

# Ten Common Questions (and Their Answers) on Medical Futility

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## Abstract

The term *medical futility* is frequently used when discussing complex clinical scenarios and throughout the medical, legal, and ethics literature. However, we propose that health care professionals and others often use this term inaccurately and imprecisely, without fully appreciating the powerful, often visceral, response that the term can evoke. This article introduces and answers 10 common questions regarding medical futility in an effort to define, clarify, and explore the implications of the term. We discuss multiple domains related to futility, including the biological, ethical, legal, societal, and financial considerations that have a bearing on definitions and actions. Finally, we encourage empathetic communication among clinicians, patients, and families and emphasize how dialogue that seeks an understanding of multiple points of view is critically important in preventing or attenuating conflict among the involved parties.

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Futile medical care and disagreements (eg, among physicians, family members, and others) about whether an individual patient's health care is futile constitute the main ethical health care–related challenges faced by the public today.<sup>1</sup> Despite progressive efforts to prevent disputes, conflicts will likely continue to increase as the aged population increases<sup>1,2</sup> and if patients are offered a list of treatment options—and treatment and technology imperatives—in a misdirected, inappropriate, and wasteful fashion.<sup>3</sup> In these instances, the term *medical futility* is often used. The following article attempts to provide health care practitioners and the public with an overview of this topic by introducing 10 questions regarding *medical futility* and offering answers to those questions on the basis of the existing literature, common values gleaned from multiple relevant fields (eg, medicine, ethics, economics, and the law), and the authors' own experiences. The ultimate goal of this overview is to provide readers information on the common concepts, language, and controversies to enhance future discussions and debate.

## QUESTION 1: WHAT IS THE DEFINITION OF MEDICAL FUTILITY?

The term *medical futility* is often invoked when an otherwise curative or disease-arresting therapy

or intervention is directed toward a seriously ill patient who has a low likelihood of recovery. Merriam-Webster's Dictionary defines *futile* as “serving no useful purpose; completely ineffective,” but it does not contain a separate listing for *medical futility*.<sup>4</sup> Despite the relevance and importance of these terms to discussions within contemporary medicine, ethics, and economics, *medical futility* is often underaddressed, and opportunities exist to educate those direly in need of information.<sup>1</sup>

Medical writers, clinicians, and ethicists have noted that definitions of medical futility (herein referred to simply as *futility*) can be “confusing, inconsistent, and controversial”<sup>5</sup> because the definition is often slanted to reflect the definer's point of view. Any working definition of *futility* should be accessible to users with different backgrounds and testable against existing standards and practices.

For example, Schneiderman et al<sup>6</sup> considered *experience* and *quantity* in their definition of medical futility: “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.” Alternatively, Youngner<sup>7</sup> defined futility via 3 major domains: quantitative (as with Schneiderman et al<sup>6</sup>), qualitative, and physiologic.



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Physiologic futility examines whether a treatment or technology is efficacious in meeting its intended purpose on a given patient. Clinicians are typically the arbiters of physiologic futility, which is relatively easy to assess in an objective manner. Examples include whether a ventricular assist device is effectively supporting cardiac output and reversing cardiogenic shock or whether hemodialysis is adequately replacing renal function.

In contrast, the quantitative and qualitative aspects of futility are often challenging for clinicians to parse out because these aspects rely on value judgments on the quality of life and its role in assessing the virtue of longevity.<sup>7</sup> What a patient or surrogate defines as quality or quantity may differ from the clinician's perspective, and one can argue that qualitative futility is only met if a treatment does not allow a patient to live his/her life according to his/her goals, preferences, and values, which we believe cannot be determined clinically or by how the last 100 patients responded in a given situation.

Clinicians are best able to accurately comment on the physiologic aspects of medical care that are not value laden.<sup>7</sup> With this tension, the American Medical Association Council on Ethical and Judicial Affairs attempted to be more definitive but recognized the limitations of defining futility as a value-based concept; instead, they determined that "a fully objective and concrete definition of futility is unattainable."<sup>8</sup> Reflecting on the difficulty in defining other elusive terms, such as *love* and *art*, Kwiecinski<sup>8</sup> commented that "most physicians now know it [futility] when they see it." Acknowledging these difficulties, we introduce, as a framework for the remainder of our discussion, the following recognizably non-comprehensive definition of medical futility: excessive (in terms of effort and finances) medical intervention with little prospect of altering a patient's ultimate clinical outcome.

## QUESTION 2: HOW DO CHALLENGES IN PROGNOSTICATION CONTRIBUTE TO MEDICAL FUTILITY?

Just as it is difficult to precisely define futility, it is difficult to define how often care is provided that is deemed futile, particularly when analyzed from the perspective of observers' diverse views on what is and is not futile care. A crude approximation can be surmised because 25% of US

Medicare dollars are spent in the final year of life. This reasoning is somewhat circular, however, in that sick people require health care resources, sicker people require more expensive resources, and the sicker one is, the more likely one is to die. Although it is impossible to be certain that someone has entered the final year of life, multiple prognostic scoring systems have been developed to more precisely predict the likelihood of patients' survival when they are receiving intensive care. Although tools such as the Acute Physiology and Chronic Health Evaluation (APACHE) have tried to link physiology, resource utilization, and likelihood of death, they have failed to be definitively useful for this role, particularly when applied to outcome in a single patient.<sup>9-11</sup>

Berge et al<sup>12</sup> used the physiologic data-based APACHE III system in an effort to identify futile medical care by looking at a group of extremely ill intensive care unit (ICU) patients (ie, study patients had predicted single-day mortality rates of  $\geq 95\%$  on 2 consecutive days). A total of 248 patients (0.68%) of 38,165 ICU admissions achieved this status. In fact, the survival rates exceeded the predicted rates by a significant margin, with 23% surviving to hospital discharge. However, all but one of these patients was ranked as "severely disabled" at discharge, and most (90%) died within the subsequent year, never having left a skilled nursing facility.<sup>12</sup> Interestingly, Berge et al reported that the opinions of experienced ICU physicians (as recorded in narrative notes within the hospital record) appeared to more accurately predict individual patient's survival than did the most finely calibrated, then-state-of-the-art, computer-based prognostic scoring system (ie, APACHE III). The report of Berge et al documents that although prognostic scoring systems are increasingly used to attempt to predict the clinical course of the sickest patients, they still are unable to determine when an individual therapy is futile.<sup>12</sup> A review of these and other scoring systems, including the Simplified Acute Physiology Score 3 and the Mortality Probability Model 3, reveals that these models may predict mortality reasonably well at a population level but tend to be less effective for individual patient prognostication.<sup>13</sup> Taken together, clinicians and the prognostic tools they use are limited in their ability to predict outcomes for individual patients, which can lead to uncertainty and

the continuation of treatments with marginal efficacy.

### QUESTION 3: WHAT AND WHO ARE THE PRINCIPAL MOVERS ENCOURAGING MEDICAL CARE THAT MAY BE CONSIDERED FUTILE?

Berge et al<sup>12</sup> found that the best predictor of prolonged and expensive ICU care in patients from whom survival was unlikely (perhaps meeting a definition of futility) was medical record documentation of “unrealistic family expectations.” However, the source of these expectations can be multiple and variable. Sources include cultural or spiritual values and personal convictions of patients, families, or clinicians, and they also can result from an inaccurate interpretation of medical information that is presented unclearly by clinicians or alternative sources of information.

The popular media and entertainment industry have an important influence on inaccurate expectations for outcomes. For example, one study<sup>14</sup> researched television medical dramas to determine how often cardiopulmonary resuscitation (CPR) is depicted as successful (ie, survival to hospital discharge with no neurologic deficits) and compared the results with those from medical studies. Although a successful outcome of CPR is no better than 10% to 15% in most situations, the television dramas depicted it as successful in an unrealistic 75% of immediate survival cases, with 67% surviving to hospital discharge.<sup>14</sup> Regardless of the penetration of the media and entertainment industries in producing erroneous views on CPR efficacy, the erroneous views are widely held. For example, even those with medical training routinely overestimate the benefits of CPR.<sup>15,16</sup>

The rare instances when extended resuscitations yield a successful outcome are reported in the medical literature<sup>17-19</sup> and often amplified in media reports.<sup>20,21</sup> (As one might suspect, failures rarely receive such attention.) That reports of such successes represent extreme outliers is generally not appreciated by the lay public or emphasized by media stories about such resuscitations.<sup>20,21</sup> For some patients and caregivers, hopes for miraculous recoveries may persist. The hope for an extremely improbable favorable outcome (sometimes perceived as a miracle outcome), although not a commonly articulated

sentiment of patients or surrogates, nevertheless can enter into the decision making of physicians, many of whom have during their careers witnessed or heard about one of these rare events.

Sometimes physicians, nurses, and other health care professionals may experience moral distress, feeling pressured to provide aggressive care as encouraged by *technology imperatives*, even though the outcome will not be altered by such interventions.<sup>22</sup> These imperatives (ie, the inexorable inertia toward intensification of care geared at life prolongation) are discussed further below.

False hopes also can be created by media and tabloid reports of the occasional “miracle” emergence from prolonged comas, such as persistent vegetative states. Wijdicks and Wijdicks<sup>23</sup> made it clear that such cases arise from initial misdiagnosis or media mislabeling of the actual form of coma and that the diagnosis of the exact nature of a coma is a subtle matter best left to neurologists with special expertise in coma diagnosis.<sup>24,25</sup> In correctly diagnosed persistent vegetative states lasting for 6 months to 1 year, there is in fact no hope for the recovery of consciousness.<sup>24</sup> Unfortunately, in reports of possible outliers, the media may promote sensationalism over clear, technically accurate reporting.

The misuse of aggressive end-of-life treatments that, in turn, impose an undue financial burden to the health care system is a multifaceted problem. Often, these exercises result in the deployment of multiple high-tech, and often unproven, therapies that may cause patients and families to miss an opportunity to spend time, money, and effort on useful alternatives, such as palliative care or hospice care. From a clinician perspective, Mueller and Hook<sup>3</sup> editorialize that when faced with impending mortality in a patient, it is often difficult for physicians to avoid bowing to interventions encouraged by “technological and treatment imperatives.”

In this case, *treatment imperative* refers to the propensity of clinicians and patients or surrogates to feel obligated to use any intervention, even if that intervention may not help the patient (eg, offering vasopressors, antimicrobial drugs, or surgical intervention simply because they are at our disposal). Similarly, *technological imperative* refers to the propensity to use technological interventions when they exist, even

if such interventions are not absolutely indicated for the individual patient (eg, using hemodialysis, pacemakers, or defibrillators simply because they exist). When offered, it is difficult for the patient or the surrogate to refuse such options simply out of desire to “do something.”<sup>3</sup> Thus, it can become a default decision to escalate and prolong therapy, even beyond the point where it only functions to prolong suffering and delay inevitable death.

#### **QUESTION 4: WHAT ARE THE FINANCIAL ARGUMENTS THAT MAY ENCOURAGE OR DISCOURAGE THE PROVISION OF MEDICALLY FUTILE CARE?**

Chronic critical illness and multiorgan failure were previously not compatible with survival. However, contemporary patients can often survive for extended and indefinite (but not infinite) timeframes if sustained by heroic measures and technological advances.<sup>3</sup> Annually, 65% of deaths in the United States take place within a hospital setting.<sup>26</sup> This can be at great cost (as stated earlier, 25% of Medicare dollars are spent in the last year of life),<sup>27</sup> which may lead to questions about health care allocation.<sup>28</sup>

A recent study evaluated care of 1136 patients in the intensive care unit within one health care system during a 3-month period. The findings revealed that approximately 11% of these ICU patients were receiving care considered to be futile, and such care was at an estimated cost of \$2.6 million (or 3.5% of total hospital costs for the patients studied).<sup>29</sup> Care considered to be unnecessary is not limited to end of life; the Institute of Medicine estimates that up to 30% of US health care expenditures may be nonindicated.<sup>30</sup>

The current financial incentives in US health care are not necessarily conducive to efficiently managing patients at the end of life. As the US population ages, Medicare and Medicaid will likely become the primary means of paying for health care, thereby placing added strain on all taxpayers.<sup>31</sup> Because patients and their families do not pay for the entire amount of health services provided, as they might for a non—health care—related commodity, the cost for potentially futile care may pit the patient against those who help fund this care (ie, those who pay insurance premiums and taxpayers). This payment process may place physicians

and other health care professionals in the unenviable position of being “stewards” of limited funds when the wishes of patients are pitted against those of society.<sup>32</sup>

In the 2010 Dartmouth Atlas report entitled *Quality of End-of-Life Cancer Care for Medicare Beneficiaries*, there was wide variation across the country in the extent of care provided within the last month or 2 weeks of a patient’s life.<sup>33</sup> The authors of the report suggested that the primary reason for these geographical differences stem from differing hospital reimbursement rates, local supply of physicians, use of medical specialists (vs generalists), and the availability of hospital beds rather than the health care status of a given population or concerns related to the best care for the patient.<sup>33-35</sup> Furthermore, discussions with patients and families concerning the negative consequences of aggressive care often do not occur because financial reimbursements for alternatives, such as palliative care and hospice care, are relatively low.<sup>33,34</sup>

Economic analysis of the benefit of continued treatment to patients in terms of quality or survival can be calculated; however, such measures should not routinely be used to determine whether care is futile. As described by Siddiqui and Rajkumar,<sup>36</sup> who explored the origins of high costs of cancer drugs, measures such as quality-adjusted life-years (defined as the number of years of life added by an intervention that is adjusted for quality of life) and incremental cost-effectiveness ratios are means commonly used in the evaluation of economic benefit of drugs and devices. These formula-based measures are often criticized for not considering the patient as a person. Furthermore, concerns about equity in health care can be raised if it appears that there is care discrimination on the basis of patient age or a bias regarding quality of life.<sup>37</sup> Despite their inherent limitations, it remains to be seen whether the tools of value-based analyses such as these will eventually make their way into futile care decision processes because the financial burden of providing unbridled end-of-life care continues to increase.

Domestic financial pressures related to futile care may influence both patients and their families. Some patients may fear that the costs incurred with aggressive treatment may have a negative effect on either their own finances

or those of their spouse.<sup>38</sup> On the other hand, patients and families may demand that futile care continue out of fear that death may cause their family to lose income from the patient's salary or pension.<sup>38</sup> With continued increases in health care—related costs, along with a shift in age demographic characteristics in the United States and implementation of evolving strategies for health care reimbursement (eg, strategies restructured under the Affordable Care Act), financial concerns related to futile care will likely continue to affect the decisions of patients, families, health care professionals, and the nation as a whole well into the future.<sup>29-31,39</sup>

One way health care reimbursement reform can affect health care delivery is by restricting potentially futile care and reappropriating the saved funds. It has been suggested that differences in ICU resources between countries in Western Europe and the United States are linked to variability in treatment withdrawal patterns.<sup>40</sup> Furthermore, because of limited resources, some argue that it is acceptable under the construct of social justice to direct care to those most likely to survive.<sup>41</sup> Thus, it is foreseeable that attempting to rein in health care costs while still providing services to the greatest number of the population may result in future adjustments to the boundaries of that care.

#### QUESTION 5: WHAT ARE THE CORE LEGAL CONCERNS THAT INFLUENCE THE PROVISION OF MEDICALLY FUTILE CARE?

Courts have maintained the importance of the principle of individual patient autonomy at the expense of historically paternalistic standards once prevalent within medical decision making. Furthermore, the states' strong desire to preserve the lives of its citizens and the courts' role of representing those state interests may potentially limit practitioners' decisions to terminate end-of-life treatment, especially when practitioners' decisions are at odds with those of patients, their families, or their surrogates.<sup>42</sup> As an example, in the 1990 landmark decision of *Cruzan v. Director, Missouri Department of Health*, the US Supreme Court spoke of concern for the irreversibility of erroneous decisions to terminate life.<sup>42</sup> Still further, legal arguments surrounding patients with disabilities have influenced the continuation of what some may consider futile treatment. In the Baby K

case decided by the US federal courts in 1993, the judiciary held that because the claim of futility was regarding an anencephalic infant (ie, a condition from which there is no recovery), withholding potentially life-sustaining treatments (eg, mechanical ventilation and CPR) was in violation of the Americans with Disabilities Act.<sup>42</sup> These 2 cases are examples of court decisions that influence futile care without directly facing the issue of futility itself. In the *Cruzan* case, the court's fear was the irreversible nature of inaccurate medical decisions, whereas in the *Baby K* case, the court used protection through classifying an ill child as disabled.<sup>43</sup>

Legal concepts factor in both encouraging and discouraging the provisions of futile care. Shiner<sup>42</sup> argued that a patient's request for treatment deemed medically inappropriate and a court's decision to support that decision may "undermine the ethical integrity of the medical profession's judgments." Furthermore, requiring a physician or other medical practitioner to treat a patient when considered at odds with their medical judgment may in turn violate their personal ethics. Many professional organizations and state laws allow practitioners to refuse treatment and transfer a patient to other facilities or practitioners when the practitioner's beliefs are at odds with a patient's treatment decision.<sup>8,42</sup>

Any rules or laws that require medical practitioners to provide care they believe futile may affect the use of scarce resources otherwise beneficial to others in need.<sup>8,42</sup> This scenario has played out in situations of mass casualties, such as the triaging of Hurricane Katrina victims regarding who would and who would not receive the most aggressive medical treatments.<sup>44</sup> Triage criteria have been enacted to attempt to guide clinicians but are not without critics.<sup>45,46</sup>

Government modulation of futile care delivery can emanate from all branches of government (ie, legislative, judicial, and executive). The executive branch of government has intervened in several cases, with subsequent executive order or legislative action leading to the creation of new law or policy. *Baby Doe* was a child born with Down syndrome and a tracheoesophageal fistula in Bloomington, Indiana, in 1982. The parents asked that the fistula not be repaired and that the child be allowed to die because of the disability. In response to the

Baby Doe case, then President Ronald Reagan worked with the US Secretary of Health and Human Services to mandate that children with disabilities be provided necessary life-sustaining treatments.<sup>47</sup> Regarding the case of Terri Schiavo, a woman in a persistent vegetative state after an anoxic brain injury, there was unprecedented intervention by then Florida Governor Jeb Bush, who ordered that Schiavo's feeding tube be continued or not removed even though it was not in his power to do so.<sup>48</sup>

When considered in aggregate, there are many examples in which legal decisions, legislative actions, and executive decisions have either encouraged or discouraged the delivery of futile care without facing the issue of medical futility directly. When physicians and hospitals have withdrawn support against family wishes, courts have typically sided with the medical professionals.<sup>43</sup> However, when medical professionals have preliminarily sought support for their decisions before stopping life-sustaining treatments, the courts have more often sided with families.<sup>43</sup> Because of the lack of legal consensus on end-of-life futility disputes, strong efforts to resolve these disagreements should best take place outside the judicial arena.<sup>43</sup>

#### **QUESTION 6: DOES THE DEFINITION OF MEDICAL FUTILITY DIFFER DEPENDING ON THE TYPE OF PATIENT?**

We believe that futility is best adjudicated by determining the clinical benefit of an intervention or lack thereof and how this affects the goals of care. This rule should be uniformly applied whether a patient is young or old, poor or rich, learned or with limited education. However, there are certain vulnerable groups that may require extra scrutiny.

Patients, in particular those who are legally minors, may require scrutiny to see whether the plan of care is consistent with the goals of care of the surrogate vs the standard of care as outlined by the clinician and the state. Mechanical ventilation of anencephalic or extremely premature infants may physiologically provide oxygenation; however, it may be incompatible with the standards of care or the patient's intermediate to long-term survival.

One upside to the pressure to extend care to patients who are minors is the length of

additional life if an intervention is successful. Clinicians have an obligation to serve as advocates for minors when social, cultural, religious, or spiritual issues on the part of parents, guardians, or surrogates encourage interventions and care that deviate from accepted standards. When challenges occur, clinical ethics consultation may be helpful, and sometime legal assistance is required.

Similar situations can occur in patients with disabilities or elderly patients because some clinicians may challenge whether a treatment is able to qualitatively or quantitatively affect outcome, given exigent confounding issues. Most futility conflicts question whether the family members or other patient surrogates are making decisions on the basis of the prior verbalized requests of the patients, proper substituted judgment, or the best interests of the patients and whether health care professionals are required to follow the dictates of the patient's surrogate.<sup>3,49,50</sup> In these situations, it is recommended that clinicians work with their legal advisers to be certain that surrogates are appropriately exerting influence on a plan of care that is consistent with norms and values that go beyond the surrogate's personal opinion.

Surrogates and families may perceive significant vulnerability—resulting from factors such as lower socioeconomic state or inadequate insurance status—when they are asked to make decisions for patients when outcome is uncertain and care options have widely divergent costs.<sup>51</sup> A recent study illustrated this concept with the finding that nonwhite patients with neurologic injuries were less likely to have mechanical ventilation withdrawn.<sup>52</sup> Clinical ethics committees are often used as advisers or arbiters when vulnerability exists. However, when the option to unilaterally withdraw treatments is available, this can amplify power inequalities between patients and surrogates vs the health care team or system.<sup>53</sup> When physicians and ethics committees are employed by the same institution, it may be difficult for the ethics committee to be unbiased.<sup>53</sup> Furthermore, despite the growth of hospital ethics consultation services during the past quarter-century, most hospital ethics committees are ill equipped with sufficient medical knowledge to have life and death decision making in their hands.<sup>53</sup>

### QUESTION 7: DO THE STANDARDS OF APPROPRIATE VS FUTILE MEDICAL CARE CHANGE WITH TIME?

With the passage of time, treatments once viewed as medically futile are no longer considered as such, and conversely many treatments once viewed as beneficial are now viewed as medically futile. Medical research and clinical experience continue to refine best evidence-based practices and how a treatment is viewed as beneficial or not.<sup>54</sup>

Advances in medications and medical technology have, in many instances, contributed to routine expectations for life prolongation and improvements in the quality and quantity of life among critically ill patients.<sup>55</sup> However, not all appealing therapies substantially alter outcomes, and, even among those that eventually prove efficacious, there can be a prolonged learning curve to identify which patients will benefit most from such treatments. In a recent editorial, Mueller and Hook<sup>3</sup> reported that patients and their families may grasp for options to arrest and reverse life-threatening illness, which, in many instances, may lead practitioners to feel compelled to offer treatments that remain yet unproven. Restated simply, there is, at times, an unrealistic pressure to simply “do something.”

As time passes, however, shifts in views may result from new outcomes-based research and reassessments of health care economics, often leading to a more objective analysis of treatment benefit or lack thereof.<sup>54</sup> One example relates to the use of left ventricular assist devices (LVADs) to treat advanced heart failure. Once considered merely a means of biding time for patients with advanced heart failure until a transplant was available, LVADs have been found to be beneficial as a *destination therapy* for a group of patients who are unable to or do not wish to undergo transplantation.<sup>56,57</sup> Appropriately selected patients can have excellent improvement in quality of life, with downstream opportunities and pitfalls shared with other patients.

Barbara et al<sup>58</sup> recently reported on 33 patients with LVAD who underwent 67 non-cardiac-related operations under general anesthesia during an approximately 7-month period. None of the patients studied died as a consequence of undergoing non-cardiac-related operations. The authors suggest that

given the global decrease in mortality after LVAD implantation (42% in 2005 vs 17% in 2009), patients likely once deemed too sick to undergo anything but emergency surgery related to their underlying cardiovascular condition will increasingly present for non-cardiac-related operations in the future.<sup>58</sup>

In another example of augmented or replaced cardiac function, Tweet et al<sup>17</sup> reported on a 46-year-old woman who presented to the emergency department with symptoms consistent with a myocardial infarction. When an unstable hemodynamic profile and cardiac arrhythmias persisted after emergency coronary revascularization, the patient was given extracorporeal membrane oxygenation for 8 days before she was able to maintain her own, life-sustaining cardiac output.<sup>17</sup> Although extracorporeal membrane oxygenation appears to be more effective for patients with in-hospital cardiac arrest vs those with out-of-hospital arrests, misunderstanding of this detail may lead to the treatment being used or requested in both subsets.<sup>59,60</sup>

Because countless examples are possible, Table 1, Table 2, and Table 3 offer additional examples of therapeutic measures once considered beneficial that now are considered futile, measures once considered futile that now are deemed useful, and those that will require further evaluation over time to determine their true benefit, respectively.

### QUESTION 8: HOW DOES ONE ADJUDICATE OUTSIDE THE LEGAL SYSTEM WHETHER MEDICAL CARE IS FUTILE AND WHETHER SUCH CARE SHOULD BE CONTINUED OR STOPPED?

The courts have preferred to distance themselves from cases that involve end-of-life treatment issues, which in turn has helped foster local efforts, including the evolution of hospital ethics committees for resolving disputes in a more germane setting.<sup>99</sup> Fortunately, most futility disputes are resolved through collaboration and effective communication involving family members, other surrogate decision makers, and health care professionals.<sup>2,100</sup> Incidentally, failure of these initial attempts at communication, and not ethical dilemmas per se, accounts for the greatest number of requests for ethics committee intervention.<sup>101-103</sup> Not surprisingly, all disputes cannot be resolved,

TABLE 1. Situations in Which an Intervention Once Thought to Be Beneficial Is Now Viewed as Futile

Scenario	Comments
Feeding tubes in critically ill patients in whom a diagnosis has not been confirmed or outcome estimated <sup>48,61</sup>	Once viewed as a temporizing measure to keep patients supported nutritionally until a diagnosis could be established, studies in calorie-deprived patients have found that this nutritional support is likely not needed short term, and it often leads to prolongation of life, enhanced complications of therapy (eg, infections), and increased medical care costs without benefit to the patient.
Prolonged deep anesthesia in patients with status epilepticus <sup>62,63</sup>	Although it is known that prolonged seizures correlate with brain injury (in part by metabolically "etching" neuronal pathways), many, if not most, patients who have status epilepticus do so because of irreversible brain injury. In these patients, deep anesthesia will temporarily interrupt the seizures; however, unless an underlying source is identified and the pathophysiologic condition reversed, the patients will simply return to status epilepticus and typically die after use of the anesthetic is discontinued.
High-dose corticosteroid therapy to treat cerebral ischemia and severe closed head injury <sup>64-67</sup>	High-dose corticosteroid therapy was once believed to beneficially affect outcome after closed head injury as a result of its antioxidant and antiedema effects. However, more recent studies have reported a toxic effect of corticosteroids, mediated through both glucose-dependent and direct cytotoxic mechanisms of action. Furthermore, the most authoritative trials of corticosteroids to date proved that they do not beneficially affect neurologic outcome after stroke or closed head injury, yet concomitantly can cause systemic adverse effects.
Antibacterial antibiotics in patients having aspiration pneumonia or severe viral infections <sup>68,69</sup>	Patients who aspirate gastrointestinal contents may experience chemical and/or microbial pneumonitis. Corticosteroids and antibacterial drugs were once given immediately after aspiration to prevent sequelae; however, concerns for superinfections with selected, drug-resistant bacteria and no proven benefit of the corticosteroids have caused practitioners to abandon this practice. In addition, antibiotics have been used in the setting of several viral infections because of concerns of risk of superinfections, but as noted above, drug-resistant infections appear to be of greater concern.
Mild induced hypothermia for cerebral aneurysm clipping <sup>70</sup>	The practice of inducing mild intraoperative hypothermia during surgery for the repair of intracranial aneurysms was routine but was proved to be nonbeneficial by the IHAST trial.

IHAST = Intraoperative Hypothermia for Aneurysm Surgery.

even with the assistance of in-house ethics experts.<sup>48</sup>

The use of clinical ethics consultation has been suggested as a means to help all involved parties identify the most appropriate plan of care. Devising a patient-centered plan of care includes examining financial and economic effect, as well as medical and psychosocial factors. For patients with the worst prognoses, these same ethics teams may work in concert with palliative medicine teams to help patients and their families deal with the inevitability of death and the quality of life during the patient's limited remaining time.<sup>104,105</sup> Using this combined approach, one study estimated that the cost savings after use of ethics consultation in the ICU approximated the cost of staffing such a service.<sup>106</sup> As such, the patient and families benefitted in an environment that was revenue neutral for the hospital, thus attenuating any real or perceived pressure to alter care simply for economic expediency.

When efforts at communication and education fail, secondary resources may be required to provide an alternative perspective on the

case. Such resources may include consultation with a hospital clinical practice committee, the hospital legal counsel, or other colleagues with experience in the area. In rare circumstances, these efforts may be insufficient to rectify insoluble problems. In these situations, the courts have been asked to intervene.

If problems continue to persist, there is often a fundamental misunderstanding of how the stakeholders use words and convey concepts of prognosis and the likelihood of success. Family members and patient surrogates should assist in making medical decisions for patients on the basis of their direct communications with those patients concerning treatments. When unavailable, substituted judgment criteria followed by best interest judgments are used. In a recent study by Combs et al,<sup>49</sup> most physicians agreed that surrogates should decide on treatment measures according to what the patient would have wanted even when perceived as not in the best interest of the patient.

States, such as Texas, have passed laws that outline a due-process approach to situations where futility concerns are invoked. The

TABLE 2. Situations in Which an Intervention Once Thought to Be Futile Is Now Viewed as Beneficial

Scenario	Comments
Induced mild hypothermia for comatose survivors of cardiac arrest <sup>71-75</sup>	Once it was thought that hypothermia would have to occur during the ischemic insult to be protective and that mild-to-moderate hypothermia was inadequate to protect the brain and instead would worsen outcome because of systemic toxic effects. Recent research has now proven the treatment beneficial.
Induced mild hypothermia for newborns who have sustained hypoxic encephalopathy at birth <sup>67,73,76,77</sup>	Same reasons as above.
Prolonged drug therapy to treat HIV/AIDS <sup>78-81</sup>	Early drugs used to treat HIV/AIDS were expensive, plagued with adverse effects, and less effective in altering outcomes, in part because of limitations of the existing drug therapies and poor treatment adherence. However, today with advances in pharmacology and treatment protocols, increasing numbers of patients are being sustained with long-term anti-HIV/AIDS medications.
Intensive care treatment involving mechanical ventilation and drug therapies to sustain and treat preterm infants born at 23-25 weeks' gestation <sup>82-85</sup>	In the earlier days of neonatology, the care of infants who were considerably preterm was less aggressive than today. Concerns at the time were that despite expensive therapies the infants may not survive or would survive but never live independently. With more experience and better therapies, there have been progressive improvements, resulting in functional survival of younger and younger preterm infants.

HIV = human immunodeficiency virus.

process in Texas operationalizes how health care professionals and institutions can seek to discontinue life-sustaining treatments if they are believed to not meet their medical objectives.<sup>107</sup> Some hospitals have established their own “futility” policies for determining whether care is appropriate and whether, under application of laws such as the Texas Advance Directive Act, care should be discontinued.<sup>107</sup> Unfortunately, the concept of unilateral withdrawal of life-sustaining measures of disputed efficacy is almost never morally or ethically justified given several concerns about what defines due process, who actually is defining futility, and the many opportunities for conflicts of interest to creep in.<sup>53,107,108</sup>

One reason that health care institutions need to have a mechanism for approaching futility—whether practice based, ethics based, or legal based—is that when concerns about futility are invoked, they are often accompanied by a sense of moral distress in physicians, nurses, and other caregivers who participate in the provision of the alleged “futile care.”<sup>5,6,109</sup> Such distress may result from professional caregivers having feelings that their immense understanding of the medical issues and their medical judgment are not being appropriately considered. A formal process to have these situations reviewed may provide caregivers a forum to express themselves and an opportunity to lessen such distress.<sup>110</sup> Having a formal

review process may also allow for discussions of the appropriate balance between the therapeutic benefits of a treatment vs its cost—to society and to the individual.<sup>111</sup>

In a commentary accompanying the recent study by Huynh et al<sup>29</sup> regarding costs of potentially futile care in the ICU, Truog and White<sup>39</sup> suggest a framework for addressing possible futile care. They recommended using the term “potentially inappropriate” instead of the word *futile* and looking to fair processes of dispute resolution over unilateral withdrawal of disputed care. In addition, Truog and White suggest that no clear rules exist that clinicians can appeal to that justify the right to outright refuse care (short of brain death). Lastly, Truog and White suggest that clinicians should see “futile” situations as an invitation to intensify communication efforts, rather than outright refusing medical interventions. In the final analysis, there is potential for all parties to benefit from these discussions.

#### QUESTION 9: HOW DOES ONE ADJUDICATE *WITHIN* THE LEGAL SYSTEM WHETHER MEDICAL CARE IS FUTILE AND WHETHER SUCH CARE SHOULD BE CONTINUED OR STOPPED?

If legal interventions are required for resolution of a situation, success (when viewed from the perspective of all parties in aggregate) becomes increasingly less likely because legal

TABLE 3. Situations in Which an Intervention May Likely Change Its Position Regarding Futility

Scenario	Comments
Prolonged extracorporeal membrane oxygenation in a patient who would otherwise die of hypoxia or ischemia (eg, massive pulmonary embolus, pulseless electrical activity after acute coronary artery thrombosis) <sup>17,86,87</sup>	Technology traditionally demanded immense cardiopulmonary bypass machines that were largely restricted to cardiac surgery operating rooms. These machines required much labor, space, and anticoagulants, and the technique was injurious to blood cells, all of which limited their use long-term. New technologies have now made it possible to provide circulation of oxygen-rich blood for prolonged periods outside the operating room until underlying conditions can be treated and the patient returns to endogenous circulation and blood oxygenation.
Prolonged cardiopulmonary resuscitation to treat refractory cardiac arrest <sup>18,19,88,89</sup>	Tradition and experience have established that patients who were not resuscitated quickly after cardiac arrest were doomed to death, either from failure to restart the heart or from brain death in patients in whom the heart was restarted but not quickly enough to maintain adequate cerebral blood flow and oxygen delivery. Recent advances in basic and advanced cardiac life support, better training of life-support providers, the use of capnography to confirm the adequacy of circulation during chest compressions, and better acute coronary care in the hospital offer the possibility of full resuscitation and return to productive life in patients requiring prolonged cardiac resuscitation.
Prolonged mechanical ventilation and other support in patients with otherwise debilitating and life-threatening upper cervical spine or brain lesions <sup>90,91</sup>	Experiences with scientist Stephen Hawking and actor Christopher Reeve have proven that technology can maintain life and useful functionality for some after an otherwise life-threatening insult to the brain and spinal cord. However, these techniques will not gain widespread use and public acceptance until the costs are reduced or new innovations (eg, stem cell therapy, brain to computer to spinal cord interfaces) are used to augment recovery.
High-dose steroids for acute spinal cord injury <sup>64,92,93</sup>	Long viewed as a panacea for a variety of acute neurologic injuries because of theoretically important antioxidant and other properties, high-dose steroids were found to be beneficial in a human trial of spinal cord injury. Despite limitations of the trial (minimal neurologic benefit, insufficient documentation of adverse effects), the therapy once became a mainstay of treatment. However, with reexamination of the flaws within the original trial, further experience with the treatment, and the introduction of better therapies, high-dose steroid therapy may migrate toward the “futile therapy” identifier with time.
Use of multiple, expensive drugs in select types of neoplastic disease in an attempt to induce “cures” <sup>36,94</sup>	Contemporary drug treatments of solid tumor cancers and hematologic malignant tumors have often relied on multiple, highly expensive drugs, given simultaneously or sequentially, in an attempt to promote a cancer cure. However, newer approaches to therapy suggest that limiting spread of or arresting the neoplastic disease, not curing it, may be the more expedient, cost-effective strategy in the long term. As such, patients who have such neoplastic diseases might someday die of other age-related diseases, not cancer.
In utero surgery for congenital abnormalities <sup>95-98</sup>	Once viewed as experimental and potentially futile, in utero surgery is proving feasible and cost-effective to treat conditions such as myelomeningoceles, cardiac defects, aberrations of the urologic system, and other disease states. With time, more experience, and evidence of favorable outcomes and long-term cost savings, these treatments should progressively become more mainstream.

intervention generally suggests that stakeholders support widely disparate approaches. A major reason that futility is difficult to adjudicate from a legal perspective is that the term *futility* is value laden, the definition of *futility* has not been successfully operationalized, and its use is often “fraught with confusion, inconsistency, and controversy” (see [question 1](#)).<sup>5</sup>

Some legal experts have suggested that dispute-resolution tools, such as mediation,

may be the best legal means of resolving futility conflicts.<sup>112</sup> However, the strong power traditionally granted to patient surrogates in health care decisions law has rendered mediation largely ineffective.<sup>112</sup> The often uncompromising perspective of the surrogate is based in part on a mistrust of the health care professionals, their unrealistic expectations of the health system, strong religious beliefs, inability to tolerate the emotional burden of their

decision, and immunity from the “costs” and consequences of their decisions.<sup>112</sup> This sometimes leaves the courts as the remaining neutral party for review. When required to adjudicate, judges typically award only temporary restraining orders or preliminary injunctions to allow time for more extensive review of the conflict among the interested parties.<sup>99</sup> In most cases, the courts are immune from further intervention because the most critically ill patients (often involved in the most contentious futility discussions) are likely to die during this preliminary review period.<sup>99,113</sup> In the small percentage of cases in which courts are required to further rule, their decisions have resulted in both limiting the time during which futile medical care is provided or conversely extending that care.

The concept that physicians should not be required to offer treatments of questionable benefit is generally supported but has been viewed variably in the law.<sup>100,114,115</sup> A Massachusetts Superior Court upheld that clinicians can withhold provision of CPR if it is judged to be futile<sup>116</sup>; however, the courts have ruled in other cases that measures that may be viewed as being of disputed efficacy cannot be stopped unilaterally.<sup>117,118</sup> Although almost all court-instructed injunctions that involve futility disputes place only a temporary hold on halting treatment, the 2009 New Jersey case of *Betancourt v. Trinitas Hospital* offers one example of how a judge’s ruling may extend the course of futile medical treatment indefinitely.<sup>113</sup> In this case, Betancourt was a 73-year-old man with irreversible brain injury. The court ruled in favor of Mr Betancourt’s surrogate and granted a permanent injunction that required the hospital not to suspend treatment.<sup>113</sup> Despite acknowledging that Mr. Betancourt remained in a persistent vegetative state, the judge argued that the court’s role was limited to appointing a guardian and that “the decision to continue or terminate life support systems is not left to the courts.”<sup>99,118</sup>

The ruling in *Betancourt v. Trinitas Hospital* was almost identical to the Minnesota court holding 17 years earlier *In Re Helga M. Wanglie*, a case that involved an elderly patient in a persistent vegetative state who was receiving mechanical ventilatory support. In this case, the hospital sought to have a ventilator removed against the surrogate’s decision.<sup>117</sup> The patient’s husband

and surrogate decision maker, Mr Wanglie, “believed that life should be maintained as long as possible, no matter what the circumstances, and he asserted that his wife shared this belief.”<sup>119</sup> The court sided with Mr Wanglie. This decision comported with the long-standing belief that appropriately appointed surrogates can make decisions that are consistent with the patient’s values, even after the patient is no longer able to make those wishes known at that time.

If Wanglie’s case had occurred in Texas (not Minnesota), where Texas Advance Directive Act legislation exists, mechanical ventilation would likely have been withdrawn because it could not restore the patient to health, which was the goal of the critical care. As Angell<sup>119</sup> states, “the [Minnesota] institution saw the respirator as ‘non-beneficial’ because it would not restore [Wanglie] to consciousness. In the family’s view, however, merely maintaining life was a worthy goal, and the respirator was not only effective toward that end, but essential.”

The court-litigated examples described above involve patients with conditions that are less “legally settled” than persons diagnosed as being brain dead or, perhaps more accurately stated, as being dead by neurologic criteria.<sup>113</sup> The legal standard of care is that once a patient is determined to be dead by neurologic criteria, health care professionals are under no obligation to continue medical treatment. However, this notion has received immense media attention recently, and public comment by both experts (in medicine, ethics, and the law) and nonexperts regarding the unfortunate case of a 13-year-old girl, Jahi McMath, who was determined to be dead by neurologic criteria as a result of massive systemic hemorrhage after a routine tonsillectomy.<sup>120,121</sup> Of note, the legal standard recognized both in this case and prior cases remains unchanged by these recent events. Consequently, we contend that the concept of medical futility as defined earlier in this article applies to patients who are alive and not to cases that involve those declared dead by neurologic criteria or other accepted biological criteria.

A final aspect to consider is the widespread acceptance of surrogates as valid participants in the decision-making process. Patients, their appointed proxies, their families, or legally appointed surrogates have the ability to make decisions on the basis of immediate (or previously exercised) self-determination or a

determination of what is in the best interest of the patient. Angell<sup>119</sup> notes, "Institutions lie outside this hierarchy of decision making and should intervene by going to court only if they believe a decision violates these standards." Disagreements between family members and/or surrogates as to what the patient may want with regard to treatment measures are thankfully rare yet often gain much media attention when they are refereed within the court system.

The events surrounding the case of Terri Schiavo make it perhaps the most widely publicized of all court decisions involving a dispute solely among family members (and not conflict between her physicians and her surrogate).<sup>48</sup> Even today, some still raise questions of whether Schiavo's feeding tube should have been discontinued and who was the appropriate surrogate to make this decision. Florida state statute is clear that in the absence of a duly-appointed health care proxy, a spouse is the highest in order of preferred surrogate decision makers. This was not the issue under contention; instead, the debated issue was whether Schiavo's spouse was indeed making decisions that were consistent with her beliefs and in accordance with her best interests.<sup>48</sup>

As discussed in earlier articles by 2 of us,<sup>100,122</sup> as well as others,<sup>114,115</sup> one of the more recent examples of physician and surrogate dispute involves the 2011 case of Albert Barnes. Mr Barnes had deteriorating health for a number of years, during which time his wife, acting as his supposed health care agent, requested 78 emergency transfers and 10 separate hospital admissions (8 within the year immediately preceding the court's decision) to Twin Cities hospitals in Minnesota.<sup>114</sup> During the court proceedings, it became apparent that Mrs Barnes had altered her husband's original advance directive documents, which confirmed that he would not have wished the treatments she was demanding of the health care professionals.<sup>100,113,114,122</sup> The courts decided that a state-appointed guardian would make further health care decisions once it was determined that Mrs Barnes had falsified her husband's advance directive. Although Mr Barnes died in the interim before this being necessary, this case still serves as an important example of how the legal system can help to terminate futile treatment when surrogates fail to represent a patient's wishes.

#### QUESTION 10: HOW DOES ONE PREVENT MEDICAL FUTILITY?

As presented throughout our article, the concept of medical futility remains a challenge to define by objective measures, and thus conflicts may be difficult to prevent. Nevertheless, we present some practical considerations regarding how to approach situations that may be viewed as futile.

First, we believe it is important to encourage medical care that is given on the basis of evidence from the best available medical research. This foundational medical research, in turn, has the best promise of helping prevent futility if it addresses challenging questions, uses sound methods, and reaches sound conclusions. Furthermore, the findings must be widely embraced by clinicians who will not only incorporate the research findings into their practices but also eagerly share with patients and their families that they are doing so.

Second, although practicing evidence-based medicine is a standard to which many clinicians aspire, it is unlikely that scientific evidence alone will guide clinicians to act prudently in all clinical situations.<sup>123</sup> Best evidence can lead to the development of standards of practice, but there must be room for exigencies and individual patient variability within such a system. Avoiding dogmatic and legalistic approaches to clinical problems, many of which come with arbitrary cutoffs for treatment (eg, hemodialysis on the basis of age or comorbidities), may help in approaching challenges that may be viewed as futile but in essence may not be.

Third, we hope that each of these approaches will lead to improved communication by clinicians with patients and their loved ones. Although clinicians and patients struggle with accurate prognostication and uncertainty regarding individual cases, it has been found that most ethics consultations result from sub-optimal communication regarding end-of-life care or advance treatment preferences.<sup>101</sup> In addition to clinician education, programs that support the lay public in meaningfully engaging their clinicians and how to communicate their health care preferences to their loved ones may be useful steps.<sup>124-128</sup> Beyond the best evidence, creating more effective communication tools, appropriately engaging in goal setting, and reestablishing the clinicians' role

in making recommendations over simply asking what the patient wants are all ways of maximizing shared decision making to optimize outcomes and to avoid situations that could be considered futile.<sup>129</sup>

Recently published research of the importance of effective, constant, and updated communication among the patient, family, surrogate, and physician is contained in the report by Jesus et al<sup>50</sup>; the report found that, although patients may have made earlier *general* decisions to forgo CPR efforts through do not resuscitate and do not intubate orders on record, these same patients often want CPR and/or tracheal intubation when provided with *specific* clinical scenarios.<sup>50</sup> An anecdote previously reported by one of us (W.L.L.) of a patient being evaluated in an emergency department reinforces this view. A patient who had received treatment for lung cancer but later had chest radiographic evidence of a possible return of disease had clearly stated and documented in his hospital record that he did not desire heroic end-of-life interventions. However, when he was admitted to the hospital with a leaking abdominal aortic aneurysm and new-onset myocardial ischemia (likely in response to blood loss and pain) and was informed by surgeons that he would almost certainly die within the next few hours without aortic surgery, the still-lucid patient reversed his long-held views. When questioned as to why, he stated, "Doctor, regarding my choices, everything that has happened to this point has been theory; this is the real thing."<sup>124</sup>

Jesus et al<sup>50</sup> emphasized that more work is required to determine the reasoning underlying these discrepancies and changes of views; however, in the interim, the fact that such alterations, of course, exist again emphasizes the need for ongoing communication about patient desires for end-of-life care. Although advance care planning has been criticized for not being flexible when needed and for being unable to anticipate future events and preferences, completion of an advance care document begins a dialogue that can likely facilitate further exploration.<sup>128,130-134</sup>

Although due-process protocols, as encouraged by the Texas Advance Directive Act and related laws in Texas, suggest that futility can be prevented by allowing clinicians to object to providing futile care, a major concern

remains in that individual human dignity may be violated. Previously, Angell<sup>119</sup> noted that "we as a society would be on the slipperiest of slopes if we permitted ourselves to withdraw life support from a patient simply because it would save money."

Previous policies that have targeted vulnerable populations have had repercussions that extend beyond the given populations. Indeed, some ill elderly patients in the Netherlands would not seek medical care when needed because of fear of the downstream effects of euthanasia laws; namely, the patients feared that physicians would ignore the restrictions placed within the law and instead begin unilaterally instituting patient euthanasia, independent of the prescribed checks and balances. As such, medical care was affected more than expected because patients feared that society's and physicians' actions might conflict with the patients' values.<sup>135</sup>

There is always opportunity to strive toward improved communication and to provide patients and their loved ones with accurate prognostic information and honest opinions regarding the potential efficacy of a treatment. Although there is no certainty regarding prognostication, opinions in the American Medical Association Code of Ethics (opinion 2.037)<sup>136</sup> and elsewhere<sup>137</sup> encourage clinicians to explore patients' goals of care to the best of our ability. Although such opinions are unlikely to fix the problem of "futility," they may be more likely to help clinicians obtain a frame of reference and a starting point in these difficult situations.

## CONCLUSION

Futility has been defined by many individuals and groups, and those definitions reflect the variable focuses of the authors. We have examined futility as excessive (in terms of effort and finances) medical intervention with little prospect of altering a patient's ultimate clinical outcome. The term is operationally defined, yet, even then, it is often challenging to determine whether a treatment is truly futile or not. Patients' goals, values, and preferences may vary, and the efficacy of a given treatment may be difficult to predict. As medical science advances, there is an ever-increasing arsenal of drugs and technologies available, and there often is an imperative to use such treatments even in the absence of expected efficacy.

Open and honest communication with patients and their families about treatment efficacy, expectations regarding outcomes, and other related considerations may help limit some futile treatments. Although ethical or legal concerns are commonly viewed as contributors to disputes about futility, in actual practice, the most common reason *futility* is invoked is when there is a fundamental difference in how information is communicated among health care professionals, patients, and surrogates. We encourage health care professionals to be cognizant of the language, particularly when conveying uncertainty and complex information to a patient or family members. Setting realistic expectations, while using language and concepts that ensure understanding by patients and families, is encouraged. Despite the best efforts by health care professionals, families, and patients, there will always be the possibility of cases that stretch the status quo and accepted definitions. Although there may be no easy answers or right or wrong in these challenges, they afford health care professionals the opportunity to explore and discuss the issues in an effort to improve the quality, affordability, and humanity of clinical decisions.

**Abbreviations and Acronyms:** APACHE = Acute Physiology and Chronic Health Evaluation; CPR = cardiopulmonary resuscitation; ICU = intensive care unit; LVAD = left ventricular assist device

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