Chapter 2
Legal Aspects and Risk Management

Learning Objectives
- Describe importance of the publication *To Err Is Human: Building a Safer Health System*
- Define 4 elements of negligence:
  - Duty to act
  - Breach of duty to act
  - Causation
  - Harm to the patient

Learning Objectives
- Describe principal goal of Good Samaritan laws
- List steps provider can take to minimize risk for medication mistakes
- Explain benefits of protocols in preventing mistakes in medication administration
Learning Objectives

- Describe Schedule I, II, III, IV, V, and VI medications and abuse potential for each
- Discuss importance of properly storing, securing, and maintaining medications
- List parts of A3E3P3 refusal guidelines

Learning Objectives

- Discuss effect of living wills and advance directives on prehospital providers
- List “dos and don’ts” of documenting medication administration
- Discuss importance of properly documenting and reporting medication errors

Introduction

- Medication administration in the field can present problems
  - Low light levels
  - Unstable environmental conditions
- Field administration must be mastered
Introduction

- Strategies for minimizing 2 key risk areas:
  - Harm to patient
  - Likelihood of a lawsuit

- Reduce possibility of poor patient outcome or lawsuit through:
  - Skill
  - Knowledge
  - Sound judgment
  - Strict adherence to protocols and procedures

Scope of Potential Legal Liability

- Medication error
  - Preventable occurrence
  - Caused by inappropriate use of a medication that has potential to harm
  - Institute of Medicine published report *To Err is Human: Building a Safer Health System*
    - 50,000 to 100,000 Americans die each year from general medical errors
    - Medical errors are 8th leading cause of death, ranking higher than breast cancer and HIV
    - Approximately 7000 people die each year from medication errors alone

- Paramedic drug calculating skills are lacking
  - Infrequent opportunities to perform drug calculations in clinical settings
  - Calculations are not routine part of EMS continuing education programs
**Principles of Negligence**

- **Ordinary negligence**
  - Failure to exercise degree of care that another reasonable person would exercise in same situation
  - Harm to another person results
  - Elements needed to prove negligence:
    - Duty to act
    - Breach of duty to act
    - Causation
    - Harm to patient

- **Duty to act**
  - Concept: Did you have a duty to provide care to the patient?
  - Must be a legal duty

- **Breach of duty to act**
  - Failure to provide level of care that EMS agency or local protocols dictate
  - Standard of care

- **Causation**
  - Plaintiff must prove that paramedic's conduct was substantial factor in bringing harm to the patient
  - Difficult to prove
  - Proximate cause
  - If patient's harm can be shown to have come from other sources, causation is not met
  - In some cases, medication errors and their effect on the patient can be isolated from initial insult on patient and can be negligent
Principles of Negligence

- Harm to patient
  - Must prove physical or emotional injury that caused damage to the patient
  - Damage can be shown through:
    - Patient testimony
    - Expert witness testimony
    - Other evidence

Immunity Defense

- Good Samaritan legislation
  - Protects bystanders without medical training from getting sued for providing assistance in an emergency
  - Some protect doctors and nurses who provide care outside their work environments
  - Some states extend to EMS providers

Immunity Defense

- Qualified immunity
  - Must prove gross negligence
    - Caregiver may not act in a reckless, wanton manner in total disregard to the patient

- Volunteer EMS personnel often have legal protection for their conduct
  - Most states require minimal level of training
  - Can render service only to that level
Immunity Defense

- Avoiding gross negligence
  - Function within certification level
  - Do not perform skills outside own scope of practice
  - Always act in good faith
  - Do not take or fail to take actions that could be considered grossly negligent
    - Function within scope of practice
    - Do not commit an action or omit an action that you had a recognized duty to perform or not to perform
    - Do no harm

Medication Errors: Mistake or Negligence

- Plaintiff must prove that all 4 elements of negligence were present
  - Usually shown that provider deviated from standard of care
  - Paramedic conduct was substantial factor in causing harm to patient
- Negligence is difficult to prove

Medication Errors: Mistake or Negligence

- Juries are sympathetic to plaintiff
  - View paramedics as no different than other health care professionals
  - Do not always decide based on law
  - Not subject to appeal unless procedural errors occurred
Medication Errors: Mistake or Negligence

- Minimizing the risk for medication mistakes:
  - Be well educated
    * Know drugs and everything about them
  - Be well rested
    * More apt to make a mistake when tired and stressed
  - Know protocols and follow them
    * Standard of care is examined
  - Maintain knowledge and skills
    * Drug calculations and medication administration should be practiced on a regular basis

Pediatric mistakes

- Errors in pediatric calculations can occur because:
  - Misplaced decimal points
  - Rushed calculations
  - Not often administered in prehospital setting
- Emotional impact to jury can transfer to higher damages awarded
- Always double check procedures
- Communicate with online medical command

Protocols as Risk Management Tool

- Established ALS protocols are a safeguard to prevent mistakes in medication administration
- Online medical direction is important
  - Paramedic must make sure that correct medication and dosage were heard and repeated back to physician for confirmation
Protocols as Risk Management Tool

- Standings orders/ALS protocols
  - Advance orders from medical direction
  - Developed ahead of time and followed by paramedics
  - Directives to be followed when certain medical conditions exist
  - Must memorize protocols
  - Considered standard of care
  - Safeguard to avoid errors

- Often written as a flow chart or decision tree
- Tend to be rigid and do not account for unique patient conditions
- If not followed exactly, can be used against paramedic in court
Protocols as Risk Management Tool

- To help ensure protocols that involve medication administration work favorably for the paramedic and the patient:
  - Keep protocols up to date
  - Know protocols

Laws Governing Prehospital Pharmacology

- Food, Drug, and Cosmetic Act of 1938 required detailed labeling of all medications
  - Package insert required in all medication packaging
    - Generic and common names of drug
    - Indications
    - Contraindications
    - Directions for use
    - Recommended dosages
    - Potential side effects

- Comprehensive Drug Abuse Prevention and Control Act of 1970
  - Classifies potentially dangerous and habit-forming drugs into different classes, with safeguards for their prescription, use, and control
Laws Governing Prehospital Pharmacology

- Comprehensive Drug Abuse Prevention and Control Act of 1970
  - Schedule I drugs
    - Most dangerous
    - Have highest potential for abuse
    - Have no recognized medical use

Laws Governing Prehospital Pharmacology

- Comprehensive Drug Abuse Prevention and Control Act of 1970
  - Schedule II
    - High potential for abuse
    - Safe and accepted medical uses
    - Narcotics
    - Stimulants
    - Depressant drugs
    - Available only by written prescription
    - Monitored by Drug Enforcement Administration (DEA)

Laws Governing Prehospital Pharmacology

- Comprehensive Drug Abuse Prevention and Control Act of 1970
  - Schedule III
    - Less potential for abuse than Schedule I and II drugs
    - Abuse may lead to moderate or low physical dependence
  - Schedule IV and V
    - Less habit-forming, pose lesser risk for harm from overdose
Laws Governing Prehospital Pharmacology

- State laws
  - Most have laws that address use and misuse of medications
  - Govern use of prehospital medications
  - Mandate disciplinary sanctions against emergency personnel who misuse approved medications
  - Follow state laws at all times

Operational Considerations

- Storage and security
  - Properly ordered
  - Inventories
  - Stored
  - Dispensed when needed
  - Central storage at organization must be kept secure with double locking systems

Operational Considerations

- Storage and security
  - Special care to ensure security of narcotic agents
  - Potential for theft and misuse
  - Signed in and out at each shift
  - Clear documentation of transfer of custody
  - Log books maintained at all times
  - All transfers should be witnessed so at no time does 1 person have access
Operational Considerations

Drug currency
- All drugs have varying shelf life
  - Period of time medication can be stored and remain suitable for use
  - Factors for length of time:
    - Chemical composition of drug
    - Stability or volatility
    - Expected period of effectiveness
  - Expiration dates must always be checked and rechecked
    - If outdated medication is used, can be negligence

Daily checks must be used to ensure that no medication is outdated or damaged.
- All outdated medications should be properly disposed of according to policies
- Must also dispose of damaged medications
Operational Considerations

- Environmental issues
  - Food and Drug Administration (FDA) has strict requirements on environmental parameters within which medication is effective.
  - Administering medication rendered ineffective because of exposure to excessive heat or cold does not benefit patient:
    - Risk for liability.
    - If vehicle is parked outside, vehicle must be connected to systems that maintain an appropriate temperature.
    - If exposed to temperature extremes while in use, properly discard and replace on return.

Exposure to Bloodborne Pathogens

- Safety of self, crew, other responders is always top priority.
- Medication administration must be conducted as risk-free as possible.
- Occupational Safety and Health Administration (OSHA) provides guidelines for EMS personnel dealing with potential exposure to bloodborne pathogens.

Exposure to Bloodborne Pathogens

- Threats:
  - HIV
  - Hepatitis
- OSHA has intensified its interest in healthcare provider safety:
  - Must review all sharps devices
  - Must obtain best possible devices to minimize exposure risk.
Exposure to Bloodborne Pathogens

- Ryan White Law
  - Provides safeguards in event of needlestick
  - Establishes mechanism of reporting so if patient tests positive for HIV, EMS personnel are advised through medical director of necessary precautions

Consent Issues and Limitations

- Every patient has right to self-determination regarding medical care
  - Application of life-saving or life-sustaining measures
  - Must be competent adult

- Paramedics must receive consent for every assessment and treatment
  - Must inform patient about what drug is being administered and reason for administration

Consent Issues and Limitations

- If patient refuses medication:
  - Ensure patient is competent
  - Carefully document refusal

- Complete refusal
  - Patient refuses all aspects of treatment

- Partial refusal
  - Patient agrees to some treatment offered, not all
Consent Issues and Limitations

- Obtain written documentation of all refusals
- A3E3P3 refusal guidelines
  - Consent and refusal of consent must be properly handled to minimize liability
  - Assess patient’s legal and mental capacity to refuse care

Consent Issues and Limitations

- A3E3P3 refusal guidelines
  - Advise patient of medical condition and proposed treatment
  - Avoid using confusing terminology when talking to patients
  - Ensure patient’s decision is informed and not coerced by others

Consent Issues and Limitations

- A3E3P3 refusal guidelines
  - Explain alternatives to patient if he or she refuses care and transportation
  - Exploit uncertainty
  - Persist in trying to persuade the patient to obtain necessary care
  - Protocols are meant to be followed
  - Protect yourself with adequate documentation of refusal
Consent Issues and Limitations

Living wills and advance directives
- All states have living will statutes
- Advance directives
  - Specific orders to the caregiver regarding what level of treatment patient wants in event of terminal illness
  - Many provide limitations on treatment with cardiac arrest or coma

Most states have strict verification requirements
- Can be overruled any time by patient
- Medication restrictions should be clearly delineated in directive
- Check state laws and local protocols for correct procedures
Patient care record (PCR) is closely scrutinized in malpractice and negligence trials.

Must be thorough and specific.

**Dos**
- Ensure that documentation of medication administration is accurate on your prehospital capabilities and your scope of practice.
- Write legibly and in complete sentences and use abbreviations correctly so all personnel can read your report.

- Document in treatment section:
  - Time
  - Medication given
  - Dose
  - Method
  - Route of administration
- Document medication refusal and state why patient refused medication.
Documentation

Dos
- Document why you gave patient a particular medication
- Document known medication allergies and any untoward reaction to any medication you administered and treatment you provided in response

Dos
- Document vital signs before and after administration of all medications
- Document any changes in vital signs, especially if patient condition worsened
- Document name of physician or medical director who has medications order and time of order

Don’ts
- Do not scribble or write illegibly
- Do not misspell words or medication names
- Do not forget to check patient’s response to a medication
Documentation

Don’ts
- Do not make up abbreviations or use inappropriate acronyms in documentation
  - Use only approved standard abbreviations
- Do not assume other crew members will do your documentation
  - If you gave the medication, you are responsible for documenting that fact
  - Do not prepare your report late if you can avoid it

Scope of Practice Issues

EMT-Is and paramedics should proceed cautiously when involving BLS personnel in ALS procedures
- Allowing BLS to perform any procedure that requires advanced training should not be allowed
  - Could be considered negligent

Scope of Practice Issues

- When administering any medication, EMT-Is and paramedics must personally complete all steps necessary
  - Ask patient about any known allergies to medications, and check for MedicAlert tag
  - Determine patient’s medical history and current medications
  - Verify that you have correct medication in correct concentration
Scope of Practice Issues

- When administering any medication, EMT-Is and paramedics must personally complete all steps necessary
  - Verify and repeat any order received to administer medication
  - Examine packaging for discoloration and unusual characteristics
  - Examine packaging and vial or ampule for expiration date

Scope of Practice Issues

- When administering any medication, EMT-Is and paramedics must personally complete all steps necessary
  - Open medication and prepare it for administration, following proper procedures for ensuring sterility
  - Administer medication according to proper procedure or protocol for particular drug
  - Observe patient for any untoward reactions, any improvement, or other change in condition

Scope of Practice Issues

- EMS providers should document according to their scope of practice
  - Do not attempt to document skills beyond what you are trained and certified to perform yourself
  - EMT should document that the paramedic provided patient care in addition to EMT’s role in care
Misdirection of Medications

- Theft of controlled substances
- Serious criminal penalties for misappropriation of medications
- Common problem: stealing an agent and replacing it with water
  - Paramedic thinks he or she is administering medication and is giving a placebo

Misdirection of Medications

- No one person should have sole access to medication supply system
  - Appropriate checks and balances should be in place
  - Should be periodically audited by individuals who are not directly associated with it

Incident Reporting

- Every medication error must be properly documented and reported
  - Essential for quality care and quality assurance and to prevent from happening again
  - Professional duty even when you know you will be subject to disciplinary actions
  - Every EMS system should have standardized system for documenting medication errors
Incident Reporting

- Incident care report should be completed promptly
  - Submitted to immediate supervisor, not attached to the PCR

- Incident should be investigated by management personnel and system’s medical director

Incident Reporting

- Many times, problems in the system contribute to the error
  - System-wide education may be needed

- Risk reduction is key to avoiding liability

- Accepting responsibility for human factors to function free of error is key to professional approach to avoiding medication errors

Questions?