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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically at http://www.regulations.gov.

Dear Colleagues,

The Fenway Institute welcomes an opportunity to comment on blood donation policy for gay and bisexual men and other men who have sex with men (MSM). We commend the FDA's recent decision to end the lifetime ban on blood donation for gay and bisexual men. We believe that this represents an important incremental step towards a science-based policy which maintains the safety of the blood supply without stigmatizing gay and bisexual men. However, we did not support the current ban on any man who had sex with another man in the past year from donating.

We believe that the new policy, while preferable to the lifetime ban for MSM, is based on a flawed understanding of male same-sex behavior. Sexually active gay and bisexual men who are at low risk (monogamous, use condoms and lubricant, or don't have condomless receptive anal intercourse) are not allowed to donate. Many gay men have sex but don't have condomless anal sex. The vast majority of gay and bisexual men are HIV-negative, and most are not at high risk of HIV infection, yet they are denied the ability to donate blood under the current policy, which requires a gay or bisexual man to abstain from any sex with another man for 12 months before being eligible to donate.

We think that a more rational policy based on individual risk assessment that would identify low-, medium-, and high-risk potential donors. Low-risk MSM, such as those who have not had any anal sex recently or those that exclusively used condoms during sex, would be allowed to donate without deferral. High-risk potential donors of any sexual orientation, such as those that recently injected drugs or performed commercial sex work, would be subject to the same lengthy deferral as indicated by current protocols. Potential MSM donors who are identified as medium-risk, including those who have engaged in higher risk sexual behaviors such as recent unprotected anal sex, would be subject to a 30 day temporary deferral before being allowed to donate. The nucleic acid test (NAT) used to screen blood can detect HIV in just 9 -11 days after infection.[1] These new technological advances greatly decrease the risk of HIV-infected blood escaping detection.

However, it is important to note that these new technologies cannot completely eliminate the risk of HIV in the blood supply. As such, we recommend that these technologies be used in conjunction with comprehensive individual risk

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assessments that can adequately screen potential donors for low- and high-risk sexual behaviors. We also urge the blood bank industry to administer Donor Risk Questionnaires using tablets, such as iPads, which convey a greater sense of confidentiality and could lead to more accurate reporting of risk data and a greater ability to screen out high-risk would-be donors. We commend the FDA for considering a deferral policy based on individual risk assessment rather than a blanket deferral for all sexually active MSM, and we provide answers to the questions raised in the Request for Comments below.

1. What questions would most effectively identify individuals at risk of transmitting HIV through blood donation?

The current Donor History Questionnaire does not adequately distinguish between lower and higher risk sexual behaviors by MSM donors or others. Both MSM and non-MSM donors can engage in low-risk sexual behaviors–such as using protection or having sex with an HIV-negative partner, or high-risk sexual behaviors–such as having unprotected sex with multiple partners of unknown HIV status. In addition, certain sexual acts are more high-risk for acquiring HIV than others (see Appendix Figure 1).[2] For example, receptive anal intercourse without protection from condoms and lubricant and/or pre-exposure prophylaxis is much higher risk than oral intercourse. Individuals who consistently practice low-risk sexual behaviors or engage in low-risk sexual acts pose little threat to the blood supply. The most effective questions for identifying individuals at risk of transmitting HIV through blood donation would screen out potential donors who engage in high-risk sexual behaviors or acts.

2. Are there specific questions that could be asked that might best capture the recent risk of a donor acquiring HIV infection, such as within the 2 to 4 weeks immediately preceding blood donation?

The CDC and the U.S. Public Health Service released guidance on pre-exposure prophylaxis (PrEP) for HIV prevention in 2014.[3] In a supplement for providers, a risk index tool is provided "to quickly and systematically determine which MSM are at especially high risk of acquiring HIV infection."[4] This risk index contains several specific questions for determining high-risk of acquiring HIV (see Appendix Figure 2).[5] These questions could provide a good basis for developing similar questions designed to ascertain HIV risk based on specific sexual behaviors for the Donor History Questionnaire.

The MSM Risk Index was based on several epidemiological studies of potential risk factors for acquiring HIV for MSM. For example, one study developed and validated a prediction model for HIV acquisition among MSM based on medical records data from an STD clinic from 2001-2008. The predictive model generates a risk score based on several important risk factors, including previous history of STIs, drug use, sex with HIV-positive partners, and number of sexual partners. The study provided a simplified risk score estimation tool that includes specific questions for ascertaining high HIV risk which could be useful for the Donor History Questionnaire (see Appendix Figure 3).[6]

3. How specific can the questions be regarding sexual practices while remaining understandable and acceptable to all blood donors? For example, could questions about specific sexual behaviors be asked if they helped to identify which donors should be at least temporarily deferred because of risk factors? To the extent the questions are explicit about sexual practices, how willing will donors be to answer such questions accurately?

The questions that are recommended by the CDC and the U.S. Public Health Service in their PrEP guidelines ask about specific high-risk sexual practices. These questions were designed specifically for MSM, so they should at least be understandable and acceptable to potential MSM donors. We believe that blood donation centers should ask all potential donors about high-risk behaviors, but they could also structure their questionnaire such that men who indicate that they have sex with other men are asked a particular set of questions such as those described above in response to question 2. Questions about specific sexual behaviors should be asked to help identify which donors should be temporarily deferred.

Reassuring all donors that any information provided on the Donor History Questionnaire will be kept confidential and potentially using technologies that enhance a sense of privacy–such as audio computer-assisted self-interviewing (ACASI) or a tablet, such as an iPad–can facilitate the collection of sensitive data. Research has shown that use of technologies that enhance a sense of privacy and minimize responding directly to a questioner in response to sensitive questions has been shown to facilitate the collection of sensitive data, including sexual orientation, substance use, and mental health issues. Respondents to a sexual health survey who used telephone audio computer-assisted self-interviewing (T-ACASI) instead of human interviewers were 1.5 to 1.6 times more likely to report same-gender sexual attraction, experience, and genital contact. The impact of T-ACASI was more pronounced (odds ratio = 2.5) for residents of communities that were less accepting of homosexuality and for respondents who were parents raising children (odds ratio = 3.0).[7] A related technology is the use of electronic patient-reported outcomes (ePRO) tablets in clinical settings. ePRO tablets have been shown effective in collecting sensitive information from HIV patients, including injection drug use, depression, and treatment adherence data.[8] Given the experience with T-ACASI and ePRO, it is likely that the use of tablet technology to administer the Donor History Questionnaire will lead to more accurate responses to individual risk assessments, thereby increasing our ability to screen out potential high-risk blood donors.

4. Under what circumstances would a short deferral period for high risk behavior be appropriate? For each short deferral period identified, please specify the duration of the deferral and provide the scientific rationale.

Potential donors should be stratified into low-, medium-, and high-risk groups based on individual risk assessment. Those who are in the highest risk group, such as donors who are injection drug users or commercial sex workers, may justifiably be subject to lengthy or permanent deferrals. Questions to identify potential donors in the highest risk group already exist in the Donor History

Questionnaire. To differentiate between low- and medium-risk MSM donors, the individual risk assessment questions should focus on recent (within 2-4 weeks) sexual history. Low risk donors would include, for example, those who have not had any recent anal sex and those who consistently use condoms and/or PrEP for anal sex. Low risk MSM should be allowed to donate without a temporary deferral. We recommend a short deferral period for potential MSM donors that are determined to be medium risk. Based on epidemiological research and CDC recommendations, criteria for being classified as medium risk can include partaking in higher risk sexual activities and behaviors such as:

- having multiple, casual male partners in the last 2-4 weeks
- having any unprotected anal sex with a man in the last 2-4 weeks
- having 1 or more HIV-positive partners in the last 2-4 weeks
- having a recent diagnosis or history of gonorrhea, chlamydia, and/or syphilis

We recommend a temporary deferral period of 30 days for MSM donors determined to be medium risk. Deferral periods that are substantially in excess of known window periods provide little additional value to ensuring disease detection.[9] Different studies have estimated the window period for various fourth-generation HIV tests to be approximately two weeks to one month in length.[10] The NAT can detect HIV in the blood in just 9-11 days after infection. Therefore, after a deferral period of 30 days, potential donors who are HIV-positive should be detected by current HIV testing technology.

5. What changes might be necessary within blood collection establishments to assure that accurate, individual HIV risk assessments are performed?

Because these individual risk assessment questions are sensitive in nature, it will be necessary to train staff who will be working with potential donors in cultural competency to do a sexual history with a gay or bisexual man. The Fenway Institute and the National LGBT Health Education Center can offer resources and training on LGBT cultural competency.

6. How best to design a potential study to evaluate the feasibility and effectiveness of alternative deferral options such as individual risk assessment?

We would recommend a study to pilot the reliability and acceptability of the individual risk assessment questions, as well as the feasibility of allowing low-risk MSM to donate with no deferral and a 30 day deferral for medium-risk MSM. The study design could involve a control arm, which would operate using current eligibility and deferral criteria for blood donation, and an intervention arm, which would specifically recruit potential MSM donors and use the new individual risk assessment questionnaire with a temporary 30 day deferral policy for those at medium risk. This study would also involve the piloting of the individual risk assessment questions to ensure that they are understood and acceptable to potential donors. The blood samples of both arms would be tested using current HIV testing technology to monitor the risk of HIV entering the blood supply. This would allow us to see if changing to an individual risk assessment questionnaire with a 30 day deferral would create a substantial increase in HIV risk compared to current protocols. As the research, education

and policy arm of a federally qualified health center focused on the LGBT community, the Fenway Institute at Fenway Health could potentially partner with a local hospital and/or blood bank to conduct such a pilot study. We could also partner with LGBT-focused FQHCs in other cities, and with other health centers and HIV clinics with which we collaborate on a number of research networks.

Other important research priorities could include studies to test the use of technologies such as ePRO tablets or ACASI to facilitate the collection of sensitive data in the individual risk assessments and studies to examine the minimum number of HIV virions necessary to make a blood sample infectious. This latter topic could have implications for deferral period for medium-risk MSM.

Thank you for this opportunity to provide comment. If you have any questions regarding the information provided, please feel free to contact Sean Cahill, PhD, Director of Health Policy Research at scahill@fenway.org or Tim Wang, MPH, LGBT Health Policy Analyst at twang@fenwayhealth.org.

Sincerely,

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Appendix. Figures

Figure 1. Estimated per-act risk for acquiring HIV from an infected source, by exposure act, CDC.[11]

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act[a]

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other[b]	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

Source: http://www.cdc.gov/hiv/policies/law/risk.html

[a] Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[b] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Figure 2. HIRI-MSM Risk Index. Smith et al., *JAIDS*, 2012.[12]

	MSM Risk Index[25]		
1	How old are you today?	If <18 years, score 0 If 18-28 years, score 8 If 29-40 years, score 5 If 41-48 years, score 2 If 49 years or more, score 0	_____
2	In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7 If 6-10 male partners, score 4 If 0-5 male partners, score 0	_____
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	If 1 or more times, score 10 If 0 times, score 0	_____
4	In the last 6 months, how many of your male sex partners were HIV-positive?	If >1 positive partner, score 8 If 1 positive partner, score 4 If <1 positive partner, score 0	_____
5	In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?	If 5 or more times, score 6 If 0 times, score 0	_____
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	If yes, score 6 If no, score 0	_____
		Add down entries in right column to calculate total score	_____ TOTAL SCORE*

* If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP.
If score is below 10, provide indicated standard HIV prevention services.

Figure 3. Simple Risk Score Estimation, Menza et al., *Sex Trans Dis*, 2009.[13]

Does your patient/client have gonorrhea, chlamydia, or syphilis, or does he have a history of these infections?	If yes, add 4 points If no, add 0 points	_____
Has your patient/client used methamphetamine or inhaled nitrites (poppers) in the prior 6 months?	If yes, add 11 points If no, add 0 points	_____
Does your patient/client report unprotected anal intercourse with a partner of positive or unknown HIV status in the prior year?	If yes, add 1 point If no, add 0 points	_____
Does your patient/client report 10 or more male sexual partners in the prior year?	If yes, add 3 points If no, add 0 points	_____
	Sum total number of points	_____ Total Points

Total Points	Estimated percentage of men with this score who will acquire HIV over 4 years
0	**<5%**
1-3	**5%-9%**
4-11	**10%-14%**
12+	**> 14%**

How to use the chart

1. Calculate your patient's/client's risk score.
2. Match the risk score with the point range provided on the table to estimate 4-year HIV risk.
3. Follow up with testing recommendations, referrals to services, and prevention intervention according to risk.

References

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[5] *Ibid*.

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[10] NAM AIDSmap. "Window Periods." Available online at: http://www.aidsmap.com/Window-periods/page/1323353/#ref1323331

[11] This graphic assumes that condoms, lubricant, and pre-exposure prophylaxis were not used.

[12] Smith D et al. 2012. "Development of a clinical screening Index Predictive of Incident HIV Infection Among Men Who Have Sex With Men in the United States." *JAIDS*. August 2012. 60(4): 421-427.

[13] *Ibid.*