

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

Transfusion Reaction

Date and time reaction occurred: _____ - ____ - ____ : _____

dd-mon-yy hh:mm 24h format

Date and time of transfusion:

dd-mon-yy hh:mm 24h format

SECTION I. PARTICIPANT INFORMATION

- 1. Age: __ (Years)
- 2. Gender:
 - [] Male
 - [] Female
 - [] Other Gender Expression
 - [] Refused
- 3. Did the transfusion occur at your facility?
 - []Yes
 - [] No

SECTION II. CASE DEFINITION AND IMPUTABILITY/

1. Transfusion associated circulatory overload (TACO)

A. Case Definition

Check all that occurred within 6 hours of cessation of transfusion (new onset or exacerbation):

[] Acute respiratory distress (dyspnea, orthopnea, cough)

[] Elevated brain natriuretic peptide (BNP)

[] Elevated central venous pressure (CVP)

[] Evidence of left heart failure

[] Evidence of positive fluid balance

[] Radiographic evidence of pulmonary edema

B. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] Patient has no other conditions to explain symptoms.

[] There are other potential causes present that could explain symptoms, but transfusion is the most likely cause.

[] Alternate explanations for symptoms are more likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

Does the patient have a history of cardiac insufficiency?

[] Yes, the patient has a history of cardiac insufficiency that could explain the circulatory overload, but transfusion is just as likely to have caused the circulatory overload. [] Yes, the patient has a history of pre-existing cardiac insufficiency that most likely explains circulatory overload.

[] No, the patient does not have a history of cardiac insufficiency.

Did the patient receive other fluids in addition to the transfusion?

[] Yes

[] No

2. Transfusion related acute lung injury (TRALI)

A. Case Definition

			Test Result Positive		
	Not Done	Negative	Cognate or cross reacting antigen present	No cognate or cross reacting antigen present	Not tested for cognate antigen
Donor or unit HLA Specificity	[]	[]	[]	[]	[]
Donor or unit HNA specificity	[]	[]	[]	[]	[]
Recipient HLA specificity	[]	[]	[]	[]	[]
Recipient HNA specificity	[]	[]	[]	[]	[]

Check all that apply

[] NO evidence of acute lung injury (ALI) prior to transfusion.

[] ALI onset during or within 6 hours of cessation of transfusion

[] Hypoxemia - defined as PaO2/FiO2 less than or equal to 300 mm Hg

[] Hypoxemia - defined as Oxygen saturation less than 90% on room air

[] Hypoxemia - defined as Other clinical evidence

[] Radiographic evidence of bilateral infiltrates

[] No evidence of left atrial hypertension (i.e., circulatory overload)

B. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] There are no alternative risk factors for ALI present.

[] There is evidence of other causes for acute lung injury.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

3. Transfusion associated dyspnea (TAD)

Case Definition

Check all that apply

[] Acute respiratory distress occurring within 24 hours of cessation of transfusion.

[] Allergic reaction, TACO, and TRALI definitions are not applicable.

Imputability

Which best describes the relationship between the transfusion and the reaction?

[] Patient has no other conditions that could explain symptoms.

[] There are other potential causes that could explain symptoms, but transfusion is the most likely cause.

[] Other present causes are most likely, but transfusion cannot be ruled out

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

4. Allergic reaction, including anaphylaxis

A. Case Definition

Check the following that occurred during or within **4 hours** of cessation of transfusion:

- [] Conjunctival edema
- [] Edema of lips, tongue and uvula
- [] Localized angioedema
- [] Erythema and edema of the periorbital area
- [] Respiratory distress; bronchospasm
- [] Generalized flushing
- [] Maculopapular rash
- [] Pruritus (itching)
- [] Hypotension
- [] Urticaria (hives)

B. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] No other evidence of environmental, drug or dietary risks.

[] There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause.

[] Other present causes are most likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

When did the reaction occur in relation to the transfusion?

[] Occurred during or within 2 hours of cessation of transfusion.

[] Occurred 2 - 4 hours after cessation of transfusion.

Did the same reaction occur after the transfusion was restarted (rechallenge)?

[] Yes

[] No

5. Hypotensive transfusion reaction

Case Definition

Check all that occurred during or within 1 hour of cessation of transfusion:

[] All other adverse reactions presenting with hypotension are excluded.

[] Hypotension-Drop in systolic BP of greater than or equal to 30 mmHg AND Systolic BP less than or equal to 80 mmHg

Check all that apply:

[] Hypotension occurs, does not meet the criteria above. Other, more specific reaction definitions do not apply.

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] The patient has no other conditions that could explain hypotension.

[] There are other potential causes present that could explain hypotension, but transfusion is the most likely cause.

[] Other conditions that could readily explain hypotension are present.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

How did the patient respond the cessation of transfusion and supportive treatment?

[] Responds rapidly (i.e., within 10 minutes) to cessation of transfusion and supportive treatment.

[] The patient does not respond rapidly to cessation of transfusion and supportive treatment.

When did the reaction occur in relation to the transfusion?

[] Occurs less than 15 minutes after the start of the transfusion.

[] Onset is between 15 minutes after start and 1 hour after cessation of transfusion.

6. Febrile non-hemolytic transfusion reaction (FNHTR)

Case Definition

Check all that occurred during or within 4 hours of cessation of transfusion:

[] Fever (greater than or equal to $38^{\circ}C/100.4^{\circ}F$ oral and a change of at least $1^{\circ}C/1.8^{\circ}F$) from pre-transfusion value

[] Chills/rigors are present

Check all that apply:

[] FNHTR is suspected, but reported symptoms and/or available information are not sufficient.

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] Patient has no other conditions that could explain signs/symptoms.

[] There are other potential causes present that could explain signs/symptoms, but transfusion is the most likely cause.

[] Other present causes are most likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

7. Acute hemolytic transfusion reaction (AHTR)

Case Definition

[] Immune Antibody: _____

[] Non-immune (specify) _____

Check the following that occurred **during**, or within 24 hours of cessation of transfusion with new onset:

- [] Back/flank pain
- [] Chills/rigors
- [] Epistaxis
- [] Disseminated intravascular coagulation (DIC)
- [] Oliguria/anuria
- [] Hypotension
- [] Fever
- [] Hematuria (gross visual hemolysis)
- [] Pain and/or oozing at IV site
- [] Renal failure
- [] Other bleeding: _____

Check all that apply:

[] Decreased fibrinogen

[] Decreased haptoglobin

[] Elevated bilirubin

[] Elevated LDH

[] Hemoglobinemia

[] Hemoglobinuria

[] Plasma discoloration c/w hemolysis

[] Spherocytes on blood film

[] Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3

[] Positive elution test with alloantibody present on the transfused red blood cells

[] Serologic testing is negative, and physical cause (e.g., thermal, osmotic, mechanical, chemical) is confirmed.

[] Physical cause is excluded but serologic evidence is not sufficient to meet definitive criteria.

[] Physical cause is suspected and serologic testing is negative.

 $[\]$ AHTR is suspected, but symptoms, test results, and/or information are not sufficient to confirm reaction

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] ABO or other allotypic RBC antigen incompatibility is known.

[] Only transfusion-related (i.e., immune or non-immune) cause of acute hemolysis is present.

[] There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause.

[] Other present causes are most likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

8. Delayed hemolytic transfusion reaction (DHTR)

Case Definition

[] Immune Antibody: _____

[] Non-immune (specify) _____

Check the following that occurred between 24 hours and 28 days after cessation of transfusion:

[] Positive direct antiglobulin test (DAT)

[] Newly-identified red blood cell alloantibody in recipient serum

[] Positive elution test with alloantibody present on the transfused red blood cells

[] Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels

[] Otherwise unexplained appearance of spherocytes

Check if applicable:

[] DHTR is suspected, but reported symptoms, test results, and/or available information are not sufficient

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] No other explanation for symptoms or newly-identified antibody is present.

[] An alternate explanation for symptoms or newly-identified antibody is present, but transfusion is the most likely cause.

[] Other explanations for symptoms or newly-identified antibody are more likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

9. Hyper-hemoloysis

Case Definition

Check all that apply:

[] Severe anemia post-transfusion with post-transfusion hemoglobin value lower than pre-transfusion hemoglobin

[] Evidence of hemolysis (check all that apply):

[] Increased LDH

[] Hemoglobinemia

[] Hemoglobinuria

[] Hyperbilirubinemia

[] Relative reticulocytopenia

[] Presenting symptoms may include fever and VOC post-transfusion

[] Acute form: less than 7 days post-transfusion, with negative DAT and no new RBC allo or auto antibodies identified

[] Delayed form: greater than 7 days post-transfusion, usually with positive DAT and new RBC allo or auto antibodies identified.

Antibody: _____

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] No other explanation for symptoms

[] An alternate explanation for symptoms, but transfusion is the most likely

cause.

[] Other present causes are most likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

10. Delayed serologic transfusion reaction (DSTR)

Case Definition

Antibody(ies):_____

_

Check all that apply:

[] Absence of clinical or laboratory signs of hemolysis

[] Positive direct antiglobulin test (DAT)

[] Demonstration of new, clinically-significant antibodies against red blood cells

[] Positive antibody screen with newly identified RBC alloantibody

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] Transfusion performed by your facility is the only possible cause for seroconversion.

[] The patient has other exposures (e.g. transfusion by another facility or pregnancy) that could explain seroconversion,

but transfusion by your facility is the most likely cause.

[] The patient was transfused by your facility, but other exposures are present that most likely explain seroconversion.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

When did the reaction occur in relation to the transfusion?

[] Occurred between 24 hours and 28 days after cessation of transfusion.

[] Occurred less than 24 hours after cessation of transfusion.

[] Occurred greater than 28 days after cessation of transfusion.

[] No new antibody was identified.

11. Transfusion associated graft vs. host disease (TA-GVHD)

Case Definition

Did patient receive non-irradiated blood product(s) in the two months preceding the reaction?

[] Yes

[] No

Check all that occurred within 2 days to 6 weeks after cessation of transfusion:

[] Diarrhea

[] Fever

[] Hepatomegaly

[] Pancytopenia

[] Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin)

[] Marrow aplasia

[] Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation.

Check all that apply:

[] Characteristic histological appearance of skin or liver biopsy.

[] Biopsy negative or not done.

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] No other alternative diagnoses.

[] Other potential causes are present (e.g., stem cell transplantation).

[] Alternative explanations are more likely (e.g., solid organ transplantation).

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

WBC chimerism:

[] WBC chimerism present

[] WBC chimerism not present or not done

12. Post Transfusion Purpura (PTP)

Case Definition

Check all that occurred after cessation of transfusion:

[] Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia.

 $[\]$ Thrombocytopenia (i.e., decrease in platelets to less than 20% of pretransfusion count).

 $[\]$ Decrease in platelets to levels between 20% and 80% of pre-transfusion count.

Check all that apply:

[] PTP is suspected, but laboratory findings and/or information are not sufficient. NOTE: For example, the patient has a drop in platelet count to less

than 80% of pre-transfusion count but HPA antibodies were not tested or were negative.

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] Patient has no other conditions to explain thrombocytopenia.

[] There are other potential causes present that could explain thrombocytopenia, but transfusion is the most likely cause.

[] Alternate explanations for thrombocytopenia are more likely, but transfusion cannot be ruled out.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

When did the reaction occur in relation to the transfusion?

[] Occurred 5-12 days post-transfusion.

[] Occurred less than 5 or more than 12 days post-transfusion.

13. Infection

Case Definition

Was a test to detect a specific pathogen performed on the recipient posttransfusion?

[] Yes

[] No

If Yes, positive or reactive results?

[] Yes

[] No

Org1 _____

Org2 _____

Org3 _____

Was a test to detect a specific pathogen performed on the donor post-donation?

[] Yes

[] No

If Yes, positive or reactive results?

[] Yes

[] No

Org1 _____

Org3 _____

Was a test to detect a specific pathogen performed on the unit post-transfusion?

(i.e., culture, serology, NAT)

[] Yes

[] No

If Yes, positive or reactive results?

[] Yes

[] No

Org1 _____

Org2 _____

Org3 _____

Check all that apply:

[] Temporally associated unexplained clinical illness consistent with infection

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] No other potential exposures to the pathogen could be identified in the recipient.

[] Evidence is clearly in favor of a cause other than transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

Check all that apply:

[] Evidence of the pathogen in the transfused component.

[] Evidence of the pathogen in the donor at the time of donation.

[] Evidence of the pathogen in an additional component from the same donation.

[] Evidence of the pathogen in an additional recipient of a component from the same donation.

[] Evidence that the identified pathogen strains are related by molecular or extended phenotypic comparison testing with statistical confidence (p<0.05).

[] Evidence that the transfused component was negative for this pathogen at the time of transfusion

[] Evidence that the donor was negative for this pathogen at the time of donation.

[] Evidence that additional components from the same donation were negative for this pathogen.

[] Evidence that the recipient was not infected with the pathogen prior to transfusion.

[] Laboratory evidence that the recipient was infected with this pathogen prior to transfusion

14. Other, specify:

14. Case Definition

List tests relevant to reaction investigation:

Test name: _____

Testing date: _____

Test result: _____

Test name: _____

Testing date: _____

Test result: _____

2. Imputability

Which best describes the relationship between the transfusion and the reaction?

[] Conclusive evidence exists that the adverse reaction can be attributed to the transfusion.

[] Evidence is clearly in favor of attributing the adverse reaction to the transfusion.

[] Evidence is indeterminate for attributing the adverse reaction to the transfusion or an alternate cause.

[] Evidence is clearly in favor of a cause other than the transfusion, but transfusion cannot be excluded.

[] There is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

[] The relationship between the adverse reaction and the transfusion is unknown or not stated.

SECTION III. OTHER SIGNS AND SYMPTOMS

Check all that apply:

Generalized:

[] Chills/rigors

[] Fever

[] Nausea/vomiting

Cardiovascular: [] Blood pressure [] Shock

	[] Edema	[] Flushing	[] Jaundice	
Cutaneous:	[] Other Rash	[] Pruritus (itching)	[] Urticaria (hives)	
Hemolysis:	[] Disseminated intravascular coagulation	[] Hemoglobinemia	[] Positive antibody screen	
Pain:	[] Abdominal pain	[] Back pain [] Flank Pain	[] Infusion Site Pain	
Renal:	[] Hematuria	[] Hemoglobinuria [] Oliguria	[] Bleeding	
Respiratory:	[] Bilateral infiltrates on chest x- ray [] Hypoxemia	[] Bronchospasm [] Shortness of breath	[] Cough	

Other, specify:

SECTION IV. SEVERITY [] Not determined (for Delayed Serologic Transfusion Reaction (DSTR))

Did the patient receive or experience any of the following?

[] No treatment required

[] Symptomatic treatment only

[] Hospitalization, including prolonged hospitalization

[] Life-threatening reaction

[] Disability and/or incapacitation

[] Congenital anomaly or birth defect(s) of the fetus

[] Other medically important conditions

[] Death

[] Unknown or not stated

SECTION V. PATIENT TREATMENT

Did the patient receive treatment for the transfusion reaction?

[] No

[] Yes

[] Unknown

If yes, select treatment(s):

- [] Medication (Select the type of medication)
- [] Antipyretics
- [] Antihistamines
- [] Inotropes/Vasopressors
- [] Bronchodilator
- [] Diuretics
- [] Intravenous Immunoglobulin
- [] Intravenous steroids
- [] Corticosteroids
- [] Antibiotics
- [] Anti-thymocyte globulin
- [] Cyclosporin
- [] Other
- [] Volume resuscitation (Intravenous colloids or crystalloids)
- [] Respiratory support (Select the type of support)

[] Mechanical ventilation

- [] Noninvasive ventilation
- [] Oxygen
- [] Renal replacement therapy (Select the type of therapy)
- [] Hemodialysis
- [] Peritoneal
- [] Continuous Veno-Venous Hemofiltration
- [] Phlebotomy
- [] Other, Specify:

SECTION VI. OUTCOME

- [] Death
- [] Major or long-term sequelae
- [] Minor or no sequelae
- [] Not determined

If recipient died,

- 1.1 Date of Death (dd-mon-yy): _____ _____ _____
- 1.2 Relationship of transfusion to death:
 - [] Definite
 - [] Probable
 - [] Possible
 - [] Doubtful
 - [] Ruled Out
 - [] Not determined
- 1.3 Cause of death:

1.4 Was an autopsy performed?

[] Yes

[] No

SECTION VII. COMPONENT DETAILS

Was a particular unit implicated in (i.e., responsible for) the adverse reaction?

[] Yes [] No [] N/A

Transfusion Start and End Date and Time (dd-mon-yy hh:mm)	Component code (check system used)	Amount transfused at reaction onset	Blood Unit number	Unit expiration Date and Time (dd-mon-yy hh:mm)	Implicated Unit?
hh:mm)				hh:mm)	



mL



Complete page 4 to report more units implicated in this adverse reaction. SECTION VIII. CUSTOM FIELDS

Comments

Complete the Serious Adverse Event (SAE) form for this reaction within 24 hours of diagnosis

SECTION VII. COMPONENT DETAILS (continued)

Transfusion Start and End Date and Time (dd-mon-yy hh:mm)	Component code (check system used)	Amount transfused at reaction onset	Blood Unit number	Unit expiration Date and Time (dd-mon-yy hh:mm)	Impl Unit	icated ?
Start: : End:	[] ISBT-128 [] Codabar	[] Entire unit [] Partial unit		[_]	Yes	[] [] No
;		mL				
Start: : End: :	[] ISBT-128 [] Codabar	[] Entire unit [] Partial unit mL		[_]	Yes	[] [] No
Start: : End: :	[] ISBT-128 [] Codabar	[] Entire unit [] Partial unit mL		 · ·	Yes	[] [] No
Start: :	[] ISBT-128 [] Codabar	[] Entire unit []		[_]	Yes	[] [] No

End:		_ Partial unit		
;		mL		
Start:		[]		
	[] ISBT-128	Entire unit		[]
End:	[] Codabar	_ [] Partial unit	 Yes :	[] No
:		mL		
Start:		r 1		
	[] ISBT-128	Entire unit		[]
End:	[] Codabar	[] _ Partial unit	 Yes :	[] No
:		mL		
Start:		[]		
:	[] ISBT-128	Entire unit		[]
End:	[] Codabar	[] _ Partial unit _	 Yes	[] No
:		mL		

Protocol source: https://www.phenxtoolkit.org/protocols/view/851001