

XV. Quality Assurance in the Blood Bank

A. Overview

1. Goals

- a. Safe transfusion
- b. Careful adherence to SOPs by trained personnel
- c. Develop comprehensive guidelines to be in compliance with JCAHO, FDA, AABB and CAP

2. Terms

- a. **Quality control** is the management of the testing process itself.
 - 1) Monitoring of equipment and instruments
 - 2) Determining that reagents are reacting appropriately.
- b. **Quality Assurance** includes the entire process of providing patient care, from the time the physician orders the test until treatment of patient based on results of test.
 - 1) Were appropriate lab tests ordered to determine the need for transfusion.
 - 2) Did the transfusion service perform appropriate testing of patient specimen and preparation of the appropriate component
 - 3) Was the transfusion administered properly.
 - 4) Did the patient obtain the anticipated benefit.
- c. **Utilization review** is the process of monitoring the appropriateness of transfusion.
- d. **Continuous quality improvement** involves reviewing the process of providing patient care with the goal of reducing rework, waste and inappropriate care.

B. Record Keeping

1. Documentation is critical and must include:

- a. Quality monitoring standards based on regulatory and accrediting agencies
- b. Written plan and documentation of testing and review must be available to inspectors.
- c. Design forms for recording QC and quality assessment activities to provide an audit trail.
- d. Values obtained.
- e. Conclusions.
- f. Corrective actions taken.

C. Procedure Manuals

1. SOPs are required for all laboratory and administrative procedures.
2. Procedures for blood bank slightly different than those for chemical based assays.
3. NCCLS has recommended elements of a procedure manual.
4. Administrative policies and technical procedures should be maintained separately.

B. Quality Assessment of Supplies and Reagents

1. Reagents may be made on site or purchased from a manufacturer.
2. Because of additional quality assessment requirements, most blood banks purchase reagents.
3. ***The following reagents must be tested each day of use:***
 - a. antihuman globulin serum
 - b. blood grouping anti-serums
 - c. lectins
 - d. antibody screening cells
 - e. reverse grouping cells
 - f. enzymes
4. For donor collection facilities the ***following must be tested with each run:***
 - a. hepatitis testing reagents
 - b. HIV testing reagents
 - c. HTLV-I/II reagents
 - d. ALT testing reagents
 - e. syphilis serology reagents.
5. When reagents and supplies are received ***each of the following must be documented during the log in process:***
 - a. date of receipt
 - b. manufacturer
 - c. lot number
 - d. expiration date
 - e. review of manufacturer's circular for changes
 - f. leaking or damaged containers
6. ***Before being placed in use reagents are tested for sensitivity and specificity.***
7. ***Daily testing is required*** to ensure the reagent has not lost potency or reactivity.
 - a. Can use a form and procedure created in-house or utilize QC kit provided by a manufacturer.
 - b. Lot numbers and expiration date of all reagents tested must be on the form.
 - c. Graded reactions recorded.
 - d. Special typing sera need only be QCd when used.
8. Final disposition of damaged or unsatisfactory reagents must be documented.

C. Equipment

1. Documentation must be made of routine maintenance, repairs and testing performed on instruments from date of receipt to date instrument is permanently removed from service.
2. **Temperature monitoring** is critical for refrigerators, freezers, incubators and waterbaths.
 - a. *Must be manually recorded daily.*
 - b. Refrigerators and freezers must have a device to record the temperature 24 hours a day.
 - c. When temperature is out of range must have documentation of reason or corrective action taken.
 - d. Alarms on refrigerators and freezers *must be tested periodically* to make sure they will sound at the appropriate temperature.

D. Components

1. Each step of the preparation of components must be documented.
2. Periodically a unit is sacrificed to test for potency, efficacy and purity.
 - a. At least four components are tested month.
 - b. Three of the four must meet minimum requirements.

E. Personnel

1. Personnel who perform tests and prepare components must have adequate education and training.
2. Must *define* tasks performed and levels of competence needed.
3. Must have a job description which should include the following:
 - a. Title
 - b. Brief description of general functions and responsibilities.
 - c. Description of specific duties.
 - d. Supervision
 - e. Qualifications
 - f. Special factors
 - g. See page 548 for MT job description
4. Once job is defined can then determine level of education and training required.
5. Potential employees are interviewed and it will be determined if they are qualified based on the job description.
6. Must have a *written training program and assessment* to determine competency of the employee.
 - a. Observation of the employee during job performance.
 - b. Checklist to document employees progress.
 - c. Procedures and policies change frequently so training is an ongoing process.

7. Competency can be assessed by *proficiency testing*.
 - a. Observing employee performing assigned tasks.
 - b. Reviewing documentation.
 - c. Assigning external proficiency testing samples on a rotating basis.
 - d. Paper and pencil testing.
 - e. Proficiency testing is used by accrediting and regulatory agencies to assess laboratory competency.

F. Quality Assessment and Utilization Review

1. Most facilities use the *10 step process* outlined by JCAHO.
 - a. Assign responsibility
 - b. Delineate the scope of care
 - c. Identify the most important aspect of care
 - d. Identify indicators
 - e. Establish thresholds
 - f. Collect and organize data
 - g. Evaluate data
 - h. Take corrective action
 - i. Assess actions and document improvement
 - j. Communicate.
2. Transfusion Committee
 - a. Medical staff responsible for assessing adequacy of transfusion services and proper use of blood components.
 - b. Reviews usage of all components for appropriateness.
 - c. Reviews records of all transfusion reactions.
 - d. Reviews order practices.
3. Quality Assessment Plan
 - a. coordination of quality assessment activities.
 - b. Select appropriate quality assessment indicators.
 - c. Indicators are a reliable measure of the quality of service provided.
 - d. Indicators selected to monitor high volume or high risk activities.

G. Utilization Review

1. Required by JCAHO
2. Used to assess the blood ordering and transfusion practices of the medical staff.
3. Crossmatch:transfusion ratio
 - a. Number of units crossmatched divided by the actual number transfused.
 - b. Used as an indicator that too much blood is being requested to be on hold.
 - c. Could result in high outdate or waste.
4. Number of autologous transfusion.

5. Number of emergency releases.
6. Calculate statistics by physician.
7. Review of records to determine if transfusion was justified.
8. Audit criteria for transfusion must be defined:
 - a. Hematocrit less than 24%
 - b. Hemoglobin of less than 8 gm/dL
 - c. Symptoms due to anemia
 - d. Recent estimated blood loss of greater than 10% of total blood volume.
 - e. If audit reveals unjustified transfusion physician is notified and asked to respond.

The End