**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:**

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| **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 | * + - * Suspected Transfusion Reaction Notification and Workup Request form       * Suspected Transfusion Reaction Investigation form (STRI) |

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| **Step** | **Action** | | **Related Documents** |
| **2** (cont.) | * 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, | |  |
| **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 whiteboard and/or 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 |  |

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| **Step** | **Action** | | **Related Documents** |
| **7** (cont.) | * Evaluate clinical signs and symptoms (continued) | |  |
| **If** | **Then** |  |
| **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** without requiring Transfusion Services Medical Director or Resident/Covering Physician approval * 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 |  |
| **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 | | * + Blood Order Processing   + Suspected Transfusion Reaction Investigation form   + SQ Blood Order Processing Test Result Guide |

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| **Step** | **Action** | **Related Documents** |
| **Phase 1 Testing: Clerical, Hemolysis Check, Serologic, and Culture (continued)** | | |
| **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. * Record on STRI form:   + Gram Stain result   + Tech name who called report   + Date/Time   + TSL Tech ID who entered results and printed report | Blood Product Culture form  Table B |
| **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 form   + Computer system   + SQ 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” |  |

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| **Step** | **Action** | **Related Documents** |
| **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 results  Determine 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 Method     - Antibody Screen by Tube Method     - Crossmatch by Tube IAT Method     - Antibody Panel by LISS IAT     - DAT by Tube Method     - SQ Blood Order Processing Test Result Guide |
| **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. |  |

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| **Step** | **Action** | **Related Documents** |
| **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 antibody screen on Post-Transfusion sample.   + Perform PEG antibody screen on Pre-Transfusion sample, if Post is POS.     - Testing on an automated platform is optional   + 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 Method * Antibody Screen by PEG Tube IAT Method * Eluate Testing Guidelines * Antibody 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 |  |
| **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 “JDJ”.     - Discard blood bag | Table A |

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

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| **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**

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| **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 | Microbiology Blood Component – Gram Stain & Culture |
| 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) |

**Table B: Microbiology – Gram Stain and Culture** (continued)

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| **Step** | **Action** | **Related Documents** |
| 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 |  |

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

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