

Update to TBC TRALI Mitigation Strategy

TRALI UPDATE

In December 2006, and following guidance from AABB, The Blood Connection (TBC) issued a Technical Bulletin outlining a three-phase approach to limit distribution of blood components known to have Transfusion Associated Acute Lung Injury (TRALI) risk. This bulletin updates progress of that program. TBC has decided to add an additional step to further reduce the risks- see Phase Four.

PHASE ONE

Phase one was completed January 15, 2007. The goal of phase one was to remove a production bottleneck limiting the number of plasma units prepared from TRALI low-risk donors. By January 15, 2007 production of frozen plasma for transfusion had shifted away from Fresh Frozen Plasma to a clinically equivalent, FDA licensed, frozen plasma product known as twenty-four hour frozen plasma. Abbreviated 24-FP, the approved product name is Plasma Frozen within 24 Hours of Phlebotomy. There was no blood service fee adjustment for providing this alternate plasma product.

PHASE TWO

Phase two was substantially complete by March 1, 2007. Phase two was a production sorting phase with the goal of employing plasma from male donors for preparation of 24-FP. By February 28, 2007 TBC's transfusable frozen plasma inventory and deliveries to customers consisted entirely of plasma from male donors.

PHASE THREE

Phase three was implemented June 13, 2010. TBC began testing for Class I and Class II HLA antibodies on female (apheresis platelet and/or plasma) donors with a history of 2 or more pregnancies. With limited results available to date, TBC is currently experiencing approximately 14% of donors tested to be positive for Class I and/or Class II antibodies. Once a donor is found to have a positive result, this donor is no longer eligible for apheresis platelet or plasma donations. TBC has not adjusted blood service fees as a result of this testing.

PHASE FOUR

Phase four will be implemented by February 1, 2013. TBC will test all apheresis (platelet/plasma) female donors who have a history of any pregnancies. This testing must be completed and must be negative prior to any platelet or plasma collection. At each donation the donor will be asked if they have been pregnant since the last negative test result. If yes, the donor will not be eligible to donate plasma or platelets until the test has been repeated and found to be negative, however, the donor is eligible for Whole Blood donations (plasma from female whole blood donors is not available for transfusion).

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