1. Futility Guidelines: A Resource for Decisions about Withholding and Withdrawing Treatment

Purpose

This paper will serve as a resource for discussions of the concept of futility from the VA perspective. It is hoped that this discussion will lead to a proposal for departmental guidelines, to a formulation of a national VA position or definition, and where appropriate to institutional policies within VA facilities compatible with their patient population mix and their complexity, mission, community, educational affiliation, and staff culture.

Background

American medicine has been struggling with the issue of "futility" under a number of guises for at least ten years. With the ever-present emphasis on "informed consent," patients and surrogates perceived correctly that they could accept or refuse the therapy offered to them. As they became more medically knowledgeable and sophisticated, they began to ask for treatments that their physicians considered not medically indicated, totally inappropriate, or having little chance of success or benefit. In some cases patients and surrogates refused to permit withdrawal of treatment that the physicians felt was not achieving any medical benefit and often was very resource intensive. At the same time, the technological explosion provided the means to support physiologic functions and to treat what had previously been

fatal conditions. However, not all outcomes were considered successful and many patients remained comatose, on life-support, or in persistent vegetative state (PVS).

Physicians used the term "futile" to try to convey to patients and surrogates that offering or continuing treatment was, in their opinion, pointless, worthless, or unlikely to produce positive results or any benefit. Unfortunately, rather than enhance communication, the term can establish a barrier with its implications of finality and hopelessness. Some patients and surrogates began to feel that their values, concerns, and concepts of quality-of-life were being overlooked, bypassed, or forgotten and that their perception of the value of even a limited quality of life or of limited percentage of success of a particular treatment was not being considered appropriately.

The debate about the meaning of futility continued, fueled by other developments of concern:

1. the exponential rise in health care costs;
2. the continued growth in development and diffusion of high-technology and the resulting question of whether the effects produced in its use (or overuse) provided benefit to patients;
3. the accelerated aging of society and the observation that the elderly and the dying appear to be the heaviest users of health services;
4. the new emphasis on outcomes research;
5. the desire to place some limitations or restrictions on patient autonomy and to focus more on concepts of justice in allocation of scarce resources;
6. evidence of continued paternalism and physician domination or physician autonomy;
7. fuzziness in the attempts at definition of the term "futility;"
8. capricious judgments involving the "social worth" of particular patients; and

9. little or no distinction of the components of judgments of futility, e.g., clinical criteria, appropriate decision makers, required communication, and documentation.

Recent Definitions

It appears that in the past the term "futility" has most often been used in individual cases, on a one-on-one basis at the bedside, where the physician felt it necessary or appropriate not to discuss, not to offer, to withhold, to withdraw, or to deny a particular therapy for one or more reasons. This plan could occur even though the patient or surrogate had requested the therapy or asked that it be continued. The "reasons" included, but were not limited to:

- totally inappropriate;
- never tried before;
- previously tried but rarely or never successful;
- previously tried but not successful in category into which patient falls;
- previously tried but unsuccessful in last 100 cases (statistical or quantitative futility);
- would produce a physiologic effect but no benefit to patient;
- benefits produced would be significantly outweighed by physical or physiologic burdens necessitated;
- results of treatment would produce negative quality of life, only preserve permanent unconsciousness, or fail to end total dependence on the Intensive Care Unit (qualitative futility); and
- benefits produced would not be worth the economic burden (non-"costworthy" or economic futility).

Much of the foregoing rationale is based upon physician decisions or physician values. It is argued that this trend is a return to paternalism or subversion of patient autonomy, to the exclusion of patients values.

The literature reveals a developing consensus that emphasizes the patient's goals and value system as critical elements in any discussion of futility. The importance of communication between physician and patient or surrogate cannot be stressed too strongly. The physician must ask about and be aware of the patient's religion, culture, family circumstances, and values and must communicate and be assured that patient or surrogate understand the diagnosis and prognosis. These elements should be factored into any judgment about "futility," or the patient or surrogate may feel isolated and alienated at a time when they may be in greatest need of support and understanding. However, some feel that acknowledging patients' goals and wishes will lead to demands for pointless or inappropriate care despite no reasonable, realistic likelihood of success or benefit. They express this concern while acknowledging the challenges of determining what is "reasonable" and determining who decides.

Do We Need to Define Futility?

It has been suggested that futile treatment be defined as that which affords no benefit or marginal benefit, weighing the intrusiveness, burdens, and risk against the ultimate outcome.

However, since the term "futility" in the clinical sense usually arises in a context of withholding or withdrawing a particular modality, and since the term has become volatile, almost inflammatory, it may be more appropriate to define those situations where diagnostic/therapeutic modalities will be withheld or withdrawn.

It is also suggested that the term "futile treatment" be used, since care is never futile.

Withholding and Withdrawing of Treatment: Refusals and Futility Assessments

A. Treatment may be withheld or withdrawn following refusals when:

   1. a competent patient refuses the treatment after having received relevant information;

2. an incompetent patient's surrogate refuses, in compliance with a valid Durable Power of Attorney for Health Care; or

3. an incompetent patient's surrogate refuses, in compliance with patient's wishes (substituted judgment) or best interest after weighing burdens and benefits.

B. Treatment may be withheld or withdrawn on the basis of futility assessments when:

1. treatment would only serve to prolong the dying process and bring no relief of a patient's suffering (death is inevitable and imminent and treatment includes artificial feeding and hydration where the patient is only being maintained in his/her current state with no hope of improvement);*

2. treatment would only maintain permanent vegetative state (PVS) once that diagnosis had been made and its irreversibility had been confirmed;**

3. continued treatment is in violation of an established medical center policy (see #2 under Guiding Principles);**

4. the patient would never leave the Intensive Care Unit for the rest of his/her life;**

5. there is clear and convincing data to indicate the lack of a successful outcome (quantitative futility)—e.g., APACHE scores, multi-system (three or more) failure in elderly patient, CPR in patient with multi-system disease, etc.;**

6. treatment provides physiologic effect but no benefit; or

7. treatment offers no realistic, reasonable expectation that the physician's medical goals and the patient's personal goals and values can be realized (requires awareness of one another's goals and concurrence).**

* requires communication between physician and patient's surrogate.

** requires communication with, and concurrence of, patient or surrogate.

Guiding Principles

1. Under no circumstances will pain relief or such care as to maintain the patient's comfort and dignity be withheld or withdrawn.
2. Decisions about futility or the withholding or withdrawal of care should not be made by the attending physician alone, but should include the advice and consultation of the treating team staff, consulting physicians, and a formally constituted, multi-disciplinary committee where appropriate. Such decisions could also be made in accordance with an established policy in the local community.
3. A local multi-disciplinary committee should be used to consider and define instances of medical futility in order to provide a consensus that assists physicians and patients or surrogates in making futility decisions. Such a committee could function in a "dispute resolution" role where consensus cannot be achieved among members of the treating team and consultants or where the patient, family, or surrogate refuses to concur in the recommendation to withhold or withdraw treatment.
4. The Ethics Advisory Committee (EAC) or a subcommittee of the EAC could serve in the role of facilitating or arbitrating decisions concerning futility. To serve in this role the EAC should be expanded beyond its traditional membership to include expertise in outcome assessment or epidemiology where appropriate and available.
5. Without a mechanism for the development of consensus concerning medical futility, physicians could make ad hoc decisions that may be overly influenced by individual bias. Also, the application of an institutional consensus can protect the patient from burdensome measures.
6. Definition of care that will not be provided should include that which is outside the limits of professional standards, that which is negligent, and that which compromises the physician's integrity.
7. The approach to withholding and withdrawing treatment presented here is based on the understanding that resource

allocation and rationing issues ought to be separate health care issues—if cost is to be a factor in withholding or withdrawing care, it should be as the result of an established and explicit institutional or national policy and not determined on an ad hoc basis by a physician or health care administrator.

Future Directions

A. Immediate Goals and Continuing Emphasis

1. Increased emphasis on the VHA's Advance Directive and Durable Power of Attorney for Health Care.
2. Early and frequent communication between physician and patient or surrogate regarding diagnosis, treatment, prognosis, treatment goals, personal goals, and value system.
3. Increased use of "time-limited" trial to allow room for compromise, with frequent reevaluation of clinical state, time for the family to accept the prognosis, grieve, etc. This often serves to establish "futility" in the minds of all involved.
4. Use of ethics committees as sounding boards to mediate, offer support, guidance, etc.
5. Patient and professional education; patient empowerment.

B. Long Range Goals

1. More outcomes research to guide decisions in the future.
2. Development of treatment guidelines and policies based upon research and supported by professional consensus that the guidelines and policies should underwrite standard medical practices.
3. Awareness throughout the community of the concepts of limitations and fairness.
4. Evolution of societal consensus by the community as a whole about which treatments are not appropriate to offer or provide

under certain circumstances—the framework includes such elements as the value of life, the inevitability of death, professional responsibility, remorse, and social justice at a time when there are both increasing needs and demands as well as diminishing, limited, scarce resources.

5. Use of a facility multi-disciplinary committee to review generic cases and to develop policy defining treatments that are futile in particular clinical situations and advising that these treatments need not be instituted and may be withdrawn.

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