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A History of Ethics and Law in the Intensive Care Unit

John M. Luce, MD⁺ and Douglas B. White, MD, MAS[#]

- + Professor of Medicine, University of California, San Francisco, and Chief Medical Officer, San Francisco General Hospital, San Francisco
- # Assistant Professor of Medicine and Member, Program in Medical Ethics, University of California, San Francisco

Abstract

Synopsis

Because they provide potential benefit at great personal and public cost, the intensive care unit (ICU) and the interventions rendered therein have become symbols of both the promise and the limitations of medical technology. At the same time, the ICU has served as an arena in which many of the ethical and legal dilemmas created by that technology have been defined and debated. In this essay, we outline major events in the history of ethics and law in the ICU. We cover 10 areas: 1) the evolution of ICUs, 2) ethical principles, 3) informed consent and the law, 4) medical decision-making, 5) cardiopulmonary resuscitation, 6) withholding and withdrawing life-sustaining therapy, 7) legal cases involving life support, 8) advance directives, 9) prognostication, and 10) futility and the allocation of medical resources. We emphasize that advancement of the ethical principle of respect for patient autonomy in ICUs increasingly is conflicting with physicians' concern about their own prerogatives and with the just distribution of medical resources.

Keywords

Biomedical ethics; end-of-life care; withholding and withdrawing life-sustaining therapy; cardiopulmonary resuscitation; do-not-resuscitate orders; critical care medicine

Introduction

Intensive Care Units (ICUs) have existed in the United States (US) and other developed countries for approximately 50 years. During that time, many patients have benefitted from mechanical ventilation and other medical interventions available in the units. However, these treatments have not been in the past and are not today uniformly effective. According to Angus and colleagues (1), one-fifth of all Americans now die after using intensive care sometime during a terminal hospital admission. Whether they live or die, many ICU patients experience

Address queries to Dr. Luce (corresponding author) at: Division of Pulmonary and Critical Care Medicine, San Francisco General Hospital, 1001 Potrero Avenue, Room 5 K1, San Francisco, CA 94110, Telephone: 415 206-8289, Fax: 415 695-1551, E-mail E-mail: john.luce@sfdph.org.

Address queries to Dr. White at: Program in Medical Ethics, University of California, San Francisco, 521 Parnassus Avenue, Suite C126, Box 0903, San Francisco, CA 94143-0903, Telephone: 415 502-8275, Fax: 415 476-5020, E-mail: dwhite@medicine.ucsf.edu

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prolonged pain and suffering. At the same time, their care comes at a high price: Multz and colleagues (2) have estimated that in 1998, ICU expenditures in the US amounted to 34% of hospital budgets, \$62 billion in health care costs, and more than 1% of the gross domestic product.

Because they provide potential benefit at great personal and public cost, the ICU and the interventions rendered therein have become symbols of both the promise and the limitations of medical technology. At the same time, the ICU has served as an arena in which many of the ethical and legal dilemmas created by that technology have been defined and debated. In this essay, we outline major events in the history of ethics and law in the ICU. We cover 10 areas: 1) the evolution of ICUs, 2) ethical principles, 3) informed consent and the law, 4) medical decision-making, 5) cardiopulmonary resuscitation, 6) withholding and withdrawing life-sustaining therapy, 7) legal cases involving life support, 8) advance directives, 9) prognostication, and 10) futility and the allocation of medical resources.

Although other countries have contributed to the history covered in this article, we highlight the US because we are most familiar with how ethical principles are applied in our country and with its laws. In addition, although nurses and other clinicians are invaluable members of the ICU team, we focus primarily on the role of physicians in causing and confronting ethical and legal issues. Finally, although we mention some men and women who have dealt with these issues and contributed to our knowledge of them, we have not been able to mention many others because of space limitations.

The Evolution of Intensive Care Units

The ICUs now commonplace in hospitals in the US and other developed countries evolved from three main sources, according to Hilberman (3). First was the postoperative recovery unit, the first of which was established for neurosurgical patients at the Johns Hopkins Hospital in Baltimore in 1923. The demand for recovery units increased during World War II with the development of field hospitals and new surgical techniques that kept patients alive but required prolonged recovery. The Ochsner Clinic in New Orleans opened a recovery unit in 1947 so that patients undergoing complicated procedures such as pneumonectomy and esophagogastrectomy could be maintained after surgery. This and other recovery units were the forerunners of today's surgical ICUs (SICUs).

The first medical ICUs (MICUs) were created primarily to care for patients with respiratory failure caused by poliomyelitis and other neuromuscular diseases. Negative pressure ventilation was used for such patients until Ibsen (4) demonstrated the superiority and wider applicability of positive-pressure ventilation during the polio epidemic in Copenhagen, Denmark in 1952. Respiratory care units were opened in Toronto, Canada, Uppsala, Sweden, and at the Baltimore City Hospital in 1958. The Baltimore unit, which was developed by Safar (5), is regarded by Ayres and Combs (6) as America's first stand alone ICU.

The first coronary care units (CCUs) were established in 1962 at Toronto General Hospital, Bethany Hospital in Kansas City, and Presbyterian Hospital in Philadelphia (3) These and the other units that followed were based in large part on advances in electrocardiographic monitoring, which revealed that potentially treatable arrhythmias often caused death in patients with myocardial infarctions, and on resuscitative techniques that could best be used in such patients if they were closely monitored. These advances included AC defibrillation, which was shown to reverse ventricular fibrillation by Zoll and colleagues (7) in 1956; closed-chest cardiac massage, reported by Kouwenhoven and colleagues (8) in 1960 to support patients who arrested while receiving anesthesia; and DC defibrillation, which was demonstrated to be superior to AC defibrillation by Lown and colleagues (9) in 1962.

Specialized units for neonatal and pediatric patients, patients with burns and neurosurgical problems, and patients recovering from heart surgery were developed after SICUs, MICUs, and CCUSs were established. Like the earlier units, these new ones were justified primarily by studies demonstrating the physiological effects of mechanical ventilation (10) and other therapies. Few outcome studies were actually available in the 1950s, 1960s, and 1970s, other than those showing improved survival due to the detection and correction of arrhythmias after myocardial infarction (11). Nevertheless, because they housed impressive innovations that could reverse physiological dysfunction and sustain life, ICUs became a standard of care. In the process, physicians and others who practiced in the units witnessed increasing conflicts among the ethical principles applied there.

Ethical Principles

In 1978, Beauchamp and Childress (12) delineated four principles that they believed could organize physicians' thinking about the ethical practice of medicine: 1) beneficence, the physicians' duty to help patients whenever possible; 2) non-maleficence, the obligation to avoid harm; 3) respect for autonomy, the patients' right to self-determination; and 4) justice, the fair allocation of medical resources. The principles of beneficence and non-maleficence underlie the fiduciary relationship through which physicians serve the best interests of their patients and hold those interests in trust. Respect for autonomy allows patients to define and prioritize their interests. Justice situates patients within the larger society and acknowledges the importance of treating similar patients in similar ways. Ethical principles are insufficient by themselves to guide practice, but instead allow physicians to identify circumstances in which ethical goals are in conflict. For example, respect for autonomy and justice may conflict if a patient requests scarce medical resources needed by others who are more likely to benefit from them.

Jonson (13) has observed that beneficence and non-maleficence are the oldest ethical principles. They were contained in the Hippocratic corpus, wherein there is no consideration of the issues of proper disclosure to patients, some of whom were slaves, or of obtaining their consent before medical interventions. Similarly, Percival's (14) historic *Medical Ethics*, which when published in 1803 was the first work to incorporate "medical ethics" in its title, makes no mention of respect for patients' self-determination or their right to make medical decisions. The first Code of Ethics of the American Medical Association (AMA) (15), published in 1847, was designed largely after Percival's British publication and was based solely on the principles of beneficence and non-maleficence, along with the virtues of physicians who applied these principles.

According to Faden and Beauchamp (16), the initial consideration of autonomy as a compelling ethical principle occurred when informed consent found its way into American medicine in the mid-20th century. One reason for this appearance was increasing legal appreciation of the right of consent, as will be discussed. Another was growing concern about civil liberties involving ethnic minorities, women, and other groups. A third reason was post-World War II realization of atrocities committed by the Nazis in the name of medical research, and of the lack of informed consent in the Tuskegee Syphilis Study in the US. The Nuremberg Code of 1947 (17) and the World Medical Association's Declaration of Helsinki in 1964 (18) grounded the principle of autonomy in biomedical research. The AMA Code of Ethics was revised to incorporate informed consent for both clinical and research purposes around the same time.

Informed Consent and the Law

The right of patients to consent to or refuse medical treatment has been contained for centuries within English and American common law. Common law also has held that physicians have a number of professional duties to patients, including the duty to endeavor to be beneficent and

to avoid harm. Before the 20th century, courts in both England and the US did not include informed consent as a duty unless "medical experts testified that such consent comprised an ordinary and beneficial part of medical therapy (16)." On the few occasions when medical experts so testified, they supported informed consent solely on the grounds of beneficence and not because they supported patient autonomy (19).

The legal obligation of clinicians to obtain consent before treating patients was established by several landmark decisions in the US in the 20th century. In the first case, *Schloendorff v. Society of New York Hospitals* (20), the Court of Appeals of New York in 1914 determined that "Every being of adult years and sound mind has the right to determine what shall be done with his own body ---." In the second case, *Salgo v. Leland Stanford University Board of Trustees* (21), which was heard in 1957, the Court of Appeals of California stated that clinicians must disclose to a patient "all the facts which mutually affect his rights and interests -- -" in obtaining consent. In the third case, *Cobbs v. Grant* (22), the Supreme Court of California in 1972 established that "The scope of the physician's communication to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision."

Medical Decision-Making

The court cases that clarified informed consent in the US were a reaction to medical decision-making influenced, if not dominated, by the traditional paternalistic model. Also called *priestly* by Veach (23) in 1975 and *parental* by Burke (24) in 1980, this model is based on the ethical principles of beneficence and non-maleficence. It allows clinicians to define what is within the best interests of their patients without necessarily knowing what the patients want or consulting them. The paternalistic model is particularly well suited to decision-making in emergency situations wherein time is of the essence, patients may be unable to communicate, and consent for treatment (but not research) can be waived because most people would prefer to be treated (but not necessarily enrolled in research) in these situations.

Emanuel and Emanuel (25) have described another model of medical decision-making that supplanted the paternalistic model in the latter half of the 20th century: the deliberative one. Under this model, clinicians help patients define their best interests, provide treatment alternatives through which the interests can be served, and assist the patients in deciding which alternative is best. The deliberative model is best suited for situations in which clinicians and patients have ample time to discuss alternatives, extensive communication is possible, and consent can be informed. Clinicians need not be neutral under this model, as Ingelfinger (26) noted in 1980. Rather, decision-making by patients and clinicians is shared, a practice that was endorsed as recently as 2003 by the 5th International Consensus Conference in Critical Care (27).

The deliberative model of medical decision-making initially was predicated on the assumption that clinicians and patients could communicate with one another. Similarly, the Nuremberg Code and the Declaration of Helsinki addressed consent for research only by subjects who could make their own decisions, just as the court cases regarding informed consent for medical purposes considered only patients who were legally competent. The question of whether incompetent patients could refuse treatment fell to courts in the second half of the 20th century, when ICUs were developed and clinicians began treating large numbers of patients whose cognitive function was impaired by critical illnesses and its treatment and could not make decisions themselves.

Cardiopulmonary Resuscitation and Do-Not-Resuscitate Orders

One of the first treatments used in critically ill patients without obtaining their consent was cardiopulmonary resuscitation (CPR). Indeed, after closed chest cardiac massage and DC defibrillation were introduced in the 1960s, most American hospitals required that they be administered to all patients who suffered cardiopulmonary arrest in and outside ICUs, as recalled by Burns and colleagues (28). This universal requirement for CPR was based on the assumptions that the nascent technology would benefit and not harm patients, that not providing CPR constituted "passive euthanasia" and was therefore unethical, and that failure to perform resuscitation might invite civil suits or criminal prosecution.

In 1983, Bedell and colleagues (29) demonstrated that although 44% of hospitalized patients responded initially to CPR, only 14% survived to hospital discharge. Decades before that publication, however, many physicians had already realized that CPR could transiently restore physiological function in some patients but often prolonged their suffering until they finally died. This led Symmers (30) in 1968 to question whether the new technology was truly sustaining life or merely interfering with the dying process. The realization also led some physicians to decide which patients should or should not be resuscitated and thus to apply this medical resource selectively.

In the early 1980s, alarmed by the death under mysterious circumstances of a patient in a Queens hospital ICU, a New York grand jury discovered that hospital physicians had been ordering that small purple dots be affixed to the charts of patients they did not want to resuscitate. The dots were removed after patients died so that their de facto do-not-resuscitate (DNR) status could not be identified (31). During the same period, physicians commonly conducted "slow codes" in which they delayed CPR or provided resuscitation in such a fashion that it was destined to fail. According to Gazelle (32), slow codes were used primarily in patients with terminal illness or dementia and those in a persistent vegetative or other comatose state. The wishes of these patients regarding resuscitation generally were unknown to their physicians, although in some cases the physicians were putting on a show for surrogates who desired that all therapies be used in their loved ones.

Purple dots and slow codes initially were surreptitious responses to universal resuscitation policies that physicians considered maleficent and perhaps wasteful of medical resources. In time, however, physicians and hospital administrators realized that some patients and their surrogates did not want CPR. Although the legal propriety of not resuscitating some patients with their or their surrogates consent remained uncertain, in 1974 the AMA (33) proposed that DNR decisions be documented in the medical record and argued that "CPR is not indicated in certain situations, such as in cases of terminal irreversible illness where death is not unexpected." Two years later, Massachusetts General Hospital (MGH) and the Beth Israel Hospital in Boston publicly reported their policies regarding end-of-life care for critically ill patients (34,35).

Although the Beth Israel Hospital policy dealt only with CPR and writing explicit DNR orders, that of Massachusetts General Hospital covered the broader topic of: "Optimum care for hopelessly ill patients." It described the on-going application on ICU admission of a system in which patients were divided into 4 categories: 1) those patients expected to live, who were to receive maximal therapeutic effort; 2) those who might die and should receive maximum effort but be evaluated daily; 3) those who were likely to die and who should receive selective limitation of therapeutic measures; and 4) those with severe neurologic impairment who should have life support discontinued after consultation with and concurrence of the patients' surrogates, who were not considered likely to initiate the process themselves.

Withholding and Withdrawing of Life-Sustaining Therapy

In an editorial entitled "Terminating life support: out of the closet!" that accompanied these reports, Fried (36) praised Massachusetts General Hospital and the Beth Israel Hospital for going public with their policies. Few other commentators would argue in print that CPR and other kinds of life support should be withheld or withdrawn from patients in 1976. However, during that year the Supreme Court of New Jersey, in its decision regarding Karen Ann Quinlan, established that incompetent patients, through their surrogates, could refuse mechanical ventilation. Along with the reports of policies from the Boston hospitals, this landmark legal case prompted a series of publications denoting how life support could be foregone in the ICU.

The first of these publications came from the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which explored the medical, legal, and ethical issues in the determination of death (37), in the patient-provider relationship (38), and in deciding to forego life-sustaining treatment (39). Coming from a body empowered by the President, these publications provided the first consensus-based ethical rationale for limiting unwanted therapy in critically ill patients with terminal illnesses. The Commission's publication on foregoing treatment in 1983 coincided with an editorial by Grenvik (40) describing how he and his colleagues used a process called "terminal weaning" to discontinue mechanical ventilation and other interventions in the terminally ill. The next year, Wanzer and colleagues (41) described limiting treatment and other aspects of "The physician's responsibility towards hopelessly ill patients" in a follow-up to the 1976 publication from Massachusetts General Hospital.

Withholding and withdrawing mechanical ventilation was the focus of a workshop convened by the National Institutes of Health (42) in 1986; Ruark, Raffin, and the Stanford University Medical Center Committee on Ethics (43) that year; and Schneiderman and Spragg (44) in 1988. In 1989, a second publication on "The physician's responsibility towards hopelessly ill patients" by Wanzer and colleagues (45) acknowledged that DNR orders, advance directives, and professional and public approval of allowing patients with terminal illnesses to forego treatment was now commonplace. Theses investigators also noted that the courts increasingly were attributing the deaths of such patients to their underlying medical conditions rather than to the withholding or withdrawal of life-sustaining therapy.

In 1990, Smedira and colleagues (46) published the first description of how and why life support was foregone in critically ill patients in the US. From their observations in two ICUs at hospitals associated with the University of California, San Francisco, these investigators determined that the withholding or withdrawal of mechanical ventilation and other therapies precipitated death in over half of the patients who died in the units during the study year. The primary reason for limiting care was poor prognosis. A small number of the patients were able to make the decision to limit care; the others were incompetent. Family members made decisions for those patients for incompetent patients with families, and physicians decided for patients who lacked surrogates.

Subsequent observational studies from other ICUs following this 1990 publication established that the limiting life support had become a standard practice in the United States (47), Canada (48) and Europe (49). In 1997, Prendergast and Luce (50) reported that the withholding and withdrawal of life support now preceded death in 90% of patients who died in the 2 ICUs studied by Smedira and colleagues 5 years earlier. Prendergast and colleagues (51) reported in 1998 that of patients who died in 131 ICUs at 110 US hospitals over a 6-month period, only 23% received full support including failed CPR. On the other hand, 77% of the dying patients either received full care without CPR or had other kinds of life-sustaining therapy withheld or withdrawn.

In addition to describing how commonly life support was foregone in ICUs, publications such as that of Wilson and colleagues (52) in 1992 detailed how and to what extent sedatives and analgesics were given to dying patients. Increasingly, commentators focused on providing palliative care while removing unwanted treatment, as highlighted by Brody and colleagues (53) in 1997. At the same time, professional societies such as the AMA (54), the Society of Critical Care Medicine (SCCM) (55), the American Thoracic Society (ATS) (56), and the American College of Chest Physicians (57) supported both the ethical and legal propriety of limiting potentially restorative treatment in patients not wanting such treatment and the necessity of providing palliation to them. These twin principles were captured in the first book on managing death in the ICU, edited by Curtis and Rubenfeld (58) in 2001, which was subtitled "The Transition from Cure to Comfort."

More recently, professional societies and investigators have strived to improve the ICU experience at the end of life not just for patients but also for their families. For example, both the American Academy of Critical Care Medicine (59) and the ATS (60) in their most recent publications include the family as a treatment focus. Curtis and colleagues (61) have demonstrated impairments in communication during physician-family conferences about end-of-life care in the ICU, whereas White and colleagues (62) have explored how communications can be enhanced. In 2006, an entire supplement of Critical Care Medicine, edited by Levy and Curtis (63), was devoted to "Improving the quality of end-of-life care in the ICU."

Legal Cases Involving Life Support

Improving end-of-life care would not have been possible without a series of legal cases involving life support. Of these, the first and most important was *In re Quinlan* (64), which was decided by the Supreme Court of New Jersey in 1976. It involved Karen Ann Quinlan, a then-22 year-old woman in a vegetative state following a drug overdose who was receiving mechanical ventilation in a New Jersey hospital ICU. Ms. Quinlan's father petitioned a trial court to be named her guardian with the avowed intent of ordering that her ventilator be removed. The trial court refused, and the hospital and Ms. Quinlan's physicians sought a restraining order against Mr. Quinlan on the grounds that removing her ventilator would constitute euthanasia. When his appeal was turned down at the Superior Court level, Mr. Quinlan appealed to the New Jersey Supreme Court.

The Court opined that, if Ms. Quinlan were to become miraculously lucid and perceptive of her irreversible condition, she would decide against further mechanical ventilation, which it considered her constitutionally-guaranteed right of privacy. Since Ms. Quinlan could not exercise this right on her own, it could be asserted by her father acting as her guardian. To assuage Ms. Quinlan's physicians and the hospital and to provide legal protection for them, the Court decreed that if the clinicians believed that she was truly vegetative, and if the hospital's Ethics Committee or a like body concurred, her ventilator could be withdrawn without incurring civil or criminal liability. Ms. Quinlan's ventilator subsequently was removed; and she died of meningitis and pneumonia in 1985 (65).

Over the 15 years following *Quinlan*, according to Annas (66), courts in almost 20 states recognized the general right of competent patients to refuse treatment, and all but two states acknowledged that the US constitution, state constitutions, or common law permitted surrogate decision-making for incompetent patients. One example of this trend was the case of *Bartling v. Superior Court* (67), in which two California physicians were absolved of murder charges for ordering that fluids and nutrition be removed from a patient with his family's consent. However, New York, in the cases of *In re Storar* (68) and *In re Westchester County Medical Center on behalf of O'Connor* (69), and Missouri, in *Cruzan v. Harmon* (70), bucked the trend.

The Cruzan case went to the US Supreme Court in 1990, in *Cruzan v. Director, Missouri Department of Health* (71).

Nancy Cruzan was vegetative as a result of an automobile accident and her subsequent resuscitation, and she required only tube feedings to stay alive in a Missouri state hospital. Having been told earlier by their daughter that she would not want to live unless she could be "at least halfway normal," Ms. Cruzan's parents sought to have her feeding tube removed, with which a trial judge agreed over the objections of the state hospital. Nevertheless, in *Cruzan v. Harmon*, the Missouri Supreme Court reversed the decision on the grounds that, because the state had a legitimate interest in preserving life regardless of its quality, life-sustaining treatment could be removed from Ms. Cruzan only if "clear and convincing evidence" confirmed that she rejected such treatment. Ms. Cruzan's parents in turn appealed this decision to the US Supreme Court.

Chief Justice Rehnquist, who wrote the Supreme Court's 5-4 majority decision in *Cruzan v. Missouri Department of Public Health*, acknowledged that "---for the purposes of this case, we assume that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition." Unlike the judges in *Quinlan*, however, he based this right not on any right of privacy but rather on the liberty interest delineated in the 14th amendment. At the same time, he opined that the Constitution does not prohibit a state from requiring "clear and convincing evidence" of prior wishes, in part because this standard promotes the state's interest in preserving life. Only New York and Missouri still maintain the standard disputed in *Cruzan*, and the Court's decision does not diminish surrogates' authority in foregoing life support. Nancy Cruzan herself died shortly following the decision, after her parents presented additional evidence of her prior wishes regarding resuscitation to the Missouri courts and her feeding tube was removed.

After *Cruzan*, the Supreme Court confirmed its approval of the foregoing of life-sustaining treatment in *Washington v. Glucksberg* (72) and *Vacco v. Quill* (73) and also provided guidelines for administering palliative care. These two cases dealt with the constitutionality of laws prohibiting physician-assisted suicide in the states of Washington and New York. In *Glucksberg*, the Court decided that patients did not have a liberty interest in receiving a physician's assistance in committing suicide. In *Vacco*, the Court drew distinctions between assisted suicide and withholding and withdrawal of life support. Thus, the Court wrote that "When a patient refuses life-sustaining medical treatment, he dies from an underlying disease or pathology; but if a patient ingests lethal medication prescribed by a physician, he is killed by that medication."

In their opinions in these two cases, Justice Breyer indicated that state laws prohibiting physician-assisted suicide might be problematic if they inhibited the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life, while Justice O'Conner wrote favorably about "relieving pain to the point of unconsciousness." In *Vacco*, the Court as a whole sanctioned terminal sedation "based on informed consent and the double effect. Just as a state may prohibit assisted suicide while permitting patients to refuse unwanted lifesaving treatment, it may permit palliative care related to that refusal, which may have the foreseen but unintended double 'effect' of hastening the patient's death."

Advance Directives

In the wake of *Cruzan*, Congress in 1990 passed the Patient Self-Determination Act (74) to help patients avoid unwanted medical interventions. Sponsored by Senator Danforth of Ms. Cruzan's home state of Missouri, the Patient Self Determination Act requires that federally-funded health care institutions inquire about the presence of advance directives on admission, record patient preferences in the medical record, and assist patients and surrogates in obtaining

advance directives if they do not already have them. The Act was the first to promote advance directives on a national level. Nevertheless, both instructional directives (e.g., living wills) and proxy directives (e.g. the durable power of attorney for health care) had been available at the local level and in many states for many years.

The first living will was developed in 1969 and distributed by the Euthanasia Education Council. In 1976, Bok (75) published a groundbreaking article on "Personal directions for care at the end of life" that cited the plight of Karen Ann Quinlan, described how to prepare a living will, and provided an example of one. Living wills were advocated by clinicians and ethicists such as Eisendrath and Jonsen (76) in 1983 as devices to promote patient autonomy while removing onerous decision-making about receiving CPR and other interventions from physicians and the patients' surrogates. Nevertheless, these commentators pointed out that living wills could cause confusion if they were vague in terminology and used for patients with uncertain prognoses.

California, which enacted the nation's first "natural death act" allowing for living wills in 1976, created the first comprehensive statute establishing a durable power of attorney (DPOA) for health care in 1983. As described by Steinbrook and Lo (77) one year later, the California statute allowed competent patients to delegate medical decision-making, including that involving decisions at the end of life, to surrogates if the patients should become incompetent. Physicians who relied on proxy decisions were granted legal immunity from criminal and civil charges and from professional disciplinary action. If they doubted the surrogates' fidelity to the patients' health-related values, judicial review could be obtained.

Other states followed California in passing statutes authorizing the use of the DPOA for health care, especially after the Supreme Court's Cruzan decision and passage of the Patient Self-Determination Act in 1990. Among others, Silverman and colleagues (78) remarked that proxy directives might be particularly helpful in states that did not automatically give legal recognition to families as decision-makers for patients who could not make decisions for themselves. Yet a DPOA could not be created if patients lacked suitable surrogates. Furthermore, even if surrogates were available, a DPOA might not be helpful if they and the patients they were speaking for had not discussed end-of-life issues previously.

Despite the wide publicity given to cases like *Quinlan* and *Cruzan*, the passage of the Patient Self-Determination Act, and the call for greater use of advance directives by Emanuel and colleagues (79) and others, observational studies conducted in the 1990s by investigators such as Danis and colleagues (80) demonstrated that few patients had advance directives and that directives did not affect their care. Schneiderman and colleagues (81), who hoped that the California DPOA "---might provide a more ethical approach to reducing health care costs," offered it to hospitalized patients with life-threatening illnesses; a control group was not offered advance directives. In 1992, these investigators reported that execution of a DPOA had no effect on the patients' well-being, health status, medical treatments, or treatment charges.

In 1984, Levinsky (82) argued that, in the face of public pressure to reduce health care expenditures, "- - physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations." After publication of the article by Schneiderman and colleagues demonstrating a limited impact of the California DPOA, Levinsky (83) questioned whether advance directives were mechanisms for reinforcing informed consent or methods "- - - whereby physicians shift their role from that of care givers to that of propagandists for limited medical treatment." Although not universally shared, Levinsky's sentiments underscored the conflict between the ethical principles of autonomy and justice that runs through the history of ethics and law in the ICU.

Prognostication

One reason for the limited use of advance directives is that patients' preferences are not static but change as their medical conditions evolve, as demonstrated by Somogyi-Zakud and colleagues (84). In other words, what patients want in terms of attempts at life prolongation varies according to their prognoses (85). Some prognostic information has been derived from ICU studies of patients with specific disorders such as chronic obstructive pulmonary disease (COPD) (87) and *Pneumocystis* pneumonia and the acquired immunodeficiency syndrome (86), and the acute respiratory distress syndrome (ARDS) (88). Other information has come from studies of certain age groups, such as the elderly (89), or certain interventions, such as mechanical ventilation (90).

Additional information has been obtained from the use of prognostic scoring systems based largely on physiological variables and diagnoses on admission to the ICU. Perhaps the best known of these systems, the Acute Physiology and Chronic Health Evaluation (APACHE), was first reported by Knaus and colleagues (91) in 1981 and has since gone through three additional iterations. APACHE and other prognostic scoring systems have been shown to be as accurate (or inaccurate) as clinical assessment by physicians and nurses (92). They also have demonstrated good calibration in that the overall hospital mortality they predict is comparable to that observed in research studies. Nevertheless, the systems have not discriminated well between individuals who survive and those who die (93).

Another limitation of prognostic scoring systems is that physicians do not necessarily use the information they provide any more than they rely on advance directives. These behaviors were demonstrated in the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT) (94), published in 1995. SUPPORT was based on a large cohort of hospitalized adult patients with advanced COPD, ARDS, and other serious illnesses. The SUPPORT investigators estimated 6-month survival using a prognostic scoring system similar to APACHE, elicited patient and family preferences, and facilitated advance care planning and patient-physician communication in an intervention group. Despite these measures, however, the incidence of timing DNR orders, physicians' knowledge of their patients' preferences not to be resuscitated, number of days spent in an ICU receiving mechanical ventilation or in a comatose state was the same in the intervention group as in controls.

Futility and the Allocation of Medical Resources

Among other things, SUPPORT showed that providing prognostic information and advance care planning did not reduce the use of medical resources or their cost. Reducing resource use or allocating medical resources to patients most likely to benefit from them has been a concern – if not an agenda item - in ICUs almost since their inception. As an example, when the Massachusetts General Hospital and Beth Israel Hospital policies regarding resuscitation were reported in 1976, Fried (36) questioned at which social good the policies were aimed: "---freeing the patient from the tyranny of a technologic (or bureaucratic-professional) imperative to keep alive at all costs---," or "--- freeing society from the burden and expense of caring for a growing multitude of extravagantly demanding moribund persons?"

Debates about the proper allocation of medical resources in the ICU are as old as the ICU itself. Sparking the debates are the realizations that ICU resources are limited, as captured in Teres's (95) paradigm of "the last bed;" that patients and families generally want ICU care despite its negative aspects, as demonstrated by Danis and colleagues (96); and that ICU rationing is therefore inevitable and ethical, as discussed by Engelhardt and Rie (97). Indeed, limiting ICU admission of patients with chest pain who were unlikely to have myocardial infarctions and of patients with medical problems but few physiologic derangements was demonstrated in the

1980s by both Singer and colleagues (98) and Strauss and colleagues (99) during times of decreased bed availability in the their ICUs.

Observational studies documenting the preclusion of ICU admission of patients with advanced illnesses and severe physiological disturbances have not been performed. Nevertheless, prognostic scoring systems could be used for this purpose, and Asch and colleagues (100) have demonstrated that some surveyed critical care physicians acknowledge withholding or withdrawing life-sustaining therapies without the knowledge or consent of patients and their surrogates or over their objections. The rationale for this behavior, as cited in the title of an article (101) on the subject, is that "Physicians do not have a responsibility to provide futile or unreasonable care if a patient or family insists."

According to Helft and colleagues (102), the concept of medical futility and its use to rationalize unilateral decision-making by physicians was introduced in the late 1980s. In 1987, Blackhall (103) noted that CPR was unsuccessful in restoring life in many situations and advocated that physicians administer it selectively. In 1990, Schneiderman and colleagues (104) defined futility quantitatively as a medical intervention that had not been useful in the last 100 cases, and qualitatively as interventions that merely preserve permanent unconsciousness or dependence on intensive medical care. Rubenfeld and Crawford (105), in 1996, argued that evidence-based guidelines could be developed for limiting the use of life support for patients such as bone marrow transplant recipients with hepatic or renal failure and a requirement for vasopressors, none of whom survived ICU admission.

The major problems with futility as a concept are summarized by Truog and colleagues (106). Outside the rare circumstances of strict physiological futility, it is a value-laden concept about which a consensus has not been achieved. Moreover, physicians sometimes invoke futility to hide what are really implicit resource allocation decisions that should be discussed explicitly. These problems were acknowledged in 1997 by the SCCM (107), which argued that "Treatments should be defined as futile only when they will not accomplish their intended (physiologic) goal. Treatments that are extremely unlikely to be beneficial, are extremely costly, or are of uncertain benefit may be considered inappropriate and hence inadvisable, but should not be labeled futile."

The AMA (108) took a stance similar to that of the SCCM two years later. In addition, it urged that decisions regarding interventions physicians considered futile or inappropriate be made through an extrajudicial conflict resolution process involving both physicians and patients and their families. This process, which was first implemented in hospitals in Houston (109), was incorporated into the Texas Advance Directives Act (110) in 1999. It allows a physician to ask an ethics or ad-hoc "medical" committee to review a patient or surrogate request for treatment the physician considers inappropriate. If the committee agrees that the request is inappropriate and no other facility will accept the patient in transfer, the treatment may be withheld or withdrawn. Despite its apparent popularity among physicians, this policy has been criticized as being disproportionately applied to disenfranchised minorities. It also implies that in debates over value-laden decisions about life and death, the physicians' values can trump those of their patients (111).

Within the last year, in widely publicized cases in Australia (112) and Canada (113–115), surrogates have asked courts to prevent ICU physicians from limiting life-sustaining therapy in relatives under circumstances that did not meet the criteria of physiological futility. In all but one (113) of these cases, the courts allowed the physicians to exercise clinical judgment, and life support was withheld or withdrawn. Australia and Canada differ from the US in that both countries provide universal health coverage, and physicians in them may consider themselves empowered to decide life-and-death issues regardless of surrogates' requests. It is

not clear that American physicians currently are so empowered, or that they would be empowered even if this country were to provide universal coverage. Nevertheless, the apparently increasing frequency of contentious legal cases in other countries suggests that the debate over who decides if treatment should be provided is likely to intensify in the US.

Conclusion

Over 30 years ago, the New Jersey Supreme Court established through its *Quinlan* decision that patients and their surrogates can refuse unwanted therapies, thereby giving the principle of respect for autonomy a privileged position in American bioethics. Today, a different movement is afoot: Physicians concerned about their own prerogatives and about the just distribution of health care resources are challenging whether their patients' right to self-determination must compel the physicians to provide treatments they consider inappropriate (112). Given our limited ICU resources, the introduction of new potentially life-saving technologies, patient demand for them, and the aging of our population, such challenges will become more commonplace in the future. So will conflicts among ethical principles in the ICU.

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