HEADS UP…

TOPIC: Monitoring and Evaluation During Blood Transfusion
SETTING: Laboratory Accreditation Program (LAB)

Why is this important?

In order to mitigate the chance of an adverse reaction during a blood transfusion, it is critical that the organization conducts effective patient monitoring and evaluation. It is the responsibility of the transfusion staff to adhere to policies and procedures related to identification, documentation and provision of testing related to blood components and characteristics. These protocols should also dictate clear directions on how to report, investigate, and address any suspected transfusion reactions. Compliance to these protocols ensures that the transfusion process has undergone the appropriate scrutiny and quality control to protect the safety and health of the patients served. (relevant standard/EP: QSA.05.18.01 EP7: The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events. The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration.

Scope of the Problem:

Time period: **July 1, 2019 –September 30, 2020**
Number of full surveys performed: **563**
Number of surveys with moderate to high-risk findings related to correlation testing **(QSA.05.18.01 EP 7): 49 (9%)**

Observations identified within a specific topic area may reveal systemic areas for improvement across the organization. These improvement opportunities might be reflected in other chapters, standards or EPs. *See also CLIA §493.1103(d) §493.1103(b)*

Sample survey observations [from surveyor notes] and contributing factors

- Staff did not follow the policy and procedures for suspected transfusion-related adverse events when the patient temperature rose by more than two degrees. Transfusion had not been stopped and required notifications not made as required.
- The organization did not notify the laboratory or the provider when the patient had shortness of breath, decreased breath sounds and elevated blood pressure during administration of a unit of packed red blood cells. All of these symptoms are indicated in the blood transfusion policy and procedure as signs and symptoms of a suspected transfusion reaction. This was confirmed by the quality coordinator and the administrative director of the laboratory.
- The organization did not follow its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration. The transfusion was stopped due to a change in the patient's condition; however, the laboratory did not receive the patient's blood samples to perform the transfusion reaction work up as required by policy.

Potential contributing factors:

- Written policies and procedures related to blood transfusion is unclear.
- Lack of oversight by leadership and/or of the laboratory manager to conduct and document annual staff competencies.
- Job duties and responsibilities involving blood transfusion are not clearly defined.

How to identify potential problems in your organization

Review policies, procedures and protocols

☐ Does the laboratory have clearly written policies and procedures related to blood transfusion?
- What are the protocols in the event of a transfusion reaction?
- What is the process for obtaining blood in an emergency?

☐ Does nursing staff, transfusion staff, and laboratory technicians have the appropriate education, training, and competencies?
- How often are competencies reassessed?

Interview staff

☐ Can the staff explain how an order for blood products in the laboratory is procured and processed?

☐ What process is followed to prepare and test the blood product before providing it to the patient?
- How are tests documented?

☐ What are the necessary steps and/or actions when there is a suspected transfusion reaction?

☐ How does the laboratory perform quality control in the blood bank and document lot numbers?
- Does this occur daily?

Assess your environment

☐ How are the blood products managed and stored?
- How often are temperature logs being updated?
- What is the labeling method and process for specimens and/or blood bags?

☐ What sort of backups are used on the main refrigerator and freezer, in case of power outages or other emergencies?

☐ Does staff have access to the written policies and procedures to effectively monitor and evaluate blood transfusions?

Evaluate implementation

☐ Directly monitor staff performing a blood transfusion process and review quality control records and test results.

☐ Review documentation of a transfusion reaction to verify that it is completed per organization policy.

☐ Review employee files and records to ensure that competence assessments related transfusion and other relevant laboratory services are performed annually.

☐ Assess staff knowledge and comprehension of testing and evaluation protocols.

☐ Review policies and procedures annually to ensure they are updated.

What are some resources that can assist in mitigating risks in these areas?

- Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart J: "Facility Administration for Non-waived Testing" §493.1103(d) §493.1103(b). Complete description of the requirement is located at https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m.