

KENTUCKY BLOOD CENTER – STATEMENT ON TRALI MITIGATION COMPLIANCE

Update Effective October 1, 2016

Today's blood supply is the safest it has ever been. While the risk of transfusion transmitted infections is very low, transfusions are not totally risk-free. The mission of Kentucky Blood Center (KBC) is to offer the safest blood supply to the community we serve, and as part of our commitment to safety, we are in compliance with federal regulations as well as those from organizations like the AABB.

In 2005, Transfusion-Related Acute Lung Injury (TRALI) was officially recognized by the FDA as the leading cause of transfusion related fatalities (and remains so today). In 2006, AABB recommended taking steps to mitigate the incidence of TRALI. Since it is known that the majority of antibodies (HLA antibodies) related to TRALI are most commonly found in females, AABB suggested limiting the transfusion of Fresh Frozen Plasma (FFP) collected from female donors. KBC implemented this recommendation in 2007 and FFP supplied by KBC has been entirely from male donors since June 1, 2008. AABB began requiring this recommendation to be followed as a new standard in the 29th edition of Standards for Blood Banks and Transfusion Services, and as detailed above, KBC has been in compliance with this since 2008. In the 30th edition of standards, AABB has added apheresis platelets to their recommendation. Please note that KBC does not manufacture whole blood for allogeneic transfusion.

5.4.1.3 Plasma, Apheresis Platelets, and Whole Blood for allogeneic transfusion shall be from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.

In light of this new standard, KBC will be testing all female platelet donors with a history of pregnancy for HLA antibodies and only allowing platelet donations by those with a negative HLA antibody screen after their last pregnancy. We will also begin allowing selected female donors without a history of pregnancy, or who test negative for HLA antibodies, to begin donating FFP.

Other recommendations from AABB, and additional accrediting agencies such as the College of American Pathologists (CAP), require hospitals to develop a plan to reduce the risk of TRALI. Other measures for hospitals to consider for TRALI mitigation include:

- 1. Physician, nursing and laboratory staff education in recognizing the signs and symptoms of TRALI
- 2. Good patient blood management (PBM) practices to avoid unnecessary transfusions of plasma containing products
- 3. Tracking and trending of transfusion reactions to look for those with symptoms of TRALI

Hospitals can also help to alleviate the impact of this standard on the supply of AB plasma by limiting unnecessary utilization. Several hospital based strategies are listed in the Association Bulletin #14-02.

The medical staff of KBC is available to help our hospital customers with education on these issues. Please contact Dennis Williams, MD, Medical Director at (859) 276-2534 or (800) 775-2522 for more information.