



Medical

Hemolysis in Stored Red Blood Cells & Need for Guidelines and Assessment Measures

**Hal Baker, Senior Vice President, Pall Medical
Advisory Committee
on Blood Safety and Availability
(BSAC) Meeting
January 25, 2005**

Objectives:

- Provide Pall BPF4 field action update
- Discuss broader issues and implications for blood safety and availability



Leukoreduction of RBCs in the US

- 14 million units collected annually
- 75% are leukoreduced
- 1/3 of those with a BPF4 filter
- Gold Standard for filtration

Situation Update

- Several US Centers reported higher than expected hemolysis in a limited number of Pall BPF4 Filters, and these events have not reoccurred
- No adverse patient events have been reported
- Since initial reports the cumulative occurrence rate has dropped to 27/100,000 filtrations.
- No interruption of filter supply or resultant shortage of blood
- Measures taken effective per discussions with AABB Interorganizational Task Force

Working Hypothesis

- Continuing investigation suggests link to possible variability in the wetting or priming of the filters
- Working closely with FDA and continue to seek guidance

Pall's Response

- Assembled Pall Technical Response Team
- Collaboration with industry (FDA/ABC/ARC) and direct communication with customers
- As agreed w/FDA - initiated Limited Voluntary recall of implicated filter lots
- Nationwide Customer Notification
- Change in IFUs to further reduce risks
- Collected all unused filters from implicated lots and replaced with new inventory

Results of On-Site Customer Technical Support Calls

- Uncertain measurement and assessment guidelines
- No reliable and reproducible methods available to visually assess plasma free hemoglobin for quality control and process validation
- No accepted standard and convenient methods to directly measure levels of plasma free hemoglobin
- No clinical standards for maximum levels of plasma free hemoglobin in transfused units



At Issue – Lack of Standards

- Blood bankers rely on visual inspection to determine unit's suitability for transfusion
 - Hemolysis noted in the segment may overestimate that found in the blood product
 - Visual inspection only roughly estimates the true level of plasma free hemoglobin
 - Value needs to be compared to some standard against which a clinical decision can be made

Benefits of a Uniform Standard for Safe Levels of Plasma Free Hemoglobin

- Provide a target for quality assurance in the processing of blood products
 - Assuring the safety of transfused units
- Assure the ready availability of RBCs for transfusion
 - Preventing the discard of units which might be safely used for transfusion

Pall Taking Steps to Assist Customers

- Provide customer support and product verification tools
 - Implement and accepted method for plasma free hemoglobin confirmatory measurement
 - Device protocol for on-site testing or at Pall Laboratories
- Customer Service Hotline (800-645-6578)
- Educational workshops thru Pall University (Spring 05')
 - Whitepaper and periodic technical bulletins



Pall Medical

- Blood Safety is our utmost priority
- Pall is committed to working together with AABB and other leading industry organizations to develop appropriate standards for the measurement and assessment of plasma free hemoglobin
- Seek BSAC recommendations in favor of a reference standard for technicians and clinicians



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Thank You