

CREATING A MEDICAL FUTILITY POLICY

Physicians at a Honolulu Hospital Describe the Experience

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The following is a hypothetical case of medical futility:

Mr. Clayton Chong, a healthy, active, married 63-year-old man with two adult daughters, undergoes percutaneous transluminal coronary angioplasty. Suddenly, the monitors blare—Mr. Chong's heart has stopped during the procedure. As emergency staff rush into the room, the doctor repeatedly shocks the patient's heart and pounds on his chest. Mr. Chong is quickly wheeled into the operating room so that the torn coronary vessel can be repaired and the blood flow restored to his body.

Following heroic efforts to save his life, Mr. Chong is comatose with nonspecific responses to pain. His family is distraught. Over the next few days, the patient progresses into oliguric renal failure with a need for hemodialysis. His neurologic status remains unchanged and his prognosis for recovery is considered very poor. However,

after discussing long-term treatment and code status, his family opts for continuing aggressive treatment in the ICU.

One week later, Mr. Chong remains comatose, his life sustained by mechanical ventilation and dialysis. A neurologist confirms the bleak prognosis for a return to a conscious state. The patient's family, however, insists on maximal therapy. "Dad's a fighter," they say. "We can't give up on him. Do everything." So Mr. Chong remains in a deep coma in the ICU, hooked up to various life-sustaining machines and tubes until he dies two and a half months later. During this time, he develops sepsis, a GI bleed requiring blood transfusion, fluid overload, and seizures. He never regains consciousness. The total cost of his hospitalization is more than \$500,000.

BACKGROUND: MEDICAL FUTILITY

In the 5th century BC, Hippocrates cautioned that doctors should strive "to do away with the sufferings of the sick, to lessen the violence of their diseases, and to refuse to treat those who are overmastered by their diseases, realizing that in such cases medicine is powerless."¹ In the last half-century, advances in medical technology have greatly expanded the range of life-sustaining treatments. And with the rise of information technology, patients and their families are now more aware of, although not necessarily more informed about, these treatment options. Add to these factors society's focus on the individual's overriding right to self-determination. Little wonder, then, that medicine's traditional paternalism has come under attack.² Laws have been enacted on issues such as informed consent and advance directives that uphold the autonomy of the patient, including his or her right to refuse a medical intervention regardless of the physician's opinion.³



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The medical futility debate, however, centers on a different question: whether patients also have a right to insist, against the judgment and advice of their treating physicians, on medical treatment that is likely to be ineffective.

But what is "medical futility"? The largest stumbling block to gaining a national consensus is in defining the term.⁴ In 1999 the American Medical Association (AMA) and its

Council on Ethical and Judicial Affairs (CEJA) published a report that emphasized a fair process for disputes over continuing treatment in medically futile situations.⁵ By doing so, the AMA sidestepped all current definitions of medical futility and, instead, emphasized a process-oriented approach to conflict resolution.

MEDICAL FUTILITY AT SFMC

St. Francis Medical Center (SFMC) is a 220-bed, tertiary, Catholic hospital located in urban Honolulu. It provides ethical and compassionate health care and supports an active hospital ethics committee that offers consultation services. Because it is the center for kidney and liver transplantation in Hawaii, SFMC has an active intensive care unit (ICU) with a team of full-time critical care specialists who serve a large population of patients with end-stage renal disease. Physicians commonly encounter futility issues in this practice setting; roughly two-thirds of all requests for ethics consultation at SFMC have involved the forgoing of treatment because of medical futility.

Members of the SFMC Ethics Committee, confronted by this recurrent issue, recently formed an ad hoc group—the Medical Futility Committee—with the purpose of developing a hospital policy on the subject. The latter committee was composed of physicians, nurses, lawyers, administrative staff, clergy, and medical students.

THE PROCESS OF DEVELOPING THE POLICY

The committee began with a review of the pertinent medical and ethics literature on medical futility, with articles obtained from personal files and MEDLINE* searches. We also obtained futility policies from a number of medical centers around the country.⁶

The futility committee met in the spring of

Do patients have a right to medical treatment that is likely to be ineffective?

2001. We set a schedule of one-hour bi-weekly meetings to encourage efficiency and to build momentum. Committee members studied the literature and relevant policies from other hospitals before gathering for the first meeting.

At that meeting, we asked ourselves whether a futility policy was even a good idea. Would such a policy be used, or would it merely sit on a shelf some-

where? Would there be any enforcement of the policy? Was there a danger of abuse of patients' rights? Would the hospital be placing itself at legal risk? There were partial answers, pro and con, and spirited debate over the merit and lack of merit in formulating such a policy. Ultimately, we concluded that the benefits would outnumber the disadvantages (for the discussion, see pp. 16-19).

Over the next several weeks, the committee developed a working draft document. The draft was written in table format with two vertical columns. On the left, we entered the policy language itself in outline form; on the right, we placed editorial notes corresponding to each line of policy text. The editorial comments highlighted important issues for discussion and debate; each referred to the source from which materials had been taken. Using the editorial comments, committee members reviewing the draft document could immediately see the sources for the item and the rationale behind its inclusion.

Committee members found the working draft document an effective tool to use in working toward the final construction of the policy. With it, they could immediately register their opinions, agreements, and disagreements. After first reading through the document in its entirety, the committee discussed the policy's key features, which resulted in line-by-line editing of the draft document. This process was repeated three times over the next six weeks. During the revisions, we incorporated relevant portions of Hawaii's Uniform Health-Care Decisions Act⁷ to ensure that the policy was consistent with state law. We then removed the editorial comments, leaving the

* MEDLINE/PubMed, a free medical literature search engine sponsored by the National Library of Medicine, can be found at www.ncbi.nlm.nih.gov/entrez/queri.fcgi.

policy to stand on its own, ready for general staff input.

We sought feedback on the policy at an ethics conference attended by some 60 physicians, nurses, and other hospital staff members. The policy was met with strong support and required only minimal revisions. It was then presented to and approved by various hospital committees and departments, including the Critical Care Committee, the Nursing Planning Committee, and the Departments of Medicine and Surgery. Final approvals came from the Medical Staff Executive Board, October 19, and SFMC's board of directors, November 28, 2001.

KEY ASPECTS OF FUTILITY POLICY

The committee deliberated over six key questions concerning the establishment of a futility policy.

Is a Policy Needed? The first issue was whether to have a hospital futility policy. The benefits are many. To begin with, a medical futility policy would support and validate the professional ethics of physicians and other health care professionals. Bedside providers would feel comfortable about forgoing nonbeneficial treatments instead of being frustrated and demoralized as they followed a course of ineffective treatment "prescribed by the family." Next, a medical futility policy would provide support and guidance for physicians in difficult decision-making situations. The policy would lay down the steps of shared decision making and conflict resolution. From a legal standpoint, such a policy would constitute an institutional consensus of a professional standard, which might amount to evidence of a community standard of care. This would protect the

St. Francis's Medical Futility Policy

FUTILE TREATMENTS

Policy No. LPAT0185

I. Purpose

- A. To assist health-care providers in decision-making regarding medically futile treatments.
- B. To affirm the moral and ethical appropriateness of forgoing medically futile treatments.
- C. To ensure that the decision to forgo treatment focuses on respect of the patient and on the minimization of suffering and indignity.
- D. To provide institutional guidelines that ensures a fair process at resolving conflict over medically futile treatment.

II. Policy

- A. It is the policy of St. Francis Medical Center that patients have the right to accept or refuse interventions once the requirements of informed consent are met. At the same time, health-care providers are not required to offer an intervention, and may refuse a request for same, if the intervention is medically ineffective or contrary to generally accepted health-care standards.
- B. Should a conflict arise between the primary physician, other health-care providers, and the patient or his/her agent, legal guardian, or surrogate (hereafter referred to as authorized decision-maker) on the decision to forgo medically futile treatments, the procedural steps set forth in this document may be implemented by any of the involved parties.
- C. If all procedural steps are followed, and it is determined that a treatment is medically futile, the physician should be encouraged and supported in the transition to palliative care.

III. Definitions

- A. Medically futile treatment: Any course of treatment that confers no beneficial outcome or is medically ineffective and contrary to generally accepted health-care standards may be considered medically futile. For example, performing CPR on a patient with widely metastatic, end-stage cancer could be a medically futile course of treatment. Declaration of a treatment as medically futile should initially be left to the patient's primary physician, recognizing the uniqueness of patients and diseases and weighing the physiologic basis for the treatment, relevant medical literature, opinions of consultants, clinical experience, patient's wishes, and patient's determinations of quality of life. Resource consumption, inability to pay, or rationing are not legitimate criteria to be used in defining medical futility.
- B. Palliative care: Care with the intent to relieve suffering and provide for the patient's comfort and dignity. It may include analgesics, narcotics, tranquilizers, nursing care, and other treatments including psychological and spiritual counseling. Palliative care is never futile.

IV. Procedure

- A. When a primary physician considers a current or requested course of treatment to be medically futile, the physician should inform the patient or authorized decision-maker of the following:
 1. The nature of the ailment, the prognosis, the reasons why the intervention is medically futile, the options including palliative care and hospice. This should include a discussion of the goal of care.
 2. The assistance of a third party, such as a nurse, social worker, chaplain, or informed relative, may be sought to facilitate the patient's or authorized decision-

medical center and its physicians in the event of litigation, since a pre-existing policy governing when treatment can be forgone might be looked upon more favorably by the courts than an arbitrary individual decision.⁸

On the other hand, there are definite risks to having a futility policy. First, it might place the medical center at risk for litigation. In the early 1990s, in cases ranging from *Helga Wanglie* to *Baby K*, courts generally ruled against the medical center's application to restrict medical treatment when it was against the family's wishes.⁹ However, *Gilgunn v. MGH*, decided in 1995, was a notable exception. In *Gilgunn*, the physicians wrote a unilateral do-not-resuscitate order against the wishes of the patient's daughter—but with the support of the ethics consultant.¹⁰ To be sure, should the medical center go to court over its policy, there is

the risk of negative publicity, with the expected allegation that the institution was enacting a policy to restrict treatment to cause premature death. Then there is the risk that a futility policy would take decision making out of the hands of physicians and create barriers between physicians, patients, and other parties, including the Ethics Committee. A policy without teeth would be ineffective. On the other hand, a policy that is too physician-centered carries the risk of abuse and minimization of patients' rights.¹¹ The futility policy then becomes a disguised vehicle for a return to paternalism. Finally, having a policy in writing means that practitioners are obligated to abide by its terms and must adhere to the proper steps and safeguards. Violating one's own institutional policies would not constitute a good defense in the event of litigation.

maker's understanding and acceptance of the physician's explanation.

3. Forgoing medically futile treatment does not constitute abandonment; rather it reinforces the commitment to continue the provision of palliative care.
- B. The primary physician should document in the patient's chart that the intervention under consideration is inappropriate and a discussion with the patient or authorized decision-maker has occurred.
- C. Exceptional reasons may exist for providing futile treatment for short periods of time in order to provide special accommodations to the family.
- D. Other health-care providers (e.g., nurses, consultant physicians, etc.), who in their clinical judgment believe a treatment to be medically futile, may directly refer the case to the hospital Ethics Committee. These health-care providers should discuss their assessment directly with the primary physician prior to referral.
- E. Conflict resolution.
 1. Communication: Every effort should be made to resolve conflicts about providing futile therapy through respectful discussion among the parties involved in the dispute.
 2. Second opinion: If, after reasonable effort, agreement is not reached between the primary physician and the patient or authorized decision-maker regarding medically futile treatment(s), the primary physician is encouraged to obtain an independent medical opinion. This second medical opinion should be from a physician who has personally examined the patient and signed a note documenting his/her findings in the chart.
 3. Hospital Ethics Committee: If disagreement about the provision of futile treatment continues, the case

should be referred to the hospital Ethics Committee for review.

- a. If the committee's decision coincides with the patient's desires but the physician remains unpersuaded, arrangement will be made for transfer to another physician within the institution.
- b. If the committee's decision coincides with the physician's judgment but the patient remains unpersuaded, arrangements for transfer to another institution may be sought. The accepting institution and physicians should be comfortable honoring the patient's or authorized decision-maker's wishes.
- c. If transfer is not possible because no physician and no institution can be found to follow the patient's or authorized decision-maker's wishes, the intervention in question need not be provided. The primary physician should inform the patient or authorized decision-maker of their right to petition the appropriate court based on Hawaii statute §327E14.

[§327E-14]. Judicial relief

On petition of a patient, the patient's agent, guardian, or surrogate, or a health-care provider or institution involved with the patient's care, any court of competent jurisdiction may enjoin or direct a health-care decision or order other equitable relief. A proceeding under this section shall be governed by part 3 of article V of chapter 560. [L199, c 169, pt of § 1]

In our committee meetings, the risks and benefits of creating a policy generated much debate. On the whole, the committee felt it could craft a policy with procedural and substantive safeguards that would minimize the drawbacks without losing the benefits.

Should the Policy Be Borrowed or Original? Another issue was whether SFMC should create a policy of its own or adopt one from another institution. We examined various policies, including those of Santa Monica Hospital Medical Center in southern California; Parkland Memorial Hospital, Dallas; and Johns Hopkins Hospital, Baltimore.¹² These policies were written in the early 1990s and had much to recommend them. However, some dealt with the broader issue of life-sustaining treatment and others lacked clear mechanisms for effective conflict resolution. We also reviewed a multi-institutional policy developed in Houston; one created by the Mercy Health System, Conshohocken, PA; and one devised by Children's Hospital and Regional Medical Center, Seattle.¹³ These offered clear procedures for conflict resolution, with the final resolution resting with either a medical director or an institutional interdisciplinary review board.

After examining these policies, the committee decided to pursue drafting a policy that would be uniquely SFMC's. This did not mean creating everything *de novo*. Our policy would be a composite that included many aspects of the institutional policies mentioned above. We also adopted those features of the AMA-CEJA guidelines that described a fair process for resolving futility disputes.¹⁴ And we wrote into our policy language that complied with the legal requirements of our state's governing law on life-sustaining treatment.

What Is Medical Futility? There is no unanimity in the ethics literature on the definition of medical futility. Although various writers have proposed specific definitions,¹⁵ the AMA has avoided defining "futility" altogether. Our committee took the position that too restrictive a definition would require an expert panel to determine the term's meaning, sacrifice flexibility, be open to criticism of the criteria, and be problematic to enforce. We therefore sought guidance from Hawaii's Uniform Health-Care Decisions Act and adopted its definition as "any course of treatment that confers no beneficial outcome or is medically ineffective and contrary to generally accepted health-care standards."¹⁶ Hawaii's actual statutory language provides that "a health-care provider or institution may decline to comply with an individual instruction or health-care decision that requires medically ineffective health care or health care contrary to generally accepted health-care standards." As formatted, our general definition of medical futility is practical,

nonrestrictive, and legally defensible.

We also chose the words "medically futile treatment" rather than "futile care" to emphasize that caring for the patient would in no way be compromised by forgoing the treatment in question. We retained the term "futile"—rather than "nonbeneficial" or "ineffective"—because of its widespread use in the clinical and ethics literature.

Our policy accords the attending physician the authority to declare a treatment to be medically futile and the responsibility for doing so. However, the policy offers a listing of several factors to guide the physician. These include recognizing the uniqueness of the patient, considering the opinions of consultants while valuing one's own clinical experiences and judgments, and respecting the patient's statements or beliefs regarding quality of life. The policy therefore explicitly acknowledges that each case should be viewed individually and holistically.

How Should the Approach Be Structured? By adopting a general definition, the committee was able to focus on a process-based approach in resolving disputes. We followed the general format of the AMA-CEJA guidelines, which strongly encourage open communication between parties and emphasize that forgoing medically futile treatment does not constitute abandonment of the patient. Our policy promotes open discussion among physicians, staff, patients, and family members. It describes the contingencies and procedural aspects involved and recommends obtaining a second opinion from a consulting physician and/or the medical center's ethics committee. Such a review process allows the attending physician the benefit of a separate judgment. Lay input from the ethics committee (which has several nonmedical representatives) confers additional safeguards, as many of the decisions may involve value judgments.¹⁷

Can a Decision to Forgo Treatment Be Unilateral? SFMC's policy does state that, in the event family members refuse to go along with the professional opinions regarding forgoing futile treatment, the attending physician may unilaterally discontinue the treatment that has been determined to be futile. In other words, consent to stop treatment is unnecessary. This is of course a decision of last resort, but its inclusion upholds the professional ethics of physicians. If it did not, the profession would be held hostage to an untenable treatment situation that confers no benefit upon the patient and causes disproportionate harm. This situation is unlikely to occur often. If the attending physician finds a treatment to be medically futile and all procedural steps (including attempts to transfer the patient) have been followed, then it is the physician's ethi-

cal obligation to cease treatment. This approach is consonant with the AMA-CEJA recommendations. However, the family is given a final opportunity to appeal the decision to the courts as provided by Hawaii law (Section 327E-14E).

Is Rationing a Factor in Futility Policy?

Some authors have argued that resource allocation and distributive justice are important reasons for creating policies on medical futility.¹⁸ The Houston policy includes "just allocation and good stewardship of medical resources"¹⁹ in its rationale for limiting medically futile treatments. Our policy, however, states that "Resource consumption, inability to pay, or rationing are not legitimate criteria to be used in defining medical futility." We agree with those writers who maintain that the just-distribution-of-scarce-resources issue belongs in a debate on rationing, and that rationing should not factor into the judgment whether a treatment course is medically futile.²⁰

THE ETHICAL AND RELIGIOUS DIRECTIVES

Both the process undertaken to establish our medical futility policy and the policy itself were supported and approved by Bishop Francis DiLorenzo of Honolulu. The policy (see **Box**, p. 16) is consistent with the moral underpinnings established in the *Ethical and Religious Directives for Catholic Health Care Services*.²¹

The introduction to Part Five of the *Directives* states in part that "we have a duty to preserve our life and to use it for the glory of God, but the duty to preserve life is not absolute, for we may reject life-prolonging procedures that are insufficiently beneficial or excessively burdensome." Directives 56 and 57 address the issue of proportionate treatment, which is at the heart of the futility debate. Directive 56 says, "A person has a moral obligation to use ordinary or proportionate means of preserving his or her life. Proportionate means are those that in the judgment of the patient offer a reasonable hope of benefit and do not entail an excessive burden or impose excessive expense on the family or the community." Additionally, Directive 57 speaks of forgoing "extraordinary or disproportionate means of preserving life. Disproportionate means are those that in the patient's judgment do not offer a reasonable hope of benefit or entail an

The issue of proportionate treatment is at the heart of the debate.

excessive burden."

Our policy recognizes that patients have a fundamental right to make an informed decision regarding the acceptance or refusal of medical treatment. It says categorically that when a current or requested course of treatment is deemed medically futile, the physician has the duty to inform the patient or the authorized decision maker about the nature of the ailment, the

prognosis, the reason why the intervention is medically futile, and the remaining options available, including palliative care and hospice. This requirement is in keeping with Directive 61, which states that "patients should be kept as free from pain as possible so that they may die comfortably and with dignity, and in the place where they wish to die." We expect that, in the vast majority of cases, patients and their families will go along with their doctor's assessment. In other cases, our approach, inspired by our hospital's department of pastoral care, is to persuade the family to pray for "the gift of acceptance." It is only in the most difficult case that we will decide to stop treatment despite a lack of agreement on the part of the patient and family. All of this is entirely consonant with the recent reminder of Fr. Kevin D. O'Rourke, OP, JCD, that "a good Catholic doctor speaks openly about death and dying with his or her patients, is frank about the limits of medical care, works hard to prolong life and never deliberately takes life, but recognizes that there are times when treatments should be withheld or withdrawn."²²

A GROWING NEED

We expect that other hospitals, both in Hawaii and elsewhere, will study our policy and perhaps improve on it. As the nation's population ages and its medical technology continues to advance, hospitals will increasingly recognize the need to formulate an effective and ethical position on the issue of medical futility. An article from Toronto exemplifies this trend.²³

SFMC's policy encourages physicians to initiate discussion on goals of treatment from the patient's perspective.²⁴ By so doing, physicians can build trust and provide information about the reasonable probabilities of an intervention to achieve the stated goals of treatment. Explana-

tions regarding palliative care and hospice are an integral part of the discussion. These conversations should be initiated before dire situations arise, thereby making greater reflection and unrushed judgments possible. □

SFMC's Medical Futility Committee was composed by Fr. Marc Alexander; Andrea Kofalvi, RN; Jennie Gamage, RN; Jim Pietsch, JD; Lewis Low, MD; Linda Markt, RN; Alan Stein, MD; and Jan Miyamoto. S. Y. Tan, MD, JD, chaired the committee. The committee thanks Howard Brody, MD, PhD, for his review of the policy.

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