The Feasibility of MSM Individual Risk Assessment Using the AABB DHQ

A Report of the AABB Donor History Task Force

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Background and Purpose of MSM Individual Risk Assessment

With a 12-month time deferral for men who have sex with men (MSM) implemented in most blood collection centers in the United States (US), there is interest in moving to individual risk assessment that may permit low-risk MSM to donate blood without a time-based deferral. In the Food and Drug Administration's (FDA), July 28, 2016 Federal Register notice, the agency established a docket and stated "FDA will consider comments and supporting scientific data received as it continues to reevaluate and update blood donor deferral policies as new scientific information becomes available. Comments are invited regarding the design of potential studies to evaluate the feasibility or effectiveness of such alternative deferral policy options." Stakeholders have also expressed interest in considering changes in donor screening. There is general consensus among blood collection centers that further research will be needed before an individual risk assessment approach could be selected.

While research may be expected to identify risk factors that can be used to identify safe donors, feasibility depends on being able to elicit the required information consistently from donors in a way that fits in the current donor screening environment in the US. Experiences in other countries where the donor screening environment is different may or may not be relevant. The AABB Donor History Task Force (the Task Force) has prepared this report to outline considerations for the feasibility of donor assessment with various approaches to individual risk assessment and to provide the opinion of the Task Force on approaches that could be applied to the AABB Donor History Questionnaire (DHQ) at the time FDA revises the required 12 -month deferral for a history of MSM. The intent of this report is to encourage discussion and focus thinking among blood collection centers and community stakeholders towards a practical donor eligibility policy. The eligibility of transgender donors is out of the scope of this report.

Methods

1) The Task Force developed a list of criteria to assess feasibility of approaches.
2) A list of potential approaches was developed based on published literature and the expertise of the Task Force.
3) The Task Force members evaluated the approaches according to the criteria.
4) The Task Force invited key informants and stakeholders in the blood collection community to provide feedback on the draft report.
5) Feedback was incorporated in the final report.

Overview of Blood Donor Screening in the US

The Task Force, comprised of professional member experts, consultants, and FDA liaisons, develops the AABB DHQ and the accompanying materials to be used as part of the screening process to establish donor eligibility. AABB submits the DHQ and accompanying materials to the FDA for review. The FDA issues guidance to formally recognize the DHQ and accompanying materials, as an acceptable "mechanism for collecting blood donor history information from donors of blood and blood components that is consistent with the FDA requirements and recommendations." The DHQ is designed for self-administration by the donor, with review and follow-up by a trained donor health historian (the donor historian). Donors can use a hard copy or computer assisted DHQ. The goals and approach for this process remain the same, regardless of administration method.

Blood donors complete the DHQ before each donation. AABB Standard 5.3.1 states "The collection facility shall have a policy to ensure that the donor qualification process is private and confidential." Providing a setting that ensures privacy while the donor is completing the DHQ is intended to help the donor answer questions without concerns that others can see personal information. In addition, the setting should provide for a confidential discussion of information to support an effective donor screening process. The accompanying materials include scripted follow-up questions, as provided in FDA reviewed flowcharts for use by the donor historian or adapted for use with electronic questionnaires to elicit additional information necessary to establish donor eligibility. The donor's responses to the follow-up questions are then reviewed by the donor historian in a private setting. This confidential, controlled process is intended to achieve consistent application of eligibility criteria at each donation, meaning that the determination of eligibility should be the same no matter which donor historian completes the donor screening.

The FDA's December 2015 Guidance, Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, provided FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection. Section II of the December 2015 Guidance includes extensive background information, including "Recent Data Relevant to the Deferral for MSM", "Evaluating Alternative Policy Options Using Available Evidence", and "Evaluating Alternative Policy Options Using Available Evidence." For compliance with the FDA's recommendations, the Task Force made the corresponding revisions to the Donor Educational Materials, DHQs and accompanying materials in the version 2.0 AABB DHQ. The v2.0 DHQ was formally recognized by FDA in May of 2016 and remains in use at the time of this report.

Limitations of Donor Screening

The following are some of the key limitations of the donor screening process that are relevant to developing questions to permit low-risk MSM to donate blood.

1. Speed and Efficiency
   Most blood collection centers attempt to complete the process for whole blood donation in a reasonable time period, typically 1 hour or less. This goal addresses both donor satisfaction and operational efficiency. Therefore, the donor screening process must be both brief and effective. Simple questions are preferable because they are more easily understood by the donor and elicit an accurate response without unnecessary delay.

2. Repetitive Process
   The DHQ must be completed by the donor on the day of and prior to each donation. This process ensures that the donor has read each question, taken time to reflect and recall relevant details, and provided a correct response. The questions begin with the day of donation and move progressively back in time to facilitate recall of events.

   To serve the many people who donate frequently, the Task Force has developed an abbreviated DHQ (aDHQ) for use with frequent donors. The frequent donors who are eligible, as defined in the DHQ User Brochure, answer "capture questions" to focus donors on essential information. Nevertheless, donors must complete a DHQ at every donation and it is recognized that the attention

of donors can be adversely affected by this repetitive process, the length and complexity of the DHQ/aDHQ, and the time required to complete the questionnaire.

3. Yes or No responses are required
   To assess each donor in a consistent fashion, a uniform process is followed. Blood collection centers provide appropriate training to donor historians. Questions requiring a yes or no response are used, removing the need for interpretation of open-ended questions. The donor historian follows a DHQ flow chart by which each yes/no response prompts either a determination of eligibility or a scripted follow-up question. This structured process is uniform and less subject to interpretation by the staff of the blood collection center.

4. Need to focus on objective behaviors
   The DHQ uses questions that focus on specific behaviors related to risk for transfusion-transmitted infections to establish donor eligibility, consistent with FDA's current recommendations and recently updated regulations in the May 2015 Final Rule. To support an effective donor screening process, the donor must not assume it is possible to assess the safety of their donation, nor deny behaviors based on their assumptions regarding the risks. Questions are developed to decrease the likelihood of multiple interpretations making the question a more reliable screening tool.

5. Social desirability bias
   It is possible that donors could provide responses they think are expected or approved of rather than provide responses that could be seen as less socially desirable. The DHQ User Brochure describes donor screening as "an interactive process involving open communication between the donor and donor historian regarding confidential information." It goes on to remind blood collection centers of the importance of privacy and confidentiality, as noted earlier. Creating a more private environment, such as with the use of a computer assisted, self-administered DHQ, provides anonymity and reduces social desirability bias. This bias may not be removed entirely because the donor's responses become part of the donor's record and may be ultimately reviewed by a person.

6. Simplicity is paramount
   At each donation the donor must read the Donor Education Materials intended to assist the donor in completing the DHQ. Before proceeding, the donor must provide an affirmative response to the question "Have you read the educational materials today?" Despite this requirement, it is possible that some donors pay little attention to the information. Therefore, screening questions should be simple and easily understood without requiring extra explanation. Complex algorithms can also be a source of staff error.

Assessment of Approaches

Criteria to Assess Screening Approaches:

The criteria used to assess types of screening questions are shown in Table 1.

A true individual risk assessment approach would involve asking all donors the same questions. An alternative approach would be to retain the current question about MSM history in the last 12 months to serve as a "capture question." An affirmative response about MSM history would be followed by questions

to assess the level of risk for transfusion-transmitted infection. The former is favored by Lesbian, Gay Bisexual, Transgender, Questioning, Intersex and Two-Spirit (also known as LGBTQI2) stakeholder groups because it does not require donors to disclose the sex of their partner and is considered to be non-discriminatory. The latter is more operationally feasible to implement because it would follow the current paradigm of using a capture question that would identify a relatively small group of donors that require further questioning to assess donor eligibility.

Assessment of 5 potential approaches are summarized in Table 2, noting items that may vary in practicality depending on whether all donors are asked all questions or capture questions are used to identify risk for a history of MSM in the past 6 months. The first two approaches, assessing risk based on the number of sexual partners in past xx months, and new sexual partner (or change in sexual partner) in the past xx months, are good candidate approaches that could be suitable for all donors. Both approaches would use a clear simple question that donors would be able to understand. For example, rather than ask a donor about the specific number of partners which might be difficult to accurately recall, the question would ask if the donor had more than one partner during a specified time period. The simplicity of recalling if there was more than one partner would be very likely to support an accurate eligibility determination. In addition, it may be difficult to enter a specific number in some computer systems due to the limits of some systems.

The DHQ currently includes questions about sexual contact with high risk partners (someone who has tested positive for HIV, is diagnosed with HIV, takes money or drugs for sex, or uses injectable drugs not prescribed by a physician) which are considered acceptable questions by most donors. However, a donor might have no way to know if a partner was at high risk for HIV infection. For that reason, these questions are only able to identify an absence of some of the higher risks for disease transmission but cannot identify with certainty a safe subset. Based on experience with the donor population, it is the view of the Task Force that questions regarding sexual behaviors, such as anal sex, would not be suitable for use with all donors because it is unlikely that all donors would be comfortable answering such questions. Questions about safe sex require donors to assess their own risk which is not consistent with the approach that discourages such assumptions. Further, it is not possible to assess the effectiveness of safe sex practices used by a donor. Safe sex assessment is not an acceptable donor eligibility criterion because a donor cannot accurately determine the risk of any sexual encounter. It is not possible to establish follow up questions regarding safe sex practices as part of an algorithm in a standard flowchart. It would require a probing or qualitative assessment by a historian that may not be consistently applied.

In evaluating these approaches, the Task Force drew upon the collective experience in screening donors, developing and using the AABB DHQs, and evaluating their effectiveness. This Risk Assessment Report has also been reviewed by members of the community with expertise in questionnaire design to assess sexual risk. It is not the intention of the Task Force that this evaluation take the place of research to evaluate specific questions that may be considered. Qualitative research methods were used to evaluate the AABB DHQ prior to its formal review and acceptance by the FDA. Cognitive interviews using think aloud techniques help us understand donor thought processes when answering questions and identify problem questions or wording. Focus groups are quicker but can be influenced by group dynamics. Both of these approaches are limited by involving a small number of participants. It is impossible to definitively determine what proportion of potential donors answer the question correctly because there is no gold standard of the donor's sexual history to use in comparison to assess risk for transfusion-transmitted infection. The collective experience of researchers and questionnaire design experts in asking sexual risk questions is, therefore, of value in determining the potential for a line of questioning to consistently yield

accurate responses. Furthermore, even with extensive risk assessment, a small "leap of faith" will be required to implement individual risk assessment questioning, with the true effectiveness ultimately validated post-implementation. Therefore, the Task Force believes that attention should be focused on lines of questioning considered *a priori* likely to be practical to implement and likely to yield accurate responses.

Conclusion

Questions intended to identify both the number of sexual partners in last xx months and new partners in the last xx months could be written that would be short, concise and suitable for donor screening if determined to be useful in identifying safe donors. Research will be needed to estimate the proportion of safe donors currently eligible who would become ineligible based on this change in donor assessment. Although not a true individual risk assessment approach, asking a capture question to identify MSM with recent sexual contact, with follow up questions about partner history and/or types of sexual behavior, would follow the current paradigm and may be feasible if determined to be useful in identifying safe donors. Implementation approaches that make use of risk reduction processes for a period of time following implementation, such as pathogen reduction technology or quarantine and re-test strategies, may offer an opportunity to study the effectiveness of individual risk assessment questions in MSM donors in the donation setting, this group being otherwise difficult-to-access for research.

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Table 1 Criteria for evaluating potential approaches to individual risk assessment of donors and the rationale

Criteria	Rationale
1. Be interpreted as intended by all donors	
a) Expressed in simple language	Donors come from a broad range of educational backgrounds and linguistic capabilities. Many are unwilling to expend effort trying to unravel complex wording even if they are capable.
b) The information sought should be crystal clear (only one reasonable interpretation)	If more than one interpretation is possible, it is never clear which the donor is answering.
c) Should be single item questions	Donors may attend more to one item than the other(s) so may be answering in relation to only one item in the question. It is never clear whether "no" refers to all or only some of the items.
d) Should use neutral language and non-emotive terms	Terms which may produce an emotional response (e.g. 'Risk') may introduce undesirable bias and should be avoided.
2. Be questions that the donor is capable of answering	
a) Should relate to the donor's own experience	It is impossible for donors to know for sure the sexual history or other risk behavior of their partner. In some cases, the partner may have told the donor about some risks, but at best questioning about this will rule out some donors with known risky partners. It cannot rule in a donor with low risk.
b) Should ask about information that is easily remembered - Shorter time frames that encompass data-based assessment of window-periods are preferable - A small number of easily identifiable experiences	To respond correctly the donor needs to remember the event. Recent experiences are more readily remembered. The donor also needs to recognize when an event she/he has experienced is the one being asked about. The donor needs to work out if the event occurred within the time frame being asked about. Recall can be aided by relating the event to some other event that the donor knows the date of. Exceptions to routine events are often difficult remember and to place in time.
c) Should avoid subjective assessment by the donor	Questions which require subjective assessment (e.g. evaluating their own risk) will be answered less consistently
3. Be questions the donor is willing to answer	
a) Should not be viewed by donors as excessively personal	If the donor is not comfortable with admitting the behavior, there is a greater chance that she/he will respond "no" even if the response should be "yes". Particularly relevant at mobile blood collection locations where the donor's friends or co-workers may be present.
b) Should appear to be relevant to the	Donors generally understand that questions are asked to reduce the risk of infectious disease. Questions that

assessment	are seen as irrelevant or unjustified call into question the validity of the entire DHQ and donors are less likely to feel compelled to respond correctly (especially when they would rather not).
c) Should not challenge the donor's loyalty (eg suspicion of partner's fidelity)	Any scenario which creates the potential for competing loyalty will reduce the likelihood of the donor responding truthfully.