Medical Ethics Collides With Public Policy: LVAD for a Patient With Leukemia

Patrick M. McCarthy, MD, Richard D. Lamm, LLB, CPA, and Robert M. Sade, MD

Division of Cardiothoracic Surgery, Northwestern University, Feinberg School of Medicine, Chicago, Illinois; Institute for Public Policy Studies, University of Denver, Denver, Colorado; Department of Surgery and the Institute of Human Values in Health Care, Medical University of South Carolina, Charleston, South Carolina

Introduction

Robert M. Sade, MD

There is a general perception that too much money is being spent on health care, and that costs are rising too rapidly. One source of the problem is believed by some to be the widespread use of expensive technologies, and this logically leads to a potential solution: get physicians to stop using such technologies. Obvious targets are cardiothoracic surgeons who have access to a substantial number of expensive technologies and a substantial number of patients to use them on.

To highlight some of the issues underlying the question of whether utilizing such technologies is justified, a case was constructed to illustrate the use of an expensive technology in a marginal clinical situation: a left ventricular assist device (LVAD) implanted in an older man with leukemia and an uncertain prognosis. To argue the question of whether or not the procedure was warranted, we recruited two outstanding proponents of differing views: Dr Patrick McCarthy, a cardiac surgeon who has broad experience with LVADs, and former Governor Richard Lamm of Colorado, one of the few public figures audacious enough to use the word “rationing” publicly. They presented their viewpoints at the Forty-first Annual Meeting of The Society of Thoracic Surgeons. The case that served as the focal point of their discussion is detailed as follows.

A 62-year-old male carpenter, Mr I. Sandy Wood, noticed that he was tiring much earlier in the day than he had just a few weeks before, and that the frequent small cuts he received at work bled much longer than in the past. His family doctor ordered a battery of laboratory tests that revealed acute myelogenous leukemia. Echocardiogram at that time was normal, with a left ventricular ejection fraction of 63%. He was told that the chance of ultimately curing his acute myelogenous leukemia with appropriate chemotherapy was about 40%, and that nearly all relapses occur within 2 years of treatment. He underwent a full course of chemotherapy, including both cytosine arabinoside and idarubicin for induction, later followed at 3 and 5 months by consolidation courses of high-dose cytosine arabinoside. Aside from nausea and fatigue during chemotherapy, he did well.

Five months after the end of chemotherapy, Mr Wood noticed increasing shortness of breath, generalized weakness, and ankle edema. An echocardiogram demonstrated a left ventricular ejection fraction of 19% and cardiac catheterization showed mild obstruction (25%) of the left anterior descending artery. Endomyocardial biopsy showed damage consistent with idarubicin-induced cardiomyopathy. Medical management included appropriate doses of an ACE inhibitor, beta-blocker, loop diuretic, spironolactone, and digoxin.

Despite intensive outpatient management, his dyspnea and edema continued to worsen, and he became dyspneic at rest. He was hospitalized 3 times during a 4-month period, requiring intravenous inotropic support and high-dose intravenous diuretics. During his third hospitalization, he failed to respond to intravenous drug therapy, and a repeat echocardiogram demonstrated an ejection fraction of 10%. He was deemed not to be a candidate for heart transplantation because of his recently active leukemia. Because he appeared unlikely to survive for more than a few weeks, he was evaluated as a candidate for support with a left ventricular assist device (LVAD) as destination therapy, was found to meet the criteria for support, and underwent placement of a HeartMate LVAD.

His postoperative course was initially uncomplicated. On the second postoperative day, the patient became febrile and was found to have septicemia with staphylococcal pneumonia. He was treated with intravenous antibiotics for 4 weeks. His septicemia cleared immediately and his pneumonia gradually improved. His LVAD flows stayed in the range of 6 to 7 L/min and he was discharged from the hospital in good condition on postoperative day 46. His health insurance company paid the discounted cost of the hospitalization and physicians’ fees, totaling $210,000. The company also agreed to pay the costs of any needed hospitalizations, estimated to be in the range of $105,000 a year. At that time, it was estimated that the LVAD gave him a 40% to 50% chance of surviving 2 years if his acute myelogenous leukemia did not relapse.
Ten months after implantation of the LVAD, Mr Wood was feeling well and walking 2 miles a day; his acute myelogenous leukemia was still in remission, now 2 years after treatment began, and therefore it was probably cured.

**Pro**

Patrick M. McCarthy, MD

The debate about the use of left ventricular assist devices (LVADs) for destination therapy has been with us for many years. An undercurrent has circulated, sometimes highly visible as in the opinion from Governor Lamm, that we will create another dialysis program, another costly burden on a burgeoning health budget under loose control [1]. The hypothetical case report in this issue of the journal crystallizes our thinking on the issues [2]. Rather than consider the medical wisdom of this issue of the journal crystallizes our thinking on the issues [2]. Rather than consider the medical wisdom of treating a cancer patient with an LVAD, let's take a fresh look at the "bigger issue" (not bigger to the patient and his family however!). How much will the United States LVAD program cost, and is it "worth it"?

First, the vast majority of the readers of this article will have to admit to a serious conflict of interest. We took an oath to treat the sick according to our ability and judgment. Nothing in the Hippocratic Oath speaks to cost of therapy, rationing, or withholding available therapy because society cannot afford it [3]. This has brought us trouble before. Coronary artery bypass was controversial when introduced because it was expensive. However, it is part of our sworn duty as physicians to offer treatment, and fortunately millions of patients are alive after having heart surgery who now thank us for it.

Let's be clear about how much money is at stake. The Institute of Medicine projected that 50,000 United States patients per year were potential destination therapy LVAD recipients [4]. If each LVAD (with batteries, support equipment, and so forth) cost $100,000, that would cost $5 billion. If hospitalization, surgery, intensive care unit stay, and so forth cost another $100,000, that would add another $5 billion, or $10 billion total. The $200,000 per patient is very similar to the Randomized Evaluation of Mechanical Assistance in Treatment of Chronic Heart Failure (REMATCH) cost ($210,187) [5].

The REMATCH experience taught us more about patient eligibility too. For each patient placed in the trial, almost 50 were screened [6]. Medical comorbidities are frequent contraindications to destination therapy (ie, diabetes with secondary complications, prior stroke with residual deficits, chronic renal failure, and elderly frail patients to name a few). Psychosocial issues may also be a problem, such as medical noncompliance and drug or alcohol abuse. Also, some patients just don't want destination therapy; they've "had enough." These factors rarely weigh heavily in the decision to use other implantable devices, such as pacemakers or implantable cardiac defibrillators, but because LVADs still require daily care and maintenance, these are important factors that limit the spread of current LVAD use.

Perhaps 10,000 patients per year would be more reasonable, which translates to $2 billion per year. Finally, the surgeons and cardiologists cull even more of the potential patient population. The medical team weighs the morbidity and mortality of the operation and the potential for LVAD infection, emboli, and device failure versus the expected gain in quality and length of life [6, 7]. Even though the HeartMate device is Food and Drug Administration approved and reimbursed by the Centers for Medicare and Medicaid Services (albeit at a low level), the true number of implants is much less than 1,000 per year, or $200 million in health care expenditures. Also, consider that this is money returning to our economy.

This adds to the healthcare bill though, and the accelerating rise in healthcare spending relative to inflation. But we are not alone. Our spending on prison populations increased from $9 billion to $49 billion between 1982 and 1999, a 444% jump [8]. Also, is $10 billion too much to pay for all potential LVAD patients? Advertising and promotions for cigarettes and tobacco products in 2001 cost $11.2 billion [9]. Which would be money better spent? Perhaps a more conservative cost of LVADs would be more appropriate, such as $2 billion for 10,000 patients. After all, United States revenue at McDonalds in 2003 rose to its highest level ever, $6 billion, due to numerous factors including Americans spending on the new McGriddle breakfast sandwich [10]. The most conservative spending on LVADs, $200 million, perhaps, is reasonable to save a thousand lives. To put this in perspective, we spent $213 million just at the box-office on "Austin Powers in Goldmember" [11]. Is it unreasonable to suggest that patients should help pay part of the $100,000 for this life-saving device? In 2001, the average retail selling price of a new vehicle was $25,800 [12]. The Transportation Department reports there are 107 million United States households with an average of 1.9 cars, but only 1.8 drivers [13]. For the first time there are more vehicles than people to drive them.

Governor Lamm has written: "To avert a collapse of the system, citizens and policy makers must come to grips with the fact that they cannot do everything for everyone" [14]. He was referring to regulation of the healthcare system. But as a former policy maker, as our government deepens its deficit spending to try to protect everyone from everything, is he equally outraged by the revived $10 billion dollars per year spending on a missile defense system (ie, Star Wars) [15]? Finally, if the policy makers and citizens didn't want us to use these devices, then why did they invest hundreds of
millions of dollars through the National Institutes of Health to help us develop them?

These are difficult questions and there are no easy answers. How we as a society spend our money in relative terms is an issue most cardiac surgeons ponder only rarely. If I had been asked to see the patient described in this report, I probably would have acted as those clinicians did. I would have tried to relieve his suffering, improve his quality of life, and hopefully prolonged his life. Those collective actions by thousands of physicians, motivated by an oath we swore when we took this job, have led to the rise in healthcare spending. One last question: Is that such a bad thing? It seems there are worse ways to spend your money.

Con

Richard D. Lamm, LLB, CPA

Decisions evaluating LVAD support in stage D chronic end-stage heart failure patients cannot be made in a vacuum. Let me suggest a proposed procedure that we should go through to truly evaluate the practicability of such a technology. Taxpayers now fund over 50% of United States health care. We can metaphorically be said to have half-socialized medicine in the United States. But LVAD support needs to be evaluated by all third party payers. When government spending is added to insurance payments, 83 cents out of every dollar in American health care is paid for by third party payers, either government or health insurers. We need to develop a system for answering this question that looks beyond individual patients, for when we fund health care with commonly collected funds, everything we do prevents us from doing something else. As General George Marshall said during WW II, “When deciding what to do, one is also deciding what not to do.”

You can’t build a modern health care system an individual at a time, and you can’t adequately evaluate an individual technology in isolation of all other needs of the funder's system. The sum total of our ethical choices, an individual at a time, has given us an unethical health care system. We see the trees but not the forests. Left ventricular assist devices compared with what? Barney Clark, the first recipient of an artificial heart, did not exist in a vacuum, but as a member of a society with a myriad of public needs. Humana’s budget for the artificial heart was approximately the same as the world spent eradicating smallpox. Barney Clark and chronic end-stage heart failure patients exist in an empirical world of many needs and demands. We cannot optimize their care and ethically deal with the whole society at the same time. Most ethical theories are built around individuals and do not take into consideration the cumulative impact of those ethics.

Unavoidably, there is a conflict between individual goods and societal goods. No person sees his or her health care in context with the other health needs of society. Just as every driver in a traffic jam pleads “not guilty,” so also no patient ever sees his or her health care as “too expensive.” But someone must set limits. We cannot simultaneously optimize the health of the individual and the health of a group.

Medical research into increasingly marginal health care such as the LVAD is crowding out many of the other needs of society. We are developing more and more high-cost, low-benefit medical technology in a society that offers health care to fewer and fewer people at a higher and higher cost. As former National Institutes of Health Director Harold Varmus has observed:

“We have a problem in this country in that there is nothing people place a higher value on than a healthy life, but I’m concerned about two things—the number we allocate to health becoming just too great to sustain even for people who are relatively well to do, but more troubling is the idea that we’re going to cut a very significant portion of our population out of the benefits of certain kinds of approaches to health that were paid for by public money and ought to be publicly accessible” [16].

The LVAD, like the artificial heart, becomes less important when we lift our eyes from Barney Clark’s bedside and view total unmet social needs.

Public policy is a different world from that of the medical bedside. Medical ethics can educate and enlighten, but they cannot control public decision making. Medical ethics are useful and hold important information but not the full picture that must be considered by third party payers. The only way third party payers have of saying yes, is saying no somewhere else. Making optimum social policy is “terra incognito” that must be mapped anew.

We are judging much of what we do and expect in health from an unsustainable yardstick. No matter how we organize and no matter how we fund health care, we will find our medical miracles have outpaced our ability to pay. It is hard to change our thinking after years of blank check medicine, but it is necessary. The price of modern medicine is to decide what to cover among the smorgasbord of treatments currently available. This is painful, but unavoidable.

Once government starts to play a role in health care, it has to prioritize needs and set limits. This is being done worldwide. The method varies, but all set limits. We are fooling ourselves when we do not admit that we ration. In fact, we limit health care in one of the cruelest ways that any nation can limit medicine by simply leaving people out of the system.

We can give compassionate and comprehensive health care to all our citizens, but we cannot give everything. We shall have to decide among a myriad of things we can clinically do in modern medicine, and what we ought to do with our
limited resources to meet all our social needs. It is doubtful that in a nation that has 43 million uninsured citizens that the LVAD would make the cut for third party funding.

In a world of limited resources, you cannot explore the best use of your resources, the so-called “opportunity costs” of each dollar unless you set priorities on what you can afford. We must start a community dialogue about how we can put our health care dollars to the highest and best use. It is an inevitable dialogue and we ought to make a virtue out of necessity.

I believe that we cannot solve our health care challenges within the current dialogue and thinking. When we focus so exclusively on treating individuals with medical care, we miss many public health measures that could gain even more health for both our society and us individually. We find ourselves in a public policy catch-22, in which public policy historically relies on medical culture and ethical standards that are bound to bankrupt it, while at the same time allows us to ignore larger, more important, nonmedical funding for other social needs. Our health care system allows us, indeed encourages us, to ignore the big picture. We fail to ask, “With all this talk about medical ethics one individual at a time, do we have an ethical system?”

No profession can claim public resources in isolation from other social needs. From a public policy viewpoint we have built the house of ethics on an inadequate foundation. To the extent that taxpayer monies fund our health care system, that system must prove its worth amidst all competing social needs. Our health care system must be consistent with our economic realities and the survival of other social priorities. The ethics of good intentions must be grounded in economic reality. Government simply cannot write into law, nor can it base a reimbursement system on an inadequate foundation. No profession can claim public resources in isolation from other social needs. From a public policy viewpoint we have built the house of ethics on an inadequate foundation. To the extent that taxpayer monies fund our health care system, that system must prove its worth amidst all competing social needs. Our health care system must be consistent with our economic realities and the survival of other social priorities. The ethics of good intentions must be grounded in economic reality. Government simply cannot write into law, nor can it base a reimbursement system on an inadequate foundation.

If public policy allows health care to trump all other considerations, we risk having a medical Taj Mahal amidst massive social squalor. Public policy tries to bring social balance to the total society and cannot allow one category of needs to trump all other social considerations. The health economy is a subpart of the larger economy and medical needs are a subpart of the total world of public and private needs. No nation or system can meet all the individual needs and desires of an aging, technologically obsessed society with pooled funds.

Our current system maximizes demands for medical services paid for with pooled resources within a system that insulates patients from the cost. People usually buy health care with free or deeply discounted dollars. No system, public or private, can allow people to consume as worried patients and fund as parsimonious taxpayers or rate payers. Someone must judge whether or not an intervention is a fair and reasonable expenditure of the group’s limited funds.

No common pool of funds collected by third party payers can ultimately ignore the law of diminishing returns. If every American would get all the “beneficial” health care demanded by current medical ethics and practice, it would create an unethical society in which medical care trumps too many other important social goods. Medical ethics provide no mechanism to weigh and balance individual health needs with other social or group needs. However elegantly reasoned, medical ethics cannot control the practical allocation of pooled funds.

As Henry Aaron of Brookings stated:

“While each of us may know that the well-being of loved ones is beyond price to us, the simple fact is that society has never placed infinite value on lives — and never will. The assertion that health care is an unlimited right invokes the principal that rights must be honored regardless of cost. This principle is violated every day and everywhere with universal approval” [18].

For a state or nation to cover all its citizens with modern medicine, it must (1) subsidize those who cannot afford coverage, (2) avoid “free riders” by compelling all citizens to pay something into the system, and (3) set limits on what health care is covered. Limits are painful but inevitable if we are to avoid crowding out all other social spending.

We need a new moral vision for health care that allows us to evaluate cases like the LVAD; I set forth what I see to be the essential elements of that new vision:

1. A nation’s health goal can never be, nor should it be, to fund the sum total of all its citizens’ individual needs. Thus, the legislature should not be limited to or controlled by the ethics of the physician-patient relationship. That relationship is important, but not exclusive. Not only is it not in the public interest to fund everything a physician may think will advance a patient’s health, but correctly analyzed it is not in the patient’s interest. All members of a health plan benefit when limited funds are directed in such a way that maximizes the health of the group, even if it sub-optimizes the health of each individual.

2. Public policy should concern itself more with extending the health care floor than raising the research ceiling. Public policy makers must care about the health of the total society as passionately as health provider’s care about an individual’s health.

3. Group funds, public or private, should maximize the health of the group. It is the duty of those distributing pooled money to optimize the health of all those in the pool. The doctor-patient relationship may be the most important relationship in health care, but it is not the only relationship. Doctors are patient advocates, but they are imperfect agents to maximize the health of a group of patients or a nation.

4. When people pool funds, they cannot maximize the amount of beneficial treatment to each member of that pool, and cost has to be a consideration when distrib-
Concluding Remarks

Robert M. Sade, MD

Dr. McCarthy and Governor Lamm have reached different conclusions about whether Mr. Wood’s should have received his LVAD: yes, I would have done the same thing, says one, but you can’t know whether he should or not, replies the other. It may seem strange, therefore, to recognize that they may both be correct.
patients. Governor Lamm, on the other hand, is a social scientist who necessarily takes the broad view of society as a whole. He accepts that physicians are ethically bound to do their best to serve the needs of their patients, arguing, for that very reason, that physicians are in a poor position to be the decision makers for allocation of commonly held resources. Health care policy makers have been remiss, he says, in failing to establish a system for setting health care priorities, preferably using a method similar to that used in the state of Oregon (series of public meetings, with the goal of setting priorities for expenditure of public funding for health care, such as Medicaid).

Governor Lamm's metaphor (ie, the house of health care) powerfully conveys the diversity of ethical obligations incumbent upon the many players in health care. In his vision, self-responsibility of patients forms the foundation of the house. Physicians together with patients in the patient-physician relationship constitute the first floor. At these levels, physicians and patients are free to decide, without external constraints, how health care dollars will be used. The second and third floors comprise health insurance plans and governmental health agencies, respectively; they provide specified health care goods and services by expending common funds. Priorities must be set for how these limited common funds should be spent, as they are insufficient to satisfy all needs and wants. Here, Governor Lamm unabashedly uses the "R" word (ie, rationing of health care goods and services). Those who wish to advance the cause of free choice in health care will want to maximize the funds available to the foundation and to the first floor and, as much as possible, to control tightly the expenditures at levels two and three. The Health Savings Accounts enacted by Congress and signed into law by President Bush in December 2003 are a step in that direction, giving individual patients far more control over their health care dollars than they have had in the past, thereby increasing the self-responsibility of individuals for both their own health and their own health care [19].

A tension exists today between commentators who wish to reinforce the paramount obligation of physicians to the welfare of their patients, which they see as sine qua non of a salutary healing relationship [20], and bioethicists who wish to redirect the focus of physicians toward social welfare, which they see as a higher obligation emanating from a purported basic right to health care [21]. One consequence of such a realignment of ethical obligations is likely to be the co-option of physicians as agents of society, helping to control health care costs by bedside rationing of such technologies as LVADs.

Dr McCarthy and Governor Lamm disagree about the need for constraints on the use of expensive technologies, such as LVAD for a patient with leukemia, but they are in agreement on an important underlyng ethical principle: physicians are obligated to do the best they can for their patients. Regardless of the outcome of the debate on limiting the use of high technology, physicians should resist the siren call to "social responsibility" and continue to advocate whatever is medically best for the patients we advise and treat. If certain technologies should not be used, it is the responsibility of insurance companies, government agencies, or sociopolitical units such as states (perhaps using an Oregon-like method) to set the limits. We physicians can and should help to develop rationing policies by participating on hospital committees, speaking at public hearings, or consulting with insurance companies and government agencies, but we should never ration technology at the bedsides of our patients. In an important sense, both McCarthy and Lamm are right.

References