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The challenges of medical futility

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The definition of medical futility continues to elude the medical profession. The tendency to aggressively treat gravely ill patients prompts physicians to consider the reliability of the treatment goals, not to mention how to justify those goals in light of their obligation to do good and avoid harm for their patients. This article examines the various concepts of medical futility and considers the feasibility of developing practice guidelines to help clarify treatment options and justify appropriate treatment goals.

Medical futility falls into the void of obscure conduits that often plague the medical community in the decision-making process. Medical futility can best be defined as an instance when a terminally ill patient and others for whom everything medically plausible, including heroic methods, has been tried; or a situation in which a patient has exhausted the course of innovative and tested therapeutic interventions, and nevertheless will die or live endlessly in a persistent vegetative state (PVS). An intervention is medically futile when there is no therapeutic benefit to the patient nor will the treatment return the patient back to an acceptable level of continued existence. When comparing the quality of the outcome to the intervention, the outcome falls below the minimally established guidelines determined by the social standards set in the community. In addition, the likelihood of medical treatment offering any positive physiological benefit to the patient would not be measurable.[5] This article seeks to clarify medical futility together with the rationale for creating a policy. It will also examine the importance of having guidelines in place and what guidelines should be embraced in order to avoid nonmaleficence and promote respect for persons and justice in the medical arena.

The concept of medical futility continues to elude the medical community. It is as individual in meaning to patients as their diagnoses. This challenges hospitals to establish medical futility guidelines and develop a policy that not only encompasses a patient's autonomy, but also supports the ethical principles of respect for persons, beneficence and justice. These principles are the basis of the physician-patient relationship. Autonomy gives the patient the right to determine what course of action is preferable, based on their own value system. The ethics of medicine refers not only to the rules, customs and beliefs of a society; it also attempts to enunciate and evaluate those rules, customs and beliefs.[9] Englehardt and Beauchamp elaborated on the ethical principles that have become the foundation of the physician-patient relationship.[9]

For more than a decade, bioethics and health care professionals have struggled to define the exact meaning of medical futility.[14] Often, by the time the physician is comfortable in labeling a patient's treatment medically futile, success of the treatment is nonexistent. The word "futile" is derived from the Latin word *"futilis,"* meaning that which easily melts. The common usage developed from the Greek legend in which the daughters of Danaus, King of Argos, murdered their husbands and as punishment, were condemned to collect water for eternity in leaking buckets. To arrive at a destination with an empty bucket, when the goal was to bring water, offers the definition of futile as something that is useless or ineffective.[1]

Two questions often arise. 1) Have we taken the respect for patient autonomy too far? 2) Does patient autonomy automatically require the physician to provide any treatment plan that the patient or surrogate desires? Treating the patient with interventions that will not improve physiologic functioning could be construed as unethical. Hippocrates advised us to refuse to treat those who are overmastered by their disease. According to the American Medical Association's Code of Ethics, physicians have no obligation to suggest futile intervention based upon the ethical principle of beneficence. We can also ascertain that nonmaleficence disallows physicians from harming patients with futile interventions that could infer injury to the patient.[3] Yet the challenge remains: define and incorporate medical futility guidelines into the continuum of care, while offering medical interventions that provide positive physiological benefit for the patient.

Four concepts of futility

In bioethical literature, four basic concepts of futility have been identified. As presented by Tomlinson and Brody from Michigan State University, the first concept is based on beneficence, and emphasizes physiological or strict futility.[10] The intervention is considered futile in the sense that it is unlikely to produce a physiological benefit. For example, a patient with a Glasgow

Coma Score of 3 after an intracerebral bleed is strictly futile as there is no expectation for spontaneous brain function to be re-established.[10] Therefore, the procedure is unlikely to be successful in achieving its objective.

The second concept introduced by Schneiderman identifies clinical or overall futility. The intervention is futile when it is unlikely to restore the patient's ability to interact with the environment and resume human development. An example is one where the patient is in a persistent vegetative state (PVS) who has irreversibly lost these capacities. Even though parenteral nutrition or the dispensing of fluids is physiologically effective, the patient will not benefit.[10] An example of this would be a patient in a PVS state who has received parenteral nutrition and remains in a PVS state indefinitely.

The case of Nancy Cruzan falls under this concept of medical futility. Nancy Cruzan, at the age of 24, lost control of her car, leaving her in a water-filled ditch. Paramedics arrived on the scene to find her heart had stopped. Although they were able to shock her heart into action, her brain had been deprived of oxygen too long, and Nancy was PVS. Nancy was kept alive with a respirator and feeding tube for seven years. Her care cost the state of Missouri $112,000 per year. In those seven years, Nancy never interacted with family or friends again. The feeding tube and respirator were merely apparatuses that connected Nancy to this world, keeping only her body, but not her mind, in the present time.

The third concept is imminent demise futility, which has been identified by Brody and Halevy.[10] An intervention is futile when the patient is unfailingly expected to die without recovering consciousness before being discharged from the clinical setting. Studies have shown that patients who have arrested outside the clinical setting and were not successfully resuscitated on arrival in the emergency department were dead at discharge, and few ever regained consciousness.[10]

Qualitative futility, the fourth element of the concepts of medical futility, was presented by Tomlinson and Brody. The intervention may be deemed futile if the quality of life after treatment is unacceptable to the patient.[10] Other guidelines extend the scope to include when the quality of life resulting from the treatment is exceedingly poor by the minimum standards, thereby substantiating medical futility. Clinical paradigms of futile care will often involve life-sustaining intervention for patients in a persistent vegetative state or resuscitation efforts.[11] This concept can also be illustrated by treatment that is so unlikely to succeed that many people would state that it is not worth the cost.

Qualitative versus quantitative futility

Further defined in the fourth element are the distinctive aspects that differ between qualitative and quantitative futility. Medical futility is associated with interventions that are unlikely to produce any significant benefit for the patient.[8] Qualitative futility is treatment that is considered futile: if "it offers no reasonable hope of recovery or physiological improvement or because the person is permanently unable to experience any benefit."[16]

One such example of qualitative futility is the case of a 65-year-old retired corporate vice president who became ill with pneumonia, needed mechanical ventilation and was admitted to the intensive care unit (ICU). His treatment in the ICU became complicated by adult respiratory distress syndrome, prolonged ventilation requiring tracheostomy and subsequent chronic pulmonary insufficiency. During his stay in the ICU, cardiopulmonary arrest occurred. Resuscitation efforts were successful, but the patient suffered severe anoxic encephalopathy secondary to the cardiac arrest and remained in a persistent vegetative state. Three months after the cardiac arrest, the neurologist concluded that the patient's chances for a meaningful recovery were slim.

The caregivers spoke to the Orthodox Jewish family about a do-not-resuscitate (DNR) order, but the family refused the order, stating religious obligations to preserve life. After lengthy discussions, the health care team called in a bioethicist. Ultimately, CPR was determined to be physiologically futile, the DNR was written

against the family's wishes, and the family sought a court injunction to remove the DNR. The decision was upheld based on the Joint Statement on Resuscitative Interventions, a position paper published by the Canadian Medical Association.

A second case of qualitative futility is that of Helga Wanglie (see sidebar). The physician felt that ventilation was futile since it could not heal her lungs, palliate her suffering, or enable the unconscious patient to reap the benefit of the life enhanced by respirator support.[3] The husband claimed the patient only wanted to extend her life and valued any life, therefore, she was entitled to ventilation even though she was in a vegetative state. This case is one of a value judgment as the physician and the patient differ in opinion. The treatment was not futile from the husband's point of view, since the physiological effect was the extension of her life. The patient's autonomy to choose continued treatment was respected, albeit the physician felt there was no benefit to the treatment and deemed it futile. Both views are value laden. Medical futility is rooted in the belief that medical treatment will offer no physiological benefit to the patient. When addressing medical futility, many have found there is no clear, concise answer.

To better understand qualitative futility, it is more explicable to assign it a value. When determining if a treatment is futile using documented futility guidelines, health care professionals can look at the percentage or value determined for the probability of the treatment. For example, a surgeon might deem a treatment futile, unless it has at least a 10% chance of success, while the dilemma arises when the patient's family or surrogate might be willing to accept a 0% or 1% chance of success.[14]

Baby K is a classic case of medical futility based on a value system. Baby K was born with the terminal condition of anencephaly. The family felt the continuation of artificial respiration was a benefit even though there was a 0% chance of Baby K becoming conscious or having any quality of life. The mother felt that the ongoing condition of life was benefit enough. According to Dr Shelton, "Our society allows people to make irrational decisions in many areas of their lives, even if the life plans they have chosen have no chance of being achieved."[14] Can medical futility be defined in a society with such a tolerance for individual choice? This raises the ethical issue of allocating scarce resources. If we allowed scarce resources to be used on Baby K, is treatment denied to others who would benefit?

Quantitative futility is when the likelihood or probability that an intervention will benefit the patient is unlikely.[8] This concept, more evident in everyday clinical settings, is more likely to be received as standard everyday practice. A physician who prescribes antibiotics for a viral infection is practicing quantitative futility. The treatment will not benefit the patient; therefore, what justification does the physician have for prescribing the drugs? Is it accurate to assume that quantitative futility is influenced by the economics of treating patients? The physician is likely to prescribe antibiotics, since not doing so might compel the patient to seek treatment from another physician. Would the physician be culpable of medical futility if the patient did receive benefit from the antibiotic although the outcome was not anticipated when the drug was prescribed?

Another illustration of quantitative medical futility can be recognized in brain death criteria. According to Dr Doty, "The diagnosis of death is uncontroversial when made at the bedside by establishing the irreversible cessation of heart, lung and brain functions. When CPR and life support systems are used, brain death often occurs despite the reversal of cardiac and respiratory arrest."[3] It is conceivable that each time CPR is administered on a patient showing signs of brain death, the functions of heart, lung and brain are still reversible.

The use of chemotherapy for incurable cancer is a clear case of quantitative futility. Despite the administration of chemotherapy treatment, the patient will die. The empirical evidence docu-

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Landmark cases: the case of Helga Wanglie

The case of Helga Wanglie is one of informed demand for nonbeneficial medical treatment. Helga was an 85-year-old woman who was taken from the nursing home where she resided to the Hennepin County Medical Center on January 1, 1990 for emergency treatment of dyspnea from chronic bronchiectasis. She was intubated and placed on a respirator. Occasionally she was in discomfit and, although she recognized her family, she could not communicate very well. In May, attempts were made to wean her from the respirator without success. She was transmitted to a chronic care hospital. One week later her heart stopped during another attempt to wean her from the respirator. She was resuscitated and taken to another hospital for intensive care.[2] She remained unconscious.

The physician at the facility suggested it might be time to consider withdrawing life support. The family opted to transfer her back to a medical center on May 31. Two weeks later, physicians concluded Helga was in a persistent vegetative state (PVS) from the result of severe anoxic encephalopathy. She was maintained on a respirator with treatments of antibiotics, recurrent airway suctioning, tube feedings, air flotation bed and biochemical monitoring. In June and July of 1990, physicians suggested to the family that life sustaining treatment be withdrawn as it was not beneficial. Helga's husband, son and daughter insisted on continued treatment. "They felt the physicians should not play God, that the patient would not be better off dead, that removing life support showed moral decay in our civilization and that a miracle could occur."[2]

Wanglie at age 86 died of sepsis on July 4, 1991, after being in a persistent vegetative state for over a year. Her case was part of the controversy over the "right to die." The court case was held just three days prior to her death. Her husband and children wanted her life maintained at all costs, while the medical institution and doctors who were caring for her felt treatment was inappropriate and futile.

This case is different from the classic cases of Karen Ann Quinlan* and Nancy Cruzan in the fact that the family here was insistent on continuing treatment; whereas in the cases of Quinlan and Cruzan, they wished to suspend treatment. Mr Wanglie believed life should be maintained as long as possible, under any circumstances and he affirmed that his wife felt the same way.

The court favored on the side of Mr Wanglie, being consistent in the opinion that affirmed the right of the family to make decisions about life-sustaining treatment. Guardianship was granted to Mr Wanglie, and the judge felt the important message was who made the decision, not what decision was made. Since Mrs Wanglie was in a persistent vegetative state, she was not suffering. This eliminated the argument that her best interests were being violated by the continued use of the respirator. The hospital argued the case that the use of the respirator failed to serve her best interests and should not be continued. This argument allowed for victory for the hospital. If Mr Wanglie had won the court case, then it would mean that patients or families could demand treatments they wished, regardless of its efficacy. The media called attention to the fact that the expense of maintaining a patient on life support should be looked at when those resources could be used for people who would clearly benefit.[1]

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** Editor's Note: Karen Ann Quinlan was another landmark right-to-die case. The 21-year-old suffered brain damage and became PVS after drinking alcohol and taking tranquilizers at a party in 1975. After the family won a long legal battle to remove life support, Quinlan stunned the nation by breathing on her own after the respirator was unplugged. She continued to live without aid until 1985.*

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menting the outcome of treatment will establish whether a treatment is futile or not.

Establishing guidelines

In the 16th and 17th centuries, Roman Catholic moral theology created a distinction between ordinary and extraordinary care that states treatment was no longer obligatory, when it was extraordinary.[4] One defines extraordinary care as treatment that is inappropriate. Administering CPR to a person with a cardiac rupture would be futile and inappropriate treatment. Guidelines for medical futility should begin with the cessation of inappropriate treatment.

The process of death is different today than it was 100 years ago. End-of-life care was regularly administered at the bedside of the patient in their residence, but the advancement of technologies has moved the location to the health care setting. It is possible to prolong life due to the significant advances of medical technology, yet this intervention may not lead to a meaningful realization of goals for the patient.[12]

Another complication is the fact that the majority of patients have not designated advanced directives to guide their end-of-life care, thereby challenging the physician administering care to act in the patient's best interest.

It is also plausible that surrogate decision making and family disagreements will cause further debate when determining medical treatment by caregivers. The acceptance of medical futility by the physician, patient and family should not lessen medical care.

Futility has been established as a concept to guide physicians in avoiding the provision of inappropriate care that could be harmful.[4] Guidelines of futility should incorporate considerations for the chance of success, cost, life expectancy and the quality of life after treatment into the decision-making process when determining whether therapeutic treatments should be offered to patients.[4] Once treatment is deemed futile, a shift in the continuum of care should be initiated with attention to the provision of palliative care. Palliative care can improve the quality of a patient's life even though it may not prolong it. While assuring the patient's autonomy is respected, the issue of pain management should be considered the standard of care. Hospice care can be instituted to deal with end-of-life pain and symptom management.

In establishing guidelines, a patient's physician should possess initial authority to consider treatment futile, although it should not be solely a unilateral decision. When the physician deems treatment futile, written guidelines will clarify issues that could arise, since each physician has different thresholds for determining futility. First, established treatment options should guide the physician when explaining the reasons supporting the futility judgment. Second, written procedures should be established for the family, if they choose to challenge the futility judgment. Also, educating the family to the conditions of medical futility is essential before a policy can be enforced. Finally, ultimate authority to determine if treatment is futile should be decided by the medical profession and should conform to the well-established standards of care.[8]

The institution should also recognize the need to address the core element of the American health care system which asserts that all Americans will be provided with adequate health care. Good communication with the family is essential to promoting beneficence and nonmaleficence. The design of a medical futility policy should meet the needs of a community as a whole and not be construed as a custom-designed policy for a particular hospital. Many hospitals are afraid of any futility policy that could be construed as a method of saving money over providing quality health care. If possible, the medical community should establish a community-wide policy that would eliminate the possibility of hospitals being accused of practicing health care rationing and cost containment as the basis of their medical futility policy.

In 1991, the Patient Self Determination Act established advance directives to give patients and surrogates a voice in the determination of care. While this aided patients, it also opened

the door for a new set of problems. With this principle, a new trend evolved as families began demanding treatment and aggressive interventions that a physician deemed inappropriate. A policy that includes conflict resolution guidelines would aid physicians in cases where they arrive at a decision of futility when the family is in complete opposition. A physician making a judgment of futility might use documented empirical evidence that reveals the outcome of an intervention for the different groups of patients.[8] The evidence in futility should show that no significant likelihood exists for a significant benefit.[8]

This approach should be supplemented with continual dialogue with the family throughout the course of treatment. According to Solomon, studies show that physicians who are involved in decisions with end-of-life care find improvement in advance care planning, quality of end-of-life decision making and lower resource utilization, when they have established an institutional routine that requires conversation about the goals of care.[15] Without these guidelines in place, medical staff often communicate unrealistic hope to the family when they fail to provide honest information regarding the patient's condition. This can produce extremely harmful discord and lack of trust between the family and caregivers.

Goals of care assessment tool (GCAT)

"The use of structure instruments that gather and organize data needed to make judgment about appropriate goals of care can be beneficial for clinicians and families."[15] The Goals of Care Assessment Tool (GCAT) is used to collect relevant clinical and narrative information crucial to the formulation of rational goals of care at the end of life.[15] The GCAT directs the clinician to estimate the patient's prognosis and convey whether the patient or surrogate knows the diagnosis and prognosis. It also lists the presence or absence of do-not-resuscitate orders and advance directives, family support and involvement, as well as pertinent psychosocial or cultural issues.[15] Pain and symptom management are also addressed. Once the information is assembled, the caregiver is instructed to formulate goals for care and interventions that will help achieve the goals. The GCAT can also be utilized when a change occurs in the patient's prognosis. Directions prompt for information about patient or surrogate knowledge regarding a terminal diagnosis or prognosis, preferences for palliative care and whether there is an expressed desire for death. It also includes information to complete a do-not-resuscitate order.

Instruments like the GCAT can promote a collaborative process for end-of-life decision making in institutional settings by providing a structure for caregivers to work with patients and families. This will assist clinicians in obtaining pertinent information that is essential to adequate decision making to minimize futility disputes and facilitate palliative care interventions.[15]

Conclusion

As the medical community struggles to establish acceptable medical futility guidelines, it is important to incorporate community values in the continuum of care and emphasize the quality of life that will be provided by that treatment. It is possible to provide care for the medically futile patient and yet maintain the patient's right for autonomy? Physicians or institutions should have the right to refuse treatment they deem to be inappropriate or extraordinary as long as the patient's family has been informed of these guidelines. Physicians should be honest with their patients and family members, as this would direct treatment that would be most conducive to the patient and alleviate much of the unrealistic hope family members have as they accept the reality of treatment being medically futile.

Even though it has been unfeasible to agree on the terms and guidelines of medical futility in the past, the medical community should continue to pursue this goal. As medical technology advances, it provides opportunity to treat the untreatable and thus it will become even more important to carefully designate care only to those who will benefit and not provide oppor-

tunity to those by treating medically futile patients, forcing physicians to spend valuable medical resources on patients who cannot benefit from them. Perhaps, health care professionals can look to Aristotle for wisdom when creating a discipline for medical futility, for it is he who said, "What lies in our power to do, it lies in our power not to do."[2]

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For additional online information about the Goals of Care Assessment Tool (GCAT) visit ***www.informed.cme.edu/material/WVPM0203.pdf***