

## HHS Advisory Committee on Blood Safety and Availability

On June 10-11, 2010, the HHS Advisory Committee on Blood Safety and Availability (ACBSA) met to discuss the current Food and Drug Administration (FDA) policy on men who have sex with other men (MSM). FDA's current policy states that men who have had sex with other men at any time since 1977 are currently deferred as blood donors.

The ACBSA engaged in deliberations and discussed the following: important factors to consider in making a policy change; scientific information including risk assessments; whether any additional studies are needed before implementing a policy change or following a policy change; monitoring tools or surveillance activities that could be implemented, and whether those should be implemented before implementing any policy change; and, whether additional safety measures, if any, are needed to assure blood safety under a revised deferral policy.

The ACBSA took two votes during the meeting. The first was to vote on whether the current policy should be changed at the present time. In the second, the Committee was asked to identify studies needed to establish a basis for a change in policy and to recommend further action needed, if any, to monitor and improve blood safety.

### **Committee Question:**

Should the current indefinite deferral for men who have had sex with another man even one time since 1977 be changed at the present time? Committee Vote: 6 = Yes; 9 = No

### **Committee Recommendations**

The HHS's Advisory Committee on Blood Safety and Availability (the Committee or ACBSA) is sensitive to the blood system and broader societal issues related to the current deferral policy for males who have had sex with another man even (MSM) one time since 1977.

Whereas we believe that the current donor deferral policies are suboptimal in permitting some potentially high risk donations while preventing some potentially low risk donations, we find that currently available scientific data are inadequate to support change to a specific alternative policy; therefore, until further evaluation, the committee recommends that the current indefinite deferral for men who have had sex with another man even one time since 1977 not be changed at the present time.

To develop and validate candidate alternative policies, we recommend research in the following areas:

1. Validate modifications to the donor questionnaire that would better differentiate low versus high risk MSM and heterosexuals, including studies to investigate

Transfusion Transmitted Infectious Disease (TTID) and Sexual Transmitted Disease (STD) markers in potential donor subsets;

2. Establish ongoing national hemovigilance program for TTID markers in blood donors linked to analysis of demographic, behavioral, and other risk factors:
  - a. Obtain a baseline on prevalence and incidence of TTIDs,
  - b. Characterize risk in different donor subgroups (e.g., younger age), and
  - c. Use above characteristics for continuous quality improvement of the donor deferral process;
3. Determine the feasibility of donor pre-testing to limit risk while characterizing donors who might be recruited under modified eligibility criteria;
4. Investigate the impact of revised donor criteria on the global availability of plasma products;
5. Evaluation of data from other countries that have changed their high risk donor evaluation programs, including MSM; and
6. Periodic reassessment of transfusion safety including consideration of multiple and cumulative blood product exposures to recipients.

Additionally, the Committee recommends the following actions.

1. Implement the January 2008 ACBSA recommendation to adopt pathogen reduction technologies for all transfusable blood components
2. Create a more robust donor education program focusing on high risk behaviors that is more inclusive of all donor groups, emphasizing the link between safe donation and recipient health
3. The Department should take action to investigate and reduce the risk of Quarantine Release Errors (QREs) in blood collection establishments
4. Recognizing the relationship between acceptance of risk of transfusion and protection from harms, further consideration should be given to mechanisms for compensation for blood injuries consistent with the recommendations of the Institute of Medicine and the U.S. Congress

Committee vote: Unanimous yes (15 votes)