New York Blood Center Enterprises

Quality
EW-POL-0131

NYBCe TRALI Mitigation

Introduction

Purpose

This policy outlines the New York Blood Center Enterprises' (NYBCe's) approach to Transfusion-Related Acute Lung Injury (TRALI) risk reduction measures.

Principle

To reduce the risk of TRALI to the patients we serve, NYBCe will adhere to AABB Standards for Blood Banks and Transfusion Services Standard, "Plasma, Apheresis Platelets, and Whole Blood for allogeneic transfusion shall be from donors who have not been pregnant, or who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies."

HLA antibody screening addresses only the risk of TRALI from HLA Antibodies.

Background

TRALI is an acute, often life-threatening reaction characterized by respiratory distress, hypo- or hypertension and noncardiogenic pulmonary edema that occurs within 24 hours of blood component transfusion. In TRALI, the causative antibodies are most often found in the plasma of the blood donor. When these antibodies are transfused, they cause activation of primed neutrophils that are sequestered in the lungs of certain patients. The activated neutrophils undergo oxidative burst, releasing toxic substances that damage pulmonary endothelium and resulting in capillary leak and pulmonary edema. Class I and II HLA and HNA antibodies have been implicated in TRALI. However, in a recent large clinical study of TRALI, HNA and Class II HLA antibodies, but not Class I HLA antibodies, were significantly associated with TRALI.

Testing for the presence of HNA antibodies is performed as part of a TRALI work up or by request of an NYBCe Physician.

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TRALI Risk Reduction Policy

Products

NYBCe's TRALI risk reduction measures apply to the following high plasma volume products:

- Whole blood / Fresh Whole Blood (FWB)
- Fresh Frozen Plasma (FFP), Frozen Plasma (FP)
- Liquid Plasma
- Apheresis Platelets
- Apheresis Plasma

- Low plasma volume Cryoprecipitate AHF may be manufactured from females with pregnancy history and unknown HLA antibody status.

Donors

NYBCe's TRALI risk reduction measures include collecting high plasma volume products for transfusion from the following donors:

- Male donors
- Females who have never been pregnant
- Females with pregnancy history who have been tested since their last pregnancy and found to be HLA antibody negative

Measures we take

Measures to accomplish TRALI risk reduction include but are not limited to:

- Identifying female donors with any history of pregnancy during the donation eligibility process, which includes identifying females who had a subsequent pregnancy after a negative HLA antibody test.
- Testing for HLA antibodies in targeted female donor populations with a pregnancy history (e.g., plateletpheresis donors and FWB donors), and retesting females who had a subsequent pregnancy following a negative HLA antibody test.
- Refraining from distributing fresh whole blood, platelet, or plasma products for transfusion purposes, if collected from female donors with a history of pregnancy and an unknown or positive HLA antibody status.
- Donors implicated in a TRALI event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.
- Donors who test positive for either HLA class I or HLA class II antibodies are restricted to donating only Whole Blood or Apheresis Red Blood Cells. The plasma products from these whole blood donations will not be used for transfusable products.

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TRALI Risk Reduction Policy, Continued

Exceptions	Exception to this policy may be made with NYBCe Medical Director and treating physician's approval.

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References and Change History

References

- Technical Manual, Bethesda, MD: AABB, Current edition
- Standards for Blood Banks and Transfusion Services, Bethesda, MD: AABB, Current edition
- AABB Association Bulletin #14-02 TRALI Risk Mitigation for Plasma and Whole Blood for Allogeneic Transfusion, January 29, 2014.

Change History

The following table lists the changes made for each document revision.

Effective date	Revision #	Change Description
See date on header	01	New document - NYBCe policy for TRALI mitigation. Replaces: BBD-SOP-0362 IBR-Policy-0027 KC-OUT-0138

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Signature Manifest

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Department Approval

Name/Signature	Title	Date	Meaning/Reason
Kendra Reynolds (IBR-KE1506A)	Vice President - Quality and Regulatory Affairs	20 Mar 2026, 01:37:00 PM	Approved

QRA Approval

Name/Signature	Title	Date	Meaning/Reason
Kendra Reynolds (IBR-KE1506A)	Vice President - Quality and Regulatory Affairs	25 Mar 2026, 09:27:11 AM	Approved
Betsy Jett (NY-BJETT)	SVP, Quality & Regulatory Affairs	26 Mar 2026, 01:09:41 PM	Approved
Adria Pena (NY-APENA)		30 Mar 2026, 01:07:54 PM	Approved
Darlene Folan (RI-DFOLAN)	RI-VP QUALITY & REGULATORY COMPLIANCE	31 Mar 2026, 04:53:35 PM	Approved

MD Approval

Name/Signature	Title	Date	Meaning/Reason
Bruce Sachais (NY-BSACHAIS)	Laboratory/Medical Director	23 Mar 2026, 10:46:52 AM	Approved
Eric Senaldi (NY-ESENALDI)	Medical Director	24 Mar 2026, 09:02:21 AM	Approved
Eric Gehrie (NY-ER22085)	Medical DIrector	26 Mar 2026, 10:12:12 AM	Approved
Johnny Ye (KC-ZH21049)	Medical Director	27 Mar 2026, 12:28:35 PM	Approved
Brian Engel (IBR-BR21035)	Medical Director	20 Apr 2026, 03:03:05 PM	Approved