

# Virtual Mentor

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## 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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