

Transfusion/Blood Bank-related Incident and/or Serious Adverse Reaction Report

Facility name/city _____

Lab PFI# _____

Instructions for reporting

Transfusion/Blood Bank-related incidents and/or serious adverse reactions must be reported to the department's Wadsworth Center within seven calendar days of the occurrence or its discovery.

Events that must be reported include, but are not limited to:

- Serious (severe) unexpected adverse reactions and incidents involving blood components that have been issued by the transfusion service
- All incidents, including near miss events, resulting in transfusion of a blood or blood component to a wrong patient
- Patient bedside identification not performed or performed incorrectly
- Issuance of incorrect product or unit for a specific patient
- Specimen labelling errors if a patient specimen used for a crossmatch was collected from the wrong patient or mislabeled, and the blood component was issued for transfusion
- Pre-transfusion testing errors of the recipient blood, if a patient sample was used in crossmatching blood or blood component that has been issued for transfusion
- Errors or accidents in collecting, testing, or processing of donor blood that are not detected prior to distribution and that may affect the safety of any product or health of the donor or recipient, including serious donor reactions

The decision to report should be based on whether the event had the potential to affect the safety or purity of any product, or the health of donor or recipient.

Definitions

Incidents related to transfusion include **errors** and **accidents** which may affect the safety, purity or potency of blood product, or health of the donor or recipient. An incident may or may not result in an adverse reaction in a transfusion recipient.

An **error** is a deviation from the requirements specified in Subpart 58-2 of Title 10 of the New York State Codes, Rules and Regulations (10 NYCRR), or the Code of Federal Regulations (CFR), or a significant deviation from the facility's Standard Operating Procedures (SOPs).

An **accident** related to transfusion is an unexpected or unforeseeable event not traceable to a deviation from Subpart 58-2 of 10 NYCRR, CFR or the facility's SOPs

Serious (severe) adverse reaction related to transfusion is reportable if the reaction is fatal or life threatening, results in hospitalization (initial or prolonged), disability/permanent damage, or required intervention to prevent permanent impairment.

What not to report:

- Non-severe adverse reactions to transfusion
- Errors and accidents that were detected prior to distribution and/or issuance of blood or blood components for transfusion
- Errors and accidents that did not have potential to affect the safety or purity of blood or blood component or health of donor or recipient
- Post-donation information
- Positive bacteria detection testing on platelets, absent a process error or severe transfusion reaction
- Nursing/Medical staff errors related to monitoring patients during transfusion, or reporting transfusion reactions, **absent adverse patient effect**
- "Lookbacks" performed by the facility, **absent infectious disease transmission in a transfusion recipient**

Facility name/city _____ Lab PFI# _____

Date of discovery _____ Facility incident number _____

Date of occurrence _____ Time of occurrence _____ AM PM

Date of report _____

Person filing report _____ Title _____

Telephone number _____ Email address _____

INCIDENT REPORT

ADVERSE REACTION REPORT

Patient effect(s)

- Not applicable
- No effect apparent
- Fatality – likely related to transfusion
- Fatality – possibly related to transfusion, cause to be determined
- Acute hemolytic transfusion reaction (AHTR)
- Delayed hemolytic transfusion reaction (DHTR)
- Graft-vs-host disease (GVHD)
- Transfusion-related acute lung injury (TRALI)
- Transfusion-associated circulatory overload (TACO)
- Transfusion-associated infectious disease (specify)
- Posttransfusion purpura
- Sepsis
 - Other (specify)
 - Allergic reaction, severe
 - Transfusion-associated dyspnea
 - Hypotensive transfusion reaction
 - Febrile non-hemolytic transfusion reaction

Donor effect(s)

- Not applicable
- No effect apparent
- Significant donor reaction (specify) _____
- Other (specify) _____

At what point(s) in the process did the incident occur?

- | | | |
|---------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------|
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Product storage | <input type="checkbox"/> Product labeling for issue |
| <input type="checkbox"/> Donor history | <input type="checkbox"/> Sample collection/labeling | <input type="checkbox"/> Product issuance |
| <input type="checkbox"/> Blood collection/donor testing | <input type="checkbox"/> Product order | <input type="checkbox"/> Product administration |
| <input type="checkbox"/> Component preparation | <input type="checkbox"/> Patient sample testing | <input type="checkbox"/> Equipment function |
| <input type="checkbox"/> Product labeling | <input type="checkbox"/> Clerical/documentation | <input type="checkbox"/> Special attribute(s) |
| <input type="checkbox"/> Product check-in | <input type="checkbox"/> Product selection | |
| <input type="checkbox"/> Product manipulation | <input type="checkbox"/> Request for pick-up | |
| <input type="checkbox"/> Other (specify) _____ | | |

How was the incident discovered? (check one)

- | | |
|---------------------------------------------------------|--------------------------------------------------|
| <input type="checkbox"/> Bedside patient identification | <input type="checkbox"/> Computer warning |
| <input type="checkbox"/> Transfusion reaction | <input type="checkbox"/> Historical record check |
| <input type="checkbox"/> Supervisory review | <input type="checkbox"/> Discrepant lab results |
| <input type="checkbox"/> Subsequent blood request | <input type="checkbox"/> Review of order |
| <input type="checkbox"/> Subsequent blood donation | <input type="checkbox"/> Reported by consignee |
| <input type="checkbox"/> Audit | <input type="checkbox"/> Other (specify) _____ |

Where did the incident occur? (check all that apply)

- | | | | | | |
|------------------------------------------------|-----------------------------------------|---------------------------------------------|-----------------------------------------------------|-----------------------------|-----------------------------|
| <input type="checkbox"/> Blood center | <input type="checkbox"/> Blood bank/lab | <input type="checkbox"/> ED | <input type="checkbox"/> ICU | <input type="checkbox"/> OR | <input type="checkbox"/> OB |
| <input type="checkbox"/> Med/Surg/Peds | <input type="checkbox"/> Outpatient Tx | <input type="checkbox"/> Limited Tx Service | <input type="checkbox"/> Limited Reinfusion Service | | |
| <input type="checkbox"/> Other (specify) _____ | | | | | |

Job function of the worker(s) involved in the incident (check all that apply)

- | | | |
|-----------------------------------------------------------|----------------------------------------------|-----------------------------------------------|
| <input type="checkbox"/> Clinical Laboratory Technologist | <input type="checkbox"/> RN, LPN, NP, PA | <input type="checkbox"/> Phlebotomist/IV Team |
| <input type="checkbox"/> Clerical/Administrative | <input type="checkbox"/> Attending Physician | <input type="checkbox"/> Housestaff |
| <input type="checkbox"/> Other (specify) _____ | | |

Product involved (check all that apply)

- | | |
|---------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Allogeneic/community donation |
| <input type="checkbox"/> RBCs | <input type="checkbox"/> Autogeneic donation |
| <input type="checkbox"/> Platelets | <input type="checkbox"/> Directed donation |
| <input type="checkbox"/> FFP/24-hour plasma | <input type="checkbox"/> Perioperative blood recovery |
| <input type="checkbox"/> Cryoprecipitate | <input type="checkbox"/> Prepared from whole blood |
| <input type="checkbox"/> Plasma derivative | <input type="checkbox"/> Collected by apheresis |
| <input type="checkbox"/> Reinfusion product | |
| <input type="checkbox"/> Other | |

Quantity administered

- | |
|----------------------------------------------|
| <input type="checkbox"/> None |
| <input type="checkbox"/> ≤25 mL |
| <input type="checkbox"/> 26-50 mL |
| <input type="checkbox"/> 51-100 mL |
| <input type="checkbox"/> 101-200 mL |
| <input type="checkbox"/> Entire unit/product |
| <input type="checkbox"/> # of units _____ |

Patient

- O pos
- A pos
- B pos
- AB pos
- N/A
- O neg
- A neg
- B neg
- AB neg

Unit

- O pos
- A pos
- B pos
- AB pos
- N/A
- O neg
- A neg
- B neg
- AB neg

Compatibility

- Compatible
- Incompatible
- N/A

Was there a reaction?

- Yes
- No
- N/A

Was a transfusion reaction workup performed?

- Yes
- No
- N/A

Incident summary (attach a separate page if necessary)

Results of investigation: investigate to determine what, who, how, why and when the event occurred.
(attach a separate page if necessary)

Was a root cause analysis performed?

- Yes
- No

Please refer to the Plan of Correction (POC) Guidance Document at <https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey> for information on performing a Root Cause Analysis.

Corrective action (attach a separate page if necessary):

Please scan the completed form and send as an e-mail attachment to brp@health.ny.gov with a subject title of Incident Report and your facility's PFI number. Alternatively, it can be mailed to the Blood Resources Program at the address below. Questions should be directed to the Blood and Resources Program at brp@health.ny.gov.

**CLEP – Blood Resources
Wadsworth Center
NYS Department of Health
Empire State Plaza
Albany, NY 12237**