

Quality Assurance

A. Perceptions of Quality

1. Quality – “the standard of something as measured against other things of a similar kind; the degree of excellence of something.”
2. Concepts of quality in healthcare
 - a. Efficacy – healthcare services have a positive impact on the patient’s health.
 - b. Appropriateness – the correct service or treatment was used for the condition, injury, or disease.
 - i. Technical aspect of care
 - ii. Collecting the right lab test correctly so that accurate results can be provided to the physician
 - c. Caring Functions – healthcare service was responsive, effective, and understanding of the patient’s needs.
 - i. Non-technical, interpersonal aspects of care
 - ii. Met the patient’s personal needs, making blood collection as pleasant as possible.
3. Phlebotomy is a major component of the Pre-Analytical Process of laboratory medicine.

B. Total Quality Management (TQM)

1. In the lab, the purpose of TQM is to minimize variations in laboratory testing.
2. TQM involves a systematic process for improving health care.
3. All employees are involved in TQM, focused on continual, gradual improvement in the quality of services provided, sometimes referred to as ***Continuous Quality Improvement (CQI)***.
4. TQM and CQI can be divided into 4 major components:
 - a. Structure – physical, personnel, and administrative structure
 - b. Process – what was done to the patient
 - c. Outcomes – what was accomplished for the patient; can be difficult to measure
 - i. Includes recovery rates, rate of healthcare associated infections
 - ii. Poor outcomes include discomfort, disease, disability, dissatisfaction, or death
 - d. Customer satisfaction – how pleased is the patient

- i. Survey of patients
 - ii. Determine which patients are happy and why
 - iii. Determine which patients are unhappy and why
- 5. **Continuous Quality Improvement** uses various types of data analysis tools, such as flow charts, bar graphs, pareto charts, cause and effect diagrams, and scatter grams. Brainstorming can be used to stimulate creative solutions as a group.
- 6. TQM involves both Quality Control (QC) and Quality Assurance (QA).

C. Quality Control (QC)

1. Quality control includes materials and methods that will lead to intended outcomes during every specimen collection procedure. QC is an important part of lab quality management.
2. Includes specific processes and procedures to ensure good quality patient care. Phlebotomy examples include:
 - a. Checking the expiration date (shelf life) of tubes and needles prior to use.
 - i. Tube expiration date is based on:
 1. Stability of additive – additives lose effectiveness over time
 2. Stability of vacuum – vacuum in tube will decrease over time.
 3. Tube draw volume must be within +/- 10 % of stated volume and should be verified with every new lot number of tubes.
 - ii. Needle expiration date based on life expectancy of rubber sheath.
 - b. Following stated procedures for proper patient identification.
 - c. Checking for needle defects during each venipuncture procedure.
 - d. Proper tube inversions for mixing of blood specimens with additives.
 - e. Daily checks of temperature blocks for specimens that must be kept warm.
 - f. Periodic check of centrifuge timers and speed.
3. All steps of each procedure are outlined in a procedure manual. The procedure manual is available to all healthcare workers who perform blood collections. Examples of the preanalytical procedures include:
 - a. Proper patient preparation – fasting, timed draws.
 - b. Proper patient identification procedures.
 - c. Steps of routine and special phlebotomy collection procedures.
 - d. Prioritizing patient draws or test requests (STAT, ASAP, routine, timed).
 - e. Specimen processing and handling procedures.

D. Quality Assurance (QA)

1. Quality Assurance involves programs to track outcomes through scheduled audits, to continually improve patient care.
2. QA can be achieved by periodically assessing the skills and technique of each phlebotomist (competencies).
3. Quality Assurance indicators must be specific and measurable (Examples: blood culture contamination rate should be 3% or less).

E. Professional Competencies and Performance Assessment

1. Competency statements, developed by various professional organizations, describe entry-level skills and tasks of various lab professions, including phlebotomy.
2. Goals of competency and performance assessment may include the following:
 - a. Evaluation of individual performance
 - b. Evaluate group or department performance
 - c. Compare laboratory performance to standards of regulatory agencies (The Joint Commission, CAP, CMS, COLA, etc.)
 - d. Address problem issues within institution
3. Process of competency and performance assessment is ongoing and includes the following areas:
 - a. Responsibility-what needs to be done that relies on one person to complete
 - b. Authority-right to act and make decisions
 - c. Accountability-measurable assessment of consequences

F. Oversight Agencies

1. Stakeholders are those who have an interest in or are influenced by health care services.
2. Internal stakeholders include individuals and groups within the healthcare organization, such as doctors, nurses, lab professionals, and administrators.
3. External stakeholders include individuals and groups outside a healthcare organization, such as the patients and their families, the community, insurance companies, and regulatory agencies.

4. ***Occupational Safety and Health Administration (OSHA)***

- a. Part of the US Department of Labor, is responsible for regulating the safety and health of workers in all industries.
- b. ***Bloodborne Pathogen Standard*** – federal law mandated by OSHA to minimize the risk of occupational exposure to bloodborne pathogens; it includes Universal Precautions.
- c. ***2001 Needlestick Safety and Prevention Act*** –
 - i. Mandates the use of needle safety features that creates a barrier between the phlebotomist hand and the needle, and that permanently contains the contaminated needle once the safety feature is activated.
 - ii. It also requires a written exposure plan and employee input on selecting engineering safety controls.
- d. ***Hazardous Communication Standard – HazMat or Right to Know Law*** – requires documentation, such as SDS (Safety Data Sheets), available to all employees and the labeling of hazardous substances.

5. ***Center for Disease Control (CDC)***

- a. Part of the US Department of Health and Human Services (HHS), it is responsible for researching and controlling diseases.
- b. ***Standard Precautions*** – recommended to prevent the spread of infection due to exposure to blood, all body fluids (except sweat), non-intact skin and mucous membranes.
- c. ***Transmission Based Precautions*** and ***Isolation Procedures*** – developed by CDC and recommended for hospitals and health care agencies.
- d. ***National Institute for Occupational Safety and Health (NIOSH)***– a research agency that is part of CDC. It approves N95 masks required for healthcare workers dealing with patients with airborne precautions (TB, chicken pox, etc.)

6. ***Center for Medicare and Medicaid Services – CMS***

- a. Part of the US Department of Health and Human Services
- b. Federal agency charged with regulating and overseeing laboratory testing performed on humans through the ***Clinical Laboratory Improvement Amendments of 1988 (CLIA 88)***
- c. Documentation of Continuing Education is a requirement of CLIA 88

d. CMS inspects hospitals, laboratories, skilled nursing facilities and other healthcare providers that receive Medicare or Medicaid payments.

7. *The Joint Commission – TJC*

- a. A voluntary, non-governmental agency charged with establishing standards for the operation of hospitals and other health related facilities and services.
- b. It conducts inspections of hospitals, medical centers, and their laboratories.
- c. Implemented changes in 2009 to focus on patient safety and the continuous quality improvement of patient care
- d. The 2014 National Safety Goals and Recommendations included the use of at least two (2) patient identifiers for accurate patient identification

8. *College of American Pathologist – CAP*

- a. A Voluntary professional organization which provides standards for quality improvement specific to clinical labs
- b. It conducts proficiency testing and laboratory inspections.

9. *Clinical Laboratory Standards Institute – CLSI*

- a. A consensus organization established to define global standards of practice for the clinical laboratory.
- b. Created standards of care which may be used in legal proceedings.

10. *Commission on Office Laboratory Accreditation (COLA)*

- a. Accredits laboratories in doctor's offices and medical clinics.
- b. Conducts proficiency testing, on site surveys and provides consultation and educational programs.

G. *Quality Standards* – what can the phlebotomist and laboratories do to promote quality.

- 1. Training programs to teach basic skills
- 2. Certification and Professional Associations
 - a. American Society for Clinical Pathology
 - b. National Phlebotomy Association
 - c. Association of Phlebotomy Technicians
 - d. American Medical Technologist

3. Code of ethics for the profession
4. Identification of competencies for the profession

H. Quality Improvement

1. For ***consistent quality specimens***, various areas must be monitored and evaluated, both for individual phlebotomist and blood collection groups, includes the following:

- a. Technique
 - i. Vein selection
 - ii. Equipment selection
 - iii. Order of draw
- b. Patient identification procedures
- c. Patient preparation issues
 - i. Fasting
 - ii. Therapeutic Drug Monitoring issues
- f. Complications
 - i. Fainting
 - ii. Hematomas
- e. Recollection rates – what is the reason, who is collecting the sample
 - i. Wrong tube collected
 - ii. Insufficient quantity of blood (QNS)
 - iii. Hemolysis
 - iv. Improper handling or storage
 - v. Labeling issues
- f. Multiple venipunctures on same patient – policy on maximum number of attempts
- g. Multiple blood collection orders (requisition) on the same patient
- h. Duplicate test orders on the same patient
- i. Waiting time, Turnaround time (TAT)
- j. Specimen handling and storage issues
- k. Standard Precautions and Infection Control

I. Blood culture contamination rate

2. When poorly performed, these issues may result in a negative outcome for the patient.
3. Monitoring and correcting problems in these areas is beneficial to the patient, the laboratory, and the phlebotomist.
4. Must target specific issues, track them, analyze the data, form policies and procedures to reduce collection errors, implement changes and reevaluate results.

I. Blood loss due to phlebotomy

1. Must be closely monitored for some patients, especially infants and small children.
2. Phlebotomist must realize blood conservation is a priority to prevent anemia and other complications.
3. Analytical variables can directly impact blood volume requirements:
 - a. Laboratory instrumentation requires minimum volume for testing
 - b. Laboratory instrumentation may require tubes of a specific size to function
 - c. Aliquoting samples for different departments or samples for reference lab
 - d. Repeat testing if machine fails QC
 - e. Add-on testing (AOT) by physician
 - f. Volume requirements by tube manufacture
4. Strategies to reduce blood loss focus on organizing and coordinating blood draws.
 - a. Morning run or other collection intervals to decrease blood draws
 - b. Other times during the day for blood draws to eliminate STAT requests.
 - c. Carefully investigate duplicate requests
 - d. Maintain daily tally of blood loss from each patient especially infants
 - e. Review standing orders, tests no longer needed due to patient improvement
 - f. Reduce turn-around times by reviewing all processes