



23 November 2016

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

Submitted via <http://www.regulations.gov>

Re: Docket No. FDA-2016-N-1502, “Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments, 28 July 2016.

Dear Dockets Manager:

AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) appreciate the opportunity to provide comments in response to the request from the Food and Drug Administration (FDA) regarding “Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.” These comments were prepared by a working group consisting of the member experts of AABB’s Donor History Task Force and Transfusion Transmitted Diseases Committee, including representatives from ABC and ARC.

Our organizations support the FDA’s continuing commitment to reevaluate and update blood donor deferral policies as new scientific information becomes available. These comments, submitted at FDA’s request, are intended to assist FDA in identifying key issues that should be considered at the time FDA begins the reevaluation process for deferral policies, specifically, the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments. This process should be structured to ensure that a safe *and adequate* blood supply is maintained while studies are completed and after implementation of any new deferral policy. Additionally, any changes in the deferral policies should focus on an effective assessment of all donors (e.g. men who have sex with men, transgender donors and others) to identify risks for transfusion-transmitted infections and must consider opinions from all stakeholders and ensure that the concerns of transfusion recipients served by the blood community and others are understood and adequately addressed.

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Background:

The FDA's adoption of less restrictive donor deferral criteria for men who have sex with men (referred to as MSM) represents a response to evidence generated in the last 10 years and longer, as noted in the FDA's December 2015 guidance. The FDA's deferral criteria moved from an indefinite deferral for MSM, even once since 1977, to the recommended one-year deferral for MSM (based on sexual contact within a 12-month period (referred to as MSM1YR)). This change is supported by the expected minimal additional risk of recipient HIV infection, in the context of current blood donation testing, associated with permitting previously deferred MSM donors with remote sexual exposure to donate blood. Against this backdrop, several areas of the MSM1YR policy and individual risk-based assessment approaches require additional evidence before policy can be further modified. The objective of individual risk-based assessment is to screen all potential donors using criteria that ensure the safety of the blood supply using an evidence-based and equitable assessment process that addresses both the desire of MSM to participate in this critical community service and the perceived "stigma" of the current criterion based on sexual identity. Whether individual risk assessment approaches can be adopted in the operational context of the nation's blood system and how donations are collected from voluntary donors and the resulting impact on inventory and blood center operations is unknown.

There are several topics representing different areas of focus which would benefit from further research.

- **Implementation Science:**
A decision to implement the MSM1YR policy and the consequences of its adoption requires further investigation. The following must be determined:
 - How have deferral rates for MSM changed in centers who have adopted MSM1YR?
 - How is implementation of MSM1YR proceeding and what future changes in donor deferral might allow shorter periods for MSM deferral, as well as for other potential donors with behaviors associated with the risk of transfusion transmitted infections, including HIV infection?
 - What barriers exist to implementation for those blood centers which have not implemented MSM1YR?
 - Are there specific issues that have not been addressed or regional differences that impact implementation?

- That infection marker rates are not significantly increased in donors accepted under MSM1YR must be confirmed:
Future individual risk assessment approaches rely on the ability to consistently identify donors with increased risks that pose potential safety threats to blood recipients versus those who do not (frequently referred to as higher versus lower risk donors). As referenced in the December 2015 FDA guidance, the Transfusion Transmissible Infections Monitoring System (TTIMS) was implemented in the United States to facilitate monitoring of the safety of the blood supply for a variety of different pathogens, including the incidence and prevalence of HIV, HCV, and HBV in blood donors. FDA should routinely review the data from TTIMS and emerging scientific evidence, to assess the effectiveness of alternatives to time-based donor deferral strategies, including individual risk assessments, as part of the reevaluation of its donor deferral policies.
 - Current data are insufficient for a full appreciation of the behavioral risk profile of newly eligible MSM under the MSM1YR policy.

- Information is not available on compliance with the MSM1YR policy. Are donors properly adhering to the 1-year period when disclosing risk or would shorter periods between donation and last sexual contact be disclosed if post-donation surveys were conducted?
- In addition, for donors who disclose MSM with in the last year and are therefore deferred what behavior risk profiles are evident?

Risk behavior studies coupled with studies of accepted, deferred and MSM who are not donors could be conducted to correlate infectious disease markers, including HIV, HBV and HCV. These studies would help to establish which types of behavioral risk segmentation may be possible. If outreach to the MSM community is included, studies should seek participation by a range of MSM from those who are married and/or in stable mutually monogamous relationships to single MSM.

- Development of effective questions for individual behavioral assessments and their acceptability:
Implementation of true individual risk assessment questions which are gender and sexual identity neutral has been proposed by some advocacy groups as the desired outcome. Development of new donor eligibility questions related to sexual risk behaviors of all donors, e.g. focused on the number of sexual partners in specified time frames, changes in sex partners during specific time frames, injection drug use and exposure to commercial sex workers may create a path forward for individual risk assessment. However, first, new questions would need to be developed and assessed for comprehension with a heightened need for accuracy of donor responses, and acceptability to a representative sample of donors and prospective donors including populations such as young adult non-donors who might become donors, and MSM must be included in this type of survey research. An assessment of new questions must include the feasibility of incorporating individual risk assessment questions into computer assisted, self-administered health history questionnaires. Developing, testing and modeling the impact of new questions on the sufficiency of the blood supply is equally as important as assessing if new questions result in an overall safer blood supply. Substantial formative work is necessary to develop questions using appropriate qualitative research methods supported by surveys of representative populations to assess willingness to be asked additional, more specific highly personal risk questions and cognitive debriefing studies of the proposed criteria/question(s).

There are suggested “stages” for questions to identify and test new criteria (in order):

- Conduct research intended to identify potential criteria or approaches for assessment of low risk MSM through questions appropriate for the donor health history questionnaire. Research in this area would include, but not be limited to simply identifying low risk groups but would also assess whether these respondents find the questions acceptable, comprehensible and fair.
- Conduct research intended to understand the impact of questions/donor criteria identified in the bullet above, on other donors and future donors. This would include acceptability of the question to donors currently eligible and assessing the number of donors currently eligible who may become ineligible from the proposed criteria.
- Develop a method for testing the safety of the new criteria/donor question(s), including testing of blood establishment computer systems (BECS) to validate additional controls are sufficient to identify donors participating in the study protocols. The BECS must

prevent cross over of donor information from the study group that could result in collection or recruitment of those donors that would not be eligible under the current deferral requirements. Evaluation approaches would need to be study designs or data collection approaches which include MSM who want to donate and allow for collection of data in large enough numbers to estimate the residual risk. For example, implementing the new criteria/question(s), allowing study populations to donate products that will undergo pathogen reduction (which serves as the safety net to protect blood safety during this research period), thus identifying the target group, allowing them to donate specified products, performing all standard blood screening and developing data capture systems documenting the entire process and outcomes so that rigorous analyses can be performed.

We would like to reiterate that FDA's process to reevaluate blood donor deferral policies should:

- Be structured to ensure that a safe *and adequate* blood supply is maintained while studies are completed and after implementation of a new deferral policy. The latter, assuring adequacy, must carefully assess the impact of proposed changes on the ability of collection facilities to operationalize them, and the willingness of the general donor population and other stakeholders to accept them.
- Focus on effective assessment of all donors to identify risks for transfusion- transmitted infections.
- Consider the concerns of all stakeholders to ensure concerns of the transfusion recipients served by this industry and others are understood and adequately addressed.

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Founded in 1962, America's Blood Centers is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The American Red Cross shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer these comments. We look forward to continuing to work with the FDA on patient and donor safety initiatives. Questions concerning these comments may be directed to SCarayiannis@aabb.org.

Sincerely,

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