Standards Updates for Busy Blood Bankers

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We’re all very busy these days implementing new standards!

Objectives

1. Review the standards that apply to prevent mistransfusion.
2. Understand the rationale for these standards.
3. Discuss different options for implementing AABB Standard 5.14.5
4. Discuss developing an implementation plan.

Standards to Mitigate Misidentification Risk - AABB

- AABB 32nd Edition of Standards for Blood Banks and Transfusion Services
  - 5.14.5 Pretransfusion Testing for Allogeneic Transfusion of Whole Blood, Red Cell and Granulocyte Components
  - There shall be two determinations of the recipient's ABO group…The first determination shall be performed on a current sample, the second determination by one of the following methods:
    - Comparison with previous records.
    - Testing a second sample collected at a time different from the first sample, including a new verification of patient identification.
    - Retesting the same sample if patient identification was verified using a validated electronic identification system.

Standards to Mitigate Misidentification Risk - CAP

- CAP Standard TRM.30575 – REVISED 06/04/2020
- Misidentification Risk Phase II
  - The facility has a system to reduce the risk of mistransfusion for non-emergent red cell transfusions.

Standards to Mitigate Misidentification Risk - CAP

- Risk reduction options that might be considered include:
  - Verifying the ABO group of the intended recipient on a second sample collected at a separate phlebotomy (including the recording of the result in the institution's historical record)
  - Utilizing a mechanical barrier system
  - Utilizing an electronic identification verification system that ensures that the patient from whom the pretransfusion specimen was collected is the same patient who is about to be transfused
  - Other approaches capable of reducing the risk of mistransfusion.

Standards to Mitigate Misidentification Risk -FDA

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER F - BIOLOGICS

Part 606 Current Good Manufacturing Practice for Blood and Blood Components

Sec. 606.151 Compatibility testing.

Standard operating procedures for compatibility testing shall include the following:
(a) A method of collecting and identifying the blood samples of recipients to ensure positive identification.

Verifying Patient Identification

Misidentification Leads to Mistransfusion

Mistransfusion occurs from misidentification of the intended recipient:

- At the time of specimen collection for pretransfusion testing
- During laboratory testing and preparation of units to be issued
- At the time of transfusion.

Misidentification Leads to Mistransfusion

- Misidentification at sample collection occurs approximately once in every 1,000 samples
- One in every 12,000 transfusion recipients receives a unit not intended for him/her
- Improper identification of intended recipient during initial sample collection for blood typing – known as “wrong blood in tube” or WBIT

Make and Informed Decision

Deciding the Best Option for Your Institution

- Second sample at a separate phlebotomy
  - Allows for two separate patient identification processes to occur.
  - Need to define the rules for when the two phlebotomy procedures should occur.
  - A second sample would require a separate stick for the patient. Consider how to explain to the patient/family.
  - Consider work impact to phlebotomists and testing laboratory.

Deciding the Best Option for Your Institution

- Retesting the same sample using a validated electronic identification system to identify the patient
  - Requires that scans be performed and not bypassed.
  - Only one stick for the patient.
  - Need electronic equipment at the bedside for blood collection.
  - Need a clearly defined back-up system for downtime.

Make a Plan

Develop an Implementation Plan

- Think about members to include on the implementation team:
  - Look at statistics to see where most first time (no historical blood type) come from samples. Be certain to include representatives from these areas as they will be greatly impacted.
  - The IT department will need to be included to assist with the hospital and blood bank information systems. This will be impacted and changes will need to be designed and implemented.
  - Nursing and phlebotomy services should be represented.
  - Hospital Educator (for staff and patients)
  - Quality and Compliance
  - Laboratory leadership
  - Blood Bank Medical Director and Managers or Supervisors
  - Human Resources

Designing Workflows

- **Second sample**
- Consider the impact to workflows for different areas
- Would you set up a reflex test or a prompt to the physician when ordering blood?
  - Inpatients
  - Emergency Room Patients
  - Perioperative
  - Laboratory – Need to balance so there isn't an onslaught of samples.

Many patients may not need blood and therefore won't require a second sample collection. This should be considered when designing workflows so that the laboratory isn't overburdened with samples.

Designing Workflows

- **Electronic Identification Verification**
- Consider how workflow is impacted for these areas
  - Inpatients
  - Emergency Room Patients
  - Perioperative

  - Is the necessary equipment available in each room?
  - Will equipment such as scanners be carried by the phlebotomist?
  - Laboratory – Will there be a way to determine if electronic identification verification was used to collect the sample?

Planning a Timeline

- When planning a timeline consider the following:
  - Technical Build – Hospital and Laboratory Information Systems
  - Writing and approving procedures and policies
  - Testing and Validation
    - Roll out testing in one area
    - Use data gathered to fine tune the process
    - Test in smaller impact areas first
  - Education and Training
    - Collection Staff
    - Laboratory Staff
    - Script to explain to patients (for second sample)

Choosing a Go-Live Date

- Usually done during a hospital slow time
  - Weekend – Overnight
  - LIS support
  - On-call administrator
  - Blood bank staff support
    - Think of how to handle patients who fall before the “cut-off” time.
    - An example would be someone with units crossmatched on a current sample
    - Be ready for questions.

Measure Effectiveness

Evaluating and Measuring Effectiveness

- Continue counting WBITS
  - Monitor Error/Safety Reports
  - Compare numbers to those prior to implementation
  - Look for trends
    - Same staff
    - Same patient care area
    - Same shift
  - Ask for feedback from users
    - Can improve processes and workflows with suggestions
  - Looking for a decrease in WBITS
    - May need to re-educate

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Questions???