Policy Statement	The Transfusion Service investigates and evaluates possible transfusion- and tissue-transmitted infections.
Purpose	To provide direction when receiving notification of a possible transfusion or tissue-transmitted infection.
Scope	This program encompasses all patients who receive blood, blood products, donor milk, or tissue products which were issued by the Transfusion Service.
Responsibility	The associate who receives a notification from Infection Prevention and Control or a patient's physician is responsible for: • Initiating TRAN 8003 Fa Look Back Form documentation for the Transfusion Service Medical Director/Lead Technologist to complete and review. The Transfusion Services Medical Director, Lead Technologist or designee are responsible for: • Documentation of implicated products on TRAN 8003 Fa Look Back Form. • Review of the case and determination of need for blood supplier or regulatory agency notification. • Notification of blood supplier, regulatory agency, and hospital representatives if indicated. • Appropriate follow up. • Look Back and medical record documentation as needed.

Procedure

Notification from Infection Prevention and Control or Patient's Physician

Notifications may be received through different modes of communication

- E-mail
- Fax
- Surface mail letter
- Phone call

The notification must include the identity of the notifying party, sufficient patient identifiers, the suspected infection, the indication that lead to the notification, and the patient's current status. Document this information in the applicable fields of TRAN 8003 Fa Look Back Form.

Determination of Implicated Products

Confirm patient identification and check the applicable databases for blood, blood products, donor milk and tissue products to which the patient may have been exposed.

- Identify any products in the patient's BBK History file.
- Identify any products in the patient's TRACS4Life files.
- Identify any products in the patient's tissue access database files.

Document any products on the TRAN 8003 Fa Look Back Form.

Review and Determination of Need for External Notification

The timeline of product exposure and disease or diagnosis is reviewed in correlation with available clinical results and history.

If the products are not able to be reasonably excluded as the source of infection, the source facility must be notified and will proceed with their investigation.

Refer to the specific supplier for their process and documentation requirements for Look Back notification.

Look Back Conclusion and Documentation

When the source facility has concluded their investigation they will communicate their findings to the Transfusion Service.

All documentation related to the Look Back will be retained by the Transfusion Service for no less than ten years.

If transfusion-transmitted infection is confirmed by the supplier and also confirmed to be the cause of a patient fatality, a report to the FDA must be submitted. Refer to TRAN 8006 R Adverse Event Reporting.