Red Cross Blood Services, Vitalant (previously known as Blood Systems, Inc.), OneBlood, and New York Blood Center) that collect ~60% of the U.S. blood supply. A primary objective of TTIMS is to monitor infectious disease marker incidence and prevalence among blood donations and identify behavioral factors associated with donor infections (Ref. 9). Thus, TTIMS provides an ongoing assessment of infection risks associated with policy changes, such as the 12-month deferral criteria for MSM. Preliminary TTIMS data and plans for a comprehensive HIV incidence data analysis based on two years of post-MSM policy change data are discussed in greater detail in section I.D., below.

When FDA announced the revised donor deferral policy for MSM in December 2015, it also committed to monitor the effect of the change and to evaluate further policy alternatives, such as individual risk assessment, if supported by scientific data. In July-November 2016, FDA sought public input on a docket (FDA-2015-N-1502) about questions that would most effectively identify individuals at risk of transmitting HIV through blood donation, individual risk assessment strategies and methods for testing the effectiveness of such strategies, and the scientific rationale that would support shorter deferral periods. Although some commenters supported further changes to the 12-month MSM deferral policy, a notable cross-section of responses representing hospitals, blood centers, plasma users and MSM advocates concluded that the data were not yet available on the effect of the 12-month deferral and a careful assessment must occur before considering any further changes to the MSM policy. These respondents concluded that substantial work would be necessary to assess the effect of any proposed changes on both the safety and availability of the blood supply.

Based on the availability of preliminary TTIMS data post-MSM policy change, and in the context of MSM policy changes since 2016 in other countries, FDA asks BPAC to consider two proposals that could potentially advance MSM policy.

B. Global developments in MSM deferral and measures to reduce the risk of TT HIV

In the U.S., MSM represent the group with the highest incidence and prevalence of HIV infection. A similar situation is found in a number of other countries, including much of Western Europe and Australia. In the mid-1980s, the prevailing approach to donor screening in most countries was the permanent or indefinite deferral of male donors who had sex with another man ever or since 1977 (10-13). Since December 2015, the FDA has recommended deferral of MSM from blood donation for 12 months after the most recent MSM contact.

The relationship between HIV and MSM, however, is not universal, with South Africa being a notable exception. South Africa has a very high HIV rate in the general population (approximately 11%), and most HIV infections are in the heterosexual population. Because the risk of HIV among MSM is similar to the general population, South Africa does not have an MSM-specific deferral policy. Rather, South Africa's deferral policy is based on high-risk sexual practices in general, such as multiple sexual partners. Comparison of MSM deferral policies in different countries therefore should first account for the unique epidemiology of HIV in each country.

Various scientific advances and social challenges have led to changes in MSM deferral policies in many countries in recent years. Australia was the first country to move from a permanent MSM deferral and adopt a national deferral policy of 12 months after the most recent MSM contact. The blood collectors in Australia demonstrated in a retrospective analysis that there was no difference in the rate of HIV reactive donations before and after the policy change (Ref. 8). Subsequently, several countries changed from a permanent deferral to a 12-month deferral. For example, the United States, Canada, Mexico, Germany, the Netherlands, Norway, Sweden, the United Kingdom and France all had a permanent deferral for MSM based on responses to a survey conducted in 2010-2011; these countries had all implemented a 12-month deferral by 2017 (Refs. 11-13).

Shorter time-based MSM deferrals have subsequently come to be used in other countries. For example, there is currently a 6-month MSM deferral in Japan, and a 3-month MSM deferral in the United Kingdom (Ref. 12). In contrast, some countries, as well as international Source Plasma collectors and fractionators in many countries have retained a permanent deferral for MSM (Ref. 11,12,14).

Other countries have implemented a different approach to donor screening instead of a time-based MSM deferral policy, asking both female and male donors about sexual risk behaviors, such as having multiple partners. In Spain and Italy, donor screening involves a predonation interview with a physician who performs an individualized risk assessment and makes eligibility determinations. This approach is substantially different from the

screening model used in the U.S. and Canada, which both have a standardized questionnaire administered by nonclinical, trained staff and uniform deferral criteria (Refs. 12,15,16).

The comparability of individual risk-based approaches and time-based deferrals is not yet known with certainty. However, recent reports suggest higher HIV rates and HIV NAT-yield (NAT-reactive, antibody-nonreactive donations) rates among donations in Spain and Italy compared to the U.S. and Canada (Refs. 7,12,15,16).

In lieu of individual risk-based approaches and time-based MSM deferrals, alternative donor screening strategies have also been proposed to mitigate a possible HIV risk associated with donations from MSM. For example, several countries have implemented or plan to implement programs to allow MSM to donate plasma intended for transfusion (Ref. 12). In Israel and France, plasma components collected from donors who report MSM are quarantined and not released into inventory unless the donor returns to donate again at least 2-4 months after the quarantined donation and has negative infectious disease screening test results and meets all eligibility criteria (Ref. 17,18). Retesting detects donors who might have been in the window period at the time of the prior (quarantined) donation and prevents release of a potentially infectious unit.

C. Epidemiology of HIV in the United States and Groups at Risk

In the United States, recent CDC estimates show that 1,008,929 people were living with HIV infection in 2016 (Refs. 19,20). An estimated 38,739 Americans became newly infected with HIV in 2017 according to a 2018 CDC report. The annual number of new HIV diagnoses has remained relatively stable in the United States from 2012-2016 despite increases in some risk groups. MSM and bisexual men continue to be the population most affected by HIV. In 2017, MSM and bisexual men accounted for 66% of all HIV diagnoses and 82% of diagnoses among males (Refs. 19,20). Heterosexual men accounted for 7% of HIV diagnoses and heterosexual women, 16% (Refs. 19,20).

By region, HIV diagnoses were not evenly distributed in the U.S. (Ref. 20). Ten states accounted for about two-thirds (64%) of HIV diagnoses among adults and adolescents in 2017, including California (12%), Florida (12%), Texas (11%), New York (7%), Georgia (7%), North Carolina (3%), Illinois (3%), Louisiana (3%), Pennsylvania (3%), and New Jersey (3%) (Ref. 18). CDC's HIV diagnostics facts indicate that in 2017, southern states continued to account for 52% (19,968) of new HIV diagnoses in the U.S., followed by the West (7,270; 19%), the Northeast (6,011; 16%), and the Midwest (5,032; 13%). Rates of HIV diagnoses per 100,000 provide a different measure of the epidemic's impact, since they reflect the concentration of diagnoses after accounting for differences in population size across states. In 2017, the population rates of HIV diagnoses were

16.1 in the South, 12.3 in the U.S. dependent territories, 10.6 in the Northeast, 9.4 in the West, and 7.4 in the Midwest. The District of Columbia had the highest rate in the nation, being nearly 4 times the national rate (Refs. 19,20).

D. Transfusion-Transmitted Infections Monitoring System (TTIMS)

Launched in September 2015, the Transfusion-Transmitted Infections Monitoring System or TTIMS, is sponsored by the Food and Drug Administration, the National Heart, Lung, and Blood Institute of NIH, and the HHS Office of the Assistant Secretary for Health. As its core function, TTIMS collects prevalence and incidence data derived from the screening of blood donors for HIV, hepatitis B virus (HBV) and HCV infection, as well as demographic variables, behavioral risk factors, and biorepository samples from donors found to be seropositive for markers of these infections. TTIMS has been designed for broad monitoring of more than 60% of the U.S. blood supply, provide data relevant to the impact of natural or policy-driven shifts in the donor base.

TTIMS is primarily carried out by two coordinating centers, the Donor Database Coordinating Center (DDCC), operated by the American Red Cross which centralizes, processes, and analyzes epidemiologic data from blood donors and donations; and the Laboratory and Risk Factor Coordinating Center (LRCC) operated by the Vitalant Research Institute. These Coordinating Centers work closely with the participating blood collection establishments (American Red Cross Blood Services, Vitalant, New York Blood Center, OneBlood) and the central testing laboratory (Creative Testing Solutions). These partners generate extensive data representing approximately 60% of the U.S. blood supply. TTIMS is governed by an Executive Committee as the decision-making body, a Steering Committee with broad representation from HHS stakeholders, and individual analysis working groups. A firewall shields FDA from receiving individual donor- or site-identified data.

The DDCC establishes and manages consensus test result definitions, and rigorously validates all data exchange processes within the study. Prevalence reports for RTTI markers for donors and donations stratified by demographic variables are produced quarterly (Tables 1 and 2). The DDCC is also leading the incidence calculations for HIV, HBV and HCV among repeat donors using classical methods. In addition to designing and implementing detailed risk interviews for seropositive donors and controls, the LRCC has initiated advanced laboratory measures to assess biological factors that may influence and/or predict blood safety. These include assessment of the TTIMS HIV-positive-donor repository using HIV-1 Limiting Antigen (LAg)-Avidity testing to determine the recency of HIV infection and support modeled estimates to predict of HIV incidence in first-time blood donors; and molecular surveillance of HIV and HCV viral genomes to assess variants that may reflect important differences in phylogenetics or

drug resistance. Recently the LRCC, in collaboration with the Centers for Disease Control and Prevention, has initiated blinded testing of targeted blood donor and control samples for evidence of recent anti-retroviral (ARV) therapy or pre-exposure HIV prophylaxis (PrEP).

TTIMS data presentations to date have included:

- No significant changes in blood collection levels at TTIMS blood establishments, December 2015 – August 2017.
- No significant change in HIV prevalence among donors at TTIMS blood collection establishments sites between December 2015 and August 2017. (Figure 1)
- LAg Avidity results among TTIMS and archived HIV seropositive donor biorepository samples demonstrated a mean duration of recent HIV infection (MDRI) of 130 days in approximately 30% of HIV seropositive donors overall with no significant annual differences 2010- Q2/2017. Recency of HIV infection did show a significant correlation with younger donor age. This biomarker holds strong promise as a means of estimating HIV incidence among first time blood donors.

As of November 30, 2018, TTIMS has collected operational data for about 22.5 million blood donations, as well as risk interview data, and biorepository samples representing all available time before and two complete years after the implementation of the December 2015 FDA-recommended changes to the MSM deferral. These changes were implemented at TTIMS blood collection establishments at various times during 2016. In early 2019, TTIMS will be analyzing operational and laboratory data collected in the periods before and after the actual MSM policy changes at each site to provide further prevalence and incidence estimates for biomarkers relevant to residual TTI risk in the U.S.

E. HIV Risk Questionnaire (HRQ) Study

FDA has proposed conducting a study to assess whether a different MSM donor deferral policy that minimizes HIV risk could be an effective alternative to the current approach. The HIV Risk Questionnaire (HRQ) study was developed through a collaborative process with the Blood Equality Working Group of community stakeholders including advocacy organizations, community health centers, blood collectors, and public health agencies.

The HRQ study is intended to determine whether low risk MSM can be identified by use of an enhanced set of donor history questions to determine high risk MSM behavior that can be linked to recent HIV infection. The predictive value of five questions related to HIV risk factors will be assessed. The study will enroll 2000 individuals potentially

interested in donating blood who have had sex with another man at least once during the past 3 months. The individuals will be drawn from 8 to 12 sites that are geographically distributed across the United States with a concentration on those locations where epidemiology indicates continued significant transmission of HIV within the MSM community. Those individuals meeting eligibility criteria (male, age 18 or older, oral or anal sex with a male within the past three months, able to respond to questions) and providing informed consent will complete a brief history questionnaire (Table 3). A blood sample will also be taken from all enrolled individuals. Infectious disease screening performed on each sample will include antibody and individual donor NAT testing for HIV, along with recency testing for HIV, if sample is HIV positive. A follow-up visit will be scheduled for approximately one week following the first visit. At that visit, additional historical information will be obtained from those with positive screening tests, and appropriate counseling and referral for follow-up will be provided.

The primary objective of the HRQ study is to initially assess the discriminant function of revised donor history questions for predicting recent HIV infection in MSM who wish to donate blood. Secondary objectives of the study are to evaluate the recency of infection in those individuals who test positive for HIV by individual NAT and antibody testing and to identify risk factors associated with recent HIV infection in individuals who are antibody negative yet HIV NAT positive. The study plans to begin to enroll MSM in November 2019. Study enrollment is expected to take approximately six months and data analysis is expected to be completed within 12 months.

F. Considerations for MSM and FDA-approved Pathogen Reduction of Apheresis Platelets

FDA has approved a pathogen reduction device for apheresis platelets that inactivates a wide range of pathogens, including HIV (Ref. 21). The approved device uses amotosalen, which targets and intercalates with nucleic acids, followed by UV illumination, which induces crosslinking and blockage of subsequent replication. Following this treatment, performed within 24 hours of collection, the residual amotosalen is removed via a compound adsorption device, and the resulting product is ready for transfusion. Although alternative technologies (e.g. riboflavin plus UV) are in use outside the United States, they are not FDA approved at this time.

The approved device can achieve a greater than or equal to 3.3-5.6 log reduction of HIV-1 titers *in vitro*, depending on the component and the viral strain, and a greater than or equal to 2.4 log reduction of an HIV-2 clinical isolate, according to the package insert (Ref. 21). While the performance of pathogen inactivation technology is based on the degree of viral titer reduction *in vitro*, its correlation with disease transmission is more

difficult to establish and depends on a number of factors including the residual viral load (Ref. 22).

The code of federal regulations requires blood establishments to assess prospective donors for risk factors closely associated with relevant transfusion-transmitting infections (RTTI) and prohibits collection from individuals found to have such risk factors. Under these regulations, FDA's 2015 guidance document recommends a 12-month deferral for MSM from the most recent sexual contact with another man. The current regulations and FDA's recommendations for donor deferral apply to all collections, even if the components will be pathogen reduced. Some blood centers have implemented pathogen reduction technology on a portion of collected apheresis platelet or plasma components, but others report technical challenges, financial constraints and operational issues¹. Currently, a minority of plasma and platelet components distributed in the U.S. are pathogen-reduced (Ref. 23).

FDA has received a request for alternative procedures from blood establishments to accept MSM apheresis platelet donors, when the collected components are both 1) tested for relevant transfusion infections (RTTIs), including HIV, as required by FDA, and 2) pathogen reduced using an FDA-approved device according to its instructions for use. Details of such a proposal will be presented to BPAC.

II. Discussion:

A. Consideration of Changes to the MSM Deferral Policy and Alternative Procedures

FDA is committed to ongoing evaluation of the current MSM deferral policy and consideration of alternative procedures that would maintain the current level of safety and reduce the risk of HIV transmission through blood and blood components.

FDA asks the committee to consider the following issues in their deliberations on the scientific evidence that exists, or could be collected, that would support changing the MSM deferral policy or would support a determination that deferrals are not necessary when donations from MSM donors are pathogen reduced, in conjunction with testing for RTTIs:

- The incidence and prevalence of HIV and other RTTI among prospective MSM donors compared to non-MSM donors;

¹ Transcript of CBER Pathogen Reduction Technologies for Blood Safety: Public Workshop, held on November 29-30, 2018 will be available at <https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm2006033.htm>

- The rate of HIV NAT-reactive, antibody-nonreactive (window period) donations among prospective MSM donors compared to non-MSM donors;
- The effectiveness of pathogen reduction technology against HIV as currently approved for use with apheresis platelets;
- The possible effect of a change in the MSM deferral policy on supply and the expected number of additional donations;
- The manufacturing process for pathogen reduced platelets and plasma as it is currently being performed in blood centers and whether the process is adequately controlled to prevent process failures;
- The process for managing a dual inventory of pathogen-reduced and untreated components and whether the process and blood establishment computer systems (BECS) are adequate to prevent release or distribution errors;
- The risk and consequences of biological product deviations (e.g., failure to perform pathogen reduction on a distributed component collected from a donor who was either not screened or reported MSM).

B. Discussion Topics for the Committee:

FDA asks the Committee to consider the current 12-month MSM deferral policy and discuss the available scientific information regarding alternative procedures, in particular:

1. Comment on what has been learned from implementing other MSM policies internationally (such as risk-based deferral methods or quarantine and retest for plasma) and how this information can inform the current United States MSM deferral policy.
2. Comment on the questions proposed for study in the HIV Risk Questionnaire and whether there are any additions or modifications to this study in order to best identify behavioral risk questions to predict risk of HIV transmission in the MSM population.
3. Discuss the use of pathogen reduction as an alternative to the current MSM deferral policy, and any associated risks and possible mitigations.

III. References

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Table 1: TTIMS data on Prevalence of HIV, HBV, HCV among Blood Donors, by Sex (Presented at BPAC, December 1, 2017, <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm543914.htm>)

Consensus Positive Rates by Sex
 HIV, HBV and HCV prevalence per 100k donations with 95% CI
 Sept 2015 – Aug 2017

Number of Positives and Prevalence Rates				
		Positives	Rate/100k	95% CI
HIV	Male	296	4.0	(3.5 – 4.4)
	Female	69	1.1	(0.8-1.3)
HBV	Male	651	8.8	(8.1-9.4)
	Female	261	4.0	(3.5-4.5)
HCV	Male	1808	24.3	(23.2-25.4)
	Female	954	14.7	(13.8-15.6)

53.4% Male donations / 46.6% Female donations

Table 2: TTIMS data on Prevalence of HIV, HBV, HCV among Blood Donors, by Donor Status (Presented at BPAC, December 1, 2017, <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm543914.htm>)

Consensus Positive Rates by Donor Status
 HIV, HBV and HCV prevalence per 100k donations with 95% CI
 Sept 2015 – Aug 2017

Number of Positives and Prevalence Rates				
		Positives	Rate/100k	95% CI
HIV	First-time	197	8.8	(7.6 -10.0)
	Repeat	168	1.4	(1.2 -1.7)
HBV	First-time	803	35.8	(33.3 - 38.2)
	Repeat	109	0.9	(0.8 - 1.1)
HCV	First-time	2285	101.8	(97.6 – 106.0)
	Repeat	477	4.1	(3.7 - 4.5)

13.9 million total donations
 16.1% First-time donations / 83.9% Repeat donations

Figure 1: TTIMS data on Prevalence of HIV by Donor Status Over Time (Presented at BPAC, December 1, 2017,

<https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm543914.htm>)

HIV
Consensus
Positive Rates
per 100k
donations
with 95% CI
by
Donor Status

First-time
8.8 (7.6-10.0)
Repeat
1.4 (1.2-1.7)

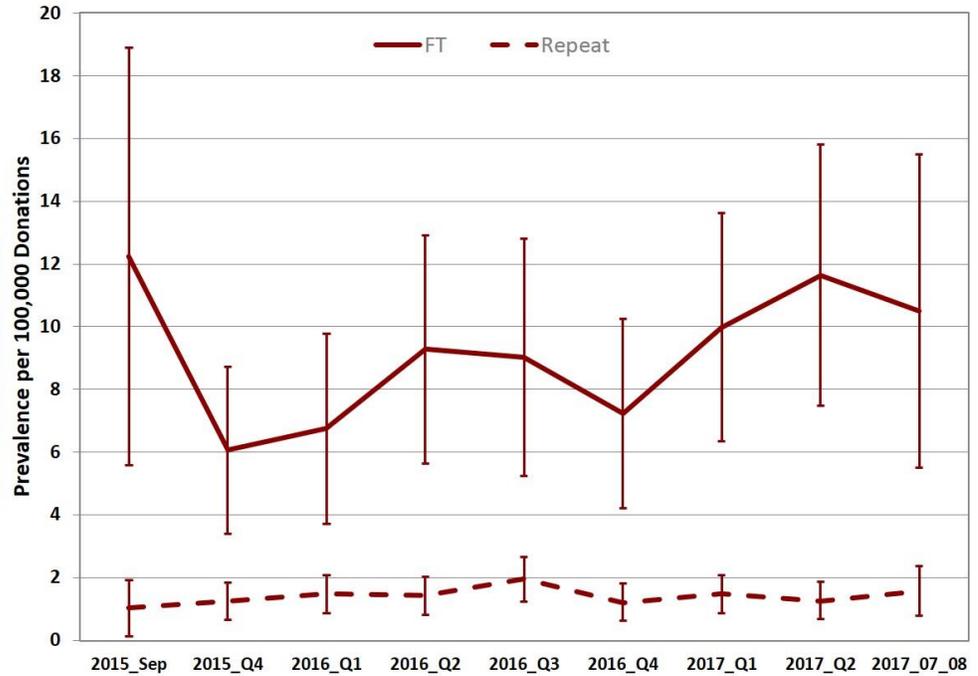


Table 3: Proposed HRQ Questions

Question	Response Format
1) How many different male sexual partners have you had sex with (defined as oral sex or anal intercourse) during the past <ul style="list-style-type: none"> a. 1 month b. 3 months c. 12 months 	<ul style="list-style-type: none"> a. Number of male sexual partners during the past 1 month b. Number of male sexual partners during the past 3 months c. Number of male sexual partners during the past 12 months
2) What kind of sex have you had with another man during the past month?	<ul style="list-style-type: none"> a. Oral sex b. Anal penetrative or receptive intercourse c. Both oral sex and anal intercourse d. Not sexually active during the past month
3) To your knowledge, have you had sex with an HIV positive partner during the past 12 months?	<ul style="list-style-type: none"> a. Yes b. No
4) Condom use: Do you..?	<ul style="list-style-type: none"> a. Always use condoms b. Use condoms sometimes c. Never use condoms
5) Have you ever taken pre-exposure prophylaxis (PrEP)?	<ul style="list-style-type: none"> a. Yes b. No
5-1) If yes, when was the last time that you took PrEP? _____	Date of last PrEP use