Estimated risks in transfusion per unit transfused in the USA.

INFECTIOUS:

Viral:

HIV 1/2:	1:2,300,000
Hepatitis B (HBV):	1:220,000
Hepatitis C (HCV):	1:1,800,000
HTLV I/II:	1:3,000,000
West Nile (WNV):	Rare; regional and seasonal risk

Bacterial contamination: Septic reaction - 1:75,000 (Platelets); 1:500,000 (RBC)

Malaria (Plasmodium sp): 1:4,000,000

Syphilis (T pallidum): Remote (no new cases reported in > 30 years)

Other Parasites: Rare; increased risk in endemic areas
Chagas' disease (T cruzi); Babesiosis (Babesia sp)

Creutzfeldt-Jakob disease (CJD/vCJD/BSE): unknown

NON-INFECTIOUS:

Transfusion-associated error: 1:14,000 – 1:19,000
'Mistransfusion' due to mislabeled and miscollected samples.

Transfusion fatality: 1:800,000 – 1:1,300,000
Leading cause: accidental transfusion of ABO-incompatible RBCs

TRALI: 1:1,300 – 1:5,000; fatality rate = 5%
(Transfusion-Related Acute Lung Injury)

TACO: 1:700 – 1:5,000; underreported
(Transfusion-Associated Circulatory Overload)

Hemolytic:

Acute:	1:6,000 – 1:20,000
Delayed:	1:2,500 – 1:11,000

Febrile, nonhemolytic: 1:300

Urticaria/cutaneous: 1:50 – 1:100

Anaphylaxis: 1:20,000 – 1:50,000

Alloimmunization

RBC antigens:	1:100
HLA antigens:	1:10

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4. Strong M, Lipton KS. West Nile Virus – recommendations for triggering individual donation nucleic acid testing and developing a communication plan. Association Bulletin No. 07-02. Bethesda, MD: AABB 2007:1-4.

5. Linden JV, Wagner K, Voytovich AE, Sheehan J. Transfusion errors in New York State: an analysis of 10 years' experience. Transfusion 2000; 40:1207-1213.

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END

Forms

HLSM-012-F-01, Investigation of Suspected Transfusion Reaction Form
HLA-100-F-01, HLA Laboratory Requisition Form

Samples

If CBC is to perform a transfusion reaction investigation, then the hospital must supply the following:

- Pre-transfusion EDTA and Red Top Samples from Recipient
- Post-transfusion EDTA and Red Top Samples from Recipient
- Residual Product or Empty Bags from Transfused Products

FDA Safety Communication

Important Information for Blood Establishments and Transfusion Services Regarding Bacterial Contamination of Platelets for Transfusion, was released by FDA December 2, 2021 and encourages blood establishments and transfusion services to contact FDA when they identify suspected contamination of platelets with Acinetobacter spp., Staphylococcus saprophyticus, or Leclercia adecarboxylata, or septic transfusion reactions involving pathogen-reduced platelet components.

- Report cases via MedWatch (https://www.fda.gov/Safety/MedWatch/default.htm) or by emailing CBER at CBEROBRRBPBInquiries@fda.hhs.gov.

Instructions

A. Refer to HLSM-012-JA-02, **Hospital Transfusion Reaction Guidelines** for steps that must be included in the Hospital's transfusion reaction protocol.

B. The Hospital must complete the unshaded sections of the **Investigation of Suspected Transfusion Reaction Form** (HLSM-012-F-01). Provide as much of the requested information as possible on the first page of the form in order to facilitate a rapid and accurate investigation of the suspected transfusion reaction.

1. Complete the first 3 sections of the **Investigation of Suspected Transfusion Reaction Form**.

2. List all **Suspect Products Transfused** on Page 2 of the form. Be sure to list the **DIN** (Donor Identification Number), **Implicated PCodes** (Product Codes), and mark the **Yes** or **No** box to answer to the question **Product Bag Available?**

3. Attach a copy of the **Transfusion Service Reaction Workup**, if performed; otherwise mark the **Workup not performed at hospital** box.

4. Attach a copy of the **Patient's Transfusion Record**, if available.

C. Hospital or transfusion service personnel must retrieve the suspected product bag(s), the pre-transfusion and post-transfusion blood samples and package them for shipment to CBC, if available.

1. Pre-transfusion and post-transfusion recipient samples and the blood bag(s) from the transfused product(s) must be packed in a CBC blood shipping box.

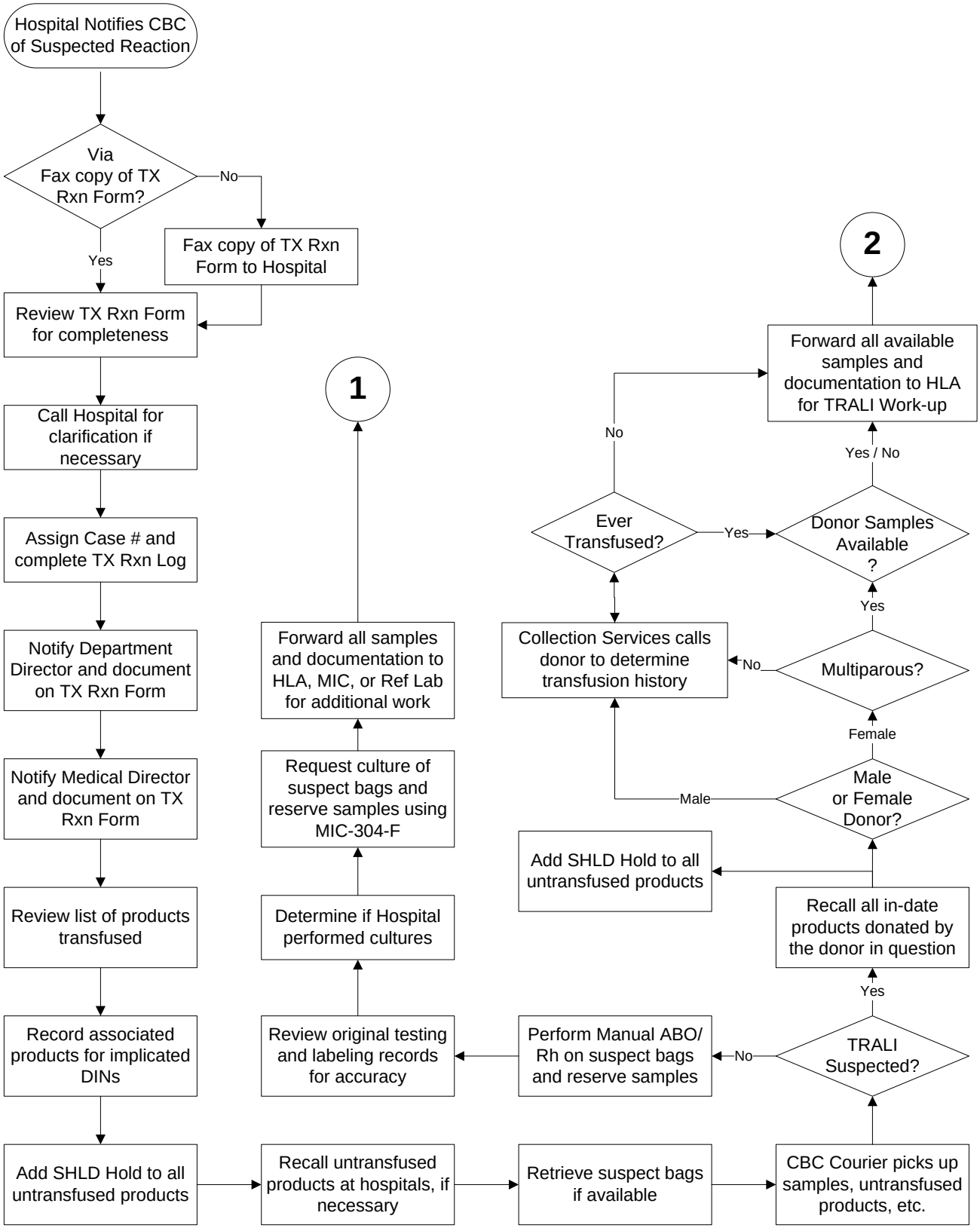
2. Both the samples and the blood bag(s) must be packed in a closed plastic bag to prevent leaking or other contamination hazards.

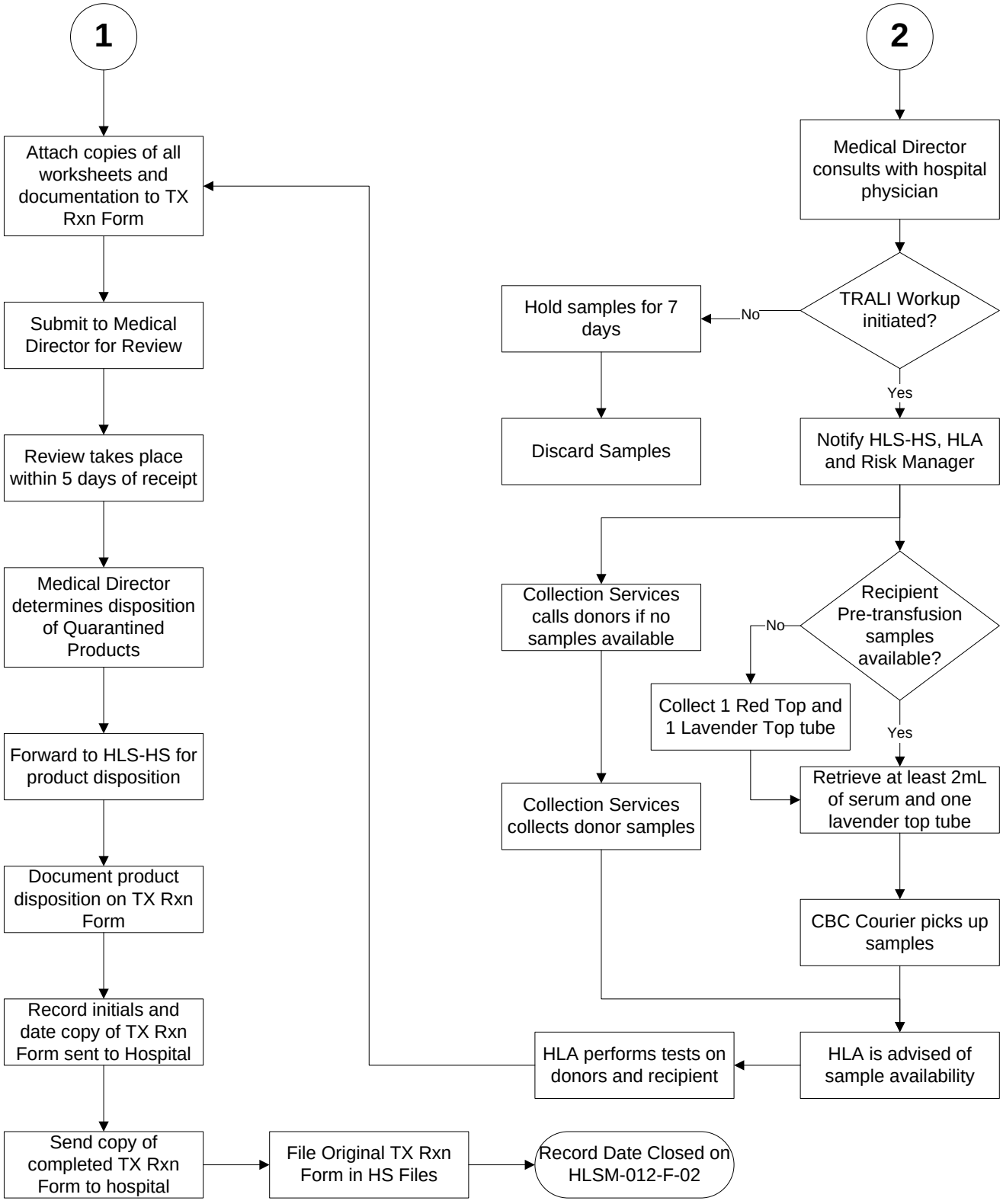
D. The completed **Investigation of Suspected Transfusion Reaction Form** including the additional supporting documentation, if available, may be faxed to CBC **or** shipped with the samples and empty blood bags.

E. The hospital must submit an **HLA Laboratory Requisition Form** (HLA-100-F-01) if TRALI is suspected.

F. CBC is to return the completed **Investigation of Suspected Transfusion Reaction Form** to the hospital upon completion of the investigation.

END


Hospital Notifies CBC of Suspected Reaction
Via Fax copy of TX Rxn Form?
No
Yes
Fax copy of TX Rxn Form to Hospital
Review TX Rxn Form for completeness
Call Hospital for clarification if necessary
Assign Case # and complete TX Rxn Log
Notify Department Director and document on TX Rxn Form
Notify Medical Director and document on TX Rxn Form
Review list of products transfused
Record associated products for implicated DINs
Add SHLD Hold to all untransfused products
Recall untransfused products at hospitals, if necessary
Retrieve suspect bags if available
CBC Courier picks up samples, untransfused products, etc.
TRALI Suspected?
No
Yes
Perform Manual ABO/ Rh on suspect bags and reserve samples
Review original testing and labeling records for accuracy
Determine if Hospital performed cultures
Request culture of suspect bags and reserve samples using MIC-304-F
Forward all samples and documentation to HLA, MIC, or Ref Lab for additional work
1
Recall all in-date products donated by the donor in question
Add SHLD Hold to all untransfused products
Male or Female Donor?
Male
Female
Multiparous?
No
Yes
Collection Services calls donor to determine transfusion history
Ever Transfused?
Yes
No
Donor Samples Available ?
Yes
Yes / No
Forward all available samples and documentation to HLA for TRALI Work-up
2


1
Attach copies of all worksheets and documentation to TX Rxn Form
Submit to Medical Director for Review
Review takes place within 5 days of receipt
Medical Director determines disposition of Quarantined Products
Forward to HLS-HS for product disposition
Document product disposition on TX Rxn Form
Record initials and date copy of TX Rxn Form sent to Hospital
Send copy of completed TX Rxn Form to hospital
File Original TX Rxn Form in HS Files
Record Date Closed on HLSM-012-F-02
2
Medical Director consults with hospital physician
TRALI Workup initiated?
No
Hold samples for 7 days
Discard Samples
Yes
Notify HLS-HS, HLA and Risk Manager
Collection Services calls donors if no samples available
Recipient Pre-transfusion samples available?
No
Collect 1 Red Top and 1 Lavender Top tube
Yes
Retrieve at least 2mL of serum and one lavender top tube
Collection Services collects donor samples
CBC Courier picks up samples
HLA is advised of sample availability
HLA performs tests on donors and recipient

END

A. Role of Hospital Clinical Service Personnel:

1. Identify adverse transfusion reactions by defined criteria.
2. Notify the Hospital Transfusion Services when such an event is identified.
3. Follow established Hospital SOPs for adverse reactions.
4. Save the blood product bag and intravenous administration set in an aseptic manner.
5. Draw recipient blood cultures, if indicated. [Draw 2 sets of cultures.]
6. Deliver the product bags, IV sets and transfusion records to the Hospital Transfusion Services for possible shipment to the Community Blood Center (CBC).

B. Role of Hospital Transfusion Service:

1. Follow already established transfusion reaction SOPs.
2. Notify CBC immediately upon the decision to involve CBC in the investigation.
3. Gram stain and culture suspected contaminated blood components.
4. Freeze any pre- or post-transfusion serum or plasma after workup is completed.
5. Refrigerate the blood component bag and administration set. Forward the blood component bag and administration set to CBC along with available samples and all required documentation, as soon as possible after notification.
6. Save culture-positive recipient blood and component isolates for species identification.
7. If a blood component bag is cultured at your facility, notify the CBC Microbiology department of the final culture results. Positive culture results should be communicated immediately to CBC.

END

TRALI is a serious but uncommon side effect of transfusion.

- The estimated incidence is 1/5000 transfusions.
- Current estimates of mortality caused by **TRALI** are 5–10%.

There have been several reports in the press recently about **TRALI** that increased the interest of blood centers and the awareness of transfusion centers.

Here is some additional information that could help recognize the problem and rule out other etiologies that may need a different treatment.

Clinical Picture:

- **TRALI** causes noncardiogenic pulmonary edema, dyspnea, cyanosis, hypotension (sometimes hypertension), fever and chills (may not be present). These symptoms usually develop within 1–2 hours of transfusion, but may occur up to 6 hours after transfusion.

- **One must rule out other causes of respiratory distress and pulmonary edema in patients receiving transfusions:** myocardial infarction, circulatory overload, and bacterial infection. When possible, normal central venous and pulmonary wedge pressures are consistent with **TRALI**.

Differential Diagnosis:

- Anaphylaxis, bacterial contamination, immediate hemolytic transfusion reaction and volume overload. **TRALI** is a diagnosis of exclusion and all of the above should be ruled out before suspecting **TRALI** since the treatment is different.

- Please remember that **Transfusion Associated Circulatory Overload (TACO)** is far more frequent and is the most confused with **TRALI**. Here are some criteria to differentiate the two:

	TACO	**TRALI**
Risk Factor:	Very old and very young	Non-identified
Pulmonary Edema:	Yes	Yes
Onset:	< 2 hours	< 6 hours
BP:	Increased	Decreased
Temperature:	No change	May be increased
CVP/P Wedge:	Increased	No change
Incidence:	1:100?	1:5000?

- In addition, the review of the **fluid input and output** in the recipient will be very helpful in suspecting or not, **TRALI**.

Pathogenesis:

- Sequestration of WBCs in pulmonary microvasculature leads to increased vascular permeability and pulmonary edema.
- Pulmonary edema arises from capillary injury rather than volume overload.

Etiology:

- Antibodies against granulocytes, HLA Class I and Class II antigens in donors or recipients.
- Recent reports implicate antibodies to monocytes.
- Biologically active lipids in stored cellular blood components.
- There will be some cases where no antibodies are identified.

Treatment:

- Supportive ventilator assistance.
- Maintenance of hemodynamic status.
- Diuretics are contraindicated.

If suspecting a TRALI, please follow the instructions in the SOP regarding what sample to send for testing. In addition, it is crucial to have well documented clinical information. After all, **TRALI** is a diagnosis of exclusion and there is no single test for detection.

Community Blood Center will obtain samples needed from the indicated donor(s). The HLA Laboratory will initiate testing for HLA class I and II antibody identification and antigen typing under the Medical Director's guidance. The neutrophil-specific antibody test will be sent out.

END