

MEDICINE AND PUBLIC ISSUES

Medical Futility: Response to Critiques

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Six years ago, we proposed a patient benefit-centered definition of medical futility that included both quantitative and qualitative components. We distinguished between an effect of a treatment that is limited to some part of a patient's body and a benefit that improves the patient as a whole. The quantitative portion of our definition stipulated that physicians should regard a treatment as futile if empirical data show that the treatment has less than a 1 in 100 chance of benefiting the patient. The qualitative portion of our definition stipulated that if a treatment merely preserves permanent unconsciousness or cannot end dependence on intensive medical care, physicians should consider the treatment futile. In this paper, we clarify and modify our original proposal and respond to the following major criticisms: 1) Medical futility is simply an attempt to increase the power of the physician over the patient and to repeal recent hard-gained advances in patient autonomy; 2) no professional or societal consensus has been achieved about the definition of futility; 3) futility is a value-laden determination, the usurpation of which by medicine is inappropriate unless only a so-called value-free or strict physiologic definition of futility is used; 4) the concept of futility is not practically useful because empirical treatment data cannot be applied with certainty to any given patient; 5) futility undermines our pluralistic society and threatens, among other things, the free exercise of religion; and 6) because cost considerations will ultimately dictate all such decisions, futility is an unnecessary concept.

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The physician-patient relationship has been strikingly transformed during the past several decades. Once characterized by strong medical paternalism, it now reflects strong patient autonomy. During the 1960s, physicians began to see their power being challenged by patients who wanted to take charge of, or at least participate fully in, medical decisions. Although the patient autonomy movement achieved many valued improvements in care, it also raised new ethical problems. Some patients and their families have begun to claim the right to receive whatever aggressive, high-tech medical interventions they wish, even if medical providers judge the interventions to be futile because they have no realistic chance of achieving the goals of medicine. What are the goals of medicine? Can we agree as a profession and as a society when medical treatment

fails to achieve such goals? Exploring these questions forces us to re-examine the fundamentals of the physician-patient relationship.

Six years ago, we proposed a definition of medical futility and explored its ethical implications (1). We started with the premise that physicians are obligated to offer only those treatments that have a reasonable chance of achieving a therapeutic benefit for the patient. In this premise, the terms "benefit" and "patient" are important. A patient is not a collection of body parts or merely a person with idiosyncratic desires. Rather, a patient is an ailing person who seeks the healing powers of the physician. The physician's goal is not merely to affect some part of the body but to benefit the patient as a whole. Medicine currently has the ability to achieve multitudinous effects, including increasing and decreasing blood pressure, speeding and slowing the heart rate, destroying cells, infusing oxygen, and transplanting organs. We have argued that none of these effects constitutes a benefit unless the patient has, at the very least, the ability to appreciate them. This circumstance is impossible if, for example, the patient remains in a permanent vegetative state. Neither does an effect qualify as a benefit if it leaves the patient incapable of surviving outside the intensive care unit—in other words, completely "preoccupied" (to use a term that Plato attributed to Asklepios [2]) with illness and treatment and therefore unable to carry out any other life goals.

We pointed out that medical futility refers not only to the quantitative probability of success or failure of a treatment but also to the qualitative results that treatment achieves for the patient.

In defining the quantitative aspects of medical futility, we proposed that "when physicians conclude (either through personal experience, experiences shared with colleagues, or consideration of reported empiric data) that in the last 100 cases, a medical treatment has been useless, they should regard that treatment as futile" (1). We suggested this approach as a commonsense way to respond to the unanswer-

able question, “How can you be absolutely certain the treatment won’t work, doctor?” Physicians are often pressured into pursuing extreme and absurd interventions as a result of this question.

Regarding the qualitative aspect of medical futility, as noted above, we proposed that if a treatment “. . . merely preserves permanent unconsciousness or . . . fails to end total dependence on intensive medical care [it] should be regarded as . . . futile” (1).

Following earlier authors (3–7), we argued that physicians are not obligated to offer a futile treatment that is demanded by patients or their family members. Later, two of us made the stronger argument that physicians are professionally obligated to resist demands for futile treatments (8).

When we presented these concepts, we stated that “we recognize—indeed invite—examination and challenge of our proposal” (1). In this paper, we revisit our original proposal, add clarifications and modifications that we believe are essential, and respond to major criticisms gleaned from published articles and discussions with colleagues.

Clarifications and Modifications

Our original proposal (1) stipulated that, in making decisions involving medical futility, individual “physicians should act in concert with other health care professionals, but need not obtain consent from patients or family members.” However, we did not sufficiently emphasize that acting “in concert” is not to be done casually; we later asserted that this obligation is grounded in general professional standards of care (9). We further clarified our position that standards of care, although they are advanced by the health care profession, ultimately require the endorsement of society (9). Failure to make this process clear in our original proposal led to protests that we were encouraging individual physicians to act “unilaterally” and “arbitrarily” (10, 11). Ironically, it was the arbitrary and unsupported use of the term “futile” by physicians that stimulated our original proposal; such use either consciously or unconsciously masked unethical reasons for refusing to offer a specific treatment (9).

We did not advocate that individual physicians “act on their subjective impressions” (12). On the contrary, we specified that decisions to withhold futile treatments should be made on the basis of the evaluation of empirical experience, including personal clinical experience and experience shared with colleagues, or on the basis of published empirical data. These empirical observations are only the first step and must be coupled with value decisions by the health care profession that are endorsed by society; specifically, ethical judgments must be made

on whether the observed outcomes constitute benefits to patients. However, we did not sufficiently emphasize the responsibility of the medical profession to carry out this first step of collecting and providing outcome data through well-conducted clinical trials. For the practicing physician, negative study results are as important as positive study results. Everyone applauds the discovery of new beneficial treatments, and physicians gladly adopt these therapies. However, physicians also need to know when a treatment has been shown to offer no significant likelihood or quality of benefit so that they can avoid causing unnecessary harm (13).

Response to Criticism

The main arguments against our proposal can be summarized as follows.

Medical Futility Is an Attempt To Increase the Power of the Physician over the Patient and Repeal Recent Hard-Gained Advances in Patient Autonomy

The basic premise underlying this argument is that the physician and patient are inexorably locked in “a war between doctor and patient over who gets to decide what” (14). In this power struggle, the physician (who has little to lose) possesses expert knowledge and control over technology. By contrast, the patient, whose life may hang in the balance, typically possesses little expert knowledge and no authority over technological interventions (10, 11, 15). Those who make this argument hold that endorsing the physician’s power to declare a treatment futile gives the physician a “trump card” (12) or “conversation stopper” (11) that interferes with the meager power the patient retains (the power of persuasion) in the physician–patient dialogue. We and others have pointed out, however, that the power to make judgments about futility is a necessary part of the physician’s duty of beneficence, that is, the duty to use only treatments that provide therapeutic benefits (16–20). This power resides not with the individual physician’s arbitrary whim but with the profession as a whole as it establishes general standards of care. In our view, abuses of power are resolved not by eliminating medical judgment and yielding to unreasonable demands but rather by exercising judgment openly and responsibly according to professional standards (17, 21–23).

Some wishes and needs are clearly beyond the scope of informed consent and the limits of the physician’s obligation. For example, a physician treating a patient for severe depression might conclude that if the patient could only get his or her finances in order, the patient would be much less

depressed. The physician might be sympathetic to the patient's distress and might even try to recommend help, but surely no one would claim that balancing the patient's bank account is an obligatory medical duty. Physicians are more often under pressure to use the vast array of technologies at their disposal when those technologies may keep organ systems functioning even though the patient is no longer able to appreciate any benefit from these interventions. Means are confused with ends, effects are confused with benefits, and available technologies are confused with obligatory medical therapies. In our experience, requests for futile treatment often represent not an appeal to respect the patient's wishes (24) but rather a misguided effort to express caring for the patient by meeting a perceived duty to "do everything" when other manifestations of devotion (such as comfort care) would be more appropriate (25, 26).

No Professional or Societal Consensus Has Been Achieved about the Definition of Futility

Impatience with the slow pace of resolving such a complex ethical issue has led some critics (27–30) to conclude that efforts to define and apply "futility" are themselves futile. Studies (31–33) have shown that physicians disagree about quantitative and qualitative thresholds for futility.

However, persons with long experience in public opinion research point out that achieving consensus is a gradual and evolving process. It begins with public awareness of an issue, proceeds to understanding by working through the issue (which, in the case of medical futility, will require changing unrealistic expectations about what medicine and science can accomplish), and finally leads to resolution on cognitive, emotional, and moral levels (34). It is worth remembering that achieving nationwide consensus on a universal definition of death according to whole-brain criteria took approximately 20 years. Compared to this, the futility debate is in its early adolescence.

To those who are concerned that the medical profession is seeking to impose its own notion of futility on the public (10, 14, 15, 27, 35, 36), we stress that every profession declares values and standards. In the case of health care, the various professions should present their values openly and repeatedly to society by advancing the standards of practice and then subjecting these values to the scrutiny of legislatures and courts (9, 37, 38). Acting through legislative, licensing, and court decisions, society accepts or rejects professional standards.

In the past 6 years, hospitals, state legislatures, and working groups of professionals and laypersons have developed consensus-based futility policies (39). In the only test of medical futility that has

been brought before a jury, the jury unanimously agreed that the hospital could refuse, on the grounds of medical futility, the cardiopulmonary resuscitation (CPR) and mechanical life support that had been demanded (37). These events suggest that the profession and society may be capable of examining, understanding, and resolving issues of medical futility. At the very least, it seems premature to exclude this possibility.

Futility Is a Value-Laden Determination Whose Use by Medicine Is Inappropriate Unless One Sticks to a So-Called Value-Free or Strict Physiologic Definition of Futility

Some critics insist that only a narrow physiologic definition of medical futility is ethically defensible because only a narrow definition is "value-free," although they do not agree on what constitutes "physiologic futility" (27). Contrary to the assertion that physiologic futility is value-free, we argue that it entails a value choice. Specifically, it assumes that the goals of medicine are to preserve organ function, body parts, and physiologic activity—an assumption that, in our estimation, departs dramatically from the patient-centered goals of medicine (40–43). Indeed, this confusion between effects and benefits can be viewed as part of the generic confusion of focusing on surrogate measures rather than on patient outcomes, which can cause physicians to misjudge the value of treatment (44).

Medical Futility Is a Useless Concept because Empirical Treatment Data Cannot Be Applied with Certainty to Any Given Patient

It is sometimes argued that no matter how much data researchers assemble about a group of patients, the physician cannot be absolutely certain that the data apply to a particular case with its own particular clinical variables (12). However, as the philosopher, Karl Popper, pointed out (45):

The old scientific ideal of *episteme*—of absolutely certain, demonstrable knowledge—has proved to be an idol. The demand for scientific objectivity makes it inevitable that every scientific statement must remain *tentative for ever*. It may indeed be corroborated, but every corroboration is relative to other statements which, again, are tentative. Only in our subjective experiences of conviction, in our subjective faith, can we be 'absolutely certain.'

This clarifies why the judgment of experienced clinicians will always be essential to rendering judgments of futility. Yet such judgments are, in this respect, no different from other medical judgments that require the application of clinical data to a particular patient. For example, in the treatment of congestive heart failure, the drugs, doses, and schedules to be prescribed to a particular patient are determined by using data collected from large

samples of other patients. The experienced physician knows that one can never be certain that every patient will have the same response; therefore, the physician does not merely pigeonhole the case "without consideration of her individual clinical circumstances" (46). However, the physician must start somewhere, namely with empirical experience. In contrast to experimental treatments, for which evidence may be promising but insufficient, futile treatments have empirically failed to show a significant likelihood or quality of benefit (44).

Some have argued that our quantitative threshold for futility is "arbitrary" and "without defense" (12). In fact, our defense is the same as the justification used in the statistical evaluation of clinical trials. This justification procedure compares treatment observations against the null hypothesis (no difference) in light of the conclusion that these observations have a 1 in 20 chance of being nonsignificant ($P = 0.05$) or, more conservatively, a 1 in 100 chance of being nonsignificant ($P = 0.01$). In other words, one can never be certain, even in large-scale studies, that a treatment is beneficial (better than no treatment or an alternative treatment); therefore, one submits observations to the test of reasonableness. The notion of reasonableness is accepted in another major sector of society where a person's life may be at stake: courts of law. A jury in a criminal trial may find a defendant guilty and subject to the death penalty if the evidence is persuasive beyond a reasonable doubt, not beyond all doubt.

Thus, the proper question to ask is not whether we can be certain a treatment will not work but how many times we are willing to see a treatment fail before we agree that it does not work (17). Contrary to the claim that our quantitative threshold provides "an illusion of objectivity" (12), we have proposed that a standard of success in fewer than 1 in 100 cases is reasonable. The experience of 100 cases is attainable in many areas of medicine. Some may prefer a higher or lower standard or different standards for different clinical circumstances, but a line must be drawn somewhere short of "absolute certainty." In contrast to our proposal, the American Heart Association guidelines for CPR and emergency cardiac care (40) declare that treatments should be considered futile only if "no survivors after CPR have been reported under the given circumstances in well-designed studies." Yet this guideline fails to provide a quantitative threshold indicating at what point one can conclude that there are "no survivors." The American Heart Association also does not indicate whether "well-designed studies" should include dozens, hundreds, thousands, or even millions of participants. Similarly, Prendergast (12), after objecting to the threshold we propose, goes on to say that

... autonomy does not require physician compliance with a patient request where the evidence shows no benefit. Where the evidence is clear and convincing, autonomy is irrelevant.

However, Prendergast fails to identify the threshold that he uses to define "clear and convincing."

Finally, we note that the few studies (published by investigators who were unaware of each others' conclusions) that recommend that a treatment no longer be attempted because of its futility show a consensus of about the same magnitude as our original proposal (47-52). Although skeptics doubt that a consensus will ever be reached, we find that professional agreement about medical futility may already be emerging.

Admittedly, the number of published studies that describe futile interventions is sparse when compared with the vast amounts of literature that describe successful interventions. However, this does not mean that such studies are not being done. In fact, data on negative clinical outcomes are being assembled by managed health care organizations and health insurance providers that are beginning to challenge the efficacy (and more particularly the cost) of many traditional treatments. So far, the reaction of many medical professionals has been to resist these perceived invasions of freedom. In our opinion, the profession should assume far more responsibility in gathering these data (53).

An exception is the important work done by medical investigators to characterize the prognosis of patients in various clinical circumstances (54, 55). Some critics argue that few futile treatments can confidently be said to have less than 1 in 100 chance of success (56). We see this as a stimulus to do further research. Not only do we encourage continuous development and refinement of scoring systems, we also point out that scoring systems are not the only guides for experienced clinicians. Some clinical conditions can be characterized without a quantitative index. For example, certain congenital malformations, chromosomal abnormalities, neurologic degenerations, and advanced pulmonary diseases have never been reversed. Their anatomical character precludes treatment benefit. At a certain point in the clinical course of disease (sometimes very early, sometimes much later), most physicians recognize that a treatment is futile according to professional standards of care.

Medical Futility Undermines Our Pluralistic Society and Threatens, among Other Things, the Free Exercise of Religion

Some maintain that religious and medical goals are inextricably intertwined and therefore that medical futility interferes with the free exercise of religion. Post (57) argues that approximately one fifth

of the New Testament gospels describe the healing of physical or mental illness and the resurrection of the dead and that “even in mainstream Protestant churches, the belief in miraculous healing exists.”

Post’s argument persuades us that religion and contemporary western medicine should be regarded as independent activities that seek the goal of healing in different ways. In the gospel stories, healing is usually achieved not through medical treatments but by the laying on of hands, so that “the blind see, the lame walk, the lepers are cleansed, the deaf hear, [and] the dead are raised” (Luke 7:22). Physicians are mentioned only in a description of how they failed to heal “a woman having an issue of blood twelve years, which had spent all her living upon physicians, neither could be healed of any.” The woman’s bleeding was immediately staunching by touching the border of Jesus’s garment (Luke 8:43–44). In contrast, medical practitioners have been forced to acknowledge the limits of their art since the time of Hippocrates. Medicine, according to gospel teachings, cannot be expected to respond to the farthest reaches of religion in which revelation, faith, and miraculous healing (including the restoration of life to the dead) are invoked. Miracles may be an important goal of prayer for many patients, but they should not be imposed on physicians as a goal of medical practice. Indeed, the very meaning of “miracle” depends on the premise that “the things which are impossible with men are possible with God” (Luke 18:27).

We do not resist when patients, families, and members of a religious faith choose to engage in meaningful religious and cultural activities; indeed, we respectfully encourage these actions. However, just as educators in the United States are not obligated to teach creationism in response to religious fundamentalists, western medical practitioners should not be expected to act contrary to personal or professional practice standards in response to persons who seek divine cures (58).

Because Rationing and Resource Allocation Will Ultimately Determine Medical Futility, Medical Futility Is an Unnecessary Concept

Some critics predict that the futility debate will inevitably be submerged in the onrushing debate about limited money and resources (10, 12, 59). We have discussed elsewhere the distinctions between futile and rationed treatments (60) and between medical and societal justice (61). In summary, rationing refers to the allocation of beneficial treatments among patients; futility refers to whether a treatment will benefit an individual patient. Although physicians have limited ethical authority to allocate finite medical resources on the basis of medical benefits to patients, only society has the

ethical mandate to decide the relevance of nonmedical criteria in the allocation of scarce resources.

Clearly, we do not endorse the use of futility by physicians as a cover for cost-containment strategies (29). Such deception makes a mockery of the physician’s assertion of professional integrity. Yet if the medical profession retreats to the position that it has no internal professional values and merely provides whatever patients, families, or insurers are willing to pay for, it can no longer claim to be a healing profession, that is, a group committed to helping and serving the sick (18, 62). Instead, medicine becomes a commercial enterprise satisfying the desires of others.

Critics who urge that the “rapid advance of the language of futility should be followed by an equally rapid retreat” (27) would dispose of a concept that has been intrinsic to medical practice since the time of Hippocrates, when the physician was mandated to “refuse to treat those who are overmastered by their diseases, realizing that in such cases medicine is powerless” (63). Simply put, medicine cannot always achieve its desired goals (64). We urge the medical profession not to banish the “language of futility” but to examine that language more deeply and to look at the roots of the practice embedded in that language. Words that are central to health care, such as “heal” (which means “to make whole”) and “patient” (which comes from the Latin “to suffer”), suggest that the goal of medicine is not merely to achieve a means, such as restoring heart-beat, unless that means leads to the end of healing the patient (43).

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