**Hemovigilance Module**

**Adverse Reaction**

**Acute Hemolytic Transfusion Reaction**

**\*Required for saving**

|  |  |  |
| --- | --- | --- |
| \*Facility ID#: \_\_\_\_\_\_\_\_\_ | NHSN Adverse Reaction #: \_\_\_\_\_\_\_\_\_\_ |  |
| **Patient Information** |
| **\*Patient ID:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  | **\*Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_\_** |
| \*Sex at Birth: [ ] M [ ] F [ ] Unknown  |  |  |  |  | \*Gender Identity (Specify):\_\_\_\_\_\_\_\_ |
| 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 |
|  | [ ]  Transitional ABO / Rh + | [ ]  Transitional ABO / Rh - |  | [ ]  Transitional ABO / Transitional Rh |
| [ ]  Group A/Transitional Rh | [ ]  Group B/Transitional Rh | [ ]  Group O/Transitional Rh | [ ]  Group AB/Transitional Rh |
| **Patient Medical History**  |
|  | List the patient’s admitting diagnosis. *(Use ICD-10 Diagnostic codes/descriptions)* |
|  | Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Description: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Description: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Description: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | List the patient’s underlying indication for transfusion. *(Use ICD-10 Diagnostic codes/descriptions)* |
|  | Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Description: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Description: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Description: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).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 H21-8, Atlanta, GA 30333, ATTN: PRA (0920-0666). |

|  |  |  |
| --- | --- | --- |
|  | 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | Additional Information \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Transfusion History**  |
|  | Has the patient received a previous transfusion? | [ ]  YES | [ ]  NO | [ ]  UNKNOWN |
|  | Blood Product: | [ ]  WB | [ ]  RBC | [ ]  Platelet | [ ]  Plasma | [ ]  Cryoprecipitate | [ ]  Granulocyte |
|  | Date of Transfusion: | \_\_\_\_/\_\_\_\_/\_\_\_\_\_ | [ ]  UNKNOWN |
|  | Was the patient’s adverse reaction transfusion-related?  | [ ]  YES | [ ]  NO |
|  | If yes, provide information about the transfusion adverse reaction. |
|  | Type of transfusion adverse reaction: | [ ]  Allergic | [ ]  AHTR | [ ]  DHTR | [ ]  DSTR | [ ]  FNHTR |
|  | [ ]  HTR | [ ]  TTI | [ ]  PTP | [ ]  TACO | [ ]  TAD | [ ]  TA-GVHD | [ ]  TRALI | [ ]  UNKNOWN |
|  | [ ]  OTHER | Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Reaction Details** |
| **\*Date reaction occurred:**\_\_\_/\_\_\_\_/\_\_\_\_ | **\*Time reaction occurred:** \_\_ \_\_:\_\_ \_\_ | [ ]  Time unknown |
| **\*Facility location where patient was transfused:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Is this reaction associated with an incident? | [ ]  Yes | [ ]  No | If Yes, Incident #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Investigation Results** |
| **\***[ ]  **Acute hemolytic transfusion reaction (AHTR)** |
|  | [ ]  Immune | Antibody: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Non-immune (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  | **\*Case Definition** |
|  | **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 |  |
|  |  |  |  |  |
|  | **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:  | [ ]  Nausea/vomiting |
|  | Cardiovascular:  | [ ]  Shock |
|  | Cutaneous:  | [ ]  Edema | [ ]  Flushing | [ ]  Jaundice |
|  | [ ]  Other rash | [ ]  Pruritus (itching) | [ ]  Urticaria (hives) |
|  | Hemolysis/Hemorrhage: | [ ]  Hemoglobinemia | [ ]  Positive antibody screen |
|  | Pain:  | [ ]  Abdominal pain |
|  | Respiratory:  | [ ]  Bilateral infiltrates on chest x-ray | [ ]  Bronchospasm | [ ]  Cough |
|  | [ ]  Shortness of breath | [ ]  Hypoxemia |  |
|  | [ ]  Other: (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
|  | **\*Severity** |
|  | Did the patient receive or experience any of the following? |
|  | [ ]  No treatment required | [ ]  Symptomatic treatment only |
|  | [ ]  Hospitalization, inlcuding 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 |
|  |
|  | **\*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 causes of acute hemolysis 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. |
|  |
|  | Did the transfusion occur at your facility? | [ ]  YES | [ ]  NO |
| **Module-generated Designations** |
| *NOTE: 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| **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)* |
|  | [ ]  Antipyretics | [ ]  Antihistamines | [ ]  Inotropes/Vasopressors | [ ]  Bronchodilator | [ ]  Diuretics |
|  | [ ]  Intravenous Immunoglobulin | [ ]  Intravenous steroids | [ ]  Corticosteroids | [ ]  Antibiotics |
|  | [ ]  Antithymocyte 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **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 |
|  |
| **Component Details** |
| **\*Was a particular unit implicated in (i.e., responsible for) the adverse reaction?** | [ ]  Yes | [ ]  No | [ ]  N/A |
| Transfusion Startand **End** **Date/Time**  | **\*Component code** (check system used) | Amount transfused at reaction onset | **^**Unit number(Required for Infection and TRALI)  | **\*Unit expiration Date/Time**  | **\*Blood group** **of unit** | **Implicated** **Unit?** |
| **^IMPLICATED UNIT** |
| \_\_\_\_/\_\_\_\_/\_\_\_ | [ ]  ISBT-128 | [ ]  Entire unit[ ]  Partial unit\_\_\_\_\_\_mL | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | Y |
| \_\_\_ \_\_\_:\_\_\_\_\_ | [ ]  Codabar | \_\_ \_\_ |
| \_\_\_\_/\_\_\_\_/\_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_\_\_ : \_\_\_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |
| \_\_\_ \_\_\_:\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_ \_\_ \_\_ | [ ]  O- | [ ]  O+ | [ ]  N/A |
| \_\_\_\_/\_\_\_\_/\_\_\_ | [ ]  ISBT-128 | [ ]  Entire unit[ ]  Partial unit\_\_\_\_\_\_mL  | \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_/\_\_\_/\_\_\_\_\_ | [ ]  A- | [ ]  A+ | [ ]  B- | N |
| \_\_\_ \_\_\_:\_\_\_ \_ | [ ]  Codabar | \_\_ \_\_ |
| \_\_\_\_/\_\_\_\_/\_\_\_ | \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ | \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ | \_\_\_\_\_ : \_\_\_\_\_ | [ ] B+ | [ ]  AB- | [ ]  AB+ |
| \_\_\_ \_\_\_:\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_ \_\_ \_\_ | [ ]  O- | [ ]  O+ | [ ]  N/A |
| **Custom Fields** |
| Label |  | Label |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |
| **Comments** |
|  |