Neonatology and the Law
Jonathan M. Fanaroff and Gilbert I. Martin
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Neonatology and the Law

 objectives After completing this article, readers should be able to:

1. Discuss the current state of medical malpractice in the United States.
2. Delineate malpractice risks that are specific to neonatology.
3. List common causes of malpractice lawsuits in neonatology.
4. Identify strategies to minimize the risk of malpractice lawsuits in neonatology.

Abstract

Neonatologists are at particular risk for malpractice. Among the medical legal issues specific to clinical neonatology are newborn resuscitation, brain injury in the newborn, hyperbilirubinemia, and group B streptococcal infection. Neonatologists can minimize the risk of malpractice by maintaining competency, honing communication skills, and maintaining detailed and timely documentation.

Introduction

Neonatologists often worry about potential malpractice liability, and there are valid reasons to be concerned. Indeed, the first American liability crisis occurred in the early 1970s, at just the same time as many neonatal intensive care units were being opened. Since then, neonatologists have faced higher and higher malpractice premiums and seen jury verdicts skyrocket.

Neonatologists are at particular risk for malpractice for a number of reasons. First, juries tend to treat babies with enormous sympathy. Justice Maynard noted that “deceased babies inflame juries with passion, causing them to run amok . . . [by] . . . throwing large sums of money at the grieving parents.” Second, some common problems, such as delivery room management or failure to treat group B streptococcal (GBS) infection adequately, can lead to severe long-term injuries. Third, because neonates are at the beginning of their lives, their lifetime costs of care easily can run into millions of dollars.

Overview of Medical Malpractice

Overall United States tort costs reached $261 billion in 2005, which amounts to approximately $3,500 per year for a family of four. Medical malpractice is one of the largest areas of growth in United States torts, with costs totaling $29.4 billion in 2005. This has led to increased malpractice insurance costs. The American Medical Association currently considers 17 states to be in a medical liability crisis.

The last 30 years have seen three malpractice crises, and as health policy researcher Michelle Mello notes, “There is every reason to suspect there will be a fourth.” The reasons for each are complex and varied, but generally involve some combination of an increased number and cost of claims compounded with decreased availability of affordable malpractice insurance. During each crisis period, many influential interest groups from all sides of the debate lobby legislators with different agendas and demands. This leads to a number of legislative responses and reforms that may make a difference but, as of yet, never have created a permanent solution to the malpractice problem.

Pediatricians have the fourth highest average indemnity, following neurology, neurosurgery, and obstetrics/gynecology. Neurologically impaired infants represent the most...
At the heart of the debate lie two important truths. The first is that malpractice does occur and that patients are injured or die as a result. The Institute of Medicine published in 2000 the landmark report *To Err Is Human: Building a Safer Health System*, which estimated that errors in United States hospitals cause the deaths of 44,000 to 98,000 patients per year. This report greatly increased public awareness and anger toward medical errors, and physicians are being held accountable for many of these errors.

The second truth is that there are many unwarranted claims filed against physicians. Studies have shown that most patients who are injured as a result of negligence do not sue, and many patients who sue are not injured as a result of negligence. A recent *New England Journal of Medicine* study comprehensively examined a random sample of more than 1,400 closed malpractice claims (including 271 plaintiffs younger than 1 year of age). Approximately one third of the claims did not have merit, meaning that the adverse outcome was not attributable to error.

Neonatologists care for critically ill babies who often are at high risk of a poor outcome (Table 1). Patients who have severe injuries often are more likely to sue. In the study of malpractice claims discussed previously, 80% of the claims involved patients who died or had a significant or major disability. Poor outcomes are common in neonatology, frequently through no fault of the clinicians; it can be very difficult to predict outcomes at the time a particular treatment decision needs to be made. In addition, the rapid advance of neonatology over the past few decades, along with selective media reporting of “miracle babies,” may raise unrealistic expectations.

The fact that neonatologists do not always control outcomes, or being sued for them, does not mean that they should not take proactive steps to try to minimize legal risks (Table 2). Strong clinical practice, clear documentation, and good communication are essential components of quality care in any area of medicine. Furthermore, some mistakes and errors occur more frequently in neonatology, putting neonatologists at particular risk, and need to be discussed in more depth.

### Medical Legal Issues in Clinical Neonatology

#### Newborn Resuscitation

The success of the Neonatal Resuscitation Program (NRP) has resulted in changes in the approach to newborn resuscitation that are offered as guidelines. Does a “guideline” represent the standard of care? If the clinician deviates from the suggested timeline, does this represent a breach in the standard of care? Many of the guidelines suggested by NRP are evidence-based, creating a greater need to follow protocol. However, very little variation is offered in the timeline, and the clinical judgment of the physician is not even considered. Most of the medicolegal implications for a “deficient resuscitation” involve sloppiness, delay, miscommunication, and most important, the perception of ineptness by close observers.
Timing of Brain Injury in the Newborn
Hypoxic-ischemic injury can occur in three periods: antepartum, intrapartum, and neonatal. In a recent publication entitled “Neonatal Encephalopathy and Cerebral Palsy,” produced by a collaboration between the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), specific essential criteria are delineated that must be present to label an intrapartum hypoxic event as sufficient to cause cerebral palsy. Five criteria are listed that collectively suggest intrapartum timing with close proximity to labor and delivery. Deficiencies in this approach remain. For example, the lack of collection of cord blood gas precludes the diagnosis of an acute intrapartum hypoxic event that is sufficient to cause cerebral palsy. Studies have shown that the antepartum period more often is involved in the causation aspect of hypoxic-ischemic encephalopathy and, therefore, the medicolegal system is putting emphasis in the wrong place. In the future, the use of sophisticated imaging techniques should add to the understanding of neurologic pathophysiology and assist in the timing of neonatal neurologic disease.

Hyperbilirubinemia
The medicolegal issues dealing with hyperbilirubinemia include not performing a screening evaluation, incomplete charting regarding jaundice, lack of recognition of high-risk conditions, not measuring total serum bilirubin (or using the bilimeter) if jaundice is noted clinically, and incomplete follow-up after discharge from the nursery. The AAP has provided clinicians with nomograms and algorithms to assist in identifying and treating infants who are at risk.

Group B Streptococcal (GBS) Infection
The obstetrical and neonatal communities have made great strides in decreasing the incidence of GBS disease in neonates. The institution of universal culturing has identified the fetus at risk and has provided a strategy for using antibiotics in labor. However, medicolegal implications remain, including the dose/duration of intrapartum antibiotics, the realization that early neonatal death still can occur despite administration of intrapartum and neonatal antibiotics, and the “gray area” for duration of neonatal therapy if it is used. The guidelines offered by the AAP and the Centers for Disease Control and Prevention are clear on the management of both mother and neonate.

Minimizing the Risk of Malpractice
In addition to paying particular attention to high-risk areas in neonatology, more general strategies can minimize legal risks. No strategy guarantees that a physician will not be sued, but the risk that a patient will sue can be reduced.

The Institute of Medicine report Crossing the Quality Chasm: A New Health System for the 21st Century found serious deficiencies in the quality of care in the nation’s health system. Creating a culture of safety, including analyzing errors and implementing steps to prevent them from occurring in the future, should decrease the number of adverse outcomes.

Neonatologists can decrease liability risk as well as fulfill their moral responsibility to patients by maintaining competency. Neonatology is a rapidly changing field. Not too long ago, dexamethasone was used routinely to wean preterm babies who had chronic lung disease from the ventilator. Further study of this practice, however, revealed possible long-term neurologic problems, and now dexamethasone rarely is used for this purpose. It is only by keeping current that neonatologists could recognize the issue and change their practice appropriately.

Communication skills are essential to the safe practice of modern medicine, especially in the round-the-clock team-oriented environments of neonatal intensive care units. Many malpractice errors originate with poor communication, leading to missed laboratory results, failure to recognize an infant who is becoming sicker, and treatment delays. Adapting techniques from other high-risk industries, such as aviation and nuclear submarines, may lead to improved communication and fewer errors.

Communication with the family not only is required morally and ethically, but is the cornerstone of establishing a trusting relationship. Furthermore, communication problems with families make a lawsuit much likelier. One study of plaintiffs’ depositions found that communication was identified in more than 70% of the lawsuits as the basis for negligence. Among the complaints were that plaintiffs felt deserted (32%) or devalued (29%), believed information was delivered poorly (26%), or felt a lack of understanding by the clinician (13%). Communication is a primary skill in medicine that the practitioner must continue to develop throughout his or her career.

Detailed and timely documentation, while important in all clinical specialties, is especially important in neonatology. Because of the long statute of limitations in many states, a lawsuit may not be filed until many years after the alleged malpractice occurs. At this point, the medical record can be one of the most important elements of a successful defense. The neonatologist should
document thoroughly decision-making, the thought process involved, and that the family was kept informed and involved in significant decisions. Furthermore, chart entries must be timely and legible.

Conclusion
Medical malpractice is a source of anxiety and frustration for almost all practicing neonatologists. Fear of litigation can lead to discord, defensive medicine, and the creation of a barrier between the physician and the family. Part of the problem is that physicians feel persecuted and helpless when an angry family threatens to sue. Yet, although there is no way to guarantee that a physician will not be sued, it is a mistake to consider malpractice litigation as a completely random event. Medical malpractice often can be prevented.

Specific high-risk areas in neonatology must be monitored carefully. Effective resuscitation involves the use of properly trained personnel who have functioning and available equipment working as a team according to established guidelines. Infants who are at risk for GBS sepsis should receive a timely evaluation and appropriate monitoring. Neonates who have risk factors for jaundice also must receive appropriate monitoring, including timely follow-up after discharge and education of parents about the identification of jaundice in newborns.

A major problem remains the separation of “guideline” from “policy” and the appreciation of “physician judgment” in following protocols. Protocols, algorithms, and guidelines were developed to assist the neonatologist in caring for patients. Unfortunately, when there is a bad result, legal review may reveal that the suggestions were not followed completely, creating the issue of the supposed violation of the standard of care.

Reforming the malpractice system to ensure access to all patients and to provide disincentives for the filing of frivolous suits and unethical behavior by attorneys and expert witnesses is an important goal. Equally important at the individual neonatologist level, however, is to continue to work to improve patient safety, communication, documentation, and education to ensure that all neonates receive high-quality, compassionate care.

Suggested Reading
Textbook of Neonatal Resuscitation. 5th ed. Dallas, Tex; Elk Grove Village, Ill: American Heart Association/American Academy of Pediatrics; 2006
NeoReviews Quiz

6. Neonatologists are at risk for malpractice liability, with the average indemnity falling only behind that of physicians in neurology, neurosurgery, and obstetrics/gynecology. Of the following, the most prevalent patient condition in neonatology malpractice suits is:
   A. Blindness from retinopathy of prematurity.
   B. Delayed diagnosis of congenital heart disease.
   C. Neurologic impairment.
   D. Sensorineural hearing loss.
   E. Vascular catheter complication.

7. The Neonatal Resuscitation Program (NRP) has standardized the approach to neonatal resuscitation, resulting in promulgation of guidelines. Of the following, the most important determinant of medicolegal risk related to neonatal resuscitation is:
   A. Delay in resuscitation.
   B. Deviation from the NRP protocol.
   C. Miscommunication with parents.
   D. Perception of ineptness by close observers.
   E. Sloppiness of technique.

8. Whereas no single strategy can safeguard a physician completely from a malpractice suit, there are several approaches that a physician can take in conjunction with his or her institution to minimize the medicolegal liability. Of the following, the most critical strategy for a neonatologist to lessen medicolegal liability is:
   A. Communicating effectively with the patient's family.
   B. Creating an institutional culture of safety.
   C. Documenting in a detailed and timely manner.
   D. Maintaining clinical competency.
   E. Obtaining appropriate consultations.