LEGAL ISSUES IN NEONATOLOGY

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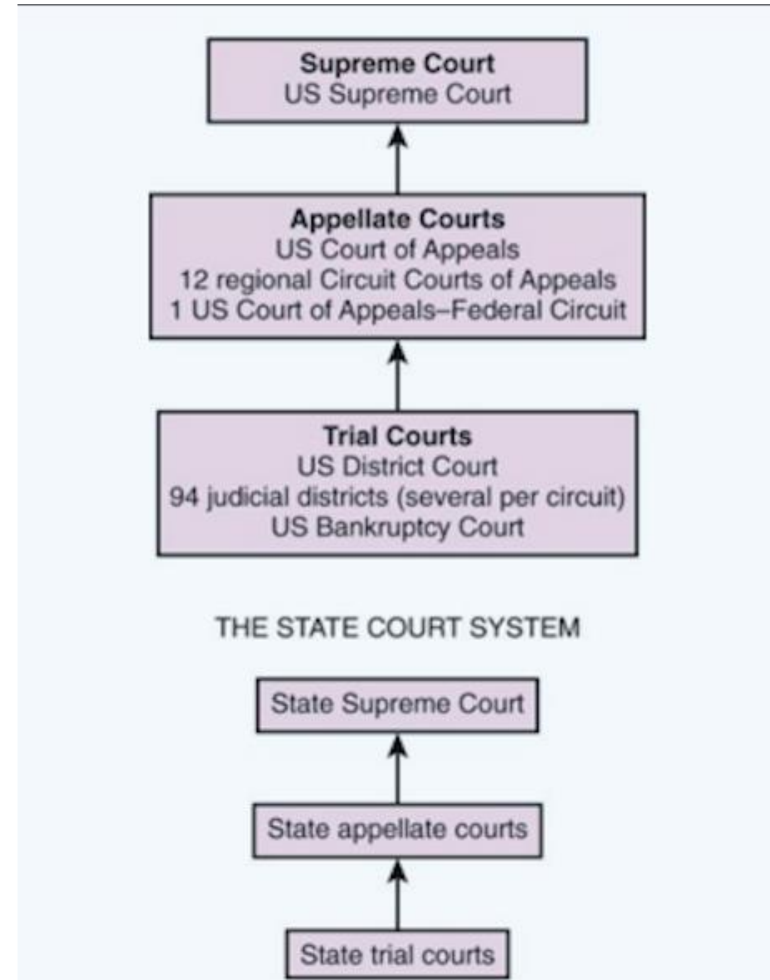
OVERVIEW

A. Background knowledge
B. Medical malpractice as it applies to the NICU
C. Legal issues related to live births
D. Legal issues related to handicapped newborns
E. Providing care against parents’ wishes
F. Maternal vs. Fetal Rights Issues

A. Background Knowledge

- Common law:
  - Created by judges evaluating disputes
  - Ex: Roe v Wade, Brown v Board of Education
- Legislative Law
  - Created by legislative bodies such as US Congress or state legislature
- Medicine generally regulated at the state level UNLESS:
  - Civil rights case
  - Dispute involving the Americans with Disabilities Act
  - Malpractice case at a military hospital
- Court and state legislature decisions not binding across states

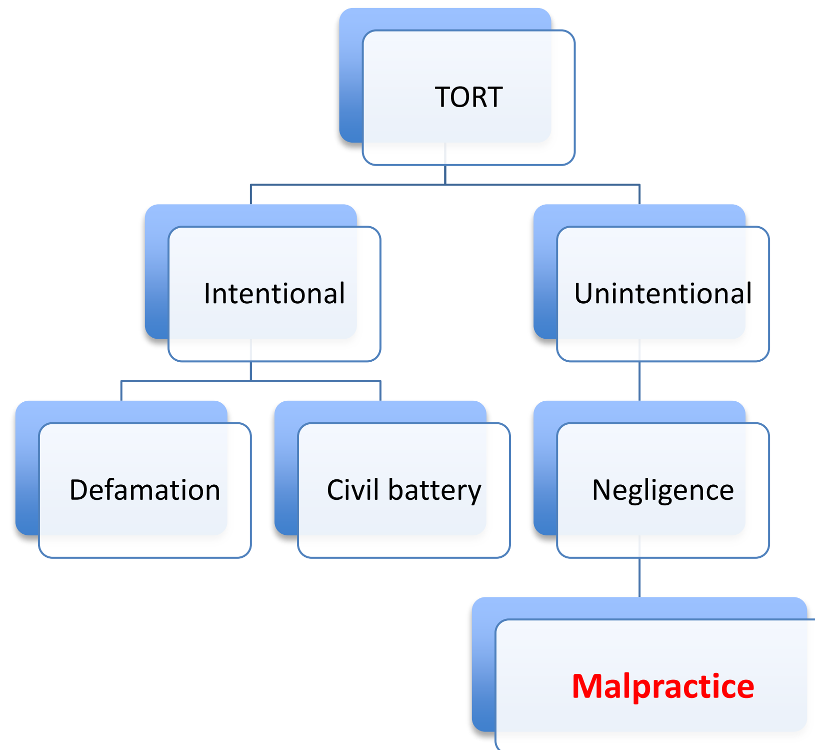


Theories of Liability

- Attending neonatologists bear ultimate responsibility for the neonates under their care
- 3 theories of liability:
  - "Captain of the ship" doctrine
  - Respondeat superior = "let the master answer"
    - Covers fellows
  - Negligent supervision

B. Medical Malpractice

- Part of *tort law* → cases involving the duties and responsibilities that individuals have towards one another



Box 5-1

Common Malpractice Suits in Neonatology

Delivery Room Management or Resuscitation

- Poor neurologic outcome
- Cerebral palsy: neonatologist named as codefendant with obstetrician-perinatologist
- Neonatal encephalopathy: plaintiff alleges some component of injury occurred postnatally

Line Complications

- Vascular accidents related to central venous lines
- Loss of fingers or toes associated with central lines
- Thrombus and complications from thrombus

Delay in Diagnosis or Treatment

- Poor blood gases, prolonged hypotension
- Delay in antibiotic administration
- Congenital hip dislocation
- Congenital heart disease

Transport Team

- Medications or care provided by transport team (e.g., excessive heparin given)

Failure to Monitor Adequately

- Blood glucose
- Blood oxygen: either hypoxia (brain damage) or hyperoxia (retinopathy of prematurity)
- Seizure

❖ **To win a malpractice suit, four elements are needed:**

- Duty
- Breach
- Causation
- Damages

❖ **Burden of proof for each of the 4 elements is on plaintiff**

Elements of Malpractice Case: 1. Establishing Duty

Duty can be established:

- Towards newborn: *Nold v Binyon*
  - "A physician who has a doctor-patient relationship with a pregnant woman who intends to carry her fetus to term and deliver a healthy baby also has a doctor-patient relationship with the fetus."
- In telephone calls: *Sterling v Johns Hopkins*
  - "Where a treating physician exercises his or her own independent judgment in determining whether to accept or reject a consultant's advice, the consultative physician should be regarded as a joint provider of medical services…"
- In prenatal consultations: *Hill v Kokosky*
  - Determined by formality of consult and presence/absence of contact with family

Elements of Malpractice Case: 2. Breach of Standard of Care

- Proving breach:
  - Requires proof of national standard of care
  - Expert witnesses often employed
  - Example: Brownsville Pediatric Associates v Reyes

UNLESS:

- *Res ipsa loquitur* → "the thing speaks for itself"
  - Can be enough to overcome the plaintiff's burden to prove breach

Elements of Malpractice Case: 3. Causation

- The defendant's breach must be the cause of the plaintiff's injury → correlation insufficient
- Most challenging burden to prove:
  - Usually requires expert testimony
- Can be very complicated: *Hubbard v State*

Elements of Malpractice Case: 4. Damages

- Plaintiffs must prove they were harmed through:
  - Pain and suffering OR
  - Loss of some kind
- Damages can be economic or noneconomic
  - Non-economic damages capped by some states
- Usually compensatory but can also be "punitive"
  - Rare in medical malpractice cases unless "spoliation of evidence"

Types of claims that can surface in malpractice cases

Wrongful Birth

- Action maintained on behalf of parent
- Parents maintain that child should have never been born
- Examples:
  - Failure of sterilization
  - Failure of genetic diagnosis: Smith Lemli Opitz case

Wrongful Life

- Maintained on behalf of newborn
- Infant would be better off it not born
- Examples:
  - Severe congenital anomalies
  - Genetic testing: Estrada case

Wrongful Death

- Claimed if death occurs as a result of negligence
  - Common claim in malpractice suits
- In some states (but not all) extends to fetus
  - Gestational age at which it applies also state-dependent

Box 5-2

Strategies to Avoid Tort Litigation

Stay current by reading journals and textbooks, and by attending continuing medical education conferences.

Maintain professional ties with a tertiary care medical center.

When facing a difficult situation, consider consulting with a colleague.

Maintain open communication with parents and families.

Practice timely documentation of procedures, communication, complications, and persons present.

Document telephone advice.

Be aware of state laws that affect your practice.

Documentation is our best defense tool.

A word on “tort reform”….

- Limits on:
  - Noneconomic damages
  - Attorney fees
- Expert witness standards
- Inadmissibility of apology statements by health care providers

C. Legal Issues re: “Live Birth”

- Fetus acquires “personhood” when there is a declaration of “live birth”
- State-to-state variation on definition of “live birth”

Until…

- <u>2002 Born-Alive Infants Protection Act (BAIPA</u>) by Congress
  - Born alive means the complete expulsion or extraction, at any stage of development, of an infant who subsequently has a beating heart, pulsation of umbilical cord, or definite movement of voluntary muscles, regardless of whether umbilical cord was cut and regardless of whether birth was by natural/induced labor, CS or induced abortion

- If infant is “born alive,” must receive a “medical screening” and appropriate care must be provided
  - AAP NRP steering committee has maintained that BAIPA should not affect our approach to extremely premature infants

D. Legal Issues re: Handicapped Newborns

Four important cases:

1. Baby Doe
   - *Conclusion: Medical treatment can be withheld when: 1) the infant is chronically and irreversibly comatose; 2) treatment would be both "virtually futile in terms of survival" and "inhumane"*
2. Baby Jane Doe
   - *Conclusion: Parents allowed to pick less aggressive therapies if option is deemed "acceptable"*
3. Baby K:
   - *Conclusion: Care cannot be withheld simply because caregivers consider it morally or ethically inappropriate*
4. Sun Hudson
   - *Conclusion: Parents' rights are not completely unlimited, especially in states that allow unilateral withdrawal*

Conclusion:

Courts support parents' interests as long as decisions are not being made solely on basis of handicap and as long as infant is not believed to be suffering.

E. Legal Issues re: Providing Care Against Parents' Wishes

- Extremely premature infants have same legal rights as all citizens

- Existing relevant cases:
  - Miller (Texas 1990-2003)
  - Montalvo (Wisconsin 1996)
  - Messenger

Maternal vs. Fetal Rights

Maternal Rights Arguments

- Freedom of choice and control based on pregnant woman's own values, preferences, circumstances
- Health of a fetus may be at risk if pregnant women avoids prenatal care

Fetal Rights Arguments

- Society should protect future child even if it means forcing the pregnant woman to change her behavior, including acceptance of an undesired treatment
- Harmful prenatal conduct can be distinguished from less significant behaviors.
- Fetus is vulnerable

Policy Statements

1. AAP "Fetal Therapy-Ethical Considerations": published 1999, retired 2007
2. ACOG Committee on Bioethics 2005

Box 5-3

When Parents and Caregivers Disagree on the Care of Critically Ill Newborns

Lessons from Existing Case Law

Parents Request Full Supportive Care and Caregivers Disagree

- General rule: provide full supportive care
- Anencephaly: Baby K case likely controls (federal case)

Parents Want No Resuscitation and Caregivers Disagree

- Miller (Texas): no liability for caregivers
- Montalvo (opinion covers Milwaukee, Wisconsin): no liability for caregivers
- Messenger (Michigan): no criminal liability for father who disconnects the ventilator

Parents and Caregivers Agree to Forgo Aggressive Treatment

- Possibly covered by Baby Jane Doe case: parents have right to make reasonable choice
- Baby Doe case: cannot make decision solely based on present or future handicap
- Montalvo (opinion covers Milwaukee, Wisconsin): parents may not have right to make reasonable choice

Conclusions

- Legal precedence is not consistent
- Exact legal status of extremely premature infants remains in question
- Wrongful life claim can be denied because parents can be deemed to have no right to refuse care in some jurisdictions
- In some jurisdictions, no criminal liability for a parent who overrules physicians

ABP Content Specifications

- Know the evolving issues of maternal versus fetal rights
- Recognize the controversies associated with treating extremely premature infants
- Recognize the controversies associated with the introduction of new technologies to treat previously fatal disorders, such as an experimental therapy that may save a life, prolong a life, or prolong death
- Recognize the controversies associated with the introduction of new genetic tests for rare and common diseases that present in the neonatal period

Practice Question

A neonatologist attends the delivery of a female infant of uncertain gestational age with an estimated fetal weight of 350 grams. She is found to have fused eyelids, translucent skin and is intermittently gasping for breath. Based on the Born Alive Infant Protection Act, the neonatologist must:

A. Ask the parents about their wishes regarding resuscitation

B. Assess this infant in order to determine the most appropriate course of action, including the decision to not resuscitate

C. Do nothing, as the infant is clearly not of viable gestational age

D. Immediately begin to resuscitate based on NRP guidelines

A. Provide comfort measures but not medical interventions as she is not of viable gestational age and unlikely to live if resuscitation were attempted.