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Roles and Responsibilities of Medical Director for Transfusion Reaction Evaluations

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document is to provide guidance to the Blood Bank staff on the responsibilities of the Blood Bank Medical Director.

II. DEFINITIONS

A. **Designee**: any blood bank technical director, or transfusion medicine fellow.

III. GENERAL INFORMATION:

A. **The Blood Bank Medical Director or designee shall:**

1. Immediately notify the patient's physician of a suspected case of a hemolytic transfusion reaction, bacterial contamination, or other serious reaction.
2. Perform a prompt and complete adverse reaction investigation report that includes an interpretation and evaluation. The complete report will be entered in the patient's electronic medical chart in the Hospital Information System (HIS).
3. Safeguard that criteria exist for the recognition of adverse reactions to blood components, and will verify that documentation exists of periodic in-service education on the recognition of adverse reactions.
4. Safeguard that documented procedures are in place that require adverse reactions to be reported to the Blood Bank immediately, and that these procedures describe appropriate actions to be taken in the event of an adverse reaction. See Blood Component/Product Administration: Adult and Pediatric Patients.

5. Be involved in the investigation and resolution of all adverse reactions or transfusion-related incidents involving a system failure (e.g., misadministration of a blood component).
6. Establish documented procedures that indicate when additional testing is required based on the initial findings of the transfusion reaction evaluation.
7. Interpret and report the findings of the transfusion reaction evaluation in a timely and effective manner. A partial notification will generally occur on the next business day and will be entered in the patient's electronic medical chart in the HIS. However, direct notification to the patient's physician may occur sooner if a serious transfusion reaction has occurred. The final report will be entered once the blood component's culture results, if applicable, are available.
8. Notify the blood supplier if a blood component is suspected as the primary cause of an adverse reaction (e.g., transfusion- related acute lung injury (TRALI) or transfusion-related infection), and document this notification in the transfusion reaction report.
9. Certify protocols exist which manage quarantines, recalls, and market withdrawals issued by blood suppliers, and which identify and quarantine blood components when notice is received that a donor tests positive for an infectious disease.
10. Establish protocols to evaluate adverse effects of transfusion, including follow-up for transfusion-transmitted diseases and delayed transfusion reactions.
11. Establish a detailed procedure, consistent with Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) guidelines and regulations, to notify and counsel recipients of potentially infectious blood components.
12. Notify the patient's physician if growth is detected in any component sent to the Microbiology Laboratory refer to Transfusion Medicine policy Suspected Bacterial Contamination of a Transfused Component. This notification will be documented in the transfusion reaction report.
13. Notify the FDA in writing within seven (7) days of a fatal reaction. Notification shall be made by telephone, facsimile, or express or electronic mail "as soon as possible" after the event, followed up with a written report within seven (7) days.
14. Develop a plan to reduce the risk of transfusion- related acute lung injury (TRALI). The Blood Bank Medical Director or designee will
    a. Track the frequency of TRALI and report cases and implicated donors to the blood supplier.

Approval Signatures

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