**Purpose**: To describe the evaluation, testing process, review and reporting of Transfusion Reaction Investigations (TRI)

**Policy:** Any untoward symptom occurring during or subsequent to the transfusion of blood or blood components should be considered a potential part of a life-threatening reaction.

**Process:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents**  |
| **Initial Notification** |
| 1 | * Receive call on a possible transfusion reaction.
* Call transferred to MLS/Lead MLS.
* MLS will begin a Suspected Transfusion Reaction Investigation form (STRI)
* MLS will identify and record:
	+ Patient name, HID and location
	+ Date and time of reaction
	+ Whether the transfusion was completed or stopped.
	+ Name of nurse/clinician reporting the transfusion reaction
	+ Symptoms of suspected reaction
	+ Recall any un-transfused products immediately.
		- ***Note****: If reaction is associated with hypotension, anaphylaxis, chest pain, flank pain, abdominal pain, pain at the site of infusion, severe respiratory distress or a rise in T ≥ 1***o***C or ≥ 38***o***C, contact Transfusion Services Medical Director/Resident/Covering Physician immediately.*
 |  |
| 2 | * + - * Advise the nurse that they should send the following to Transfusion Services:
* Suspected Transfusion Reaction Notification and Workup Request form (TRRX Form)
* Copy of Transfusion tag, if available
* Product bag of transfused unit with attached infusion set/IV tubing and intravenous fluids
	+ If the decision is made to discontinue the transfusion without the possibility of re-starting the component following evaluation
	+ OR once the transfusion is completed
* Advise the nurse that they should send the following to Transfusion Services:
* Post transfusion sample drawn in pink top EDTA tube unless symptoms limited to **Category 1 reactions**:
* Temperature rise < 1oC without any other change in clinical status, Mild urticarial rash, hives, redness or itching/pruritus
 | Suspected Transfusion Reaction Notification and Workup Request formSuspected Transfusion Reaction Investigation form (STRI) |
| **Step** | **Action** | **Related Documents**  |
| **Receipt**  |
| 3 | * + - * Perform computer order entry: TRRX battery. Order is always STAT.
 | SQ Order Entry Process |
| 4 | * + - * Take request form, sample (if received), and product bag (if received) to an MLS for emergency processing.
 |  |
| 5 | * + - * Hold all in process orders.
			* *The patient may ONLY receive emergency release universal donor RBC & plasma (O RBCs, AB plasma), or group AB, A or B platelets until a hemolytic transfusion reaction has been ruled out.*
 | Receiving and Processing Emergency Release Orders |
| **Evaluation** |
| 6 | * Notification of Medical Director/Resident/Covering Physician:
* Refer to posted on-call schedule
* Additional notification instructions will be communicated on the shift hand off
 |  |
| 7 | * Evaluate clinical signs and symptoms
 |  |
| **If** | **Then** |  |
| * Symptoms are incomplete or question “back to baseline” is not answered
 | * + - Contact the clinical care staff to obtain further information
 |  |
| **Category 1:**Symptoms limited to:* Mild Allergic Reaction, i.e:
* Rash
	+ Urticaria
	+ Flushing
	+ Itching/pruritus
* Temperature rise <1oC
 | * Further blood products **may be released** without requiring Transfusion Services Medical Director or Resident/Covering Physician approval
* Sample NOT required
* Contact Medical Director/Resident/Covering Physician with investigation results
 |  |
| **Category 2:*** Symptoms are not typical of reaction definitions
* Symptoms do not match Category 1 or Category 3
 | * Further blood products **may not be released** until Transfusion Services Medical Director or Resident/Covering Physician approval is obtained
* Sample required
* Contact Medical Director/Resident/Covering Physician with investigation results
 |  |
| **Category 3:** Symptoms suggest severe transfusion reaction* Rise in temperature of ≥10C
* Temperature ≥38C
* Back/flank, chest, or abdominal pain
* Pain at infusion site
* Hypotension
* Respiratory distress
* Anaphylaxis

Gram Stain Positive | * Notify Transfusion Services Medical Director or Resident/Covering Physician **immediately**
* Sample required
* Further blood products **cannot be released** without Transfusion Services Medical Director or Resident/Covering Physician approval
 |  |
| **Step** | **Action** | **Related Documents**  |
| **Phase 1 Testing: Clerical, Hemolysis Check, Serologic, and Culture** |  |
| 8 | * Utilizing the Suspected Transfusion Reaction Investigation form (STRI), perform and record findings for the investigation.
* Perform clerical check of the following, if applicable:
* Post-transfusion sample
* Suspected Transfusion Reaction Notification and Workup Request Form (TRRX form)
* Computer record
* Transfusion Tag/Unit Label
* Autologous or Directed Bag Tag, if applicable
* Pre-sample if discrepancy found
* If there is any discrepancy request a redraw and notify the Transfusion Services Medical Director or Resident/Covering Physician
* Result Clerical Check test in SQ:
* [CLCKP] for passed clerical check
* [CLCKF] for failed clerical check
* Result Clerical Check on the STRI form
* No Discrepancy
* Discrepancy: describe findings
* Add Comments if applicable
 | SQ Blood Order ProcessingSuspected Transfusion Reaction Investigation formSQ Blood Order Processing Test Result Guide |
| 9 | * + Result test “UNO” (free text field) and STRI form:
* Enter unit number or “multiple, see attached report”
* Add component type: RBC, PLT, Plasma, Cryo
* If “multiple”, attach BBI printout of Transfusion History
	+ If the product bag is received, examine the bag, residual product, and attached administration set and IV fluids (if submitted)
	+ Record findings on the STRI form.
	+ Add Comment test and record results in SQ.
	+ If bag is not received, indicate in Comments and on the STRI form.
	+ **Note:** Store transfusion reaction related unit bags and attachments on the Quarantine Shelf as soon as possible to preserve condition
 | SQ Blood Order Processing Test Result Guide |
| 10 | * + - Submit appropriate order and request to Microbiology for unit gram stain and culture when:
			* **If Rise in temperature of ≥10C or ≥ 38C**
				+ No medical director order required
			* Medical Director/LMR requests submission to Microbiology
		- If Gram Stain reported Positive,
			* Call Medical Director/Resident/Covering Physician immediately.
			* Notify blood supplier. Document on paperwork who was called.
* Record on STRI form:
	+ Gram Stain result
	+ Tech name who called report
	+ Date/Time
	+ TSL Tech ID who entered results and printed report
 | Blood Component Gram Stain and Culture formTable B |
| **Step** | **Action** | **Related Documents**  |
| **Phase 1 Testing: Clerical, Hemolysis Check, Serologic, and Culture (continued)** |
| 11 | * + Perform Phase 1 testing on post-transfusion sample
	+ Hemolysis check of post-transfusion specimen (POSTSP)
	+ Direct Antiglobulin test (DAT) with Polyspecific AHG (DBS, DIG, DCD)
	+ ABO/Rh (ABR): Record comparison to pre-ABO/Rh testing
	+ Record results in the LIS and on the STRI form.
 | STRI formSQ Blood Order Processing Test Result Guide  |
| 12 | * If the ABO/Rh matches the pre-transfusion results, and there is no visible hemolysis, and the DAT is Negative:
	+ Report to the clinician or nurse: “No evidence of a hemolytic transfusion reaction”
	+ Record phone call on TRRX form.
	+ Contact the Transfusion Services Medical Director/Resident/Covering Physician and obtain approval for the patient to receive further/routine blood products
	+ Enter into BBC comments the statement: “Patient Approved/Not Approved to receive further blood products”
* If the ABO/Rh is discrepant, request a redraw and notify the Transfusion Services Medical Director or Resident/Covering Physician
 |  |
| **Phase 2 Testing: Evidence of Hemolysis and/or a Positive DAT** |
| 13 | * + - If there is any evidence of hemolysis and/or a positive DAT:
			* Notify the Transfusion Services Medical Director/Resident/Covering Physician immediately:
			* Perform Phase 2/extended testing as directed by the Transfusion Services Medical Director / Resident / Covering Physician utilizing a patient sample drawn previous to the TRRX event. If multiple accession numbers are available, select the sample closest to the TRRX event. *Sample may not be truly pre-transfusion but should reflect status of patient prior to the TRRX event.*
				+ Pre-transfusion sample hemolysis check
				+ Pre-transfusion sample DAT
				+ Pre/Post transfusion sample eluate
				+ Pre-transfusion sample ABO/Rh
				+ Post-transfusion sample antibody screen/identification
				+ Pre-transfusion sample antibody screen/identification
				+ Pre/Post-transfusion sample compatibility testing (donor retention sample/segment from blood bag)
				+ Blood product culture
				+ Red Cell Reference Laboratory referral

Notify the Transfusion Services Medical Director/Resident/Covering Physician of resultsDetermine if patient approved to receive further blood products * + - Record results in the LIS:
			* Pre-transfusion sample hemolysis check (PRESP)
			* Pre-transfusion sample accession number (PRETX)
 | ABO/Rh by Tube MethodAntibody Screen by Tube MethodCrossmatch by Tube IAT MethodAntibody Panel by LISS IATDAT by Tube MethodSQ Blood Order Processing Test Result Guide |

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents**  |
| **TRALI Investigation** |
| 14 | Suspected TRALI--After consultation with Transfusion Medical Director/Resident/Covering Physician:* Search product inventory for other components with the same unit number, and quarantine any that are found.
* Call blood supplier to notify them about the unit in question and possible TRALI.
* Consult with Medical Director/Resident/Covering Physician to order HLA type on recipient. *Note: HLA testing is sent out through SPS.*
 |  |
| **Notification of Supplier**  |
| 15 | * The collecting facility is notified immediately by the Medical Director when there is a fatality or serious adverse event that may be related to the product or donor of a transfused product.
* The notification must subsequently be done in writing.
 | Quality Policy—Management of Nonconforming Events  |
| **Delayed Hemolytic Transfusion Reaction (DLHRX) Investigation** |
| 16 | * Investigate transfusion history for **all DAT Only orders and Problem Investigations that have a POS DAT result**
* If patient has been transfused in the last 4 months, the potential for delayed transfusion reaction exists and must be investigated:
	+ Perform parallel DAT on Pre-Transfusion sample, if available.
	+ Perform PEG or TANGO antibody screen on Post-Transfusion sample.
	+ If Post antibody screen is positive, repeat pre-transfusion antibody screen
		- Note: Perform antibody screen using PEG or TANGO. If discrepant with TANGO, repeat screen using PEG.
	+ Perform eluate(s) as indicated per SOP.
* Complete ABID worksheet and Eluate Testing Form.
* If the Elution is positive:
* Antigen type the donor unit(s) for the antigen to the antibody eluted, using the retention segment, if available.
* Notify the Medical Director/Resident/Covering Physician immediately.
	+ - If Medical Director/Resident/Covering Physician determines that DLHRX has occurred:
* Order TRRX
* Enter results of investigation.
* Result Interpretation as DLHRX
* Result TXPATH once the Path Consult report is finalized.
	+ - Record all conversations, inquiries and observations on the TRRX form.
 | DAT by Tube MethodAntibody Screen by PEG Tube IAT MethodTANGO Patient and Donor Sample Requirements and PreparationEluate Testing GuidelinesAntibody Elution Using Gamma ELUkit |
| **Investigation Completion** |
| 17 | * + - Request a 2nd technologist to review workup and LIS entry.
		- Record review on the STRI form
 |  |
| 18 | * + - Route to the Medical Director:
			* **Original STRI** plus copies of other paperwork for signature, designation of reaction type and written consult
			* Retain copy and original worksheets until consult has been completed.
			* Positive culture results
 |  |
| **Step** | **Action** | **Related Documents**  |
| **Investigation Completion (continued)** |
| 19 | * + - Result TXRINT with the U.S. Biovigilance designation, based on the Medical Director review.
		- After Medical Director has completed the consult, result TXPATH, with the code for the Medical Director
		- Discard blood bag
 | Table ASQ: Blood Order Processing Test Result Guide  |

**Table A: U.S. Biovigilance Network Adverse Reactions**

|  |  |
| --- | --- |
| **SQ Code** | **Type of Reaction as listed by US Biovigilance Network** |
| **DLHRX** | Delayed hemolytic transfusion reaction |
| **DSTRX** | Delayed serologic transfusion reaction |
| **HYTRX** | Hypotensive transfusion reaction |
| **OTH** | Other |
| **PTPUR** | Post transfusion purpura |
| **TAGVH** | TA-Graft versus host disease |
| **TRALI** | Transfusion related acute lung injury |
| **TRDYN** | Transfusion related dyspnoea |
| **TRPUNK** | Unknown pathophysiology |
| **TXALL** | Allergic Reaction |
| **TXCULT** | Transfusion associated infection (bacterial, viral, parasitic, other) |
| **TXFEB** | Febrile non-hemolytic transfusion reaction |
| **TXHEM** | Acute hemolytic transfusion reaction |
| **VOLO** | Transfusion associated circulatory overload |

**Table B: Microbiology – Gram Stain and Culture**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| 1 | Complete form:* + Check type of component
		- “Other” may be used for Cryoprecipitate or special product description
	+ Accession Number of TRRX Order
	+ Unit number (separate forms for each unit)
	+ Date/time/Tech ID submitted to Microbiology
	+ Patient Name, HID and DOB
 | Blood Component Gram Stain and Culture form |
| 2 | Make a copy of the Microbiology form for the TRRX folder. |  |
| 3 | Deliver the unit and form to Microbiology Receiving, GWH  |  |
| 4 | Microbiology process:* + Assign HID to order using “HTSL –“ plus patient’s HID
	+ ***Example:*** *HTSL – 1232345*
	+ Perform Gram Stain STAT
	+ Phone Gram Stain result to MLS in TSL
	+ Set up culture

***Note****: Results will NOT display in ORCA/EPIC under the patient HID.*  | Suspected Transfusion Reaction Investigation form (STRI) |
| 5 | Record on STRI form:* + Gram Stain result
	+ Tech name who called report
	+ Date/Time
	+ TSL Tech ID who entered results and printed report

Print a copy of the Gram Stain report from LIS Laboratory Inquiry:* + Search by HTSL number
	+ Record Accession Number on the Gram Stain report
 |  |
| 6 | Record in BBC Comments on the TRRX battery:* + “Submitted to Microbiology”
	+ Gram Stain results and date.
 |  |
| 7 | Hold TRRX folder in the black organizer until the final Microbiology report is printed and resulted as a BBC comment.* Report will print on the designated LIS printer
* Record in LIS and STRI form
* File report in TRRX folder and store in TRRX drawer of the filing cabinet
* Submit final culture report to Medical Director for review.
* Medical Director/Designee will report the final culture report for positive gram stain results to the blood supplier
 | Quality Policy—Management of Nonconforming Events |

**References**

Standards for Blood Banks and Transfusion Services, Current Edition, Bethesda, MD: American Association of Blood Banks.

Roback J (ed). Technical Manual, 16th Edition. AABB Press, Bethesda, MD. 2008.

Popovsky MA (ed). Transfusion Reactions, 3rd Edition. AABB Press, Bethesda, MD. 2007.