



# Futile medical treatment and patient consent

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■ What are a physician's ethical responsibilities when a patient or surrogate demands futile life-saving treatment? Recent attempts to define medical futility have implications for physician responsibility and may create exceptions to acquiring patient consent. Wording is proposed for a "futility clause" for use in do-not-resuscitate policies.

□ INDEX TERMS: LIFE SUPPORT CARE; RESUSCITATION ORDERS; INFORMED CONSENT □ CLEVE CLIN J MED 1993; 60:151-154

**P**HYSICIANS ROUTINELY make professional judgments to not offer treatments they deem medically or surgically ineffective or harmful without sufficient benefit. However, discussions about medical futility are now more frequent and have taken a new turn. The new focus of controversy is the proposal to withdraw or withhold life-prolonging treatments (eg, mechanical ventilators) or life-saving techniques (eg, cardiopulmonary resuscitation) based exclusively on a medical determination of futility.

There are two main reasons for the recent discussions about medical futility. First, over the past few decades, health care has swung away from a dominantly paternalistic model of the physician-patient relationship. In determining health care decisions, medical judgment of benefit has been subordinated to informed consent and refusal by patients or their surrogates, even if the patient's decision leads to death. Although many noted legal cases supporting patient informed consent<sup>1</sup> were initially resisted by physicians and care facilities, and although a minority (primarily "medical vitalists")<sup>2</sup>

holds that regardless of the patient's condition or wishes it is inappropriate to cease efforts to preserve life, an ethical and legal consensus has emerged in the United States that an adult patient's informed consent or refusal for medical treatment should be sought and honored.

The second reason is the appearance of a new class of cases, problematic because they appear to further extend patient autonomy in medical decisions. These cases<sup>3,4</sup> are distinguished by the patient's or surrogate's insistence that life-prolonging treatments be provided or continued even though medical judgment concludes that the treatments are ineffective or harmful. A good example is the case of Helga Wanglie, which recently underwent judicial review in Minnesota.<sup>5-7</sup>

These cases exemplify the major ethical and legal issues at stake in the discussion of medical futility: Is the value of patient self-determination so significant that not only can patients refuse life-saving measures against medical advice, but they can also demand life-prolonging treatments which physicians judge to be futile? Should a determination and declaration of futility by attending physicians create an exception to the principle of informed consent? If patients demand futile treatment, how will this affect physicians' professional integrity and responsibility as moral agents to act in the best interests of their patients according to

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their professional values and their understanding of acceptable practice?<sup>8</sup>

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CAN MEDICAL FUTILITY BE DEFINED?

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How should we define medical futility?<sup>9</sup> This question is especially pertinent if discussions of medical futility seek to establish institutional policy or social policy about withholding or withdrawing “futile” treatment without patient or surrogate consent. An equitable and consistent application of futility policies would depend on generally agreed upon understandings of what constitutes futility in various situations. Is there sufficient consensus within the health care community about what constitutes futility?

In attempting to define futility in clinical practice, various cautions, definitions, and distinctions have been proposed. Problems with proposed definitions include the appropriateness of incorporating quantitative elements (eg, retrospective and prognostic statistical data) or qualitative elements (eg, value judgments, especially by attending physicians).

Lantos et al<sup>10</sup> contend that futility is ambiguous and undefinable. They feel that semantic errors, multiple interpretations of similar statistical data, and disagreements about the goals of therapy render a precise definition of futility impossible. In their view, a decision to forgo life-saving treatment would be inappropriate if it is based solely on qualitative physician judgments of futility and if it excludes explicit consideration of the patients’ values and goals.

Schneiderman et al<sup>11</sup> affirm both quantitative and qualitative elements in medical futility and offer a practical approach to its definition. For the quantitative component, they suggest that when a medical treatment has failed in the last 100 cases (using published empiric data and unpublished professional experiences), that treatment should be regarded as futile. Lack of success in 100 consecutive cases yields a 95% confidence interval that no more than three successes would occur in each 100 comparable trials. This confidence range would narrow as the number of observations increased. They also propose a qualitative component: a treatment should be considered futile if it merely preserves permanent unconsciousness or cannot end dependence on intensive medical care (ie, preserves biologic life without consciousness or autonomy). The American Thoracic Society’s Bioethics Task Force concurs with this qualitative criterion, unless the patient had specified in an advance directive that such an existence would be of value.<sup>12</sup>

To assist physicians in judging the futility and the goals of a medical intervention, Schneiderman et al distinguish a treatment’s effect from its benefits. “Effect” is limited to the patient’s anatomy, physiology, or chemistry (eg, nutritional support preserving organ systems in a patient in persistent vegetative state, but not restoring a conscious or sapient life); “benefits” refers to an appreciable improvement of the person as a whole. In applying this distinction, treatment that fails to provide benefit, whether or not it achieves its intended physiologic effect, would be regarded as futile.

The opinion of Tomlinson and Brody<sup>8</sup> combines aspects of some of these views. Like Lantos et al, they assert that physician determinations of futility are based on probabilities, not absolute certainty. However, like Schneiderman et al, they also see the necessity of integrating qualitative elements (such as the value judgments of physicians) into definitions and determinations of medical futility. By including value judgments made by physicians as part of reasonable medical practice, the question becomes not whether physicians can make appropriate value judgments, but which value judgments physicians may use in deciding whether to meet patients’ demands.

The American Medical Association’s Council on Ethical and Judicial Affairs has issued guidelines for do-not-resuscitate (DNR) orders<sup>13</sup> which specifically discuss futility as a basis for withholding cardiopulmonary resuscitation. The Council’s statement attempts to steer a middle course between the approaches summarized above. It allows for the “unusual circumstance” of a unilateral physician decision to withhold cardiopulmonary resuscitation (eg, when it clearly cannot restore heartbeat or when it would fail to achieve the expressed goals of the informed patient), but cautions against undermining patient autonomy by basing futility judgments on the values of someone other than the patient.

The various attempts to define and describe medical futility show signs of some emerging agreements. Medical prognostication is limited and imperfect, and accumulation of quantitative data will not in most cases obviate value judgments by physicians in determining medical futility, nor will it totally eliminate fears of legal liability. Nevertheless, consensus on medical futility seems possible through multilevel dialogue involving patients, health care professionals, institutional ethics committees, and national scientific and bioethics panels, aided by the accumulation of empirically based prognostic indicators for medical and surgical conditions.<sup>8,14-19</sup>

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 IMPLICATIONS FOR PHYSICIANS
 

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If a medical and societal consensus were achieved on what constitutes futility in some clinical situations, what changes would occur in the duties and practice of physicians? It has been recently proposed that determination of medical futility could in some restricted circumstances obviate consent by the patient or surrogate to withhold or withdraw life-saving treatment.<sup>8,11-13,20</sup> At first glance such unilateral decisions by physicians might seem to erode patient autonomy and represent a return to unwarranted paternalism. But a countering, paradoxical assertion has been made that physician authority over the determination of futile treatment actually protects patient autonomy.<sup>8</sup> This assertion is based on the theory that autonomous choice is undermined by offering a treatment (implying possible benefit) that cannot contribute to the patient's welfare or interests.

This proposed exception to acquiring patient consent would not excuse physicians from a duty to inform patients or their surrogates about the decision to withhold or withdraw futile treatment.<sup>11-13,21</sup> Clear, candid, and compassionate communication is indispensable for maintaining trust between physician and patient: the absence of communication when life and death decisions are being made could be a major violation of this trust relationship. Discussions about futility may help patients and families better cope with the inevitability of impending death; they may bring to light a special patient or family value that might support continuation of futile treatment,<sup>21</sup> at least temporarily; and they may also open discussion of appropriate alternatives, such as obtaining a second opinion, or arranging for transfer of care to another physician or institution.

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 IMPLICATIONS FOR POLICY
 

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A futility-based exception to informed consent has significance for institutional and societal policy.<sup>22,23</sup> In particular, policies for DNR orders and forgoing life-supporting therapies should state explicitly the possibility of futility-based exceptions and their accompanying duties and expectations.

Policies for end-of-life decision-making should mandate that a process of informed consent involving

patients or surrogates be followed and maintained, but with the explicit acknowledgment that an exception to this usual practice is allowed under strict conditions. A specific exception to informed consent might be formalized as follows:

*Cardiopulmonary resuscitation may be withheld and a DNR order written without patient or surrogate consent when (1) the primary physician judges that cardiopulmonary resuscitation would not restore effective cardiopulmonary function, or would be harmful with little or no benefit to the patient, and (2) a second concurring opinion is obtained from a licensed physician. The patient or surrogate should be informed about this decision.*

This proposed policy affirms the professional authority of physicians to make determinations of medical futility and to choose to forgo a futile treatment without patient or surrogate consent. It distinguishes between the effect and the benefit of a treatment,<sup>11</sup> and it affirms the physician's duty to inform the patient or surrogate about the decision. An alternative or addition to the requirement of a second medical opinion could be an automatic prospective review by the institution's ethics committee.<sup>20</sup> In allowing physician judgment to have a role in determining benefit, this proposal goes beyond the limitations set by the American Medical Association, whose narrower position could reasonably be challenged.<sup>16,24</sup>

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 CONCLUSION
 

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Discussion of medical futility reflects an apparent conflict, in some clinical cases, between respect for patient autonomy and the preservation of the ethical integrity of the medical profession. However, practical agreement on what constitutes futility is possible in some situations.

The dangers of a futility-based exception to informed consent include the reemergence of paternalism and physician avoidance of difficult discussions with patients about dying and death. These dangers need not become realities. Policies that do not require patient consent in situations of futility should require that the physician inform the patient or surrogate in cases of a futility-based decision to withhold or withdraw treatment. Arbitrary paternalism could be avoided by prospective review of futility judgments by medical second opinions and institutional ethics committees.

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