Ethical Issues in Pediatric Critical Care Neurology

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Ethical issues in the critical care unit frequently arise in children with neurological problems. These ethical issues frequently challenge our medical management of such cases and can be quite problematic. This article reviews key ethical issues that may arise including informed consent, futility, justice/rationing, clinical research conduct and the severely compromised patient who is in either a permanent vegetative or minimally conscious state.

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WITHIN THE confines of the pediatric critical care unit (CCU), much drama unfolds. The topic of ethics concerns itself with doing the “right thing” when faced with a choice between possible actions or options to undertake.1 At times the most appropriate ethical choice is not readily apparent, due to variations in basic principles, interpretations, moral values, or particular viewpoints of relevant participating decision makers.3 Ethical dilemmas within pediatrics are exacerbated, and tensions often increased, due to the inherent vulnerability of the subject population.

Another factor is a contextual one, in that a child and family may arrive in the CCU by different routes, which will affect the decision making process, both intellectually and emotionally. A child may have been previously entirely well and whole and abruptly be rendered tenuous and severely compromised by an unforeseen acquired trauma. Alternatively, arrival in a CCU may be the endpoint of a long process of steady decline and deterioration that is the result of an often genetically determined neurodegenerative process or a byproduct of compromise and/or intervention in a nonneurologic organ system (eg, congenital heart disease).

Areas of particular relevance to those providing care to the vulnerable patient in a CCU include the following: informed consent, futility, justice/rationing, clinical research, and neurologic determination of death/permanent vegetative state/minimally conscious state. These topics do not exist independently or in isolation, but rather are interrelated. Despite this, each is considered sequentially in detail in the following sections.

INFORMED CONSENT

To some extent, the basic dictum of medical ethics since Hippocrates of primum non nocere (“first do no harm”) has been supplanted over the past half-century by the guiding principle of respect for individual self-determination and autonomy.2 Indeed, the physician’s obligation to obtain a voluntary informed consent from the patient and/or the patient’s responsible surrogate or guardian has become the “ethical cornerstone of contemporary medical practice”.3

Three conditions must be fulfilled for a consent to be valid:
1. Sufficient information must be provided to allow for a rational refusal or consent for treatment as proposed.
2. Consent or refusal must be voluntary and provided in the absence of any implicit or explicit coercive influences.
3. The decision maker (eg, the patient) must have the necessary capacity to make rational decisions.3

This capacity to provide consent is termed “competence” and can be conceptualized as “the capacity to understand the context of the decision, the choices available, the likely outcome of these choices, and can process this information rationally to reach a decision about consent.”3

In the absence of patient competence, a surrogate or proxy decision maker is required. The authority to act as a surrogate for the pediatric patient is traditionally granted to the child’s parents.9 Standards for proxy decision making exist that follow an ethical hierarchy with respect to patient self-determination (ie, autonomy). In descending order, this ethical hierarchy of proxy consent is (1) expressed wishes, (2) substituted judgment, and (3) best interest.5 Certain evidence of a patient’s expressed wishes for a particular
situation is rarely encountered in clinical practice. Substituted judgment requires that the surrogate have knowledge of the patient’s specific value systems, which is then applied to arrive at a choice in a particular clinical situation. The best-interest standard applies the surrogate’s perception of the perceived benefits and burden to various options to render a particular value judgment, on which a treatment or intervention decision is then predicated.5

The pediatric patient population is not uniform, ranging from birth to age 18 years and with a wide range of cognitive capabilities acquired developmentally with maturation, with variation between individual children and adolescents readily apparent. The infant and preschool-age child are not yet competent. During the school years, the child begins to acquire the necessary cognitive skills that are prerequisite to providing a competent consent to medical treatment. Studies have shown that independent consent by those under age 11 is not yet feasible, whereas it is feasible in those over age 15, with those between these two ages representing a gray zone of comprehension.6 Thus a graduated program of increasing participation and responsibility for medical decision making is an acceptable developmental paradigm. This has led to the concept of assent and dissent in pediatric care.7

The concept of assent and dissent was articulated by the American Academy of Pediatrics Committee on Bioethics in its report/position statement titled “Informed Consent, Parental Permission and Assent in Pediatrics.”8 This report advised including the older child and adolescent in the medical decision making process at a developmentally appropriate level. This inclusion requires that for a valid consent to exist, in addition to consent of the parent or surrogate, the active assent or dissent of the older child/adolescent also should be solicited and respected whenever possible. The older child/adolescent assent and the parent’s/surrogate’s consent are needed independently, but each is insufficient alone to proceed. Both are required elements, with the older child/adolescent’s dissent overriding parental/surrogate consent. If such a conflict does occur, typically it arises in the setting of the chronically or terminally ill older child or adolescent who refuses to continue with painful or compromising interventions while the parents wish to continue the treatment.9 Such conflict may be rooted in differences regarding expectations or in long-standing interpersonal/intrafamilial dynamics. Far preferable to outside intervention measures (ie, judicial review) are such measures as counseling, psychiatric intervention, additional medical consultation, or referral to a hospital ethics consultant/committee, which often lead to satisfactory compromise and resolution.10

A single uniform exception to the need to obtain voluntary informed consent before implementing a treatment path of particular relevance to the CCU is a medical emergency.11 The emergency treatment doctrine allows for the implementation of generally accepted therapy appropriate to the level of the emergency on the basis of a presumed consent, because it is presumed that any rational individual would favor the option that permits the maintenance of life. Indeed, an AAP policy statement advocates the removal of all barriers to effective and timely treatment in pediatric emergency situations.12

It can be expected that the physician providing neurologic care in the CCU will encounter the rare parent/surrogate who refuses, despite strong medical recommendations, to permit potentially life-saving or curative treatment intervention. Sometimes this refusal is based on a genuine desire to minimize the child’s pain and suffering.5 Such a refusal is typically based on compassion and is resolved by medical reassurance that full attention will be given to palliative and pain minimization aspects of care. At other times, the refusal is based on a preference for what has been labeled “alternative medicine” or on profoundly held religious beliefs (eg, Jehovah’s Witnesses’ refusal of blood products).13 For the former, the option of parallel simultaneous treatment may suffice, whereas for the latter, consultation with relevant religious or spiritual authorities or, ultimately, judicial review may be necessary.

A final relevant aspect of informed consent in pediatrics to consider is the concept of emancipated and mature minors.14 Emancipated minors are those under age 18 deemed to be fully independent due to such circumstances as parenthood, marriage, military service, or disownment, who are fully capable of consenting to medical care in the absence of a parent’s/surrogate’s coexisting approval. Mature minors are those over age 14 years who are capable of independently consenting to a
medical treatment of lower risk than that encountered in the CCU, typically pertaining to matters relating to sexuality, contraception, or substance abuse, where privacy constraints may limit access to appropriate care if a parental/surrogate consent was also required.3

FUTILITY

The issue of futility in medicine is not a byproduct of our modern era. Hippocrates stated that “to attempt futile treatment is to display an ignorance that is allied with madness.”15 No universally accepted consensus definition for medical futility currently exists.16 Perhaps the broadest definition is one that characterizes medical futility as occurring when a proposed intervention offers either no benefit to the patient above a minimally accepted qualitative or quantitative threshold or demonstrates only limited likelihood of advancing the patient’s expressed goals.17 Left open to interpretation at the bedside is what exactly this threshold is. Furthermore, as is often the case in a neurologically compromised patient and invariably in a not yet competent (ie, pediatric) patient, is the question of what are the patient’s expressed goals regarding intervention.

Futility can also be conceptualized in terms of probability and scientific evidence, that is, overwhelming improbability in the face of possibility.18 Although a desired outcome is possible, it is highly unlikely—indeed, quite remote. In addition, futility can be recognized in the setting in which an intervention has no appreciable chance of improving the patient’s medical condition or when the quality of the most probable outcome for a particular proposed intervention is overwhelmingly poor.19

From the foregoing, one can pragmatically identify situations in which care is futile. Examples would include when care simply preserves unconsciousness, fails to end dependence on the requirement for intensive care or technological support (beyond periodic dialysis), serves only to prolong the process of dying, or offers no realistic expectation of palliation, improvement, or survival.16 Explicit recognition of futility has been recognized by authorities as a condition for withholding or withdrawing treatment or for terminating the care of hopelessly ill newborns.

Futility thus operates to limit the physician’s obligation to provide total care. There is simply no medical or ethical obligation to provide care that can be deemed futile.20,21 Providing such care is misleading (providing hope where none exists) and violates the trust placed in physicians by patients to provide care that is beneficial and nonmaleficient in character.16

Clearly, the variety of possible clinical situations that may be encountered in practice will prevent the establishment of an uniform, all-encompassing set of guidelines with reference to futility.19,21 It has been noted that discrepancy and conflict may arise between values and the threshold for futility; indeed, the actual threshold for futility will often be an elusive target, highly dependent on the perspective of the particular observer. Conflicts will also sometimes arise between the patient’s concept of an acceptable life to live and the physician’s concept of what can reasonably be done.22 Goals on both sides may be unrealistically held, put forward, and clung to tenaciously.

Given the potential for such conflict and discrepancy, mechanisms for resolving disagreement must be in place.23 Such mechanisms “must be fair, encompassing qualities of being open, conciliatory and accountable. [They] should take place within a context and framework that recognizes existing professional standards, uses relevant outcome studies employing meaningful measures, and in which there is a reasonable deference to the wishes of patients.”16 The decision making should not be unilateral or arbitrary. Education, counseling, clear communication in understandable language, reflection, and anticipation of events to come should be considered to arrive at an acceptable consensus to all parties involved.24 If consensus remains elusive despite best efforts, then care may need to be transferred or, in extreme situations, referred to legal authorities for decision making. Before this, once again referral to a hospital ethics consultant or committee should be attempted.

JUSTICE/RATIONING

Whereas futility involves an individual decision taken at the bedside involving the reconciliation between personal values and scientific reality (as best that can be determined),19 rationing reflects an economic decision based on the realization of limits due to costs and/or avail-
ability of the delivery of health care resources to the population. These are very separate (indeed nonoverlapping) issues. Futility should not be a pretext by which rationing is achieved, and neither should the mechanism of rationing or its need be used to label potential interventions as futile.

Rationing reflects decisions regarding economic policy as applied to health care that are taken at a macro or societal level. It is a conscious, explicit decision to restrict services, frequently technologically intensive and expensive ones, with the aim of limiting costs. To be valid, such a decision must be made collectively and transparently subsequent to thorough discussion involving all affected stakeholders by agents legally empowered to do so (ie, democratically elected, constitutionally relevant representatives).

The principles of justice in ethics is concerned with fairness. All members of a society having the quality of “personhood” must be valued equally. There is explicit recognition, both legally and morally, of the premise that particular aspects of our personhood (ie, gender, race, ethnicity, religious creed, socioeconomic status, disability, sexual orientation) are not to be used as instruments for discrimination. Whether affecting medical decisions at the bedside or rationing, equal access is a valued goal that ultimately protects our own individual best interests. Health care is not a privilege, but a right in our sophisticated developed economies. The challenge has been in realizing and operationalizing this maxim or guiding principle. Physicians do indeed have a leadership and advocacy role in this regard.

CLINICAL RESEARCH

For any field of medicine to advance, applied clinical research is ultimately necessary. For the societal good of advancing knowledge and improving medical care, clinical research requires that some individuals be put at a potential risk. Thus there exists a potential for exploitation and harm to the subjects of clinical research. Considerable efforts have been expended over the past half-century to minimize this adverse potential.

The necessary requirements for the ethical conduct of clinical research include the following elements: scientific value, scientific validity, informed consent, favorable risk–benefit ratios, fair subject selection, and respect for subjects. The first three of these elements apply consistently to all clinical research and require that there be potential for a discernible improvement in health care, proper methodology and research design, and validation through independent review external to the vested interests of the study’s investigators.

The latter four elements for the ethical conduct of clinical research have unique issues within pediatrics. As noted earlier, informed consent in pediatrics requires a need for a proxy consent that provides a safeguard to protect the interests, dignity, and integrity of the child. Because children are not yet competent, the proxy (typically the parent) must apply a best-interest model for decision making that has as its highest priority those choices that preserve the child’s well-being and maintains the child’s capacity to ultimately develop into an autonomous decision maker. As noted earlier, wherever possible and whenever developmentally appropriate, the child’s assent or dissent with respect to research involvement should be sought.

The inherent vulnerability of children due to their natural incompetence confers on them a right of custody, that is, to be taken care of and sheltered as best as possible from harm on both a familial level and a societal level. Although in all clinical research activity the principles of nonmalfeasance and beneficence mandate a favorable risk–benefit ratio, we are especially risk-averse when children are subjects. Benefits to research participation must be evident to both the individual child and children in general to allow participation. Harm is broadly assessed, with potential benefits conservatively estimated and not overstated.

“Minimal risk” is the standard for the threshold of harm to which children can be exposed in clinical research without additional procedural protection. Minimal risk has been defined as a level of harm or discomfort that is not greater than those risks that a child may encounter in daily life. Research activities that meet this minimum standard include chart review, blood and urine sampling, vaccination, and routine psychological and physical examination, the former involving questionnaires or observational techniques.

For those studies involving any increment beyond minimal risk, the risk must be consistent with the actual medical situation experienced by that
particular child (ie, investigations and procedures that would normally be considered), and the research must involve a direct potential benefit to the affected child or to the class of children (ie, those with the same disease) to which the child belongs.\(^3\)\(^1\),\(^3\)\(^2\)

Fair subject selection protects against samples of convenience.\(^3\)\(^5\) Participants in a clinical research project should be determined solely by the scientific goals of the study design, with rigid inclusion and exclusion criteria consistently applied as the sole arbiter of study entry.\(^2\)\(^7\) Research on children in a CCU should be directed solely at the study of the condition affecting the child. Respect for subject necessitates that the distinctiveness of children be recognized in study design and execution. These twin principles also mandate that despite the challenges of conducting pediatric clinical research, the health care needs of children should not be ignored, and children should not become “therapeutic orphans.”\(^2\)\(^6\),\(^3\)\(^4\) It would be unfair and unjust to deny a whole class of patients the potential benefits of research efforts aimed at alleviating or minimizing suffering.

**NEUROLOGIC DETERMINATION OF DEATH/ PERMANENT VEGETATIVE STATE/MINIMAL CONSCIOUS STATE**

The development of CCUs and the mechanisms for long-term cardiorespiratory support precipitated the conceptualization of “brain death” in which the irreversible cessation of cerebral and brainstem activity is compatible with the end of life.\(^3\)\(^6\) Explicit standards and protocols for the neurologic determination of death (NDD) have been developed for both adults and children.\(^3\)\(^7\) Brain death is a biological construct, not an ethical construct, and for this author its recognition and diagnosis at the bedside according to established professional standards poses absolutely no barrier to termination and withdrawal of care and the harvesting of organs if the requisite proxy consent for doing so is obtained.

A vegetative state is one in which there is “complete unawareness of the self and the environment accompanied by sleep-wake cycles with either complete or partial preservation of hypothalamic and brainstem autonomic functions.”\(^3\)\(^8\)\(^3\)\(^9\) A permanent vegetative state (PVS) exists if the condition is evident 3 months subsequent to a nontraumatic (ie, anoxic) brain injury or 12 months subsequent to a traumatic brain injury.\(^3\)\(^8\),\(^3\)\(^9\) A minimally conscious state (MCS) has been defined as a “condition in which minimal but definite behavioral evidence of self or environmental awareness is demonstrated.”\(^3\)\(^0\),\(^4\)\(^1\) Such awareness may be demonstrated by reproducible voluntary or purposeful behavioral responses to a variety of stimuli, evidence of language comprehension or simple expression, simple command following, or evidence of the experience of pain and/or suffering.\(^4\)\(^1\)

Unfortunately, some children with neurologic compromise in a CCU will evolve into a PVS or permanent MCS condition. The major ethical issues with respect to these two patient groups has focused on the withdrawal of care.\(^4\)\(^1\) Both groups are unable to perform activities of daily living and remain entirely dependent for life on the sustenance of others (eg, feeding tubes, round-the-clock nursing care) with no hope for improvement. Furthermore, in the absence of explicit, clear advanced directives (invariably so in pediatrics), the affected individual is incapable of expressing treatment preferences in any meaningful or discernable way.

Legally, courts have supported the withdrawal of treatment if requested by the appropriate proxy for those in PVS.\(^4\)\(^2\) The courts have not yet done so with individuals with MCS, deciding to err on the side of caution and to choose life.\(^4\)\(^3\) Thus those with MCS have an elevated moral status compared with those with PVS, even though one can make a case that their ability to experience pain and suffering suggests a fate worse than PVS. It must be remembered that although a “right to die” exists for those in PVS, there is no “duty to die” though often these two entities have been historically confused by proponents of euthanasia.\(^4\)\(^4\)

**CONCLUSION**

The neurologically compromised child in a CCU poses a complex medical challenge to caregivers. Concurrent with these medical and scientific challenges is an ethical challenge to maintain appropriate standards of care that are consistent with our most valuable principles of respect for persons, beneficence, and nonmalfeasance. To provide the best overall quality of care, these principles must be embraced and put into practice as rigorously and with as much enthusiasm at the bedside as our latest advances in therapeutics.
REFERENCES