**Hemovigilance Module**

**Adverse Reaction**

**Transfusion Related Acute Lung Injury**

**\*Required for saving**

|  |  |  |
| --- | --- | --- |
| \*Facility ID#: \_\_\_\_\_\_\_\_\_ | NHSN Adverse Reaction #: \_\_\_\_\_\_\_\_\_\_ |  |
| **Patient Information** |
| **\*Patient ID:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | **\*Date of Birth:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_ |
| **\*Sex:** [ ] M [ ] F  |  |
| Social Security #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Secondary ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Medicare #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Middle Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Ethnicity (Specify): | [ ] Hispanic or Latino | [ ] Not Hispanic or Latino | [ ] Unknown | [ ] Declined to respond  |
| Race (Select all that apply): | [ ] American Indian or Alaska Native | [ ] Asian | [ ] Black or African American | [ ] Middle Eastern or North African |
| [ ] Native Hawaiian or Pacific Islander | [ ] White | [ ] Unknown | [ ] Declined to respond |
| Preferred Language (Specify from the list provided):\_\_\_\_\_\_\_\_\_\_\_\_ | Interpreter Needed:  | [ ] Yes  | [ ] No  |
|  | [ ] Declined to Respond  | [ ] Unknown |
| **\*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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| --- | --- | --- |
|  | 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** |
| \*[ ]  **Transfusion related acute lung injury (TRALI)** |
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|  |  |  |  |
| --- | --- | --- | --- |
|  | Not Done | Negative | Test result positive |
| 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 | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

 |
|  | **\*Case Definition** (*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) |
|  | Other signs and symptoms: (check all that apply) |
|  | Generalized: | [ ]  Chills/rigors | [ ]  Fever [ ]  Nausea/vomiting |  |
|  | Cardiovascular: | [ ]  Blood pressure decrease | [ ]  Shock |
|  | Cutaneous: | [ ]  Edema | [ ]  Flushing | [ ]  Jaundice | [ ]  Itching | [ ]  Hives | [ ]  Other rash |
|  | Hemolysis/Hemorrhage: | [ ]  DIC [ ]  Hemoglobinemia | [ ]  Positive antibody screen |  |
|  | Pain: | [ ]  Abdominal pain | [ ]  Back pain | [ ]  Flank pain | [ ]  Infusion site pain |
|  | Renal: | [ ]  Hematuria | [ ]  Hemoglobinuria | [ ]  Oliguria |
|  | Respiratory: | [ ]  Bronchospasm [ ]  Cough [ ]  Shortness of breath | [ ]  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? |
|  | [ ]  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. |
|  | 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** |
|  |