
MEMORANDUM

The American Red Cross and TRALI Mitigation

The Red Cross is committed to providing the safest possible blood supply. A leading cause of transfusion-related mortality is transfusion-related acute lung injury (TRALI), and the Red Cross is taking firm action to mitigate the risk of this adverse reaction.

In October 2016 AABB Standards #5.4.1.2 and #5.4.1.2.1. went into effect for platelets. The Standard initially stated: “*Plasma 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 and 5.4.1.2.1 For apheresis platelet components, Standard 5.4.1.2 shall be implemented by October 1, 2016*”.

On April 1, 2020, # 5.4.1.2 was amended to state: *Donors implicated in a transfusion related acute lung injury (TRALI) event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.*

To be compliant with this Standard, Red Cross tests all first-time female apheresis platelet and plasma donors for HLA antibodies as well as those who report a history of pregnancy or subsequent pregnancy. Only products from males and female apheresis donors with a negative test for HLA antibodies are released for transfusion. All whole blood-derived plasma and whole blood for transfusion that Red Cross provides is collected from either females without a history of pregnancy or male donors. Whole blood donations from females who report a history of pregnancy are not HLA tested, however plasma and whole blood for transfusion are not manufactured from these donations. Donors whose donations are involved in a TRALI event are deferred from donating until they are evaluated regarding their donation eligibility; if they are found to have risk factors (e.g., a history of pregnancy or transfusion) they are tested for HLA antibodies (and in some instances HNA antibodies). If the results are negative, a Red Cross Medical Director may remove the deferral. If positive, the donor is permanently deferred from apheresis platelet and plasma donations.

The following summarizes the measures that the Red Cross has taken to mitigate the risk of TRALI:

Platelets, Plasma, and Whole Blood

All apheresis platelet and plasma products released for transfusion are collected from male donors, female apheresis donors who have never been pregnant, or female donors with a history of pregnancy who test 'negative' for the presence of HLA antibodies since their last pregnancy. Whole blood and whole blood derived plasma released for transfusion are collected from males and females without a history of pregnancy.

HLA Antibody testing

All female platelet apheresis donors who report a history of pregnancy since their last donation are tested for HLA antibodies. Those who test 'positive' (i.e., who test above an agreed upon cutoff level for HLA antibodies) are redirected to donate whole blood and neither platelets nor plasma collected from these donations are released for transfusion.