# Legal Issues for the Traumatologist

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## <u>Goal</u>

At the conclusion of the presentation, the audience should be able to discuss and identify legal issues affecting the traumatologist



## <u>Objectives</u>

1. Name and describe established laws

2. Identify legal issues in the treatment of trauma patients

3. Identify legal issues in practice management



1. The Emergency Medical Treatment and Labor Act (EMTALA)

2. Health Insurance Portability and Accountability Act (HIPAA)

3. The Abused Patient



- The Emergency Medical Treatment and Labor Act (EMTALA) 1986
  - Requires Emergency Departments (ED) to:
    - Screen patients for emergent conditions and stabilize these conditions
    - Cannot discriminate on demographics or ability to pay
    - Patient must be treated till stabilized or emergent condition resolved
  - Also know as "anti-dumping" law
    - Cannot prematurely transfer un- or underinsured patients
    - Strict Transfer guidelines



- The Emergency Medical Treatment and Labor Act (EMTALA) 1986
  - EMTALA does not apply to stable patients
  - An unstable patient may be transferred if:
    - Benefits of transfer outweigh the risks as certified by a physician
    - Written transfer request is made by patient after the risk-benefit of the transfer is discussed AND the patient knows the hospitals requirements under EMTALA
  - Transfer guidelines
    - Transfers must be "appropriate" as defined by the law:
      - Transferring hospital must continue care within capabilities until transfer
      - Supply copies of medical records
      - Receiving hospital has agreed to the transfer and has qualified personnel and space
      - Qualified personnel and medical equipment required for transfer
  - Hospitals cannot transfer to a lower level of care



- The Emergency Medical Treatment and Labor Act (EMTALA) 1986
  - Penalties for violation
    - Loss of hospital and/or physician's ability to see Medicare patients
    - Hospital fines
    - Physician fines
    - Receiving hospitals can sue for damages from another hospitals EMTALA violation



- Health Insurance Portability and Accountability Act (HIPAA) 1996
  - Designed to "protect sensitive patient health information" from being shared without patient "consent or knowledge"
  - HIPAA is enforced using two rules
    - HIPAA Privacy Rule
    - HIPAA Security Rule



- Health Insurance Portability and Accountability Act (HIPAA) 1996
  - HIPAA Privacy Rule
    - Addresses the "use and disclosure" of protected health information by "covered entities"
    - Allows patients to control how health information is used
    - Goal is to allow patient information to be shared to provide high quality patient care, but to do it in a protected manner
    - Examples of Covered entities:
      - Insurance companies
      - Healthcare providers
      - Business entities (i.e. hospitals)



- Health Insurance Portability and Accountability Act (HIPAA) 1996
  - HIPAA Privacy Rule
    - "Covered entities" can disclose information to:
      - The patient
      - Individuals or groups involved in treatment, payment and healthcare operations
      - Research, public health, other approved datasets (if redacted)
      - Persons/entities requested by the patient
      - Situations of public interest/benefit such as but not limited to:
        - Abuse Victims
        - Law enforcement
        - Identification of deceased person
        - Health Oversight
        - When required by law



- Health Insurance Portability and Accountability Act (HIPAA) 1996
  - HIPAA Security Rule
    - Applies to any electronic protected health information (e-PHI)
    - Does not apply to PHI communicated in writing or orally
    - To be compliant a "covered entity" must:
      - Ensure "confidentiality, integrity, and availability of all e-PHI"
      - Identify and protect information from security threats
      - Protect information from potential improper uses or disclosures
      - Ensure that workforce is compliant



- Health Insurance Portability and Accountability Act (HIPAA) 1996
  - Penalties for violations
    - All complaints reported to HHS Office for Civil Rights
    - Monetary penalties
    - Can carry criminal penalties
    - Severity of penalty is related to the level of negligence



- The Abused Patient
  - Children, adults and elders are all at risk for abuse
  - As a physician it is your responsibility to identify abuse
  - As a physician you need to report abuse according to governing rules and laws
  - Abuse can be the reason for presenting with a medical complaint



- The Abused Patient
  - Child abuse
    - Definition: "Any recent act or failure to act on the part of a parent or caretaker, which results in death, serious physical or emotional harm, sexual abuse or exploitation."
    - Occurs in over 1 million children per year in the United States
    - Presentation/Suspected Abuse:
      - Inconsistent story from caregiver
      - Femur fracture in non-ambulatory child
      - Multiple bruises in multiple stages of healing
      - Delayed presentation for care
      - Corner fractures on x-ray
      - Skin changes most common





- The Abused Patient
  - Child abuse
    - Child Abuse Prevention and Treatment Act (CAPTA) is a federal law that sets:
      - Minimal standards for reporting
      - Mandates states have mechanism to report
    - In the all US States child abuse is required to be reported to child protective services (CPS) if suspect by a healthcare provider
    - Reporters only need to report the facts and do not bear the "burden of proof."
    - Importance of reporting
      - Child abuse is the second most common cause of death
      - Up to 50% chance of repeat abuse and up to 10% chance of death





- The Abused Patient
  - Adult/Domestic Abuse
    - Definition: "Pattern of behaviors used by one partner to maintain power and control over another partner in an intimate relationship."
      - Also known as: intimate partner violence, relationship abuse
    - Affects women more than men
      - Around 1/3 of women presenting to ED with injuries are due to domestic violence
    - Child abuse can be as high as 50% in homes with domestic abuse



- The Abused Patient
  - Adult/Domestic Abuse
    - Risk Factors:
      - Female
      - Pregnant
      - Short relationship
      - Low-Socioeconomic status
    - Presentation/Suspected Abuse:
      - Flat Affect
      - Repeat ED visits
      - Refusal or excuses to delay discharge home
      - Delay between injury and seeking treatment



- The Abused Patient
  - Adult/Domestic Abuse
    - Reporting
      - Unlike child abuse most states physicians do not have the authority to report suspect abuse
    - If abuse suspected
      - Be familiar with state law requirements
      - Enquire if patient is safe at home
      - Provide resources
      - Encourage patient to report incidents to law enforcement
      - Document encounter and interventions carefully



- The Abused Patient
  - Elder Abuse
    - Definition: Is the exploitation, abuse or neglected of an adult over 65 years old.
      - Exploitation is often monetary in nature
    - Male and Female Genders affected equally
    - Around 2 million elders in American affected a year



- The Abused Patient
  - Elder Abuse
    - Risk Factors:
      - Functional or cognitive impairment
      - Increasing age
      - Caretake is dependent on the elder person (i.e. financially)
    - Presentation/suspected abuse:
      - Burns/bruising
      - Sudden changes to daily activities or cognition.
      - Drastic changes to financial situation/status
      - Tense relationships or reoccurring arguments between elder and caregiver.



- The Abused Patient
  - Elder Abuse
    - Reporting
      - All states have a mechanism to report elder abuse and physicians are mandated to report
      - Concerns are reported to Adult Protective Services (APS)
      - If elder is in immediate danger you can:
        - Call law enforcement
        - Admit to hospital



1. Informed Consent

2. Medical Power of Attorney (MPOA) and Living Will

3. Do not resuscitate/Do not intubate (DNR/DNI)



#### Informed Consent

- Definition: The process of telling a patient their diagnosis, the recommended treatment, and the risks and benefits of pursuing or not pursuing the recommended treatment.
- All patient should have the opportunity to ask questions in the informed consent process to understand their condition and procedure.
- A consent form should be signed establishing agreement between the surgeon and patient.
- If informed consent is not obtained it can be considered assault/battery if procedures are performed.



- Informed Consent
  - Some patients cannot give informed consent due to:
    - Age Under 18 (minors)
      - Parents or guardian can give informed consent
      - Certain states have exceptions for minors to give informed consent (i.e. pregnant minors, emancipated minors, minor seeking treatment for drug dependence).
    - Cognitive disability
      - Appointed guardian (parents, family, state official) can give informed consent



- Informed Consent
  - Some patients cannot give informed consent due to:
    - Emergent situations
      - Every attempt should be made to obtain informed consent per state and hospital policy especially before surgical procedures.
      - If informed consent cannot be obtained and emergent procedure and treatment is needed then implied consent should be utilized
      - Implied consent assumes that if the patient was aware of their emergent situation, they would want their emergent conditions treated under the "reasonable man" standard to save their life/limb.
      - If implied consent is used patient, family or guardian should be informed as soon as possible about the applied intervention during the emergent situation



- Medical power of attorney (MPOA) and Living Will
  - In situations where a patient cannot make decisions two pathways exist for decisions to be made on the patient's behalf according to their wishes
  - Medical Power of attorney (MPOA) is a person appointed by the patient to make medical decisions on their behalf if they cannot
  - A Living Will is a document that the patient expresses treatment wishes in to help guide treatment if they cannot make their own decisions
  - MPOA and a living will are not mutually exclusive and if both exist the directives in a living will take precedent over the MPOA.



## Comparison of MPOA and Living Will

#### MPOA

- Person appointed to make decisions
- MPOA and patient discuss wishes
- MPOA is expected to make the best decision with patient wishes in mind

- Living Will
  - Patients own wishes written out
  - Usually refers to specific situations and action to take
  - If living will take precedent over MPOA if the will addresses the situation



- Do not resuscitate/Do not intubate (DNR/DNI)
  - Patients can have very specific wishes regarding life saving measures.
  - A <u>Do Not Resuscitate</u> order (DNR) states that no life saving measures (i.e. hemodynamic support with medication) should be taken to keep them alive
  - A <u>Do Not Intubate</u> order (DNI) means the patient does not want intubation to keep them alive but does not in itself exclude measures or resuscitation.
  - Like a living will DNR/DNI orders override MPOA orders, but an MPOA can decide to make a patient DNR/DNI if that patient has stated so



## Comparison of DNR and DNI

- DNR
  - No resuscitative measures used to keep alive
    - No vasopressors for hypotension
    - No ventilation for respiratory failure
    - No antibiotics to treat infection
    - No Cardiopulmonary Resuscitation (CPR)

- DNI
  - No intubation can be used to keep patient alive

**BUT....** 

- Patient can be given resuscitative measures to keep alive
  - Vasopressor to treat hypotension
  - Antibiotics to treat infection
  - Can perform CPR



- Do not resuscitate/Do not intubate (DNR/DNI)
  - Some procedures are considered palliative in nature such as:
    - Cephalomedullary nail for hip fracture in an elderly patient to control pain
    - Treatment of long bone metastatic disease to prevent fracture
  - In these situations a patient may have a DNR/DNI in place and <u>discussion</u> <u>should be pursued about suspending these for the duration of the palliative</u> <u>procedure</u>
    - Not all states/hospitals require DNR/DNI to be suspended during palliative procedures
    - Suspension allows the treatment team to correct life-threatening conditions during and around the procedure to allow the patient to live to benefit from the intervention



1. Conflict of Interest (COI)

2. Second Opinion Doctors

3. Advertising



- Conflict of Interest (COI)
  - Definition: "A situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties as, say, a public official, an employee, or a professional."
  - Patients should be informed of potential COIs when appropriate to completely disclose and inform them of the treatment plan
  - In Orthopaedics COIs can occur through a few different mechanisms.
  - Therefore it is important to recognize and disclose all possible COIs



- Conflict of Interest (COI)
  - Royalties
    - Payments made from a company to physician.
    - Payments can occur for:
      - Speaking for the company
      - Designing implants
      - Global implant utilization
      - Conducting research/trails
    - If utilizing an implant on a patient, you should disclose any royalties or conflicts related to using that implant to the patient



- Conflict of Interest (COI)-Mitigation
  - The Physician Payments Sunshine Act (PPSA) 2010
    - Part of the Affordable Care Act
    - Requires medical product manufactures to report all and any payments made to physicians
    - Goal was to increase transparency of the relationship between the physician and the medical industry –pharma and implants
    - Database available on the internet for public to access
      - https://openpaymentsdata.cms.gov/



- Conflict of Interest (COI)
  - Physicians can also own interest in surgery centers, medical equipment such as MRIs, and therapy centers which can create a conflict of interest.
  - Physicians can be conflicted to self-refer patients for health services to entities they own which potentially could carry civil law consequences
  - These conflict have been managed and addressed by Antikickback Statute and Physician Self-Referral Laws (Stark Laws)



- Conflict of Interest (COI)-Mitigation
  - Anti-kickback Statute
    - Criminal statute
    - Prohibits the "exchange of anything of value, in an effort to induce the referral of business reimbursable by federal health care programs." Prohibited activities include:
      - Financial incentives for referrals
      - Waving co-payments either as practice or selectively
    - Kickbacks have led to increasing healthcare costs
    - Violators can face fines, jail time and risk being excluded from seeing Medicare/Medicaid patients



- Conflict of Interest (COI)-Mitigation
  - The Physician self-referral laws (Stark Laws)
    - Civil Law
    - Stark I: prohibited physicians from referring Medicare patients to a clinical laboratory that the physician or their family had a financial interest in.
    - <u>Stark II:</u> expanded Stark I to included Medicaid patients. Stark II also prevent physicians from referring patients to Designated Health Services (DHS) that a physician had financial interest in.
    - DHS included but are not limited to:
      - Durable medical equipment/prosthetics
      - Home health services
      - Outpatient pharmacy services



- Conflict of Interest (COI)-Mitigation
  - The Physician self-referral laws (Stark Laws)
    - Exceptions to Stark Laws include but are not limited to:
      - Referral to a doctor who is a member of the same group practice
      - Services are done in the same location as the treating doctor
      - Intra-family rural referrals
    - Penalties for Stark Law violations
      - Carries no jail time
      - Can have significantly higher financial penalties compared to Antikick back laws



- Second opinion doctor
  - Occasionally patients or doctors will seek a second opinion to help care for the patient
  - The "second opinion doctor" has an ethical, but no legal obligation to discuss previous care that deviated from the standard of care.
  - If your patient seeks a second opinion you:
    - Should supply medical records with their consent
    - Cannot terminate the physician patient relationship
  - The "second opinion doctor" does not have to assume the patient's care



- Advertising
  - Physician advertising is governed by the Federal Trade Commission Act
  - Advertising is allowed as long as advertising is not "false, deceptive or misleading"
  - Examples of misleading advertising
    - Bloodless surgery
    - Painless surgery
    - Offering a cure for a disease which no cure exists



#### <u>Summary</u>

- Multiple laws ensure that the care of trauma patients is consistent, and penalties exist for those surgeons and entities that do not comply
- While child and elder abuse is reportable, reporting domestic violence between adults varies by state and local laws.
- Multiple situations exist where patient may not be able to give informed consent and mechanisms to ensure patients are cared for by their wishes even when they cannot give consent
- Conflicts of interest can arise from royalties, physician payments and referrals. Knowledge of the laws and disclosure of these conflicts are important in provide transparent patient care.
- Advertising by physicians is not illegal; but advertisements cannot be deceptive in nature.



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