Other or Unknown

Other: Use this option if the recipient experienced an adverse reaction that is not defined in the Hemovigilance Module surveillance protocol (e.g., transfusion-associated acute gut injury (TRAGI), transfusion-associated immunomodulation (TRIM), iron overload, microchimerism, hyperkalemia, thrombosis).

Unknown: Use this category if the patient experienced transfusion-related symptoms, but the medical event that caused those symptoms could not be classified.

Note: Reporting 'Other' and 'Unknown' reactions is not required by CDC.

REPORTING OPTIONAL		
Case Definition	**Severity**	**Imputability**
Not Applicable: CDC does not specifically define the 'Other' or 'Unknown' adverse reaction categories, therefore the case definition criteria may only be reported as N/A.	**Non-severe:** Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function. **Severe:** Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function. **Life-threatening:** Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death. **Death:** The recipient died **as a result of the adverse transfusion reaction. Death** should be used if death is **possibly**, **probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as appropriate given the clinical circumstances related to the reaction. **Not Determined:** The severity of the adverse reaction is unknown or not stated.	**Definite:** Conclusive evidence exists that the adverse reaction can be attributed to the transfusion. **Probable**: Evidence is clearly in favor of attributing the adverse reaction to the transfusion. **Possible:** Evidence is indeterminate for attributing the adverse reaction to the transfusion or an alternate cause. **Doubtful:** Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded. **Ruled Out:** There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion. **Not Determined:** The relationship between the adverse reaction and the transfusion is unknown or not stated.

Adverse Reaction Glossary

Antibodies often associated with AHTR, DHTR, DSTR:

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

Bronchospasm (wheezing): A contraction of smooth muscle in the walls of the bronchi and bronchioles, causing acute narrowing and obstruction of the respiratory airway. This constriction can result in a rasp or whistling sound while breathing.

Chills/rigors: A feeling of cold with shivering or shaking and pallor.

Disseminated intravascular coagulation (DIC): Bleeding disorder characterized by reduction in the factors involved in blood clotting due to their use in widespread clotting within the vessels. The intravascular clotting ultimately produces hemorrhage because of rapid consumption of clotting factors.

Edema: Swelling of soft tissues as a result of excessive fluid accumulation.

Epistaxis: Bleeding from the nose.

Fever: For the purposes of hemovigilance, an increase of at least 1°C in temperature over the pre-transfusion value.

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

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

Hemoglobinuria: Presence of free hemoglobin in the urine.

Hypoxemia: Abnormal deficiency in the concentration of oxygen in arterial blood. PaO2 / FiO2 less than or equal to 300 mm Hg OR oxygen saturation is less than 90% on room air.

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

Oliguria: New onset of decreased urinary output (less than 500cc output per 24 hours).

Other rash: Non-urticarial skin rash.

Pruritus: Itching.

Shock: A drop in blood pressure accompanied by a drop in cardiac output including rapid heart rate (increase to 100 beats per minute or more), 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).

Urticaria (hives): Raised wheals on the skin.

Section 4. Hemovigilance Module Incidents

Required Reporting
All incidents (i.e., accidents or errors) that are **associated with a reported adverse reaction** must be reported to NHSN using a detailed Incident form (CDC 57.305). If multiple incidents occur in association with an adverse reaction then report all. Incidents may occur before (e.g., wrong product released) or after (e.g., failure to report adverse reaction to blood bank) an adverse reaction. Each reaction must be reported using the detailed incident form; the incident result must be coded as 'Product transfused, reaction' to enter the associated patient identifier on the form. After the incident record is entered, the adverse reaction record must be linked to the incident record in the NHSN web application.

Incident Classification
Use the incident codes provided at the end of this section to classify incidents. If there is uncertainty then please contact NHSN User Support

Optional Reporting
Any incident may be optionally reported to NHSN using the detailed Incident form (57.305) or the Monthly Incident Summary form (57.302). Approved deviations from standard operating procedure are not considered incidents because they did not occur by accident or in error. However, approved deviations may be optionally reported for a facility's use. Incidents that are optionally reported will not be aggregated or analyzed by CDC.

Form
CDC 57.305 Hemovigilance Module Incident

Form Instructions
CDC 57.305 Hemovigilance Module Incident Table of Instructions

Summary Form (Optional)
CDC 57.302 Hemovigilance Module Monthly Incident Summary

Summary Form Instructions (Optional)
CDC 57.302 Hemovigilance Module Monthly Incident Summary Table of Instructions

Incident Codes

Note: Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

Product Check-In
(Transfusion Service)
Events that occur during the shipment and receipt of products into the transfusion service from the supplier, another hospital site, satellite storage, or clinical area.

- PC 00 Detail not specified
- PC 01 Data entry incomplete/incorrect/not performed
- PC 02 Shipment incomplete/incorrect
- PC 03 Products and paperwork do not match
- PC 04 Shipped/transported under inappropriate conditions
- PC 05 Inappropriate return to inventory
- PC 06 Product confirmation incorrect/not performed
- PC 07 Administrative check not incorrect/not performed (record review/audit)
- PC 08 Product label incorrect/missing

Product Storage
(Transfusion Service)
Events that occur during product storage by the transfusion service.

- US 00 Detail not specified
- US 01 Incorrect storage conditions
- US 03 Inappropriate monitoring of storage device
- US 04 Unit stored on incorrect shelf (e.g., ABO/autologous s/directed)
- US 05 Incorrect storage location

Inventory Management
(Transfusion Service)
Events that involve quality management of the blood product inventory.

- IM 00 Detail not specified
- IM 01 Inventory audit incorrect/not performed
- IM 02 Product status incorrectly/not updated online (e.g., available/discarded)
- IM 03 Supplier recall/traceback not appropriately addressed/not performed
- IM 04 Product order incorrectly/not submitted to supplier
- IM 05 Outdated product in available inventory
- IM 06 Recalled/quarantined product in available inventory

Product/Test Request
(Clinical Service)
Events that occur when the clinical service orders patient tests or blood products for transfusion.

- PR 00 Detail not specified
- PR 01 Order for wrong patient
- PR 02 Order incompletely/incorrectly ordered (online order entry)
- PR 03 Special processing needs not indicated (e.g., CMV negative, autologous)
- PR 04 Order not done
- PR 05 Inappropriate/unnecessary (intended) test ordered
- PR 06 Inappropriate/unnecessary (intended) blood product ordered
- PR 07 Incorrect (unintended) test ordered
- PR 08 Incorrect (unintended) blood product ordered

Product/Test Order Entry
(Transfusion Service)
Events that occur when the transfusion service receives a patient order. This process may be excluded if clinical service uses online ordering.

- OE 00 Detail not specified
- OE 01 Order entered for wrong patient
- OE 02 Order incompletely/incorrectly entered online
- OE 03 Special processing needs not entered (e.g., CMV-, autologous)
- OE 04 Order entry not done
- OE 05 Inappropriate/unnecessary (intended) test order entered
- OE 06 Inappropriate/unnecessary (intended) blood product order entered
- OE 07 Incorrect (unintended) test ordered
- OE 08 Incorrect (unintended) blood product ordered

Sample Collection
(Service collecting the samples)
Events that occur during patient sample collection.

- SC 00 Detail not specified
- 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 arrived without samples
- SC 10 Wristband incorrect/not available
- SC 11 Sample contaminated

Incident Codes

(continued)

Note: Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

Sample Handling
(Service collecting the samples)
Events that occur when a patient sample is sent for testing.

- SH 00 Detail not specified
- SH 01 Sample sent without requisition
- SH 02 Requisition and sample label don't match
- SH 03 Patient ID incomplete/illegible on requisition
- SH 04 No Patient ID on requisition
- SH 05 No phlebotomist/witness identification
- SH 06 Sample sent with incorrect requisition type
- SH 07 Patient information (other than ID) missing/incorrect on requisition
- SH 08 Requisition sent without sample
- SH 09 Data entry incorrect/incomplete/not performed
- SH 10 Sample transport issue (e.g., sample broken/inappropriate conditions)
- SH 11 Duplicate sample sent in error

Sample Receipt
(Transfusion Service)
Events that occur when a sample is received by the transfusion service.

- SR 00 Detail not specified
- SR 01 Sample accepted in error
- SR 02 Historical review incorrect/not performed
- SR 03 Demographic review/ data entry incorrect/not performed
- SR 04 Sample incorrectly accessioned

Sample Testing
(Transfusion Service)
*Events that occur during **patient sample** testing by the transfusion service.*

- ST 00 Detail not specified
- ST 01 Data entry incomplete/incorrect/not performed
- ST 02 Appropriate sample checks incomplete/incorrect/not performed
- ST 03 Computer warning overridden in error or outside SOP
- ST 05 Sample test tube incorrectly accessioned
- ST 07 Sample test tubes mixed up
- ST 09 Sample test tube mislabeled (wrong patient identifiers)
- ST 10 Equipment problem/failure/not properly QC'd
- ST 12 Sample testing not performed
- ST 13 Incorrect sample testing method chosen
- ST 14 Sample testing performed incorrectly
- ST 15 Sample test result misinterpreted

Sample Testing (continued)

- ST 16 Reagents used were incorrect/inappropriate/expired/not properly QC'd
- ST 17 ABO/Rh error caught on final check
- ST 18 Current/historical ABO/Rh mismatch
- ST 19 Additional testing not performed
- ST 20 Confirmatory check incorrect/not performed (at time work performed)
- ST 21 Administrative check incorrect/not performed (record review/audit)
- ST 22 Sample storage incorrect/inappropriate

Product Manipulation/Processing/Testing
(Transfusion Service)
Events that occur while testing, manipulating (e.g., pooling, washing, aliquoting, irradiating), processing, or labeling blood products.

- UM 00 Detail not specified
- UM 01 Data entry incomplete/incorrect/not performed
- UM 02 Record review incomplete/incorrect/not performed
- UM 03 Incorrect product (type) selected
- UM 04 Incorrect product (patient) selected
- UM 05 Product labeled incorrectly (new/updated)
- UM 06 Computer warning overridden in error or outside SOP
- UM 07 Special processing needs not checked
- UM 08 Special processing needs misunderstood or misinterpreted
- UM 09 Special processing needs performed incorrectly
- UM 10 Special processing needs not performed
- UM 11 Equipment problem/failure/not properly QC'd
- UM 12 Reagents used were incorrect/inappropriate/expired/not properly QC'd
- UM 13 Confirmatory check incorrect/not performed (at time work performed)
- UM 14 Administrative check incorrect/not performed (record review/audit)

Incident Codes

(continued)

Note: Incident codes are based on MERS TM (US) and TESS (Canada) incident classification schemes.

Request for Pick-up
(Clinical Service)
Events that occur when the clinical service requests pick-up of a blood product from the transfusion service.

- RP 00 Detail not specified
- 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, but patient not available
- RP 05 Product requested for pick-up, but IV not ready
- RP 06 Request for pick-up incomplete (e.g., patient ID/product type missing)
- RP 07 Pick-up slip did not match patient information on product

Product Issue
(Transfusion Service)
Events that occur when the transfusion service issues blood product to the clinical service.

- UI 00 Detail not specified
- UI 01 Data entry incomplete/incorrect/not performed
- UI 02 Record review incomplete/incorrect/not performed
- UI 03 Product issued for wrong patient
- UI 04 Product issued out of order
- UI 05 Product issue delayed
- UI 06 LIS warning overridden in error or outside SOP
- UI 07 Computer issue not completed
- UI 08 Issued visibly defective product (e.g., clots/aggregates/particulate matter)
- UI 09 Not/incorrect checking of unit and/or patient information
- UI 10 Product transport issues (e.g., delayed) by transfusion service
- UI 11 Unit delivered to incorrect location by transfusion service
- UI 12 Product transport issue (from transfusion service to clinical area)
- UI 18 Wrong product issued for intended patient (e.g., incompatible)
- UI 19 Inappropriate product issued for patient (e.g., not irradiated, CMV+)
- UI 20 Confirmatory check incorrect/not performed (at time work performed)
- UI 21 Administrative check incorrect/not performed (record review/audit)
- UI 22 Issue approval not obtained/documented
- UI 23 Receipt verification not performed (pneumatic tube issue)

Satellite Storage
(Clinical Service)
Events that occur while product is stored and handled by the clinical service.

- CS 00 Detail not specified
- CS 01 Incorrect storage conditions of product in clinical area
- CS 02 Incorrect storage location in the clinical area
- CS 03 Labeling issue (by clinical staff)
- CS 04 Floor/clinic did not check for existing products in their area
- CS 05 Product transport issues (to or between clinical areas)
- CS 06 Monitoring of satellite storage incorrect/incomplete/not performed
- CS 07 Storage tracking/documentation incorrect/incomplete/not performed

Product Administration
(Clinical Service)
Events that occur during the administration of blood products.

- UT 00 Detail not specified
- UT 01 Administered intended product to wrong patient
- UT 02 Administered wrong product to intended patient
- UT 03 Transfusion not performed in error
- UT 05 Bedside check (patient ID confirmation) incomplete/not performed
- UT 06 Transfused product with incompatible IV fluid
- UT 07 Transfusion delayed beyond pre-approved timeframe
- UT 09 Transfused unsuitable product (e.g., outdated/inappropriately stored)
- UT 10 Administered components in wrong order
- UT 11 Appropriate monitoring of patient not performed
- UT 14 Transfusion volume too low (per order or SOP)
- UT 15 Transfusion volume too high (per order or SOP)
- UT 16 Transfusion rate too slow (per order or SOP)
- UT 17 Transfusion rate too fast (per order or SOP)
- UT 18 Inappropriate preparation of product
- UT 19 Transfusion protocol not followed (not otherwise specified)
- UT 22 Order/consent check incorrect/not performed
- UT 23 Transfusion documentation incorrect/incomplete/not performed
- UT 24 Transfusion documentation not returned to transfusion service
- UT 26 Transfusion reaction protocol not followed

Other

- MS 99 Other

Occupation Codes

Laboratory	
IVT	IVT Team Staff
MLT	Medical Laboratory Technician
MTE	Medical Technologist
PHL	Phlebotomist/IV Team
Nursing	
LPN	Licensed Practical Nurse
CNA	Nurse Anesthetist
CNM	Certified Nurse Midwife
NUA	Nursing Assistant
NUP	Nurse Practitioner
RNU	Registered Nurse
Physician	
FEL	Fellow
MST	Medical Student
PHY	Attending/Staff 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
CSS	Central Supply
CSW	Counselor/Social Worker
DIT	Dietician
DNA	Dental Assistant/Technician
DNH	Dental Hygienist
DNO	Other Dental Worker
DNT	Dentist
DST	Dental Student
FOS	Food Service
HSK	Housekeeper
ICP	Infection Control Professional
LAU	Laundry Staff
MNT	Maintenance/Engineering
MOR	Morgue Technician
OAS	Other Ancillary Staff
OFR	Other First Responder
OH	Occupational Health Professional
OMS	Other Medical Staff
OTH	Other
OTT	Other Technician/Therapist
PAS	Physician Assistant
PHA	Pharmacist
PHW	Public Health Worker
PLT	Physical Therapist
PSY	Psychiatric Technician
RCH	Researcher
RDT	Radiologic Technologist
RTT	Respiratory Therapist/Technician
STU	Other Student
VOL	Volunteer

Incident Glossary

Incident Result

Product transfused; reaction (No recovery; harm):
A product related to this incident was transfused; the patient experienced an adverse reaction.

Product transfused; no reaction (No recovery; no harm):
A product related to this incident was transfused; the patient did not experience an adverse reaction.

No product transfused; unplanned recovery (Near miss; unplanned recovery):
No product related to this incident was transfused; the incident was discovered ad hoc, by accident, by human lucky catch, etc.

No product transfused; planned recovery (Near miss; planned recovery):
No product related to this incident was transfused; the incident was discovered through a standardized process or barrier designed to prevent errors.

Section 5. Hemovigilance Module Denominators

Required Reporting
Facilities must report the total number of units and aliquots of specified blood components transfused and total number of discards each month. When reporting aliquots, the units from which they are made should **NOT** be counted as a transfused unit. The components transfused count should include autologous units. The total number of patient samples collected and total crossmatch procedures must also be reported. This form must be completed each month that surveillance is conducted and data can only be entered once the calendar month is over. For instance, February data must be entered after March 1st. Additionally, data cannot be entered for upcoming months.

Pathogen Reduced Blood Products
The total number of transfused units of blood components which are produced with pathogen-reduction technology (PRT) should be reported each month, if applicable. These PRT units are reported in Table 2 and are a subset of total number of units and aliquots transfused that are reported in Table 1. Table 3 relates to pathogen reduced apheresis platelets, if reported in table 2. For more guidance please refer to the Denominator QuickLearn on the NHSN Blood Safety Surveillance website.

Electronic Reporting
In January 2017, the NHSN Hemovigilance module can accept electronically reported denominator data via clinical documentation architecture (CDA). Compared to manual reporting, electronic reporting will decrease the time required for data collection and reporting, reduce data entry errors, and increase data granularity. In order to electronically report date, facilities' software system must have CDA functionality. For more information about electronic reporting and CDA, review CDA Frequently Asked Questions guidance on the NHSN Blood Safety Surveillance website.

Form
CDC 57.303 Hemovigilance Module Monthly Reporting Denominators

Form Instructions
CDC 57.303 Hemovigilance Module Monthly Reporting Denominators Tables of Instructions