

Virtual Mentor

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Medical futility: legal and ethical analysis

by Peter A. Clark, SJ, PhD

For the past decade a debate has been raging within the medical, ethical and legal communities on the concept of medical futility. Despite its emergence as a dominant topic of discussion, especially as it applies to end-of-life care, the concept of medical futility is not new. Physicians at the time of Hippocrates recognized some medical conditions as impossible to cure and recommended no further treatment for those patients [1]. What has fueled the fires of the current multifaceted debate is the patients' rights movement and the perception that the right of self-determination extends not only to the refusal of medical treatments but to demands for overtreatment [2].

The patients' rights movement began as a reaction to the paternalism of physicians who unilaterally overtreated patients and prolonged their lives against their wishes or the wishes of their surrogate decision makers and family members. The perception of physician-driven overtreatment resulted in a series of legal cases ranging from the Quinlan case in 1976 to the Cruzan case in 1990, which gave patients or their appropriate surrogates the legal right to refuse medical treatment, even if doing so resulted in the patient's death. Despite physician or hospital administration arguments that treatment was appropriate, the courts ruled in favor of the patient's right to refuse treatment and the patient's surrogate's right to withhold treatment, generally on the condition that there was clear and convincing evidence that the patient would refuse life-sustaining treatment if he or she were conscious and able to do so.

In the 1990s, patients and patient surrogates began demanding treatments that physicians believed were *not* in the best interest of the patient because they were medically futile and represented an irresponsible stewardship of health care resources. In legal cases such as Wanglie in 1991 and Baby K in 1994, the courts ruled in favor of the right of patients or their surrogates to request even those medical treatments from which physicians believed they would receive no medical benefit [3]. What has been problematic for the judges in these cases has been the lack of professional or institutional policies on medical futility against which they could judge physician and hospital compliance or noncompliance [4]. These complex cases have set the stage for the present debate over medical futility, which pits patient autonomy against physician beneficence and the allocation of social resources.

Patients and surrogates make the ethical argument that, if they have the right to refuse or discontinue certain medical treatments on the basis of their best interest, they have the right to request certain medical treatments on that same basis. Physicians argue that many of the requested interventions are both burdensome for the patient and medically inappropriate because they fail to achieve the desired physiological effect and result in a misallocation of medical resources. Although providing these treatments can compromise physicians' professional integrity, many feel compelled to comply with the patient's or surrogate's wishes because they believe that society has mandated the provision of such interventions unless there is an agreement to withhold them [5]. The ever-present fear of litigation has not only fueled this debate, it has placed the very foundation of the patient-physician relationship in jeopardy.

The position of absolute patient autonomy ignores the fact that a well-established "best interest" standard assumes both a connectedness of the patient to family and physician and a communication process that allows surrogates to take into account objective, community-based best interest standards [6]. A resolution of these concerns will have to avoid both the traditional physician-driven overtreatment and recent patient- and patient surrogate-driven overtreatment by balancing patient/surrogate rights with physician/societal rights [7]. From an ethical and a legal perspective, one way to foster this balance is to apply a process-based approach to futility determinations on a case-by-case basis. The goal of a process-based approach would be a medical futility policy that protects the patient's right to self-determination, the physician's right of professional integrity and society's concern for the just allocation of medical resources and is securely rooted in the moral tradition of promoting and defending human dignity.

Legal implications

Perhaps one of the biggest challenges in implementing a futility policy is recognition by physicians and health care institutions that adopting such a policy carries with it the threat of litigation. Texas took the lead in addressing the issue of medical futility from both a medical and legal perspective.

In 1999, Texas legislation combined three preexisting laws regulating end-of-life treatment into a single law, the Texas 'Advance Directives Act.' This law established a legally sanctioned extrajudicial process for resolving disputes about end-of-life decisions. This mechanism for dispute resolution may be used in response to a surrogate, living will, or medical power of attorney request to either "do everything" or "stop all treatment" if the physician feels ethically unable to agree to either request [8].

The Texas law became a model for other states and for individual hospitals seeking to make changes in statutory regulations and institutional policies regarding end-of-life treatment decisions. Futility policies are a relatively new initiative in health care, and there was uncertainty as to how the courts would respond when confronted with a "futile treatment" case.

The Texas law was tested in March 2005 when Sun Hudson, born with thanatophoric dysplasia, a typically fatal form of congenital dwarfism, was removed from a breathing tube against the wishes of his mother, Wanda Hudson. The breathing tube was removed pursuant to Chapter 166 of the Texas Health and Safety Code, the Advance Directive Act [9]. Under this act, the doctor's recommendation to withdraw support was confirmed by the Texas Children's Hospital ethics committee. Although it is not required under the act, Texas Children's Hospital took the extra step of getting a judge to rule on its decision. The judge found that the act authorized the hospital to withdraw life support over the objection of the baby's mother.

Wanda Hudson was given 10 days from receipt of written notice to find a new facility to accommodate Sun if she disagreed with the hospital decision, but she was unable to find another facility. Texas Children's Hospital stated that it attempted to contact 40 facilities, but it, too, was unable to find one willing to accept the boy.

On March 15, 2005, physicians at Texas Children's Hospital sedated Sun for palliation purposes and removed the breathing tube; he died within a minute [10]. This was the first time a hospital in the United States had allowed removal of life-sustaining support against the wishes of the legal guardian, and it became a precedent-setting case that should help relieve some of the anxiety of physicians and hospital administrators about invoking a medical futility policy in future cases. It appears that the court acted in the best interest of the patient—who doctors said was certain to die and most likely to suffer before doing so—using a process-based approach.

One of the goals in implementing a futility policy is to facilitate communication between the patient or surrogate and the health care staff so that all parties can come to an acceptable agreement regarding the proposed treatment. If agreement is not reached between the physician or hospital and the patient or surrogate, either party may seek injunctive relief from the courts, or the patient/surrogate may file medical malpractice action.

Physicians are particularly adverse to litigation. The physician who loses a malpractice claim risks damage to his or her professional reputation and the possibility of an increase in malpractice payment premiums. Perhaps even more dreaded though, is the report that will be filed with the National Practitioner Data Bank confirming that the physician lost a medical malpractice suit [11]. A data bank report will follow the physician for the remainder of his or her career, since all hospitals are mandated to query the data bank on a regular basis. Even the physician who prevails in a professional malpractice action expends substantial time defending himself by meeting with attorneys, answering interrogatories, appearing for deposition and testifying at trial. Obviously then, the threat of litigation alone will deter some physicians from ever invoking a futility policy.

For those physicians who are willing to risk litigation for the sake of preserving their professional integrity, a futility policy offers legal benefits. Although a futility policy will not insulate a physician from litigation, it should enable him or her to fashion a strong defense in a medical malpractice claim. As a general rule, to prevail in a professional malpractice action the plaintiff must establish that the harm he or she suffered resulted from the physician's having breached the standard of care. Implementing a futility policy requires consensus from other physicians and other interdisciplinary committees within the institution that the proposed treatment is not beneficial to the patient. Such a consensus among physicians can then be submitted as evidence in legal proceedings to demonstrate that the standard of care was not breached.

Implementation of a futility policy may also give rise to claims for injunctive relief. The patient or surrogate may file an action asking a court to order that the "futile" treatment be administered. Likewise, a physician or institution may petition the court for an order that futile treatment not be initiated or, if already initiated, be discontinued, as in the Wanglie case [12]. If the physician has withheld or discontinued treatment in accordance with the institution's futility policy, the court may be more inclined to conclude that the treatment is, indeed, inappropriate.

Ethical implications

Futility is defined as "inadequacy to produce a result or bring about a required end; ineffectiveness" [13]. Medically, the concept of "futility," according to the American Medical Association, "cannot be meaningfully defined" [14]. Essentially, futility is a subjective judgment, but one that is realistically indispensable [15]. There is consensus within the medical community that at specific times during the course of an illness some treatments are medically futile; consensus ends however, when attempts are made to formulate a fully objective and concrete definition. As a result, futility has been confused with interventions that are harmful, impossible and ineffective. Distinguishing futility from the concept of harmful and ineffective interventions has led to some clarity. In general, a medically futile treatment is

an action, intervention, or procedure that might be physiologically effective in a given case, but cannot benefit the patient, no matter how often it is repeated. A futile treatment is not necessarily ineffective, but it is worthless, either because the medical action itself is futile (no matter what the patient's condition) or the condition of the patient makes it futile [16].

But until we have a more clear understanding of what medical futility means at the bedside, there will not be widespread agreement on definitions and implications of futility in general [17].

Ethicists Baruch Brody and Amir Halevy have distinguished four categories of medical futility that set the parameters for this debate. First, physiological futility, also known as quantitative futility, applies to treatments that fail to achieve their intended physiological effect. These determinations are based not on vague clinical

impressions but on substantial information about the outcomes of specific interventions for different categories of illness states. The second category, imminent-demise futility, refers to those instances in which, despite the proposed intervention, the patient will die in the very near future. (This is sometimes expressed as “the patient will not survive to discharge,” although that is not really equivalent to dying in the very near future.)

Brody and Halevy use the third term, lethal-condition futility, to describe those cases in which the patient has a terminal illness that the intervention does not affect and that will result in death in the not-too-distant future (weeks, perhaps months, but not years) even if the intervention is employed. The fourth category, qualitative futility, refers to instances in which an intervention fails to lead to an acceptable quality of life for the patient [18]. When a treatment is judged to be qualitatively futile, the claim being made is that, although the treatment may succeed in achieving an effect, the effect is not worth achieving from the patient’s perspective [19].

Medically, a consensus concerning the clinical features of medical futility remains elusive. Ronald Cranford’s conclusion is representative: “Whatever futility means, it seems obvious that this is not a discrete clinical concept with a sharp demarcation between futile and non-futile treatment” [20]. Brody and Halevy’s four categories emphasize that decisions on medical futility must be made on a case-by-case basis and must include both a substantive component and a role for patient and surrogate input. Determining whether a medical treatment is futile basically comes down to deciding whether it passes the test of beneficence; that is, will this treatment be in the patient’s “best interest”? The test of beneficence is complex because determining whether a medical treatment is beneficial or burdensome, proportionate or disproportionate, appropriate or inappropriate, involves value judgments by both the patient and the physician.

The Catholic perspective

The medical futility debate is, at bottom, a conflict between respect for patient autonomy, on one hand, and physician beneficence and distributive justice, on the other. In seeking a balance between the values and goals of the patient and the values and goals of medicine, individual autonomy cannot be so inflated in importance as to destroy the principle of beneficence and overlook the equitable distribution of medical resources in society. To find the balance, physicians must reach a consensus on what constitutes a reasonable medical treatment, and patients and surrogates must restrict their self-advocacy to what is fair and equitable for all [21]. The reasonable treatment decision must center on the best interest of the patient, without failing to recognize that every individual is also a member of society. If a physician believes, after carefully considering the patient’s medical status, values and goals, that a particular medical treatment is futile because it violates the principles of beneficence and justice, then the physician is ethically and professionally obligated to resist administering this treatment. The justification of medical treatments on the basis of weighing the benefits and burdens and the appropriate use of medical resources is

firmly rooted in the Catholic moral tradition of the ordinary versus extraordinary means distinction.

Various church documents from *Veritatis Splendor*, to the Pontifical Academy of Life's *Respect for the Dignity of the Dying* to *Evangelium Vitae* make it quite clear that individual autonomy is not an absolute. Pope John Paul II applied this principle to medical treatments in *Evangelium Vitae* when he stated: "Certainly there is a moral obligation to care for oneself and to allow oneself to be cared for, but this duty must take account of concrete circumstances. It needs to be determined whether the means of treatment available are objectively proportionate to the prospects of improvement" [22].

The Catholic tradition maintains that if a medical intervention is judged to be ordinary it is viewed as morally mandatory. If extraordinary, it is morally optional. It is said to be ordinary if it offers a reasonable hope of benefit for the patient and could be used without excessive inconvenience, which includes risk, pain and expense. If it offers no reasonable hope or benefit or is excessively burdensome, it is extraordinary [23].

Pius XII further clarified the ordinary versus extraordinary means distinction when he declared that "we are morally obliged to use only ordinary means to preserve life and health—according to circumstances of persons, places, times and culture—that is to say means that do not involve any grave burden for oneself or another" [24]. Pius XII bases the distinction between ordinary and extraordinary means on the idea that human life is a basic good, but a good to be preserved precisely as a necessary condition for existence of other values. One must examine the circumstances of a particular situation, which include cost factors and allocation of resources, because these circumstances dictate the balance to be considered between life and these other values. Due to the imprecision of the terms ordinary and extraordinary and the rapid advances in medicine and technology, the Catholic Church now speaks of proportionate and disproportionate means. In determining whether a medical treatment is beneficial and proportionate, the Congregation for the Doctrine of the Faith in *The Declaration on Euthanasia* concludes that,

...it will be possible to make a correct judgment as to the means [proportionate or disproportionate] by studying the type of treatment being used, its degree of complexity or risk, its cost and possibilities of using it, and comparing these elements with the result that can be expected, taking into account the state of the sick person and his or her physical and moral resources [25].

This statement, which is rooted in the Catholic tradition, gives physicians the ethical justification to refuse medical treatments if they are either gravely burdensome or medically futile for the patient.

Catholic hospitals are called to embrace Christ's healing mission, which means they must offer patients those treatments that will be beneficial to them. These treatments should restore their health, cure them when possible, relieve pain and suffering, provide comfort care, and improve quality of life. The test of beneficence is whether or not physicians can achieve these goals, not just any goals or any interests [26]. A process-based futility policy will assist physicians in providing patients with medical treatments that are in their best interest, will foster a responsible stewardship of health care resources, and will provide the courts with a fair standard to be used in adjudicating these cases.

Notes and references

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2. In medical futility cases the patient or surrogate wants to pursue the goal of preserving life even if there is little chance or no hope of future improvement, while the other party, the physician, sees dying as inevitable and wishes to pursue the goal of comfort care. For a more detailed analysis, see Medical futility in end-of-life care: a report of the Council on Ethical and Judicial Affairs. *JAMA*. 1999;281:937-941.
3. The two prominent cases here would be the Helga Wanglie case and the Baby K case. For a more detailed analysis of both cases, see *In re Helen Wanglie*. PX-91-238 Minn Dist Ct, Probate Division, 1991; and *In re Baby K*, 16 F3d 590, *Petition for Rehearing en banc Denied*, no. 93-1899 (L), CA-93-68-A, March 28, 1994. It should be noted that in the Wanglie case the court never addressed the question of whether physicians or the medical center could refuse to provide requested treatment, and thus the conflict between nonmaleficence and beneficence and autonomy was not resolved. The court ruled that Mr. Wanglie should be his wife's conservator on the grounds that he could best represent his wife's interests. In the Baby K case physicians and ethics committees argued in Virginia that providing certain treatments such as mechanical ventilation to an anencephalic newborn was "futile" and "would serve no therapeutic or palliative purpose," and was "medically and ethically inappropriate." The courts ruled against them.
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 10. Associated Press. *Baby at Center of Life Support Case Dies*. March 15, 2005. <http://www.msnbc.msn.com/id/7190468/>. Accessed April 16, 2007.
 11. The Health Care Quality Improvement Act requires professional liability insurers to report payments made on behalf of physicians to the National Practitioner Data Bank provided the payment is \$10,000.00 or greater. See USCS, 11131-11137.
 12. *In re Wanglie*, No PX-91-283 (Minn. Dist Ct, Probate Ct Div July 1, 1991).
 13. Futility. *The Oxford English Dictionary*. Vol IV. Oxford, England: Oxford University Press; 1989:626.
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 20. Cranford, 895.
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 22. Pope John Paul II. Chapter III. In: *Evangelium Vitae*. March 25, 1995. http://www.vatican.va/edocs/ENG0141/_PR.HTM. April 10, 2007.
 23. According to ethicist Gerald Kelly, SJ, and his classic interpretation of the ordinary/extraordinary means distinction in the Catholic tradition: "ordinary means of preserving life are all medicines, treatments, and operations, which offer a reasonable hope of benefit for the patient and which can be obtained and used without excessive expense, pain, or other inconvenience, *Extraordinary* means are all medicines, treatments, and operations, which cannot be obtained or used without excessive expense, pain, or other inconvenience, or which, if used, would not offer a reasonable hope of benefit." Kelly G. *Medico-Moral Problems*. St. Louis, MO: The Catholic Health Association of the United States and Canada; 1958:129. Emphasis in the original.
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26. Drane, Coulehan, 32.

Peter A. Clark, SJ, PhD, is a professor of theology and health administration and director of the Institute of Catholic Bioethics at Saint Joseph's University in Philadelphia. He is also a bioethicist for the Mercy Health System in Philadelphia. Father Clark is author of To Treat or Not To Treat: The Ethical Methodology of Richard A. McCormick, S.J. as Applied to Treatment Decision for Handicapped Newborns and numerous articles on medicine and ethics.

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