The National Healthcare Safety Network (NHSN) Manual

Biovigilance Component

Protocol
Hemovigilance Module

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Background

Patient safety related to medical intervention has become an increasing public health concern in recent years. The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) intends to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. In 2006, the Department of Health and Human Services' (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) convened to make recommendations to improve patient safety related to transfusion and transplantation. ACBSA membership includes liaisons from federal public health agencies as well as representatives from industry, patient advocates, and the blood collection and transfusion communities. A recommendation was given to the Secretary of HHS by ACSBA that a national system was needed for surveillance of recipient outcomes of blood and blood products. Such systems, often referred to as hemovigilance, exist in most other developed countries, but not in the United States. Subsequently, the American Association of Blood Banks (AABB) formed an Inter-organizational Task Force on Biovigilance, with representation from both governmental and non-governmental organizations in the United States. The committee defined as their main task to develop "a comprehensive and integrated national patient safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs. The program should be outcome driven with the objectives of providing early warning systems of safety issues, exchanging of safety information, and promoting education and the application of evidence for practice improvement." While biovigilance also includes organ and tissue transplant safety, blood safety, or hemovigilance, was the first topic of focus.

After a review of the different systems that can be used to collect transfusion safety data, the AABB Biovigilance Task Force recommended a public-private partnership using CDC's National Healthcare Safety Network (NHSN) as the surveillance system that could most closely meet the data requirements for a national surveillance system for blood transfusion adverse event tracking.

In evaluating patient safety, the system was envisioned to capture both adverse events and errors and accidents. Using the International Society of Blood Transfusion (ISBT) definition, an adverse event is defined as an undesirable and unintended occurrence before, during or after transfusion of blood or blood components that may be related to the administration of the blood or blood component. It may be the result of an incident and it may or may not result in a reaction in a recipient.

An incident is defined as an accident or error that could lead to an adverse event affecting a) the safety, efficacy, or quality of blood, blood components, or plasma derivatives; or b) the safety of recipients. An accident is an unexpected or unplanned event, not attributable to deviation from standard

operating procedures; while an error is an unexpected, unplanned deviation from standard operating procedure that is likely attributable to a human or system problem (derived from Canadian Transfusion Adverse Event Reporting Form User Manual – April 2004). The system includes the tracking, trending, and analysis of transfusion errors and deviations from standard operating procedures or hospital policies that have led to mistransfusions, which may or may not have led to an adverse reaction. Included in incident reporting is the reporting of a near-miss, which is an incident that is discovered before the incorrect product reaches the patient.

I. Hemovigilance Module

Introduction

Based on the last published Nationwide Blood Collection and Utilization Survey Report[1], the total supply of whole blood and red blood cells collected in the United States in 2004 was approximately 15 million units which were processed into 29 million blood products. Recipients received on average, 2.7 units each, resulting in a national estimate of 5.3 million patients transfused.

While the risk of infectious disease as a result of transfusion can often be estimated (for example, the risk of HIV is approximately 1 in 2 million), estimates of transfusion related non-infectious adverse reactions and incidents associated with transfusion are not collected in the United States using a routine reporting system with standard definitions. Therefore, actual numbers or percentages of events are unknown. In the survey of data from 2004, 1,322 medical facilities reported 32,128 transfusion-related reactions that required diagnostic or therapeutic intervention[1]. While any transfusion-associated adverse reaction is considered rare, the general consensus in the United States is that there could be considerable underreporting based on surveillance reports of similar events from national surveillance programs in the United Kingdom and Canada. Collection of data regarding near-misses helps to increase the comprehensiveness of incident surveillance.

Five layers of safeguards established by the Food and Drug Administration (FDA) have become standard operating procedure for blood establishments and others involved in the collection and distribution of blood and blood products. These safeguards include: screening of blood donors, testing of blood for bloodborne pathogens (including HIV, hepatitis B & C viruses, syphilis, West Nile virus and others), maintaining lists of deferred donors (persons either temporarily or permanently excluded from blood donation), routine quarantine of all blood products until infectious disease testing and final donor eligibility determination has been completed, and investigation of any problems associated with blood

products including breaching of safeguards, errors, accidents, or any other event that could jeopardize blood product safety.

Despite the rigorous safeguards in place, non-infectious complications of transfusion can still occur due to the complex physiological mechanisms involved in transfusions. In addition, the risk of error associated with administration of a particular blood product to a particular patient is a persistent concern. In 1999, the Institute of Medicine report, To Err is Human, estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. In terms of blood safety, mistransfusion of blood (failure to give the right product to the right patient) is the error of greatest concern.

The purpose of the Hemovigilance Module is to collect, analyze, and report information on blood transfusion-related adverse events. This will include two sections: adverse reactions and incident reporting.

A. Adverse Reactions

Over the past three decades, emphasis on the detection and prevention of infectious disease transmission through transfused blood and blood products led to FDA requirements for routine testing of each blood unit for a variety of bloodborne pathogens. With enactment of these testing requirements and the subsequent decrease in the incidence of transfusion transmitted infections, the remaining problem of reactions from non-infectious causes became more apparent. A recent review article[2] classified these reactions as early (onset during or within hours of the transfusion) or late (onset days to months following transfusion) and provided estimates of reaction occurrence. Although the estimates varied considerably depending on the study, severe reactions have fatal event rates of 1 per million to 1 per 8 million transfused components. Severe early reactions such as Transfusion Related Acute Lung Injury (TRALI) showed fatal events to be 1 for every 3-6.6 million blood products administered. Febrile non-hemolytic reactions, while uncomfortable for the patient, usually are not associated with severe morbidity or mortality and are reported to occur in ~ 1 in 100 per products transfused depending upon the type of product. The lack of consistent reporting of transfusion related adverse reactions demonstrates the need for routine national surveillance to provide data that are more representative of actual events.

Settings

Surveillance should be performed by hospital transfusion services and can be performed in any adult or pediatric acute or chronic care facility where transfusion occurs, including patient care areas for

emergency and general medical and surgical patients, obstetrics and gynecology, orthopedic, cancer, other chronic disease, and any other patient care setting with transfusion services.

Requirements

All blood or blood component transfusion-associated adverse reactions in a 12-month period are to be reported. A reporting plan should be filed at the beginning of each month. Adverse reactions considered to be transfusion-associated are those for which imputability (relationship to transfusion) is determined to be definite, probable, or possible (see definitions in Appendix C). Adverse reactions for which imputability is *doubtful* or *ruled out* should not be routinely reported. The only time *doubtful* or *ruled out* categories should be used is when a reaction that was initially reported in the system to be transfusion-related was later determined not to be transfusion-related based on new or additional information. Adverse reaction reports should be entered into NHSN after the investigation of the reaction has been completed and imputability has been determined (to the extent possible). Ideally, most reports should be entered within 30 days of the month of the event. However, new information can be entered at any time.

Please Note: Reporting of adverse reactions into the NHSN hemovigilance surveillance system does **NOT** take the place of current reporting requirements for blood transfusion-associated adverse events to Food and Drug Administration (FDA). Hospitals and transfusion services should immediately report complications that may be related to the blood donor or to the manufacture of the blood components to the collection facility (Code of Federal Regulations. Title 21 CFR 606.170(a), 2006) and are required to report suspected transfusion-related fatalities directly to FDA (Code of Federal Regulations Title 21 CFR 606.170(b), 2006).

Definitions Signs and symptoms definitions are in Appendix A. Specific adverse reaction definitions and case definition criteria are in Appendix B. Common antibodies associated with hemolytic transfusion reactions are listed in Appendix D.

Adverse event – An undesirable and unintended event occurring before, during or after transfusion of blood or blood components that may be related to the administration of the blood or component. It may be the result of an incident (error or accident) and may or may not result in a reaction in the recipient.

Adverse reaction – An undesirable response or effect in a patient temporally associated with the administration of blood or blood component(s). It may or may not be the result of an incident or an interaction between a recipient and blood, which is a biologically active product.

Forms

Hemovigilance Module Monthly Reporting Plan (CDC 57.301) – Complete one plan at the beginning of each month. See tables of instructions for form completion details.

Hemovigilance Monthly Reporting Denominators (CDC 57.303) – Use this form to report monthly denominators that will be used in the calculation of rates. See tables of instructions for form completion details.

Hemovigilance Adverse Reaction (CDC 57.304) – Report each transfusion-associated adverse reaction using this form. Report one reaction per form. If a patient experiences more than one adverse reaction during or following the same transfusion episode, complete a separate form for each reaction making sure that the definition of one reaction is not included in the definition of the other (e.g., hypotensive transfusion reaction should only be reported if hypotension is not a part of the symptom description of another, more specific reaction experienced by the patient during the same episode).

Methods

Denominators – (minimum time period for a report is monthly)

- Number of units of any particular product transfused

Numerators

- Each reported adverse reaction. Adverse reactions that meet case definition criteria as a definitive or probable case will be included as the numerator in all reports unless stated otherwise.
- Deaths related to transfusion
- Others as needed depending on the analysis

Proposed Data Analysis and Output

Facilities will have the ability to generate a number of custom reports. In addition, certain reports will be generated using information from all participating facilities after the first year of data collection is completed. Mechanisms for facilities to use the NHSN hemovigilance module to help generate FDA required reports are being developed.

Aggregate analysis:

1) Rates of each adverse reaction by product transfused
2) Comparison of reaction rates as compared to other facilities of similar structure and size
3) Fatality rates

4) Other analyses and reports may be generated as need dictates

Facility level reports:

1) Detailed line listing of all reactions by selected time period. This includes patient demographics, reaction occurrence details (time, location, etc.), component information, protocol criterion met, grade and relationship, patient outcome.

2) Frequency report

Month, numbers of each reaction per product transfused, total of each product transfused for the time period

3) Fatality report

Patient ID, date of reaction, type of reaction, product(s) received, date of death, relationship to transfusion

4) Adverse reaction rates by type of product (case definition criteria = definitive or probable) – line data

5) Adverse reaction – symptom report

Patient ID number, date, adverse reaction (case definition criteria = definitive, probable or possible), product(s) received, signs & symptoms, severity

6) ABO Incompatibility report – events where blood group of recipient is different than blood group transfused

Patient ID number, date, blood group of recipient, blood group of unit, product transfused, adverse reaction

B. Incidents

In transfusion medicine most incidents do not result in harm to the patient. Studies have shown the risk of erroneous or mistransfusion of red cell (RBC) units to be approximately 1 in 14,000 to 1 in 38,000 [3]. A mistransfusion is failure to give the correct blood to the intended recipient and is a preventable human error; in the worst consequence, this can result in major ABO incompatibility and patient illness or death. Transfusion incidents can involve errors in more than one step of the process of getting the right blood to the right patient. Identification of where in the process these incidents occur can provide information that will help facilities improve their procedures.

Data collection for incident reporting is intended to provide numbers of occurrences and types of incidents and near misses (where the error is discovered before the incorrect product reaches the patient).

Settings

Surveillance should be performed by hospital transfusion services and can be performed in any adult or pediatric acute or chronic care facility where transfusion occurs, including patient care areas for general medical and surgical patients, obstetrics and gynecology, orthopedic, cancer, other chronic disease, and any other patient care setting with transfusion services.

Requirements

Participating facilities are required to report all incidents but have two reporting options:

1) Individual, detailed reports for every incident reported OR
2) Total numbers of all incidents reported by incident code with detailed incident reports required of high priority events (includes any incident associated with an adverse reaction regardless of incident code).

Option 1) is recommended for facilities that do not have an electronic reporting method for incidents and may want to use NHSN for this purpose. For facilities that maintain their own in-house system, option 2) may be preferable.

Report any incident for which an incident report has been filed in blood transfusion services. Detailed incident reports must be filed for any incident associated with an adverse reaction regardless of whether it resulted in harm to the patient or not. "Near miss" reports should be documented as robustly as errors and negative outcomes. All reports should be entered within 30 days of the month of the "date of discovery" for the event when possible.

Definitions (See Appendix F for descriptions of Incident Result and Root Cause Analysis Result)

Adverse event - An undesirable and unintended occurrence before, during, or after transfusion of blood or a blood component and may be related to the administration of the blood or component. It may be the result of an incident and it may or may not result in a reaction in a recipient.

High priority incident – Any incident that has high potential for wrongful transfusion in a recipient (i.e., wrong blood in tube). These include sample labeling errors, wrong patient collected, and special processing needs not indicated, not done, misunderstood, misinterpreted, etc.

Incident – Any error or accident that could lead to an adverse outcome affecting a) the safety, efficacy, or quality of blood, blood components, or plasma derivatives; or b) the safety of recipients.

Near miss - An incident that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient.

Forms

Hemovigilance Monthly Reporting Plan (CDC 57.301) - Complete one plan at the beginning of each month. See tables of instructions for form completion details.

Hemovigilance Module Blood Product Incidents Reporting – Summary Data (CDC 57.302) - Required if **Incidents Reporting - summary data with detailed reporting of high priority incidents** is selected as the method of choice on the monthly reporting plan. High priority incidents are indicated by a + next to the code. Detailed incident reports for those resulting in an adverse reaction should be completed regardless of code. In addition, detailed incident reports can be filed for any incident where additional information is desired, regardless of the method of reporting used. Be sure to include the detailed reports in your totals on the summary data form.

Hemovigilance Monthly Reporting Denominators (CDC 57.303) - Use this form to report monthly denominators that will be used in the calculation of rates. See tables of instructions for form completion details.

Hemovigilance Incident (CDC 57.305) – Use one form per reported incident. See tables of instructions for form completion details.

Methods

Denominators (monthly)

- Number of products transfused
- Number of samples collected for type and screen or crossmatch

Numerators

- Each reported incident
- Adverse reactions associated with incidents
- High priority incidents
- Other form variables as needed

Proposed Data Analysis and Output

Facilities will be able to generate standard and custom reports. In addition, certain reports will be generated using information from all participating facilities after the first year of data collection is

completed. Mechanisms for facilities to use the NHSN Hemovigilance Module to help generate FDA required reports are being developed.

Aggregate analysis and reports could include:

1) Incident rates based on numbers of reported incidents per number of samples collected for type and screen or crossmatch
2) "High priority" incident rates derived from numbers of reported incidents with high priority incident codes per number of samples collected for type and screen or crossmatch
3) Adverse reaction rates derived from number of incidents resulting in adverse reactions per number of samples collected for type and screen or crossmatch

Facility level reports:

1) Line listing of detailed incidents reported in a time period. Includes discovery date, time, location; occurrence date, time, location; event code for where in process the incident first occurred, incident result, product action, other action
2) Custom report of incidents of a particular type (for example, sample labeling errors)
3) Incidents resulting in adverse reactions

REFERENCES

1. AABB Survey. *The 2005 nationwide blood collection and utilization survey report.* Available at: http://www.aabb.org/apps/docs/05nbcusrpt.pdf.
2. Eder AF, Chambers L. Noninfectious complications of blood transfusion. *Arch Pathol Lab Med*. 2007; 131: 708-718.
3. Linden JV, Wagner K, Voytovich AE, Sheehan J. Transfusion errors in New York State: an analysis of 10 years' experience. *Transfusion.* 2000; 40: 1207-1213.

Appendix A

Signs & Symptoms Related to Transfusion Reactions, Laboratory Definitions

Chills/rigors – A feeling of cold with shivering or shaking and pallor, occurring during or within 4 hours of transfusion.

Dark urine – Urine becomes dark or reddish brown.

Decrease in blood pressure – A drop in systolic blood pressure by ≥ 30 mm Hg during or within 4 hours of the completion of transfusion.

Diffuse hemorrhage – Characterized by diffuse uncontrollable bleeding at puncture sites, catheter wounds (including hematuria), surgical wounds or diffuse mucocutaneous bleeding during or within 4 hours of the completion of transfusion.

Fever – An increase of ≥ 1° C in temperature over the pre-transfusion temperature during or within 4 hours of the completion of the transfusion.

Hematuria – Presence of blood or red blood cells in the urine.

Hemoglobinemia – The presence of free hemoglobin in the blood plasma.

Hypoxemia – Abnormal deficiency in the concentration of oxygen in arterial blood. PaO_2 / FiO_2 > 300 mm Hg OR Oxygen saturation is < 90% on room air.

Increase in blood pressure – A rise in systolic blood pressure by ≥ 30 mm HG during or within 4 hours of the completion of transfusion.

Jaundice – New onset or worsening of yellow discoloration (icterus) of the skin or sclera (scleral icterus) secondary to an increased level of bilirubin.

Nausea/vomiting – Nausea and/or vomiting experienced during or within 4 hours of the completion of transfusion.

Oliguria – New onset of decreased urinary output within 72 hours of the identification of the blood transfusion reaction (< 500 cc output per 24 hours).

Other skin rash – Other (non-urticarial) skin rash experienced during or within 4 hours of the completion of transfusion.

Pain (abdominal, back, chest, flank, headache, pain at infusion site or other pain) – Pain experienced at any site during or within 4 hours of completion of transfusion.

Pruritis – itching.

Shock – A drop in blood pressure accompanied by a drop in cardiac output including rapid heart rate (increase to ≥ 100 beats per minute), rapid breathing, cutaneous vasoconstriction, pallor, sweating, decreased or scanty urine production, agitation and/or loss of consciousness that required fluid resuscitation, with or without inotropic support.

Shortness of breath (dyspnea) – New onset or significant worsening of shortness of breath; or a significant increase in respiratory rate (with or without hypoxemia) during or within 24 hours of the completion of transfusion.

Urticaria – Raised red spots with or without itching, or generalized itching without redness during or within 4 hours of the completion of the transfusion.

Appendix B

Adverse Reaction Definitions and Case Definition Criteria

1. **Allergic reaction –** The result of an interaction of an allergen with preformed antibodies. In some instances, infusion of antibodies from an atopic donor may also be involved. It may present with only mucocutaneous signs and symptoms.

Case Definition Criteria		Grade (Severity)	Relationship to Transfusion (Imputability)
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: ≥ 2 of the following occurring during the transfusion: • Morbilliform rash with or without pruritus • Urticaria (hives) • Pruritis • Generalized flushing • Localized angioedema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Conjunctival edema • Respiratory distress, bronchospasm • Hypotension. **Probable: N/A** **Possible: N/A**	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	**Grade 1:** No immediate risk to the life of the patient **AND** Responds quickly to symptomatic treatment. **Grade 2 – 4:** Involves respiratory and/or cardiovascular systems and presents like an anaphylactic reaction. There is anaphylaxis when, in addition to mucocutaneous symptoms there are airway symptoms or hypotension (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs during or very shortly after transfusion. For the purpose of classification this type of allergic reaction would be graded as 2 (severe), 3 (life-threatening) or 4 (death) depending on the course and outcome of the reaction.	**Definite:** No other evidence of environmental, drug or dietary risks **AND** Occurs within 1-2 hours of transfusion. **Probable:** Other potential causes in an individual with known susceptibility (atopic; previous allergic reactions to transfusions). **AND** Occurs within 1-2 hours of transfusion. **Possible**: Other likely causes such as medication or exposures but transfusion cannot be ruled out, usually a first reaction of this sort. **AND** Occur 2-4 hours after transfusion.

2. Hemolytic transfusion reaction - A reaction where there are clinical and laboratory signs of increased destruction of transfused red blood cells. Hemolysis can occur intravascularly or extravascularly and can be immediate (acute) or delayed.

A. Acute hemolytic transfusion reaction (AHTR) - Rapid destruction of red blood cells immediately after or within 24 hours of a transfusion. Clinical and laboratory signs of hemolysis are present. No single criterion exists to definitively diagnose this rare disorder. See Appendix D for common antibodies associated with AHTR.

<table>
<tr><th colspan="2">Case Definition Criteria</th><th>Grade (Severity)</th><th>Relationship to Transfusion (Imputability)</th></tr>
<tr><th>Signs & Symptoms</th><th>Laboratory/Radiology</th><td rowspan="2"></td><td rowspan="2"></td></tr>
<tr><td colspan="2">Clinical or laboratory signs of hemolysis</td></tr>
<tr><td>Definitive:
Occurs during, immediately after, or within 24 hours of transfusion WITH ANY of the following:
• Chills/rigors
• Fever
• Back/flank pain
• Hypotension
• Hemoglobinuria occurring during or shortly after transfusion
• Epistaxis
• Oliguria/ anuria
• Renal failure
• Disseminated intravascular coagulation (DIC)
• Pain and/or oozing at IV site

AND EITHER
ABO incompatibility or other allotypic RBC antigen incompatibility
OR
Clerical check indicates that the patient’s name and blood group on the blood unit are different than the recipient’s name and blood group.

Probable:
Any combination of clinical features as above

Possible:
N/A</td><td>Definitive:
Positive direct antiglobulin test for anti-IgG or anti-C3
AND
Positive elution test with alloantibody present on the transfused red blood cells
AND
≥ 2 of the following:
• Elevated LDH
• Elevated bilirubin
• Low haptoglobin
• Hemoglobinuria
• Low fibrinogen
• Elevated plasma hemoglobin

Probable:
Incomplete definitive criteria laboratory confirmation.

Possible:
N/A</td><td>Use severity grades as provided in Appendix C.</td><td>Definite:
Occurs during, immediately after or within 24 hours of transfusion.
AND EITHER
There is known ABO or other allotypic RBC antigen incompatibility
OR
Serologic work-up c/w AHTR
AND
No other cause of acute hemolysis.

Probable:
No serologic evidence
AND
Blood bank testing usually shows abnormal results but AHTR may also be due to erythrocyte auto-antibodies in the recipient.

Possible:
Evidence of non-immune contributing factors e.g., mechanical factors inducing hemolysis (malfunction of a pump, a blood warmer, use of hypotonic solutions, etc.).</td></tr>
</table>

B. Delayed hemolytic transfusion reaction (DHTR) – The recipient develops antibody to RBC antigens. Usually manifests between 24 hours and 28 days after a transfusion and clinical or biological signs of hemolysis are present. See Appendix D for common antibodies associated with DHTR.

Case Definition Criteria		**Grade (Severity)**	**Relationship to Transfusion (Imputability)**
Signs & Symptoms	**Laboratory/Radiology**		
Clinical or laboratory symptoms		Use grades as provided in Appendix C.	**Definite:** Newly identified red blood cell alloantibody **AND** Occurs between 24 hours and 28 days after a transfusion **AND** Positive direct antiglobulin test with identification of a new antibody either in the serum or eluate **AND** No other explanation for drop in hemoglobin. **Probable:** Occurs between 24 hours and 28 days after a transfusion. **AND** No other explanation for drop in hemoglobin. **AND** No confirmation on serologic testing. **Possible:** N/A
Definitive: Patient may be <u>asymptomatic</u> or have similar, but milder symptoms to AHTR. <u>Examples of milder</u> symptoms include: (NOTE: These are NOT required to meet case criteria.) • Chills/rigors • Fever • Jaundice • Back/flank pain • Hypotension • Hemoglobinuria/ hematuria • Oliguria/ anuria.	**Definitive:** Positive direct antiglobulin (Coombs) test **AND EITHER** Positive elution test with alloantibody present on the transfused red blood cells **OR** Newly identified red blood cell alloantibody in recipient serum **AND EITHER** Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels **OR** Otherwise unexplained appearance of spherocytes **NOTE**: If performed, post transfusion increases in LDH and bilirubin, which subsequently falls back to baseline in the following days.		
Probable: Same as above except there is no serologic confirmation of HTR. **Possible:** N/A	**Probable:** Newly identified red blood cell alloantibody. **Possible:** N/A		

C. Delayed serologic transfusion reaction (DSTR) – Demonstration of new, clinically significant alloantibodies against red blood cells between 24 hours to 28 days after a transfusion despite an adequate hemoglobin response to transfusion that is maintained. See Appendix D for common antibodies associated with DSTR.

Case Definition Criteria		**Grade (Severity)**	**Relationship to Transfusion (Imputability)**
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: No clinical or laboratory signs of hemolysis. **Probable**: N/A **Possible**: N/A	**Definitive:** After a transfusion there is demonstration of new, clinically significant antibodies against red blood cells which were not present in the pre-transfusion specimen **EITHER THROUGH:** Positive direct antiglobulin test **OR** Positive antibody screen with newly identified RBC alloantibody. **Probable**: N/A **Possible**: N/A	Use grades as provided in Appendix C.	**Definite**: Recent RBC transfusion with subsequent formation of newly identified RBC alloantibody **OR** Positive direct antiglobulin test. **Probable**: N/A **Possible**: N/A

3. Hypotensive transfusion reaction - Drop in systolic and/or diastolic blood pressure of > 30 mm Hg occurring during or within one hour of completing transfusion.

Case Definition Criteria		Grade (Severity)	Relationship to Transfusion (Imputability)
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: **ALL OF THE FOLLOWING:** • Hypotension (Drop in systolic and/or diastolic blood pressure of > 30 mm Hg). (**NOTE:** Other symptoms like facial flushing, dyspnea or abdominal cramps may occur but usually hypotension is the sole manifestation.) • Occurs within 15 minutes after the start of the transfusion • Responds rapidly (within 10 minutes) to cessation of transfusion and supportive treatment • All other categories of adverse reactions presenting with hypotension must have been excluded. **Note**: If the patient meets the criteria for another, more specific adverse transfusion reaction (with hypotension as a symptom of that reaction), the specific adverse reaction should be reported rather than the hypotension.	**Definitive:** N/A	**Grade 1:** The recipient required no more than discontinuation of transfusion and symptomatic management **AND** No long-term morbidity. **Grade 2:** The recipient required in-patient hospitalization or prolongation of hospitalization due to hypotension; or hypotension led directly to long-term morbidity (e.g., brain damage) **AND** Vasopressors not required. **Grade 3:** The recipient required vasopressors. **Grade 4:** Patient died as a result of hypotensive transfusion reaction or as a result of treatment directed at resolving symptoms of hypotensive transfusion reaction.	**Definite:** Meets **definitive** protocol criterion. The patient has no other conditions that could explain hypotension. **Probable:** Other conditions that could explain hypotension are unlikely but not fully excluded. **Possible:** Other conditions that could readily explain hypotension are present.
Probable: Same as definitive criteria **EXCEPT:** Onset is greater than 15 minutes after start of transfusion. **OR** Does not respond within 10 minutes to cessation of transfusion and supportive treatment	**Probable:** N/A		
Possible: Same as definitive criteria **EXCEPT:** Other conditions are present or were present before the transfusion that could explain hypotension.	**Possible:** N/A		

4. **Febrile non hemolytic transfusion reaction (FNHTR) –** Fever and/or chills without hemolysis occurring in the patient up to 4 hours during and after transfusion. If transfusion-related the most common cause is a reaction to passively transfused cytokines or a reaction of recipient antibodies and leukocytes in the donor's blood.

Case Definition Criteria		**Grade (Severity)**	**Relationship to Transfusion (Imputability)**
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: Fever (≥ 38°C oral or equivalent and a change of ≥ 1°C from pre-transfusion value) **AND** Occurs during or within 4 hours of transfusion **Probable:** N/A **Possible:** N/A	**If Performed (but not required to meet definitive criteria):** • Negative culture of residual component • Negative post-transfusion patient blood culture • Lab findings not consistent with acute hemolysis as cause of fever.	Use grades as provided in Appendix C.	**Definite:** Meets **definitive** protocol criterion and the patient has no other conditions that could explain symptoms. **Probable:** Other conditions that could explain fever/chills are unlikely but not fully excluded. **Possible:** Other conditions are present or were present before the transfusion that could explain the symptoms.

5. Post transfusion purpura (PTP) – Characterized by thrombocytopenia usually arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen(HPA) system.

Case Definition Criteria		Grade (Severity)	Relationship to Transfusion (Imputability)
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: Thrombocytopenia (decrease to < 20% of pre-transfusion count) **AND** Occurs 5-12 days post-transfusion.	**Definitive:** Alloantibodies in the patient directed against HPA -1a or other platelet specific antigen detected at or after development of reaction.	Use grades as provided in Appendix C.	**Definite:** Protocol criterion = Definitive **OR** Probable **Probable:** N/A **Possible:** Protocol criterion = Possible
Probable: Thrombocytopenia (decrease to < 20% of pre-transfusion count) **BUT** 5-12 days post-transfusion timeframe not met **OR** Thrombocytopenia (decrease to < 20% of pre-transfusion count) with competing explanations **OR** Drop in platelets between 20% and 80% of pre-transfusion count.	**Probable:** Alloantibodies in the patient directed against HPA-1a or other platelet specific antigen detected at or after development of reaction.		
Possible: Clinical and Laboratory presentation meet definitive or probable criteria; **BUT** alternate explanations more likely. **OR** Clinical presentation meets definitive or probable criteria; **HOWEVER**, HPA antibodies not tested or negative.	**Possible:** See Possible Clinical criteria for Laboratory criteria.		

6. **Transfusion associated circulatory overload (TACO)** – Volume infusion that cannot be effectively processed by the recipient either due to high rates and volumes of infusion or underlying cardiac or pulmonary pathology.

Case Definition Criteria		Grade (Severity)	Relationship to Transfusion (Imputability)
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: Characterized by new onset or exacerbation of ≥ 3 of the following within 6 hours of transfusion: • Acute respiratory distress (dyspnea, orthopnea, cough) • Evidence of positive fluid balance • Elevated BNP (Brain Natriuretic Peptide) • Radiographic evidence of pulmonary edema • Evidence of left heart failure • Elevated CVP (central venous pressure). **Probable:** N/A **Possible:** N/A	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	Use grades as provided in Appendix C.	**Definite:** Meets definitive protocol criterion and no other cause of volume overload. **Probable:** Judgment call by the attending physician. Patient received other fluids, and transfusion is likely contributory to volume overload. **Possible:** For patients with pre-existing cardiac insufficiency, imputability should not be classified higher than "possible".

7. Transfusion associated dyspnea (TAD) - Characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition.

Case Definition Criteria		**Grade (Severity)**	**Relationship to Transfusion (Imputability)**
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: Acute respiratory distress **AND** Occurs within 24 hours of transfusion **AND** TRALI, TACO, allergic reaction and patient's underlying condition ruled out. **Probable:** N/A **Possible:** N/A	**Definitive:** N/A **Probable:** N/A **Possible:** N/A	Use grades as provided in Appendix C.	Use the general criteria of Imputability in Appendix C.

8. Transfusion associated - graft vs. host disease (TA-GVHD) - The introduction of immunocompetent lymphocytes into susceptible hosts. The allogeneic lymphocytes engraft, proliferate and destroy host cells.

Case Definition Criteria		Grade (Severity)	Relationship to Transfusion (Imputability)
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: A clinical syndrome occurring from 2 days to 6 weeks following transfusion characterized by symptoms of: • Fever • Characteristic rash (erythematous, maculopapular eruption centrally that spreads to extremities and may progress to generalized erythroderma and hemorrhagic bullous formation in severe cases) • Hepatomegaly • Diarrhea **Probable:** Clinical presentation c/w TA-GVHD described above. **Possible:** Clinical presentation c/w TA-GVHD described above.	**Definitive:** Liver dysfunction (elevated ALT, AST, Alkaline phosphatase) and elevated bilirubin **AND** Pancytopenia (**NOTE:** If performed, marrow study shows hypoplasia, aplastic anemia, or marked hypocellularity with a lymphohistiocytic infiltrate). **AND** WBC chimerism in the absence of alternative diagnoses (i.e., not attributable to a source other than transfusion) **AND** Characteristic histological appearances on skin biopsy or liver biopsy. **Probable:** Meets definitive criteria **EXCEPT** not confirmed by chimerism (i.e., not done or negative) **Possible:** Meets definitive criteria **EXCEPT** neither confirmed by chimerism (i.e., not done or negative) nor biopsy results.	**Grade 1:** N/A **Grade 2:** Patient had marked symptoms, responded to treatment. **Grade 3:** Patient alive due to treatment (e.g. immunosuppression). **Grade 4:** Patient died from TA-GVHD.	**Definite:** Meets definitive protocol criterion and related to blood donor. Matching chimeric alleles in donor and recipient. **Probable:** Presentation consistent with TA-GVHD; however, chimerism demonstrated in recipient but matching alleles could not be tested in the donor. **Possible:** Apparent TA-GVHD when alternative explanations of cause are likely but TA-GVHD cannot be confirmed, such as with negative chimerism studies or in the setting of allogeneic solid organ transplantation.

9. Transfusion-related acute lung injury (TRALI) – Acute hypoxemia with PaO_2/fraction of inspired oxygen [FIO_2] ratio of 300 mm Hg or less combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). There is abrupt onset in association with transfusion.

Case Definition Criteria		**Grade (Severity)**	**Relationship to Transfusion (Imputability)**
Signs & Symptoms	**Laboratory/Radiology**		
Definitive: NO evidence of acute lung injury (ALI) prior to transfusion **AND** Acute onset of ALI during or within 6 hours of transfusion **AND** Hypoxemia defined by: • PaO_2 / $FiO_2 \leq$ 300 mm Hg **OR** • Oxygen saturation is < 90% on room air **OR** • Other clinical evidence **AND** NO evidence of left atrial hypertension (i.e. circulatory overload) **AND** NO temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion.	**Definitive:** Bilateral infiltrates on chest radiograph	Use grades as provided in Appendix C.	If protocol criterion = **Definitive** then relationship is **Definite** If protocol criterion = **Possible** then relationship is **Possible**
Probable: N/A	**Probable:** N/A		
Possible: Same as definitive **EXCEPT** there is a temporal relationship to one of the following alternate risk factors: • Direct Lung Injury o Aspiration o Pneumonia o Toxic inhalation o Lung contusion o Near drowning • Indirect Lung Injury o Severe sepsis o Shock o Multiple trauma o Burn injury o Acute pancreatitis o Cardiopulmonary bypass o Drug overdose	**Possible:** N/A		

10. Infection

Any infectious organism is available from the pathogen list in NHSN. The pathogens in this table appear at the top of the drop-down list because 1) they have public health significance for hemovigilance 2) are common blood stream infection pathogens and/or 3) are routinely screened in blood donors.

Bacterial	Viral	Parasitic	Other
Escherichia coli *Klebsiella oxytoca* *Klebsiella pneumoniae* *Pseudomonas aeruginosa* *Serratia marcescens* *Staphylococcus aureus* *Staphylococcus epidermidis* *Staphylococcus lugdunensis* Syphilis (*Treponema pallidum*) *Yersinia enterocolitica*	Cytomegalovirus (CMV) Enterovirus Epstein Barr (EBV) Hepatitis A Hepatitis B Hepatitis C Human Immunodeficiency Virus 1 (HIV-1) Human Immunodeficiency Virus 2 (HIV-2) Human Parvovirus B-19 Human T-Cell Lymphotropic (or, leukemia) Virus – 1 (HTLV-1) Human T-Cell Lymphotropic (or, leukemia) Virus – 2 (HTLV-2) West Nile Virus *(Flaviviridae*)	Babesiosis (*Babesia microti*) Chagas (*Trypanosoma cruzi*) Malaria (*Plasmodium spp)*	Creutzfeldt -Jakob Disease, Variant (vCJD)

Investigation triggers for infections thought to be transfusion-transmitted:

Any of these:

1. Identification by testing (e.g., gram stain, other smear/staining, culture, or other method) of an unexpected bacterial, mycobacterial, or fungal organism in a recipient within the time period from exposure (i.e., transfusion) to onset of infection appropriate for the suspected pathogen
2. Identification of an unexpected virus in the recipient by testing (e.g., culture, direct fluorescent antibody or polymerase chain reaction) within the time period from exposure (i.e., transfusion) to onset of infection appropriate for the suspected virus
3. Identification of an unexpected parasite in the recipient by blood smear, histopathology or stool testing for ova/parasites within the time period from exposure (i.e., transfusion) to onset of infection appropriate for the suspected parasite
4. Any of the above laboratory findings in the recipient unit upon residual testing
5. Unexplained clinical events occurring after transfusion that are consistent with transfusion-transmitted disease, such as:
    a. Encephalitis, meningitis, or other unexplained central nervous system abnormalities
    b. Sepsis with or without multi-system organ failure
    c. Recipient death
6. In addition, for infections routinely screened in the blood donor, any infection in the recipient occurring within 6 months after transfusion if:
    a. The index donation testing was negative and
    b. The donor was subsequently found to be infected, but
    c. The recipient had no pre-transfusion history of the same infection.

For a decision on imputability, the following evidence is considered:

1. Evidence of contamination of the recipient unit upon residual testing
2. Pre- and post- transfusion infection status (e.g., seroconversion) in the recipient

3. Evidence of other recipients with infection from the same organism who received blood from the same donor
4. Evidence of donor infection with the same organism.

<u>Imputability</u> (only report definite, probable, or possible)

Definite:

1. An investigation trigger with laboratory evidence of the suspected organism in the recipient AND
2. Laboratory evidence that the same recipient was negative for this organism prior to transfusion AND
3. Laboratory evidence of the same organism in the donor (NOTE: For bacterial cases, identification of the organism in the unit upon residual testing is equivalent to laboratory evidence of the same organism in the donor).

AND EITHER

4. Laboratory evidence of the same organism in any other recipients from the same donor as the initial case recipient OR
5. Laboratory evidence of the same organism in the recipient unit upon residual testing.

Probable:

1. An investigation trigger with laboratory evidence of the suspected organism in the recipient

Plus any <u>two</u> of the following:

2. Laboratory evidence that the same recipient was negative for this organism prior to transfusion *OR*
3. Laboratory evidence of the same organism in other recipients (if any) from the same donor as the initial case recipient *OR*
4. Laboratory evidence of the same organism infecting the donor *OR*
5. Laboratory evidence of the same organism in the recipient unit upon residual testing.

Possible (indeterminate):

1. An investigation trigger
2. Information essential for confirming or ruling out a case is missing, not available, or cannot be obtained
3. Case fails to meet definition for **definite, probable** or **ruled out.**

Doubtful or Ruled Out: (Do not file a report with NHSN)

1. Laboratory evidence that the donor is negative for infection
   OR
2. Laboratory evidence that the recipient had infection with this organism prior to transfusion.

Appendix C

Severity Grade and Imputability for Adverse Reactions

Severity

Grade 1 (Non-Severe):

- Medical intervention (e.g. symptomatic treatment) required but lack of such would not result in permanent damage or impairment of a body function.

Grade 2 (Severe):

- Inpatient hospitalization or prolongation of hospitalization directly attributable to the event and/or:
  - Persistent or significant disability or incapacity

  OR
  - A medical or surgical intervention that is necessary to preclude permanent damage or impairment of a body function.

Grade 3 (Life-threatening):

- Major intervention required following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death

Grade 4 (Death):

- The recipient died following an adverse transfusion reaction. [**Note:** Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be graded as 1, 2 or 3 as appropriate.]

Imputability

Once the investigation of the adverse transfusion reaction is completed, this is the assessment of the strength of the relationship between the transfusion and the adverse reaction.

Definite (certain):	Conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion
Probable (likely):	Evidence is clearly in favor of attributing the adverse event to the transfusion
Possible:	Evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause
***Doubtful**:*	*Evidence is clearly in favor of attributing the adverse event to causes other than the transfusion*
***Ruled Out:**	*Conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion*
Not Determined:	The relationship between the adverse reaction and the transfusion is unknown or not stated.

* Adverse reactions for which Imputability is *doubtful* or *ruled out* should not be routinely reported. The only time these categories can be used is where a reaction was initially thought to be transfusion-related but later information revealed a non-transfusion related cause.

Appendix D

Common Antibodies Associated with Hemolytic Transfusion Reactions (AHTR, DHTR, DSTR)

Anti-A
Anti-B
Anti-A,B
Anti-C
Anti-D
Anti-E
Anti-c
Anti-e
Anti-K
Anti-k
Anti-Jk^a
Anti-Jk^b
Anti-S
Anti-Fy^a
Anti-Fy^b
Anti-M
Other

Appendix E

NHSN Occupation Type (Job Function) Codes

Lab

MLT	Medical Lab Technician
IVT	IVT Team Staff
PHL	Phlebotomist/IV Team
MTE	Medical Technologist

Nursing Staff

CNA	Nurse Anesthetist
LPN	Licensed Practical Nurse
NMW	Nurse Midwife
NUA	Nursing Assistant
NUP	Nurse Practitioner
RNU	Registered Nurse

Physician

FEL	Fellow
MST	Medical Student
PHY	Physician
RES	Intern/Resident

Technicians

EMT	EMT/Paramedic
HEM	Hemodialysis Technician
ORS	OR/Surgery Technician
PCT	Patient Care Technician

Other Personnel

CLA	Clerical/administrative
TRA	Transport/Messenger/Porter

Additional Occupation Types

ATT	Attendant/orderly	PHA	Pharmacist
CSS	Central Supply	PHW	Public Health Worker
CSW	Counselor/Social Worker	PLT	Physical Therapist
DIT	Dietician	PSY	Psychiatric Technician
DNA	Dental Assistant/Tech	RCH	Researcher
DNH	Dental Hygienist	RDT	Radiologic Technologist
DNO	Other Dental Worker	RTT	Respiratory Therapist/Tech
FOS	Food Service	STU	Other Student
HSK	Housekeeper	VOL	Volunteer
ICP	Infection Control Professional		
LAU	Laundry Staff		
MNT	Maintenance/Engineering		
MOR	Morgue Technician	OTH	Other (Specify)
OAS	Other Ancillary Staff		
OFR	Other First Responder		
OH	Occupational Health Professional		
OMS	Other Medical Staff		
OTT	Other Technician/Therapist		

Appendix F

Incident Codes (based on MERS-TM & TESS)

☐ **Product Check-In** (Products Received from Outside Source)
PC 01 Data entry incomplete/not performed/incorrect
PC 02 Shipment incomplete/incorrect
PC 03 Product & paperwork do not match
PC 04 Shipped under inappropriate conditions
PC 05 Inappropriate return to inventory
PC 06 Product confirmation
PC 07 Administrative check (2nd check)

☐ **Product/Test Request** (Clinical Service)
PR 01 Order for wrong patient
PR 02 Order incorrectly entered on-line
PR 03 Special needs not indicated on order (e.g., CMV negative, auto)
PR 04 Order not done/incomplete/incorrect
PR 05 Inappropriate/incorrect test ordered
PR 06 Inappropriate/incorrect blood product ordered

☐ **Sample Collection** (Service Collecting Samples)
SC 01 Sample labeled with incorrect patient name
SC 02 Not labeled
SC 03 Wrong patient collected
SC 04 Collected in wrong tube type
SC 05 Sample QNS
SC 06 Sample hemolyzed
SC 07 Label incomplete/illegible/incorrect (other than patient name)
SC 08 Sample collected in error
SC 09 Requisition arrives without samples
SC 10 Wristband incorrect/not available
SC 11 Sample contaminated

☐ **Sample Handling** (Service Collecting Samples)
SH 01 Sample arrives without requisition
SH 02 Requisition & sample label don't match
SH 03 Patient ID incorrect/illegible on requisition
SH 05 No phlebotomist/witness identification
SH 06 Sample arrives with incorrect requisition
SH 07 Patient information (other than ID)

☐ **Sample Receipt** (Transfusion Service)
SR 01 Sample processed in error
SR 02 Historical review incorrect/not done
SR 03 Demographic review/data entry incorrect/ not done
SR 04 Sample incorrectly accessioned (test/product)
SR 05 Duplicate sample sent

☐ **Sample Testing** (Transfusion Service)
ST 01 Data entry incorrect/not performed
ST 02 Appropriate sample checks not done
ST 03 Computer warning overridden
ST 05 Sample tube w/ incorrect accession label
ST 07 Sample tubes mixed up
ST 09 Test tubes mislabeled (wrong patient name/number)
ST 10 Equipment problem
ST 12 Patient testing not performed
ST 13 Incorrect testing method chosen
ST 14 Testing performed incorrectly
ST 15 Test result misinterpreted
ST 16 Inappropriate/expired reagents used
ST 17 ABO/Rh error caught on final check
ST 18 Current & historical ABO/Rh don't match
ST 19 Additional testing not performed
ST 20 Administrative check at time work performed
ST 22 Sample storage incorrect/inappropriate

☐ **Product Storage** (Transfusion Service)
US 01 Incorrect storage of unit in transfusion service
US 02 Expired product in stock
US 03 Inappropriate monitoring of storage device
US 04 Unit stored on incorrect ABO shelf

☐ **Available for Issue** (Transfusion Service)
AV 01 Inventory audits
AV 02 Product status not/incorrectly updated in computer
AV 03 Supplier recall
AV 04 Product ordered incorrectly/not submitted

☐ **Product Selection** (Transfusion Service)
SE 01 Incorrect product/component selected

☐ **Product Manipulation** (Transfusion Service)
UM 01 Data entry incomplete/incorrect
UM 02 Record review incomplete/incorrect
UM 03 Wrong component selected
UM 04 Administrative check (at time of manipulation)
UM 05 Labeling incorrect
UM 07 Special processing needs not checked
UM 08 Special processing misunderstood or misinterpreted
UM 09 Special processing not done/incorrectly done

☐ **Request for Pick-up** (Clinical Service)
RP 01 Request for pick-up on wrong patient
RP 02 Incorrect product requested for pick-up
RP 03 Product requested prior to obtaining consent
RP 04 Product requested for pick-up pt not available
RP 05 Product requested for pick-up IV not ready
RP 06 Request for pick-up incomplete
RP 10 Product transport issues

☐ **Product Issue** (Transfusion Service)
UI 01 Data entry incomplete/incorrect
UI 02 Record review incomplete/incorrect
UI 03 Pick-up slip did not match patient information
UI 04 Incorrect unit selected (wrong person or right person wrong order)
UI 05 Issue delayed
UI 06 LIS warning overridden
UI 07 Computer issue not completed
UI 09 Not checking/incorrect checking of unit and/or patient information
UI 11 Unit delivered to incorrect location
UI 19 Wrong product issued
UI 20 Administrative review (self, 2nd check at issue)
UI 22 Issue approval not obtained/documented

☐ **Product Administration** (Clinical Service)
UT 01 Administered product to wrong patient
UT 02 Administered wrong product to patient
UT 03 Product not administered
UT 04 Incorrect storage of product on floor
UT 05 Administrative review (unit/patient at bedside)
UT 06 Administered product w/ incompatible IV fluid
UT 07 Administration delayed
UT 08 Wrong unit chosen from satellite refrigerator
UT 10 Administered components in inappropriate

missing/incorrect on requisition SH 10 Sample transport issues	SE 02 Data entry incomplete/incorrect SE 03 Not checking/incorrect checking of product and/or patient information SE 05 Historical file misinterpreted/not checked SE 07 Special processing needs not checked SE 09 Special processing needs not understood or misinterpreted SE 11 Special processing not done	order UT 11 Appropriate monitoring of patient not done UT 12 Floor/clinic did not check for existing products in their area UT 13 Labeling problem on unit UT 19 Transfusion protocol not followed ☐ **Other** MS 99

Appendix G

Incident Reporting Definitions

Incident Result

1 = No Recovery, harm
Product was transfused and the patient experienced an adverse reaction.

2 = No Recovery, no harm
Product was transfused, but the patient did not experience an adverse reaction.

3 = Near miss, unplanned recovery
Product was not transfused. The incident was discovered ad hoc, by accident, a human lucky catch, etc. It was not discovered through formalized facility standard operating procedures or other previously instituted checks and balances.

4 = Near miss, planned recovery.
Product was not transfused. The incident was discovered through standardized processes or barriers built into the system to prevent errors.

Root Cause Analysis Result(s)
Technical:

- Technical failures beyond the control and responsibility of the facility
- Failure due to poor design of equipment, software, labels or forms
- Correct design but not constructed properly or set up in in-accessible areas
- Other material defects.

Organizational:

- Failure at an organizational level beyond the control and responsibility of the facility or department where the incident occurred
- Failure resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff
- Failure relating to the quality and availability of the protocols/procedures within the department (e.g., too complicated, inaccurate, unrealistic, absent or poorly presented)
- Internal management decisions when faced with conflicting demands or objectives. Failures resulting from collective approach and its attendant modes of behavior to risks in the investigating organization. These are organizational cultural attitudes and behaviors. For example, if the organizational culture is one where compliance with safety related procedures is low or procedures are not enforced.

Human:

- Human failures originating beyond the control and responsibility of the investigating organization. This could include individuals in other departments
- Inability of an individual to apply their existing knowledge to a novel situation. Example: a blood bank technologist who is unable to solve a complex antibody identification problem
- The incorrect fit between an individual's training or education and a particular task. Example: expecting a technician to solve the same type of difficult problem as a technologist
- A lack of task coordination within a health care team. Example: an essential task not being performed because everyone thought that someone else had completed the task

- Incorrect or incomplete assessment of a situation including related conditions of the patient and materials to be used before starting the transfusion. Example: failure to correctly identify the patient by checking the wristband
- Faulty task planning and execution. Example: washing red blood cells using the same protocol as that used for platelets
- Failure in monitoring a process or patient status. Examples: a trained technologist operating an automated instrument and not realizing that a pipette that dispenses a reagent is clogged. Failure of the patient care staff to observe an allergic reaction in a patient after a transfusion is started
- Failure in performance of highly developed skills. Example: a technologist adding drops of reagents to a row of test tubes misses a tube or a computer entry error
- Failure in whole body movements. "Slips, trips and falls." Examples: a blood bag slipping out of one's hands and breaking; or a person tripping over a loose tile on the floor.

Patient-related

- Failures related to patient characteristics or conditions which are beyond the control of staff and influence treatment.

Other

Cannot be classified under any of the other categories.

References

MERS TM (2001). *Medical Event Reporting System for Transfusion Medicine reference manual version 3.0.* New York. Available at http://www.mers-tm.net

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