

Public Health and the Law

Ethics Committees in Neonatal Care: Substantive Protection or Procedural Diversion?

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Ethics committees are widely acclaimed in this country as a possible way out of the dilemmas of decision making in the neonatal intensive care unit, as well as in other critical care areas. Nonetheless, the concept remains ill-defined, the committees' mission and structure vague, and the impact on patient care uncertain. To be a positive influence in patient care, their goals must be clearly defined, their substantive principles clearly articulated, and their procedures fair.

In late April 1984, the American Academy of Pediatrics (AAP) released their *Guidelines for Infant Bioethics Committees*, and urged all hospitals to establish such committees.¹ The guidelines were developed by the Academy as a response to the Reagan Administration's Baby Doe regulations, and as an alternative to them.^{2,3} The Department of Health and Human Services (HHS) recommended the use of similar Infant Care Review Committees at the request of AAP as a part of Baby Doe regulations,⁴ and the President's Commission for the Study of Ethical Problems in Medicine suggested that in difficult cases "an 'ethics committee' or similar body might be designated to review the decision-making process."⁵

Types of "Ethics Committees"

The concept of ethics committees is not new; indeed, in one variation or another they have been used in the hospital setting whenever there has been a value conflict that has been explicitly identified and which cannot be ignored. For example, prior to *Roe v. Wade*,⁶ some state statutes prohibited abortions unless an abortion review committee found that the pregnant woman's life was in danger.⁷ And in the human experimentation setting, Institutional Review Boards (IRBs), designed to approve the research proposal and the consent process, have existed in most hospitals since the early 1970s.⁸ Committees were mandated in Oregon and California to review the individuals for whom psychosurgery was recommended.⁹ And when Dr. Barney Clark received his artificial heart, a multidisciplinary committee—which included the surgeon, a member of the IRB, a social worker, and another individual—reviewed his medical history and

suitability prior to approving him as a candidate.¹⁰ All of these committees differ from one another, however, and the term itself is contentless, and means different things to different observers.

The use of such ethics committees has had neither universal appeal nor consistent success. In Seattle, in the late 1960s, patient selection committees were used to decide which of the candidates for kidney dialysis should have access to this life-saving procedure. The decision was based not on some general theory of justice or fairness, but on the notions that some individuals may be more worthy than others, and that a "worthiness" decision should not be made by a physician alone. As one physician member put it, "it's a lot more reassuring to play one-fifth God—to share the decision with other people."¹¹ As laudable as the notion of community decision making may be, the public perception that social worth was used as a criterion for living or dying was repulsive and led to the abandonment of the committee.¹¹ Likewise, the New Jersey Supreme Court in the Karen Ann Quinlan case envisioned a multidisciplinary committee to review decisions to remove individuals from mechanical ventilators if they were in a persistent vegetative state to "diffuse the responsibility"¹² for the decision. This was soon seen as an improper use of such a committee: the court found medical prognosis the determining factor, and only qualified physicians can make this determination. Thus New Jersey "ethics committees" have been replaced by "prognosis committees" made up entirely of consulting physicians.^{5,13}

Committee Functions

These examples demonstrate that the use of "ethics" committees for complex treatment decisions has arisen for a variety of reasons, from confirming a medical diagnosis or prognosis, to selecting among candidates for a medical procedure, to reviewing research protocols. There is no obvious way to classify such committees, but they can be usefully viewed from the perspective of public policy if they are classified functionally. There are primarily two functions such committees play: protecting the health care institution and providers, and protecting the patient.

Protecting the Institution

Institutions and their staffs often see the primary function of ethics committees as protecting them against potential legal liability for treating or not treating particular patients. This is, for example, the primary function of the early abortion review committees, the dialysis patient selec-

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tion committees, and the Karen Quinlan prognosis committees.¹³ By using committee review, legal liability is either drastically minimized, or eliminated altogether. This is a legitimate institutional goal, but such committees should probably be termed "risk management" or "liability control" committees instead of ethics committees.

Protecting the Patient

The much more important potential function of ethics committees is the protection of the autonomy and dignity of individual patients. This is, for example, the primary function of IRBs, and psychosurgery and artificial heart committees, although their use also protects the institution. The notion is that, because of their unique vulnerability, some categories of patients merit special protection to ensure that their human rights are not violated. Some settings also lend themselves to the Human Rights Committee approach, such as institutions for the mentally ill and mentally retarded. Handicapped newborns may also be such a category of patients meriting protection, and a properly structured committee whose purpose is to protect infants (instead of institutions) may be desirable.

Infant Review Committees

The President's Commission concluded that "seriously erroneous decisions about the treatment of newborns" in this country "appear to be very rare."⁵ Those that do occur tend to happen because of one or more shortcoming in the current system:

- failure to communicate appropriate information to all involved in the decision;
- failure of all involved to understand the basis of a decision to treat or not to treat;
- taking actions without the informed approval of the parents or other surrogates.⁵

These concerns can probably be most directly and constructively addressed by requiring an expert consultant in the child's condition to explain the child's prognosis and treatment alternatives to both the attending physician and the child's parents. In cases where treatment would be beneficial to the child, it should, of course, be rendered. In cases in which the benefits of therapy are "less clear," the President's Commission opined that an ethics committee "might be designated to review the decision-making process."⁵ The purpose of this review would include verification of the information used to make the decision, confirmation of the propriety of the decision, resolution of disputes concerning the decision, and, where necessary and appropriate, referral of the case to public agencies, including child protection services.

In the Baby Doe regulations, the Administration takes a step beyond the Presidential Commission's cautious suggestions about the potential usefulness of ethics committees and "encourages" each recipient of federal funds that cares for infants to establish an Infant Care Review Committee (ICRC). The proposed committee is composed of at least seven members, including a practicing physician, a practicing nurse, a hospital administrator, a lawyer, a representative of a disability group, a lay community member, and a member of the facility's medical staff who shall be chairman.⁴ The committee's function is twofold: 1) assist the facility in developing standards, policies and procedures for treating handicapped infants; and 2) assist in making decisions concerning medically beneficial treatment in specific cases.⁴ When specific cases are decided, the ICRC shall designate one member to act as a special advocate for the

infant to ensure that "all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC." The ICRC will also engage in retrospective record review of "all records involving the withholding or termination of medical or surgical treatment to infants."⁴

The proposal by the American Academy of Pediatrics is similar in spirit to the Administration's, but it tilts more in the direction of protecting the institution by keeping difficult cases out of court than of protecting the infant. The core committee itself is identical to the Administration's, with a pediatrician knowledgeable about the nursery taking the place of a staff physician, and three additions: a social worker, a member of the clergy, and a "person trained in ethics or philosophy."¹ This composition enhances the likelihood that "ethics" rather than medical issues will be discussed. The requirement for a special advocate for the infant has been eliminated, however, making it unclear whose function, if anyone's, it is to advocate in favor of treatment. This is troublesome given the ability of the committee to exclude even the infant's parents from "the deliberative portions of the meeting." Also, unlike the Administration's proposal, the AAP proposal contains no substantive rules for the ethics committee to apply, not even the "Principles of Treatment of Disabled Infants" (which the AAP itself helped draft) which provide, among other things:

When medical care is clearly beneficial it should always be provided. . . . In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. . . . a presumption always should be in favor of treatment.⁴

What Role for Ethics Committees?

Four basic roles have been suggested for ethics committees: education, consultation, policy making, and decision making. Ethics education is a laudable mission, but, to be effective, it generally requires an expert in the field. A group of non-experts is unlikely to be able to teach much of substance to other non-experts, and thus the diverse ethics committee is likely to fail as an effective educator of medical ethics in the institution. Similarly, consultation is crucial, but almost always demands the knowledge or experience of an expert. If consultation concerning the patient's prognosis is indicated, for example, a medical expert in the particular condition from which the patient is suffering should be consulted, not a committee of generalists. On the other hand, if consultation is thought of broadly, to include a forum for discussion, an ethics committee might fulfill this function (although a forum could be provided without a formal committee structure).

This leaves two realistic roles for ethics committees: policy making, and individual decision making. These are the functions of legislatures and courts, but are sometimes combined, for specialized regulation, in an administrative agency. Specifically, administrative agencies develop and promulgate agency policy through regulation or rule-making procedures (the procedures followed, for example, in developing the Baby Doe regulations). These regulations have *general applicability* to all persons who are subject to the agency's authority. In performing this function, the agency acts like a legislature. Secondly, these agencies determine in individual cases whether or not a *specific person* has violated its regulations through an adjudicatory process. In performing this function, the agency acts like a court. Agencies

are set up to regulate certain areas because of their expertise and because their procedures are less formal and thus more efficient than either legislatures or courts. This is, of course, the stated rationale for ethics committees: they have the expertise and closeness to the hospitals that legislatures lack, and they may be able to make quicker, less public, and more efficient decisions than the courts.

Policy Making

Ethics Committees have neither the authority nor the jurisdiction to make policy. And even if the hospital trustees delegated such authority to them, they are unlikely to succeed in formulating policy in the long run. Ultimately, it will be seen as unjust to have fundamentally different policies regarding the treatment of handicapped newborns at different hospitals. Policy in this area will have to be nationally based and thus consistent from one hospital to another. In the short run, however, while there is no national consensus on the appropriate treatment of certain categories of handicapped newborns, some diversity may be both tolerable and desirable as a method to develop more universal policy. But as soon as a national consensus does develop, it will not be fair or feasible for individual hospitals to ignore it and set their own idiosyncratic policies. To give an easy example, a brain death definition must be universal and socially acceptable. Hospitals cannot alter the definition to suit their own purposes.

Individual Case Adjudication

Individual case adjudication is the only function ethics committees might be uniquely suited to perform in the long run. Such adjudication should have three characteristics: 1) an impartial and competent tribunal; 2) the right of affected parties to participate through special procedural devices like notice, opportunity to produce evidence, and the right to cross-examine opposing witnesses; and 3) a requirement that the decision be based on the record established before the tribunal, and that it be consistent with accepted principles and rationally explained.¹⁴ In the ethics committee context, some modifications might be appropriate, but fairness to the parents and the child demands that each should be represented throughout the proceedings, with the opportunity to present and cross-examine witnesses. Whatever decision is reached should be on the basis of the evidence presented to the committee, which is reviewed in a written decision that contains a reasoned and principled basis for the decision. This implies two things: 1) a set of substantive principles

upon which to base decisions must be developed before this procedure can be used in a non-arbitrary manner; and 2) since "due process" must be the primary concern of adjudication, a lawyer should be the chairman of the committee.

New decision-making procedures will ultimately be judged on the basis of three criteria: accuracy, efficiency, and social acceptability.¹⁴ Ethics committees will probably be as accurate as the current doctor-patient model, and more accurate if they can gather relevant information that might not otherwise be considered; less efficient in terms of time and effort; and worthy of public acceptability only if their primary function is the protection of the infant. If their primary function is protection of the institution, such committees will serve only to postpone the day of patient-centered reform by temporarily creating the illusion that something is being done to protect vulnerable patients. Experimentation with such committees seems in order; but it is premature to pretend that they can solve the very difficult substantive issues raised by neonatal rescue medicine by simply adding a procedural layer to the decision-making process. The development of substantive standards for decision making remains our first priority.

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