Ethics & Professionalism Curriculum in Neonatology

**Ethics and the Law in the NICU**

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**Case Topics** – ethics, law, legal precedents, case law, Supreme Court cases

**Overview**

Law and legal policy usually reflect a society’s morals and ethical underpinnings. Medical decisions made by clinicians and families on behalf of sick infants in the neonatal intensive care unit (NICU) are nearly always concordant with the law. Rarely, however, clinicians find that adherence to ethical principles and norms diverge from established legal precedents. While clinical ethics and law have many overlapping themes, there are some important distinctions between the two fields. Clinical ethics involves a system of moral principles and frameworks applied to the practice of medicine to help clarify values, judgments, and preferences and arrive at mutually acceptable decisions about treatment. In neonatology, consideration of the family’s values and beliefs are crucial when developing treatment plans together with families for infants. Law, on the other hand, involves a system of rules, unique to different societies, countries, states, and cities, that regulates social behavior and conduct. Violating the law may result in criminal or civil penalties. This module reviews several key laws and court cases that are relevant to the practice of neonatal medicine. Two theoretical case examples are provided that highlight the balance between ethical principles and legal precedents that should be considered when providing care for infants and their families in the NICU.

**Disclaimer:** The content of this module should not be viewed as legal advice or counsel and is for educational purposes only. Please seek appropriate hospital legal advice for questions concerning specific cases.
Suggested Reading

1. DeTora AD, Cummings CL. Ethics and the Law: Practical Applications in the NICU. *NeoReviews*. Jul 2015;16(7):e384-e392. [https://neoreviews.aappublications.org/content/16/7/e384](https://neoreviews.aappublications.org/content/16/7/e384) [https://neoreviews.aappublications.org/content/17/11/e685](https://neoreviews.aappublications.org/content/17/11/e685)


Learning Objectives

After participation in this module, the learner will:

1. List several landmark court cases relevant to the practice of neonatal-perinatal medicine.
2. Describe legal precedents, policy statements, and ethical principles that govern appropriate medical care of neonates.
3. Describe how the Emergency Medical Treatment and Active Labor Act (EMTALA) and Born-Alive Infant Protection Act (BAIPA) legislation may affect decision-making in neonatology.
4. Define “potentially inappropriate” treatments and distinguish between futile, legally proscribed, and legally discretionary therapies.

Case #1 Summary

You are the fellow on call overnight at a busy level III NICU. One of your patients, Richard, is a 2 day-old male infant born at 36 5/7 weeks’ gestation with Pierre Robin sequence (glossoptosis; downward displacement of the tongue, micrognathia, and cleft palate). He was intubated by otorhinolaryngology (ORL) in the delivery room due to airway obstruction and inability to ventilate with a bag-valve mask, and deemed to have a “critical airway.” The plan for Richard is to have a jaw distraction in the OR the following day. You are now called emergently to his bedside to evaluate the integrity of his endotracheal tube. The nurse and respiratory therapist have discovered that the tape around the tube has become loose and should be re-taped. Richard is moving around vigorously and appears uncomfortable, agitated, and in pain. You suggest a low dose of morphine to sedate the infant to allow for tube re-taping. Richard’s parents are at the bedside and refuse the medication. You feel that re-taping the tube without sedation is an unsafe plan as the tube could become dislodged and the infant could deteriorate rapidly given his critical airway. What should you do?
Case Questions:

1. Which ethical principles should be considered when deciding what to do for this infant? What about legal precedents?
2. Who should make decisions for the infant if there is a disagreement between the parents and the medical team?

Case Discussion

Which ethical principles should be considered when deciding what to do for this infant? What about legal precedents?

In the United States, the ethical principle that often dominates adult medical care and decision-making is autonomy (“self-rule”). Since infants are never able to voice their own opinions regarding what treatments they would or would not want to receive, parents traditionally assume the role of surrogate decision-makers. This notion of parental authority and responsibility has been supported in many court cases, including the case of Baby K, which involved an infant with anencephaly whose mother insisted that Emergency Department physicians intubate her infant for respiratory distress. The court stated, “Absent finding of neglect or abuse, parents retain plenary authority to seek medical care for their children, even when the decision might impinge on a liberty interest of the child.” However, should parents have the final say in what medical treatments their infants’ receive, or are there other factors that must be considered?

Other ethical principles that could be applied to this case include best interests standard, beneficence (do good), non-maleficence (do no harm), and justice (fairness, treat like cases similarly). The team in this case should work with Richard’s parents to try and develop mutual goals of care, including a plan that is safe, effective and in the best interests of the infant. From the clinical perspective, a safe plan for manipulating an endotracheal tube for any infant with a critical airway includes adequate sedation. The risk of accidental extubation in this infant could likely lead to airway obstruction, and possibly even respiratory and cardiac arrest. Because manipulation of an endotracheal tube can be uncomfortable and even painful, the medical team should always strive to adequately treat pain.

The parental perspective is also important. It is crucial to attempt to understand reasons for parental declination in a non-judgmental manner, in order to clarify any misunderstandings or misinterpretations and move forward. In this case, for example, parental fears of addiction from opiate exposure should be explored. Although parents generally have the right to make decisions for their children, parental authority is not absolute. In the case of Miller v HCA, the parents of an infant born at 23 weeks’ gestation who received resuscitation sued the hospital for providing treatment against their consent. The court held that the hospital was not liable, stating, “[A]lthough parents have a right to determine health care decisions for their children, this is not an absolute right, and the state also has an interest in the health of children.” The best interests of the infant in this case include maintaining an adequate airway (so as to maintain life) and being comfortable while intubated. The minimal risks of morphine clearly outweigh the potential risk of losing an established airway in an infant with a critical airway. This should be explained to the parents clearly and compassionately. Furthermore, the parents should also be prepared for the post-operative period, which will undoubtedly require attention to pain and additional administration of narcotics to ensure comfort and safety.
Who should make decisions for the infant if there is a disagreement between the parents and the medical team?

In emergency situations (e.g. respiratory or cardiac arrest in the NICU), clinicians are generally protected by law to provide life-sustaining interventions (LSIs), even without parental permission given time constraints. For example, the Emergency Medical Treatment and Active Labor Act (EMTALA)\(^4\) is a federal law that mandates that hospitals stabilize any patient who presents to the emergency department (ED) with an emergency condition. Although initially intended to apply only to the ED, it has been extended to other areas of the hospital. This law does not directly apply to patients but rather mandates that each individual state develops laws to ensure the availability of emergency medical services for all patients. The American Academy of Pediatrics (AAP) has issued a policy statement supporting just care, stating that, “all children deserve effective medical treatment that is likely to prevent substantial harm or suffering or death.”\(^5\) While policy statements differ from law, they generally provide a solid framework for decision-making. Abiding by such national policies and guidelines would certainly help to support clinicians should a case actually end up in court.

There are only a few legal cases involving neonates that have received nationwide attention. In the above case of *Miller v HCA*, the supreme court of Texas stated, “[P]arents have no right to refuse urgently-needed life-sustaining medical treatment to their non-terminally ill children.”\(^2\) This ruling, only applicable in Texas, supports providing emergency care for children, absent life-limiting illness or some pre-existing legal document of limitations of medical treatment (e.g. a Medical Orders for Life-sustaining Treatment (MOLST) form). In the case above, if Richard needed sedation to permit safe re-taping of his endotracheal tube, then clinicians should feel confident in administering appropriate medications. In non-emergent situations, there may be sufficient time to consult hospital legal counsel for further assistance. In rare cases, referral to state child protective agencies may be appropriate and a court-ordered guardian may be necessary only as a last resort to provide consent for treatment. Thankfully, this situation is infrequently encountered in the NICU, as parents and clinicians generally act as a team to provide the best medical care possible for neonates.

**Case #2 Summary**

A pregnant woman, Kayla, presents to the Emergency Department in active labor. She has received no medical care throughout pregnancy, but is estimated to be term or near term. A brief medical history reveals that she is a 45-year-old G5P4 woman with no major medical problems. Kayla has previously given birth to four healthy infants at term. She admits to recreational use of benzodiazepines over the past few years, but denies any other illicit or prescribed drug use. She adds that fetal movement during this pregnancy has been much less compared with her previous pregnancies, but she attributed this to the benzodiazepines, saying they “make the baby sleepy.” The obstetrician quickly performs a limited ultrasound to determine fetal presentation prior to delivery. The ultrasound shows suspected anencephaly, and the NICU team is urgently consulted. As the NICU fellow, you explain to Kayla the likely diagnosis of anencephaly and extremely poor prognosis. She insists that her child receive all resuscitative measures possible. A live-born infant with anencephaly is delivered several minutes later.
**Case Questions**

1. *What laws may be applicable to the care of this infant?*
2. *Are there any similar court cases that may be relevant?*
3. *What moral and ethical arguments could be made to support/withhold resuscitation or intensive treatment?*

**Case Discussion**

*What laws may be applicable to the care of this infant?*

This may differ slightly depending on where in the US the infant is delivered, as different laws govern each state. The Born-Alive Infants Protection Act (BAIPA) is a federal law that was passed by the House of Representatives and the Senate in 2002. The law states:

- “In determining the meaning of any Act of congress…the words ‘person’, ‘human being’, ‘child’, and ‘individual’, shall include every infant member of the species homo sapiens who is born alive at any stage of development.”
- “The term ‘born alive’…means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.”

The Baby Doe Amendments, which were added as an amendment to the Child Abuse Prevention and Treatment Act (CAPTA), were created in response to several controversial cases involving infants with disabilities (see Table 2 in reference #3 below). The amendments, commonly known as the Baby Doe Regulations, were created to prevent “withholding of medically indicated treatment from disabled infants with life threatening conditions.”

The regulations were not intended to require intensive treatment in all cases, however. Specifically, treatment is not required when “…such treatment would prolong dying, not be effective…be futile in terms of survival…be virtually futile…and treatment itself…would be inhumane.”

While it seems that these federal laws and regulations would be applicable in this case, it is difficult to apply federal laws to this particular infant since there may be different state laws that also govern clinical practice. Admittedly, this can be confusing and frustrating since these laws are often difficult to locate and even more challenging to understand and interpret in a clinically relevant context. Fortunately, hospital legal counsel may be available for assistance with specific cases.

*Are there any similar court cases that may be relevant?*

This case has some similarities to the case of *Baby K*, an infant born with anencephaly in Virginia in 1992. After receiving initial care in the NICU, the infant was eventually discharged home. However, she was subsequently brought to the emergency department on several
occasions for respiratory distress, frequently requiring intubation for stabilization. The case was brought to the Virginia Fourth Circuit court of appeals where the medical team argued to avoid intubating her due to poor quality of life and futility. However, the court held that since the infant was presenting to the Emergency Department in respiratory distress, and intubation is a standard treatment for any patient with respiratory failure, the physicians were required to intubate the infant under EMTALA (see above). Some have argued that this ruling undermined the right of physicians to make sound medical decisions.

Interestingly, the limitations of the Baby K decision and EMTALA were discussed just a few years later in the case Bryan v Rectors of the University of Virginia. In this case, an elderly woman was admitted with respiratory distress. She was treated in the ICU for several days without much improvement; the hospital team then instituted a DNR order against the family’s wishes. The patient died several days later and the family sued the hospital for failing to provide stabilizing treatment under EMTALA, which caused the patient to die. The court found that EMTALA was not violated since it only applied to the immediate stabilization of the condition and not ongoing treatment, which was covered by state malpractice laws. In their decision, the courts discussed the case of Baby K stating that “…the requirement was to provide stabilizing treatment of the condition of respiratory distress… The case did not present the issue of the temporal duration of that obligation, and certainly did not hold that it was of infinite duration.”

What ethical arguments could be made to support/withhold resuscitation or intensive treatment?

In support of the view that resuscitation and intervention should be performed in this case, one could argue that since this infant was born alive, she should be granted basic human rights. Core Americas values include, “life, liberty, and the pursuit of happiness.” Happiness, however, is subjective. What makes one person happy may make another person miserable. Medical decisions by parents rely not only on scientific data, but also on individual values, morals, beliefs, and emotions. In one recent study, many parents caring for infants with Trisomy 13 or 18 expressed that physicians often “did not look beyond the grim statistics of these conditions.” Although infants with these conditions often die at a young age, parents generally reported that the child’s life, however short, held significant meaning for their family. This study revealed the stark contrast between physician and family perspectives. Pictures of infants with Trisomy 13 or 18 in medical texts (Figure 2 in reference #12) highlight dysmorphology and disabilities, while pictures submitted by parents (Figure 3 in reference #12), show smiling infants surrounded by their loving families. Thus, informed families should be given wide discretion in such cases.

In opposition, one could argue that providing intensive treatment for an infant with anencephaly is not ethically justified. Most infants with anencephaly lack the majority of the cerebrum, skull and scalp. Up to 75% are stillborn, and the majority of those that survive often live for only days to weeks, although some can live longer, months to a few years. There are no neurosurgical options. There is debate regarding the ability of infants with anencephaly to interact with others and the environment, or to have a meaningful life. Many people would judge the quality of life of these infants to be extremely poor, even unacceptable. Some physicians may feel uncomfortable providing resuscitative care for patients who are anencephalic or who have such an extremely poor perceived quality of life.
This is certainly a challenging case with no clear best answer. Thus, parental preferences should generally be upheld. Although most of the medical community would support non-intervention based on “futility”, the concept of futility is highly debated and certainly subjective.\textsuperscript{15} The American Thoracic Society recently published joint guidelines on potentially inappropriate treatments in intensive care units. These guidelines state that, “the term ‘futile’ should only be used in the rare circumstance that an intervention simply cannot accomplish the intended physiologic goal.”\textsuperscript{16} Instead, the term “potentially inappropriate should be used…to describe treatments that have at least some chance of accomplishing the effect sought by the patient, but clinicians believe that competing ethical considerations justify not providing them.”\textsuperscript{16}

The policy statement characterizes treatment requests by patients into 4 categories:

1. Futile (not able to achieve physiologic goal, see above),
2. Legally proscribed (prohibited by law, e.g. euthanasia),
3. Legally discretionary (physicians can refuse to administer treatments based on laws or precedents), and
4. Potentially inappropriate (see above).

An algorithm (Figure 1, reference #16) and a table including appropriate steps one should take to achieve conflict resolution are also available (Table 4, reference #16). Most importantly, the clinician should not act in isolation, but rather seek input from other colleagues, and the hospital ethics committee.

Parents are entitled to request, and infants are entitled to receive, appropriate medical treatment, particularly in emergent circumstances involving unclear prognoses. As moral agents, physicians should not be required to provide care contrary to their beliefs, although this occasionally may be unavoidable in practice. For instance, if there were only one provider available at a precipitous delivery of an infant with anencephaly, then it would be inappropriate to refuse to provide care in such an emergent situation, given insufficient time to identify another physician. Time permitting, however, it would be best to consult a multi-disciplinary team including legal counsel, ethics, social work, and other colleagues to work with the medical team and family together to agree upon the best course of action. Ideally, this would occur before delivery. If the infant were delivered without adequate time for counseling and a mutually agreed-upon treatment plan, one approach would be to provide a trial of resuscitation and see how the infant responds in the NICU. The medical team could continue to discuss different treatment options, including withdrawal of life-sustaining measures, with the parents.

Developing the physician-parent relationship over time often leads to improved communication and resolution of disagreements.

**Conclusion with Suggestions**

Ethics and the law often intersect in the NICU. In most cases, parents and physicians will agree upon appropriate goals and treatment (whether cure-oriented or not), which align with the law, legal precedents and court cases. However, challenging cases may occur in which physicians and parents strongly disagree upon the best course of action. Ethical dilemmas in neonatology often operate along a spectrum. On one end, medical decisions or treatments are clearly harmful to infants with little to no benefit. On the other end of the spectrum, medical decisions or treatments are clearly beneficial with little to no harm. In the middle exists a murky area where ethics, goals, values, hopes, science and the law all must be weighed together with
the family to determine the best course of action. The authors strongly encourage physicians to become familiar with local laws and regulations, and seek consultation with hospital ethics committees and legal counsel for assistance with these difficult cases.

References