Primary Transfusion Reaction Investigation Form

Hospital Name and Address

I. Initial Notification

Place LIS label for PRXN Here

Patient Name _____ Contact Person _____ (RN, MD, TECH)

Medical Record Number _____ Time of Notification _____ Date _____

Donor Unit Number _____ Product Type _____ Tech _____

Signs and Symptoms _____ Incident Report: _____

Blood product, tubing, and fluids retured to the blood bank Date _____ Time _____

Contact nursing personnel if blood product bag, tubing, and fluids are not received within 30 minutes of initial notification.

II. Instruct the Transfusionist

Instruct the transfusionist to follow the instructions located in the transfusion band of iView. Tell the nurse to click on the blue reference text that says, "Transfusion Reaction Activities." During downtime, the nurse will complete the back of the Downtime Blood Administration Form.

III. Primary Investigation--Clerical Check

_____ Check (√) if uritcaria or hives is the only symptom. **If checked, no additional workup is necessary.** Credit the testing per SOP.

	Check (√) One			Tech
	OK	Not OK	N/A	
1. The recipient's name is identical on the patient/unit label, pre-reaction specimen, and post-reaction specimen.				
2. The recipient's medical record number is identical on the patient/unit label, pre-reaction specimen, and post-reaction specimen.				
3. The blood product unit number or donor identification number match on the blood product label and the patient/unit label.				
4. The blood group and type match on the blood product label and the patient/unit label.				
5. The blood group and type of the blood product is compatible with the blood group and type of the recipient.				
6. The blood product expirationd date matches on the blood product label and the patient/unit label and the expiration date has not been exceeded.				
7. The recipient's T&S specimen is complete and all interpretations are correct in the LIS.				
8. The returned blood product, administration set, and IV bag appear normal. There is no discoloration, visible hemolysis, cloudiness, fluids other than saline, or incorrect tubing.				

If a clerical error exists, immediately determine if another patient is involved, notify a pathologist, and complete the entire workup.

Comments: _____

IV. Primary Investigation--Testing

	ABO/Rh							Polyspecific DAT*				Hemolysis/Icterus**		
	Anti-A	Anti-B	Anti-D	A_1 cell	B cell	Ctrl	Interp	IS	5'RT	CC	Interp	None	Same as Pre-Rxn Spec	Greater than Pre-Rxn Spec
Post-Reaction Specimen														

* Perform IgG and C_3 DAT if positive. **Refer to procedure if hemolysis present.

V. Pathologist Review and Interpretation

_____ Allergic (ALRE)
_____ Acute Hemolytic Immune (HEMR1)
_____ Acute Hemolytic Non-Immune (HEMR2)
_____ Hypotensive (HPOR)
_____ Febrile, Non-Hemolytic (FEBR)
_____ Post-Transfusion Purpura (PTP)
_____ Transfusion-Associated Circulatory Overload (TACO)
_____ Transfusion-Associated Dyspnea (TAD)
_____ TRALI (TRALI)
_____ Transfusion-Transmitted Infection (TTI)
_____ Reaction Unrelated to Transfusion (NORX)

Comments: _____

Pathologist Signature: _____ Date: _____

Electronic Document Control System

Document No.: SGAH.BB137[3]
Title: Transfusion Reaction Investigation, Immediate
Owner: LESLIE BARRETT
Status INWORKS
Effective Date: 01-Mar-2017 **Next Review Date:**

Non-Technical SOP

Title	**Transfusion Reaction Investigation, Immediate**	
Prepared by	Stephanie Codina	Date: 6/9/2012
Owner	Stephanie Codina	Date: 6/9/2012

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/1/00

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1. PURPOSE

Certain risks are associated with the transfusion of blood products and a small percentage of patients experience reactions. Any adverse event associated with transfusion or transfusion error **must** be investigated immediately and thoroughly to provide the clinical staff with timely information necessary for treatment of the patient.

2. SCOPE

This procedure applies to any reported suspected adverse reaction associated with a transfusion.

3. RESPONSIBILITY

All blood bank staff must understand and adhere to this procedure when a suspected transfusion reaction is identified or reported to blood bank.

4. DEFINITIONS

Transfusion Reaction-- any adverse outcome associated with the infusion of blood and blood components. A transfusion reaction can occur during, immediately following, or up to weeks or months following the transfusion of a blood product.

5. SPECIMEN REQUIREMENTS

Pre- and post-transfusion red or lavender top tubes. Refer to the SOP 'Sample Specifications for Blood Bank Testing' for labeling requirements.

6. PROCEDURE

6.1 General Considerations

Step	Action
1	All transfusion reaction evaluations are performed stat; workup must be started within 15 minutes of sample receipt.

Form revised 3/31/00

Step	Action
2	**No additional blood products may be issued for the patient until initial testing is completed and a hemolytic reaction is ruled out.** **In emergency situations,** the Clinical Pathologist on duty will determine whether blood products may be issued. Give O-negative red cell products and AB plasma products until a hemolytic reaction has been ruled out.

6.2 Transfusion Reaction Notification

Step	Action
1	The blood bank will be notified by the transfusing personnel of **all** suspected transfusion reactions/incidents/errors. Lack of symptoms does not preclude an investigation if a transfusion error is suspected or known. A. Signs and symptoms suggesting a transfusion reaction include: a. Thermal i. Temperature elevation (1°C or 2°F rise in temperature above normal (37°C or 99°F) in a patient who has not been running fevers). ii. Hypothermia b. Dermatologic i. Rashes ii. Urticaria iii. Flushing iv. Pruritus v. Angioedema vi. Cyanosis vii. Jaundice viii. Pallor c. Pulmonary i. Dyspnea ii. Tachypnea iii. Orthopnea iv. Stridor v. Increased/Frothy Secretions vi. Wheezing vii. Rales viii. Cough ix. Hoarseness d. Cardiovascular i. Blood Pressure Changes ↑↓ ii. Pulse Changes ↑↓ iii. Dysrhythmias iv. Circulatory Shock/Collapse

Step	Action
	e. Neurologic i. Pain (IV access site or other locations such as head, chest, lumbar region, abdomen) ii. Central, Peripheral, or Autonomic System Dysfunction iii. Anxiety iv. Tetany f. Gastrointestinal or Genitourinary i. Nausea ii. Vomiting iii. Diarrhea iv. Urinary Output Changes (Oliguria, Anuria, Hemoglobinuria) g. Hematologic i. Excess Bleeding ii. Excess Clotting B. Signs and symptoms may be masked in a comatose or anesthetized patient. In an anesthetized or comatose patient, the only signs may be generalized bleeding at surgical sites, shock and/or hemoglobinuria.
2	Obtain a "Primary Transfusion Reaction Investigation Form" and complete sections I and II while maintaining phone contact with transfusing personnel. Instruct the transfusionist to follow the instructions for transfusion reaction that are located as reference text in the transfusion band of the electronic medical record or on the "Downtime Blood Administration Form" when Cerner is not available. A. Immediately stop the transfusion. Change the tubing and transfuse saline through the line. B. Repeat the clerical check to ensure the correct product was transfused to the correct patient. C. Notify the attending provider to manage the patient symptoms. D. Monitor vital signs and monitor I&Os per procedure. E. Enter a nursing note about the reaction and all notifications into the electronic medical record. Print a copy of the nurse's note and send to blood bank. The pathologist who interprets the reaction will obtain this documentation from Cerner if the RN does not send a copy to the blood bank. F. Return the blood product, tubing, and IV fluids to the blood bank. G. Submit an online hospital incident report (we can obtain this number retroactively if the RN has not already submitted the incident report).
3	Order a transfusion reaction investigation (TRXN) in the LIS per appendix A and dispatch a phlebotomist to collect the post-transfusion reaction specimen (unless the nurse wishes to collect the sample). A. Instruct the phlebotomist to leave the blood bank armband on the

Step	Action
	patient's wrist. The blood bank armband should NOT be removed. B. Refer to Appendix B for instructions to order a transfusion reaction investigation in the LIS. C. The specimen does NOT need to be collected if urticaria is the only symptom.
4	If at any time there is reason to believe an incompatible transfusion has occurred (wrong patient or wrong unit transfused): A. **Immediately** notify the Clinical Pathologist on duty. B. **Immediately** initiate the transfusion reaction protocol. C. **Immediately** recall to the Blood Bank any other components that might be involved in a mix-up.
5	Notify the clinical pathologist on call immediately if there is reason to believe a septic transfusion reaction has occurred. This includes symptoms of high fever, chills, hypotension, rigors. Suggest that the pathologist order cultures on the blood product AND the patient for investigation.
6	Contact the nursing unit to request the blood product, tubing, and IV fluids if they have not been received within 30 minutes of the initial telephone notification. Document the call.
7	If urticarial is the only symptom, no additional testing is needed. Credit the ABO, Rh, and DAT testing, because it will not be performed.

6.3 Primary Transfusion Reaction Investigation

Step	Action
1	Perform a clerical check. Proceed through the clerical checklist on the evaluation form. **NOTE: All units transfused to the recipient in the previous 8 hours must be checked.** A. Record a checkmark in the "OK" column for each item if no errors are detected. B. Record a checkmark in the "Not OK" column if an error or discrepancy is detected. C. Record tech initials. Verify the following: A. Perform a clerical check of the blood product label, the patient/unit label, the computer, and the pre- and post-transfusion blood specimen labels. a. Make a note on the form if all of these are not verified and list the reason why. b. Clerical check is not required for urticarial reactions. Ensure that the following information is correct and matches EXACTLY where present. a. Recipient's first and last name. Middle name is not required. However, if the middle name is present, it must be correct.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td></td><td>b. Recipient's medical record number.
c. Blood product unit number or donation identification number.
d. Blood group and type.
e. Blood product expiration date and time (if applicable).

B. Review the results of the current type and screen. Verify that the testing is complete and interpretations are correct via function Blood Order Processing.</td></tr>
<tr><td>2</td><td>
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>All information is correct and identical</td><td>Document on the "Primary Transfusion Reaction Investigation Form" by checking the "OK" box for each check and proceed to step 3.</td></tr>
<tr><td>A clerical error exists</td><td>1. Immediately determine whether another patient is involved by searching current record to determine if a misidentification of samples or incorrect issue of components has put another patient at risk.
2. Immediately notify the Medical Director or pathologist on call. Document the notification.
3. Perform the secondary transfusion reaction investigation.
4. Complete a PI/Variance report and hospital incident report promptly when time permits.</td></tr>
<tr><td>Another patient is at risk</td><td>1. Immediately contact the nurse of the second patient and tell him/her to IMMEDIATELY STOP THE TRANSFUSION and initiate a transfusion reaction investigation. Document the notification.
2. Quarantine all blood products for both patients until the workup is complete.</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Perform a visual inspection of the returned blood product, administration set, and saline IV bag for abnormal appearance. Abnormalities include, but are not limited to, discoloration, visible hemolysis, cloudiness, fluids other than saline attached, or incorrect tubing. Note any problems on the "Transfusion Reaction Evaluation" form.</td></tr>
</table>

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>4</td><td>Centrifuge the recipient's post-reaction specimen and compare the appearance to the recipient's pre-reaction sample. Look for hemolysis or icterus.
A. If the post-reaction specimen is normal or similar to the pre-reaction specimen in appearance, note this on the "Transfusion Reaction Evaluation" sheet and proceed to step 5.
B. Request that another specimen be drawn if hemolysis exists in the post-reaction specimen but is not present in the pre-reaction specimen OR if the degree of hemolysis is greater in the post-reaction specimen. The second specimen will help determine if the hemolysis is due to the transfusion reaction or specimen collection. Repeat the visual comparison when the new specimen arrives.
C. Immediately notify the Blood Bank Medical Director or pathologist-on-call if the hemolysis or icterus is not due to the collection technique. Record the degree of hemolysis on the "Transfusion Reaction Evaluation" form. Perform secondary transfusion reaction investigation.</td></tr>
<tr><td>5</td><td>Perform a polyspecific DAT on the recipient's post-reaction specimen per procedure, "Direct Antiglobulin Test (DAT)." DAT specimens must be examined both macro- and microscopically when investigating suspected transfusion reactions.
<table>
<tr><th>If the post-reaction DAT is…</th><th>And the pre-reaction DAT is…</th><th>Then…</th></tr>
<tr><td>Negative</td><td>Positive, Negative, or Unknown</td><td>Record the results on the "Transfusion Reaction Evaluation" form and proceed to step 6.</td></tr>
<tr><td>Positive</td><td>Unknown</td><td>Perform a DAT on the pre-reaction specimen and record results on the "Transfusion Reaction Evaluation" form.</td></tr>
<tr><td>Positive</td><td>Negative</td><td>1. Perform monospecific IgG and C3b,C3d DAT testing and eluate testing if indicated. Refer to procedures "Direct Antiglobulin Test (DAT)" and "Acid Elution."
2. Record results on the "Transfusion Reaction Evaluation" form.
3. Perform the secondary transfusion reaction investigation.
4. Notify the patient care per the Critical Results policy.</td></tr>
<tr><td>Positive</td><td>Positive</td><td>Record results on the "Transfusion Reaction Evaluation" form. Notify the Blood Bank Supervisor, Medical Director, or designee if the strength of the post-transfusion reaction DAT is greater than the pre and perform the secondary transfusion reaction investigation.</td></tr>
</table></td></tr>
</table>

Step	Action
6	Perform ABO/Rh testing on the post-reaction specimen per procedure, "ABO/Rh Testing (Manual Tube)." Record results on the "Transfusion Reaction Evaluation" form. A. No further testing is needed if the pre- and post-reaction ABO and Rh types match. B. If the ABO or Rh types differ on the pre- and post-reaction specimens, a. Proceed to secondary transfusion reaction investigation section below. b. Notify the Blood Bank Medical Director or pathologist-on-call immediately. Document the notification.
7	A. Proceed with the secondary transfusion reaction investigation if indicated. a. If clerical error exists b. If the post-reaction sample is hemolyzed and collection technique has been ruled out c. If the post-reaction DAT is positive when the pre-reaction DAT was negative or if the post-reaction DAT is positive at greater strength than the pre-reaction DAT d. If the ABO or Rh types of the pre-reaction and post-reaction specimens do not agree B. If the secondary transfusion reaction investigation is not indicated, no further action is required. a. Submit the "Transfusion Reaction Investigation Form" to the Clinical Pathologist On-Call for review and interpretation. b. The pathologist will document actions taken on the Transfusion Reaction Evaluation form within 24 hours of notification of a hemolytic or anaphylactic reaction. All other reactions must be evaluated and signed by the pathologist within 72 hours. c. Retain the blood bag, tubing, and fluids in a blood bank refrigerator for 10 days post-reaction. Place the bag in a zip-lock bag and label with the date of the reaction. Discard by incineration at the end of 10 days. d. Additional blood products may be issued if requested. i. Blood products previously crossmatched on the pre-reaction sample may be issued without further testing as long as 1. There is no evidence of hemolysis. 2. The post-reaction DAT is negative (or if DAT is positive with strength ≤ pre-reaction DAT results). And 3. The ABO/Rh types on the pre- and post-reactions samples match. ii. Additional red blood cell products should be crossmatched to the pre-reaction specimen prior to issue.

6.4 Secondary Transfusion Reaction Investigation

Step	Action
1	The secondary investigation only needs to be performed if indicated during the primary investigation or at the request of a pathologist. It is unlikely that the secondary investigation will need to be completed for reactions involving non-red cell components. Contact a supervisor or pathologist if questions exist.
2	Request a new sample. A. Order a stat Type & Screen specimen with the comment code "TRAN" (post-transfusion specimen) in the LIS via function "Order Entry." B. Retrieve the label and deliver it to a phlebotomist with instructions to draw a properly labeled sample immediately. The previous Blood Bank armband must be removed and a new one applied. C. If a post-transfusion sample cannot be obtained within one hour, notify the pathologist and document on the reaction workup form.
3	Repeat steps 4 and 5 of the Primary Transfusion Reaction Investigation above. Document the ABO typing in Sunquest.
4	Repeat the ABO and Rh testing on the recipient's pre-transfusion specimen per procedures, "ABO/Rh Testing (Tube Method)." Record results on the "Transfusion Reaction Investigation Form." If the ABO/Rh results of the recipient's pre- and post-reaction samples disagree: A. Suspect a sample mix-up or mislabeling incident. B. Have a new specimen collected to confirm the discrepant results are reproducible. C. Search current records to determine if a misidentification of samples or incorrect issue of blood products has put another patient at risk. If another patient is at risk…. A. Quarantine all units for both patients involved until the investigation process is complete. B. Contact the nursing unit to stop the other patient's transfusion (if blood products have been issued). Document the notification. C. Notify a supervisor or manager and a pathologist immediately. Document the notification. D. Complete a PI/Variance report and hospital incident report as soon as time permits. Systemic failures will be brought to the attention of the Blood Bank Medical Director via the hospital incident reporting system.
5	Perform antibody screen testing on recipient's pre- and post-reaction specimens per procedure. If the pre-reaction specimen is negative and the post-reaction specimen is positive, perform antibody identification on the post-reaction specimen.

Step	Action
6	Perform an extended crossmatch per procedure, "Crossmatch." A. Test the recipient's pre-reaction specimen against all implicated red cell components. B. Test the recipient's post-transfusion specimen against all implicated red cell components. If the pre-reaction specimen is compatible and the post-reaction specimen is incompatible…. a. Repeat the crossmatch on the pre-reaction specimen to confirm results. b. Perform a polyspecific DAT on the red cell unit in question per procedure, "Direct Antiglobulin Test (DAT)." c. Repeat any applicable phenotyping on the red cell unit per procedure, "Antigen Typing." d. Consult with a supervisor, manager, or pathologist.
7	Record all results on the "Transfusion Reaction Investigation Form."
8	Confirm the ABO and Rh type of the blood product issued per procedure "Reprocessing Blood From Outside Sources." If the ABO or Rh of the blood product does not agree with the ABO or Rh on the label: A. Contact the blood supplier. Document the notification. B. Complete a PI/Variance form and hospital incident report when time permits. C. Notify a supervisor, manager, or pathologist as soon as possible. Document the call.
9	If no abnormalities or discrepancies are noted from the testing and clerical checks, no further action is required. Submit the form to the clinical-pathologist on-call for review and interpretation. A. The pathologist will document actions taken on the "Transfusion Reaction Investigation Form" within 24 hours of notification of a hemolytic or anaphylactic reaction. B. All other reactions must be evaluated and signed by the pathologist within 72 hours.
10	Retain the blood bag, tubing, and fluids in a blood bank refrigerator for 10 days post-reaction. Place the bag in a zip-lock bag and label with the date of the reaction. Discard by incineration at the end of 10 days.

6.5 Additional Testing

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>The pathologist reviewing the transfusion reaction may decide to order additional testing to complete the investigation. Potential test orders include:
<table>
<tr><th>If the symptoms suggest…</th><th>Then the pathologist may request the following additional testing….</th></tr>
<tr><td>A hemolytic transfusion reaction</td><td>• Hemoglobin levels
• Lactate dehydrogenase (LDH)
• International normalized ratio (INR)
• Bilirubin levels
• Blood urea nitrogen (BUN)
• Haptoglobin levels
• Potassium levels</td></tr>
<tr><td>A septic transfusion reaction</td><td>• Gram stain on blood product
• Blood cultures on blood product
• Blood cultures on recipient
• Notification to blood supplier
• Refer to Appendix C for additional instructions</td></tr>
<tr><td>An anaphylactic reaction</td><td>• Quantitation of IgA levels and testing for anti-IgA on recipient’s pre-transfusion specimen
• IgA-deficient blood products to be provided until the results of testing for IgA are available and have been evaluated</td></tr>
<tr><td>Post-Transfusion Purpura (PTP)</td><td>• Platelet count
• Platelet antibody detection and identification
• Crossmatched platelets</td></tr>
<tr><td>Transfusion-Related Acute Lung Injury (TRALI)</td><td>• Testing of donor and/or recipient for HLA antibodies and/or granulocyte antibodies
• Notification to blood supplier</td></tr>
</table></td></tr>
<tr><td>2</td><td>Document any additional tests requested by the pathologist on the “Transfusion Reaction Evaluation” form.</td></tr>
</table>

Step	Action
3	Ensure that the tests are ordered and the appropriate pre- or post- transfusion specimen is obtained for testing.
4	Print the results of the testing and provide them to the pathologist for interpretation.

6.6 Blood Product Cultures

Step	Action
1	The pathologist may order gram stain and/or cultures on the blood product AND patient if a septic reaction is suspected. Symptoms of septic reaction include high fever, chills, hypotension, rigors.
2	Gram stain and culture on the patient will be ordered per routine procedure.
3	Order the blood product culture per appendix C. **NEVER order blood product cultures on the patient MRN.** A. Request a stat gram stain and culture. B. Include the unit number and the recipient's name and medical record number on the form. Complete one form for each unit in question.
4	Deliver the LIS labels and the blood product(s) to microbiology per procedure.

6.7 Notification

Step	Action
1	The pathologist will be responsible for notifying the recipient's physician when a hemolytic or septic reaction has occurred or is suspected to ensure the patient receives all necessary care. The pathologist may choose to notify the patient's physician in other situations.

Step	Action
2	The FDA requires that we notify our blood supplier if the blood product caused (or is suspected of causing) the transfusion reaction. This includes: A. Reactions due to compatibility problems when a reference laboratory such as the American Red Cross Immunohematology Laboratory performed any of the testing or provided specially selected (e.g. antigen-negative) blood products. B. All transfusion reactions in which a problem with the manufacturing may have caused the reaction. This includes, but is not limited to, the following possible or confirmed reactions: a. Septic reactions b. Transfusion-related acute lung injury (TRALI) c. Serious allergic reactions d. Some hemolytic reactions (e.g. hemolysis in a group A recipient of group O platelets with a high-titer anti-A) If any of these reactions are suspected, the pathologist reviewing the transfusion reaction must complete the "American Red Cross Possible Transfusion Reaction Case Report" form.
3	The FDA requires that we notify our blood supplier if the blood product caused a possible transfusion-transmitted infection in the recipient. All types of possible recipient transfusion-transmitted infections should be reported to ARC including, but not limited to, hepatitis B, hepatitis C, and HIV. If any of these are suspected, the pathologist reviewing the transfusion reaction must complete the "American Red Cross Possible Recipient Transfusion-Transmitted Infection Case Report" form.
4	All suspected transfusion-related fatalities must be reported to the Center for Biologics Evaluation and Research (CBER) via telephone within 1 day and via written report within 7 days of the initial reaction. Refer to procedure, "Biologic Deviation Reporting—FDA Reportable Event."

7. RELATED DOCUMENTS

Form: Primary Transfusion Reaction Investigation Form (AG.F197)
Form: Secondary Transfusion Reaction Investigation Form (AG.F197)
SOP: Sample Specifications for Blood Bank Testing
SOP: ABO/Rh Typing (Manual Tube)
SOP: Direct Antiglobulin Test (DAT)
SOP: Antibody Screen
SOP: Crossmatch
SOP: Antibody Identification
SOP: Antigen Typing
SOP: Acid Elution
SOP: Biologic Deviation Reporting - FDA Reportable Event

American Red Cross Form 11.4.frm059 v-1.0 "Recipient Complication - Transfusion Reaction Report."
American Red Cross Form 11.4.frm058 v-1.0 "Possible Recipient Complication - Infectious Disease Report."

8. REFERENCES

1. Standards for Blood Banks and Transfusion Services, AABB, 30th edition, 2016.
2. Fung, MK, Grossman, BJ, Hillyer, CD, and Westhoff, CM. AABB Technical Manual, 18th edition, 2014.
3. Code of Federal Regulations, 21 CFR 606.170, current edition.

9. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAH.BB52.000,SGAH.BB54.000		
000	2.19.13	Sections 6.5 & 10: Added appendix C	SCodina	NCacciabeve
001	1.29.15	Section 6: removed references to the Blood Product Tag and Administration Record. Updated nursing instructions to document in the EHR and not on paper (unless downtime). Added reference to the new "Downtime Blood Administration" form. Added requirement to call the pathologist immediately if a septic transfusion reaction has occurred. Updated culture information for clarity. Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina	NCacciabeve
2	1.30.2017	Header: Added WAH Section 6.2: Added requirement for hospital incident report (per Risk Mgmt); clarified instructions for clerical check when urticarial is only symptom Section 7: Updated form. Section 10: Added Appendix D per AABB stds.	SCodina	NCacciabeve

10. ADDENDA AND APPENDICES

Appendix A: Ordering a Primary Transfusion Reaction Evaluation in the LIS
Appendix B: Resulting a Primary Transfusion Reaction Evaluation in the LIS
Appendix C: Ordering Testing on a Blood Product in the LIS System
Appendix D: Classification Criteria for Suspected Transfusion Reactions

Appendix A
Ordering a Primary Transfusion Reaction Evaluation in the LIS

Step	Action
1	Access Sunquest function, "Order Entry."
2	In the "Lookup by" field, select "Patient ID" from the dropdown menu.
3	At the "Value" prompt, type the patient's medical record number.
4	Select the correct patient from the pop-up list and click the "Select" button.
5	Press the "Tab" button to default the current date in the "Collect date" field. In the "Collect time" field, type "N" for now and press the "Tab" key.
6	At the "Order physician" prompt, type in the number of the physician or click the ellipse button to lookup the physician by name then press the "Tab" key.
7	In the "Order Code" box, type "TRXN" for transfusion reaction evaluation and press the "Tab" key.
8	Click the "Save" button.
9	Notify phlebotomy staff that the order has been placed and the sample should be collected ASAP. Note: If urticaria is the only symptom of reaction, no sample is required. Receive the specimen in the LIS per procedure. Notify phlebotomy that the sample does NOT need to be collected.
10	Adhere a LIS label for the transfusion reaction workup to the investigation form.

Appendix B
Resulting a Primary Transfusion Reaction Evaluation in the LIS

Entry Prior to Pathologist Interpretation

Step	Action
1	Access Sunquest function "Blood Order Processing."
2	At the "Lookup By" prompt, click on the dropdown menu to select "Patient ID."
3	In the "Value" prompt, type in the patient's medical record number and click "Search."
4	Select the correct patient from the pop-up menu, if applicable.
5	Select the "TRXN" specimen from the list and click on the "Select" button.
6	Enter the ABO/Rh results per procedure, "ABO/Rh Typing (Manual Tube)." Enter the DAT results per procedure, "Direct Antiglobulin Test (DAT)." If urticaria was the only symptom, type ";HIDE" in the data entry fields that do not apply to the reaction. You must also credit any ABO, Rh, or DAT tests that were not performed. In the Add Spec Test field, type the mnemonic that corresponds to the credit test to be ordered: A. Type ";CABO" to credit the ABO test. B. Type ";CRH" to credit the Rh test. C. Type ";CDAT" to credit the DAT test.
7	In the Clerical Check field, A. Type "T" for acceptable if the clerical check revealed no errors. B. Type "Q" for not acceptable if the clerical check revealed errors.
8	In the Post Hemolysis Check field, A. Type "T" for acceptable if no hemolysis or icterus was noted in the post-reaction specimen. B. Type "T" for acceptable if hemolysis or icterus was noted in the post-reaction specimen, but was less than that in the pre-reaction specimen. C. Type "Q" for not acceptable if hemolysis or icterus was noted in the post-reaction specimen and it was either not seen in the pre-reaction specimen or was seen in smaller amounts in the pre-reaction specimen.
9	In the Visual Inspection field, A. Type "T" for acceptable if the blood product passed visual inspection and only normal saline or Plasmalyte were attached. B. Type "Q" for unacceptable if the blood product failed visual inspection or if a fluid/medication other than saline or Plasmalyte was infused with the blood product.

Step	Action
10	The Pathologist Interpretation field will remain blank until the investigation has been reviewed and interpreted by a pathologist.
11	Click the "Save" button.

Entry Following Pathologist Interpretation

Step	Action
1	Access Sunquest function "Blood Order Processing."
2	At the "Lookup By" prompt, click on the dropdown menu to select "Patient ID."
3	In the "Value" prompt, type in the patient's medical record number and click "Search."
4	Select the correct patient from the pop-up menu, if applicable.
5	Select the "TRXN" specimen from the list and click on the "Select" button.
6	Enter the pathologist interpretation when available: A. ALRE = Allergic transfusion reaction B. HEMR1 = Acute hemolytic transfusion reaction (immune) C. HEMR2 = Acute hemolytic transfusion reaction (non-immune) D. DHRH = Delayed hemolytic transfusion reaction E. DSRX = Delayed serologic transfusion reaction F. HPOR = Hypotensive transfusion reaction G. FEBR = Febrile, non-hemolytic transfusion reaction H. PTP = Post-transfusion purpura I. TACO = Transfusion-associated circulatory overload J. TAD = Transfusion-associated dyspnea K. TTI = Transfusion-transmitted infection L. TRALI = Transfusion-related acute lung injury M. TAGVHD = Transfusion-associated graft-versus-host disease
7	Add a blood bank comment to the panel. Enter the commented, "Transfusion reaction interpreted by *name of pathologist*, MD."
8	Click the "Save" button.
9	The evaluation worksheet is retained in the Blood Bank file, after LIS documentation is completed.

Appendix C
Ordering Testing on a Blood Product in the LIS System

Step	Action
1	Access Sunquest function "Order Entry."
2	When the lookup screen appear, click the "New Patient" box in the lower, right-hand corner of the screen.
3	In the "Patient ID" field, type "**BB-**" then click the "Create" button.
4	A new screen will open. Complete the following fields. Press the "Tab" button after each entry. A. Patient name: Enter "Unit" followed by a comma "," then the unit number. B. Date of birth/age: Enter the date of the transfusion reaction. C. Sex: Select "Unknown."
5	When all data has been entered, click the "Save" button on the lower, right-hand corner of the screen.
6	A new MRN will be generated and Sunquest will automatically default to the order entry screen.
7	Order testing that has been requested on the unit. A. GS is ordered for gram stain. B. XBLC is ordered for blood culture.
8	Record the MRN and accession number of the testing on the transfusion reaction investigation form.

Appendix D
Classification Criteria for Suspected Transfusion Reactions

Acute Hemolytic Transfusion Reactions

A. CAUSE: Immune acute hemolytic transfusion reactions (AHTR) are caused by the interaction of pre-formed antibodies with red cell antigens. The most severe reactions are associated with transfusion of red cells that are ABO incompatible with the recipient's ABO antibodies, resulting in the acute destruction of the transfused (donor) cells. Alternatively, transfusion of ABO-incompatible plasma, as in apheresis platelets, has been shown to cause hemolysis of the patient's red cells. This form of hemolysis is not usually clinically significant but can be severe if the donor has high titer ABO antibodies.

Non-immune mediated hemolysis is caused by mechanical hemolysis of the transfused red blood cells. Hemolysis may occur if the red blood cell component is exposed to improper temperatures or handling, microwave ovens, hot water baths, malfunctioning blood warmers, small-bore needles, pressure infusion pumps, addition of drugs or hypotonic solutions, or bacterial growth in the unit.

B. CLINICAL MANIFESTATIONS:
Occurs during or within 24 hours of cessation of transfusion with new onset of **ANY** of the following signs/symptoms:

- Back/flank pain
- Chills/rigors
- Disseminated intravascular coagulation (DIC)
- Epistaxis
- Fever
- Hematuria (gross visual hemolysis)
- Hypotension
- Oliguria/anuria
- Pain and/or oozing at IV site
- Renal failure

AND

2 or more of the following:

- Decreased fibrinogen
- Decreased haptoglobin
- Elevated bilirubin
- Elevated LDH
- Hemoglobinemia
- Hemoglobinuria
- Plasma discoloration consistent with hemolysis
- Spherocytes on blood film

AND EITHER

Immune-mediated

- Positive DAT for anti-IgG or anti-C3

AND

- Positive elution test with alloantibody present on the transfused red blood cells

Non-immune mediated

- Serological testing is negative, and physical cause (e.g., thermal, osmotic, mechanical, chemical) is confirmed.

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. The amount of blood product transfused is directly proportional to the symptoms of the AHTR, therefore prompt recognition is imperative. Support blood pressure and respirations, induce diuresis, treat shock and DIC if present. If intravascular hemolysis has occurred:
   a. Monitor renal status (BUN and creatinine), initiate diuresis, analyze urine for hemoglobinuria.
   b. Monitor coagulation status (PT, APTT, fibrinogen, platelet count).
   c. Monitor for signs of hemolysis (lactate dehydrogenase, bilirubin, haptoglobin, plasma hemoglobin).

D. PREVENTION: Avoid clerical errors; ensure proper sample and recipient identification. Equipment will be properly maintained and used according to manufacturer's instructions as well as hospital policy. Transfusing personnel will be trained in the proper use of equipment, intravenous solutions, and drugs used during blood transfusion. Policies and procedures will be followed for all aspects of procuring, processing, issuing, and administering blood components.

Transfusion-Related Sepsis

A. CAUSE: Transfusion of bacterially-contaminated blood products.

B. CLINICAL MANIFESTATIONS: Fever (generally >101°F or 38.5°C) and shaking, chills, hypotension during or shortly following transfusion of blood products. In severe cases, shock, renal failure, and DIC may be present.

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. The amount of blood product transfused is directly proportional to the symptoms of the septic reaction, therefore prompt recognition is imperative. Immediately begin aggressive resuscitative therapy and broad-spectrum antibiotics if a septic reaction is suspected. The blood product will be sent to the blood bank for culture and gram stain. Blood cultures will be drawn on the patient as early as possible.

D. PREVENTION: Strict adherence to hospital policies and blood product storage standards is imperative. Blood products will not be stored at room temperature or in non-blood bank refrigerators and storage containers. All transfusions will be stopped a maximum of 4 hours from the time the blood products is removed from a blood bank storage container (generally the time of issue or time of removal from a blood product transport cooler). Perform a thorough visual inspection of the blood product prior to transfusion.

Febrile Non-hemolytic Transfusion Reactions (FNHTR)

A. CAUSE: Febrile transfusion reactions are likely caused by antibodies in the recipient's plasma reacting against antigens present on the donor's white blood cells (WBCs) and/or platelets **OR** by cytokines released from WBCs and platelets into donor plasma during product storage. This type of reaction tends to occur in patients who have had multiple transfusions or multiple children.

B. CLINICAL MANIFESTATIONS:
Occurs during or within 4 hours of cessation of transfusion.
AND EITHER
Fever (greater than or equal to 38°C/100.4°F oral and a change of at least 1°C/1.8°F from the pre-transfusion value
OR
Chills and rigors are present

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. The amount of blood product transfused is directly proportional to the symptoms of the FNHTR reaction, therefore prompt recognition is imperative. Give antipyretics such as acetaminophen or a non-steroidal anti-inflammatory agent for fever, and 25-50 mg meperidine for rigors. DO NOT restart the transfusion once a fever has occurred.

D. PREVENTION: Pre-medication with antipyretics or a non-steroidal anti-inflammatory agent. Aspirin-containing products will not be given to patients with thrombocytopenia. Antihistamines play no role in prevention of FNHTRs.

Allergic Reactions

A. CAUSE: A mild urticarial allergic reaction that develops due to a pre-existing antibody in the patient directed against an antigen present in the donor plasma or a pre-existing antibody in the donor plasma against an antigen present in the patient. Severe allergic reactions (anaphylactoid or anaphylactic) are usually caused by hypersensitivity of the recipient to allergens in donor plasma. Approximately 18% of severe allergic reactions occur in recipients who have demonstrated antibodies towards IgA.

B. CLINICAL MANIFESTATIONS:
Two or more of the following occurring during or within 4 hours of cessation of transfusion:

- Conjunctival edema
- Edema of lips, tongue, and uvula
- Erythema and edema of the periorbital area
- Generalized flushing
- Hypotension
- Localized angioedema
- Maculopapular rash
- Pruritus (itching)
- Respiratory distress; bronchospasm
- Urticaria (hives)

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. If urticaria is the only symptom, notify blood bank, but serologic transfusion reaction workup is not necessary. Give antihistamines for mild reactions. The transfusion may be restarted after treatment at the request of a physician. Severe or anaphylactic reactions may require treatment with epinephrine, steroids, vasopressors, and intubation.

D. PREVENTION: Transfusion of blood components to patients who have had previous severe allergic reactions to blood products will be discussed with the Blood Bank Medical Director or designee. Pre-transfusion treatment with high-dose corticosteroids or antihistamines and washed cellular components will be considered. Recipients with congenital IgA-deficiency will receive blood products from donors who are also IgA-deficient.

Transfusion-Related Acute Lung Injury (TRALI)

A. CAUSE: The precise mechanism of lung injury in TRALI has not been determined. TRALI is thought to be caused by the infusion of donor antibodies that interact with the recipient's white cells. This infusion initiates a sequence of events that results in cellular activation and damage of the basement membrane. Pulmonary edema occurs secondary to leakage of protein-rich fluid into the alveolar space.

B. CLINICAL MANIFESTATIONS:
NO evidence of acute lung injury (ALI) prior to transfusion
AND
ALI onset during or within 6 hours of cessation of transfusion
AND
Hypoxemia defined by any of these methods:
- PaO2/FiO2 les than or equal to 300 mmHg
- Oxygen saturation less than 90% on room air
- Other clinical evidence

AND
Radiographic evidence of bilateral infiltrates
AND
No evidence of left atrial hypertension (i.e. circulatory overload)

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. Support blood pressure and respirations. Provide oxygen support and intubation if necessary. 80% of TRALI courses are transient, but the remaining 20% of patient who do not improve rapidly will have either a protracted clinical course or a fatal outcome.

D. PREVENTION: The reaction is normally due to a specific donor/recipient interaction. Do not transfuse another component from the same donor if the donor is known (as in directed donation).

Transfusion Associated Circulatory Overload (TACO)

A. CAUSE: Acute pulmonary edema caused by volume overload during transfusion. Patients who have compromised cardiac or pulmonary status are more susceptible.

B. CLINICAL MANIFESTATIONS:
New onset or exacerbation of 3 or more of the following within 6 hours of transfusion:
- Acute respiratory distress (dyspnea, orthopnea, cough)
- Elevated brain natriuretic peptide (BNP)
- Elevated central venous pressure (CVP)
- Evidence of left heart failure
- Evidence of positive fluid balance
- Radiographic evidence of pulmonary edema

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. Place the patient in a sitting position, provide oxygen support, and give diuretics. If symptoms persist and diuretic support is unsuccessful, therapeutic phlebotomy will be considered.

D. PREVENTION: Monitor total fluid input and output will be monitored. Adjust the transfusion volume and rate (slow infusion) for patients at risk of TACO.

Transfusion-associated dyspnea (TAD)

A. CAUSE: Unknown. This type of reaction has been associated with HLA antibodies, but is defined as respiratory distress that is temporarily associated with transfusion and cannot be assigned to known pulmonary reactions.

B. CLINICAL MANIFESTATIONS:
Acute respiratory distress occurring within 24 hours of cessation of transfusion
AND
Allergic reaction, TACO, and TRALI definitions are not applicable

C. MANAGEMENT: STOP THE TRANSFUSION IMMEDIATELY. Support blood pressure and respirations. Provide oxygen support and intubation if necessary.

D. PREVENTION: None

Hypotensive Transfusion Reactions

A. CAUSE: Thought to be due to activation of the contact system, leading to generation of two vasoactive kinins (bradykinin and des-Arg^9 BK). The contact system activation occurs when plasma comes into contact with a negatively charged surface (e.g.leukocyte reduction filters). Vasoactive kinins are mainly metabolized by angiotensin-converting enzyme (ACE). This type of reaction is more likely to occur when the patient has a history of hypotensive reactions, is on a an ACE inhibitor, is transfused using a negative charged bedside leukocyte reduction filter or apheresis circuit, or is transfusion with platelets.

B. CLINICAL MANIFESTATIONS:
All other adverse reactions presenting with hypotension are excluded
AND
Hypotension occurs during or within 1 hour after cessation of transfusion.

- Adults (18 years and older)
  Drop in systolic BP of greater than or equal to 30 mmHg
  AND
  Systolic BP less than or equal to 80 mmHg
- Infants, children and adolescents (1 year to less than 18 years old)
  Greater than 25% drop in systolic BP from baseline (e.g., drop in systolic BP of 120 mmHg to below 90 mmHg)
- Neonates and small infants (less than 1 year old OR any age and less than 12 kg body weight)
  Greater than 25% drop in baseline value using whichever measurement is being recorded (e.g.mean BP)

C. PREVENTION: Use prestorage leukocyte reduced blood products instead of bedside filters. Discontinue use of ACE inhibitors prior to therapeutic apheresis procedures.

Delayed Hemolytic Transfusion Reactions (DHTR)

A. CAUSE: A patient may make an antibody to a red cell antigen he or she lacks after transfusion, transplantation, or pregnancy. These red cell antibodies will shorten the life span of transfused red cells that contain the corresponding red cell antigens. Delayed reactions may also be observed in ABO/Rh mismatched hematopoietic, bone marrow, and solid organ transplants.

B. CLINICAL MANIFESTATIONS:
Positive direct antiglobulin test for antibodies developed between 24 hours and 28 days after cessation of transfusion
AND EITHER
Positive elution test with alloantibody present on the transfused red blood cells
OR
Newly-identified red blood cell alloantibody in recipient serum
AND EITHER
Inadequate rise of post-transfusion hemoglobin level or rapid fall in hemoglobin back to pre-transfusion levels
OR
Otherwise unexplained appearance of spherocytes

C. MANAGEMENT: Notify the blood bank immediately when a transfusion reaction is considered. Monitor the recipient's renal function (BUN and creatinine), signs of hemolysis (hemoglobin, hematocrit, bilirubin, lactate dehydrogenase, and haptoglobin), and coagulation parameters (PT/APTT, platelet count, and fibrinogen).

D. PREVENTION: All future red cell transfusions will lack the antigen responsible for the anamnestic response even if the antibody becomes undetectable.

Delayed Serologic Transfusion Reactions (DSTR)

A. CAUSE: A patient may make an antibody to a red cell antigen he or she lacks after transfusion, transplantation, or pregnancy. These red cell antibodies will shorten the life span of transfused red cells that contain the corresponding red cell antigens. Delayed reactions may also be observed in ABO/Rh mismatched hematopoietic, bone marrow, and solid organ transplants.

B. CLINICAL MANIFESTATIONS:
Absence of clinical signs of hemolysis
AND
Demonstration of new, clinically-significant antibodies against red blood cells
BY EITHER
Positive direct antiglobulin test (DAT)
OR
Positive antibody screen with newly identified RBC alloantibody

C. MANAGEMENT: Notify the blood bank immediately when a transfusion reaction is considered. Monitor the recipient's renal function (BUN and creatinine), signs of hemolysis (hemoglobin, hematocrit, bilirubin, lactate dehydrogenase, and haptoglobin), and coagulation parameters (PT/APTT, platelet count, and fibrinogen).

D. PREVENTION: All future red cell transfusions will lack the antigen responsible for the anamnestic response even if the antibody becomes undetectable.

Refractoriness in Platelet Transfusion

A. CAUSE: HLA antibodies in the recipient destroy platelets from a donor that possess the corresponding HLA antigen. As a result, the recipient demonstrates a less-than-expected rise in platelet count following platelet transfusion.

B. CLINICAL MANIFESTATIONS: Refractoriness will be suspected when two consecutive platelet transfusions lead to 1 hour post-transfusion corrected count increments (CCI) of less than 5000 platelets x m^2 per μL. The CCI is calculated by using the following formula:

$$CCI = \frac{\text{Body surface area } (m^2) \times \text{Platelet Count Increment} \times 10^{11}}{\text{Number of Platelets Transfused}}$$

C. MANAGEMENT: Identify the HLA antibody that is causing the increased platelet destruction.

D. PREVENTION: Crossmatched platelets or HLA-matched platelets will be given for all subsequent platelet transfusions. Consult with the Blood Bank Medical Director or designee to obtain crossmatched or HLA-matched platelets. The blood bank will need 3-7 days to obtain platelets for transfusion in these situations.

Transfusion-Associated Graft-vs-Host Disease (TA-GVHD)

A. CAUSE: Donor T lymphocytes engraft in the recipient bone marrow, proliferate, and attack the recipient's host tissue. This normally occurs when cellular components from a HLA-homozygous donor are transfused to an immunocompromised recipient who is heterozygous for the HLA haplotype allows lymphocytes.

B. CLINICAL MANIFESTATIONS:
A clinical syndrome occurring from 2 days to 6 weeks after cessation of transfusion characterized by:
- Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation
- Diarrhea
- Fever
- Hepatomegaly
- Liver dysfunction (i.e., elevated ALT, AST, alkaline phosphatase, and bilirubin)
- Marrow aplasia
- Pancytopenia

AND
Characteristic histological appearance of skin or liver biopsy

C. MANAGEMENT: There is currently no effective treatment for TA-GVHD. Emphasis will be placed on prevention.

D. PREVENTION: Cellular blood products from blood relatives and HLA-matched blood products will be irradiated prior to transfusion. Cellular blood products for severely immunocompromised recipients will be irradiated per hospital policy.

Post-Transfusion Purpura (PTP)

A. CAUSE: A patient who has previously developed platelet-specific allo-antibodies is transfused with a blood product whose cells contain the platelet antigen that corresponds to the antibody. The recipient's antibodies destroy the donor platelets and autologous platelets for unknown reasons. PTP is seen following the transfusion of red blood cells, plasma, and platelets.

B. CLINICAL MANIFESTATIONS:
Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia
AND
Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count).

C. MANAGEMENT: IVIG is the treatment of choice for PTP; generally patients respond to IVIG treatment within 4 days. Steroids, exchange transfusion, and plasma exchange have also been used to treat PTP.

D. PREVENTION: All subsequent transfusions will come from antigen-matched donors and family members.

Transfusion-Transmitted Infection

A. CAUSE: Transfusion of blood products infected with bacteria, viruses, protozoa, or prions.

B. CLINICAL MANIFESTATIONS:
Laboratory evidence of a pathogen in the transfusion recipient.

C. PREVENTION: Vigilant donor screening, advances in disease testing methods, and strict adherence to hospital policies and regulatory standards minimize transfusion-transmitted disease. However, despite testing, infections can still be transmitted via blood transfusion.

D. MANAGEMENT: Management will depend on the infectious agent. Prophylactic treatment may be considered. Reporting suspected cases of transfusion-transmitted infection to the blood bank and donor center are imperative.

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