

Chapter 2: Quality Assurance and Legal Issues

Objectives

1. Define the key terms and abbreviations listed at the beginning of this chapter.
2. Identify national organizations, agencies, and regulations that support quality assurance in healthcare.
3. Define quality and performance improvement measurements as they relate to phlebotomy.
4. List and describe the components of a quality assurance (QA) program and identify areas in phlebotomy subject to quality control (QC).

Objectives (cont' d)

5. List areas in phlebotomy subject to QC and identify QC procedures associated with each.
6. Demonstrate knowledge of the legal aspects associated with phlebotomy procedures by defining legal terminology and describing situations that may have legal ramifications.

National Standard and Regulatory Agencies

- The Joint Commission
 - Voluntary, nongovernmental agency
 - Oldest & largest healthcare standards-setting body in nation
 - Establishes standards for operation of hospitals & other health-related facilities and services
 - Seeks to improve healthcare for public through evaluation
 - Focuses on improving safety for patients & residents

National Standard and Regulatory Agencies (cont'd)

- The Joint Commission
 - New Accreditation Measurements implemented in 2009
 - Using the following program-specific screening criteria
 - Direct Impact Standards Requirement
 - Indirect Impact Standards Requirement
 - Situational Decision Rules
 - Immediate Threat to Health and Safety

National Standard and Regulatory Agencies (cont' d)

- The Joint Commission
 - Sentinel event policy
 - Helps organizations identify safety issues & prevent them
 - If sentinel event occurs, organization is required to:
 1. Perform a thorough & credible analysis of root cause
 2. Put improvements to reduce risk into practice
 3. Monitor improvements to determine if they are effective

National Standard and Regulatory Agencies (cont' d)

- The Joint Commission
 - **National Patient Safety Goals (NPSGs)**
 - Part of the overall CQI requirements
 - Overseen by a safety panel, physicians, nurses, risk managers, and other healthcare professionals
 - Patient Safety Goals for 2010
 - Identify patients correctly
 - Improve staff communication
 - Prevent infection

National Standard and Regulatory Agencies (cont' d)

- College of American Pathologists (CAP)
 - All members are board-certified pathologists
 - Offers proficiency testing & continuous lab inspection
 - Designed for pathology/lab services only
 - Meets Medicare/Medicaid standards

National Standard and Regulatory Agencies (cont' d)

- Clinical Laboratory Improvement Amendments of 1988
- (CLIA '88)
 - Federal regulations passed by Congress
 - Establish quality standards that apply to all laboratories
 - Standards address:
 - Quality assurance
 - Quality control
 - Proficiency testing
 - Laboratory records
 - Personnel qualifications

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National Standard and Regulatory Agencies (cont' d)

- Clinical and Laboratory Standards Institute (CLSI)
 - A global, nonprofit, standards-developing organization
 - Has representatives from the profession, industry, & government
 - **Mission:** to develop & promote best practices in clinical & laboratory testing
 - Develops voluntary guidelines & standards for all areas of the laboratory

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National Standard and Regulatory Agencies (cont' d)

- National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)
 - An authority on educational quality
 - An autonomous nonprofit organization
 - Provides accreditation & approval of clinical laboratory sciences educational programs
 - Accreditation process involves external peer review of the program
 - Phlebotomy program review designed to improve student outcomes and maintain quality education

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Quality Assurance in Phlebotomy

- Definition of Quality Assurance (QA)
 - A program that guarantees quality patient care by tracking outcomes through scheduled reviews of the following elements of patient care:
 - Appropriateness
 - Applicability
 - Timeliness

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Quality Assurance in Phlebotomy (cont' d)

- QA Indicators
 - Guides to monitor all aspects of patient care
 - Must be:
 - Measurable
 - Well-defined
 - Objective
 - Specific
 - Clearly related to an important aspect of care

Quality Assurance in Phlebotomy (cont' d)

- Quality System Essentials (QSEs)
 - 12 fundamental components identified by CLSI
 - Used to develop a quality management process
 - Are universal: can be applied to simple or complex operations
 - Require processes, policies, & procedures be written & monitored
 - Three processes of “path of workflow”:
 1. Preanalytical
 2. Analytical
 3. Postanalytical

Quality Assurance in Phlebotomy (cont' d)

- Threshold Value
 - A level of acceptable practice beyond which quality patient care cannot be assured
 - Must be established for all quality indicators
 - Exceeding threshold should trigger evaluation
 - Corrective action plan may be established

Quality Assurance in Phlebotomy (cont' d)

- Process and Outcomes
 - Both process & outcomes must be reviewed to improve outcome
 - Process must be followed from start to finish
 - Measurement & evaluation must be standardized
- Quality Control (QC)
 - Component of a QA program & a form of procedure control
 - Uses operational checks to ensure procedures are performed correctly
 - Quality results when standards are met all of the time

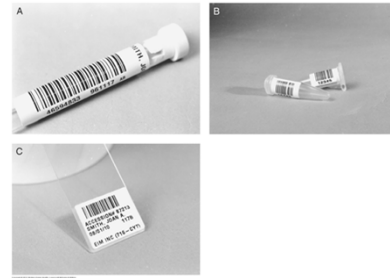
Areas of Phlebotomy Subject to QA

- Patient Preparation Procedures
- Specimen Collection Procedures
 - Patient identification (use of bar codes) **Video: Proper identification**
 - Equipment
 - Puncture devices
 - Evacuated tubes
 - Labeling
 - Technique
 - Collection priorities

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Areas of Phlebotomy Subject to QA (cont' d)

- Tube, containers, & slide with bar codes for patient ID



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Documentation

- The Patient's Record
 - A chronologic documentation of medical care given
 - Required by law for hospital patients
 - Every notation should be legible, precise, & complete
 - **Purposes**
 - To aid practice of medicine
 - To aid communications between healthcare providers
 - To serve as a legal document (may be used in court)
 - To help hospital evaluate performance outcomes

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Documentation (cont' d)

- QA Documents for Blood Collectors
 - Nursing Services Manual/Specimen Collection Manual
 - Detail how to prepare patient & special collection instructions
 - Contain in chart form:
 - Type & minimum amount of specimen needed
 - Special handling required
 - Reference values for test
 - Days testing is available
 - Normal turnaround time

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Documentation (cont' d)

- **Laboratory Procedure Manual**
 - States policies & procedures for each test/practice
 - Must be available to all laboratory employees
 - Must be updated at least annually
- **Safety Manual**
 - Contains procedures related to:
 - Chemical, electrical, fire, & radiation safety
 - Exposure control
 - Disaster plans
 - Handling hazardous materials

Documentation (cont' d)

Infection Control Procedure Manual

- **Most effective way to break the chain of infection: HANDWASHING!!!**
 - Hand washing & other decontamination procedures
 - Precautions when dealing with patients or handling specimens
 - Procedures to implement after exposure incidents
- QA Forms
 - Equipment check forms
 - Internal (incident) reports
 - Identify **problem**, state **consequence**, describe **correction**
 - Should state *facts*, not *feelings*

Risk Management

- Definition
 - Identifying & minimizing risks to patients & employees
 - Two ways of managing risk:
 - Controlling risk to avoid incidents
 - Paying for occurrences after they happen
- Steps
 1. **Identification** of risk
 2. **Treatment** of risk
 3. **Education** of employees & patients
 4. **Evaluation** of what should be done in future

Legal Issues

- Tort: Definition
 - A wrongful act against person, property, reputation
 - Committed without just cause, intentional or not
- Tort: Types
 - Assault
 - Battery
 - Fraud
 - Invasion of privacy
 - Breach of confidentiality
 - Malpractice
 - Negligence
 - *Res ipsa loquitur*
 - *Respondeat superior*
 - Standard of care
 - Statute of limitations
 - Vicarious liability

Legal Issues (cont' d)

- Malpractice Insurance
 - Compensates insured in event of malpractice liability
 - Individual workers are not typically targets of lawsuits
 - Workers may be named as codefendants, though
 - Depending on risk, worker may need professional liability policy

Legal Issues (cont' d)

- Avoiding Lawsuits
 1. Acquire informed consent before collecting specimens
 2. Respect a patient's right to confidentiality
 3. Strictly adhere to accepted procedures & practices
 4. Use proper safety containers & devices
 5. Listen & respond appropriately to patient's request

Legal Issues (cont' d)

- Avoiding Lawsuits
 6. Accurately & legibly record all patient info
 7. Document incidents or occurrences
 8. Participate in continuing education to maintain proficiency
 9. Perform at prevailing standard of care
 10. Never perform procedures you are not trained to do

Legal Issues (cont' d)

- **Informed Consent**
 - Implies voluntary & competent permission
 - Requires adequate information given to patient
 - Nontechnical terms
 - Obtained before procedure

Legal Issues (cont' d)

- **Expressed Consent**
 - Should be specific & cover all procedures to be performed
 - **Verbal:** should be followed by entry in patient's chart
 - **Written**
 - Gives best possible protection
 - Must be signed by provider & patient
 - Must be witnessed by 3rd party

Legal Issues (cont' d)

- **Implied Consent**
 - Patient's actions imply consent
 - May be necessary in emergencies
 - Laws vary from state to state
- **HIV Consent**
 - Most states have legislation for consent for HIV tests
 - Client must be advised on:
 - Test & its purpose
 - How test will be used
 - Meaning of test & its limitations

Legal Issues (cont' d)

- **Consent for Minors**
 - Minor cannot give consent for medical treatment
 - Parental or guardian consent is required
 - Personnel who violate this rule are liable for assault & battery
- **Refusal of Consent**
 - Patient has constitutional right to refuse medical procedure
 - Refusal may be based on religious or personal beliefs
 - Refusal usually must be verified in writing

Legal Issues (cont' d)

- **Litigation Process**
 - **Phase 1:** Patient incident occurs or injury is recognized
 - **Phase 2**
 - Injured party consults attorney
 - Attorney requests medical records, takes case
 - Negotiations for settlement
 - If no settlement, complaint is filed
 - **Discovery:** taking depositions & interrogating witnesses
 - **Phase 3:** Trial
 - **Phase 4:** Appeal

Legal Issues (cont)

- **Tort:** Wrongful act other than breach of contract committed against someone's person, property, reputation or other legally protected right.
- **Assault:** Act or threat causing another to be in fear of immediate battery (harmful touching)
- **Battery:** Intentional harmful or offensive touching of, or use of force on, another person without consent or legal justification.
- **Invasion of Privacy:** The violation of one's right to be left alone
- **Breach of confidentiality:** Failure to keep privileged medical information private
- **Negligence:** The failure to exercise due care, the level of care that a person of ordinary intelligence and good sense would exercise under given circumstances. What a reasonable person would or would not do.

Test Info Chapter 2: Quality Assurance & Legal Issues

- What department coordinates with lab for TDM?
- Know: HIPAA, OSHA, CLIA '88, CLSI, CAP, NAACLS, Joint Commission, NPSGs
- Legal Issues: assault, battery, invasion of privacy, breach of confidentiality, tort, fraud etc.
- Difference between implied and informed consent
- Good Samaritan Law
- Quality assurance, quality indicators, delta check, importance of documentation, outcomes, threshold values, risk management
- Manuals: safety, collection, procedure
- There will also be situation questions
- Know your study questions