Dignity Health Central Coast Service Area

SUBJECT: Investigation of Suspected Transfusion Reactions 7540.BB.FH.30

ORIGIN: Laboratory/Blood Bank

Document Category:			
☒ Policy	☒ Procedure	☐ Standardized Procedure	☐ Other:

Applies to:		
☐ Santa Maria Campus, Marian Regional Medical Center	☐ Arroyo Grande Campus, Marian Regional Medical Center	☒ French Hospital Medical Center
☐ St. John's Pleasant Valley Hospital	☐ St. John's Regional Medical Center	

I. PURPOSE:

The purpose of this policy is to outline the steps involved in properly documenting and evaluating a suspected transfusion reaction. All suspected transfusion reactions will be evaluated promptly and to the extent considered appropriate by the Pathologist. Any adverse reaction of the patient associated with a transfusion is a suspected transfusion reaction.

II. DEFINITIONS:

N/A

III. POLICY:

It is the policy of French Hospital Medical Center to provide a detailed procedure for the evaluation of suspected transfusion reactions.

IV. PROCEDURE:

EQUIPMENT REQUIRED/ITEMS TO ASSEMBLE:

A. Transfusion Reaction worksheet, parts 1 and 2 (if applicable). Blood Bank module is to be used to record all graded reactions.

B. WHO CAN PERFORM: All Clinical Laboratory Scientists who are licensed and found competent in Blood Bank procedures and the Pathologist.

PROCEDURE:

A. In the event of a suspected transfusion reaction the nursing personnel attending the patient shall immediately stop the blood transfusion and notify the attending physician and the blood bank transfusion service.

B. Nursing will provide patient vitals as documented on the blood bank requisition along with the blood container, whether or not it contains any unused blood, and the transfusion set and attached intravenous solutions.

C. Nursing will wait for further instructions as to the disposition of the unit of blood and further units of blood ordered.

D. A new suitable, properly labeled, blood sample (EDTA pink top) will be obtained from the patient, avoiding hemolysis, and must be sent promptly to the blood bank transfusion service.

IMMEDIATE EVALUATION MUST INCLUDE:

A. The label on the container of blood and all other records must be reexamined to assure that there has been no error in identifying the patient or the blood.

B. Comparative inspection of patient's pre-transfusion and post-transfusion serum or plasma for hemolysis or icterus.

C. Direct antiglobulin testing of the post transfusion specimens of recipient red cells. If post transfusion direct antiglobulin testing is positive, then perform direct antiglobulin testing on pre transfusion specimen.

D. A repeat ABO group determination will be performed on the post transfusion specimen.

E. A urine specimen is obtained immediately and another obtained five hours post transfusion reaction. These will be tested for hemoglobin by dipstick and sediment examined microscopically for cells if any occult blood is found to be present.

A PATHOLOGIST WILL BE NOTIFIED IMMEDIATELY AFTER THE ABOVE WORKUP IS COMPLETE:

A. Call the Pathologist on call during the PM, graveyard and weekend shifts.
   1. Record conversation on the worksheet, including name of Pathologist and time of notification.
   2. The Pathologist will evaluate if further testing is necessary.

FURTHER TESTING IF NECESSARY MAY INCLUDE:

A. Determination of ABO and Rh type on the pre reaction specimen from the patient, a sample from the blood container or attached segment.

B. Repeat testing for recipient unexpected antibodies and crossmatch using the pre and post reaction specimens and donor blood from the attached sealed segments.

C. Examination of post reaction urine for hemoglobin and its derivatives and observe the patient's urinary output.

D. Determination of bilirubin concentration on serum preferably obtained 5 to 7 hours after transfusion. Serum haptoglobin and LDH may also be useful (Sent to Marian Hospital).

E. Examination of stained smear of plasma gram stain and culture of contents of blood container for bacteria is to be done STAT at Marian Hospital.

RESULTS WILL BE REPORTED IMMEDIATELY TO THE PATHOLOGIST FOR INTERPRETATION AND EVALUATION.

A. Call the nurse in charge of the patient immediately after the evaluation is made.

B. If results suggest a hemolytic reaction, TRALI (Transfusion Associated Lung Injury), transfusion associated sepsis (bacterial contamination), anaphylaxis or other serious complication of transfusion, the physician shall be notified immediately.

C. If a delayed transfusion reaction is detected or suspected, tests shall be performed to determine the cause of the reaction. The results of the evaluation shall be reported to the patient's physician.

D. Report all fatal reactions within 24 hours by phone (301-827-6220), email (fatality2@cber.fda.gov), or fax (301-827- 6748).
   1. A written report must be submitted within 7 days [21 CFR 606.170(b)] to:
      FDA Center for Biologics Evaluation and Research (CBER)
      CBER Director
      Office of Compliance and Biologics Quality
      Attn. Fatality Program Manager (HFM-650)
      1401 Rockville Pike
      Rockville, MD 20852-1448
   2. The report should include a description of any new procedures implemented to avoid recurrence.

If reaction is suspected to be due to an attribute specific to the donor or the processing of the blood product, complete and submit the Vitalant form “Report of Transfusion Adverse Reaction”. Retain a copy of report submitted for our patient records, file with FHMC Transfusion Reaction.

V. REFERENCES:

AABB Technical Manual, 14th Edition 2002.
Standards for Blood Banks and Transfusion Services, 22nd Edition, AABB, 2003, pages 87-92.

VI. ASSOCIATED DOCUMENTS:

N/A