

Virtual Mentor
American Medical Association Journal of Ethics

October 2008, Volume 10, Number 10: 611-687.
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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 613-615.

FROM THE EDITOR

Ethically Responsible Use of NICU Capabilities

This issue of *Virtual Mentor* explores the complex decisions that advances in neonatal intensive care have forced physicians, parents, and society to confront. The neonatal intensive care unit is widely celebrated as one of the great triumphs of the medical community in the past 30 years. Not only are NICUs credited with highly publicized cases of “miracle babies” born at the extremes of prematurity who go on to become highly successful members of society, they have also emerged as major profit-generating centers for financially challenged hospitals.

The threshold of viability—the age at which neonatologists will consider resuscitating premature infants—has dipped to 23 weeks’ gestation in some centers. This increasingly early threshold for intervention, commonly viewed by the public as a medical triumph, has in turn decreased the gestational age at which obstetricians will perform invasive procedures for fetal well-being, often with major long-term morbidity for the mother. Although the overall survival of these extremely premature infants has increased with the development of sophisticated technological interventions, so too has our understanding of the serious short- and long-term sequelae of prematurity. The short-term morbidities associated with prematurity are described in this issue’s clinical pearl by Tara Randis. Costs associated with intensive care as well as ongoing chronic care for long-term sequelae of prematurity are immense. Moreover, the ability of current treatments to bring extremely preterm infants to childhood both physically and neurologically intact remains tenuous. A large Norwegian cohort studied for 16 years showed increased medical and social disabilities in adults born at decreasing gestational ages, findings that compel us to question the true social cost of resuscitating increasingly premature infants [1].

Challenges for Physicians and Parents

Three clinical cases illustrate ethical challenges that confront NICU physicians. The first case, in which an infant with a possible diagnosis of trisomy 21 is born at 23 weeks’ gestation, examines the limits of parental autonomy in determining whether to resuscitate the extremely preterm infant. Eric Eichenwald, Frank A. Chervenak, and Laurence B. McCullough summarize the clinical facts and physicians’ ethical obligations that are critical in resolving disagreements between parents and physicians over resuscitation.

A NICU team struggles to make difficult treatment decisions in the absence of parent advocates in the second case, raising the question of whether it is possible to develop a rule-based approach to administration of neonatal care. Steve Leuthner and J.M. Lorenz argue that widely accepted, evidence-based guidelines for resuscitation have

been forged, but no rules or guidelines can cover every possible case, and, when the limits of those guidelines are reached, physicians must determine the best interest of the infant at hand.

Balancing the interests of mother and fetus is a constant struggle for obstetricians who encounter women with medical conditions that necessitate delivery at the threshold of viability. The third case explores an obstetrician's dilemma in counseling a woman about a delivery mode that may subject the unborn fetus to significant morbidity and mortality. The reverse of this is also true. Anne Drapkin Lyerly describes the pitfalls in using nondirective counseling with patients concerning the mode of delivery for periviable fetuses. Lyerly makes a persuasive case for framing medical options in a way that offers parents socially and ethically sound choices.

Questions for Society

NICU successes and their place of prominence in U.S. hospitals entreat us to think about our shared social values. What does society's drive to exert effort and resources into resuscitating increasingly premature infants say about us? Does the fact that the Medicaid reimbursements for NICU care are among the program's highest reinforce the idea that we value supporting our most vulnerable members? Or, does it suggest an inability to regulate our own technological advances and an unwillingness to apply them in a more socially prudent manner?

In "Resuscitating the Extremely Low-Birth-Weight Infant: Humanitarianism or Hubris?" Patrick Jones and Brian Carter explain some of the social pressures for resuscitating extremely low-birth-weight infants. And Annie Janvier, in "Jumping to Premature Conclusions," describes how the goals of fertility specialists can conflict with those of neonatologists.

In their health policy commentary, "The Cost of Saving the Tiniest Lives: NICUs versus Prevention," Jonathan Muraskas and Kayhan Parsi detail the resources currently devoted to neonatal intensive care that may be better spent in prenatal care and prevention of preterm birth. Ferdinand Yates' op-ed piece exhorts physicians and parents to work together to decide on treatment for marginally viable premature infants that is in the infant's best interest.

Medical students' and residents' preparation to counsel women giving birth at the threshold of viability is a topic of urgent concern. Katherine Singh and Patrick Catalano describe the challenge of developing and teaching sound ethical judgment in the context of a rigorous obstetrical training program at a county hospital. In her personal narrative, Judette Louis offers her perspective on how delivering her own twins at 25 weeks' gestation altered the way she counsels high-risk patients facing a preterm birth.

Through these commentaries, *Virtual Mentor* readers are invited to explore their own attitudes toward prematurity. Those pursuing careers in pediatrics, neonatology, and

obstetrics/gynecology will grapple daily with decisions about a patient's best interest—from pregnant women to prematurely born infants to concerned NICU parents. Please allow the commentaries and articles that follow to deepen your appreciation for the powerful therapeutic capacity of the NICU even as you develop a sense of our responsibility as physicians to implement this resource in a morally and socially responsible manner.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 616-624.

CLINICAL CASE

Physician and Parental Decision Making in Newborn Resuscitation

Commentary by Eric C. Eichenwald, MD, Frank A. Chervenak, MD, and
Laurence B. McCullough, PhD

An ultrasound performed on a woman who was 23-weeks pregnant revealed multiple findings suspicious for trisomy 21 syndrome, (Down syndrome). The woman and her husband were devastated, saying they could not possibly raise a child with mental retardation and physical anomalies, and they requested a termination. The obstetrician recommended amniocentesis for chromosomal analysis that would give definitive diagnosis of trisomy 21, and the test was performed. The parents said they planned to terminate the pregnancy if the results of the chromosome analysis confirmed Down syndrome.

Before the results were returned, the woman arrived at the labor and delivery unit with a tender abdomen, purulent discharge from the cervix, and high fever. She appeared to have an acute intrauterine infection from the amniocentesis procedure. Antibiotics were started, but it soon became clear that the woman was becoming septic; the obstetrician on call recommended rapid delivery of the fetus. The woman and her husband again clearly stated that they wanted no resuscitation performed on the infant after delivery. The couple and the physicians agreed that, given the probability of a severely anomalous infant, the plan would be to provide only comfort care measures.

The woman's labor was induced and she delivered a liveborn female infant, surprisingly robust. The infant had a strong cry, kicked vigorously, and was much larger than anticipated. The neonatologists examining the infant found themselves reconsidering their decision to withhold resuscitation. Suddenly the seemingly certain prenatal diagnosis of Down syndrome appeared implausible, given the appearance of a strong infant without apparent anomalies. The NICU team realized that, under any other circumstance, resuscitation measures would be well under way; they became uneasy as they watched the premature infant's forceful kicking and energetic cries. Within minutes to hours the female infant's lungs would tire and she would die without respiratory support.

The physicians announced to the parents their decision to reverse their previous plan to withhold care based on the healthy appearance of the neonate. The neonatologist described the resuscitation measures they planned to begin. The parents were infuriated. "We had an agreement," the father retorted. "My wife and I made it very clear to you that we cannot manage an impaired child. This is our decision to make—we're the parents, and it is your duty to respect our wishes."

Commentary 1

by Eric C. Eichenwald, MD

Decisions about whether to provide intensive care to periviable infants remain some of the most difficult in neonatology. These decisions do not occur in a vacuum; rather they are complex interactions among parental concerns and rights; societal norms, which may be regional rather than national; and the neonatologist's opinions about viability and medical futility. The case presented is an excellent example of the potential conflicts among these competing demands, and it helps focus some of the issues surrounding prenatal consultation and parental decision making.

Clinical Facts

So, what are the facts about outcomes of extreme prematurity? We know that below a certain gestational age (approximately 22 weeks), because of immaturity of the major organ systems, death is certain even with aggressive care—hence, providing intensive care is medically futile. With advancing gestational age, the chances of survival increase, though this may come at the cost of significant long-term morbidity, especially in those infants born between 23 and 24 weeks' gestation. For example, in the Vermont Oxford Network (a voluntary network for data collection in more than 650 neonatal intensive care units in the U.S. and abroad), among infants born between 1996 and 2000 with a birth weight of 401 to 500 grams and a mean gestational age of 23.2 weeks, mortality was 83 percent, and survivors often had serious short-term medical complications [1]. The EPICure study reported outcomes for all infants born at a gestational age of 20 to 25 weeks over a 10-month period in 1995 in the U.K. and Ireland. Only 811 of the 4,004 infants (20 percent) received intensive care, and 39 percent of those survived to discharge [2]. Of the survivors, 16.5 percent had ultrasonographic evidence of severe brain injury. Of these surviving infants who were evaluated at 30 months of age, half had a motor, cognitive, or neurosensory disability; in approximately one quarter of the children, the disability was considered severe.

The National Institutes of Child Health and Development Neonatal Research Network recently analyzed outcomes at 18 to 22 months of age of 4,446 infants born between 22 to 25 weeks' gestation at 19 centers in the United States [3]. Of these, 83 percent received intensive care in the form of mechanical ventilation. Of the infants for whom outcome could be determined, 49 percent died, 61 percent died or had profound impairment, and 73 percent died or had impairment (defined as mental retardation, moderate or severe cerebral palsy, blindness, or deafness). Factors in addition to gestational age that were found to affect a favorable outcome to intensive care included being female, exposure to antenatal corticosteroids, singleton gestation, and birth weight. A web-based tool to approximate survival without impairment based on these data is available at the National Institutes of Health web site [4].

How Neonatologists Act on These Facts

How do neonatologists interpret these data when it comes to decisions in the delivery room about resuscitation of an individual infant? A cross-sectional survey of 149 practicing neonatologists in six New England states queried attitudes about whether intensive care was beneficial at different gestational ages [5]. At or below 23-0/7 weeks gestation, 93 percent of the reporting neonatologists considered treatment futile. In contrast, at 24-1/7 to 24-6/7 weeks and 25-1/7 to 25-6/7 weeks' gestation, 41 percent and 84 percent of respondents, respectively, considered treatment beneficial. When asked to consider parental requests, 91 percent of the neonatologists responding reported that they would resuscitate in the delivery room despite parental requests to withhold treatment if they considered treatment to be clearly beneficial.

When respondents considered treatment to be of uncertain benefit, 100 percent reported that they would resuscitate if parents requested, 98 percent reported that they would resuscitate if parents were unsure, and 76 percent reported that they would follow parental requests to withhold. Thus, while parents' requests about their infant's resuscitation influence the neonatologist's decision making in the delivery room, these decisions are also heavily influenced by the physicians' beliefs about the gestational age bounds of clearly beneficial care, which are strikingly variable among physicians.

These data reinforce the need for prenatal consultation with parents prior to the expected delivery of an extremely preterm infant. In the same survey of New England neonatologists, respondents were queried as to the content of prenatal consultation [6]. The results showed that neonatologists consistently discussed the clinical issues anticipated with the expectant parents, but they varied when it came to discussing the social and ethical issues surrounding an extreme preterm birth. Of note, while 77 percent of the neonatologists surveyed indicated they thought that decisions about withholding resuscitation should be made jointly with parents, only 40 percent said that the decision is made by both parties in actual practice.

While it is clear that the consulting neonatologist's beliefs about the benefits of providing intensive care influence how the consultation is performed, it is also evident that how the message is framed to parents influences decisions. In a survey of adult volunteers, a hypothetical vignette of a threatened delivery at a gestational age of 23 weeks was given to participants [7]. Respondents were randomly assigned to receive the same prognostic outcome information framed as either likelihood of survival with lack of disability (positive frame) or the chance of dying and likelihood of disability (negative frame), and asked to decide on resuscitation or comfort care. Overall, 24 percent of respondents chose comfort care, and 76 percent chose resuscitation. More participants chose to provide comfort care rather than resuscitation when the vignette was presented in a negative frame.

In practice, because of the uncertainty surrounding outcomes in periviable infants, after prenatal consultation even, many parents are unable to state definitively

whether they desire resuscitation or not. In these circumstances, it is left to the neonatologist to decide whether to intervene in the delivery room. Many neonatologists use their initial assessment of the infant at birth and the response to initial resuscitative efforts to help them decide whether to proceed with further intensive care. In a study of outcomes of infants with a birth weight equal to or less than 750 grams, proxy measures of “how the infant looked” in the delivery room (Apgar scores and heart rate at one and five minutes) were neither sensitive to nor predictive of death before discharge, survival with neurologic disability, or intact neurologic survival [8].

Guiding Principles for Decision Making

Where are we left with these difficult decisions about what to do in the delivery room when a periviable infant is born? First, prenatal consultation should provide the expectant parents with factual information about survival and outcomes, unfettered by the neonatologist’s personal beliefs. Second, it is essential that the parents’ beliefs and attitudes about quality of life be sought and understood. Finally, respect for the parents as decision makers for their unborn infant must form the basis for these conversations. It must remain clear, however, that after the infant’s birth, the neonatologist’s first duty is to his or her patient—the newly born infant. While the judgment to offer resuscitation to an individual infant should be heavily influenced by the parents’ wishes, if clinical circumstances are found to be different after birth than was expected, the physician must first consider the rights of the baby.

This case presents exactly that dilemma—a prenatal diagnosis which is unconfirmed, and an infant perhaps more mature and vigorous than expected. Here, several errors may have been made which influenced the parental decisions. It is unclear whether the parents were provided a sense of the uncertainty of the diagnosis of trisomy 21 based on the ultrasound findings. Many findings “associated” with an aneuploidy may also be seen in a normal fetus. When the mother developed chorioamnionitis after the amniocentesis, the decision to resuscitate the infant needed to be reconsidered and discussed with the parents in the context of what to do if the diagnosis of trisomy 21 was incorrect. It is possible that the parents, when provided with the full information about the outcomes of extreme prematurity, might have chosen resuscitation in the absence of a chromosomal abnormality.

Lastly, as is true for any prenatal consultation, uncertainty about the gestational age needs to be clarified—it is clear that differences of 1 week of gestation can profoundly alter outcome and influence the decision to provide intensive care. While the neonatologist does indeed have a duty to respect the parents’ wishes, he or she also has an obligation to provide care that is, in his or her opinion, beneficial to the baby. I would argue in this case, since the gestational age of the infant is certain to be 23 weeks or less, our knowledge of outcomes would swing the first duty to the parent’s strongly expressed wishes for no resuscitation, and, regardless of the condition of the infant after birth, comfort care would be appropriate.

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Commentary 2

by Frank A. Chervenak, MD, and Laurence B. McCullough, PhD

This case involves the physician’s ethical obligations to a pregnant woman and her husband during pregnancy and also the physician’s ethical obligations to a neonatal patient and its parents after liveborn delivery. The difference between these two sets of ethical obligations is crucial for understanding how the team should respond to the refusal of intervention by the child’s parents.

The Pregnant Woman as a Patient

The physician’s ethical obligations to a pregnant woman are both beneficence-based and autonomy-based. As her fiduciary, i.e., a professional committed to protect and promote her health-related interests, the physician has a beneficence-based obligation to offer, recommend, and perform clinical interventions that are reliably expected to result in the greater balance of clinical goods over clinical harms for the woman in the course of her pregnancy. Pregnant women have their own perspective on health-related and other interests, and the ethical principle of respect for patient autonomy obligates the physician to provide the pregnant woman with the

information relevant to her decisions about the clinical management of her pregnancy and then to implement only those clinical interventions that she authorizes as a result of the informed consent process [1].

The Fetus as a Patient

The physician also has beneficence-based obligations to protect and promote the health-related interests of the fetus, but only when the fetus is a patient. The physician does not have autonomy-based obligations to any fetus, because its developmental state does not support the complex psychosocial functioning by virtue of which an individual generates its own moral status. In the language of ethics, the fetus is not capable of generating independent moral status or rights, hence the concept and discourse of fetal rights are best avoided in determining a physician's ethical obligations to a pregnant woman.

The fetus is a patient when it is presented to a physician or other health care professional for clinical interventions. In the language of ethics, the fetus has dependent moral status when there are links between its current existence in utero and its later becoming a child. Before viability (the ability of the fetus to survive ex utero with full technological support) the only link between a fetus and its later becoming a child is the pregnant woman's autonomous decision to confer the dependent moral status of being a patient on her fetus. Prior to viability the pregnant woman is free to withhold conferring moral status or, having conferred it, to withdraw it.

When a woman presents herself to a physician or other health care professional after viability (typically after 24 weeks' completed gestation by reliable ultrasound dating), the fetus is a patient, and the physician has beneficence-based obligations to protect and promote its health-related interests. We emphasize that the fetus is not a separate patient, because these beneficence-based obligations must always be balanced against the physician's autonomy-based and beneficence-based obligations to the pregnant woman [1].

It is well accepted in obstetric ethics that a pregnant woman is free to withdraw the conferred moral status of being a patient from a previable fetus whether the fetus has an anomaly or not. Therefore, a woman is free to continue or end her pregnancy in either case. When there is a suspicion of trisomy 21 with ultrasound late in the second trimester, the obstetrician should attempt to resolve this uncertainty as expeditiously as possible with invasive genetic diagnosis.

In this case scenario, the physician would have been ethically justified to offer the pregnant woman invasive intervention to cause in utero fetal death by intracardiac potassium chloride injection before labor was induced [2]. A major preventive ethics aspect of this case, unmentioned in the scenario, is that this option should have been discussed with the parents by the physician. Because the fetus is previable, the pregnant woman's autonomous decision making determines whether or not it has conferred status as a patient. Had she decided to withdraw the status of being a

patient from her fetus at that time, it would no longer have been a patient. Terminating the life of a previable fetus in utero does not violate any professional, beneficence-based obligations to a fetal patient and is therefore permissible in obstetric ethics.

If her pregnancy had continued to viability, then the fetus would have become a patient. We have argued elsewhere that it is permissible to perform an abortion of a viable fetus but only when one of two conditions is met: “a very high probability of a correct diagnosis...[with] either (a) a very high probability of death as an outcome of the anomaly diagnosed or (b) a very high probability of severe irreversible deficit of cognitive developmental capacity as a result of the anomaly diagnosed” [3]. Neither condition, we emphasize, can be competently judged to be met by presence of Down syndrome, much less the increased risk of Down syndrome. Therefore it would be unethical to perform termination of a viable pregnancy in this context.

The Neonate as a Patient

A fundamental component of the ethical concept of the previable fetus as a patient is that this moral status is a function of the pregnant woman’s autonomous decision to confer it. In contrast, infants born alive in the presence of health care professionals become patients independently of the autonomy of their parents. This is because the general ethical concept of being a patient requires only that the human being in question be presented to a physician or other health care professional and that there exist clinical interventions that are reliably expected to result in the greater balance of clinical goods over clinical harms to that human being. Moreover, parents of a liveborn infant become his or her moral fiduciaries, and they, too, are obligated to protect and promote the health-related interests of their child. Thus, a liveborn infant simultaneously acquires two kinds of mutually reinforcing moral status—one as a patient of health care professionals to whom the infant is presented and a second as a child of his or her parents. As their child’s fiduciaries, parents have a beneficence-based obligation to authorize clinical intervention when their child’s health care professionals have beneficence-based obligations to intervene [4].

Neonatal resuscitation and subsequent neonatal critical care management are understood to be trials of intervention. They are undertaken to achieve the short-term goal of preventing imminent death and the long-term goal of an acceptable clinical outcome. For infants, acceptable outcomes should be understood from a clinical perspective: is continued critical-care intervention reliably expected to preserve some interactive capacity that will support some psychosocial development that is not overwhelmed by the child’s condition or the iatrogenic complications of treatment?

The ethical analysis of the neonate’s status as a patient has important clinical implications in this case. The outcomes for infants born at reliably estimated 23 weeks’ gestation vary according to the infant’s sex, its singleton versus multiple status, and administration of steroids [5]. Outcomes also vary by the presence and severity of anomalies [6, 7].

Resuscitation and transfer to the neonatal intensive care unit (NICU) is reliably expected to prevent this neonate's imminent death, hence the short-term goal of clinical intervention, preventing imminent demise, can be reasonably expected to be achieved for this patient.

Concerning the long-term goal of achieving an acceptable clinical outcome, we note that this infant was a singleton and is female, factors that increase her chance of survival and decrease the risk of developmental impairment. In addition, no anomalies have been identified. Even if trisomy 21 had been confirmed by genetic evaluation, that anomaly cannot be reliably predicted to eliminate interactive capacity and psychosocial development; most infants with Down syndrome have mild or moderate mental retardation, both of which are compatible with significant psychosocial development.

The father's express concern that he and his wife are not able to manage an impaired child has uncertain bearing on decision making at this time, because a prediction that their child would be significantly developmentally impaired as a result of extreme prematurity is uncertain. It is ethically impermissible for the team to discontinue clinical management of this neonatal patient at this time, because it cannot be reliably expected that the second goal of critical care intervention—an acceptable clinical outcome—will not be achieved.

The judgment that there is sufficient clinical and ethical justification to resuscitate and transfer the infant to the NICU should be explained to both parents. They should be counseled about continuing clinical management as a trial of intervention that will be reconsidered should evidence-based clinical reasoning subsequently support a prognosis of imminent death that cannot be prevented or of irreversible, profound loss of developmental capacity from the child's condition or iatrogenic complications.

Another preventive ethics aspect of this case is that both parents should be informed prior to birth, that when physicians and other health care professionals have a fiduciary, beneficence-based obligation to continue clinical management, parents have a directly parallel fiduciary responsibility to authorize such management. The goal of the discussion should be to prepare the parents for the shift from obstetric to neonatal ethics and the relatively diminished force of parental autonomy in the latter circumstance. We have argued that these parallel and mutually reinforcing fiduciary obligations are still substantial despite predicted caregiving burdens [1, 3].

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 625-634.

CLINICAL CASE

Can Rule-Based Ethics Help in the NICU?

Commentary by Steven R. Leuthner, MD, MA, and J.M. Lorenz, MD

The NICU team was called to the trauma bay of the emergency room where obstetricians had just performed a perimortem cesarean section on a pregnant woman who died on arrival to the hospital after a vehicle crash. The NICU team successfully resuscitated the infant after several attempts. The neonatologist evaluated the infant, a male, and estimated him to be 26 weeks' gestation. The infant's condition deteriorated over the next few days, and he required intubation, ventilatory support, and IV medications to maintain his blood pressure. No family members came forward to claim the extremely premature infant.

The infant developed large bilateral intracranial hemorrhages and had daily seizures. He became septic and hemodynamically unstable. On several occasions the NICU team considered withdrawing care, but ultimately the decision was made to continue. Over months he gradually recovered, but it became clear that the baby was severely neurologically impaired; his body took on rigid postures and he had recurrent seizures. He was unable to suck and relied on tube feeds for nutrition. He barely responded to external stimuli. When he was finally discharged as a ward of the state to a long-term care facility for neurologically impaired children, the cost of the infant's care exceeded several hundred thousand dollars.

The executive board of the hospital convened a meeting with the ethics committee and the NICU staff to develop a policy for such cases. A member of the executive board stated that the hospital's budget was too tight to provide hundreds of thousands of dollars of care in medically futile cases when they could help hundreds of other infants with the same funds. The board argued that the social and financial costs of prolonged NICU stays for infants destined to be wards of the state surpassed the care capabilities of the hospital. One particularly blunt executive stated, "No one wanted that baby to live; the mother is gone, there is no family, the baby himself kept trying to die and you all wouldn't let him, and now he's in a lonely institution his whole life as a permanent vegetable, all at taxpayers' cost of a half-a-million dollars—who are we helping here, guys?"

A resident physician proposed a rule-based approach to resuscitation decisions: "Why do we struggle with this same decision with every delivery of a 500-gram infant? We need to set up guidelines that will take the difficulty out of these tough situations. Let's make a standard policy of when to resuscitate and when to withdraw care—we could take some of the agony out of these situations." A more senior physician disagreed: "The practice of medicine is not a cookbook. If a set of fixed

rules governed all of our resuscitation decisions then we may as well have the accountants take over. A universal policy would destroy the art and humanity of medicine.”

Commentary 1

by Steven R. Leuthner, MD, MA

To answer whether it is possible to practice rule-based ethics in the NICU, we must first discuss reasons for—and problems with—rules. The first argument against rule-based ethics is that there can never be enough rules to cover everything we recognize as an ethical situation. This is due to the complexity of life. The promulgation of rules to serve the entirety of our ethical dimension can encourage an “exception” or loophole mentality so that the practice of ethics becomes one of manipulation. A second problem is that rules often conflict. Do we create more rules to adjudicate conflicts among rules? What if those meta-rules conflict? In an obvious example, two of the most basic ethical principles for physicians—act in the patient’s best interest and respect the patient’s right to make his or her own health care decisions—often conflict.

A third potential problem is that, at its core, rule-based ethics represents a legalistic approach, which is perhaps why no one really seems too pleased with outcomes of legal cases in these situations. Focusing on rules and actions makes us think of ourselves in terms of what we do, and not who we are and who our patients and families are. In the end all rules need interpretation.

So do we simply forget about rules? We really cannot do without some rules. Not to follow any rules is itself a rule. Rules are essential for understanding the difference between what is indisputably right and what is indisputably wrong, helping define the main parameters of what is expected of everyone. They coordinate human behavior in a rough and ready way. Rules function as helping guidelines or synopses of cumulative moral experience and wisdom. They can clarify fundamental issues at stake in a practical problem. So while rules may have problems when they are the end of the ethical discussion, they have some benefit when they help outline and begin the ethical decision making.

Keeping these general concepts in mind in this case, and for the NICU in general, there are two areas where we can explore the possibility of some rule-based practice. The first is resuscitation in the delivery room, and the second is determining rules of withdrawal of treatment.

The Decision to Resuscitate

Of the two topics, the area of delivery-room resuscitation at the limits of viability has the more robust literature with recommendations and discussion about rules. The ethical debate has narrowed the range of deliberation to a few weeks and a few hundred grams. Despite a lot of talk that seems to indicate that much controversy surrounds this issue, most of the published recommendations are very similar [1-5].

The Nuffield Council on Bioethics confirms much of the published recommendations that before 22 weeks there should be no resuscitation, 25 weeks and beyond should require resuscitation, and the 22- to 24-week range remains the gray area [6]. Within this gray area there can be guidelines with recommendations and exceptions. For example, the Nuffield Council recommends resuscitation in the 24th week unless parents and physicians agree that doing so is not in the baby's best interest. It recommends that at 22 weeks there be no resuscitation unless parents request it after full disclosure of information and risks. Here we are getting into rules that allow both medical and parental values to come into play.

While these rules are helpful, there are some potential weaknesses. A common argument against them is the claim that gestational dates cannot be certain; only after the neonatologist's physical assessment of the baby, and perhaps even its response to resuscitation, can one make the final determination. This "out" is not really justifiable except in situations where there is no prenatal care, however, because data support that obstetrical dating of gestation is the most accurate, that neonatologists overestimate maturity [7], and, there is no real evidence that response to initial resuscitation is prognostically significant other than when it doesn't work [8]. There is concern that this argument—uncertainty about gestational age—reflects discomfort in allowing a baby to die or serves as an excuse to follow the rule of resuscitating all life. The concern arises in part because the argument can be used by a neonatologist to justify overriding the parental request not to resuscitate, ignoring the medical evidence of overestimated maturity to support their interest in saving a life. In these cases, physicians' values trump the parental values.

Despite the potential concerns of abusing or manipulating the rules, they can be useful guides for discussion and, again, are fairly well agreed upon. Whether they should remain practice-based guidelines that offer a starting point for discussions within a practice and with patients or should become hospital policy is another question. Hospital policies seem to hold more weight, require more justification to break, and may lead to more legal concerns than practice-based guidelines.

In the clinical case we are considering here, a policy or set of guidelines would have led to the same initiation of the emergency cesarean delivery and resuscitation because there was no prenatal information, making the neonatologist's estimation of the newborn to be at 26 weeks' gestation the best medical information. One of the ethical justifications for resuscitating preterm infants at 23-24 weeks is that this gives them a chance at life and allows response to treatment to be assessed, on the understanding that treatment can be withdrawn if the infant does not respond to medical care [9]. This course of action is consistent with the ethical principle that there is no distinction between withdrawing and withholding treatment (contrary to the thinking that prevailed when resuscitation capability was in its early days that, once begun, withdrawing care called for greater justification); in fact, it may take greater ethical justification to withhold than withdraw treatment. Hence our second question, can there be rules to address withdrawal of treatment in the NICU?

Withdrawal of Life-Sustaining Treatment

This is a far more difficult question with fewer published studies for guidance. The palliative care literature suggests that there are three categories of neonates that might be suited for palliative care: those at the limits of viability, those with congenital anomalies considered incompatible with prolonged life, and those with overwhelming illness [10, 11]. In our case, the newborn's gestational age is thought to be 26 weeks, which is above what most consider the limits of viability, and he has no described anomalies incompatible with life. Does the infant meet the criteria of overwhelming illness? It seems that the NICU team was at least questioning this when it discussed and decided against stopping treatment. It sounds like the executive on the hospital board thought the infant had overwhelming illness, or at least didn't like paying for the illness he did have. The question is, "How is 'overwhelming' defined?" Or more importantly, "Who defines it?"

The Sanctity-of-Life Rule. One simple and objective rule is that we should try to keep everyone alive no matter what it takes—the sanctity-of-life approach. If the infant dies despite our maximal effort, that is acceptable. This is the classic wait-until-certainty approach first described by Rhodan [12]. There are parents who make this choice, and there is concern that the law might require that this rule be followed; namely that, unless the infant is in a persistent vegetative state, it would not be in its best interest to be allowed to die [13]. The problem with this requirement is that it makes all infants objects of technology and all physicians servants of technology. While it may be acceptable for parents or families to choose the sanctity-of-life approach for their infant, it does not seem fair to enforce that same value-based rule for all infants and families.

A majority of people appreciate that there can be an outcome worse than death, mainly that of a life of intolerable deficits and burden [14]. As Kipnis points out, the difficulty here is that, on the technological continuum with its goal of saving a life, death occupies the extreme position, followed by survival with intolerable deficits and then survival with tolerable-to-no deficits. On the moral continuum of desired results, survival with intolerable deficits occupies the extreme position, followed by death and then by survival with tolerable or no deficits.

The Quality-of-Life Approach. So what can be the rule to overcome the uncertainty of predicting deficits in the first place, or in deciding what is intolerable? In other words, what quality of life, or what burden of continued care for a particular level of benefit is acceptable, and who makes this decision? Is there a rule that in this case would have allowed the physicians to withdraw care? Once the large bilateral intracranial hemorrhages and seizures occurred, the physicians could predict a significantly poor neurologic outcome. This is why they had discussions about whether to continue or not. In the end they either chose to follow the technological vector or they happened to value the sanctity-of-life approach. The real difficulty with this case was that physicians had no surrogate decision maker, i.e., parent, to help them morally evaluate whether the poor prognostic outcome met the criteria for

intolerable deficits. They needed someone, a parent or guardian, to help them make the moral decision.

The Parental-Values Approach. This leads to what I consider the single most important rule in helping make these types of decisions, namely that parents bring the moral values that most reliably determine what is in the best interest of preterm infants in most situations [15]. They should be informed of the potential spectrum of long-term outcomes—neurologic, pulmonary, etc.—and then be offered withdrawal of support if they determine these to be intolerable. It can always be argued that there are limits to parental authority. But the responsibility is upon the professionals to have the certainty and outcome data to override that authority. It is this certainty and outcome data that allow us to come up with some of the guidelines for delivery-room resuscitation such as the Nuffield Council recommends. Of note, there are exceptions at 22, 23, and 24 weeks precisely because our certainty is less, and the risk of what many consider intolerable deficits is high enough to allow a moral choice. Parents are the ones who have to live with this choice, so they must be given the ability to choose based on their moral values.

In this particular case, because there is no parent to make any moral choice, the physicians should have had a guardian appointed. While most guardians in these circumstances do what the physicians recommend, having one would have opened up discussion, particularly about legal concerns the physicians may have had in allowing the baby to die. Of course the costs to society in cases like this, as suggested by the hospital executive, can also provoke discussion about bigger societal rules for consideration.

In conclusion, there are some reasonable delivery-room resuscitation rules or guidelines to consider that have acquired consensus. Whether these need to be formal hospital policy may be institutionally decided. However, once in the NICU, it is more difficult to make a rule-based set of guidelines specifically for this population. The accepted moral rule at this time is to determine the best interest of the neonate. Reasonable people can differ in their opinions about sanctity and quality of life and, because of this, it seems ethically sound that the rules for decision making should be based on moral values.

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Commentary 2

by J.M. Lorenz, MD

Before addressing whether it is possible to practice rule-based ethics in neonatal intensive care units, several suppositions made in the case must be examined.

The first supposition is that a rule is needed because there is no process in place to make management decisions under circumstances and a rule would obviate the need for an onerous process. But there is such a process in place: the appointment by the

court of a guardian *ad litem*. How this process is initiated, who or what agency may function as a guardian *ad litem*, and how decisions are made within this structure vary among jurisdictions. While use of a guardian *ad litem* is admittedly not as satisfactory as having parent decision makers, the guardian represents *the best interests of the infant* distinct from the interests of the health care team, hospital, or state. This process grants primacy to the best interest of the patient in health care decisions for those who have never had capacity to do so for themselves; it is a principle espoused by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Sciences [1]. Rule-based ethics may assist this process, but cannot substitute for it.

The second supposition is that the benefit-burden ratio of intensive care for the infant in this case was low enough to have ethically justified withholding care. Since intensive care was clearly effective in promoting survival of this infant, the questions become: is quality of life ever a sufficient criterion to justify withholding or withdrawing intensive care and, if it is, how severely diminished must that quality of life be? There is an almost universal belief that human life has intrinsic value and ought to be preserved. One extreme of this principle holds that *biological* human life has intrinsic value and ought to be preserved without regard to the *quality* of that biological life. Another view holds that only life of some minimum quality to the person ought to be preserved.

Rhoden argues persuasively that “quality of life judgments are appropriate, necessary, and in fact inevitable” in dealing with imperiled newborns [2]. There is, however, no consensus on what constitutes the minimum quality of life that ought to be preserved. The President's Commission concluded:

that a very restrictive standard is appropriate... permanent handicaps justify a decision not to provide life-sustaining treatment only when they are so severe that continued existence would not be a net benefit to the infant... net benefit is absent only if the burdens imposed on the patient by the disability or its treatment would lead a competent decision maker to choose to forego the treatment [3].

The Child Abuse Amendments of 1984 are more specific:

withholding treatment from an infant is permissible only if: (a) the infant is chronically and irreversibly comatose; (b) the provision of such treatment would (i) merely prolong dying, (ii) not be effective in ameliorating or correcting all the infant's life-threatening conditions, or (iii) otherwise be futile in terms of survival of the infant; or (c) the provision of such treatment would be virtually futile in terms of survival of the infant and the treatment itself under such circumstances would be inhumane [4].

Robertson argues that intensive care must be provided only if (in addition to the exceptions specified in the Child Abuse Amendments of 1984) the child possesses or has the potential to possess some threshold level of cognitive ability beyond mere consciousness, specifically “the capacity for symbolic interaction and

communication” [5]. Rhoden proposed preliminary guidelines that aggressive treatment is not mandatory if an infant: (1) is in the process of dying; (2) will never be conscious; (3) will suffer unremitting pain; (4) can live only with major, highly restrictive technology which is intended to be temporary (e.g., artificial ventilation); (5) cannot live past infancy (i.e., a few years); or (6) lacks potential for human interaction as a result of profound retardation [6].

Whatever the criteria for withholding intensive care, it is usually presupposed that there is parental concurrence with the decision. Any outcome that would justify the withdrawal of intensive care over parental wishes would certainly require a much lower benefit-to-burden ratio. This suggests that the minimum quality of life that justifies withholding intensive care in the absence of a caring parent who represents the interests of the infant might be poorer than when a parent is available.

Even if agreement could be reached on what minimum quality of life obligates the provision of intensive care, how likely must it be that that minimum quality of life will not be achieved? This is critical in cases like this in which the prognosis can only be estimated when time-management decisions must be made. Is a 5 percent, 10 percent, or 15 percent chance of achieving the minimally acceptable quality of life sufficient grounds to forgo life-sustaining treatment? The likelihood of a major disability, much less the lack of capacity for symbolic interaction and communication, cannot be accurately predicted for individual infants during the NICU course with the data currently available. For example, the positive predictive value of cystic periventricular leukomalacia for major disability has been reported to be 71 percent and 83 percent [7, 8]. In other words, 1 in every 4 to 6 children with cystic periventricular leukomalacia will not have a major disability. And certainly not all major disabilities preclude a quality of life sufficient to justify life-sustaining treatment.

The problems are how to define the best interests of an infant with an ambiguous future and how much to weigh the opinions of the key players—the parents and health care professionals. In this case, let us accept that the outcome of this infant at discharge would ethically have justified forgoing life-sustaining treatment. The issue then is whether this outcome could have been predicted in the infant’s course with sufficient reliability to justify withdrawal when withdrawal of life-sustaining treatment was a realistic option. With the information provided we cannot know.

The third supposition made is that the provision of intensive care to this infant is an inappropriate use of limited health care resources. This is an oblique reference to health care rationing—most broadly defined as implicitly or explicitly allowing patients to go without health care services that are of some benefit to them because of cost [9, 10]. The United States has not shown much of an appetite for the explicit

rationing of health care resources. If this is to be done, however, it must be at a higher level than that of an individual institution. Distributive justice requires that finite health care resources be fairly and equitably allocated. These allocation decisions must be made at the community level if they are to be reflective of the range of values within the community and be applicable across the community. Rationing at any level, while unavoidable, is fraught with moral problems that some argue are unavoidable [11]. The authors of the most prominent example of an attempt to ration health care, the Oregon prioritization plan, admitted that there was no perfectly objective, uniquely rational, or indisputably fair way of rationing [12]. It was a “process question to be resolved through open democratic dialogue whose outcome was shaped by both social value judgments and medical information” [13].

The case at hand does not refer to the universal moral rules that underpin utilitarian or Kantian ethical theories, but rather rules for more specific circumstances that are based on one or another ethical theory. We cannot do without some ethical rules; they are essential to understanding what is morally right and wrong. In the best circumstances, they represent a summary of cumulative moral experience and wisdom, but they cannot obviate the need for moral deliberation. To be useful, rules must be general enough to be applicable to a range of circumstances. There cannot be enough rules to cover every ethical dilemma. Moreover, rules may conflict with one another. Thus, rules must be applied to specific circumstances, and application to specific circumstances requires moral deliberation. Focusing on rules emphasizes what we ought to do, rather than the reasons for what we ought to do.

Annas has suggested that adherence to reasonable *process* for making management decisions for extremely premature infants may be the best we can do “because clear rules seem to be impossible to formulate in this arena” [14]. Today, process includes candid conversation among parents, physicians, and other health care professionals; consideration of all the relevant facts and interests; and, in extremely difficult or refractory cases, consultation with an ethicist or institutional ethics committee. In the case at hand, with no parent available, court involvement may be required as well.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 635-639.

CLINICAL CASE

Reframing Neutral Counseling

Commentary by Anne Drapkin Lyerly, MD, MA

A 19-year-old woman who said she was 25 weeks' pregnant was rushed into labor and delivery crying from the pain of regular uterine contractions. Her cervix was dilated to 3 cm, and she was diagnosed with premature rupture of membranes and preterm labor. An ultrasound revealed a fetus measuring 21 weeks' gestation in vertex position. The woman had had no ultrasound during her pregnancy but stated that she was sure of the date of her last period. Fetal heart tracing was suspicious for acute fetal distress, and the obstetrician worried that the woman's due date was not accurate and that the fetus might be too preterm to have any chance at resuscitation. The woman begged the obstetrician, "Please save my baby."

The obstetrician knew that a classic cesarean section with a vertical incision on the uterus would be the least traumatic means of delivery for the infant. Very premature infants with thin epidermis and partially ossified skulls are at risk for major intracranial bleeding and tissue ecchymosis from passage through the birth canal. A vertical uterine incision, however, would make future vaginal deliveries impossible for the woman due to the risk for uterine rupture with a future labor. The obstetrician knew further that the emergency induction of general anesthesia needed for immediate delivery of the distressed fetus places pregnant women at particularly high risk for serious respiratory complications. Given the conflict between the mother's statement and the ultrasound report, the fetus could be 21 weeks old and not yet viable, or it could be a growth-restricted 25-week fetus.

Knowing the risks of both courses of action, the obstetrician counseled the mother on her options: (1) a classic cesarean section under general anesthesia with serious short- and long-term risks to the mother and baby that may not survive, or (2) labor with likely birth trauma to an extremely preterm fetus already in severe distress. The obstetrician considered the unwritten rule that seemed to shroud these situations. The move toward nondirective counseling had been so roundly endorsed that physicians felt unable to share their years of experience with patients out of fear of inappropriately influencing patient decisions. Patients, lacking preparation or experience to make such difficult decisions, routinely asked for advice about how to proceed. Neutral counseling, now mandated by hospital policy, left the obstetrician with little comfort, feeling that mothers were increasingly undergoing invasive interventions to save impaired infants with marginal chances at normal lives, in large part because they were ill-equipped to make the decisions.

Commentary

Decisions at the threshold of viability are some of the most difficult in perinatal medicine. Like other thresholds, the space of questioned viability is fraught with ambiguity—about the roles of obstetricians and neonatologists, responsibilities of pregnant women and their partners to the life they have created, and the fine line between the maintenance of hope and imposition of harmful interventions at what may well be the inevitable end of a life.

Oftentimes the angst associated with these decisions stems from uncertainty about the optimal course of action—whether, for example, cesarean delivery or aggressive resuscitation would be beneficial. This case poses a very specific challenge, since the optimal clinical course, expectant management and vaginal delivery, is clear. Consider first the question of gestational age. Is this fetus a previable 21-week fetus or a growth-restricted 25-week fetus, as menstrual dating suggests? According to the American College of Obstetricians and Gynecologists (ACOG), most ultrasound fetal-weight formulas estimate gestational age within two weeks of menstrual dating [1]. With a discrepancy of more than two weeks between the ultrasound and menstrual dating, the ultrasound estimate is used, signifying that 21 weeks is the correct gestational age—an age at which there is no chance of resuscitation, and no reason for surgical intervention.

What about the possibility, however slim, that the dating discrepancy is the result of severe fetal growth restriction and the fetus's gestational age is 25 weeks—clearly beyond the critical threshold of viability? Like gestational-age estimates, weight estimates strongly urge expectant management: neonatal survival at an estimated fetal weight of less than 400 grams (estimated fetal weight for a 21-week fetus is 360 grams) is not reported [1]. Again, the facts leave us without a good reason for aggressive intervention.

According to the case narrative, the obstetrician “knows” that a classic cesarean would be the least traumatic means of delivering the infant, but the facts, again, suggest otherwise. Although some clinicians cautiously raise the possibility of a role for surgery in cases of extreme prematurity with fetal growth restriction [2], ACOG points out that numerous retrospective, nonrandomized studies have failed to demonstrate a benefit of cesarean delivery for an extremely preterm fetus [1, 2]. It can also be argued that what is lost in a cesarean delivery—a gentle vaginal birth and the opportunity for a premature infant to be held in the minutes or hours before its inevitable death—constitutes significant trauma in itself.

The loss of opportunities to deliver future children vaginally and potential for complications during future pregnancies as a result of the vertical uterine scar are added costs borne by the woman. It is difficult to resist intervening in circumstances that appear dire, but the facts tell us this is exactly what we should do.

Nondirective Counseling

What the case facts don't tell us is how to counsel the patient. In many areas of reproductive medicine (and of medicine generally) neutrality in counseling has been advocated. For prenatal counseling, the commitment to nondirectiveness stems in part from the troubling legacy of eugenic movements in the early decades of the 20th century. In nondirective counseling [3], statistical probabilities are presented as neutrally as possible so that both continued gestation and pregnancy termination of a chromosomally (or otherwise) abnormal fetus appear to be reasonable options, depending on a patient's values and life context. The goal of nondirective or neutral counseling is to promote patient autonomy, or self rule, by avoiding the undue influence of another's values. But in the case at hand, what might seem to be neutral or nondirective counseling has a very different effect.

Consider what nondirective counseling might entail in this case. The physician would present the options: expectant management and vaginal birth versus classic cesarean delivery aimed at maximizing any chance of saving the fetus. Inasmuch as the evidence does not support the latter, the real difference between the two options is the level of risk to the woman. What the patient hears in this neutral presentation, however, is that the option that poses an increased risk to her holds greater promise of saving her baby. Many obstetricians will attest that most women will make the only choice they can as mothers-to-be—accepting the risk to “save the baby.” Despite nondirective counseling, only one choice emerges as reasonable.

Here we see the limitations of nondirectiveness. Two questions arise: (1) is the pregnant woman's choice to accept risk the better clinical choice? And (2) is her decision truly autonomous? The literature and statistics reviewed above suggest strongly that the answer to the former question is no. For an answer to the latter, we can look to the work of scholars who have recently investigated whether decision making following neutral disclosure of information can ever, in fact, be autonomous. Bioethicist Rebecca Kukla argues that “respecting autonomy has more to do with the overall shape and meaning of [patients'] health care regimes” than ensuring that patients “make their own decisions” [4]. According to Kukla, the practitioner's responsibility is not simply to disclose relevant information, but to be aware of the ways that this information is understood and acted upon.

In a society that valorizes maternal sacrifice and the miracle babies of modern neonatal medicine, many patients find it morally reprehensible to decline a cesarean delivery, even in the face of impossible odds presented accurately. If the physician wants (as she should) to make the option of nonintervention reasonable or reachable for this patient, something else is needed.

The Importance of Framing

In this and many other cases, that something else is framing, presenting options to patients in a way that is meaningful and understandable in the context of their lives as patients, aspiring parents, and moral agents. Framing is not accomplished by informing patients of probabilities, however accurate, of morbidity associated with expectant management and vaginal birth versus classical cesarean. For one thing,

such disclosure implies that the question of delivery mode is reasonably open, when, clinically, it is not. Rather, framing requires communicating effectively that this woman's fetus has an incalculably small chance of survival, pursuing that chance would come at a dear cost to woman and fetus alike, and expectant management is a medically and morally appropriate approach.

How might framing be accomplished for the perinatologist who is much more familiar with welcoming life than bidding it farewell? For one, the physician should take great care not to frame the decision about the delivery mode in terms of providing or withholding technology. The decision to proceed with expectant management and vaginal delivery at the threshold of viability is often framed as withholding treatment, which makes the decision to resist the use of technology counterintuitive if not inexcusable to a parent-to-be.

The sense of moral wrongness associated with withholding treatment from one's newborn undermines the goal of nondirective counseling, which is to assure meaningful, uncoerced informed consent. Instead it calls into question the very meaning of autonomous decision making and the circumstances that, as Kukla points out, foster autonomy. The choice of vaginal delivery should be framed as a good, compassionate option, and one that a loving mother could choose. Cesarean delivery should be described as a medical intervention that carries costs to the woman and infant alike, and one without clinical evidence to support its use; it should not be framed as an act of hero(ine)ism.

If a patient proceeds with vaginal birth, she and the physician may call the impending delivery what it is—a miscarriage. As a technical medical term, “miscarriage” is often reserved for fetuses born prior to 20 weeks' gestation. But this cut-off point is used to denote an inevitable delivery at a gestational age at which the neonate is incapable of surviving—circumstances that apply in the case we are discussing. Moreover, the term miscarriage has profound cultural and social meanings that transcend its clinical denotation. It names a process that is inevitable and sad. Use of the term creates space for mourning and reverence and directs others toward the task at hand, which is to care for the pregnant woman as she undergoes the loss of a desired pregnancy.

Some will debate the use of the term miscarriage in this setting, but the lesson is less contestable. At the threshold of viability, neutral disclosure of probabilities associated with cesarean and vaginal delivery restricts true autonomy by forcefully setting as a default the use of technology and surgical intervention. To present an expectant mother whose fetus is in danger with the option of assuming risk to herself to increase the chances of her infant's survival, when the latter is not supported by clinical evidence, is neither responsible nor nondirective. Instead, it directs most women to choose an option that imposes loss without benefit and removes a choice in which many women would find meaning. Rather than detached objectivity, the task of compassionate obstetrical care is to accompany patients through the weighty

decisions, transformations, and (all too often) the mourning that choices at the threshold of viability entail.

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Acknowledgment

I am grateful to Maggie Little for many helpful and enlightening conversations on this topic.

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 640-642.

MEDICAL EDUCATION

A Nonpaternalist Approach to Counseling Patients with Extremely Premature Delivery

Patrick Catalano, MD, and Katherine Singh, MD

Every new physician reaches a point at which he or she feels inadequately prepared for the clinical or ethical decision at hand. The situation matches nothing learned from books and nothing seen in the clinic or hospital. This happens, of course, to every primary care and specialist physician, but when the interests at stake are those of patients who cannot speak for themselves—children, newborns, the comatose, or the unborn—the decisions seem even more confounding.

In the commentary that follows my short introduction, Katherine Singh, MD, describes the ethical concerns she had during residency about the modes of delivery for extremely premature infants. The formal curriculum of the Case Western Reserve/MetroHealth/Cleveland Clinic ob/gyn residency program doesn't integrate ethical questions like those Dr. Singh asked herself. We teach, of course, the modes of delivery for extremely premature newborns; we can give residents the statistics on survival rates for these infants and the morbidities associated with extreme prematurity. We address the legal issues—a woman's right to control her body and what cannot be done to it without her consent. And residents learn that the physician, too, has responsibilities and cannot comply with all patient requests—for example, a woman's request for an emergency cesarean delivery of an obviously previable fetus (less than 20 weeks' gestation).

Dr. Singh brings up the many clinical and ethical decisions that are unique to specific circumstances of a particular mother-to-be. In our county hospital, as in many others, these decisions must often be made quickly because the patient arrives under emergency conditions, having had no prenatal care, and unknown to any of those who are suddenly responsible for her care. Time is not always available to discuss the risks and benefits of treatment options. When it is, our job is to provide patients with information and guidance about their specific circumstances and treatment options, not to make decisions for them.

A Resident's Story

by Katherine Singh, MD

As a medical student, I knew obstetrics involved many complex medical and ethical dilemmas. The challenge of counseling and caring for a patient when the well-being of not one but two lives were in question seemed obvious. Group discussions embedded in the curriculum posed ethical questions about the delivery of previable infants. We learned about different health belief models and examined the

differences among legal, moral, and ethical principles and guidelines. The complexity of decision making was one of the many fascinations that drew me to pursuing a residency in ob/gyn.

I learned during my first month of residency, however, that no class or group discussion could prepare me completely for the real thing. During the early hours of the morning on one of my first on-call shifts, a young woman arrived at the labor and delivery unit about to go into labor after approximately 23 weeks' gestation. Her fetus was in breech position. She had had no prenatal care, so the age of the fetus was determined by ultrasound upon her arrival. She wanted "everything" done to save her baby. So many questions rushed into my mind.

Does she know what is happening? Does she understand what a classic cesarean section is and what it means for her future? Does she know about the pain, recovery time, and risks that go with surgery? Does she understand the morbidity and mortality associated with an infant of 23 weeks' gestation? Can she imagine what it is like to raise a severely disabled child for the remainder of its life—what the physical, emotional, and financial burdens are? Does she have support for her situation, whatever its outcome? What are her personal beliefs? If she didn't plead to have everything done, would she feel guilty for the rest of her life? Is the decision she makes now the one she would make if she had more time to think about it?

I felt so unprepared to help this patient with her predicament. I knew the best thing I could do was to give her as much information as possible, but, as an intern, that wasn't much. I quickly summoned the attending physician and tried to absorb everything he told her.

That is how we learn in residency. We are eager observers in our early years, and the learning curve is steep. I watched many attending physicians counsel many patients about delivery in the setting of extreme prematurity. Each had his or her own way of doing so. I observed a wide spectrum of maternal decision making and saw many outcomes. Some neonates died; some lived with many long-term problems and would never have normal lives; still others were discharged after a long stay in the neonatal intensive care unit with relatively few problems.

Seeing severely ill, suffering infants initially inclined me toward counseling a woman about likely neonatal morbidities and trying to influence her decision—"directive counseling." But soon I learned that no one can predict the outcome for any given baby, and assuming that one can is not in the patient's best interest. I sometimes found myself frustrated with the law—when for example, it dictates the gestational age at which termination of a pregnancy is legal. I know the law is there to protect the vulnerable, but its presence in such sensitive, personal circumstances can seem intrusive and blunt. The lawmakers are not those living with the consequences of a periviable fetus who dies or a permanently disabled child who survives.

Now, after four years of residency, I am starting my first of year of a maternal-fetal medicine fellowship, and here I am again—intrigued and challenged by the complexity of the ethical decisions in obstetrics. My questions about patients' beliefs and understandings remain, but I understand a great deal more about counseling patients effectively. I have learned about my style of empathy. Strange as it may sound, separating myself emotionally makes me a more empathic counselor. I have discovered the importance of being a truly nonjudgmental and nonpaternalistic provider of information. That is my job: give as much information as I can and continue until I know that the patient really understands me; bad news often needs to be repeated. These are crucial principles because, after the information is provided and the news given, it is the patient's decision to make; she will be living with it.

By watching and trying I learned the lessons that cannot be taught in the classroom. Laws and definitions can, and it was helpful to get the input of my peers during group discussions. But laws and discussions cannot prevent one from being sideswiped by real life. Only when you are alone with a patient do you learn that you must be able to look at her for feedback and communicate with her alone. It is then that you must challenge yourself to glimpse where she is coming from and how she is feeling. It is then that you learn about yourself and how you react during times of stress and confusion. Then look at the result of your work and learn how to do it even better.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 643-646.

JOURNAL DISCUSSION

A Bias Observed? Janvier's Claim of Prejudice against Premature Infants

Patrick M. Jones, MD, MA

Janvier A, Bauer KL, Lantos JD. Are newborns morally different from older children? *Theoretical Medicine and Bioethics*. 2007;28(5):413-425.

In introducing the October 2007 issue of *Theoretical Medicine and Bioethics*, physician and philosopher Lainie Friedman Ross posed the question, "Are newborns morally different than other children?" This query was prompted by ongoing conversation with neonatologist Bill Meadow and a presentation by Annie Janvier to the bioethics panel at the 2006 Society of Pediatric Research meeting. Ross explained that Meadow said he had asked parents in numerous informal polls what they would do if they had to choose between saving their 6-year-old child and their 6-hour-old child. Meadow said that, when forced to give an answer, parents would typically decide to save the 6-year-old.

Janvier reported on research that she conducted with Isabelle Leblanc and Keith Barrington that claimed to discover a similar bias. The physicians and students they surveyed were less willing to resuscitate a premature infant of 24 weeks' gestation than an older patient with a projected outcome that was similar or even worse than that of the premature infant. Her intellectual curiosity piqued, Ross dedicated an entire issue of *Theoretical Medicine and Bioethics* to the above question; the article reviewed here was one of the seven invited contributions [1].

Demonstrating a Bias against Extremely Premature Infants

Janvier has two major tasks in this paper. The first is to establish that a bias exists against extremely premature infants, specifically in the realm of resuscitation decisions, and the second is to explore the reasons for this proposed bias. Janvier begins with the results of a research project conducted at McGill University, the one presented at the above-mentioned 2006 SPR meeting. Two hypothetical patients from this project are discussed: a previously healthy 2-month-old baby, now with bacterial meningitis, and a 24-week gestational-age infant with respiratory distress syndrome. Why is it, Janvier asks, that initiation of intensive care treatment would be considered obligatory for the 2-month baby in the first case but optional for the premature infant in the second case despite the fact that the long-term prognosis is worse for the 2-month-old?

Later in the paper, Janvier relates a research exercise in which she asked subjects to rank eight hypothetical patients, answering the question, "In what order should the patients be resuscitated if they all needed intervention at the same time?" She found

that, overall, a premature infant, with an equal or better long-term prognosis than the others was placed in the seventh position, just before a demented 80-year-old with new-onset stroke. Again she asks, why the apparent reluctance to provide the premature infants with intensive care? The conclusion she reaches is that the premature infant is being thought of as occupying a special moral category, and outcome data are being applied to decision-making processes in a manner that would not be acceptable in decision making for an older patient.

As evidence for this conclusion, Janvier points to the report of the 1983 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that devoted a special section to newborns, separating this population from the larger discussion on issues of withholding or withdrawing life-sustaining treatments [2]. She claims that "such distinctions, though well intentioned, have reified the dichotomy that has isolated newborns from the rest of the population, kept them in a separate moral universe, and allowed decisions to be made upon a different basis than those made for any other age group" [3]. She also points toward clinical examples in which an infant may be treated more aggressively because he or she is the product of assisted reproduction techniques, the so-called "precious children," conceived after years of infertility, or less aggressively because his or her care might distract from the care of the older children at home. These decisions, Janvier argues, would not be allowed unless infants had been placed into some unique moral category that permits such factors, outside of the best interest of the patient, to be pertinent in these end-of-life decisions.

In further support of her "special category for newborns" conclusion, Janvier discusses the proposed use of age-based rationing of hospital resources—the idea that one can put an age restriction on the receipt of resuscitation or major surgery. She sees inconsistency in the fact that age is used in the adult population, but only as one of many factors to consider in decision making, yet many professional societies "explicitly use gestational age alone as a criterion for initiating or withholding resuscitation" [4]. If the projected outcomes are similar, or even better, for an extremely premature infant, she reasons, this inconsistency can only be due to the fact that "the relative value placed on the life of newborns, in particular the preterm, is less than expected by any objective medical data or any prevailing moral frameworks about the value of the individual lives" [5].

Exploring the Causes of Bias

After she has attempted to convince the reader that bias exists against premature infants, Janvier's second task is to put perinatologists, neonatologists, and ethicists "on the couch" for a session that explores the causes of this "systematic devaluation of the newborn" [6]. In attempting this second task, her paper goes awry. The problem with exploring the potential causes of bias against extremely premature infants is that there is still important work to be done to prove it exists in the first place. As her work stands, Janvier has appropriately expressed concern about apparent discrepancies she has observed in the treatment of premature infants, and she has stated a hypothesis as to why this exists, but in rushing to speculate about

underlying influences on the care of premature infants, she has assumed her hypothesis to be true without subjecting it to any type of formal testing.

Janvier's original research revealed two main findings: a willingness in those surveyed to overrule their own personal feelings regarding the best interest for a premature infant in order to respect family wishes not to resuscitate [7], and a tendency, should such a hypothetical situation present itself, to triage a premature infant toward the back of the line during an emergency involving eight persons in need of intensive care at the same time. Other hypotheses can be offered as to the cause of these findings. For example, those surveyed may not feel competent to judge the best interest of a 24-week infant. Can one assess, for example, how a 3-month NICU stay, with its procedures, noise, handling, and associated morbidities weighs against the benefits of survival? A physician acquiescing to families who hold a conflicting view of whether resuscitation is in the best interest of their premature infant may not be devaluing the infant at all; instead, he or she may be recognizing the complexity found in applying the best-interest standard to an extremely premature infant. Regarding her findings on the order in which people would typically triage a neonate, does this represent bias or simply a doubting of one's clinical skills? It is possible that the subjects were simply intimidated by the idea of resuscitating a 700-gram newborn.

The articles that Janvier lists to support her claim of bias add little power to her argument. First, the article on precious children discusses the concept's supposed effect on the obstetric treatment of the mother, but gives no evidence for its influence in the resuscitation or treatment of premature infants [8]. Second, to claim that the use of gestational age as a criterion for resuscitation is similar to age-based rationing of health care is to misunderstand the concept. Gestational age is being used to describe an expected set of comorbidities found with a certain level of prematurity; it is like stating that a patient has Group B streptococcal meningitis or a certain type of cancer. The science of prognostication for the extremely low-birth-weight infant is hampered by relatively small numbers (less than 1/2 percent of all U.S. births fall into this category) and a history of progress in neonatal intensive care that makes prediction of survival a moving target. Gestational age is still helpful information for families and practitioners as they make difficult decisions for a critically ill infant.

Space permitting, this discussion could continue for several pages, offering alternative explanations for Janvier's research findings and observations. The important point to be recognized is that, without further investigation, these alternative hypotheses are potentially just as valid as Janvier's hypothesis of a pervasive bias against premature infants. It must be recognized that her research relates current attitudes and practices but does not yet truly investigate the reasons for her findings. It is critical to remember this when others claim that "recent research suggests that many people treat neonates as a special moral category" [9] and cite Janvier's work in support of that statement. While her work is valuable in pointing out potential inconsistencies in end-of-life decision making for premature infants, going beyond this limited claim represents improper extrapolation of her

data. Janvier and her colleagues are left with the task of exploring what lies behind these observations and whether or not they truly represent a pervasive bias against premature infants.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 647-650.

CLINICAL PEARL

Complications Associated with Premature Birth

Tara M. Randis, MD

Parents of preterm infants and those at risk for preterm delivery face two major unknowns: Will this child survive? And, if he or she does, will major long-term disabilities ensue? Caregivers attempt to use the limited information available to guide parents as they make complicated decisions regarding the initiation, escalation, or withdrawal of intensive care for their children. An understanding of the early complications and long-term morbidities associated with premature birth provides the foundation for this guidance.

Complications in the Early Newborn Period

Respiratory distress syndrome. The earliest recognized complication associated with premature birth is respiratory distress syndrome (RDS). RDS is the result of insufficient surfactant production by the immature lung, leading to decreased lung compliance and inadequate gas exchange. Both the incidence and severity of this disorder are inversely related to the infant's gestational age. Within hours of delivery, affected infants develop symptoms of respiratory distress that include tachypnea, grunting, retractions, hypoxemia, hypercarbia, and acidosis. Administration of antenatal steroids, improved ventilatory strategies, and surfactant replacement therapy have improved survival rates, but RDS remains a leading cause of morbidity and mortality in premature infants.

Sepsis. Sepsis is a systemic inflammatory response, often uncontrolled, resulting from infection, such as bacterial infections with *Staphylococcus* or *Streptococcus*, or a blood stream infection with gram negative bacteria. Studies suggest that as many as 25 percent of very low-birth-weight infants (those weighing less than 1,500 grams) have one or more positive blood cultures over the course of their hospitalization [1]. This relatively high rate of infection is understandable, given that the preterm infant is an immune-compromised host; both the innate and adaptive immune systems are underdeveloped. Moreover, many of the procedures required to sustain these infants, such as central line placement, endotracheal intubation, and frequent blood draws, increase the risk of infection from invasive bacteria. In severe cases, sepsis progresses to multi-organ system failure and sometimes death, despite appropriate antimicrobial therapy. An uncontrolled inflammatory response can be more hazardous than the primary infection itself. Neonatal sepsis has been associated with poor neurodevelopmental and growth outcomes, particularly in infants with recurrent infection.

Necrotizing enterocolitis. The most serious gastrointestinal complication affecting preterm infants is necrotizing enterocolitis (NEC). The pathogenesis of NEC is complex and remains poorly understood despite decades of research. Immaturity of the gastrointestinal mucosa results in compromised barrier functions, immune defense, and abnormal motility. This intestinal immaturity together with abnormal bacterial colonization and ischemic insult are all theorized to contribute to the development of NEC [2]. The onset of disease may be insidious, with mild abdominal distention, lethargy, and feeding intolerance. Alternatively, it may begin abruptly with sudden development of intestinal perforation, hypotension, metabolic acidosis, and disseminated intravascular coagulopathy. Medical management consisting of antibiotic therapy and bowel rest is sufficient in the majority of cases. However, 20 to 40 percent of infants typically need intervention. Long-term morbidities include feeding intolerance, intestinal strictures, and short bowel syndrome. Preterm infants with a history of NEC—particularly those who require surgical management—are at increased risk for neurodevelopmental disabilities. Mortality rates for infants who develop NEC range from 15 to 30 percent [2, 3].

Intraventricular hemorrhage and periventricular leukomalacia. The most significant forms of perinatal brain injury observed in premature infants are intraventricular hemorrhage (IVH) and periventricular leukomalacia (PVL). IVH refers to bleeding within the ventricles of the brain, which, in severe cases, may extend into the surrounding parenchyma. The hemorrhage originates in the subependymal germinal matrix, a site of neuronal proliferation in the developing fetus, which typically begins to regress at 32 weeks' gestational age. The blood vessels supplying this tissue matrix are extremely fragile and may rupture with abrupt alterations in cerebral blood flow and pressure. The bleeding can destroy cerebral tissue and, in some cases, lead to post-hemorrhagic hydrocephalus. A recent study found that infants with severe IVH have a 28 to 37 percent mortality rate [4]. Surviving infants face a significant risk for long-term disabilities that include cognitive impairment, cerebral palsy, and recurrent seizures.

PVL is a form of cerebral white matter injury that has been highly correlated with the subsequent development of cerebral palsy. The key factors implicated in the development of PVL are cerebral ischemia and systemic inflammation following intrauterine or neonatal infection. These injurious processes result in the activation of brain microglia, which in turn release a variety of toxic mediators including cytokines, reactive oxygen species, and excitatory amino acids that damage the premyelinating oligodendrocytes [5]. PVL may be diagnosed in the early neonatal period by magnetic resonance imaging, which frequently reveals the presence of parenchymal cysts, areas of abnormal signal intensity, or reduced white and gray matter volumes. The associated neurocognitive and motor deficits, however, often do not manifest until well after discharge from the hospital.

Long-Term Complications

Bronchopulmonary dysplasia. Bronchopulmonary dysplasia (BPD) is a chronic lung disease of preterm infants typically defined by the presence of a supplemental

oxygen requirement at 36 weeks' gestational age and affects nearly 30 percent of extremely low-birth-weight infants [6]. Factors such as inflammation, barotrauma, and the production of reactive oxygen species are all believed to contribute to the pathogenesis of BPD by injuring small airways and interfering with alveolarization and the development of the pulmonary microvasculature. Therefore, preterm infants who require prolonged or aggressive ventilatory support and those with a history of antenatal or postnatal infection are at increased risk for developing BPD [7]. These individuals commonly experience recurrent pulmonary infections, increased airway reactivity, and poor postnatal growth.

Retinopathy of prematurity. Retinopathy of prematurity (ROP) is a major cause of severe visual impairment or blindness in infants born prematurely, with approximately 50,000 infants affected worldwide each year [8]. The disease is characterized by abnormal vascular proliferation in the immature retina, likely due to the presence of increased local reactive oxygen species and angiogenic growth factors. Extreme prematurity, growth restriction, male gender, hyperoxia, and septicemia are most consistently associated with the development of ROP [8]. Although changes in clinical practice, namely more judicious oxygen administration, have resulted in a decreased incidence of ROP in developed countries over the past several years, affected infants are still at risk for subsequent ophthalmologic complications such as strabismus, amblyopia, cataracts, and impaired visual acuity.

In sum, preterm infants, particularly those who experience one or more of the complications discussed above, are at risk for neurodevelopmental disabilities such as cerebral palsy, developmental delay, and mental retardation. Approximately 42 percent of very low-birth-weight infants have been found to have borderline IQ scores (70-84), and 7 percent had subnormal IQ scores (less than 70) when tested at 20 years of age, compared to 31 percent and 2 percent respectively in normal-birth-weight infants [9]. An additional 6 to 9 percent of these infants were classified as having cerebral palsy. Recent follow-up studies have also revealed that these infants may demonstrate more subtle impairments such as learning disabilities, impaired social skills, and behavioral problems, particularly attention-deficit-hyperactivity disorder [10].

Although we have data describing significant long-term morbidities and neurodevelopmental outcomes based upon birth weight and gestational age at delivery, the early identification of individuals at risk for these impairments remains an ongoing challenge for physicians. Recognizing and acknowledging our limited capability to predict which infants will be most severely affected is crucial for effective and honest communication with families.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 651-654.

HEALTH LAW

Unilateral Termination of Life-Sustaining Treatment in Neonatal Care: A Legal Overview

Jonathan Rohde

Physicians regularly use medical technology to prolong and improve the quality of their patients' lives. There often comes a point, however, when treating the illness no longer affords the patient any benefit, and aggressive measures are needed merely to sustain life. At this point physicians routinely shift the goal of care toward comfort and closure [1].

In many such situations, a surrogate must speak for the patient. This is always true in the case of newborns; physicians interact with the surrogate decision maker or decision makers who are legally empowered to act in the infant's best interest. Typically this is the infant's parent or parents, and most often the physician and surrogates come to an agreement about what is best for the infant [2]. There are times in a futile care situation, however, when surrogates and physicians cannot agree on the decision to terminate life-sustaining treatment. When this occurs, the physician's first duty is to advise the surrogates of alternatives; that is, they may transfer the care of the infant to another physician or to another health care institution [1]. If the infant's surrogates are unwilling or unable to take advantage of the alternatives, a physician is acting ethically if he or she decides to withdraw life-sustaining treatment [1]. Is the physician's unilateral decision to terminate life-sustaining treatment legal? What legal consequences may occur as a result of this action?

Once the primary physician makes it clear to the infant's surrogate that he or she is unwilling to continue aggressive life-sustaining treatment and intends to withdraw it, several courses of action are available. The surrogate may seek to force the hospital to continue treatment. The physician can attempt to gain custody of the child in states that have temporary protective custody statutes. A statutory process may exist to handle the dispute, or, if the physician withdraws treatment unilaterally, the surrogate can attempt to punish the physician through retributive litigation.

Preventive Litigation

The surrogate who disagrees with the physician's decision to terminate life-sustaining treatment for a neonate can seek a declaration from a court to force treatment. Historically, the judicial system is as likely to grant this kind of injunction as not [3]. This type of litigation has produced odd and inconsistent results. In the Baby K case, a judge invoked the Emergency Medical Treatment and Active Labor Act (EMTALA) perhaps inappropriately to prevent the physician from withdrawing

treatment [4]. In a controversial Michigan case (Baby Terry), the court had the mother declared incompetent in order to appoint a state guardian who eventually went along with the physician's decision to cease life-sustaining measures [4].

The intent of preventive litigation—to protect and advocate for the rights of the surrogate—is certainly worthy. But the infant must be kept on aggressive life-sustaining medical treatment throughout the legal procedure, a situation that is clinically and ethically offensive to the health care team. This type of litigation subjugates the rights and ethical duties of the physician and hospital to those of the surrogate, often not in the best interest of the patient.

Temporary Protective Custody

In states that permit law-enforcement officers or physicians to take temporary protective custody of a child at risk for abuse or neglect (Illinois and Iowa, for example), a physician may be able to gain custody of an infant if he or she believes the parents are not acting in the baby's best interest [5]. It is debatable that gaining custody from a parent in order to end the life of the child is encompassed by the purpose of these statutes. The potential gray area of statutory interpretation coupled with the effect of depriving the surrogate of his or her rights is likely to lead to retributive litigation replete with significant disadvantages.

Legislative Remedies: Advance Directives Acts

Because judicial decisions have been inconsistent and potentially unethical, several state legislatures have enacted statutory guidance. Maryland, Virginia, and Texas have all passed statutes that attempt to address the unilateral removal of life-sustaining medical treatment [6-8]. The Maryland and Virginia laws do not define terms like, "ethically inappropriate treatment" or "medically ineffective," nor do they provide any type of process or instruction [9]. As of today these two laws are untested by the judicial system [10]. I will say more about the Texas law after discussion of the fourth course of action—retributive legislation.

Retributive Litigation: Asking For Forgiveness

The idiom, "it is better to ask for forgiveness than to seek permission," comes to mind when reviewing the case law that has dealt with this situation. In these cases, the surrogate did not seek legal intervention, the physician unilaterally withdrew life-sustaining treatment without the permission of the surrogate, and the infant died. The recourse for the surrogate is to sue for damages in a tort claim or file a medical malpractice claim [11]. Historically physicians have prevailed in these cases [12]. Judges are reluctant and typically unwilling to punish physicians who acted in accordance with the appropriate established standard of care [13]. Even in jury cases, the tendency to favor the physician's decision is evident [14]. As long as the physician did not make unrealistic promises and clearly described the consequences of the action he or she was about to take, he or she is unlikely to be found legally liable to the surrogate for the death of the baby [15].

Retributive litigation, however, ignores the rights of the surrogate, who is legally empowered to make medical decisions for the child and is supposed to work with the physician to achieve the desired treatment. The subjugation of the surrogate's rights will most likely invite a legal battle after the death of the patient. The time and money spent on this kind of litigation help neither patients nor physicians. A physician can end up in court and possibly in the news. Patients can risk significant amounts of money in the form of legal fees and lose more often than not.

Texas Advance Directives Act

In 1999 the American Medical Association adopted an opinion detailing the ethics of futile care [1]. The Texas legislature incorporated much of that opinion in the Texas Advance Directives Act (TADA). TADA clearly defines procedures for the physician, surrogate, and judicial system to follow when resolving impasses over termination of life-sustaining medical treatment [5]. The act states that, once the primary care physician makes the determination that continuing life-sustaining treatment is futile and inappropriate, he or she must notify the hospital and infant's surrogate [8]. If the surrogate disagrees, the physician and surrogate meet with an ethics committee to determine whether withdrawal of life-sustaining treatment is justified [8]. If the ethics committee agrees with the physician's judgment, the hospital gives the surrogate 10 days to find a health care institution that is willing to continue the treatment [8]. The surrogate can appeal for an extension in court [8]. At the appeal, the judge decides whether granting more time would make it possible for the surrogate to find a willing health care provider [8]. If the surrogate does not seek an extension, or the judge rules against it, the life-sustaining medical treatment may be withdrawn by the physician against the wishes of the surrogate with immunity from civil or criminal prosecution [8].

The law allows a physician to feel more comfortable when confronted with this situation [10]. When physicians have a clear, legally approved process, they are willing to use it openly [10].

While physicians and health care providers in Texas are required to follow this law, it has some definite shortcomings. Of primary concern is the fact that surrogates are not required to demonstrate that they fully understand the course of events that the committee and physicians end up implementing [5]. It is important that there is a reasonable attempt to make sure that surrogates are adequately informed and can understand the gravity of the situation to the fullest extent possible; if they do not, the hospital and physicians will most likely face retributive litigation.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 655-658.

POLICY FORUM

The Cost of Saving the Tiniest Lives: NICUs versus Prevention

Jonathan Muraskas, MD, and Kayhan Parsi, JD, PhD

In an incisive Narrative Matters piece in *Health Affairs*, John Lantos made the following observation about neonatal intensive care units (NICUs):

Neonatal intensive care is one of the triumphs of modern medicine. Babies who inevitably would have died a few decades ago routinely survive today. But the success of NICUs should not lead us to see them as the only solution to infant mortality or as an adequate moral response to our children's health needs. We should constantly remind ourselves that the need for so much intensive care for so many babies is a sign of political, medical, and moral failure in developing ways to address the problems that sustain an epidemic of prematurity [1].

Lantos writes eloquently about how NICUs have emerged over the last several decades as major revenue generators in the world of inpatient pediatric care. Like transplantation, neonatal medicine captures the public's imagination as few other areas of medicine do—patients who would have surely died years ago are now miraculously saved. NICUs and transplantation are also valence issues for the public: everyone supports saving premature children and extending people's lives. The questions that Lantos poses for policymakers and health care leaders are, "Why do we have such an epidemic of prematurity in the United States?" and "Why don't we do a better job of addressing this public health problem?"

In the United States alone, 4 million babies are delivered annually, with almost 15 percent of those (500,000) being premature, defined as less than 37 weeks' gestational age. Of these, 5 percent (25,000) are born weighing less than 2 pounds, of which 75 percent (18,750) survive [2]. Approximately 75 percent of NICU admissions are related to prematurity and 25 percent are term newborns with a variety of pathology.

Daily NICU costs exceed \$3,500 per infant, and it is not unusual for costs to top \$1 million for a prolonged stay. Expenditures to preserve life are limited in every society, and, although third-party payers have questioned this level of expenditures, courts have consistently reaffirmed the rights of parents to determine the treatment of their newborns.

Initiating NICU Care

Lantos has stated that he does not believe reimbursement influences treatment decisions in the NICU [1]. In our estimation, the following factors have more often trumped cost considerations in the decision to initiate NICU care: (1) Fear of litigation and a 30 percent cesarean section rate. Despite popular belief, no significant differences exist in the outcomes of premature infants delivered by vaginal versus the surgical method. Yet, the medical-legal focus often rests on the final 2 hours of a 7,000-hour pregnancy so the pressure to practice defensive medicine is strong. (2) A substantial rise in the use of assisted reproductive techniques, which triggers a heightened “rescue” mentality because parents have incurred physical and financial burdens in seeking to conceive and deliver a baby. (3) Legislation such as the Baby Doe law. The Baby Doe legislation in the early 1980s, prompted by the case of a newborn with Down syndrome and a nonlethal condition treatable by surgery, stated that newborns should receive proper medical care unless therapy was deemed futile [3, 4].

Lifelong Cost

NICU costs are just the beginning. The extraordinary cost of managing the medical, educational, and social needs of extremely low-birth-weight newborns, as well as term newborns with perinatal asphyxia, often are not discussed with parents early in the infant’s care. Advances in neonatal medicine in the last 20 years give an infant born 13 weeks early and weighing 2 pounds a 90 percent chance of survival. But, short- and long-term outcomes have not improved significantly in the last 2 decades. The incidence of cerebral palsy remains essentially unchanged. Approximately 25 percent of all newborns younger than 26 weeks’ gestation have a handicap severe enough to prohibit them from functioning independently [5, 6].

While devastating handicaps such as blindness, deafness, and cerebral palsy often figure prominently in discussions of withdrawing or withholding life-sustaining treatment, many mild and moderate handicaps are associated with preterm and low-birth-weight babies. Asthma, attention-deficit disorder, visual problems, “mild” cerebral palsy, and the need for special education can drain a family financially, physically, emotionally, and spiritually [7]. Cerebral palsy is not diagnosed until well after 1 year of life, and diagnostic tests in the neonatal period cannot predict long-term outcomes. It would seem that a truly informed consent process would demand disclosure of these milder disabilities. Since clinicians and families share a built-in bias to treat aggressively, parents should at least be informed of the potentially long-term struggles in raising a child with special needs.

Most U.S. clinicians practice a “wait until death appears certain” strategy in the management of newborns [8]. A strategy of withholding treatment on grounds of a statistically grim prognosis can be implemented for a short period of time. An extremely premature newborn or an asphyxiated, term newborn has a “clinical honeymoon” period that usually ends by the third day of life. The incidence of infection, respiratory deterioration, bleeding in the brain, and seizures can surface at this time. An experienced clinician, using evidence-based medicine and ethics, could

redirect a family's focus to the future of its newborn if the clinical scenario suggests considering withdrawal or withholding of intensive care medicine [9].

Alternate Means for Saving Babies

NICU costs are relatively small in the big picture of the U.S. health care economy. For instance, in a \$2-trillion health care economy, the total economic costs of preterm birth has been estimated to be \$26 billion (between 1 and 2 percent of total health care expenditures) [10]. Nonetheless, \$26 billion is a substantial amount of money. Could the money saved from prolonging death in certain cases be directed to improving prenatal care? Could better prenatal care or other preventive interventions stave off the cascade of NICU interventions immediately after birth (and later during the child's development)? Studies suggest that infections during pregnancy may be related to preterm birth. Unfortunately, most studies have not conclusively demonstrated links among antibiotic therapy, infections during pregnancy, and reduced preterm births [11]. Stress has also been identified as a risk factor for preterm birth, but epidemiologists have reported difficulty in designing studies to further research this issue [11].

Lantos' critique of neonatology is well taken—NICUs have done an amazing job of saving countless lives. Yet, as with transplantation, there is little discussion of the role of prevention. Would greater preventive efforts yield substantial cost savings and reduce morbidity and mortality of children? Perhaps, but the current health care system offers clinicians little incentive to focus on such efforts. In many ways, the world of neonatology is a microcosm of our health care system which greatly rewards rescuing our most vulnerable patients through a panoply of technological interventions but downplays the role of prevention. Physicians, policymakers, and political leaders should pay greater attention to the needs of pregnant women to reduce the number of infants that are born preterm and require high-tech interventions of the NICU.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 659-664.

POLICY FORUM 2

Jumping to Premature Conclusions

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In the United States, one in eight babies is born prematurely, accounting for more than 500,000 births each year. Before the 1970s, babies that were even mildly premature often died, but recent scientific developments have led to a decrease in their mortality. Contemporary with the birth of the neonatology field was the birth of modern bioethics. Ethical questions posed as a result of improved treatment of prematurity have been numerous—one prominent concern being the tiny baby at the “limits of viability.” To assume that extreme prematurity is the main ethical problem in neonatology, however, is to jump to premature conclusions. The large majority of preterm infants are between 32 and 36 weeks’ gestation, and these “late preterm” births impose the largest emotional and financial burdens on families and society.

This article will discuss prematurity, the recent technological advances that led to increased neonatal survival, and the complexity of decision making for treatment of these infants. I will focus on a neglected ethical issue of great importance: the rising number of premature births. As a consequence of lax governmental investment in the prevention of preterm birth, society, babies, and families continue to pay more every year—financially, physically and emotionally—for avoidable burdens of prematurity.

Neonatology is a recent subspecialty of pediatrics that focuses on the medical care of newborn infants who require intensive monitoring and treatment. The majority of patients in neonatal intensive care units (NICUs) are born prematurely. A normal gestation lasts 40 weeks after the mother’s last menstrual period, and prematurity is defined as a gestation lasting fewer than 37 weeks. In 1963, Patrick Bouvier Kennedy, son of the late President John F. Kennedy, was born at a gestational age of 35 weeks and died 2 days later. At that time, to be born 5 weeks early was a substantial risk. Three recent developments in neonatology—respirators, antenatal corticosteroids, and surfactant replacement therapy—have given babies born at 35 weeks’ gestation mortality rates only slightly higher than those of full-term infants.

Babies born in the last 20 years are more likely to survive and less apt to develop a disability than those at the same gestational age born before 1980. Even so, the number of premature babies with disabilities or significant morbidity as a result of prematurity has remained relatively unchanged because, even though a lower percentage of survivors have impairments, more babies survive. And prematurity rates are continuing to rise. Although all developed countries have rising rates of preterm births, the United States retains the highest rate among industrialized countries with 12.5 percent in 2004 [1], and most of these preterm babies in NICUs are late preterm, with gestational ages

between 32 and 36 weeks. Babies that are extremely preterm, with a gestation of fewer than 28 weeks or a weight of less than 1,000 grams (also called extremely low-birth-weight babies), comprise 0.8 percent of all deliveries and about 10 percent of NICU admissions. Currently, infants weighing 1,000 grams or born at 27 weeks' gestation have an approximately 90 percent chance of survival, with the majority having normal neurological development [2].

The earlier in its gestation that a baby is delivered, the greater the risks of complications, mainly developmental delay, cerebral palsy, chronic pulmonary disease, learning disability, hyperactivity, and, much less frequently, deafness and blindness. Babies of less than 26 weeks' gestation, as noted, form a minority of babies in the NICU. Of the survivors, about half are without disability at 3 years of age, and 25 percent have a major impairment such as cerebral palsy (10 percent), blindness (2 to 5 percent), deafness (2 to 5 percent), and developmental delay. These are the babies that make the headlines in newspapers and receive much attention from bioethicists regarding the decision-making dilemmas they pose.

The questions are of three main types: (1) whether to intervene medically, (2) whether a medical intervention should be stopped once it has started, and (3) who should be primarily responsible for these decisions and how. The decisions are critical; failure to provide the medical care in question often leads to death, whereas intervening often brings a chance of survival, either with or without serious impairments. Dilemmas arise on a case-by-case basis, raising one of the most profound questions regarding human life: which life with disability is worse than death?

Thankfully decision making for the majority of preterm infants is much simpler; more than 80 percent of NICU preterm admissions are babies born after 30 weeks' gestational age. Mortality in these babies is extremely low, and individual outcomes are generally excellent. On a population basis, however, the implications of the large numbers of late preterm infants are more important. About 10 percent of babies are born late preterm in the United States, and the frequency of long-term disabilities such as cerebral palsy, although low, is higher in these babies than in those born at term. More babies with disabilities originate each year from this group of patients than from extremely preterm or full-term infants. Half the patients in cerebral palsy registries were not admitted to a NICU at birth. For the remaining half, most were of a gestation greater than 28 weeks at birth. In general, there would be no ethical question about whether to admit these babies to the NICU. In order to substantially decrease disability rates from late prematurity in the population and the NICU costs, one would have to let patients of 28 to 36 weeks' gestation die, which would of course be morally unacceptable.

Preventing Prematurity

A major issue in neonatal ethics is how to prevent babies from being born preterm in the first place. Because of advances in obstetric surveillance, the number of medically induced preterm births for fetal or maternal reasons has grown,

accompanied by a decrease in the stillbirth rate. About 25 percent of preterm deliveries are medically induced because of risk to the fetus or mother [3]. Limiting this source of prematurity may be neither feasible nor desirable.

Today, multiple pregnancies (twins, triplets, or more) and delayed childbearing account for a significant, and potentially reducible portion in the rate of prematurity. The substantial increase in multiple births over the last 2 decades [1, 4, 5, 6] is attributable, in large part, to artificial reproductive technologies (ART). Multiple gestations can occur following ovarian stimulation or when more than one embryo is transferred during in vitro fertilization (IVF). In the United States, 32 percent of live births following IVF are multiple pregnancies. Multiple births increase the risks of fetal, maternal, and neonatal morbidities. Fifty percent of twins and more than 90 percent of triplets are born preterm and admitted to the NICU.

Also contributing to growing numbers of preterm babies is the fact that the average maternal age is increasing; women who deliver after 40 years of age have a greater than 16 percent risk of delivering preterm [1]. As women age, their fertility declines and more employ ART to get pregnant, which places them at even greater risk for premature delivery because now they may have twins or triplets.

Given these biological realities and their consequences for newborns, our society should inform women about the risks of delayed child bearing and encourage them to have children earlier. On average, women in their early twenties have fewer financial resources than those over 35. When a woman decides to have children in early adulthood, does the government provide generous maternity leave, social and economic support for their education, and subsidized, universal childcare services when the child is young? The answer, unfortunately, is no. Society rewards performance, work, and wealth, creating an incentive to delay childbearing. The same women who would receive very limited financial incentives were they to become pregnant at an earlier age when the risks of prematurity were lower end up paying for expensive ART services years later and increasing their risks.

Conflicts between Goals of ART and Best Interest of Newborns

Infertility is a health problem that ART can help treat. There are some alternatives to ART, mainly adoption (local and international) and surrogacy, but these alternatives can be complicated and costly, and are unacceptable to some. ART services are neither reimbursed nor regulated by the Canadian and U.S. governments, which creates discrimination in access to treatment due to the cost of services. Physicians who provide ART are vulnerable to conflicts of interest. ARTs are effective—the rate of conception for fertile couples trying to conceive a baby naturally is about 25 percent per cycle. Some IVF providers, on the other hand, state a success rate per cycle as high as 60 percent [7]. This efficacy comes with a cost: an epidemic of multiple births created by physicians and governments that oftentimes produces complications for babies, their families, and society.

Infertile couples are emotionally vulnerable, which can mean they are willing to take greater health risks to acquire a baby. Because patients pay per cycle of IVF, a “two- or three-for-one” deal is an appealing alternative. But having twins is a lottery; 50 percent of IVF twins are preterm, some extremely preterm. It is also a gamble for women, inasmuch as every risk associated with pregnancy increases when a woman carries more than one fetus. In one study, despite being adequately informed of the risks, patients in fertility clinics still wanted twins: 85 percent of childless women in one study had the goal of getting pregnant with twins [8]. In fertility literature, success of a cycle of infertility treatment is counted as a live birth after 20 weeks’ gestation. By implanting more than one embryo and impregnating patients with fewer treatment cycles, the success rate of a fertility clinic improves, which attracts more clients and improves financial competitiveness: multiple pregnancies can therefore also be seen as beneficial for the fertility physician. These conflicts of interest are largely responsible for the tremendous increase in multiple pregnancies in the United States and Canada. Hence, in a society where the patient pays for IVF, there is a perverse economic incentive for both patients and physicians to increase the risk of complications for mothers and disabilities in babies.

While the ethics hot topics in the reproductive world are pre-implantation genetic diagnosis, selection of various performance genes, and pregnancy in woman over 60, the numbers involved in those endeavors are very small, or even theoretical. In contrast, we calculated that 17 percent of NICU admissions were multiple gestations following ART [9]. Most of these could have been avoided by rigorously controlling the clinical practices relating to the treatment of infertility. It’s easy to envision a public policy to decrease multiple births. Unlike Canada and the United States, some countries—Sweden, Belgium, Finland, and Denmark, for example—regulate and reimburse ART services. In these countries, single-embryo transfer during IVF is the norm. Where financial conflicts of interest related to ART are avoided, patients and physicians seem far less willing to take the unnecessary risk of multiple births in order to become pregnant as quickly as possible. Having children with the least risk for the mother and infant seems to be the morally responsible position.

The cost of IVF treatment goes beyond fees for the procedure itself; it includes the cost of health care to women and their children born from such techniques. Reimbursement for ART should be contingent upon regulating IVF and ovarian stimulation. Exceptions to single-embryo transfer could be considered only for mothers over 38, where the transfer of two embryos can be acceptable to achieve a singleton pregnancy. Medical societies and health-system regulations in the United States and Canada have a moral responsibility to reduce the frequency of multiple gestations following IVF to a level similar to that found in countries where single-embryo transfer is the norm, for example to 6 percent in Sweden (compared to about 32 percent in the United States). Restricting embryo transfers without including reimbursement will likely lead to “reproductive tourism”—women traveling abroad to find unregulated fertility centers where they can continue to have multiple-embryo transfers and hope for multiple gestations with the attendant risks and costs.

Do U.S. hospitals want to decrease NICU stay? While in most areas of pediatrics, frequency and duration of hospitalization have decreased over several years, NICU admissions have gone up mainly because of the increase in prematurity. According to pediatrician and ethicist John Lantos, “NICUs have become the economic engine that keeps children’s hospitals running [10].” Lantos adds, “It almost seems as if society, by some mechanism, is working against health to produce more and more low-birth-weight babies, and that medicine is then working against society, desperately trying to patch the wounds caused by some nameless thing that is forcing our babies from the womb too soon [11].” Countries that have made single-embryo transfer the norm have drastically reduced the rate of multiple births without affecting the pregnancy rate. These countries have lower prematurity rates. Why do we see the epidemic of multiple births as an immutable social and political phenomenon when so many countries have demonstrated that this epidemic is controllable? Do our institutions also have conflicts of interest?

Canada and the United States are successful in developing specialists who have the skills to make preterm babies survive with a good prognosis. NICUs are the most efficient and cost-effective ICUs in modern medicine, but they should not be seen as the only solution to prematurity. In my NICU, physicians and our government are responsible for a preventable 17 percent of the admissions and for significant avoidable mortality and morbidity, which produce unacceptable financial and emotional costs [9]. Medical developments have changed the way physicians and society respond to diseases of neonates, to their illnesses, and to the pain and suffering of their parents. We have to question whether we are responding adequately to these new challenges. Rising prematurity rates and the continued unchecked epidemic of multiple births are a sign of political and moral failure.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 665-669.

MEDICINE AND SOCIETY

Resuscitating the Extremely Low-Birth-Weight Infant: Humanitarianism or Hubris?

Patrick M. Jones, MD, MA, and Brian S. Carter, MD

In any complex, controversial topic, attempts at open dialogue run the risk of shipwrecking on the shore of preconceived, deeply held opinion. For example, walk into a room that contains people at opposite ends of the political spectrum and toss out the phrase “universal health care.” If we had the ability to project their initial reactions onto a screen, they would range from a Technicolor utopian society, dancing hand-in-hand with their health care providers to a stark, gray picture of huddled masses in long outdoor lines awaiting their catheterization for emergent cardiac failure. In a similar way, reactions vary when the phrase “resuscitation of a 24-weeker” is uttered in mixed health-professional company. On one side of the spectrum a person will see the advances in neonatal care that allow a disease (respiratory distress syndrome) that killed President Kennedy’s son only 45 years ago to be consistently and successfully treated today in a premature child born to the least advantaged of our society. Others, should they include pediatric and family physicians, will harken back to their residency days and recall the former premature infant who lived all 6 months of its life on a ventilator in the hospital’s neonatal intensive care unit.

Providing intensive care to extremely low-birth-weight infants (birth weight of less than 1 kilogram) and extremely premature infants (infants born between 22 and 25 weeks’ gestation) raises many questions: (1) Who benefits, and when do these benefits cease? (2) Does survival come at any and all costs to the patients, their families, and the health care staff? (3) And is a technology-dependent child truly reaping what is in his or her best interest?

With the birth, growth, and development of the bioethics community during the last 60 years, these questions have entered the public forum, and neonatology has at times found itself to be the perceived “poster-child” for medical hubris—aggressively treating any newborn, ethical concerns be damned. No doubt, parts of the complex technical, sociopolitical, and ethical history of neonatology moved clinical innovation, research, and practice in this direction [1], but we would argue that this history is neither unparalleled nor limited to neonatology. Indeed, all realms of critical care medicine have struggled with these and similar questions, yet a cloud of prejudice lingers over neonatology, casting its life-saving work into shadow and hiding the complexity of decisions made on behalf of extremely premature infants by families and physicians. The brevity of this article prohibits an in-depth discussion of the history and literature on resuscitation of increasingly smaller and younger

premature infants. Nevertheless, it is our hope that we can guide the reader through some commonly held notions about neonatology that will serve as an impetus for identifying preconceived notions or biases, reflecting on the matter in a more informed manner, and considering a reexamination of this topic's complexities.

Neonatology Constantly Pushes the Line of Viability Downwards

Not really. In fact, the results of neonatologists' ability to save infants as young as 23 weeks' gestational age has been facilitated by a few major advances in applied technology, pharmaceuticals and procedures—not a gradual and persistent push toward saving younger and younger babies. These advances have occurred in a manner described by the evolutionary concept of punctuated equilibrium—large shifts in the evolution of a species followed by small incremental improvements until the next big shift. For neonatology, those shifts have been the advances in thermal regulation; modification of mechanical ventilators used with adults for use with newborns (improved initially by the addition of end-expiratory pressure, and later—with the advent of microcircuit technology—by the capability to synchronize respirations with the neonatal patient); discovery and utilization of prenatal steroids on fetal lung development (so that this obstetrical intervention contributes largely to improved neonatal outcomes); and the development of exogenous surfactant for the treatment of respiratory distress syndrome.

Presently, we are limited in sustaining life for fetal neonates by the developmental biology of the lung and its circulation. This limit will most likely persist inasmuch as further ability to support cardiopulmonary function in the smallest and youngest newborns is not foreseeable without disrupting vital organ development. Since the advent of surfactant therapy 18 years ago, clinical research has not for the most part resulted in the ability to save ever-younger babies. The very real limits of fetal biological development forces neonatologists and others to question the appropriateness of attempting to sustain extra-uterine life when the costs borne by the patient (organ system maldevelopment or failure) argue for considering not simply survival but the quality of the life saved. Hence, the bulk of research in recent years has been directed towards producing better long-term outcomes for newborns who survive prematurity.

Neonatologists Compete to Save the Smallest Premature Infant

Media attention garnered by certain medical centers upon graduating another in a series of “tiniest babies” saved, makes one wonder whether each NICU has a plaque with a revolving set of numbers that change to announce the weight of its smallest baby saved. The senior author on this paper (BC) has failed to interact with any colleague over the past 20 years at four major medical centers who boasted of saving the smallest baby. Nor has the neonatal fellow (PJ), who has trained at three separate institutions in the past 10 years, had any such interaction. In other words, it is not neonatologists who promote such feats.

The greatest pressure to resuscitate extremely premature infants often comes from outside NICUs. In our health care system, NICUs are substantial revenue generators

for hospitals and academic medical centers. As a result, there is a tendency to market women's and infant services in hospitals that have NICUs. The marketing can be done discreetly and with evidence-based local outcomes, or blatantly with large billboards strategically placed on main thoroughfares in a community or in newspaper, television, or Internet advertisements—replete with the seemingly obligatory photo of a tiny baby held in the palm of someone's hand. Considering that health care dollars expended in neonatal services reap more long-term rewards than those spent at any other time in life and with the lowest cost-per-year of life gained [2], the idea for marketing neonatal services comes from offices other than those of neonatologists. The result, however, is that families understandably come to us with the expectation that their premature infant will be as advertised: tiny, cute, and healthy.

Neonatologists Know the Abysmal Outcomes for these Infants, but Push on Regardless

Outcome data is available, but the field is still developing. Making use of follow-up data, investigators are gradually adding to the knowledge base of outcomes for extremely low-birth-weight and early gestation infants [3-6]. The absolute number of these patients is very small (less than 0.5 percent of all U.S. births), and a large number (up to 50 percent, depending upon gestational age) of them die prior to discharge from the NICU. As a result, few infants remain to be tracked in neonatal follow-up clinics that collect information and perform longitudinal neurodevelopmental testing (generally over no more than 2 to 7 years). The follow-up is poorly organized and underfunded in the United States, and, because of this, the existing extremely low-birth-weight outcome literature is based on relatively few numbers. The neonatologist's capacity to prognosticate the outcome for a premature infant, then, is not generally comparable to that of his or her adult medicine colleague who addresses more common, thoroughly studied diseases in larger populations.

Predicting the individual outcome for most extremely low-birth-weight infants remains elusive. Patient information is at times difficult to discover. Depending on a mother's access to and utilization of prenatal care services, estimates of an infant's gestational age can be unreliable. Furthermore, birth weight can vary due to factors other than developmental maturity, allowing children of the same weight to have markedly different chances for survival. But even when all of the desired patient information is available, clinicians are left with the fact that population-based predictions only provide an estimate of outcomes that may or may not accurately reflect the morbidity and mortality risk for any extremely low-birth-weight infant [7].

Two bodies of work that reveal this difficulty are Ambalavanan's attempt to use multiple logistic regression and neural network models to predict extremely low-birth-weight death [8] and Meadow's research on caregiver intuition regarding an individual patient's survival to discharge [7, 9]. While neonatologists may be able to tell prospective parents that, in general, the 22-week gestational age infant will

almost certainly die and the 26-week infant will likely do well, they are not good at predicting the individual outcomes of those who fall in between these age brackets.

Even if our predictive abilities were excellent, there would still be limitations to its use. Parents have an understandable habit of hoping. Should a clinician's ability to predict death or severe disability for an individual patient be so accurate that he or she was wrong only 10 percent of the time, it would still mean to the family that its child had a 1-in-10 chance of living or not being severely disabled. What risk threshold is acceptable and who decides? Do clinicians—as both members of society and the community of health care professionals—stand ready to refuse intensive care to a patient, regardless of the family's wishes? And does giving outcome data to families facilitate their decision-making capabilities [10]?

Conclusion

The dilemmas over resuscitation of extremely low-birth-weight infants reach far beyond the medical profession's obsession with technology (no more present in neonatology than elsewhere in modern medicine), misleading media stories of the tiniest survivor, and forgoing the best interest of the patient to satisfy a family's or physician's agenda. These issues cut to the heart of the human questions that permeate medicine: (1) Who decides best-interest? (2) Who speaks for patients when they cannot speak for themselves? (3) What constitutes futile care? (4) And can we even define the word "futile" in the same manner for persons of different age or religious, educational, socioeconomic, and cultural backgrounds?

Recognizing this complexity allows us to approach the question of infant resuscitation with less hubris and more humanitarianism, humility, and compassion—appreciating why physicians and families continue to struggle to make resuscitation decisions for extremely low-birth-weight infants.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 670-672.

MEDICAL NARRATIVE

Physician Self-Disclosure and Patient Counseling

Judette Louis, MD, MPH

As I looked at the monitor, my eyes filled with tears: cervix measurement—6 mm. I knew what that meant because I had been here before. That time, I had been 18 weeks pregnant with a short cervix and it was a sad ending. This time things looked worse. My cervix was shorter and I was carrying twin A and twin B. My blur of tears was interrupted only by the nurse taking vital signs and bad television.

“No, I don’t want visitors.”

“No, I am not interested in a support group.”

“Sure, the chaplain can come by, but to what end? God clearly does not want me to be happy.”

And I am sure I thought and said many things that were more heretical than that.

Then everything changed. On hospital day 3, my obstetrician looked at me in exasperation and said, “Look, Ms. Doom and Gloom, if hope and prayer work for cancer, what makes you think they don’t work for pregnancy?”

Lying there, I had plenty of time to think about what he had said, and slowly I began to agree. Instead of approaching my situation with fear and inevitability as I had last time, maybe I should try hope and positivity. Of course, I was still realistic about the possible outcome, but I dared to hope that this time it would be different. I requested a calendar and marked off each day. Twin A and twin B became Camille and Kingsley. I celebrated their every movement and the differences in their personalities as I perceived them. I looked at baby furniture (thanks to Wi-Fi). I built a wall of positivity around me. The only people I let know I was in the hospital were those who could help me maintain that wall.

As for the doctors? No matter what words emerged from the lips of some of them, their eyes spoke volumes of pity. When it was time for those pitying physicians to round, I pretended I was asleep. It worked only 60 percent of the time but it was worth the gamble. And slowly the time did go by. I met the viability mark and made it to 25 weeks before the twins needed urgent cesarean delivery. Some were sad for us. But my husband and I were elated because this time, unlike the last, we had a fighting chance in a NICU that boasted an 85 percent survival rate for babies the gestational age of our twins.

It goes without saying that my time in the hospital changed my understanding of the patient's experience. And it complicated the day-to-day challenges I face as a practicing perinatologist. Over time, I have changed my approach to some of these challenges, particularly to two of the most common and obvious: physician self-disclosure and patient counseling.

Physician Self-Disclosure

Because the predominant feeling I had during my hospitalization was one of extreme loneliness, I vowed always to be open about my experience to patients. My physicians admitted that going through the experience with me made them more empathic and taught them a lot about what a patient goes through. Eventually, though, I discovered the difference between "openness" and physician self-disclosure. Physician self-disclosure has received mixed reviews in the literature. While it may improve patients' perceptions of surgeons, it may not do the same in the case of primary care physicians [1]. An investigation that was part of a larger study of patient communication and health outcomes funded by the Agency for Healthcare Research and Quality actually suggested that physician self-disclosure might be disruptive. One hundred primary care physicians agreed to accept two unannounced and secretly recorded visits by people trained to play patient roles. Of the 113 transcripts reviewed, 34 percent of the visits contained at least one self-disclosure. None of the self-disclosures was patient focused, while 60 percent were physician focused, the investigators concluded. Eighty-five percent of the disclosures were considered not useful and 11 percent were viewed as disruptive [2].

It is difficult to predict the impact of physician self-disclosure on a person confronting the shock of an abnormal pregnancy. Initially, I thought, like many physicians, that it was a way to enhance the patient-physician relationship. I have since reconsidered. In delicate situations I now believe that self-disclosure can be harmful and disruptive. It can draw attention away from the patient just when the patient needs that attention most. When a patient asks about my personal experience, the pause during which I have the internal conversation about whether to lie or tell the truth invariably speaks volumes to the patient. A decidedly poor liar, I often abbreviate the truth and try to redirect the conversation toward the patient. And in those moments I long for the days when my answer was, "No, I have never been pregnant."

Patient Counseling

When counseling patients about possible outcomes and therapeutic alternatives, it used to be easy to quote a low rate of intact survival rate for prematurity at the limits of viability—(23-25 weeks). It is more difficult now that I no sooner put my bag down in the front hall than the twins come running up to hug me. And yet, providing statistics is what I have to do and I do it. Counseling affects patient decisions, and it is critical to do it in an unbiased way.

On the other hand, physicians' attitudes have been shown to affect both the probability that an intervention for fetal benefit will take place and infant survival [3]. I don't take this lightly. I still provide the facts and statistics. I still ascertain parents' understanding of the facts. But then I ask them open-ended questions about their thoughts and take cues from them. For those who need more medical facts and information, I provide that. But there is another subset. It is the group that wants hope. Often it is a patient who has been down this path before. For her I am willing to offer hope. Not false hope. Directed hope. It can be hope that her fetus will make it to viability, or that her infant will do better than expected. It might be hope that she will one day heal from this experience or that she will bond and enjoy the time she has with her child. Some are able to celebrate their infants while they have them; to name the child and collect ultrasound pictures. After all, if you thought another loved one was going to die soon, isn't that what you would do?

The challenges continue and my response to them continues to evolve. Overall, I believe my experience has made me more sympathetic to patients with pregnancy complications and has helped me anticipate some of their questions and fears. But their experiences are not mine. What I say to each must serve her needs, not mine.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 673-676.

OP-ED

Medical Decision Making for the Marginally Viable Infant

Ferdinand D. Yates Jr., MD, MA

How should expectant parents react when they learn that the pregnancy will quickly end with the birth of an extremely premature infant? These fragile infants—at the margins of viability—demand extremes of life-sustaining care that often require months in the neonatal intensive care unit (NICU) connected to tubes in various orifices. And after this protracted period of time, what sort of guarantee do the parents have that the infant will be fine? Or, if we suspect that the infant will not be fine, what drives parents to sustain and endure such an intense level of anguish? What rights does the voiceless premature infant have? Does the medical team have the authority to override the medical decisions made by the parents?

Acquiring Good Clinical Facts

Neonatology involves life-and-death decision making, which should begin with accurate medical details [1]. Neonatology has witnessed substantial improvements in the equipment and care provided to the marginally viable infant. But, although currently available prenatal diagnostic equipment is excellent for most settings, major errors can arise in the accurate assessment of gestational age. Accurate gestational age is critical because the variation of 1 week in the determined age of an extremely premature infant (25 weeks instead of 24 weeks, for example) produces a far different set of prognostic implications. The initial complete examination at birth is the best way to assess gestational age accurately. In the early minutes to hours of the life of the marginally viable infant, much medical information becomes available and—typically—drives the decision-making process. At this point, predictions are made, outcomes are assessed, and a medical plan is put in place. It is not unusual for conflict to arise between a medical team and the parents at this juncture when future care is discussed in the context of medical futility. The discussion of medical futility should be framed using only the medical details and facts of the case. It should never be reduced to the notion of the value or quality of a premature baby's life.

Edmund Pellegrino offers the helpful triad of benefits, burdens, and efficacy in assessing medical futility [2]. In this analysis, Pellegrino considers not only the benefits and burdens of a particular treatment, but also the notion of how effective the treatment is in producing the desired results. Quite often, when physicians use these terms, they refer to the importance of benefits, burdens, and efficacy in a utilitarian way and, when speaking of withholding or withdrawing medical care from the marginally viable infant, they typically employ such data as (1) low probability of survival, (2) high probability of severe disability, and (3) high projected costs of medical care (neonatal and throughout) [3]. On the other hand, true medical futility

consists in a treatment plan that is not working in the infant's best interest or the infant's requiring increasingly aggressive treatment to stabilize his or her status.

The Best-Interest Standard

In general, the best-interest standard is the ethical model for medical decision making for the marginally viable infant (and all young children). Decision making under best-interest standards requires the decision maker to use medical information (diagnosis, prognosis, and treatment options) objectively in deciding among various modes of treatment. In its purest form, the standard concerns nothing but the best interest of the patient [4]; preferences of the parents, health care team, and even of the patient (if he or she could express them) are not taken into consideration.

Practically speaking, such a strict standard is extremely difficult to implement because, to the degree that the infant will require significant future care, his or her best interest is inseparable from that of his or her family. Any chronically ill child places great demands upon the family, and decision making directly impacts family resources—time, money, and presence (being at the bedside and establishing a bond). Furthermore, the potential long-term support and care of the marginally viable infant after hospital discharge adds direct care services and financial costs [5]. Clearly the medical best interest is the highest ethical standard; there are times, however, when the best interest of the infant is not so clear. In these difficult situations, the preferences and best interest of the parents may be given more direct consideration in the decision-making process.

Parents and other individuals who advocate for continuing aggressive medical treatment of a marginally viable premature infant often point to notions such as (1) the sanctity of human life made in the image of God, (2) the inherent value of any human life (even if medically compromised), (3) the right, once born, to live a life, (4) future advances in medical science that may mitigate the infant's impairments, and (5) future blessings that continuation of the infant's life may confer. Some parents feel obligated to ask for aggressive medical treatment when an experienced neonatal team observes that providing it can be medically inappropriate and may even hold high risk of harm or pain accompanied by little likelihood of benefit. These parents may feel that the infant's life—no matter how short, or burdensome, or painful—is a life worthy to be lived. Some point to the possibility of medical breakthroughs and to the expectation of unknown (but expected) blessings as they care for their premature infant. Although physicians at the bedside may have difficulty understanding these parental feelings, they must, nonetheless, respect them as a parental privilege.

If the premature infant remains hospitalized for a prolonged period of time, the medical team may be able to suggest parameters which, if reached, would preclude further aggressive medical care. If the premature infant is safely discharged, a thorough discussion with the baby's primary care physician can be instrumental in establishing guidelines that grant both doctor and parents permission to choose not to readmit the infant should certain medical situations arise.

Decision-making authority for the marginally viable premature infant typically falls upon the birth parents (complications may arise if surrogate birth is involved), in large part due to the foundational presumption in our society that parents act in the best interest of their child. The American Academy of Pediatrics refers to this presumption of parental commitment to the child's best interest [6]. Nevertheless, parental decision-making authority is not an absolute right to be obeyed without question. It is possible that the medical decision reached by the parents vetoes treatment that the medical team considers reasonable and appropriate because it has substantial benefits, minimal burdens, and acceptable risks. If the standard of care supports the medical team's decision, then the treating physicians have the ethical and moral obligation to consider overriding parental refusal of treatment. This physician stance should only be taken when medical facts are reasonably certain, and the medical standard of care is easily ascertained.

Medical decision making for the marginally viable premature infant will always be difficult. The medical team should demand dependable medical facts, and the parents should similarly demand full and clear communication regarding these details. Health care professionals must demonstrate a strong bias in the support and preservation of survivable life. The parent, with recognized decision-making authority, and the physician, with professional knowledge and expertise, must work together in evaluating the developments and complications of the infant's medical progress and in making decisions in the infant's best interest. It is appropriate to grant the parent some decisional latitude in this process. Both parents and physicians must recognize that there are certain situations in which the physician's medical-ethical responsibility to the patient dictates overriding a parental request that is medically inappropriate in terms of either excessive or inadequate treatment.

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Acknowledgment

The author wishes to thank Robert Orr, MD, for review of and assistance with this manuscript.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 677-684.

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Virtual Mentor

American Medical Association Journal of Ethics
October 2008, Volume 10, Number 10: 685-687.

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