**1.0 Purpose**

1.1 To define a system for investigating suspected adverse reactions to transfusion.

1.2 To provide protocol for determining the extent of testing required in identifying the cause of reaction.

1.3 To define a method for evaluating and interpreting the results of the investigation.

**2.0 Scope**

Transfusion Reaction Investigations are performed promptly and the extent of testing must include techniques required to classify the type of reaction. This procedure directs the investigative process.

**3.0 Specimen**

* 1. Post transfusion 7 ml EDTA anticoagulated blood

3.2 Returned product bag, tubing and administration set

3.2 Post transfusion urine specimen

3.3 Pre transfusion specimen (if available)

**4.0 Equipment**

4.1 Blood Bank **Transfusion Reaction Report** (**Attachment 1)**

4.2 Blood component container

4.3 Centrifuge

4.4 Equipment required by specific test procedures performed

**5.0 Quality Control**

5.1 Clerical checks are performed on all documentation referenced in this procedure

5.2 The Blood Bank Supervisor and the Medical Director/Designee review all aspects of the Transfusion Reaction Workup. The Medical Director/Designee summarizes the findings of the Transfusion Reaction Workup.

**6.0 Procedure**

6.1 Receive **Transfusion Reaction Report** from floor (Attachment 1):

6.1.1 Ensure that the following information is documented on the **Transfusion Reaction Form**:

* + - 1. “**Nursing Clerical Check”**- to include:
				1. Results of Clerical Check
				2. Pre and Post Transfusion Vital signs
				3. Signature of RN performing clerical verification

6.1.1.2 **“Signs and Symptoms”**

6.1.1.3 **“Reaction Occurred”**

6.1.1.3.1 Patient’s Clinical Diagnosis

6.1.1.3.2 Unit number

6.1.1.3.3 Product name

6.1.1.3.4 Amount administered

* + - * 1. Type of solution with blood (if applicable)

6.1.1.3.6 Total number of units transfused within prior 6 hours

6.1.1.4 **“Post Transfusion Specimen Collection”**

6.1.1.4.1 Signature of phlebotomist who drew post-transfusion specimens

Signature of witness

6.2 **Blood Bank** **Initial Workup is performed at both EMCP and EMC-EP:**

6.2.1 Perform clerical check:

 6.2.1.1 Compare the unit transfused to the paperwork attached and the results in Cerner (LIS).

6.2.1.2 Notify the Blood Bank Supervisor/Designee immediately if any discrepancies are detected

6.2.2 Order a transfusion reaction workup in the LIS system as follows:

6.2.2.1 Order a “**TRXN**” on the Post transfusion sample

 6.2.3 Perform visual check for hemolysis:

6.2.3.1 Centrifuge a properly labeled EDTA pre (if available) and post transfusion sample for five (5) minutes.

 6.2.3.2 Inspect plasma for evidence of hemolysis

6.2.3.2 Indicate on the **Transfusion Reaction Form** the presence or absence of visible hemolysis. **Any evidence of hemolysis in the post sample (when the pre sample was clear) must be reported to the Blood Bank Supervisor/Lead Technologist and the Medical Director/Designee immediately**. Document physician notification in the comments of Patient Product Inquiry.

6.2.4 Perform DAT on both pre and post specimen (Refer to **Procedure BB06-010**)-Follow DAT procedure for site specific instructions.

6.2.5 Perform ABORH on post sample (this ensures sample integrity)

6.2.6 If directed by the Medical Director/Designee, forward the blood unit container to the microbiology department at EMCP for gram stain and/or culture

6.3 ***An extended transfusion reaction workup is performed if:***

6.3.1 Visible hemolysis in centrifuged post-reaction specimen (and pre specimen was clear)

6.3.2 Clerical check performed by the patient care team has **not** verified accurate unit/patient documentation.

 6.3.3 Post transfusion sample demonstrates a positive DAT (and pre sample was negative)

6.4 **Extended Workup:**

6.4.1 Take urine sample specimen to Urinalysis section to be tested for free hemoglobin

* + - 1. Indicate on the **Transfusion Reaction Form** and document in **Patient Product Inquiry**, the presence or absence of free hemoglobin. **Any evidence of hemolysis must be reported to the Blood Bank Supervisor/Lead Technologist and the Medical Director/Designee immediately.**

6.4.2 Examine the blood container for evidence of hemolysis:

6.4.2.1 Indicate on the **Transfusion Reaction Form** and document in **Patient Product Inquiry**, the presence or absence of visible hemolysis. **Any evidence of hemolysis must be reported to the Blood Bank Supervisor/Lead Technologist and the Medical Director/Designee immediately**

6.4.3 Perform **Antibody Screen Test** on the pre and post reaction specimens as directed by the Antibody Screen procedure:

6.4.3.1 Pre specimen results: record reactions and interpretations in Patient Product Inquiry

6.4.3.2 Post specimen results: Create a new accession number to result interpretations

 6.4.4 Perform **Extended** **Compatibility Testing** on the pre and post-reaction specimens against the donor unit using an attached segment (if available) or a sample retrieved from the unit bag as directed by the compatibility test procedure:

6.4.4.1 Record reactions and interpretations in Patient Product Inquiry

6.4.5 Forward the blood unit container to the EMCP microbiology department for gram stain and/or culture if directed by the Medical Director/Designee

6.4.6 Forward the post transfusion specimens to the clinical laboratory for further chemical and/or coagulation studies as directed by the Medical Director/Designee

6.4.7 If the post DAT is positive and the pre DAT is negative perform an **elution** on the post specimen.

 6.4.7.1 If an antibody is identified in the eluate a delayed transfusion reaction should be suspected. Check the patient’s transfusion history.

 6.4.7.1.1 If the patient has been transfused in the past 14 days: retrieve a segment from each unit and antigen type the segment for the

 antigen of the antibody identified.

 6.4.7.1.1 Enter antigen typing results and result the antibody if identified in the computer as per applicable sop.

 **NOTE:** Antibody screen can be negative while the elution is reactive

6.5 Sign and date **Transfusion Reaction Form:**

6.5.1 Forward all documentation to the Blood Bank Supervisor or Lead Technologist.

6.6 Complete patient Blood Bank record:

6.6.1 Document in LIS that a transfusion investigation was performed. Include the name of the nurse notified, the component type, unit number and serologic test results and interpretations

6.6.2 If an extended workup was performed, document in the **BB01-020 Form A
:Critical Callback Log** date, time, and nurse notified according to **Procedure BB01-020**

6.7 Upon completion of workup, notify the Pathologist/Pathologist on call of workup results. **ADDITIONAL PRODUCTS WILL NOT BE RELEASED UNTIL CLEARED BY THE PATHOLOGIST.**

6.7.1 Once cleared by the pathologist, document in Patient Product Inquiry and on the Transfusion Reaction Form the date, time, and name of pathologist.

6.7.2 If the workup is received on third shift and the results are negative and no products are requested leave a message in the communication log and patient product inquiry for dayshift staff to notify pathologist.

6.8 Store all patient blood samples and blood components (including attached saline, etc) at 1-6°C for 10 days.

6.9 Review Transfusion Reaction Workup:

6.9.1 The Blood Bank Supervisor/Lead Technologist reviews and summarizes all clerical checks and serological results for all transfusion reaction investigations.

6.9.2 The Medical Director/Designee reviews and summarizes all clerical checks and serological results and the patient condition for all transfusion reaction investigations.

6.9.2.1 The Medical Director/Designee classifies each transfusion reaction in the investigation summary.

6.9.2.2 All reactions involving dyspnea are thoroughly investigated in conjunction with ruling out TRALI by the Medical Director/Designee.

6.9.3 The Medical Director/Designee relates any additional laboratory investigations and/or subsequent transfusion considerations to the Blood Bank staff. The Blood Bank staff documents any applicable instructions in Patient Product Inquiry

6.10 Inform primary physician of transfusion investigation findings:

6.10.1 The Blood Bank Supervisor or Medical Director/Designee notifies the primary physician immediately upon the detection of a hemolytic reaction

6.10.2 The Medical Director/Designee relates any subsequent transfusion considerations to the physician primarily responsible for the care

**7.0 Interpretation**

7.1 Hemolysis is interpreted as a pink or red supernatant evident in the serum or plasma of a blood specimen.

7.2 Serologic test results are interpreted as directed by the procedure specific to the test performed.

7.3 The Medical Director/Designee summarizes the transfusion reaction workup findings and determines the likely cause of the reaction based on clerical/visual examination results, serologic test results and the patient condition.

**8.0 Reporting Results**

8.1 Transfusion Reaction results are documented on the **Blood Bank Report** and in the Blood Bank computer record:

8.1.1 Document all results in LIS (Result Entry)

* 1. The Medical Director/Designee provides a summary of the transfusion reaction workup to the primary physician, which is added to the patient’s chart and/or medical record.
	2. The Blood Bank staff verbally reports a transfusion-related fatality to the Medical Director/Designee:
		1. The Medical Director/Designee subsequently notifies the FDA about the fatality within 24 hours

**9.0 Procedure Notes**

9.1 Immediately perform an investigation of a suspected adverse transfusion reaction upon notification.

9.2 Immediately report any discrepancies discovered during the investigation of a transfusion reaction to the Blood Bank Supervisor/Lead Technologist.

* 1. Immediately report any evidence of a hemolytic reaction to the Blood Bank Supervisor and/or the Medical Director/Designee. Document notification in the comments of Patient Product

 Inquiry.

* 1. It is permissible to use the post DAT specimen to perform a crossmatch if blood is requested under the following conditions:

9.4.1 The specimen meets all criteria for being properly labeled according to **Procedure BB05-004**

 9.4.2 A *complete* ABO/Rh and an antibody screen must be performed

**10.0 Limitations of the Procedure**

10.1 If the symptoms and signs of reaction appear such that the reaction is likely to have been caused by faulty components (mislabeling, etc.) and/or related to the manufacture or distribution of the product, notify the Medical Director/Designee, Blood Bank Supervisor and blood supplier immediately. The Blood Bank Supervisor directs any further action:

* + 1. Notify the collecting facility immediately and submit a “**Recipient Complication-Transfusion Reaction Report**” to the ARC. Go to [www.redcrossblood.org/hospitals/case-reports](http://www.redcrossblood.org/hospitals/case-reports) to complete form.

10.2 Notify the Medical Director/Designee and the Blood Bank Supervisor immediately if at any point during or after transfusion signs, symptoms and clinical condition indicate the possibility of a transfusion-transmitted disease. Document notification in the comments of Patient Product Inquiry. The Blood Bank Supervisor directs any further action:

* + 1. Notify the collecting facility immediately and submit a “**Possible** **Recipient Complication-Infectious Disease Report**” to the ARC. Go to [www.redcrossblood.org/hospitals/case-reports](http://www.redcrossblood.org/hospitals/case-reports) to complete form.
	1. Any adverse reaction to blood or blood components must be investigated for cause in order to guide therapy and prevent future reactions
1. **References**

11.1 Roback, John D., ed. Technical Manual, 18 th ed. Bethesda, MD: American Association of Blood Banks, 2014

11.2 Standards for Blood Banks and Transfusion Services, 30th ed. Bethesda, MD:

American Association of Blood Banks, 2016

**12.0 Records**

* 1. Records supporting the workup related to an adverse reaction to a transfusion are retained indefinitely. A copy of the Transfusion Reaction Report is retained indefinitely.

12.2 The Blood Bank record system makes it possible to recheck any records applicable to the investigation of an adverse transfusion reaction.

**13.0 Attachments/Appendix/Forms/Documents**

* 1. Attachment 1: **Transfusion Reaction Report**
	2. **BB01-020 Form A: Critical Callback Log**

**Approval Signatures**

|  |  |  |
| --- | --- | --- |
| **Date** | **Printed Name** | **Signature** |
| 9/1/16 | Pettina WaltonBlood Bank Supervsior |  |
| 9/1/16 | Vanessa RawlingsElkins Park Supervisor |  |
| 9/1/16 | Manjula Balasubramanian, MDSection Director, Blood Bank |  |
| 9/1/16 | Nancy A. Young, MDMedical Director |  |

**History Review**

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| **Date Reviewed** | **Reviewed By** | **Revisions** |
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