



ACOT Update on the Advisory Committee for Blood and Tissue Safety and Availability

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November 2014 ACBTSA Meeting

- **November 13 and 14, 2014**
- **Topics of meeting**
 - MSM blood donor deferral policy
 - Hemoglobin S testing
 - Blood system issues in addressing babesia
 - Subcommittee report on informed consent
- **Recommendations made on MSM blood donor deferral policy**
- **Recommendations made on hemoglobin S testing**



MSM Questions and Recommendations

1. Do the completed HHS MSM Blood Donor Deferral Studies, along with other additional studies and data, provide the ACBTSA with sufficient information to support a change from the current MSM deferral policy (deferral for MSM, even once, since 1977) to an alternative policy that would permit blood donations by some MSM?

Committee voted: 16 in favor, 2 against

2. After hearing the MSM study results, if the committee determines that a policy change is supported by the evidence, what deferral time frame does the committee recommend for a change to the MSM Blood Donor Deferral Policy recommendations?

Committee voted for one-year deferral: 16 in favor, 2 against



MSM Questions and Recommendations

3. Based on the Donor History Questionnaire (DHQ) study performed by CDC's National Center for Health Care Statistics, and the data from the REDS III Study (Blood DROPS), what approaches does the ACBTSA recommend for exploration of potential enhancements to the DHQ format and associated public health education and outreach to blood donors and public stakeholders?



MSM Questions and Recommendations

- **The ACBTSA recommends to the Secretary the following in regards to the recommended change in MSM policy:**
 - Implementation of the recommendations made during the December 2013 ACBTSA meeting, especially those regarding surveillance of transmissible diseases
 - Develop and implement a coordinated communication plan regarding a change in MSM deferral policy focused on all relevant stakeholders
- **In addition, the ACBTSA recommends for all donations that the Secretary:**
 - Undertake studies to evaluate the effectiveness of the administration of the DHQ
 - Take steps to improve transparent communication to recipients of the relative risks and benefits of blood, organs, cells and tissues
 - Evaluate and revise the donor education material in order to improve its uptake, comprehension, and utility to promote accurate disclosures of risk
 - Improve the sensitivity and specificity of the donor selection criteria to identify donors at increased risk of transmissible diseases



Previous Steps in MSM Policy Discussion

- 1983** Deferral of sexually active homosexual or bisexual men with multiple partners
- 1984** Deferral for even one MSM contact since 1979
- 1985** Deferral for even one MSM contact since 1977
- 1992** FDA's current guidance on deferrals for increased HIV risk
- 2010** ACBTSA recommends policy suboptimal, additional studies need to be done before any change
- 2010-2014** One Operational Assessment and 3 Studies were performed to increase understanding
 - Quarantine Release Error
 - UDHQ Study
 - REDS-II TTVI Rate and Risk Factor Study
 - REDS-III BloodDROPS Study



Previous Steps in MSM Policy Discussion

- **2014 Nov** ACBTSA Recommends change in MSM Blood Donor Policy to one year
- **2014 Dec** BPAC discusses Strategies to Monitor HIV Incidence and Recency in Blood Donors. (While policy was discussed, there were no formal recommendations)
- **2014 Dec** BOTSEC meets and makes recommendations to ASH
- **2014 Dec** FDA Commissioner announces that FDA will take steps to change MSM blood donor deferral policy to a one-year deferral



Next Steps in MSM Policy Discussion

- **FDA is drafting a guidance which will include proposed MSM blood donor policy change**
 - Draft guidance policy will be issued for comments
- **FDA will establish a transfusion transmitted infectious disease monitoring system**
 - Jointly funded by NHBLI



Hemoglobin S Questions

1. Donor consent

- a. Should blood centers inform blood donors that testing for Hb-S will be performed? If so, specify what elements of information should be provided.

2. Donor management

- a. What are the obligations, if any, of blood centers to notify blood donors of positive screening tests for Hb-S?
- b. Can a blood donor “opt out” of being notified of their Hb-S test results?
- c. Should blood centers perform confirmatory testing (for example, hemoglobin electrophoresis) on Hb-S screen positive donors?
- d. What are the obligations of blood centers to provide medical counseling and follow-up?



Hemoglobin S Recommendations

The committee recommends the Secretary take steps to assure that:

- Donors are informed within the framework of routine consent for donation that their donations may be tested for hemoglobin S and that they will be notified of positive results
 - Implicitly, donors who do not wish to be tested or notified may decline to donate
 - Donors who test positive for hemoglobin S or present with known history of sickle cell trait may be encouraged to donate plasma or apheresis platelets
- Opportunity is provided for donors to become informed about the significance of sickle trait



Hemoglobin S Recommendations

- In order to facilitate donor notification, transfusion services will inform the blood collection establishment in instances where a product is found to be positive for hemoglobin S
- Given the possibility of false positive tests for hemoglobin S with certain technologies and in certain donor groups, collection centers should be encouraged to provide information on the specificity of test results (e.g. through confirmatory testing) though this is not a primary responsibility of the blood establishments
- Additional research and dissemination of findings of the impact of sickle trait to clinicians and the public be performed

Committee voted 12 in favor, 0 against



Future ACBTSA Meetings

- **April 7 and 8, 2015**

- 5635 Fisher Lane, Rockville MD
- Focus on improving safety of tissue tracking and traceability
- Exploring:
 - Federal and State regulations that impact tracking and traceability
 - Mechanisms currently in place which impact tracking and traceability
 - Current gaps to effect tracking and traceability
 - Health IT developments that may facilitate tracking and traceability

- **Late Fall 2015 (November or December)**

- Topic still be determined, will focus on blood safety and availability



Symposium on Accessibility and Development of Tissue Products for Emergency Preparedness

- **Date** May 11 and 12, 2015
- **Location** National Archives, Washington, DC,
- **Sponsored by** OASH and ASPR in collaboration with DoD Medical Research and Materiel Command (MRMC)
- **Public Event but requires pre-registration** - <http://www.hhs.gov/ash/bloodsafety/>
- **Builds upon previous ACBTSA recommendations about lack of emergency preparedness for tissues**
- **Symposium will**
 - Build common awareness of threats and preparedness goals amongst key stakeholders
 - Bring together stakeholders from US government, academia, industry, and end-users to engage in dialogue