

*Promoting the highest standard of care for
patients and donors in all aspects of
blood banking and transfusion medicine*

AABB Standards to Reduce the Risk of Bacterial Contamination of Platelets

American Association of Blood Banks
8101 Glenbrook Road
Bethesda, MD 20814-2749

Kathleen Sazama, MD, JD

April 7, 2004

Risk of Bacterial Contamination

- Bacterial contamination of platelets is the most significant current **infectious** risk of transfusion
- Risk = 1:1000 to 1:3000 units of platelets
- Second leading cause of death from transfusion – mortality rates approx. 1:60,000 transfusion

Longstanding Problem: FDA and CDC Actions

- 1986 – BPAC recommended reverting to 5-day storage interval due to concern re bacterial sepsis
- 1992, 2001, 2002, 2003 – BPAC addressed bacterial contamination
- 1992 – CDC recommended improved surveillance
- 1995, 1999, 2002 – FDA workshops
- 1998 – CDC supports BaCon Study
- 2002 – FDA clearance of BacT/ALERT culture bottles and Pall Bacterial Detection System

Relationship to Pathogen Reduction

- Unlikely introduction in near future of pathogen reduction technology highlighted need to act on bacterial contamination
 - August 2002 FDA Workshop on pathogen reduction
 - August 2002 open letter to transfusion community from leading physicians

AABB Committees Identify Bacterial Contamination as a Priority

- Clinical Transfusion Medicine Committee
- Transfusion Transmitted Diseases Committee
- Standards Committee

November 2002 – Proposed Standard

- Std. 5.1.5.1: The blood bank or transfusion service shall have a method(s) to detect bacterial contamination in all platelet components

December 2002 Association Bulletin

- Update to AABB members re new information on and additional means of addressing bacterial contamination of platelets
- Included annotated bibliography
- Stresses comment period for proposed standard

Public and AABB Member Comments

- AABB's Blood Bank – Transfusion Service Standards Program Unit (SPU) received more than 50 comments, which were carefully considered by the SPU and AABB's Board

March 2003 – Revised Standard

- Std. 5.1.5.1: The blood bank or transfusion service shall have methods to limit and detect bacterial contamination in all platelet components. Standard 5.6.2 applies
 - This standard shall be implemented by March 1, 2004
- Std. 5.6.2: The venipuncture site shall be prepared so as to minimize the risk of bacterial contamination. Green soap shall not be used

Guidance to AABB Members

- March 2003 memo announcing final standard to be implemented in March 2004 and outlining possible ways to meet the standard
- August 2003 Assn. Bulletin – guidance re strategies to meet standard
- October 2003 Assn. Bulletin – extensive background re risks plus guidance re various approaches to implement
- CD – Swirling demonstration

HHS Action

- February 26, 2004 HHS requested that AABB delay implementation of standard. Agency noted potential serious effects on availability and the need to address:
 - Quality control methods applicable to pre-release testing
 - Potential extension of platelet dating
 - Pooling of random donor platelets
 - Surveillance and reporting protocols for positive test results

Implementation Issues: Continued Guidance / Education

- AABB Assessment process flow charts
- Articles in *Weekly Report* and other AABB publications
- AABB staff available to answer member questions
- Future Association Bulletins, as needed

Conclusions

AABB's bacterial contamination standard will help improve patient care and save lives