

TRAINING UPDATE

Lab Location: SGMC and WAH **Date Implemented:** 12.11.2017
Department: Blood Bank **Due Date:** 12.31.2017

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Transfusion-Transmitted Disease Investigation

Description of change(s):

Added instructions for Inova units to the procedure.

Electronic Document Control System



Document No.: SGAH.BB86[1]

Title: Transfusion-Transmitted Disease Investigation

Owner: LESLIE BARRETT

Status: INWORKS

Effective Date: 04-Jan-2018

Next Review Date:

Non-Technical SOP

Title	Transfusion-Transmitted Disease Investigation	
Prepared by	Stephanie Codina	Date: 3/27/2011
Owner	Stephanie Codina	Date: 3/27/2011

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

Review:		
Print Name	Signature	Date

Document: SGAH.BB86[1] Status: INWORKS, Effective: 1/4/2018, Check Version Before Use

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE..... 2

2. SCOPE..... 2

3. RESPONSIBILITY..... 2

4. DEFINITIONS..... 2

5. PROCEDURE..... 3

6. RELATED DOCUMENTS 4

7. REFERENCES 4

8. REVISION HISTORY..... 5

9. ADDENDA AND APPENDICES..... 5

1. PURPOSE

All suspected post-transfusion infections with bacteria, viruses, protozoa, or prions for which no other identifiable cause exists will be reported to the blood bank. This procedure outlines the steps that will be taken to report and investigate the suspected transfusion-transmitted infection by blood bank staff members.

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.

2. SCOPE

This procedure applies to any situation in which a post-transfusion infection has been reported to the blood bank.

3. RESPONSIBILITY

All blood bank staff members must understand the steps that must be followed when a suspected transfusion-transmitted disease is reported to the blood bank.

4. DEFINITIONS

Suspected Transfusion-Transmitted Infection: Any case of infection where transfusion cannot be reasonably excluded as the source of infection. Ordinarily, this means that the interval between transfusion and disease or diagnosis is consistent with the known incubation period for the infection, and the recipient does not have an obvious alternative source of infection risk (risk factor).

Document:SGAH.BB86[1] Status:INWORKS,Effective:1/4/2018, Check Version Before Use

Form revised 1/11/00

Document: SGAH.BB86[1] Status: INWORKS, Effective: 1/4/2018, Check Version Before Use

5. PROCEDURE

Step	Action
1	<p>Blood bank will receive notification that a case of suspected transfusion-transmitted disease has occurred. Notification may be made by:</p> <ul style="list-style-type: none"> A. Letter or telephone notification by the physician. B. Letter or telephone notification to the pathologist. C. Letter or telephone notification by the transfusion recipient/recipient family member. D. State of Maryland notification form via the Infection Control department.
2	<p>Blood bank will immediately determine which blood supplier distributed the unit.</p>
3	<p>For Red Cross units:</p> <ul style="list-style-type: none"> A. Blood bank staff will immediately complete the "Possible Recipient Transfusion-Transmitted Infection (PRTTI)" form. <ul style="list-style-type: none"> a. The recipient's physician will be listed as the contact person along with his/her telephone number. b. The patient's medical record may be obtained from the Medical Records department if needed for additional information. c. The recipient's physician can be contacted if additional information is needed to complete the form. It is permissible for the recipient's physician to complete the form. d. Transfusion records will be searched and all blood products to which the recipient was exposed will be listed in part II of the form. <ul style="list-style-type: none"> i. WBN = unit number ii. Transfusion date iii. Component iv. Expiration date B. The report is forwarded to the Blood Bank Medical Director for review. C. The completed form is submitted to the American Red Cross per instructions on the form. D. One copy of the form is maintained in blood bank.
4	<p>For Inova units:</p> <ul style="list-style-type: none"> A. Document the information on a delayed transfusion reaction form. B. Notify Inova Blood Donation Services as soon as possible and follow additional instructions for follow-up. C. Notify the Blood Bank Medical Director and document the notification on the form.

Form revised 3/31/00

Document: SGAH.BB86[1] Status: INWORKS, Effective: 1/4/2018, Check Version Before Use

Step	Action
5	Notify the FDA if a suspected or confirmed transfusion-related fatality occurred. Refer to procedure, "FDA Reportable Event Notification Process."
6	The blood supplier will send a letter to the hospital when their investigation has been completed. Follow-up will be based on the findings of the blood supplier and the disease process.
7	The Blood Bank Medical Director or designee will determine if additional notifications should be made: <ul style="list-style-type: none"> A. Patient's provider B. Risk management C. Infection control
8	The procedure for reporting cases of suspected transfusion-transmitted diseases is outlined in the hospital policy for Transfusion Reaction. Nursing staff will be educated annually via the Learning Suite Transfusion and Transfusion Reaction module.

6. RELATED DOCUMENTS

SOP: Transfusion Reaction Investigation

SOP: FDA Reportable Event Notification Process

ARC Form: Possible Recipient Complication—Infectious Disease Report. American Red Cross form 11.4.

7. REFERENCES

1. Fung, MK, Grossman, BJ, Hillyer, CD, and Westoff, CM. 2014. Technical Manual of the AABB, 18th ed. AABB Publishing, Bethesda, Maryland.
2. Standards for Blood Banks and Transfusion Services, 2016. AABB, 30th ed. AABB Publishing, Bethesda, Maryland.
3. American Red Cross Donor and Client Support Center, "The Transfusion Service Customer Handbook." ARC Document ARC-DOC-009329, Version 1.2.
4. 21CFR606.170

Form revised 3/31/00

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAH-SGAH B520.01		
000	12.4.17	Header: Added WAH Section 5: Added Inova process Footer: Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

NA