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Laboratory Evaluation of a Suspected Transfusion Reactions

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide instructions for the Blood Bank staff to perform a Suspected Transfusion Reaction Evaluation.

II. SCOPE:

A. The suspected transfusion reaction evaluation involves the patient's nurses and physicians, the laboratory staff, and the Blood Bank Medical Director.

B. The scope of this document is primarily on the medical technologist's role. For specific policies relating to the role and responsibilities of the Blood Bank Medical Director refer to Transfusion Medicine policy, Roles and Responsibilities of Blood Bank Medical Director for Transfusion Reaction Evaluations.

III. INTRODUCTION:

A. Although it is believed that today's blood supply is safer than at any time in history, it is still impossible to prevent or predict all transfusion risks. Therefore, it is imperative that all staff involved with the blood transfusion process recognize possible adverse reactions to a transfusion.

B. The standard transfusion reaction evaluation includes clerical checks, testing on the post-reaction sample and possible testing on the pre-transfusion sample and donor unit. At the conclusion of the evaluation, the Medical Director considers the patient's adverse reactions and laboratory results and classifies the type of reaction.

C. There are numerous transfusion reaction classifications. Statistics show that the greatest risks (although minimal) are from bacterial contamination and non-infectious complications. These include febrile non-hemolytic, immediate or delayed hemolytic, circulatory overload, allergic, and TRALI (Transfusion Related Acute Lung Injury) classifications.

D. Urticarial reactions occur in 1-3% of all transfusions and are believed to be caused by antibodies in the recipient to donor plasma proteins. Urticarial reactions are characterized by urticaria (hives), pruritus (itching), or flushing. If an urticarial reaction resolves with antihistamine therapy, the transfusion may be resumed and Blood Bank testing is not indicated. Urticarial reactions that resolve with antihistamine therapy are the only type of reaction in which the transfusion may be resumed refer to Transfusion Medicine policy, Urticarial Reactions.

IV. ADVERSE REACTION SIGNS AND SYMPTOMS:

A. fever (38°C or greater **AND** at least 1°C or 2°F above pre-transfusion temperature)

B. chilly sensation/chills, with or without rigors (shaking)

C. hives, itching or flushing

D. respiratory distress including wheezing, coughing, or dyspnea (shortness of breath)

E. changes in systolic blood pressure (↑ or ↓ of 30 mm Hg)

F. tachycardia (≥ 120 bpm or ↑ 40 bpm)

G. hemoglobinuria (red urine)

H. jaundice

I. shock

J. angina

K. skin manifestations, including color changes and localized edema

L. pain at the infusion site

M. abdominal, chest, back, or flank pain other unusual pain

V. DEFINITIONS:

A. **Designee**: any blood bank technical director, or transfusion medicine fellow.

B. **Pre-transfusion sample**: the sample drawn *before* the transfusion reaction, and tested according to Operating Procedures.

C. **Post-reaction sample**: the sample drawn *after* the transfusion reaction and tested according to the procedures in this document .

D. **WBIT**: wrong blood in tube, when a sample is drawn from the wrong patient so that the identifying information on the label does not correlate with the blood in the tube.

E. **Mistransfusion:** when a blood component is transfused to a patient who was not the intended recipient.

F. **Hemolytic transfusion reaction**: the immunologic destruction of transfused RBCs, nearly always due to incompatibility of an antigen on transfused cells with an antibody in the recipient's circulation; i.e., transfusion of ABO incompatible RBCs. Laboratory indications of a hemolytic transfusion reaction include a positive DAT and hemolysis in the 2nd post-reaction sample.

G. **LIS:** Laboratory Information System

H. **TRALI**: Transfusion Related Acute Lung Injury, a transfusion reaction associated with acute increased permeability of the pulmonary microcirculation, usually occurring within 6 hours of transfusion and requiring aggressive respiratory support.

I. **TACO**: Transfusion Associated Circulatory Overload, an event associated with the transfusion of excessive volumes or at excessively rapid rates which can lead to pulmonary edema, especially in elderly patients.

J. **TAD:** Transfusion Associated Dyspnea, characterized by respiratory distress occurring within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reactions. Note: respiratory distress should not be explained by the patient's underlying condition.

VI. SPECIMEN COLLECTION:

The preferred specimen is a properly labeled 6 mL EDTA sample. The post-transfusion specimen must be collected after the transfusion is stopped. The pre-transfusion specimen (if available) will also be evaluated. See Transfusion Medicine policy Identifying and Triaging Acceptable Samples for Testing

VII. FORMS:

A. F-1566, *Record of Transfusion*

B. Electronic dispense form, or downtime dispense form F-1564, *Blood Product Dispense Form*.

C. *Suspected Transfusion Reaction Evaluation* form.

VIII. POLICIES:

A. **Training of Personnel Involved in the Transfusion of Blood Components**

1. All personnel involved in transfusion must be trained in the identification of transfusion recipients and blood components, and in the observation of recipients during and after transfusion for adverse reactions, with in-service education at least annually.
2. All personnel who administer blood components must be trained to identify transfusion recipients and components and to closely observe patients during and for a period of time after blood administration.
3. This training includes the BH mandatory on-line, self-paced course *Blood Product Administration*. This course includes the recognition of transfusion reactions and must be completed every year by Beaumont nurses and by the Blood Bank medical technologists.

B. **Reporting of Suspected Transfusion Reaction**

1. Suspected transfusion reactions should be reported immediately to the Blood Bank by the caregivers. The patient's physician or any Blood Bank personnel (Medical Director, Supervisor, Medical Technologist) have discretion to initiate a Suspected Transfusion Reaction Evaluation.

C. **Urticarial Reactions**

1. Urticarial reactions occur in 1-3% of all transfusions and are believed to be caused by antibodies in the recipient to donor plasma proteins.
2. Urticarial reactions are characterized by:
    a. urticaria (hives)
    b. pruritus (itching)
    c. flushing.
3. If an urticarial reaction resolves with antihistamine therapy, the transfusion may be resumed and Blood Bank testing is not indicated.
4. Urticarial reactions that resolve with antihistamine therapy are the only type of reaction in which the transfusion may be resumed.
   Refer to Transfusion Medicine policy, Urticarial Reactions.

D. **Requirement to Perform a Type & Screen**

1. A Type & Screen must be performed on the post-reaction sample of every transfusion reaction evaluation except for urticarial reactions, as indicated in Transfusion Medicine policy, Urticarial Reactions.

E. **Obtaining the Patient History**

1. A patient history shall be obtained on patients who are being evaluated for a suspected hemolytic transfusion reaction (positive DAT and hemolysis in the 2nd post reaction sample).
2. If the patient's transfusion history indicates that the patient has received ABO-incompatible plasma components, then eluate testing with a_1 and b cells may be required.

F. **Workflow Process for Transfusion Reactions**

1. All technologists on all shifts will begin transfusion reaction evaluations when they are ordered. Transfusion reaction evaluations are documented in the blood bank computer. Section I of the *Suspected Transfusion Reaction Evaluation form* (attachment) is also documented for each evaluation. Transfusion reaction evaluations have priority over all routine Blood Bank work.
2. In some cases, additional testing will be required; e.g., eluates, antigen typing, additional crossmatches, repeat ABORh typing, etc. This testing is described in Transfusion Medicine policy, Additional Testing for Transfusion Reactions.
3. The Medical Director reviews all transfusion reactions and completes the *Pathologist Consult of Reaction.*

G. **Policies for Notification of the Medical Director**

1. Blood Bank staff will notify the Medical Director immediately in the following cases:
    a. Transfusion of an incompatible RBC product (consider ABO, Rh, and other blood group systems)
    b. Bacterial contamination of a transfused blood product, refer to Transfusion Medicine policy, Suspected Bacterial Contamination of a Transfused Component.
    c. "Wrong Blood in Tube" collection errors coupled with a suspected transfusion reaction
    d. Mistransfusion of a blood component (refer to the *Definitions* section / mistransfusion)
    e. Significant adverse reaction to transfusion (i.e. Significant hemolysis in the post transfusion specimen)
    f. Suspected acute hemolytic transfusion reactions
    g. If additional testing is indicated. Refer to Transfusion Medicine policy, Additional Testing for Transfusion Reactions.
2. Any instructions provided by the Medical Director will be documented in the Blood Bank Computer or on the *Suspected Transfusion Reaction Evaluation Form*.

H. **Critical Value Notification**
A suspected acute hemolytic transfusion reaction is defined as a critical value. The Blood Bank Medical Director (or designee) and the patient's caregiver will be notified of the critical value immediately. The **CVRXN** code is used to document the notification. For additional information, refer to, Critical Value Notification Policy – Transfusion Medicine.

I. **Communication with the Supplier**
In some cases, the Blood Bank Medical Director or supervisor is required to notify the blood supplier and/or outside agencies. Refer to Transfusion Medicine policy, Roles and Responsibilities of the Blood Bank Medical Director for Transfusion Reaction Evaluations.

J. **Policies Relating to Suspected Bacterial Contamination of a Transfused Component**
1. If the component bag has been returned to the Blood Bank, then the patient's adverse reactions must be compared to the Guidelines for Suspected Bacterial Contamination of a Transfused Component.
2. If the patient's adverse symptoms match these guidelines, then the component bag will be sent to the Microbiology Laboratory for a culture.
3. These guidelines, and complete directions for this protocol, may be found in Transfusion Medicine policy, Suspected Bacterial Contamination of a Transfused Component.

K. **Clerical Checks**
1. In order to identify potential ABO incompatibility and prevent associated complications, clerical checks should be performed as soon as a transfusion reaction is suspected. Clerical checks are performed by verifying that patient and donor information is complete, accurate, and in agreement in several locations:

a. the pre-transfusion and post-reaction samples,

b. copies of form F-1566 *Record of Transfusion*,

c. the dispense form,

d. the component face label, and

e. the unit tag attached to the component (if returned).

L. **Interpretation of Clerical Checks**

1. The clerical check is documented as "OK" and the interpretation is "pass" if the information noted during the clerical check is complete, accurate, and in agreement (as described above).
2. The clerical check is documented as "NotOK" and the interpretation is "fail" if the information noted during the clerical check is incomplete, inaccurate, or not in agreement (as described above). If the clerical check fails, then the technologist will investigate the cause of the unsatisfactory clerical check and

    a. Consider whether to consult the Medical Director; refer to above policy *Policies for Notification of the Medical Director.*

    b. Document the unsatisfactory clerical check in the Blood Bank computer and on *Suspected Transfusion Reaction Evaluation* form.

    c. Consult a supervisor.

M. **Serologic Indications for Possible Delayed Transfusion Reaction**

1. Blood Bank staff will consult the Medical Director (MD) to determine whether a transfusion reaction evaluation should be ordered if each of the following conditions is met:

    a. The patient has a positive antibody screen on the current sample in which new, unexpected antibody reactivity is detected, **and**

    b. An antibody screen performed within last two (2) weeks was negative, or did not demonstrate the same unexpected reactivity present in the current sample, **and**

    c. The patient received a RBC transfusion in the last two (2) weeks.

    d. The patient may have a positive autocontrol or DAT.

2. The Medical Director's instructions will be documented in the blood bank computer as a comment.

IX. PROCEDURE:

The Suspected Transfusion Reaction procedure is standardized regardless of which classification of transfusion reaction may be occurring, or which type of component was transfused. However, if the reaction is an urticarial reaction that has subsided with antihistamine therapy, then proceed to Transfusion Medicine policy, Urticarial Reactions.

A. Upon notification of a transfusion reaction inform the patient's caregiver(s) to proceed

according to the directions on the back of the of the Record of Transfusion (F-1566) and to return this form (complete with patient's adverse reaction symptoms) and the blood component to the Blood Bank.

B. **The caregivers or medical technologist should order a transfusion reaction evaluation in EPIC.**

1. Out date the Pre-transfusion specimen and take down any other units selected for the patient.
2. A Transfusion Reaction must be ordered with a new order number. When the Transfusion Reaction is ordered in EPIC a new order number will be automatically generated and interface to the Softbank as the test code POST1. Refer to Blood Bank CDM - *Beaker Order Entry.*
3. Directions for the nurses are located on the reverse side of F-1566, *Record of Transfusion* form. The nurse should complete the reverse side of this form (to include the patient's adverse reaction symptoms) and return this form to the Blood Bank with the unit.
4. Confirm the transfusion and document the nurse and symptoms as directed in Blood Bank CDM-Transfusion Reaction Workup.

C. **Gather the following items:**

1. F-1566, *Record of Transfusion* form
2. The dispense form
3. The blood component bag; including (whenever possible), the entire administration set and the intravenous solutions, with the needle removed. The bag tag should still be attached.
4. The pre-transfusion sample
5. The post-reaction sample
6. *Suspected Transfusion Reaction Evaluation Form*

D. With a Sharpie, write the words "pre" and "post" on the corresponding patient samples.

E. Reprint and affix a Beaker accession label for the POST1 sample in the space provided on the reaction evaluation form.

F. **Section I**: After performing each of the following steps, place your initials in the space provided on the reaction evaluation form to signify that you performed the step.

1. Document the patient's name in the space provided in section I on the evaluation form. Verify that the patient's name matches and is accurate in for each of the locations listed (in the non shaded areas) on the evaluation form. Place a check mark in the appropriate boxes on the form to signify that the clerical check for the patient's name is satisfactory. Initial the form to indicate that you performed this clerical check.
2. Repeat step above for the patient's medical record number (MRN), B#, patient's ABORh, donor unit #, and donor ABORh.
   Note: The patient's band number on the Record of Transfusion form should appear

twice: once by the Blood Bank (computer generated) and once handwritten by the patient's nurse when the patient was identified.

3. Verify that the correct kind of blood product was issued and transfused by comparing the dispense form with the returned blood product. In other words, if RBCs were requested on the dispense form, verify that RBCs (not platelets or plasma) were issued and transfused.
4. Perform a visual inspection of the returned blood product and any attached tubing, solutions, etc. Document the visual inspection as "S" (satisfactory) or "U" (unsatisfactory) as described in Transfusion Medicine policy Visual Inspection of Blood Products - Blood Bank.
5. Determine the approximate volume that was transfused and document this volume in the Blood Bank computer and on the form.
   The nurse may have documented this information on the form F-1566 *Record of Transfusion*.
6. Place the returned product and any attached tubing, solutions, etc. on the quarantine shelf. Do not quarantine the unit in Soft Bank; do not return the unit in Soft Bank.
7. Release any other blood products that were selected or crossmatched before the reaction occurred to available inventory.
8. Document the Communication Log or Board with a notation about the pending reaction evaluation.

G. **Section II:** Perform the following checks / tests that are listed in Section II on the evaluation form. These steps will be documented in the computer as described in the Blood Bank CDM- Transfusion Reaction Workup. Note: For computer downtimes, these checks / steps may be documented on the form. After performing each of the following steps, place your initials on the form to signify that you performed the step.

   1. Document the clerical checks of the post- and pre-reaction samples as "OK" or "NotOK," and interpret as "pass" or "fail."
   2. Inspect the post- and pre-reaction samples for hemolysis, document the hemolysis check as "-" (hemolysis absent) or "+" (hemolysis present), and interpret as "neg" (hemolysis absent) or "pos" (hemolysis present).
      a. If the post-reaction sample is hemolyzed, then perform the following:
      b. Collect 2nd post sample STAT, to see whether hemolysis is in vivo or due to collection technique. If 2nd post is not hemolyzed, proceed to step c.
      c. If the 2nd post sample is significantly more hemolyzed than the pre-reaction sample, then communicate this critical value to the Medical Director or designee and to the patient(s) caregiver. Refer to above policy, *Critical Value Notification*.
      d. Instruct the caregiver(s) to collect a first post-reaction urinalysis.
      e. Obtain the patient history for all hemolytic transfusion reactions (even if the antibody screen is negative). Refer to Transfusion Medicine policy, *Obtaining a Patient History - Blood Bank*.

3. Inspect the post- and pre-reaction samples for icterus, and document the icterus check as "-" (icterus absent) or "+" (icterus present), and interpret as "neg" (icterus absent) or "pos" (icterus present).
4. Perform a DAT on the post-reaction sample and document the results. If the DAT on the post-reaction sample is positive, also perform a DAT on the pre-reaction sample and document the results. Refer to Transfusion Medicine policy, *Direct Antiglobulin (DAT) Test by Tube Method - Blood Bank*
    a. In a Transfusion Reaction workup the age of the Pre sample can be >24 hours.
5. Perform ABORh typing (VISION™ or tube method is acceptable) on the post-reaction sample and document the results.
6. Perform an antibody screen (VISION™ or manual gel method is acceptable) on the post-reaction sample and document the results. If indicated, perform an antibody investigation.

H. **Section III**: Document section III of the evaluation form as described below.
1. Evaluate the following four (4) conditions as true or false
    a. The ABO and Rh of the pre-reaction and post-reaction sample are in agreement
    b. An antibody investigation on the post-reaction sample is not indicated.
    c. The DAT of the post-reaction sample is negative, or the DAT of the post-reaction sample is less than or equal to the strength of the pre-reaction DAT.
    d. The post-reaction sample is not hemolyzed.
2. Determine whether additional testing is indicated, as follows:
    a. If each of the 4 conditions is true, then additional serologic testing is not indicated. Notify the caregivers, document this notification in the Comment Text special message, and crossmatch additional blood products if needed.
        i. For example, notify the nurse that "the Blood Bank has found no clerical or serologic evidence that would explain the patient's adverse symptoms; to be reviewed by the Blood Bank pathologist."
    b. If any of the 4 conditions are false, then additional serologic testing is indicated:
        i. Proceed to Transfusion Medicine policy, Additional Testing for Transfusion Reactions.
        ii. The Blood Bank Medical Director must be consulted before additional blood products may be issued. Additional products may not be issued until additional testing is completed, unless the patient's physician authorizes emergency issue.

iii. The Medical Director's directions from this consultation should be documented in the Blood Bank computer and in section IV on the *Suspected Transfusion Reaction Evaluation* form.

I. Eligible products should be sent to Microbiology for a culture; take the product to Microbiology. Document the computer as "ST" (sent) or "NS" (not sent), as described in Blood Bank CDM -Transfusion Reaction Workup. Refer to above policy, *Policies Relating to Suspected Bacterial Contamination of a Transfused Component.*

J. Print the Transfusion Reaction Workup Interim Report from Softbank.

K. Place all paperwork in the review box.

L. Report will be reviewed for completeness by the Supervisor, Lead Technologist or designee.

M. Scan or deliver all paperwork associated with this transfusion reaction evaluation to the Medical Director. Be sure to include the reverse side of the form, F-1566, *Record of Transfusion* with the scan.

N. After the Medical Director completes the *Pathologist Consult of Reaction,* perform the following steps:

1. Update the computer record with the code corresponding to the Medical Director's impression as described in the *Blood Bank CDM - Pathologist Transfusion Reaction Consult (CRXN)* . The impression may be obtained from the *Pathologist Consult of Reaction report.*
2. Update the Medical Director's ID in the physician field.
3. Print the *Patient Transfusion Reaction Workup Report.*
4. File report in the Transfusion Services department.

X. REFERENCES:

1. AABB, *Technical Manual*, current edition.
2. AABB, *Standards for Blood Banks and Transfusion Services*, current edition.
3. American Association of Blood Banks Circular of Information for the use of Human Blood and Blood Components, October 2017. A copy of this document is available on the laboratory web page.
4. College of American Pathologists, Transfusion Medicine Checklist, current edition.

Attachments

Transfusion Reaction Evaluation Form

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	6/21/2022
	John Pui: Chief, Pathology	6/20/2022
	Ryan Johnson: OUWB Clinical Faculty	6/20/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy [IH]	6/17/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	6/15/2022
	Karrie Torgerson: Supv, Laboratory	6/15/2022
	Kelly Sartor: Supv, Laboratory	6/8/2022
	Kelly Sartor: Supv, Laboratory	6/8/2022

Beaumont HEALTH

Affix patient label here

SUSPECTED TRANSFUSION REACTION EVALUATION FORM

Section I: Clerical Checks

		Pre RXN Sample	Post RXN Sample	Report of Blood TxN	Dispense Form	Transfused Unit	
						Face label	ABO Tag
Patient's Name							
MRN							
B #							
Patient ABO/Rh			TBD				
Donor Unit #							
Donor ABO/Rh							

Other units that were XM'd placed in available inventory?	Circle Yes / No	*Blood Product Dispense Form* documented completely and accurately?	Circle Yes / No
Transfusion confirmed in Soft?	Circle Yes / No	Sent for Culture?	Circle Yes / No
Sample outdated in Soft?	Circle Yes / No	Correct kind of component was dispensed, and exp. date acceptable?	Circle Yes / No
Approximate volume transfused:			
Visual inspection unit, tubing, solutions, etc. upon return (S/U):		Date & time RN Notified of Result (RN / Date / Time / Tech)	
Completion of section I -Tech's Initials/Date:			

Section II: Computer Downtime Documentation (when computer is available, attach *Transfusion Reaction Report*)

RXN Post Specimen					RXN Pre Specimen				
Clerical Check (circle response)	OK	Not OK	Pass	Fail	Clerical Check (circle response)	OK	Not OK	Pass	Fail
Hemolysis Check (circle response)	+	0	Pos	Neg	Hemolysis Check (circle response)	+	0	Pos	Neg
Icteric Check (circle response)	+	0	Pos	Neg	Icteric Check (circle response)	+	0	Pos	Neg
DAT RXN post specimen	IS	RT	CC	INT	DAT RXN pre specimen	IS	RT	CC	INT
Polyspecific					Polyspecific				
IgG (if indicated)					IgG (if indicated)				
Complement (if indicated)					Complement (if indicated)				
ABORh									
Antibody Screen	I:	II:	INT:						
Date /Tech completing Sec II (post)					Date /Tech completing Sec II (pre)				

Section III: Blood Bank Physician Review

Diagnosis / HPI / Allergies:	**Reaction Classification:**
	Febrile Non-hemolytic
	Non-specific
	Allergic
	Immediate Hemolytic
	Delayed Hemolytic
	Bacterial Contamination
	TRALI
	Circulatory Overload (TACO)
	Not a Reaction
	Other:

Approximate volume transfused:	Transfusion start time:
Culture:	Reaction time:
Dr./ Service:	Transfusion stop time:
Pathologist: / Date:	

Computer Record Updates

SoftBank:	SoftBank RXN Code:	Tech / Date:

Section IV: Additional Technologist Notes / Additional Testing

Applicable procedure: *Laboratory Investigation of a Suspected Transfusion Reactions*

SUSPECTED TRANSFUSION REACTION EVALUATION FORM

Section V: Additional Notes from Physician Review