Bioethics *in brief*

April 2005

UNIVERSITY HOSPITAL OF SUNY UPSTATE MEDICAL UNIVERSITY SYRACUSE, NEW YORK

CASE OF THE MONTH

Medical Futility

CASE

AZ, an 86-year-old man with end-stage Alzheimer disease, congestive heart failure, recurrent aspiration pneumonia, pulmonary fibrosis, and Parkinson disease, was admitted to the hospital from a nursing home with adult respiratory distress syndrome. He was placed on a ventilator, from which he has been unable to be weaned over a period of three months, and is minimally conscious. Since admission he has required a tracheostomy and operative placement of a stomach feeding tube.*

Five years ago, when his Alzheimer's disease was diagnosed, AZ created a living will, witnessed by his lawyer, refusing all life-supporting treatments when his dementia became severe. He also named Ms. Z, his daughter, as his health care proxy (HCP) agent. Ms. Z says that her father revoked his living will in conversation with her after he returned from the lawyer's office, claiming he did not understand what the lawyer had written and "wanted to live." Currently, AZ does not recognize his daughter, and cannot walk, talk or feed himself. Prior to this admission, AZ's life expectancy was less than six months.

AZ's attending physician, Dr. A, asks Ms. Z to consent to a Do Not Resuscitate (DNR) order, stating "he will never get off the ventilator, and cardio-pulmonary resuscitation (CPR) just wouldn't work." Ms. Z refuses. Dr. A calls for an ethics consultation because she believes that CPR would be futile. The ethics consultant advises Dr. A that she cannot put in place a DNR order based on futility over the objection of Ms. Z; however, dispute mediation is available. Eventually the case goes to court. The judge agrees with Ms. Z but rules that both the living will and the HCP had been revoked, so that Ms. Z is no longer the health care agent. Mr. Z is weaned from the ventilator and returns to his nursing home. One day later Mr. Z is re-admitted to the hospital in respiratory distress and reattached to the ventilator. A son in Hawaii consents to a DNR, and Mr. Z dies after a cardiac arrest while still on the ventilator.

**names and other identifying details have been changed.*

DEFINING FUTILITY

"Medical Futility" has been described in a variety of ways, including: 1) failing to provide benefits such as healing disease or providing comfort; 2) inability to accomplish intended goals; 3) merely preserving permanent unconsciousness, total dependence, or ICU existence (poor quality of life); 4) treatment effective in less than one case in 100 (statistical futility); 5) treatment that can't work physiologically (for example, treating a virus with penicillin); and 6) treatment not appropriate to the goals of medicine (e.g., maintaining a brain-dead patient on a ventilator).

The physician's claim that CPR for AZ is futile may really be an expression of the frustration of dealing with AZ's daughter, who wants CPR even though it has only a small chance of restoring life, and would not improve the patient's baseline condition. Indeed, the physician may actually see CPR as cruel and harmful, or only supportive of a very low quality of life. However, a patient's quality of life is best determined by the patient/family and not the physician. New York law on "Orders Not to Resuscitate" defines CPR as medically futile when "…cardiopulmonary

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Bioethics in Brief is a newsletter of the Center for Bioethics and Humanities, in cooperation with University Hospital's Ethics Committee.

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Have a question about an ethical issue?
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Design and production: Marketing and University Communications, Melanie Rich, Director

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SUNY Upstate Medical University
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MEDICINE AT ITS BEST®

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Medical Futility

resuscitation will be unsuccessful in restoring cardiac function or the patient will experience repeated arrest in a short period of time before death occurs." CPR is commonly thought to be unsuccessful if the patient does not live to discharge from the hospital (which may take days, weeks, or months). The average success of CPR to discharge from the hospital is around 14 percent. In the case of a terminally ill patient like AZ, the success rate to discharge of CPR is about three percent. However, it is difficult to predict the response of an individual patient like AZ to CPR. One could make a good case for futility of DNR for patients who are unable to sustain their blood pressure even with pressor agents.

"NOW THE TABLES HAVE TURNED. IN SOME CASES, PATIENTS AND FAMILIES WANT TO CONTINUE TREATMENTS IN THE FACE OF IMMINENT DEATH, AND PHYSICIANS ARE MORE LIKELY TO CRY 'FUTILITY.'"

WHY DO PHYSICIANS/ NURSES WORRY ABOUT FUTILITY?

Not long ago, physicians and hospital administrators argued that all dying patients who need life-supporting measures should get them. The idea of being tethered to ventilators and feeding tubes did not seem like dignified dying to some patients and families, and they rejected it.

Now the tables have turned. In some cases, patients and families want to continue treatments in the face of imminent death, and physicians are more likely to cry "futility." Behind this is the desire of physicians not to cause harm to patients without evidence of overriding benefit. With AZ near death, CPR or another aggressive treatment might actually be considered disrespectful. Some physicians may consider the potential legal liability of overriding AZ's previous wishes not to be resuscitated, or the liability of ignoring Ms. Z's wishes should the patient arrest and die. Many physicians feel they are not morally obliged to provide treatments which they believe are futile, yet they may be unwilling to burden colleagues by seeking to transfer the patient to another physician or hospital. Other physicians, even in the face of futility, feel they would be abandoning their patient if they resigned from their care, especially in end-of-life situations.

Finally, health care providers are also stewards of hospital and community resources, such as ICU beds, and should worry about using these resources wisely.

WHAT DO THE MEDICAL PROFESSION AND THE LAW SAY ABOUT FUTILE CARE?

The American Medical Association states that physicians are not ethically obligated to deliver care that, in their professional judgment, will not have a reasonable chance of benefiting the patient. The New York State Task Force on Life and the Law states: "…neither patients nor those who decide in their behalf have…the right to insist on treatment that offers no…benefits in terms of cure, care, or the prolongation of life.… Physicians… have no duty to provide treatment that is futile…." New York physicians may enter a DNR order based on futility without approval of the patient or surrogate only when the patient lacks capacity and there is "…no surrogate… reasonably available…willing… or competent to make a decision."

In cases of disagreements regarding DNR orders, University Hospital has a dispute mediation process that can be initiated by calling the chair of the ethics committee or hospital administration. In the case of AZ, where the court invalidated his living will and HCP, if Mr. Z's son, as a legal surrogate, refused to consent to DNR after dispute mediation, there would be no way to override Ms. Z's wishes, short of going back to court.

FUTILITY AND THE GOALS OF TREATMENT

Whether it is futile to artificially feed a patient with end-stage dementia depends on the goals of treatment. If the goal is to keep AZ alive, artificial feeding is not futile. If the goal were to allow AZ to improve his cognitive and physical function, most would agree this goal cannot be met and is therefore futile.

AN APPROACH TO FUTILITY

In cases where medical futility is a concern, the following protocol has been suggested. 1) Explore the request for seemingly futile treatment. What are the values of the patient/surrogate? Knowing AZ's and his daughter's religious beliefs might help us understand Ms. Z's desires to maintain her father's life, even on a ventilator. 2) Take time to fully consider with patient/surrogate the pros and cons of treatment. Many people do not understand how infrequently CPR succeeds in a terminally ill patient, or what the physical or neurological consequences may be. AZ probably has a less than three percent chance of leaving the hospital alive if he has a cardiac arrest. 3) Try respectful persuasion. If you feel strongly that a treatment cannot work or will cause great harm and little benefit, continue the discussion with the patient/surrogate or get another opinion. Would Ms. Z or AZ's minister or a chaplain be helpful? 4) Set goals for questionably futile treatment with the patient/surrogate. Perhaps Ms. Z and her physician might agree to try CPR once and then if the patient did not recover to pre-DNR status or show other desired improvement, not to try again. Trials of questionably effective treatment, called time-limited trials, can apply to the use of a ventilator, feeding tube, antibiotic, dialysis and any life-supporting treatment. Of course, if after the allotted time the hoped-for improvement has not happened, the patient/surrogate may back out of the treatment plan. 5) Get an ethics consultation. Thoughtful consideration and a full hearing of Ms. Z's concerns/fears/hopes may lead to compromise. 6) If you find providing "futile" treatment morally objectionable, after discussing your concern with the patient/surrogate, arrange to transfer the patient to another physician or institution if possible.

ETHICAL TENSIONS

Futility is difficult to define or prove. Concerns about futile treatments that may polarize physician and patient/surrogate relationships demand thoughtfulness and consideration of the patient's/surrogate's beliefs and values. Probably it will take the cooperation of our community's hospitals in dialogue with its citizenry to put in place a policy on futile medical treatment that most of us can accept. The AMA recommends that hospitals develop a policy on futility. Hospitals in some communities, such as Houston, TX, have taken this a step further and have joined together to adopt a shared policy on futile treatment. Currently, University Hospital does not have a separate policy on futility. ■

—Joel Potash

ETHICS Q&A

Q: A patient with end-stage heart failure and pneumonia was transferred out of the ICU to my service because her family had chosen "comfort care." Does "comfort care" mean that I should stop her antibiotics? What about the intravenous fluids?

—Perplexed Intern

A: "Comfort Care" is not a precise order set and can be interpreted differently by various clinicians, patients, and family members. In many respects, all patients want to be comfortable, and comfort should be an explicit consideration in everyone's care. The use of the term "Comfort care" (or, occasionally, "Comfort care only") generally implies that the patient has forgone interventions that might, although at the cost of some discomfort, improve his/her underlying illness or extend the patient's life, and that the focus of care is now the patient's comfort.

To that end, assuming that clinicians, family, and (if able) the patient shared this understanding, anything that would contribute to a patient's comfort ought to be continued, and anything that does not make the patient more comfortable ought to be stopped. If antibiotics were relieving dyspnea or cough, they should be continued. If, however, the patient was comfortable and any sense of dyspnea was relieved by oxygen, antibiotics might be discontinued. Checking routine labs does not contribute to patient comfort (and causes some pain) and should be discontinued. Among imminently dying patients, continued administration of intravenous fluids increases lung secretions and worsens respiratory distress, making patients less comfortable in the final stages of dying. Experts from the Palliative Care Service are helpful in sorting out these issues of comfort and the means to achieve it.

Properly understood, "Comfort care" clarifies the goals of care and is a useful yardstick for determining which interventions should be continued, which should be started, and which should be discontinued. ■

—K. Faber-Langendoen, MD

HOT TOPICS IN BIOETHICS

Human Growth Hormone

Only 20 years ago, the only source of human growth hormone (hGH) was cadaveric pituitary glands, and its use was restricted to children with diagnosed growth hormone deficiency. The advent of biosynthetic hGH in 1985 has led to an enormous expansion of supply, though growth hormone therapy is still extremely expensive at a minimum cost of $15,000 per year.

The FDA has approved growth hormone therapy for the treatment of growth hormone deficiency, chronic renal insufficiency, and for certain genetic conditions such as Turner Syndrome and Prader-Willi Syndrome. Beyond unjustified claims about anti-aging effects and athletic performance enhancement, the most controversial use of hGH is the treatment of idiopathic short stature (ISS). ISS is not a disease; it simply means that a person's height is below the 2nd percentile of age and gender specific national norms, and that the shortness is unassociated with any known cause.

Critics of hormone therapy make a distinction between "treating" a diagnosed hormone deficiency and "enhancing" the height of someone with ISS. The effectiveness of growth hormone therapy for ISS is also in question since, on average, it may yield only a one- to three-inch gain in height. Supporters of hGH therapy argue that people with short stature experience physical and psychological harm due to their height, and that ameliorating this harm ought to be a primary concern of physicians. Though above-average height is correlated with social benefits like income and social esteem, recent studies of social stigma and stature in high school students found no correlation between height and peer perception.

Whether shortness should be seen as something that demands treatment is a complex issue. Although some parents and physicians believe that the correlation between height and social benefits gives reason enough to use hormone therapy, there are no guarantees that such treatment will increase a child's success. And long-term effects of such treatment are not yet known. ■

—Fareed Awan

Registering Clinical Drug Trials Regardless of Outcome

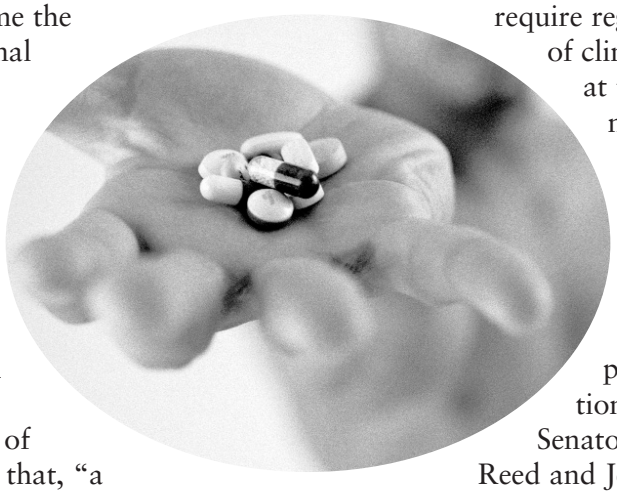
The movement to create a national registry for clinical drug trials is gaining support, although not from the pharmaceutical industry. On June 17, 2004, the American Medical Association (AMA) announced its recommendation that the Department of Health and Human Services create a centralized registry for all clinical trials, whether publicly or privately funded. The AMA also suggested that institutional review boards require registration in the database before a study is approved. A national registry would make it easier for clinicians and researchers to access information on drug trials, and would allow all clinical trials to be evaluated. Drug trials with negative results are often never published, especially if conducted privately by a pharmaceutical company.

HAS THE PUBLIC BEEN MISLED?

The AMA's recommendations came soon after New York State Attorney General Eliot Spitzer filed a lawsuit against GlaxoSmithKline. Spitzer alleges that the company misled the public by concealing information about the antidepressant Paxil. GlaxoSmithKline did not report the evidence of increased suicidal thoughts among children taking Paxil, nor did they report that the drug causes severe withdrawal symptoms. In September, Merck withdrew its popular arthritis drug Vioxx from the market, leading to the more troubling revelation that Merck had been aware of the dangers with this drug at least four years earlier.

HAVE PARTICIPANTS BEEN DECEIVED?

While drug companies, including GlaxoSmithKline and Merck, have reported they will provide information about all late-stage clinical trials, the industry does not seem to welcome the idea of a national registry. In an article by the Associated Press on June 17, 2004, Alan Goldhammer of the Pharmaceutical Research and Manufacturers of America stated that, "a public registry could lead to misrepresentation, especially if it lacked specifics including details on study size." While this may be true, providing sufficient information about each trial would prevent any misinterpretation.



Supporters of a national clinical trials database argue that a contract between researcher and subject is broken if the information from the study is not made available. Participants are told that they will probably receive little or no direct benefit, and that they are contributing to a greater societal good. They believe doctors will learn from the study, no matter what the results, and that others will benefit from the research. If the information is not released, the subjects have been deceived since nothing is learned.

REGISTRATION BEFORE PUBLICATION?

To support the development of a national database, the International Committee of Medical Journal Editors is considering a policy that would require registration of clinical trials at the beginning of the study, in order to be considered for later publication. U.S. Senators Jack Reed and Jeff Bingaman have also taken action by writing to Deputy Commissioner Lester Crawford of the Food and Drug Administration (FDA), asking how the FDA plans to make the clinical trial process more "transparent."

The FDA and the Department of Health and Human Services have yet to respond to these recommendations and inquiries. Recent disclosures about Vioxx, Paxil, and other drugs, however, give this initiative substantial momentum. ■

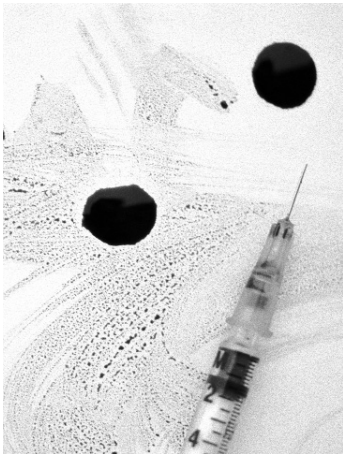
—Michelle Waite

Do Physicians Have a Duty to Treat in the Face of a Disease Outbreak?

When a 10 year-old girl in Rockford, Illinois, contracted monkeypox last year (one of more than 30 confirmed cases in the Midwest), some health care professionals refused to treat her. One physician and nurse team, husband and wife, cared for her through recovery. Both had recently been vaccinated against smallpox, the best protection against other forms of the pox virus. In times of disease outbreak, is there a duty to treat, despite perhaps significant personal risk? Or should we see the choice to care for the sick in the face of a contagious, naturally-occurring disease — or an intentional bioterror attack — as heroic self-sacrifice?

Ethical codes and extant law offer no definitive answers. Principle VI of the AMA Code of Medical Ethics embraces the general principle that physicians as a group are free to choose their patients, except in emergencies. The AMA position stands in stark contrast to its first Code of Ethics (1847) which proclaimed that physicians should face the dangers of pestilence even at risk of death. Post-9/11, the AMA House of Delegates adopted a Declaration of Professional Responsibility (less authoritative than the Code) calling on physicians to affirm a social contract to accept risks in service to humanity. But whether this signals a return to the high ideals of an earlier era remains to be seen. The Declaration offers no clarification of the nature or magnitude of risk physicians should be prepared to accept in response to contagion. Emergency physicians are perhaps unique in their embrace of a more specific "ethical duty to respond" to disasters as "a special resource" in the community, unqualified by the degree of personal risk.

Echoing the AMA, the law embraces the foundational premise that physicians are free to choose their patients. Under the federal Emergency Medical Treatment and Active Labor Act (EMTALA), hospitals with emergency services are required to accept every patient and to diagnose and stabilize the patient's condition regardless of ability to pay. And public hospitals are legally bound to open their doors to all. But these limited rights to emergency care establish no uniform duty of physicians or other health care providers to respond to medical emergencies beyond the institutional setting. Most state "Good Samaritan" laws are grounded in the free-to-choose philosophy. These laws typically encourage and reward going to the aid of others with the promise of immunity from liability, but do not require health care providers to do so. This may be "part of the job" for MICUs, firefighters and other first responders, but generally the law does not translate heroism into legal obligation.



Experience with the HIV/AIDS epidemic offers some limited lessons. Here the health professions firmly embrace a duty to treat (as does disability and nondiscrimination law). But comparison to other infectious or contagious diseases offers only an imperfect analogy. Formal statements of the duty to treat HIV/AIDS patients typically identify the professional's personal health risk as a countervailing consideration; they do not articulate an absolute duty. For example, in the early years of the epidemic the American Nurses' Association identified a "special" duty to treat, a duty not to "walk away from those in need," but also embraced the proviso that care should not "present more than minimal risk to the health care provider."

Today's medicine offers effective protection against and treatment for HIV infection, but if, by comparison, medicine's arsenal against other deadly agents is weak, can it fairly be said that the

risk is minimal? Whether physicians, nurses, and public health personnel are duty-bound to put themselves at more than minimal risk in the face of highly infectious, possibly life-threatening disease is ill-defined. Last year's SARS outbreak illustrates that reasonable persons can disagree about where to draw the line between acceptable and obligatory risk and substantial and optional risk-assumption.

The health professional's calling involves inherent occupational risk. Today's public health threats, like past epidemics, lack a coherent professional ethic delineating the parameters of a duty to treat. Such an ethic should seriously consider how much risk physicians, public health and other health care workers should be expected to accept.

Deeper reflection on the nature and scope of the duty to treat warrants careful assessment of both public health benefits and associated professional risks, such as occurred in recent debate over the administration's plans for smallpox vaccination. Many believe that physicians and public health workers ought not be compelled to accept arguably significant risks associated with vaccination against a disease. Should they be duty bound to treat those afflicted with this very same disease? ■

*—Robert S. Olick**

* Portions of this essay are adapted from Robert S. Olick, "Ethics, Epidemics and the Duty to Treat," *Journal of Public Health Management and Practice* 10(4) (July-Aug. 2004): 366-67.

Gattaca: There Is No Gene for Ethics. Yet.

Film is a useful teaching instrument that can present bioethical principles in an entertaining as well as informative package. Film also speaks to our media-oriented generation of students, illustrating the social potential and dangers of scientific and medical breakthroughs in a spectacular and seductive medium. Because movies engage our emotions and our imagination, they invite us to identify with characters and their plights, involving us more deeply in the ethical problems.

Gattaca (1997, dir. Andrew Niccol) is set in a future time when social divisions are determined by genetic makeup, and genetic screening for identity is as common as our use of employee ID badges, ATMs and credit cards. The society depicted in *Gattaca* is divided into the genetically engineered elite (the "Valids") and the "In-Valids" or "de-generates"—those un-engineered individuals who comprise the laboring underclass of their society. The story depicts one such "In-Valid," Vincent Freeman, overcoming his culture's DNA-based prejudices with sheer determination and subterfuge. In the process, he raises many of the issues we are currently debating as science unravels the genome and attempts to improve upon human nature. Only by using another man's bodily fluids is Freeman able to "pass" for perfect and achieve his dream of becoming an astronaut, leaving Earth and its prejudices behind.

Gattaca presents the main concern of the film, genetic engineering, within a social context with the complications of the kinds of ancillary problems one would encounter in our world. The Internet abounds with websites offering great suggestions for using *Gattaca* to teach bioethics. Two good ones are **BioTeach (http://bioteach.ubc.ca/TeachingResources/Bioethics/GATTACAActs.html)** and **Bioethics and the Movies (http://www.cbhd.org/resources/movies/adam_2003-07-14.htm).** ■

—Rebecca E. Garden, PhD

Center for Bioethics and Humanities
750 East Adams Street
Syracuse, New York 13210

05.046 0305 6610 UBC