



Current Status: Active

PolicyStat ID: 3821181



**Origination:** 03/2017  
**Effective:** 09/2017  
**Last Approved:** 09/2017  
**Last Revised:** 09/2017  
**Next Review:** 09/2019  
**Owner:** *Tim Malone: Manager, Transfusion Services*  
**Policy Area:** *Lab / Transfusion Services*  
**References:**  
**Applicability:** *St. Francis Hospital  
St. Anthony Hospital  
St. Clare Hospital  
St. Elizabeth Hospital  
St. Joseph Medical Center*

## Transfusion Reaction – Immediate Recipient Complications, M-W-TS-0750-07

### PURPOSE

To describe the steps for managing a transfusion complication which occurs during or immediately following the transfusion of a blood component.

### BACKGROUND

The CDC's National Healthcare Safety Network includes a biovigilance component directed toward transfusions which is known as the Hemovigilance Module. It was created to implement national surveillance of transfusion-associated adverse events aimed at improving patient safety, minimizing morbidity and mortality of transfusion recipients, and identifying emerging complications and pathogens associated with blood transfusion. As part of this activity, defined categories of transfusion reactions as currently listed are found below. It should be noted that mild allergic reactions (hives, urticarial) are **not** mentioned. Each type of reaction is carefully defined to contain specific clinical symptoms.

|               |  |
|---------------|--|
| • TACO        | Transfusion-associated circulatory overload                                |
| • TRALI       | Transfusion-related acute lung injury                                      |
| • TAD         | Transfusion-associated dyspnea   |
| • Allergic    | Transfusion reaction (where severity = severe, life threatening, or death) |
| • Hypotensive | Transfusion reaction   |
| • FNHTR       | Febrile non-hemolytic transfusion reaction                                 |
| • AHTR        | Acute hemolytic transfusion reaction                                       |
| • DHTR        | Delayed hemolytic transfusion reaction                                     |

|          |   |
|----------|---|
| • DSTR   | Delayed serologic transfusion reaction        |
| • TAGVHD | Transfusion-associated graft vs. host disease |
| • PTP    | Post-transfusion purpura                      |
| • TTI    | Transfusion-transmitted infection             |

For more information, see <http://www.cdc.gov/nhsn/PDFs/Biovigilance/BV-HV-protocol-current.pdf>

## RELATED DOCUMENTS

|              |  |
|--------------|--|
| R-W-TS-0750  | <a href="#">Transfusion Reaction – Immediate Recipient Complications</a>   |
| J-W-TS-0755  | <a href="#">Transfusion Reaction – Delayed Recipient Complications</a>   |
| J-W-TS0760   | <a href="#">FDA Reporting of Biological Deviations</a>   |
| J-F-TS-1033  | <a href="#">Culture of Blood Component Form</a>  |
| J-F-TS-1048  | <a href="#">Transfusion Reaction Workup Form</a>   |
| (FHS) 586188 | <a href="#">Suspected Transfusion Reaction Investigation Form</a><br>(attached to Transfusion Record - Suspected Transfusion Reaction Investigation Form Instructions 1089.00) |

## MATERIALS / SUPPLIES

1. **Specimens** – each labeled with name, MRN, DOB, Date/Time collected, & phlebotomist initials
  - Pre-transfusion patient EDTA specimen. BBID # sticker attached – if prior to Aug 1, 2017
  - Post-transfusion patient EDTA specimen. BBID # sticker attached – if prior to Aug 1, 2017
  - Post-transfusion urine specimen, **if necessary** to perform extended workup
2. Reagents
  - ABORH typing reagents
  - Anti-AHG, Poly
  - Anti-IgG
  - Anti-C3
  - Check cells
  - Elution Kit

# STEPS FOR INITIAL REACTION INVESTIGATION

1. If adverse symptoms are experienced by a patient during a transfusion, then according to clinical nursing standards, the transfusionist is instructed to:
  - Stop the transfusion immediately
  - Check vitals
  - Check all patient identifying information and blood unit information for correctness.
  - Notify the ordering physician of signs and symptoms of the reaction.
  - Notify the Transfusion Service.

**Note:** Signs and symptoms suggestive of **mild** allergic reactions (eg, urticaria) do **not** need to be reported to the transfusion service.

2. Upon receipt of notification, the transfusion service staff will verify with the nurse whether or not the **physician** has requested a transfusion reaction work-up.
3. If a work-up has been ordered, staff from the remote site or the transfusion service will arrange for a post-transfusion blood sample to be drawn from the recipient as soon as possible (no longer than 45 minutes).

**Note:** If blood bands are used, a Blood Band ID # sticker is removed from the patient's armband and placed on the specimen.

4. The transfusionist will complete the "Nursing Report" portion of the Suspected Transfusion Reaction Form.
5. The transfusionist will return the following to either the SJMC Transfusion Service or to the remote-site laboratory:
  - Suspected Transfusion Reaction Form
  - The blood product container (whether it contains any unused blood or not),
  - The attached Transfusion set and intravenous solutions which have had the needle removed.
  - Post-transfusion blood sample if collected by the nurse
6. If the Transfusion reaction occurred at SAH, SCH, SEH, or SFH, the on-site tech receiving the forms and blood container from the nursing unit will re-examine the following for clerical errors in patient or unit identification by verifying patient name, MRN, date of birth, blood type, and blood band number if used, in each of the following places.
  - Patient adhesive label on the back of the blood unit
  - Suspected Transfusion Reaction Form
  - Unit Face Label (blood type, product, expiration date, BBID# sticker if used)
7. The tech will then record the word "Verified" along with tech ID, date, and time on the Suspected Transfusion Investigation Form next to the words "Clerical Verification".

**For example:** "Verified. A25 2/18/09 0445"

8. Investigate any clerical discrepancies if they are present.

9. Remote Sites call SJMC immediately to alert them that samples, etc. will be coming to them.

**Note: At this point, remote sites will send all of the above items listed in steps #3 and #5 to the SJMC Transfusion Service STAT.**

10. The Transfusion Service at SJMC will complete the Initial Investigation section of the Transfusion Reaction Workup Form and any other remaining steps.

- Perform and document detailed clerical check as shown on form.
- Record all units transfused within the last 12 hours and note if any were cultured.

11. Centrifuge and examine the pre- and post-transfusion samples for hemolysis and/or icterus. Pink or red discoloration in the post- but not the pre-transfusion sample indicates hemolysis. Record visual results.

**Note:** A post-transfusion specimen may also be hemolysed due to imperfect collection technique. Recollection is advised for confirmation of hemolysis.

12. If the strength of the DAT reaction in the **post**-transfusion sample is stronger than the reaction in the **pre**-transfusion sample, further steps will need to be taken as found in the Extended Reaction Investigation.

13. Interpret the results of the initial investigation as follows:

| Presumed Non-hemolytic Reaction  | Possible Hemolytic Reaction   |
|--|---|
| 1. Hemolysis and/or icterus on post sample negative or is < hemolysis and/or icterus on pre sample | 1. Hemolysis and/or icterus on post sample > hemolysis and/or icterus on pre sample |
| 2. ABO on post-sample compatible with unit ABO   | 2. ABO on post sample not compatible with unit ABO type                             |
| 3. DAT on post sample negative or reaction strength ≤ strength on pre sample                       | 3. Post-sample DAT reaction strength > pre-sample                                   |

14. If the recipient has a temperature increase of  $\geq 1^{\circ}\text{C}$  (or  $\geq 1.8^{\circ}\text{F}$ ) complete the Culture of Blood Component Form, affixing it with a TRXN accession # instrument label, and take the blood component to microbiology for culture.

**Note:** If the recipient experiences rigors, cardiac collapse or shock, perform an immediate gram stain on the unit in addition to culturing it.

15. If the transfusionist reports that the recipient is having breathing difficulties and that Transfusion Related Lung Injury (TRALI) is suspected, notify the Transfusion Service Manager and the Medical Director immediately. Give the workup to the Medical Director to complete once the workup is complete.

16. If none of the results fall into the possible hemolytic reaction category, notify the transfusionist that the investigation is negative. Document the call on the Transfusion Reaction Workup Form.

17. If any of the investigation results fall into the Possible Hemolytic Reaction category, OR if the recipient's condition suggests a hemolytic episode, i.e. hemoglobinemia or hemoglobinuria as noted by nurse or clinician, it will be necessary to proceed with the extended investigation below.

18. Store the blood bag in the quarantine bucket in the refrigerator until the Medical Director review has been completed. Serious adverse events may require that the blood bag be stored for a longer period of time as the Medical Director designates.

# Tx ADDENDUM 1 – INITIAL TRXN WORKUP

1. Check the little "e" button to determine if an electronic order is present. Record the patient CSN#. Close the window.
  - Look for the Beaker order "Transfusion Reaction Evaluation"
2. Top menu bar: **Open > Patient Profile**. Bring in the patient. Update CSN (if necessary)
3. Record the post-transfusion specimen
4. Bring in the transfusion reaction order
  - **File > New > Order > TXRX**
  - In the New Order window record:
    - Priority = STAT
    - Add Post-Specimen accession number
      - **Note:** Leave the Pre-Specimen field blank
    - Record Reaction Date and Time
  - Click **OK** and the window will close
  - With the Order Profile still open, select **Orders > Add Electronic Orders**
  - In the "Select Pending Electronic Order" window,
    - If no order appears in the grid, uncheck the "Restrict by Ext. Visit No." box and select Query. The grid will populate with order information
    - Select the order from the Pending Electronic Orders grid
    - Click the **OK** button.
  - In the Order profile window, the electronic order items now display in the items grid.
  - Enter a time for each order item and save.
5. Check the pending log (**PW**), query, and select the patient's TRXN RXN INITIAL order
6. Verify the specimen and result the tests. Save and close
7. **Check the At-A-Glance bar**
  - Verify that the upper case, red, "X" is present indicating that there has been a transfusion reaction.
  - Click it and review to verify that the information has been updated
8. Notify the Medical Director of the TRXN. Include patient name and patient ID #.
9. Until the Medical Director completes the TRXN review and enters the required analysis, SafeTrace knows that the order has not been completed. SafeTrace is not designed to allow the issuing RBCs until the order has been completed.
10. If the patient is bleeding and the physician wants to transfuse while the transfusion workup is being completed, call the Medical Director.
11. In this situation, it may be necessary to override warnings if you need to issue additional blood.
12. **Under no circumstances will you record information in the Reaction Type, Diagnosis, or Treatment areas of the patient's transfusion reaction order.** This is only for the Medical Director to

result. We have learned that if we enter information and save it, the Medical Director can see it and change it – but the new information will NOT cross to Epic.

## Tx ADDENDUM 2 – EXTENDED TRXN WORKUP

1. Phone the pathologist on call immediately.
2. Verify that the transfusionist has called the patient's physician; if not, advise them to do so immediately.
3. Ask the transfusionist to send the first voided urine to the laboratory.
4. Manually order TRXN EXT
  - **File > New > Order > TXRN EXT**
  - In the New Order window record:
    - Priority = STAT
    - Add Post-Specimen accession number
    - Add Pre-Specimen accession number
    - Record Reaction Date and Time
  - Click **OK** and the window will close
5. Complete the extended investigation as outlined below and record results in the Extended Investigation portion of the Transfusion Reaction Workup Form:
  - Use the pre-transfusion specimen to perform a repeat pre-DAT whenever the post-DAT has a stronger positive result than the pre-DAT. The discrepancy could be significant.
  - Repeat ABO Rh and antibody screen on both the pre-transfusion sample and the post-transfusion sample
  - ABO Rh on all units transfused within the last 12 hours of the reaction.
  - Perform an anti-IgG gel method crossmatch on each of the above units with both pre- and post-transfusion samples
  - Perform a bilirubin on the post transfusion sample. If a specimen drawn before the transfusion occurred is available, perform a bilirubin on it as well.
  - Perform a visual examination on the post transfusion urine sample for hemoglobin and intact RBC

**Note:** Intact RBCs are **not** indicative of a hemolytic reaction
6. The pathologist on call may request additional testing, which should be ordered and performed in the Extended Transfusion Reaction Workup.
7. Orderable tests for the TRXN EXT include:

| PRE-TXRN SAMPLES | POST-TXRN SAMPLES | MISCELLANEOUS TESTS |
|------------------|-------------------|---------------------|
| ◦ PREABID1       | ◦ POSTABID1       | ◦ BILI              |
| ◦ PREABID2       | ◦ POSTABID2       | ◦ HAPTO             |
| ◦ PREABORHT      | ◦ POSTABORH       | ◦ LDH               |
| ◦ PREABSCG       | ◦ POSTABSCG       | ◦ REPEATXM1         |
| ◦ PREDATC3       | ◦ POSTDATC3       | ◦ REPEATXM3         |

| PRE-TRXN SAMPLES  | POST-TRXN SAMPLES   | MISCELLANEOUS TESTS  |
|---|---|--|
| <ul style="list-style-type: none"> <li>◦ PRECATCTL</li> <li>◦ PREDATIGG</li> <li>◦ PREDATPOLY</li> <li>◦ PREELU1</li> <li>◦ PREELU2</li> <li>◦ PREHEMO</li> </ul> | <ul style="list-style-type: none"> <li>◦ POSTDATIGG</li> <li>◦ POST ELU1</li> <li>◦ POSTELU2</li> <li>◦ POSTHEMO</li> <li>◦ POSTDATCTL</li> <li>◦ PSTDATPOLY</li> <li>◦ PSTURINE</li> </ul> | <ul style="list-style-type: none"> <li>◦ REPEATXM3</li> <li>◦ REPEATXM4</li> <li>◦ UNITABORH1</li> <li>◦ UNITABORH2</li> <li>◦ UNITABORH3</li> <li>◦ UNITABORH4</li> </ul> |

8. If any previously unidentified antibodies are detected in the antibody screen during the investigation, work up the antibody to identify it. Antigen type the units which were transfused for the antigen corresponding to any antibody discovered.
9. Report the results of the extended investigation to the pathologist as well as to the nurse caring for the patient. Should the pathologist's interpretation of the results indicate that they are suggestive of hemolysis, bacterial contamination, TRALI, or other serious adverse event related to the transfusion, the interpretation must be reported to the patient's physician immediately.
10. Leave the completed forms and test results for Transfusion Service Manager and Medical Director review and further reporting as appropriate.
11. If discrepancies or errors are identified, proceed with the occurrence management process as soon as possible by filling out a Quality Form or submitting an IRIS.
12. If another patient's sample and/or unit(s) are involved, call the caregiver ASAP and include this patient in the investigation process.
13. If a transfusion fatality or other serious, unexpected adverse event occurs that is suspected to be related to an attribute of a donor or a unit, the collecting facility shall be notified immediately by phone and subsequently in writing.
14. Any fatality due to a transfusion must also be reported as soon as possible to the FDA, ideally within 24 hours. See "FDA Reporting of Biological Deviations"

## REFERENCE

AABB Technical Manual, current edition

AABB Standards for Blood Banks and Transfusion Services, current edition

### Attachments:

No Attachments

### Approval Signatures

| Approver                                   | Date    |
|--|---------|
| Arlene Brennan: Administrative Coordinator | 09/2017 |
| Adam Saenz: MD, Medical Director           | 09/2017 |
| Brian Folz: Medical Director               | 08/2017 |

| <b>Approver</b>                            | <b>Date</b> |
|--|-------------|
| Linda Burkhardt: MD, Medical Director      | 08/2017     |
| Shane Anderson: MD, Medical Director       | 08/2017     |
| Joren Keylock: MD, Medical Director        | 08/2017     |
| Arlene Brennan: Administrative Coordinator | 07/2017     |
| Teri Emerson: Manager-Transfusion-Quality  | 07/2017     |

COPY