

Chapter 7

Medical Futility: Its Meaning and Ethical Implications

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Reprinted, with permission, from *Annals of Internal Medicine* 112(12):949-54, June 15, 1990.

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The notion of medical futility has quantitative and qualitative roots that offer a practical approach to its definition and application. Applying these traditions to contemporary medical practice, we propose that when physicians conclude (either through personal experience, experiences shared with colleagues, or consideration of published empiric data) that in the last 100 cases a medical treatment has been useless, they should regard that treatment as futile. If a treatment merely preserves permanent unconsciousness or cannot end dependence on intensive medical care, the treatment should be considered futile. Unlike decision analysis, which defines the expected gain from a treatment by the joint product of probability of success and utility of outcome, our definition of futility treats probability and utility as independent thresholds. Futility should be distinguished from such concepts as theoretical impossibility, such expressions as "uncommon" or "rare," and emotional terms like "hopelessness." In judging futility, physicians must distinguish between an effect, which is limited to some part

of the patient's body, and a benefit, which appreciably improves the person as a whole. Treatment that fails to provide the latter, whether or not it achieves the former, is "futile." Although exceptions and cautions should be borne in mind, we submit that physicians can judge a treatment to be futile and are entitled to withhold a procedure on this basis. In these cases, physicians should act in concert with other health care professionals, but need not obtain consent from patients or family members.

A 62-year-old man with irreversible respiratory disease is in the intensive care unit. He is severely obtunded. During 3 weeks in the unit, repeated efforts to wean him from ventilatory support have been unsuccessful. There is general agreement among his physicians that he could not survive outside of an intensive care setting. They debate whether therapy should include cardiopulmonary resuscitation if the patient has a cardiac arrest or antibiotics if he develops infection. The patient gave no previous indication of his wishes nor executed an advance directive. Some physicians argue that a "do not resuscitate" order may be written without consulting the family, because resuscitation would be futile. Other physicians object, pointing out that resuscitation cannot be withheld on grounds of medical futility, because the patient could survive indefinitely in the intensive care unit. They agree to consult the family on this matter. At first there is considerable disagreement within the family until a son asks whether there is any hope at all that his father might recover. The physicians look at each other. There is always hope. This unites the family. They insist that if the situation is not hopeless, the physicians should continue all measures including resuscitation.

How should these physicians deal with this family's demands? The answer depends on both how the physicians define futility and the weight they give it when patients or surrogates strongly express treatment preferences. Are these issues perhaps too complex or ambiguous to resolve?^{1,2} We submit that they are not, and we offer both a theoretical and practical approach to the concept of futility, an approach that we believe serves in this case and more generally in similar cases by restoring a common sense notion of medical duty. We recognize that if futility is held to be nothing more than a vague notion of physician discretion, it is subject to abuse; therefore, we propose specific standards by which this idea can be appropriately invoked. In our view, judgments of futility emerge from either quantitative or qualitative evaluations of clinical situations. Such evaluations determine whether physicians are obligated to offer an intervention. If an intervention is judged to be futile, the duty to present the intervention as an option to the patient or the patient's family is mitigated or eliminated. We recognize—indeed invite—examination and challenge of our proposal.

The Glare of Autonomy

Less than a few decades ago, the practice of medicine was characterized by a paternalism exemplified in the expression, "doctor's orders." Physicians determined by themselves or in consultation with colleagues the usefulness of courses of treatment. The art of medicine was considered to include selectively withholding as well as disclosing information in order to maintain control over therapy. The dramatic shift toward patient self-determination that has taken place in recent decades almost certainly received much of its momentum from society's backlash to this paternalism. In addition, philosophical and political concerns about the rights of individuals and respect for persons elevated the principle of autonomy to a position in ethics that it had not previously held. Today, ethics and the law give primacy to patient autonomy, defined as the right to be a fully informed participant in all aspects of medical decision making and the right to refuse unwanted, even recommended and life-saving, medical care. So powerful has this notion of autonomy become that its glare often blinds physicians (and ethicists) to the validity of earlier maxims that had long defined the range of physicians' moral obligations toward patients. Among these was the maxim, respected in ethics and law, that futile treatments are not obligatory. No ethical principle or law has ever required physicians to offer or accede to demands for treatments that are futile.^{3,4} Even the so-called Baby Doe regulations, notorious for their advocacy of aggressive medical intervention, permit physicians to withhold treatment that is "futile in terms of the survival of the infant" or

"virtually futile."⁵ Even when this maxim is accepted in theory, however, physicians frequently practice as though every available medical measure, including absurd and overzealous interventions, must be used to prolong life unless patients give definitive directions to the contrary.^{6,7} Some physicians allow patients (or surrogates) to decide when a treatment is futile, thereby overriding medical judgment and potentially allowing the patient (or surrogate) to demand treatment that offers no benefit.⁸

Comparison of Effect and Benefit

In the early nineteenth century, all medications were, by definition, effective: They inevitably brought about the effect that their names described. Emetics could be counted on to cause vomiting; purgatives to cause laxation; sudorifics, sweating; and so on.⁹ These effects, given the medical theories of the times, were presumed always to be beneficial. Failure to heal was a defect of nature, not of the physician or the treatment. However, one advance of modern medicine, particularly with the introduction of controlled clinical trials, was to clarify by empiric methods the important distinction between effect and benefit. In examining the notion of futility, physicians sometimes fail to keep this distinction in mind.

For example, a recent discussion of futility includes the following: "[Physicians] may acknowledge that therapy is effective, in a limited sense, but believe that the goals that can be achieved are not desirable, as when considering prolonged nutritional support for patients in a persistent vegetative state. Physicians should acknowledge that, in such situations, potentially achievable goals exist. Therapy is not, strictly speaking, futile."² On the contrary, we believe that the goal of medical treatment is not merely to cause an effect on some portion of the patient's anatomy, physiology, or chemistry, but to benefit the patient as a whole. No physician would feel obligated to yield to a patient's demand to treat pneumonia with insulin. The physician would rightly argue that (in the absence of insulin-requiring diabetes) such treatment is inappropriate; insulin might have a physiologic effect on the patient's blood sugar, but would offer no benefit to the patient with respect to the pneumonia. Similarly, nutritional support could effectively preserve a host of organ systems in a patient in persistent vegetative state, but fail to restore a conscious and sapient life. Is such nutritional treatment futile or not? We argue that it is futile for the simple reason that the ultimate goal of any treatment should be improvement of the patient's prognosis, comfort, well-being, or general state of health. A treatment that fails to provide such a benefit—even though it produces a measurable effect—should be considered futile.

Approaching a Definition

The word futility comes from the Latin word meaning leaky (*futilis*). According to the *Oxford English Dictionary*, a futile action is "leaky, hence untrustworthy, vain, failing of the desired end through intrinsic defect." In Greek mythology, the daughters of Danaus were condemned in Hades to draw water in leaky sieves. Needless to say, their labors went for nought. The story conveys in all its fullness the meaning of the term: A futile action is one that cannot achieve the goals of the action, no matter how often repeated. The likelihood of failure may be predictable because it is inherent in the nature of the action proposed, and it may become immediately obvious or may become apparent only after many failed attempts.

This concept should be distinguished from etymologic neighbors. Futility should not be used to refer to an act that is, in fact, impossible to do. Attempting to walk to the moon or restore cardiac function in an exsanguinated patient would not be futile acts; they would be physically and logically impossible. Nor should futility be confused with acts that are so complex that, although theoretically possible, they are implausible. The production of a human infant entirely outside the womb, from in-vitro combination of sperm and egg to physiologic viability, may be theoretically possible but, with current technology, is implausible.

Further, futile, because the term is not merely descriptive, but also operational, denoting an action that will fail and that ought not be attempted, implies something more than simply rare, uncommon, or unusual. Some processes that are quite well understood and quite probable may occur only occasionally, perhaps because of their complexity and the need for many circumstances to concur at the same time. For example, successful restoration to health of a drug addict with bacterial endocarditis might require a combination of medical, psychological, social, and educational efforts. These interventions could work but, due to various factors (including limited societal resources), they rarely work. However, they are not futile.

Futility should also be distinguished from hopelessness. Futility refers to the objective quality of an action; hopelessness describes a subjective attitude. Hope and hopelessness bear more relation to desire, faith, denial, and other psychological responses than to the objective possibility or probability that the actions being contemplated will be successful. Indeed, as the chance for success diminishes, hope may increase and replace reasonable expectation. Something plausible is hardly ever hopeless, because hope is what human beings summon up to seek a miracle against overwhelming odds. It is possible then to say in the same breath, "I know this is futile, but I have hope." Such a statement expresses two facts, one

about the objective properties of the situation, the other about the speaker's psychological state.

Futility refers to an expectation of success that is either predictably or empirically so unlikely that its exact probability is often incalculable. Without specific data, one might predict futility from closely analogous experience. (For example, one might avoid a trial of a particular chemotherapy for one type of cancer based on failures seen when used for treating similar forms of cancer.) Or one may have accumulated empiric experience insufficient to state precisely the likelihood of success, but sufficient to doubt the likelihood of success. (For example, physicians have had only a few years of experience with a currently popular medication to cure baldness, but sufficient experience to be dubious of its long-term success.)

Reports of one or two "miraculous" successes do not counter the notion of futility, if these successes were achieved against a background of hundreds or thousands of failures. Such rare exceptions are causally inexplicable, because any clinical situation contains a multitude of factors—in addition to treatment—that might affect outcome. As Wanzer and colleagues¹⁰ stated, "The rare report of a patient with a similar condition who survived is not an overriding reason to continue aggressive treatment."

Quantitative and Qualitative Aspects

The futility of a particular treatment may be evident in either quantitative or qualitative terms. That is, futility may refer to an improbability or unlikelihood of an event happening, an expression that is quasi-numeric, or to the quality of the event that treatment would produce. Thus, determining futility resembles using decision analysis—with one important distinction. In decision analysis, the decision to use a procedure is based on the joint product of the probability of success and the quality (utility) of the outcome.¹¹ Thus, very low probability might be balanced by very high utility. In our proposal of futility, however, we treat the quantitative and qualitative aspects as independent thresholds, as minimal cutoff levels, either of which frees the physician from the obligation to offer a medical treatment.

This independence of futility determinants can be traced back to medical antiquity.^{12,13} The perception of futility derived from the Hippocratic corpus might be considered, in modern terms, to be quantitative or probabilistic. A book titled "The Art"¹⁴ enjoins physicians to acknowledge when efforts will probably fail: "Whenever therefore a man suffers from an ill which is too strong for the means at the disposal of medicine, he surely must not even expect that it can be overcome by medicine." The writer further admonishes the physician that to attempt futile treatment is to display an ignorance which is "allied to madness."

Plato's *Republic*,¹⁵ on the other hand, has a qualitative notion of futility, one that emphasizes the inappropriateness of efforts that result in patients surviving, but leading literally useless lives. According to Plato, the kind of medicine "which pampers the disease" was not used by the Asclepian physicians:

Asclepius . . . taught medicine for those who were healthy in their nature but were suffering from a specific disease; he rid them of it . . . then ordered them to live as usual. . . . For those however, whose bodies were always in a state of inner sickness he did not attempt to prescribe a regimen . . . to make their life a prolonged misery. . . . Medicine was not intended for them and they should not be treated even if they were richer than Midas.

Thus, both the quantitative and qualitative aspects of futility are recognized in the most ancient traditions. Hippocrates rejects efforts that are quantitatively or probabilistically unlikely to achieve a cure; Plato objects to a cure consummating (qualitatively) in a life that "isn't worth living." Both quantitative and qualitative aspects relate to a single underlying notion: The result is not commensurate to the effort. The effort is, on the part of the agent, a repeated expenditure of energy that is consistently nonproductive or, if productive, its outcome is far inferior to that intended.

Defining Futility

We propose that, on the basis of these considerations, the noun "futility" and the adjective "futile" be used to describe any effort to achieve a result that is possible but that reasoning or experience suggests is highly improbable and that cannot be systematically produced. The phrase, "highly improbable," implies that a statistical statement about probability might be applicable. In the strict sense, such a statement cannot be made, as proper conditions for determining probability (that is, prospective comparisons of precisely controlled treatment and nontreatment on identically matched subjects) will never be present. We introduce the concept of "systematic" to point out that if a rare "success" is not explicable or cannot be predictably repeated, its causality is dubious, because it is uncertain whether treatment, some extraneous influence, or random variation caused the result.

Quantitative Aspects

In keeping with the quantitative approach to futility, we propose 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. Technically, we cannot say that observing no successes in 100 trials means that the treatment never works. However, such an observation serves as a point estimate of the probability of treatment success. Although we cannot say with certainty that the point estimate is correct, statistical methods can be used to estimate a range of values that include the true success rate with a specified probability. For example, if there have been no successes in 100 consecutive cases, the clinician can be 95% confident that no more than 3 successes would occur in each 100 comparable trials (3 successes per 100 trials is the upper limit of the 95% CI). This confidence range would narrow as the number of observations increased. If no successes were seen in 200 cases, the upper limit of the 95% CI would be 1.5 successes per 100 cases and, for no successes in 1000 observations, the upper limit would be approximately 0.3 successes per 100 cases. In practical terms, because data from controlled clinical trials can only rarely be called on and applied to a specific case, practitioners usually use their extended experience as the source of their conclusions. Here, speciality practice contributes an essential element; for example, an intensive care pulmonary specialist who sees several hundred patients who have similar disease conditions and receive similar therapy can often group together "futility characteristics" better than a generalist who does not see cases in so focused a manner.

Without systematic knowledge of the various factors that cause a therapy to have less than a 1% chance of success—knowledge that would allow the physician to address these factors—we regard it as unreasonable to require that the physicians offer such therapy. To do so forces the physician to offer any therapy that may have seemed to work or that may conceivably work. In effect, it obligates the physician to offer a placebo. Only when empirically observed (though not understood) outcomes rise to a level higher than that expected by any placebo effect,¹⁶ can a specific therapy be considered to be "possibly helpful" in rare or occasional cases and its appropriateness evaluated according to rules of decision analysis. In the clinical setting, such judgments also would be influenced, of course, by considering such tradeoffs as how cheap and simple the intervention is and how serious or potentially fatal the disease (*see* Exceptions and Cautions).

Although our proposed selection of proportions of success is admittedly arbitrary, it seems to comport reasonably well with ideas actually held by physicians. For example, Murphy and colleagues¹⁷ invoked the notion of futility in their series of patients when survival after cardiopulmonary resuscitation was no better than 2% (upper limit of 95% CI as calculated by authors), and Lantos and colleagues¹⁸ when survival was no better than 7% (upper limit of 95% CI as calculated by authors).

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