



Hemovigilance Module Adverse Reaction Acute Hemolytic Transfusion Reaction

*Required for saving

*Facility ID#: _____ NHSN Adverse Reaction #: _____

Patient Information

*Patient ID: _____ *Gender: M F Other *Date of Birth: ___/___/___
 Social Security #: _____ Secondary ID: _____ Medicare #: _____
 Last Name: _____ First Name: _____ Middle Name: _____
 Ethnicity Hispanic or Latino Not Hispanic or Not Latino
 Race American Indian/Alaska Native Asian Black or African American
 Native Hawaiian/Other Pacific Islander White
 *Blood Group: A- A+ B- B+ AB- AB+ O- O+ Blood type not done

Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.)

(part 1) List the patient's admitting diagnosis. (Use ICD-10 Diagnostic codes/descriptions)

Code: _____ Description: _____
 Code: _____ Description: _____
 Code: _____ Description: _____

(part 2) List the patient's underlying indication for transfusion. (Use ICD-10 Diagnostic codes/descriptions)

Code: _____ Description: _____
 Code: _____ Description: _____
 Code: _____ Description: _____

(part 3) List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. (Use ICD-10 Diagnostic codes/descriptions)

UNKNOWN
 NONE

Code: _____ Description: _____
 Code: _____ Description: _____
 Code: _____ Description: _____

Continued >>

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Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333 ATTN: PRA (0920-0666).

CDC 57.307 Rev.1 v8.8

Acute Hemolytic Transfusion Reaction

| Patient Medical History (Use worksheet on page 4 for additional codes and descriptions.) | |
|---|---|
| <p>(part 4) List the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay. (Use ICD-10 Procedure codes/descriptions)</p> <p>Code: _____ Description: _____</p> <p>Code: _____ Description: _____</p> <p>Code: _____ Description: _____</p> | <input type="checkbox"/> UNKNOWN <input type="checkbox"/> NONE |
| <p>(part 5) Additional Information _____</p> <p>_____</p> <p>_____</p> | |

| Transfusion History (Use worksheet on page 4 for additional transfusion history.) |
|--|
| <p>*Has the patient received a previous transfusion? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> UNKNOWN</p> <p>**If yes, provide information about the transfusion event. If not, skip to Reaction Details section.</p> <p>Blood Product: <input type="checkbox"/> WB <input type="checkbox"/> RBC <input type="checkbox"/> Platelet <input type="checkbox"/> Plasma <input type="checkbox"/> Cryoprecipitate <input type="checkbox"/> Granulocyte</p> <p>Date of Transfusion: ___/___/___ <input type="checkbox"/> UNKNOWN</p> <p>Was the patient's adverse reaction transfusion-related? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If yes, provide information about the transfusion adverse reaction.</p> <p>Type of transfusion adverse reaction: <input type="checkbox"/> Allergic <input type="checkbox"/> AHTR <input type="checkbox"/> DHTR <input type="checkbox"/> DSTR <input type="checkbox"/> FNHTR</p> <p><input type="checkbox"/> HTR <input type="checkbox"/> TTI <input type="checkbox"/> PTP <input type="checkbox"/> TACO <input type="checkbox"/> TAD <input type="checkbox"/> TA-GVHD <input type="checkbox"/> TRALI <input type="checkbox"/> UNKNOWN</p> <p><input type="checkbox"/> OTHER Specify _____</p> |

| Reaction Details |
|---|
| <p>*Date reaction occurred: ___/___/___ *Time reaction occurred: ___:___ <input type="checkbox"/> Time unknown</p> <p>*Facility location where patient was transfused: _____</p> <p>*Is this reaction associated with an incident? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, Incident #: _____</p> <p>After recognition of the transfusion reaction, was the current transfusion:</p> <p><input type="checkbox"/> Continued <input type="checkbox"/> Stopped and restarted <input type="checkbox"/> Stopped indefinitely</p> |

| Investigation Results |
|--|
| <p>*<input type="checkbox"/> Acute hemolytic transfusion reaction (AHTR)</p> <p><input type="checkbox"/> Immune Antibody: _____ <input type="checkbox"/> Non-immune (specify) _____</p> |
| <p>*Case Definition</p> <p>Check the following that occurred during, or within 24 hours of cessation of transfusion with new onset:</p> <p><input type="checkbox"/> Back/flank pain <input type="checkbox"/> Chills/rigors <input type="checkbox"/> Epistaxis <input type="checkbox"/> Disseminated intravascular coagulation (DIC)</p> <p><input type="checkbox"/> Oliguria/anuria <input type="checkbox"/> Hypotension <input type="checkbox"/> Fever <input type="checkbox"/> Hematuria (gross visual hemolysis)</p> <p><input type="checkbox"/> Pain and/or oozing at IV site <input type="checkbox"/> Renal failure <input type="checkbox"/> None of the above</p> <p style="text-align: right;"><i>Continued >></i></p> |

Acute Hemolytic Transfusion Reaction

Investigation Results (continued)

- 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.

Other signs and symptoms: (check all that apply)

- | | |
|---|--|
| Generalized: | <input type="checkbox"/> Nausea/vomiting |
| Cardiovascular: | <input type="checkbox"/> Shock |
| Cutaneous: | <input type="checkbox"/> Edema <input type="checkbox"/> Flushing <input type="checkbox"/> Jaundice |
| | <input type="checkbox"/> Other rash <input type="checkbox"/> Pruritus (itching) <input type="checkbox"/> Urticaria (hives) |
| Hemolysis/Hemorrhage: | <input type="checkbox"/> Hemoglobinemia <input type="checkbox"/> Positive antibody screen |
| Pain: | <input type="checkbox"/> Abdominal pain |
| Respiratory: | <input type="checkbox"/> Bilateral infiltrates on chest x-ray <input type="checkbox"/> Bronchospasm <input type="checkbox"/> Cough |
| | <input type="checkbox"/> Shortness of breath <input type="checkbox"/> Hypoxemia |
| <input type="checkbox"/> Other: (specify) _____ | |

***Severity**

Did the patient receive or experience any of the following? *(Response definitions listed in the protocol)*

- Symptomatic treatment only Hospitalization, including prolonged hospitalization
- Life-threatening reaction Disability and/or incapacitation
- Congenital anomaly or birth defect(s) of the fetus Death
- Other medically important conditions Unknown or not stated

***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.
- 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.

Did the transfusion occur at your facility? YES NO

Continued >>

Acute Hemolytic Transfusion Reaction

Investigation Results (continued)

Designations for case definition, severity, and imputability will be automatically assigned in the NHSN application based on responses in the corresponding investigation results section above.

Do you agree with the case definition designation? YES NO

Please indicate your designation _____

Do you agree with the severity designation? YES NO

Please indicate your designation _____

Do you agree with the imputability designation? YES NO

Please indicate your designation _____

Additional Information _____

Patient Treatment

*Did the patient receive treatment for the transfusion reaction? YES NO UNKNOWN

If yes, select treatment(s):

Medication (Select the type of medication)

- | | | | | |
|---|---|---|---|------------------------------------|
| <input type="checkbox"/> Antipyretics | <input type="checkbox"/> Antihistamines | <input type="checkbox"/> Inotropes/Vasopressors | <input type="checkbox"/> Bronchodilator | <input type="checkbox"/> Diuretics |
| <input type="checkbox"/> Intravenous Immunoglobulin | <input type="checkbox"/> Intravenous steroids | <input type="checkbox"/> Corticosteroids | <input type="checkbox"/> Antibiotics | |
| <input type="checkbox"/> Antithymocyte globulin | <input type="checkbox"/> Cyclosporin | <input type="checkbox"/> H1 receptor blockers | <input type="checkbox"/> 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: _____

Outcome

*Outcome: Death Major or long-term sequelae Minor or no sequelae Not determined

Date of Death: ____/____/____

^*If recipient died, relationship of transfusion to death:

- Definite Probable Possible Doubtful Ruled Out Not determined

Cause of death: _____

Was an autopsy performed? Yes No

Acute Hemolytic Transfusion Reaction

| Component Details (Use worksheet on page 4 for additional units.) | | | | | | | |
|--|---|--|----------------|----------------------------|--|--|------------------|
| *Was a particular unit implicated in (i.e., responsible for) the adverse reaction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | | | | | | | |
| Transfusion Start and End Date/Time | *Component code (check system used) | Amount transfused at reaction onset | Unit number | *Unit expiration Date/Time | *Blood group of unit | | Implicated Unit? |
| ^IMPLICATED UNIT | | | | | | | |
| ____ / ____ / ____ : ____ / ____ / ____ : | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit mL | _____ _____ | ____ / ____ / ____ : | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | | Y |
| ____ / ____ / ____ : ____ / ____ / ____ : | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit mL | _____ _____ | ____ / ____ / ____ : | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | | N |
| ____ / ____ / ____ : ____ / ____ / ____ : | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit mL | _____ _____ | ____ / ____ / ____ : | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B+ <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | | N |

| Custom Fields | |
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| _____ | _____ |
| Comments | |
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| _____ | |
| _____ | |



Form Approved
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Exp. Date: xx/xx/20xx
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Hemovigilance Module Additional Worksheet

Patient Medical History

(part 1) List the patient's admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)*

| | |
|-------------|--------------------|
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |

(part 2) List the patient's underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)*

| | |
|-------------|--------------------|
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |

(part 3) List the patient's comorbid conditions at the time of the transfusion related to the adverse reaction. *(Use ICD-10 Diagnostic codes/descriptions)*

UNKNOWN
 NONE

| | |
|-------------|--------------------|
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
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(part 4) List the patient's relevant medical procedure including past procedures and procedures to be performed during the current hospital or outpatient stay. *(Use ICD-10 Procedure codes/descriptions)*

UNKNOWN
 NONE

| | |
|-------------|--------------------|
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |
| Code: _____ | Description: _____ |

(part 5) Additional Information _____

Hemovigilance Module Additional Worksheet

| Transfusion History |
|--|
| <p>Has the patient received a previous transfusion? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><i>**If yes, provide information about the transfusion event. If not, skip to Reaction Details section.</i></p> <p>Blood Product: <input type="checkbox"/> WB <input type="checkbox"/> RBC <input type="checkbox"/> Platelet <input type="checkbox"/> Plasma <input type="checkbox"/> Cryoprecipitate <input type="checkbox"/> Granulocyte</p> <p>Date of Transfusion: ___/___/___ <input type="checkbox"/> UNKNOWN</p> <p>Did the patient experience a transfusion adverse reaction? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If yes, provide information about the transfusion adverse reaction.</p> <p>Type of transfusion adverse reaction: <input type="checkbox"/> Allergic <input type="checkbox"/> AHTR <input type="checkbox"/> DHTR <input type="checkbox"/> DSTR <input type="checkbox"/> FNHTR</p> <p><input type="checkbox"/> HTR <input type="checkbox"/> TTI <input type="checkbox"/> PTP <input type="checkbox"/> TACO <input type="checkbox"/> TAD <input type="checkbox"/> TA-GVHD <input type="checkbox"/> TRALI <input type="checkbox"/> UNKNOWN</p> <p><input type="checkbox"/> OTHER Specify _____</p> |
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Hemovigilance Module Additional Worksheet

| Component Details | | | | | | |
|--|---|--|--|--|---|------------------|
| *Was a particular unit implicated in (i.e., responsible for) the adverse reaction? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | | | | | | |
| Transfusion Start and End Date/Time | *Component code (check system used) | Amount transfused at reaction onset | Unit number | *Unit expiration Date/Time | *Blood group of unit | Implicated Unit? |
| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |
| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |
| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |
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| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |
| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |
| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 <input type="checkbox"/> Codabar | <input type="checkbox"/> Entire unit <input type="checkbox"/> Partial unit _____mL | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |
| ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> ISBT-128 | <input type="checkbox"/> Entire unit | ____-____-____ ____-____-____ ____-____-____ | ____/____/____ ____:____ ____/____/____ ____: | <input type="checkbox"/> A- <input type="checkbox"/> A+ <input type="checkbox"/> B- <input type="checkbox"/> B <input type="checkbox"/> AB- <input type="checkbox"/> AB+ <input type="checkbox"/> O- <input type="checkbox"/> O+ <input type="checkbox"/> N/A | N |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--------------------------|---------------|---|----|--|--|--|----------------------------|--------------------------|--------------------------|--------------------------|---|-----|-----|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|----|-----------------------------|-----|--------------------------|
| _____ : _____ _____ / _____ / _____ _____ : _____ | <input type="checkbox"/> Codabar _____ | unit <input type="checkbox"/> Partial unit _____ mL | _____ _____ | _____ : _____ | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">A-</td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/> B</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">+</td> <td style="text-align: center;">AB-</td> <td style="text-align: center;">AB+</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">O-</td> <td style="text-align: center;"><input type="checkbox"/> O+</td> <td style="text-align: center;">N/A</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> | A- | | | | <input type="checkbox"/> B | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | + | AB- | AB+ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | O- | <input type="checkbox"/> O+ | N/A | <input type="checkbox"/> |
| A- | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> B | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | |
| + | AB- | AB+ | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | |
| O- | <input type="checkbox"/> O+ | N/A | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | |