Name of Policy: Laboratory Investigation of Adverse Reaction to Transfusion

Policy Number: 3364-108-501

Department: Pathology/Laboratory – Blood Bank

Approving Officer: Chief Executive Officer – UTMC
Associate Professor, Director, Clinical Pathology/Hematopathology

Responsible Agent: Core Lab Manager
(Michelle Bartkowski, MT(ASCP)SBB)
Administrative Director, Lab (Cynthia O’Connell)

Scope: Pathology/Laboratory – Blood Bank

Effective Date: 03/01/2017
Initial Effective Date: 10/1986

(A) Policy Statement

The Blood Transfusion Service investigates all suspected transfusion reactions.

(B) Purpose of Policy

To determine the need for patient care and surveillance in confirmed cases of adverse reaction to transfusion. To report adverse affects due to product quality to the collection center.

(C) Procedure

1. The following symptoms may indicate an adverse reaction to blood transfusion, especially when not present prior to transfusion: chills and fever (1.0°C or 1.8°F rise in temperature), flushing, rash, itching, dyspnea, nausea and vomiting, back pain, hypotension, shock, generalized bleeding, chest pain, headache, hemoglobinemia, hemoglobinuria. Recognition of signs and symptoms of Blood Transfusion Reaction and instructions for investigation and interventions are explained in the UTMC Nursing Policies: Standards of Care: Blood and Blood Products, section C5. Blood Transfusion Service personnel must proceed according to procedure 200.040 (Attachment #1) when notified by clinical services of a suspected transfusion reaction.

2. A copy of the Transfusion Record (bottom half completed) and "Laboratory Investigation of Adverse Reaction to Blood Transfusion" form, including the interpretation of the results of the investigation will be part of the patient's clinical record.

3. If blood unit quality is suspected as a cause of an adverse reaction (contaminated, infected, mislabeled, etc.) the BTS Medical Director will notify the ARC Medical Director by established protocol. See ARC Adverse Effects Reporting File.

4. Fatalities are reported to the FDA as described in policy #3364-108-106.

5. If a delayed hemolytic reaction is suspected by physician (unexplained rise in bilirubin or drop in hemoglobin in a recently transfused patient) or delayed serologic reaction is detected by the Blood Transfusion Service in subsequent compatibility testing (positive antibody screen, positive direct antiglobulin test in a patient previously testing negative or new antibody present in a recently transfused patient), studies are performed to determine the cause of the delayed hemolytic or serologic reaction. Results of this investigation are part of the patient's clinical record.
Laboratory Investigation of Adverse Reaction to Blood Transfusion

Clinical Investigation
1. Nursing unit notifies Blood Transfusion Service of a possible transfusion reaction.
2. Nursing unit completes a bedside clerical check; notifies resident or attending physician; sends post transfusion reaction blood specimen and urine specimen (if ordered), donor unit with I.V. set attached to laboratory. Blood bag and transfusion set must be returned to the BTS, except in mild, allergic reactions (urticaria).

Laboratory Investigation
1. Perform preliminary investigation as follows:
   - clerical verification
   - direct antiglobulin test on pre and post transfusion reaction blood specimen
   - visual inspection of pre and post transfusion reaction serum/plasma for hemolysis
   - ABO/Rh on pre and post transfusion reaction blood specimen
2. If results of the preliminary investigation are negative, investigation is complete. Notify the O.D. or BTS Medical director of the reaction unless the only symptoms were skin rash or itching. If results of the preliminary investigation are positive or inconsistent with pre-transfusion testing results, or a 1°C rise in temperature was reported, proceed with the following tests using the post transfusion reaction blood specimen:
   - ABO grouping and Rh typing on all donor units transfused in the previous 24 hours
   - Antibody screen of post reaction blood specimen.
   - Crossmatch of donor units by AHG technique.
   Retain segments from units in Blood Transfusion Service for further study.
3. If 1°C rise in temperature was reported, send donor unit bags and attached I.V. for Gram stain and culture. Residual blood in the bag should be used for the testing. Do not use blood segments for bacterial contamination testing. Instruct clinical care staff to order for blood culture for recipient.
4. If results of additional testing are negative, notify the O.D. or director of Blood Transfusion Service to inform the attending physician and determine the need for additional investigation.
5. If results of additional testing differ from pre-transfusion testing, repeat tests using pre-transfusion specimen to verify pre-transfusion testing results. Notify O.D. or BTS Medical Director immediately and proceed with special studies to determine the source of the incompatibility.
6. If Gram stain results are positive, notify the O.D. or BTS Medical Director and inform the patient's physician.
7. The O.D. or Medical Director of Blood Transfusion Service will notify the patient's physician of results of laboratory investigation and the need for further study and treatment. Coagulation studies, BUN and creatinine should be obtained at the time of a confirmed hemolytic reaction, as well as serum methemalbumin, bilirubin and haptoglobin 5-7 hours after the reaction. Urine output should be monitored.
8. Additional studies for investigation of anaphylactic reactions or reactions suggestive of TRALI will be determined by the BTS Medical Director.
6. A report of clinical and laboratory investigation of reported adverse reactions to transfusion will be written and signed by the BTS Medical Director and will become part of the patient’s permanent medical record. Adverse reactions due to quality of donor blood must be reported to the American Red Cross by established protocol. See ARC Adverse Effects Reporting File.

REFERENCES
<table>
<thead>
<tr>
<th>Approved by:</th>
<th>Review/Revision Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert L. Booth, Jr., M.D.</td>
<td>6/96</td>
</tr>
<tr>
<td>Associate Professor</td>
<td>6/9/2008</td>
</tr>
<tr>
<td>Director, Clinical Pathology/Hematopathology</td>
<td>1/98</td>
</tr>
<tr>
<td></td>
<td>3/25/2011</td>
</tr>
<tr>
<td></td>
<td>2/99</td>
</tr>
<tr>
<td></td>
<td>3/01/2013</td>
</tr>
<tr>
<td></td>
<td>11/99</td>
</tr>
<tr>
<td></td>
<td>3/02/2015</td>
</tr>
<tr>
<td></td>
<td>3/02</td>
</tr>
<tr>
<td></td>
<td>3/1/2017</td>
</tr>
<tr>
<td></td>
<td>12/07</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review/Revision Completed By:</th>
<th>Next Review Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daniel Barbee, RN, BSN, MBA</td>
<td>3/1/2019</td>
</tr>
<tr>
<td>Chief Executive Officer - UTM C</td>
<td></td>
</tr>
</tbody>
</table>

Policies Superseded by This Policy:

Reference: Current Edition of AABB Standards for Blood Banks and Transfusion Services