Defining Medical Futility in Ethics, Law and Clinical Practice: An Exercise in Futility?

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The debate as to the meaning of medical futility and what physicians should do in clinical practice dates back to the time of the writings of Hippocrates and Plato where it was said, “To attempt futile treatment is to display an ignorance that is allied to madness”. In simpler times assertions regarding the obvious were sufficient to indicate what was thought “fitting” as a medical practitioner. In recent times, however, modern technology, professional values and power, patient autonomy, limited health care resources and societal expectations, make for a much more potent and potentially explosive mixture. In this article we argue that futility is a problem that will not go away, both because of increased health expectations and emerging technologies that keep making possible what was previously impossible. The problem of definition and its ramifications in terms of institutional policies is one in which the legal profession and its process (which often represents and reflects societal values) has a key role to play by way of critical reflection and appraisal.

Introduction

Physicians and ethicists have long been concerned about patients and their surrogates who insist on receiving life-sustaining treatment that others judge to be medically futile. The concept of medical futility is often used clinically (but loosely) to describe treatments that fail to provide the patient with worthwhile benefits and is one of the oldest in medical practice. The Hippocratic Corpus, for example, encouraged physicians to recognise the limits of medicine, “to refuse to treat those who are...
overmastered by their diseases, realising that in such cases medicine is powerless". Christian ethics have also recognised the implications of futility determinations by way of the Doctrine of Ordinary and Extraordinary Means which, it is claimed, offers patients and doctors, regardless of their religious beliefs, a reasonable and straightforward basis for determining how much to strive to keep patients alive. In recent years, "futility" has been incorporated into numerous biomedical policy statements and legislation as justification for physician non-treatment.

The claim that an intervention is futile is frequently used to justify a shift in the ethical obligations owed to a patient. For instance, patients are said to have entitlement or prima facie rights to certain sorts of health care, for example, primary and emergency care. However, where a treatment is judged to be futile or useless, a patient is not entitled to it, nor is the clinician under any legal or ethical obligation to offer it. In the recent English case of Airedale NHS Trust v Bland, Lord Goff of Chieveley said:

"[M]edical treatment is [not] appropriate or requisite simply to prolong a patient's life, when such treatment has no therapeutic purpose of any kind, as where it is futile because the patient is unconscious and there is no prospect of any improvement in his condition."

In the past few years, however, the concept of futility has come under increasing academic, public and professional scrutiny, particularly in relation to the ethical implications for professional practice and institutional policies and guidelines that flow from determining that a treatment is futile.

Futility is a problem that will not go away, both because of increased health expectations and because emerging technologies keep making possible what was previously impossible. For example, a number of discussions regarding futility have focused on the issues of cardiopulmonary resuscitation and the persistent vegetative state (PVS), framing the debate as a conflict between patient rights or autonomy and physician integrity regarding who has the right to determine when a medical intervention is inappropriate. The much-publicised case of Helga Wangile, an elderly patient in a persistent vegetative state whose treatment was sustained at her husband's insistence in spite of physician and hospital evaluations that continued care was futile, is perhaps the most well-known example of a continuing debate concerning its clinical relevance, ethical implications, and the limits of society's obligation to provide continuing health care resources.

Some definitions

The current debate on medical futility seems to revolve around two distinct though related areas of concern. First, there is the problem of whether it is possible to define what we mean by the concept of medical futility and whether we can identify sufficient defining or operational attributes which would assist patient-treatment assessments. The second area of concern is the issue of who should determine when a treatment is futile and how.

The earliest known attempt to define futility comes from the Hippocratic Corpus, where what is now called the quantitative definition was clearly recognisable. Schneiderman has proposed that if a treatment has not been successful in the last 100 cases, then common sense dictates that such a

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6 Ibid at 869 (emphasis added).
9 Op cit n 1.
treatment should be regarded as quantitatively futile. On the other hand, Plato had a qualitative perspective of futility which emphasised the inappropriateness of persisting with treatment which leaves the surviving patient with a "useless" life:

"medicine was not intended for them and they should not be treated even if they were richer than Midas." Qualitatively, a futile treatment is one which does not achieve its desired goals and is said to be inconsistent with the "ends" of medicine. In general, the quantitative and qualitative aspects of medical futility may be seen as conceptual umbrellas under which clinical contributions to the debate can be placed.

**Some problems**

In recent times, the problems associated with defining futility have encompassed patient rights and speculations about the limits of patient autonomy, economics, professional integrity and the role of the physician in the physician-patient relationship, as well as the lack of shared values as to what may be regarded as medically necessary in a particular case. More specifically, there are two problems associated with Schneiderman's proposed definition of quantitative futility. The first problem arises from the nature of clinical uncertainty and the language of probability. Most medical situations are characterised by uncertainty and seldom is there room for absolutes such as never or always. Indeed, most judgments are a matter of probability rather than certainty, where futile treatment may represent one end of a spectrum of therapies of variable efficacy and where benefit becomes infinitely small before it becomes negative. Clinical uncertainty is the norm rather than the exception.

The second problem relates to the nature of empirical or statistical interpretations of medical benefit. Clinically, it may not be possible to define futile treatment on the basis of a statistical threshold as there may be insufficient data to make accurate prognostications. Expressions of probability may also mean different things to different physicians or to individual patients. For example, some may invoke futility if the success rate is 0 per cent whereas others may invoke futility for treatment with a success rate as high as 10 per cent. Indeed, it has been suggested that medical science may be sufficiently imprecise to allow accurate determinations of futility, given that a number of studies have demonstrated the limitations of physicians' clinical estimation of both diagnosis and prognosis.

The problems associated with reaching agreement regarding the meaning of qualitative futility are more formidable and include:

- disagreements about the goals of therapy, and the ends of medicine;
- whose values should determine decision-making;
- the limits of patient autonomy; and
- professional integrity.

**Values and goals of therapy**

It is clear that statistical probability alone cannot be the sole determinant of futility. Many determinations of futility embody assessment of the goals of therapy and there can be no doubt that such assessments of outcome are intrinsically value-
Effects, benefits and burdens: Who decides?

The qualitative aspect of futility highlights the need to weigh and compare the expected effects, outcome benefits and burdens that might come from medical intervention and raises the issue of who it is who should decide whether such medical intervention is futile. The provision of medical treatment should always be subject to ethical reflection as to whether it is medically necessary or medically futile. One of the more usual ways of determining whether a medical treatment is obligatory or optional is to consider its expected effects and outcome, benefits and burdens. For example, it is clear that, when one incorporates outcome assessments in decisions regarding treatment, one considers both quantitative and qualitative criteria such as:

- the duration of medical benefit;
- the likelihood of medical benefit;
- the quality of benefit; and
- the value of the benefit to the patient.

As we have noted, there are fundamental difficulties in attempting to identify benefit merely on the basis of potentially quantifiable factors such as survival time. Some would argue that such decisions (incorporating determinations of futility) are the domain of the doctor, and indeed there is adequate evidence to suggest that this is the case. For example, surgeons do not advocate surgery in the face of overwhelming risks of operative mortality; oncologists do not routinely offer chemotherapy to cachectic, semi-conscious patients with widely disseminated malignancy; and intensivists do not continue endless ventilation for patients with hypercapneic respiratory failure and chronic airways limitation. Indeed, from a legal perspective, the question of futility is regarded as an issue of medical fact. In Bland, Lord Goff of Chieveley said:

Callahan, op cit n 7; Lantos, op cit n 4; H Brody, "The Physician's Role in Determining Futility" (1994) 42 (8) Journal of the American Geriatrics Society 873.

Schneiderman et al, op cit n 10.

Mitchell et al, op cit n 7.


"The truth is that, in the course of their work, doctors frequently have to make decisions which may affect the continued survival of their patients, and are in reality far more experienced in matters of this kind than are the judges. It is nevertheless the function of the judges to state the legal principles upon which the lawfulness of the actions of doctors depend; but in the end the decisions to be made in individual cases must rest with the doctors themselves."

The decision to withhold a futile treatment does not mean that the physician should avoid discussion about this with the patient. The decision not to provide admission to intensive care for intubation and ventilation is an instance of where the physician, dependent on the patient's competence and state of mind, should discuss with the patient or surrogate the reasons why such treatment will not be provided.

The problem with making determinations of futility purely the prerogative of the physician is that assessments of outcomes, benefits and burdens incorporate and reflect the values, concerns and perspective of the individual making the assessment. We are entitled to examine the relevance of values inherent in the determination of both quantitative and qualitative futility. In quantitative futility, the value judgment rests in the meaning and value of the probability. In qualitative futility the value judgment rests in the meaning and value of continued life, and determining what is a good outcome is dependent only in part on what is medically good for the patient. In other words, even though a doctor may regard treatment as futile relative to medical goals, the patient may value treatment and the potential benefits of treatment, as enormously good from their own perspective, and taking into account their own goals. As Youngner notes, a decision that treatment is futile or that certain goals are not worth pursuing may reflect a conflict of values and that to use the language of futility runs the risk of "giving opinions disguised as data".

There are a number of other difficulties in the assumption that assessments of outcome, benefits or burdens are solely the domain of the medical practitioner.

- Physicians and other health care professionals have been shown to be poor judges of patients' preferences regarding treatment.
- There is most likely a fundamental inappropriateness in making judgments regarding the quality of the life of others and basing treatment on that. Indeed, different patients, different people, different doctors, may have differing standards or criteria by which they judge their own quality of life.
- So-called "objective indicators" of a patient's quality of life have been shown to correlate poorly with patients' assessments of their own goals and subjective evaluation of their own lives and quality of life.

**Professional integrity and the limits of patient autonomy**

It is now clearly established in ethics and in law that a competent patient has the right to choose or refuse medical treatment. This is not problematic where a patient's request coincides with clinical judgment, but incites controversy where a patient's request conflicts with clinical judgments of medical appropriateness. Some would argue that in such cases patients retain the right to choose treatment

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and doctors are obliged to provide it, whereas others deny that patients have the right to demand treatment that is useless or rationed on the basis of scarce medical resources. Legal judgment has generally reinforced the notion that a doctor is under no obligation to offer treatment that is "futile" or not "medically indicated". Kennedy and Grubb, commenting on Re J (A Minor), noted that, although patients can refuse treatment and absolve the physician from the duty to provide appropriate treatment, the patient cannot demand a form of care which the doctor,

"in the exercise of reasonable medical judgment determines is futile, in that it will be of no benefit of any kind to the patient. As in all cases where a doctor has formed a reasonable and responsible clinical judgment that treatment is not called for, the law will not second-guess him by ordering him to provide the treatment."

Dix et al make a similar point:

"The law does not require that all possible steps be taken [to preserve a patient's life]. Not surprisingly, there are no case authorities directly in point."

Even if one rejects the notion of futility, however, this does not imply that patients should have unrestricted access to medical therapy or medical interventions. Nor does it imply that it is necessary to abandon the use of outcome research or clinical epidemiology as tools to identify clinical success and failure. It is clear that autonomy cannot function in isolation from other important moral values. For example, if respect for autonomy was absolute, then one could argue that a competent patient's choice would always determine clinical management. Yet this is clearly not the case. Physicians are not legally or ethically obliged to provide useless treatments such as, for example, antibiotics for the common cold. Physicians are entitled to refuse such treatments as they are not only inconsistent with the duty of care but may also violate the physician's duty to benefit and not harm the patient.

**Shared decision-making: balancing values and qualitative futility**

Much of the ambiguity and conflict associated with determinations of qualitative futility can be reduced by ensuring that the patient is both informed and involved interactively in the decision-making process throughout the health-care period. We propose that progress towards ethical determinations of futility will best take place within a model of shared decision-making that recognises both technological criteria, probability assessment and clinical practice on the one hand, and intrinsically value-laden and patient-centred aspects of medicine on the other. Despite the continuing ambiguities associated with qualitative definitions of futility and the subjective nature of outcome assessment, some physicians still ignore the role that should be played by the wishes and values of the patient. What should be obvious is the need for the patient (or surrogate) to be informed so that the autonomy and interests of the patient can help guide clinical management.

The benefits of shared decision-making are that it may:
- promote open and honest discussions between patients and physicians and will assist in clarifying (a) the relevant values, beliefs and concerns that relate to clinical management; and (b) the goals of treatment, including the relative importance of curative, palliative or rehabilitative care;
- improve communication and decision-making where inadequate information disclosure, or deficient physician-patient interaction, has contributed to unrealistic expectations or requests; and

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32 Callahan, op cit n 7; Mitchell et al, op cit n 7; Schneiderman, op cit n 7.
34 [1992] 4 All ER 614.
36 Brody, op cit n 17.
39 Ibid.
• ensure that the clinical encounter will take into account the perspectives of both physician and patient regarding their understanding of disease and its impact.

**Clinical practice: Guidelines and policies**

We now return to the two “principles” with which we began this article. It is likely that the medical profession, together with ethicists, lawyers and others, will eventually elucidate parameters of medical benefit or a socially acceptable definition of *quantitative* futility. It will then be important for the medical and legal professions – the latter often reflecting and representing societal values – to establish standards of care and a *uniform* standard of clinical practice in order to limit variability between physicians and across both medical specialties and target populations. Clinical trials may well indicate that the best estimate of what will constitute *quantitative* futility will be any treatment which has less than a 1 per cent chance of restoring health. The restoration of health means, in this context, a return to either the pre-presentation level of functioning, or to a lower level of functioning that is still seen by the patient as sufficient to make life worth living.

**Ethical obligations and options**

The goals of medicine may still be a matter of debate but we believe that in the 20 years since *Quinlan* an ethical consensus has begun to emerge regarding limiting treatment to cases where the patient, as a whole, benefits from its application. The debates regarding the ethical obligations owed to PVS patients like Karen Quinlan have led to a clearer distinction between treatment which is medically futile and treatment which should not be given because it is expensive and should be rationed and conserved for others who can benefit. The provision of artificial nutrition and hydration for the PVS patient, like other medical treatments (for example, the use of antibiotics), is subject to ethical reflection as to whether it is morally obligatory or morally optional. One of the more usual ways of determining whether a medical treatment is obligatory or optional is to consider its *expected* effects, benefits and burdens. For example, in the case of PVS, doctors may argue that artificial nutrition and hydration is effective in a *limited* sense, as alimentation or nutritional support intended to achieve carefully defined *physiological* objectives or goals. As a physiological intervention, alimentation is a *medical* treatment and can be effective in keeping PVS patients alive for years. But what *benefit* does the PVS patient derive from continued existence? Nutritional support can effectively preserve multiple-organ systems in a PVS patient, but it cannot restore that patient to a conscious, reflective life. Though alimentary support is generally of no great burden to the PVS patient, we may well ask whether it is *qualitatively* futile, especially since the patient remains totally dependent on medical care. It may be argued that it is qualitatively futile because the ultimate goal of any medical intervention should be improvement of the patient’s prognosis, comfort, well-being or general state of health. Alimentation, though it produces certain positive and measurable physiological effects, does not, in the case of the PVS patient, ultimately result in either short- or long-term benefits of the kind consistent with our humanity.

**The way forward**

The way forward is clearly through continuing discussion as to the meaning of medical futility, the determination of acceptable *criteria* of quantitative futility and the *decision-making process* in those cases where issues of qualitative futility arise. Further discussion on what constitutes futility will necessarily involve a re-examination of medicine’s existing values and their current extension and expression as health care *goals* in a time of rapidly...

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40 Pearlman, op cit n 24; Schneiderman, op cit n 7.
41 Schneiderman et al, op cit n 10.
42 *Quinlan* 70 NJ 10; 355 A 2d 647 (1976).
43 Mitchell et al, op cit n 7.
expanding technology.46 The legal profession has a vital role to play, both during the discussion regarding the clarification and meaning of futility and later, in assisting the medical profession and institutions to standardise clinical practice. As Lord Goff notes in *Bland*:

"Mutual understanding between the doctors and the judges is the best way to ensure the evolution of a sensitive and sensible legal framework for the treatment and care of patients, with a sound ethical base, in the interests of patients themselves."

Futility and the cost of health care, particularly in the case of a specific patient, should be kept as separate considerations. It is evident to all that our society must limit futile care if we are to control the cost of health care. However, no matter what the cost of a particular technology, the ethical issue regarding its use should only be whether such use is consistent with the goals and practice of medicine where these have societal approval.

Finally, the linkage between medical futility, health care costs, institutional policies, cost containment and rationing — already evident in a number of medical specialities (for example, intensive care units, haematology, oncology and geriatrics) — can only be ethically justified where all those potentially affected have been represented in the policy decisions. Health care professionals, lawyers and society in general cannot avoid the sad realities of resource allocation and the central role of judgments of medical benefit. As noted in *Re J (A Minor)*:

"[The order from the lower court] does not adequately take account of the sad fact of life that health authorities may on occasion find that they have too few resources, either human or material or both, to treat all the patients whom they would like to treat in the way in which they would like to treat them. It is then their duty to make choices."

..."I would also stress the absolute undesirability of the court making an order which may have the effect of compelling a doctor or health authority to make available scarce resources (both human and material) to a particular child, without knowing whether or not there are other patients to whom those resources might more advantageously be devoted."49

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47 *Airedale NHS Trust v Bland* [1993] AC 789 at 871.


49 Ibid at 625.