Do No Harm

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Difficult ethical issues that require attention on the organizational level are emphasized here through the use of case scenarios. Only through adherence to a strong vision of the organization's role in the health care marketplace and a mission to do what is right for those for whom it cares can the organization consistently make appropriate ethical decisions in difficult situations such as these.

he Medical Director entered her office on ⚠ Monday morning at the usual 7:30 start time. Sitting on the desk before her was a request from the case management nurse. It had been submitted late on the preceding Friday afternoon. The patient was a young child with a rare genetic disease — Hurler's Syndrome. Until recently, the diagnosis resulted in a slow and certain death but now, as the result of a major advance in genetic drug engineering, the disease can be controlled. To the medical director as a physician, the accomplishment represents the true greatness of modern medicine, but to the physician as a medical director, the advancement poses an increasingly frequent conundrum. The medication costs over \$400,000 per year and treating this one patient will severely compromise the bottom-line of this small and growing for-profit managed care company. Money that had originally been budgeted for implementation of a high-risk pregnancy outreach program will no longer be available.

During the days of rampant inflation in medical spending, the pressure to reduce cost and lessen the inflationary spiral drove clinical management efforts which were supported by many interested stake holders. There was significant waste in the system and the room to cut was enough to drive costs southward without the medical managers having to face much ethical pain. While medical technology progressed, the envelope was only beginning to be pushed. This allowed managed care to promote medical appropriateness standards in an ad hoc manner. Many

of the early efforts were arbitrary, back-of-theenvelope systems developed with the best intentions and little supporting science. Genetic engineering was in its infancy, transplants for malignancies were confined to leukemia, cardiovascular procedures centered on standard bypass procedures, and the laparoscope was largely a diagnostic instrument.

We have now arrived at a new place in time. Fat still exists in the system but the inflationary pressures have abated. Many communities are still very new to managed care and are amenable to the tried and true methods of reducing inpatient stays as the primary vehicle for reducing medical costs. Future savings, however, will be increasingly derived through the use of more sophisticated management processes that focus on specific approaches to ambulatory care and disease prevention management. The attention to quality of care has increased, and the adoption of clinical pathways, once believed to be the bogeyman of "cookbook medicine," is now aggressively pursued by practitioners. Where, then, does the ethical problem lie?

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Alongside the advancement of medical technology and refinement in medical management practices, there has been a corresponding change in corporate expectations for managed care. Forprofit entities are aggressively in the marketplace, seeing great opportunities to prosper in a one trillion dollar industry. Not-for-profit companies are abandoning their missions in large numbers, pushed by the increasing need for organizational discipline, operational efficiency, and the need for access to capital markets. Now these organizations are looking to corporate medical executives and the practitioners in the network not only to deliver efficient, quality care, but also to make value judgments about how much care is enough. While one may suggest that the efficiency brought about by greater discipline will actually relieve some of these pressures, the more likely result is that the potential for larger profit margins will increasingly drive the system.

Tuesday, at 2 P.M., the medical director received a call from a network oncologist about a forty-yearold woman, the mother of three young children, who has advanced breast cancer. She had failed standard treatment regimens and now is desperately seeking some way of surviving to see her children grow into adulthood. The oncologist realizes that the nature of her illness renders all aggressive treatment futile. Still, he feels duty bound to advocate for this woman for whom he has exhausted all other forms of therapy. Both physicians realize that even were they to agree about performing a bone marrow transplant, the woman would be subject to an uncomfortable path to her all but certain death. Worse still, her remaining time might actually be shortened.

Technology has enhanced our lives. The information age, the internet, digital imaging, and telemedicine have contributed to an explosion of heretofore impossible medical scenarios. Rural communities are now served by the most advanced technology, often connected to prestigious institutions. The most complete medical libraries in the world are a keyboard and phone line away from anywhere. Medical experts are available, via on-line chat groups, for consultations. Movement

of images, photographically sharp, do not have boundaries of time or space. In an era that challenges only the imagination as to how far medicine can be pushed, how can anyone withhold treatment with even the slightest chance to correct an illness, to promote one more day of life?

Transplant technology, which has always had ethical issues surrounding it, has evolved significantly since the days of replacing sick, solid organs with healthy ones. Middle-aged practitioners remember the committees that determined acceptable candidates for dialysis and potential kidney transplantation. Diabetics whose kidneys failed were routinely denied transplants because they had an underlying incurable disease that would eventually cause the new kidney to fail. They now receive pancreatic transplants along with the kidney, which can cure the diabetes as well.

The arena of bone marrow transplantation has evolved beyond its traditional domain of blood disorders, like leukemia. It now is used to rescue solid-tissue cancer sufferers from the massive doses of chemo and radiation therapy that are needed to eradicate all malignant cells from their bodies. The medical profession triumphs and the public applauds the potential for miraculous cures, while medical industrialists gear up for new product lines. The eventual survivors of this treatment form have yet to be clearly defined. Debates still rage as to who represents the most appropriate candidate. Who, then, should say "no"? Community hospitals have recognized and responded to the profit opportunity that exists in the treatment of millions of breast cancer sufferers. These women are being sold chances at life and many are understandably willing to undergo whatever it takes to live an additional three months, even if chances are poor and the quality of life is miserable.

The cardiologist made his Wednesday morning hospital rounds. Two eighty-year-old patients were on the list to be seen — both members of the new Medicare risk HMO. As part of his IPA agreement, the doctor has agreed to accept the capitated

amount of money which was allocated to cardiologists each month for the enrolled membership. The first enrollee to be seen today was an eighty-year-old woman. She fit a common profile—frail, homebound, not willing or able to fix much food beyond tea and toast. Her family noted that she had begun to "slip" with signs of forgetfulness but she could still read the daily paper and enjoyed seeing her grandchildren. The second patient was a male who looked the picture of health. At eighty, he could run most people half his age off the tennis court. He maintained a schedule that had not diminished since he stepped down as the CEO of a large corporation.

Both of these patients had begun to experience debilitating chest pains to an extent that altered their daily routines. Medication and decrease in exercise had failed to control the male patient's problem. The female patient's problem also was not well-controlled, but she experienced less-frequent problems due to her already diminished state of activity. A treatment decision needed to be made for each; the cardiologist's intuition was to perform an angioplasty on both patients. Then he paused, realizing that the procedure's cost would come directly from the fixed reimbursement he was receiving from the IPA. He began to rethink the appropriateness of the woman's procedure, questioning whether she really needed to have the work performed. He placed a call to the medical director.

The ability to use fiber optics and miniature operative tools has created a new era of minimally invasive surgery. It was not long ago that endoscopic tools, devices which could peer into the body through its natural orifices or small incisions, were primarily used for diagnostic purposes and were followed by normal operative procedures. Now an increasing number of surgical procedures are performed via endoscopes. The age of Nintendo-like, hand-eye coordination has led to operations performed through tiny incisions through which miniature tools are inserted, with the procedure being viewed on a television screen via fiber optic image transmission. The obvious impact is a dramatic decrease in opera-

tive morbidity. Patients leave the hospital more rapidly, suffer fewer infectious complications, and have less pain and more immediate mobility.

A significant secondary benefit has been the broadening of the definition of an acceptable operative candidate. Patients who previously had not been considered viable candidates due to age or other medical conditions are now able to undergo these less traumatic surgeries more safely. The most profound impact has been the opening up of opportunities to the Medicare population for whom disease is frequent and the age of the patient previously prohibited surgical intervention. The unintended result of this technological advancement is the "why not try" attitude that has begun to pervade medical decision making. This is seen often in the cardiac arena with the technology to perform angioplasties. Because of its lack of bodily intrusion, this procedure, inserting a tube into the coronary artery and inflating a small balloon to push aside blockages, is so enticing that not recommending it seems like malpractice. Without firm selection criteria in place, nearly everyone with any type of coronary blockage becomes a "reasonable" candidate. And why not? No harm, no foul. Now enter the newest form of cardiac surgery, the minimal incision coronary bypass. Here the candidate can undergo actual bypass surgery without having a full chest incision and the need for cardio-pulmonary bypass.

Technology has once again opened doors for patients who previously could not qualify for surgery but also for those practitioners who wrap themselves in "why not" as a justification for treatment at all costs to all patients.

The cardiologist in the case scenario is having second thoughts about his standard approach to care. This questioning is the positive result of managed care. It is a necessary step in determining what is best for the patient. The benefit of the managed care process is that it makes clinical criteria and guidelines readily available to help define the treatment course that provides the patient with the best potential outcome. The ethical concern is how many physicians are allowing their

best clinical judgment to be swayed by economic drivers?

Thursdays at 10 A.M. the medical director meets with her case management staff to review the weekly roster of members who need intensive personalized attention. She reviews the usual list of post-discharge patients who are receiving intravenous antibiotics at home and others who are in need of ongoing physical therapy. Then she hears the case of the twelve-year-old boy found face down in a swimming pool two weeks previously.

The child was extracted lifeless from the water but, as a result of aggressive intervention by family friends who were competent in CPR, the boy was resuscitated. It was not known exactly how long he had been submerged but it was clearly over ten minutes. The boy's vital signs remained stable at the hospital, but he was dependent upon a respirator to breathe and showed no signs of awakening from his coma. Serial EEGs revealed the absence of meaningful brain wave activity. The attending neurologist believed that the boy was indeed brain dead.

The nurse who presents the case at the meeting had participated in hospital team meetings and he states that the father is ready to disconnect the child from the respirator and donate the child's organs to the regional organ bank. The mother and her parents are deeply religious and feel certain that the child will emerge from his current state unharmed. The medical director quietly asks for the nature of the contract with the hospital and she is told that each pediatric intensive care day is costing the plan \$1,800.

The last case presented is that of a ninety-yearold woman who has fallen and broken her hip. While the corrective surgery was successful, she suffered a series of mishaps in the hospital, which have resulted in a serious post-operative infection and led to a rapid decline in both her physical and mental status. During her enrollment into the Medicare risk plan, she had signed an advance directive, requesting that extraordinary means not be employed to promote her life. Her current status is precarious and a decision regarding placement on a respirator is imminent. Her two sons and one daughter are adamant that she be given every opportunity to live and all available means should be undertaken, especially in light of the fact that they blame the doctors for her current situation. The medical director is told that the per diem rate for pulmonary intensive care is \$2400.

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Morals, technology, malpractice, and profits have all merged into medicine. The physician's mantra of "do no harm" is now amended, qualified, managed, and scrutinized. With the inception of employer-sponsored health insurance, it was very easy to invoke "everything at any cost." Employer sponsors were happy to pay, insurers were happy to pass along the costs, and practitioners were paid for production. This cycle eventually led to double-digit medical cost increases and set the stage for managed care. The benefit language, "medically necessary," which managed care uses to justify its management decisions, has become subject to increasing debate. In large part, this has occurred because of the advancement of medical technology and litigation surrounding the practice of medicine.

Another difficult aspect is the lack of a consistent and clear moral stand among Americans. One needs only to look at former Governor Lamm of Colorado who suffered dearly when he suggested that the elderly and their families should know when to yield to disease and infirmity. His message, that the country can no longer support "anything for anyone at all costs," fell on hostile ears. The independent spirit of the United States populace forces medical managers to be consistent, to use the best information available for decisions, and to apply rules without discrimination. This is not bad. What is bad is the fact that managed care organizations, their physician managers, and

their network providers have been placed by default into the role defending a moral high ground. Many politicians are unwilling to legislate morals or provide protection for practitioners who attempt to set their own paths.

The largest confounding element is money. The increasing profit margins and market-based pressures to show quarterly gains cast a lengthening shadow over the health care industry. No matter how well intentioned the decisions made regarding the case studies detailed above will be, they should all be suspect for being driven by a profit motive. Medical managers, physicians, or others will have more and better data upon which to make utilization management decisions, but they will never escape the reality that money management is an integral part of their job. They will always be faced with the issue of serving a population and unfortunately it will fall upon their shoulders to determine where and how to allocate the available funds. Our government and public sector ethicists have not advocated for the population in general — they typically invoke the fundamental belief of our society that emphasizes the individual. Who will stand up to say that more resources should be spent on teen pregnancy than on terminal care for the elderly? Who will publicly admit that we will have a far greater impact on our future by allocating resources towards efforts to stop smoking and reduce drinking alcohol than for the few thousand individuals saved by transplants each year? Who would blame anyone with a terminally ill child for demanding that "anything at all costs" is the moral way to go?

The public always has been happy to rally around the sad, emotional story of a child. Remember back to the teenage girl whose liver transplant was failing and who could not get funding for a new procedure. The public came to the rescue with intense media pressure and money. She underwent two subsequent transplant procedures and eventually died. We need to ask ourselves how many pregnant teenagers could have received better pre-natal care had those funds been allocated differently — or, perhaps more importantly, who were the patients on the organ trans-

plant waiting list unable to receive their new chances at life? The point is that medical directors or physician executives in managed care organizations are being asked to serve as providers of infinite wisdom, moral judgment, and fiscal management in a system that refuses to address the fundamental issues head on.

We are only at the beginning of this road. Our success at new medical advancements, especially in the area of genetic engineering, will only accelerate and complicate all of these concerns. The intense pressure in the medical delivery industry for merger, acquisition, and profit will continue to cloud every analysis. The day has come when every decision is being made with the cost of care in mind. Since it is unlikely that the nation will be able to address issues of medical resource allocation and prioritization, these decisions will be left to the profession and its financiers. As entitlement programs move increasingly into the private sector, protection of the health care for this dependent population is entrusted to those with profit motives. It is not clear how much responsibility the medical community is willing to relegate to the judicial system. Presently, the courts, followed by state legislatures, are setting requirements for the practice of medicine based upon nothing more than anecdote and public persuasion.

Both for profit and not-for-profit managed care corporations have a responsibility to embrace a strong ethical code of conduct. This code must be promulgated throughout the organization, from the CEO down to each employee. The organization's ethics need to relate to more than just business practices. They must take into account the approach to care for the population that the organization serves. There are not easy answers to the situations presented in this paper; health care organizations need a guiding light. Only through adherence to a strong vision of the organization's role in the health care marketplace and a mission to do what is right for those for whom it cares can the organization consistently make appropriate ethical decisions.

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From the physician's perspective, it is folly to suggest that there are easy or satisfying answers to the uncomfortable situations presented here. Indeed, the issues will become more, not less, complex. What needs to emerge is an activist medical community, which will advocate for the individual patient as well as the community of patients. Practitioners must engage in active dialogue with corporate health managers to facilitate the evolution of a proper check and balance mentality. Medical resource decisions will need to be made on more complete and accurate data. Privacy issues must be balanced with the need to aggregate health information to allow for research to move forward. Government and managed care companies must continue to fund populationbased research with an eye toward protocol development. Physicians will make better judgments when they have a credible basis upon which to determine how medical treatments will impact clinical and functional outcomes. Until such time, physicians will continue to make the best informed judgments, factor in the cost care against the expected outcome, and hope to "do no harm."

Friday had come and as the day wore on it appeared as if only routine issues were in front of her. She longed to spend a relaxing weekend without a new complicated case to worry over. The nurse who specializes in prenatal management entered the door. A woman who was looking forward to becoming a mother had called seeking coverage information. She was fifty-three years old and a gene carrier for cystic fibrosis. She had avoided having children because with her husband being a carrier as well, they were unwilling to take any chances. Recently she had heard that through genetic engineering, there was reason to believe that the illness could now be cured in those children who are unfortunate enough to have both genes and thus the illness. She visited a physician who was willing to reverse her menopause, making it possible for her to conceive. She was ecstatic at the possibility. The medical director drew a long breath and told the nurse to inform the woman that she would get back to her early next week.