
The Houston Process-Based Approach To Medical Futility

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The concept of medical futility has emerged as one of the dominant topics in the discussion of appropriate end-of-life care. While many agree that health care professionals have no obligation to provide futile treatment, little agreement exists as to the definition of "futile." An alternative to a substantive definition of futility is a procedural approach of determining futility on a case-by-case basis. The authors report on the development and implementation of a process-based approach to this difficult problem that was developed by a multi-institution collaboration in Houston, Texas.

Appropriate medical treatment at the end of life has become an important bioethics topic in both the professional and lay press over the past two decades. Moreover, our understanding of the various facets of this complex subject continues to expand. The acceptance that end-of-life decision making is dependent on individual values and the emphasis on advance directives and durable powers of attorney were responses in the 1970s and 1980s to the problem of perceived physician-driven overtreatment, as evidenced by cases ranging from Quinlan to Cruzan. More recently, however, there exists a growing consensus that demands for overtreatment can come, not only from the health care team, but also from patients and surrogates.

The claim that the health care profession has no duty to provide futile or inappropriate treatment has emerged as a response to this problem of perceived patient-driven overtreatment. In the past eight years, many professional organizations, numerous ethicists, lawyers, and policy makers have contributed to the ongoing debate; what began as a theoretical concept was transformed by the editor of *JAMA* into a call for nearly all hospitals to develop operational futility policies.

However, any hospital or group of hospitals

that desired to create an operational futility policy was confronted by the dilemma of defining "futility." While many agree that physicians have no obligation to provide futile or inappropriate treatment, there was little agreement regarding the definition of "futile" or "inappropriate." Many substantive futility definitions emerged in the literature, each of which was supported by some major groups and rejected by others. We have previously categorized the various conceptions of futility and proposed criteria to operationalize any futility definition or policy (Brody and Halevy 1995). The criteria include preciseness, prospectiveness, social acceptability, and sufficient numbers. We concluded, with supporting data on the low incidence of futility under various operational models that we published elsewhere (Halevy et al. 1996; Sachdeva et al. 1996), that none of the substantive definitions were workable for operational policies.

However, we continued to see difficult cases in our affiliated teaching hospitals, and colleagues at other hospitals around Houston continued to report that they were faced with patient or surrogate-based demands for futile or inappropriate treatment. Such cases included a newborn with multiple congenital abnormalities who underwent sequential amputation of three limbs in an attempt to "do everything" as demanded by the parents.

Another case involved a public hospital serving an indigent community of several hundred thousand. A ventilator-dependent patient in a persistent vegetative state was kept alive in one of sixteen, fully occupied, MICU beds, while several newly admitted ventilator patients were kept in the emergency department; the daughter insisted on full support in anticipation of a miracle.

Many hospitals in the Houston area wanted futility policies to deal with such cases but were intimidated by the confusing array of essentially unworkable definitions and the legal uncertainties of creating a policy mechanism to deal with the problem of patient-driven overtreatment. In response, in the fall of 1993 we convened an ad hoc group representing most of the major hospitals in Houston.

The task force quickly abandoned hope of creating a workable, substantive definition of futility. Instead, the group reaffirmed the clinical reality that patients and disease processes are unique and that individual review would be necessary to determine appropriateness in a particular case. We concluded that while we could not substantively define futility given the clinical complexities and subtleties of individual patients, health care professionals can recognize clinical situations in which application of a particular intervention would be inappropriate or futile. In other words, we cannot define it but we know it when we see it. This approach to value-laden, context-dependent questions was first espoused in the original pornography debates in the 1960s and more recently in a number of other situations (Gewirtz 1996).

The Houston Policy

Three points that guided the Houston task force emerged during the first few meetings:

- Rather than relying on a substantive definition of futility, the policy should rely on a procedural approach that recognizes the importance of thorough institutional review of each case.

- The policy should be based on open and fair processes that reflect the values and needs of the community.
- The policy should be clearly grounded on an ethical principle—professional integrity—as a balance to patient autonomy.

A more thorough discussion of the task force's activities is found elsewhere (Halevy and Brody 1996).

In early 1995, the task force produced guidelines for institutional policies on the determination of medical futility (see appendix 1). The recommended approach is a multistep, process-based policy, triggered by the attending physician, which allows for individual review of a case. In its initial steps, the process requires full disclosure and discussion with the patient or surrogate and provides the option of intra- or inter-institutional transfer to another physician who does not believe that the requested intervention is futile. If no resolution has been reached, the process creates a binding decisional process that would review the case.

The Houston approach offers three major advantages when compared with other efforts to create operational futility policies. The first advantage is that it is a procedural policy. By creating a process that safeguards the interests of all the parties involved in the dispute, rather than by attempting to define futility, the Houston approach requires review of each case, which allows for consideration of the subtleties and nuances that are the hallmarks of caring for actual patients.

The second advantage of the Houston approach is that it grew out of a fair and open process of determining futility based on the values and opinions of the community as reflected by a diverse group of institutions and individuals, rather than a more limited viewpoint reflecting one hospital or one particular professional group. Participating institutions included teaching and nonteaching hospitals, not-for-profit and for-profit hospitals, public and private hospitals, and religious-order and secular hospitals. In all,

institutions accounting for a majority of the greater Houston hospital bed capacity participated. Participating individuals included physicians, nurses, social workers, attorneys, chaplains, administrators, and ethicists. Public comment was solicited in a 1994 public conference on futility hosted by the Houston Bioethics Network, which drew over 150 individuals. In addition, each of the participating institutions reviewed the proposed guidelines internally in various committees and their respective boards of trustees. While no document or process can satisfy every need or desire of every individual, by consciously striving to include many different voices, the resultant process can be argued credibly to reflect community values.

The consideration of diverse views resulted in a process of determining futility that is fair and open and allows the Houston process to avoid four problems encountered by some policies:

- nonparticipation by the patient/surrogate
- unilateral physician action
- ignoring patient transfer options
- the potential for patient abandonment

The Houston policy requires that patients or their surrogates be included throughout the entire process. The first three steps require the attending physician to explain the various options and to involve the patient or surrogate in the decision-making process. The patient or surrogate is encouraged to be present at the institutional review to express his or her views and reasons for the requested intervention. In addition, the institutional review cannot occur for at least seventy-two hours after the official notification of the patient or surrogate to allow for adequate preparation time.

As opposed to some suggested policies, the Houston policy insists that physicians may not act unilaterally. Any disagreement over treatment that cannot be resolved by discussions, including the use of institutional resources such as social workers or chaplains, must be referred to an interdisciplinary review mechanism within the institution.

Moreover, the responsible physician is required to obtain a second opinion and provide the review body with pertinent clinical and scientific information. Finally, no binding determination of medical inappropriateness can be made without concurrence of the institutional review body.

The Houston policy also clearly preserves the patient's right to be transferred. The second step of the process requires the responsible physician to discuss the option of patient transfer to another physician within the institution or to another institution. If the interdisciplinary review affirms that the intervention is inappropriate or futile, the policy bans only intra-institutional transfers to another physician to obtain the futile intervention.

Finally, the Houston policy prevents patient abandonment by either the physician or the institution. An institutional determination that a particular intervention is inappropriate in any particular case results only in the withdrawing or withholding of that intervention; all other interventions that are appropriate for the care of the patient are continued or initiated. Continuing appropriate care is so important that the policy requires that a plan of care emphasizing comfort measures and the preservation of patient dignity be established prior to withholding or withdrawing any intervention determined to be inappropriate.

The final major advantage of the Houston policy is that it is firmly grounded on an accepted ethical principle, that of professional integrity. An overview of the concept is developed in the preamble to the policy. Essentially, we believe that health care professionals and health care institutions have values and principles, much as patients and families do. The value of patient autonomy grounds a prohibition on health caregivers from forcing unwanted treatments on patients. The value of integrity grounds a prohibition on patients and families from forcing providers and institutions to provide treatments they judge inappropriate.

The concept of integrity developed in the

guidelines includes several aspects. The first of these is that there is institutional, as well as individual, professional integrity. Care of actual patients is not accomplished solely by the physician; rather it involves the dedicated efforts of many health care professionals and the support of significant institutional resources. The policy requires both the responsible physician who initiates the review process and the institution to consider whether provision of the disputed intervention would be compatible with the maintenance of their own professional and institutional integrity.

The ultimate question is not whether a futility policy is value free, but whether it is based on defensible values.

The policy also addresses reasons that an intervention might violate integrity. The physician and institution must determine if the requested intervention harms the patient without a compensating benefit, provides unseemly care (for example, the case of the newborn with multiple amputations), or whether the demanded intervention represents a poor stewardship of community resources (the case of the vegetative patient in the full ICU).

The linkage between integrity and stewardship is the third important aspect of the policy's concept of integrity. While the principle of just distribution of limited resources has been advocated by some as an appropriate basis of futility policies, others have rejected such a defense as confusing rationing with futility (Jecker and Schneiderman 1992). We agree that justice and resource allocation alone cannot sustain a futility policy because many cases have nothing to do with resources. However, our policy maintains that responsible stewardship of resources is a professional duty of physicians and thus can be the basis of a violation of professional integrity in certain cases.

An ethical basis for overruling patient autonomy is essential to a viable futility policy in order to respond to critics who argue that any futility policy is unethical because of imposed values (Truog, Brett, and Frader 1992). Futility policies are not, and cannot be, value free. However, it is also an unfounded value judgment that patient autonomy is inviolate and must always trump other legitimate competing values. The ultimate question is not whether a futility policy is value free, but whether it is based on defensible values. We believe that the Houston policy meets the challenge because it provides a case specific mechanism which strikes an appropriate balance between patient autonomy and professional integrity.

Adoption, Dissemination, and Results

Much has happened, both locally and nationally, in the three years since the task force guidelines were disseminated to the original participating hospitals. The original plan was to secure support in principle from the various participating institutions and then begin a public education campaign coupled with a legislative initiative. Within the first year, all the participating institutions formally affirmed their support of the guidelines in principle, as did the Harris County Medical Society. However, several of the hospitals believed that it was important to immediately operationalize the guidelines into working policies and initiate the education campaign simultaneously. A futility policy is now part of the operational policies at five major hospitals and several smaller hospitals in the region. In at least this regard, the process has been a success in that it has created a de facto community standard, grounded in professional integrity, to deal with individual cases of demands for futile interventions.

Part of the push to formally adopt policies based on the guidelines resulted from a change in national AMA policy. Early in the futility debate, the Council on Ethical and Judicial Affairs of the American Medical Association attempted to substantively define futility (1991). Their initial definition and all other substantive definitions that were shown to be unworkable were rejected by

the Council in 1994 when CEJA concluded that futility "could not be meaningfully defined" (1994). However, in December of 1996, the House of Delegates of the AMA approved a new CEJA report that "recommends defining futility on a case-by-case basis, taking full account of the context and individuals involved, and using a due-process approach to achieve this case-by-case definition" (Resolution 14 1996). The report referenced the Houston policy, which had been published earlier in the year in *JAMA*, as an example of such a policy.

We now have several years of experience with the use of the policy in various hospitals. So far, it has worked as envisioned and desired in individual cases by fostering an atmosphere of respectful discussion and mutual exchange of views and values. There has yet to be a case that could not be resolved in the first three steps of mandatory discussion, facilitated by institutional resources (such as the ethics committee, chaplaincy, or patient care representative) and/or by transfer. In several cases, an interdisciplinary review board was almost convened but a resolution was reached prior to the expiration of the seventy-two-hour waiting period. We believe that the mere existence of such a process-based policy as an option of last resort results in a better appreciation for the appropriate balance between the values and beliefs of the patients and those of the

health care professionals and institutions.

Eventually, a case will not be resolved and will necessitate implementing the binding review mechanism. Despite the American Medical Association endorsement, there is still residual uncertainty regarding the legal standing of such a policy. The Fourth Circuit Court of Appeals in the Baby K decision (1994) struck down the notion of futility as an exception to the Emergency Medical Treatment and Active Labor Act. A trial jury in Boston sided with an institution that invoked futility in refusing aggressive treatment to a patient (*Gilgunnj v. Massachusetts* 1995). The legal question has not been clearly answered yet. The hospitals that have adopted a policy believe that process-based protections included in the guidelines will pass judicial review. Several other hospitals that have endorsed the guidelines in principle would like to see either clear legislative initiatives on the state or national level or similar process-based policies developed in other cities and states.

The job is not over. However, the Houston approach of an open and fair process of determining futility, which balances patient autonomy with professional integrity, has been a useful tool to resolve the disagreements raised by many futility cases and can serve as a model to others around the country.

GUIDELINES ON INSTITUTIONAL POLICIES
ON THE DETERMINATION OF MEDICALLY INAPPROPRIATE INTERVENTIONS

Appendix One

Policy

The traditional goals of medicine have been to heal and to relieve suffering and pain. In recent years, the goal of respecting autonomous patient choices has motivated the establishment of policies that permit patients (or surrogate decision makers) to exercise that autonomy by refusing or limiting an unwanted intervention. These policies are limited to situations in which patients (or surrogate decision makers) refuse an intervention. This current policy, designed to supplement rather than to supplant currently existing policies on limiting life-prolonging therapies, provides a conflict resolution mechanism to follow when a patient (or surrogate decision maker) requests, rather than refuses, an intervention that the responsible physician¹ assesses to be medically inappropriate (commonly referred to as medically futile).

This policy affirms both the traditional goals of medicine and the moral value of physician and institutional integrity in discerning the limits of medical interventions. Respect for this integrity provides the basis for the right to refuse to provide a medically inappropriate intervention. It complements the right of patient determination that must be given both voice and effect in any forum for medical decision making. This appeal to integrity is generally rooted in a combination of concerns such as avoiding harm to patients, avoiding provision of unseemly care, and just allocation and good stewardship of medical resources. This policy affirms the value of integrity so long as appropriate institutional review supports the determination of medical inappropriateness.

After following the procedures set forth in this policy, a medically inappropriate intervention may² be withheld or withdrawn without

obtaining the agreement of the patient (or surrogate decision maker).

Procedures

1. When the responsible physician determines that an intervention is medically inappropriate but the patient (or surrogate decision maker) insists that it be provided, the responsible physician should discuss carefully with the patient (or surrogate decision maker) the nature of the ailment, the options — including palliative care and hospice care — the prognosis, and the reasons why the intervention is medically inappropriate. The responsible physician should explain that not providing the intervention in question does not mean abandoning appropriate medical care and humane care designed to promote comfort, dignity, emotional, and spiritual support.
2. The responsible physician should address with the patient (or surrogate decision maker) the options of patient transfer to another physician or to another institution and of obtaining an independent medical opinion concerning the medical inappropriateness or medical futility of the intervention in question. The responsible physician should also provide the patient (or surrogate decision maker) with a copy of these guidelines.³
3. The assistance of institutional resources (such as nursing, patient care representatives, chaplaincy, social services, or the biomedical ethics committee) shall be made available to the patient (or surrogate decision maker) and to the responsible physician.

4. If, after reasonable effort by the responsible physician using the available institutional resources, agreement is not reached between the responsible physician and the patient (or surrogate decision maker), the responsible physician who still wishes to limit the intervention must obtain a second medical opinion from a physician who has personally examined the patient and must present the case for review by an institutional interdisciplinary body and must provide to that body clinical and scientific information pertinent to the determination that the intervention is medically inappropriate.
5. The responsible physician must notify the patient (or surrogate decision maker) that this process has been invoked, what it involves, and what are its possible outcomes, when and where the review will take place, and that the option of transfer before the meeting exists, but that arranging such a transfer is the responsibility of the patient (or surrogate decision maker). Absent patient (or surrogate decision maker) consent to an earlier time, the meeting cannot take place for at least seventy-two hours after the patient (or surrogate decision maker) is notified.
6. During the institutional review process, the responsible physician and the patient (or surrogate decision maker) are encouraged to be present together to express their views for consideration including alternative plans of care.
7. If a finding of medical inappropriateness is affirmed⁴ by the institutional review body, medically inappropriate intervention may² be terminated and a plan of care established that addresses comfort care and the preservation

of patient dignity.⁵ If, however, the institutional review body does not concur with the responsible physician's determination of medical inappropriateness, then orders to limit the intervention will not be recognized as valid without patient (or surrogate decision maker) agreement.

8. If the institutional review process agrees with the determination of medical inappropriateness, intrainstitutional transfers of the care of the patient to another physician to provide palliative care are allowed. However, intrainstitutional transfers to another physician to provide the intervention that has been judged by the institutional review committee to be medically inappropriate will not be allowed.
9. The procedures set forth in this policy may be invoked only by the responsible physician or as otherwise authorized by the hospital's medical staff by-laws. Concerns on the part of other health care providers, hospital officials, or family members should be addressed through already existing institutional mechanisms.

Endnotes

1. The term "responsible physician" should be defined by each institution.
2. Institutions may wish to substitute "... must be terminated even though the agreement of the patient (or surrogate decision maker) has not been obtained."
3. Each institution may insert the title of their policy.
4. Each institution should determine the voting requirements for its review mechanism affirmation.
5. An institution may impose a finite grace period after the determination that an intervention is medically inappropriate or medically futile but prior to the termination of the intervention.

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"Sorry I'm late, but they had me on a life-support system for two months."

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