

15. Legal and Regulatory Issues

A. General Ethical Legal Principles

1. Laws governing medicine and medical ethics complement and overlap each other.
 - a. In the past, decisions were made by doctors and other health professionals.
 - b. Consumers and patients have become more aware, more critical and much more willing to sue anyone the lawyer feels is at fault, including the phlebotomist.
2. Must act in a professional and respectful manner at all times.
 - a. Follow professional code of ethics
 - b. Evaluate difficult situations and apply the code of ethics.
 - c. Take responsibility for actions
2. Statutory laws are written laws enacted by state legislatures and the US congress, up to courts to interpret application of law..
3. Administrative law is the implementation of statutes and ordinances by the executive branch of government through its departments and agencies.
4. Judicial law resolves disputes in accordance with laws.
 - a. State and federal trial courts
 - b. Appeals courts (intermediate courts)
 - c. Supreme court

B. General Legal Terminology - *fill in the following portion of the lecture guide (1-20) on your own.* You will be responsible for these terms on the upcoming exam.

1. Assault
2. Battery
3. Bioethics
4. Breach of duty

5. Civil Law
6. Criminal actions
7. Defendant
8. Ethics
9. False imprisonment
10. Felony
11. Informed consent
12. Invasion of privacy
13. Liable

14. Litigation process

15. Malpractice

16. Misdemeanor

17. Negligence

18. Plaintiff

19. Respondeat superior

20. Tort

C. Negligence

1. There has been a significant increase over the years in the number of legal cases in which the lab is directly or indirectly involved.
2. Negligence is “violation of duty to exercise reasonable skill and care performing a task”.
3. Involves four key points.
 - a. Duty-responsibilities of HCW to patient
 - b. Breach of duty-was duty unavoidably breached
 - c. Proximate causation-did breach of duty contribute to or cause injury.
 - d. Damages-patient must show they were actually damaged by negligent act.

D. Patient confidentiality

1. Violation of the right of privacy, another example of negligence.

2. Confidentiality
 - a. No one but the patient may release patient results without a clinical need to know.
 - b. Patient/employee lab results are strictly confidential.

3. Negligence can be sought if employees or patient's drug abuse results are released to anyone but the patient's doctor or authorized individuals.
 - a. Employee or athlete drug or alcohol abuse screening or HIV testing are examples.
 - b. Confidential materials includes:
 - 1) communications between doctor and patient,
 - 2) patient's verbal statements,
 - 3) and non-verbal communications such as lab result.

4. HIV status of patient
 - a. Some states do not allow HCWs to know the HIV status of a patient
 - b. In case of accidental needle stick patient must give consent for testing.

E. Malpractice

1. Defined as improper or unskillful care of a patient by an HCW, or any unreasonable lack of skill or professional misconduct.

2. Relationship between doctor and patient is a contractual one involving the following elements:
 - a. Offer by the physician to provide a service.
 - b. Acceptance by the patient for treatment.
 - c. Consideration - patient accepts treatment and pays for care.

3. Contract implies obligations on both parts.

4. Physician must provide a standard of care.
 - a. Patient hurt during blood collection.
 - b. Patient must prove that HCW failed to follow standard of care.
 - c. Standard of care determined by what a reasonably prudent person would do under similar circumstances

F. Standard of Care

1. If patient is injured during blood collection must prove that standard of care was not followed
2. Based on standard practice in the field, what are the most a reasonably prudent person would do under similar circumstances.
3. For laboratories this is an expanding area as national standards are set.

G. Informed consent

1. Defined-"voluntary permission by a patient to allow touching, examination, and/or treatment by health care providers."
2. If patient requires treatment that is of potential risk, the doctor must explain risks and alternatives prior to asking patient to sign informed consent form.

- 3 Form is required for surgical experiments or other invasive procedures.
4. Largest area of litigation which is the primary reason the phlebotomist must explain blood collection procedures in simple terms.
4. Special consent for children, unconscious adults or emergency situations.
5. ***Implied Consent*** exists when immediate action is required to save a patient's life or prevent permanent impairment.

H. Statute of Limitations

1. Law that defines how soon after injury a plaintiff must file a lawsuit or be forever barred from doing so.
2. Purpose is to prevent threat of lawsuit for forever
3. Two year limit in most states for professional negligence
4. Complete and accurate documentation is critical

I. Legal claims and Defense in Malpractice Suit

1. First pleading filed is complaint-states cause of action
2. Proceeds to discovery-oral testimony from witnesses
3. Deposition-testimony of witness in writing
4. Court orders can be obtained to examine documents pertaining to case.
5. If you are involved in a deposition follow the following guidelines:
 - a. Answer only the questions asked.
 - b. Be organized in your recollections
 - c. Do not be antagonistic
 - d. Explain lab/blood collection process in simple terms
 - e. Do not overdramatize the facts
 - f. Dress neatly and groom appropriately
 - g. Be polite, sincere and courteous
 - h. Be sure to ask for clarification on questions you do not understand
 - I. In you are not sure of an answer indicate that in your response
6. Expert Witness
 - a. Gives information concerning practices patterns and levels of skill.
 - b. Patient's expert witness will testify that care was negligent and the standard of care was not provided.
- 7 Evidence is used to prove or disprove a lawsuit
8. How to avoid a lawsuit
 - a. Perform blood collection according to National standards
 - b. Obtain consent
 - c. Do not violate confidentiality
 - d. Maintain blood collection area with appropriate supplies, esp safety
 - e. Exhibit good listening skills
 - f. Report incidents immediately and document

9. Respondeat superior (“let the master answer”) the concept whereby actions of one individual may be imputed to another person having control.
 - a. Holds employers responsible for action of employees
 - b. Employer may be included in lawsuit
 - c. Injured party may sue BOTH the employee and employer

J. Medical Records are vital due to individuals forgetting details as time goes on.

1. Requirements
 - a. Must be neat, legible and accurate.
 - b. Errors must be corrected properly, never use white out.
 - c. Extremely important in malpractice cases.
2. Serve four purposes:
 - a. Allows for continuity of patient care.
 - b. Provides documentation of patients illness and treatment.
 - c. Documents communication between doctor and health care team.
 - d. Provides legal documentation that can be used by patient, hospital or health care worker to protect legal interests.
3. Medical records primarily used for non-medical purpose such as billing, utilization reviews, and QI.

K. Cases Resulting From Improper Technique and Negligence

1. Individuals performing phlebotomy must be thoroughly trained to avoid problems in blood collection arising from:
 - a. Wristband/ID error
 - b. Hematomas
 - c. Abscess at puncture site
 - d. Patient falls
 - e. Fainting
 - f. Nerve damage
 - g. Emotional distress
2. Failure to follow proven or recommended procedures may cause permanent injury to patient resulting in legal action.

L. HIV Related Issues

1. HCW may become infected with HIV during course of performing their duties.
2. Usually covered by workman’s compensation benefits
 - a. Worker must demonstrate causal connection between infection and job
 - b. Always document exposure if it occurs.
 - c. Lifestyle may be investigated
3. May be eligible for unemployment if no longer able to work.

4. POCT testing allows results of HIV testing to be available in 5 minutes.
 - a. Must prepare for ethical and legal implications
 - b. False negatives/positives may occur
 - c. Must inform patient that positive results will have confirmatory test performed.

M. Malpractice Insurance

1. Blanket policy used to cover health care staff in hospitals or clinic labs.
 - a. If employed by a pathologist, usually covered under his/her policy.
 - b. Pathologists have lowest premiums because of low risk level.
 - c. Labs rarely named in malpractice suits.
 - d. “Deep pocket”, will go after individuals with money.
2. Considerations when purchasing
 - a. Adequate coverage
 - b. Coverage limitations
 - c. Procedures to follow for coverage to be provided
 - d. Lawyers generally represent employer, may be wise to have your own legal counsel.

N. Management of Risk

1. Concepts of risk
 - a. Exposure to the chance of injury or loss.
 - b. HCW face many risks each day.
 - c. Should be active in understanding risk for benefit of patient, and protection of employers and employees.
 - d. Use carefully planned objectives that categorize “pre-loss”, reduce or prevent losses, and post-loss, how facility can recover from loss.
2. Goals and objectives of risk management program.
 - a. Risk identification and analysis.
 - b. Risk treatment - use of safety manuals, policies, procedures to prevent harm/loss.
 - c. Educate patients, employees and visitors.
 - d. Risk transfer/postponement - shift risk to other parties (liability insurance contract services or others).
 - e. Risk evaluation, assessment of what should be done.
3. Identification of risks.
 - a. Review incident, accident or occurrence reports that involve lab employees, including phlebotomists.
 - b. Is not limited to incidents resulting in injury.
 - c. Accident report is a misnomer, implies that error occurred.
 - d. Careful evaluation of incident reports can aid in changing policies, procedure to prevent additional incidents.

4. Risk treatment - two elements
 - a. Loss/risk control
 - 1) Department should attempt to reduce frequency of errors or events that can potentially cause financial loss.
 - 2) Example: reduce excessive venipuncture which will reduce number of hematomas.
 - b. Risk Finance - How to pay for losses which occur.
 - 1) Liability insurance or other.
 - 2) Example: Patient faints and injures self, provide free services for person to recover.
5. Risk transfer.
 - a. Done through the use of malpractice insurance, contracting for services.
 - b. Federal and state laws are changing to include contract personnel and services.
 - c. This suggests that health care facilities might be held liable for services performed by those with whom they have contracts.
6. Evaluation of the elements of risk management may show need for changes in procedures, employee counseling or education programs.

O. **Clinical Laboratory Improvement Amendment (CLIA)**

1. Passed in October 1988, went into affect September 1992.
2. Created to ensure quality and accuracy of laboratory testing.
3. Applies to every clinical laboratory testing facility in the US and requires certification of the lab.
4. Labs performing moderately and highly complex testing are required to undergo inspections.
5. Requires documentation of employees education, continuing education, and all procedures steps in lab testing.
6. It is important that you have basic knowledge of **CLIA 88** as it will have an impact on you in your employment and tests that you can and cannot perform.

The End

Revised May 25, 2004