LifeStream
GIVE HOPE | GIVE LIFE | GIVE BLOOD

WE HELP SAVE LIVES BY CONNECTING DONORS
AND PATIENTS THROUGH THE GIFT OF BLOOD.

Reporting Serious Transfusion Associated Adverse Events

Section 606.170(b) of 21CFR requires the transfusing facility to notify the FDA directly after confirming a transfusion related fatality.

In addition, in accordance with AABB Standards, transfusion services must report transfusion fatalities and other serious, unexpected adverse events, which are suspected to be related to an attribute of a donor or a blood component to the collection facility immediately and subsequently in writing. The hospital has a responsibility of notifying the blood bank if there is suspicion of sepsis, acute hemolysis, anaphylaxis, TRALI, or any adverse event that could be attributed to the transfusion of a blood product. We collect all apheresis platelet products using techniques designed to minimize the risk of contamination. This includes site preparation, use of sterile equipment, and diversion of the first portion of the collection.

To report an event:

- Contact LifeStream's Hospital Services Department at 909.386.6829.
- Complete the form "AABB Report of Adverse Transfusion Reaction to Blood Suppliers" available at this link: LStream.org/wp-content/uploads/2023/03/1625F1-AABB-REPORT-OF-ADVERSE-TRANSFUSION-REACTION-TO-BLOOD-SUPPLIERS.pdf
- Fax completed form to our Medical Surveillance Department at 909.386.6817.

Reference:

1. Notification Process for Transfusion Related Fatalities and Donation Related Deaths, FDA, 9/23/2021, available at: https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/transfusiondonation-fatalities

2. Report of Adverse Transfusion Reaction to Blood Suppliers—AABB Common Transfusion Reaction Reporting Form version 2.0 available at: https://www.aabb.org/docs/default-source/default-document-library/resources/aabb-transfusion-adverse-reaction-form.pdf?sfvrsn=d0c99dd_0