

Principles of Ethical Leadership Illustrated by Institutional Management of Prion Contamination of Neurosurgical Instruments

TIM LAHEY, JOSEPH PEPE, and WILLIAM NELSON

Introduction

In the Introduction to *Managerial Ethics in Healthcare*,¹ the editors argue the most important responsibility of a healthcare leader is to protect a hospital's ethical core values despite challenges. The Joint Commission, responsible for accrediting healthcare organizations, likewise directs the leadership of institutions "to carry out their patient care and business arrangements in an ethical manner."²

The ethical principles that are foundational to organizational values and the leadership of hospitals include respect for patient autonomy, prioritizing patient interests, and the delivery of care in a just and equitable manner. The Institute of Medicine's six aims for healthcare delivery—quality, effective, patient-centered, efficient, safe, and timely—align perfectly with these fundamental ethical principles.³ Taken together, these values should drive hospital decisions in a concrete fashion.

This point is unambiguous: ethics-grounded values are the core of today's healthcare organizations, and the success of a hospital and its leadership is measured by the alignment of their decisions and actions with those values. This is true every day; however, it is during significant challenges and times of uncertainty that the true measure of a hospital's ethical character is tested and displayed.⁴

In this article, we detail how the leader of Catholic Medical Center in Manchester, New Hampshire confronted

a challenge that would test his moral compass of the leadership and overall character of the hospital: news that neurosurgical instruments used in the care of multiple patients may have been contaminated with a lethal transmissible infection. In so doing, this leader revealed key principles of ethical leadership of healthcare organizations.

We begin with a report of the original case before delineating next steps in the hospital investigation and communications response. In so doing, we discuss ways in which the leadership of Catholic Medical Center exemplified ethical leadership in a time of great challenge.

Brief Case Report

In May 2013, a 70-year-old male presented to Catholic Medical Center in Manchester, New Hampshire, with severe vertigo and difficulty walking. Routine blood work, computed tomography of the brain, and consultation by neurologists and psychiatrists showed no explanation for the symptoms, which worsened despite physical rehabilitation. Magnetic resonance imaging (MRI) revealed a brain cyst and signs of elevated intracranial pressure, but lumbar puncture and spinal fluid analysis did not improve symptoms or reveal additional diagnoses. Given the diagnostic uncertainty, and concern that the brain lesion was contributing to elevated intracranial pressure, the patient underwent neurosurgical decompression of the cyst.

During the postoperative period, the patient developed myoclonus, which was originally attributed to an undefined metabolic derangement. Eventually the patient was discharged to a rehabilitation center for postoperative recovery. Weeks later, the patient was brought to the emergency department with rapidly deteriorating neurological symptoms, including progressive cognitive impairment. Repeat MRI showed abnormalities on both sides of the brain regions known as the caudate and the putamen. These findings were interpreted as suggestive of a long list of diagnostic possibilities including Creutzfeldt–Jakob disease (CJD), a rare transmission prion disease, for which a consulting neurologist felt the patient’s symptoms were atypical.

Physicians admitted the patient to Catholic Medical Center for additional evaluation including electroencephalography, additional brain imaging, and spinal fluid analysis, including for the presence of two proteins found in patients with CJD, 14-3-3 protein, and the tau protein. Within days, the hospital received word that cerebrospinal fluid testing showed positive tau protein and 14-3-3 protein. The National Prion Center, which by policy contacted the laboratory director and head of infection control of Catholic Medical Center, indicated that these findings were highly suggestive of the diagnosis of CJD.

Leadership Response

The same day in mid-August that the laboratory was notified of the positive 14-3-3 and tau protein results, the executive leadership team at Catholic Medical Center alerted the neurosurgeons involved in the case. Because the prion agent of CJD can contaminate neurosurgical instruments in a fashion not removed by standard sanitation

measures, all neurosurgical instruments used in the patient’s brain surgery were quarantined and all neurosurgery at Catholic Medical Center was halted temporarily.

Multiple internal communications ensued, including e-mails, meetings, and phone calls among the CEO, hospital leadership, risk management, infection control, legal department, and quality department about the potential exposure of other patients who had had neurosurgery procedures following the index patient’s procedure. Early on, the hospital CEO directly contacted the New Hampshire Department of Health and Human Services (NH DHHS) to promise that the ensuing collaboration between the hospital and the state would be a model for others to follow. During these contacts, the hospital’s CEO clarified that patient safety was the highest priority, above financial, legal, and personal considerations. NH DHHS promised full support for Catholic Medical Center, and initiated an epidemiological investigation.

Close to this time, the patient died, and, therefore, state officials obtained permission from his family to conduct a brain autopsy. Initially, pathologists at Catholic Medical Center proposed to take a week to conduct the autopsy. Concerned that this timeline did not align with the urgency of the situation, the CEO contacted the executive team to emphasize the seriousness of the situation and to urge a more rapid action. The autopsy was finally completed in in mid-September.

Prior to knowing the autopsy results, the CEO convened an incident management team days after the cerebrospinal fluid results were made known. In their inaugural meeting, the CEO reminded the incident management team that although potential contamination of neurosurgical instruments could not be changed, the hospital was in control of

its reaction to the situation. He called for leadership, attention, teamwork, and full engagement. He delegated responsibilities to individuals based on talent even when higher-ranked individuals might have been the default choice. For example, instead of appointing a hierarchically default appointee, a vice president, the CEO appointed the compliance officer as the incident commander. She was charged with collecting, processing, and supervising information about the incident action plan because of her known attention to detail, sense of urgency, history of close follow-up, and team approach to solutions.

The CEO's incident management team reviewed related hospital policies, and instigated a root cause analysis. Alert flags were placed in the electronic medical records of patients on whom the potentially contaminated neurosurgical instruments had been used, in the unlikely event that any of them presented with the need for invasive treatment, and notification was made to another hospital in the same city, which rented the instruments, to do the same.

The incident management team partnered with experts in sterilization standards and other prion-related issues, including a consultant at the National Institutes of Health. Hospital risk management was involved in the investigation; however, the CEO promised to all involved that the institution's first priority was the expeditious and thorough protection of patient interests. He specified that the potential legal ramifications of the contaminated neurosurgical instruments would not preclude the institution from doing the right thing for patients, their families, and the community.

At this time, the CEO and hospital leadership decided to tell exposed patients and the community immediately on confirmation of the diagnosis at autopsy. Soon thereafter, the hospital

learned that the results of confirmatory testing during autopsy would take several weeks to return from the National Prion Laboratory. The CEO felt this was an unacceptable delay, and decided to notify potentially exposed patients and the community immediately rather than wait for a definitive index case diagnosis.

This decision was controversial. Some members of the hospital's leadership team and outside consultants were hesitant to inform potentially exposed patients out of concern for inflicting unnecessary worry on notified patients, and also because the risk of contracting CJD from contaminated neurosurgical instruments is extremely low. (There have been only four cases reported of CJD transmission from contaminated neurosurgical instruments.)⁵ This concern was heightened by the fact that CJD is invariably lethal, and there is no test available to determine whether a potentially exposed patient has truly been exposed or if that patient will develop the disease even years later. There were conversations among senior hospital management about legal exposure, bad publicity, and even potential loss of jobs, including that of the CEO. The CEO dismissed those concerns as irrelevant to what patient safety and institutional trust required.

The CEO emphasized that the institution had an obligation to be truthful, and that anxiety among potentially exposed patients could be mitigated by ensuring that notification was respectful, compassionate, and accompanied by solid education and ongoing counseling. The CEO felt strongly that potentially exposed patients needed to know what had happened so that they could make informed choices about organ donation, participate in CJD-related clinical studies, make end-of-life planning decisions or, in most cases, do nothing. He also wanted to ensure that

those potentially exposed neurosurgical patients did not unwittingly risk further transmission by undergoing additional neurosurgery in another institution where their potential exposure was unknown. The CEO also wanted to protect patient and community trust in the hospital by showing that it would act in a trustworthy manner. To ensure the institution took the right path, the hospital CEO consulted ethicists who supported his decision to disclose the potential exposure to affected patients.

Close to the same time, the hospital considered if it should destroy two sets of potentially contaminated neurosurgical instruments, as it was not known which was used in the original case. This decision was complicated by conflicting and often unclear recommendations from the Centers for Disease Control (CDC) and several consultants.^{6,7,8,9} Given this uncertainty, and the desire to protect future neurosurgical patients, the instruments (costing more than \$200,000) were permanently quarantined for later destruction.

Two weeks after Catholic Medical Center learned of the CJD diagnosis, representatives of the hospital notified primary care physicians of the potentially exposed patients, and educated them about the risk to patients and measures that the hospital was taking to ameliorate it. The hospital provided reference materials to help primary care physicians give informed and consistent advice to patients.

The chief medical officer of Catholic Medical Center and a patient navigator met with all eight patients (or their legal representatives) individually. The patient navigator was chosen based on a reputation for being a compassionate and nuanced communicator. In addition to reviewing the facts of the situation in a compassionate and respectful manner, and apologizing for the potential exposure, hospital representatives provided

patients with written information plus directions to additional informational resources. Catholic Medical Center arranged for patients to have a dedicated cell phone line that potentially exposed patients could call at any time of the day or night.

Once all patients were notified, hospital representatives communicated to the hospital's board, medical staff, the mayor of Manchester, New Hampshire, the office of the state governor, and then, all hospital employees. Educational e-mails, meetings, multimedia documents, and other reference materials were delivered to key stakeholders. The hospital also notified the CEOs of other hospitals, local business leaders, and even legislators. The hospital held a joint press conference with the state DHHS and the city public health department and a letter to the community and FAQs were posted on the hospital's website.

Soon after these public announcements were made, news of the contaminated neurosurgical instruments became international news. The story appeared in the *Wall Street Journal*, and on CNN and Fox News, among other media outlets. Most media reports were accurate. The hospital communications department corrected errors when needed, and the CEO called all eight patients (or their representatives) to address personally any questions or concerns prompted by the media coverage.

To preclude contamination of additional neurosurgical instruments during procedures performed on the potentially exposed patients, they were told to call Catholic Medical Center if they ever needed any surgical or invasive procedure. Catholic Medical Center let them know that they would be contacting the patients in the future to inquire about their health and to help answer any clinical questions or handle additional health needs.

When hospital leadership learned that one potentially exposed patient was to undergo additional neurosurgical and non-neurosurgical procedures at Catholic Medical Center, the hospital supplied disposable equipment and ensured that any instruments that could not be disposable were quarantined for disposal at a future date should the patient someday be diagnosed with CJD.

On September 20, the National Prion Laboratory confirmed the diagnosis of CJD. In the ensuing weeks, Catholic Medical Center hosted visits from the Joint Commission, the Center for Medicare Services, and the Food and Drug Administration. Each made positive comments about the way that the hospital had handled the incident. A local newspaper praised the hospital's ethical and transparent response. This feedback was disseminated to hospital personnel and the board of directors, many of whom commented on how proud they felt to be a part of such a principled organization.

The root cause analyses undertaken after the hospital learned of the index patient's CJD diagnosis resulted in some process changes at Catholic Medical Center. New checklists for screening patients preoperatively on certain procedures were instituted. A new alert in the electronic medical record was built to automatically notify the chief medical officer, the vice president of laboratory services, the nursing coordinator, and the infection control officer whenever CJD testing was ordered. Education and root cause analyses are ongoing, and the hospital continues to provide clinical and educational support for the eight potentially exposed patients. The chief quality officer of Catholic Medical Center presented the case to the New Hampshire Quality Assurance Commission, which has representatives from all New Hampshire's hospitals and ambulatory surgical centers.

Thus far, one potentially exposed patient has filed a lawsuit. Most patients and their families have expressed gratitude for the information and support they received.

Summary and Lessons Learned

Ethical healthcare leaders make certain their institutional mission and values, including the prioritization of patient interests, are prioritized over secondary issues such as financial gain, avoidance of legal liability, and the protection of senior management job security. Healthcare leaders need to recognize that every decision they make on behalf of the organization has the potential to diminish or enhance the moral foundation of the organization. In its core values, Catholic Medical Center specifically trumpets compassion, human dignity, excellence, respect, and patient-centered care in its mission statement. Therefore, when the leadership of Catholic Medical Center aligned its response to potentially contaminated neurosurgical instruments on these values, they exhibited ethical leadership.

A key feature of Catholic Medical Center's ethical leadership response was to signal the specialness and urgency of the situation. Without the explicit recognition that an unusual and defining ethical challenge was before them, leadership at all levels would have been less likely to reflect which actions were most ethical, or the need to act decisively. Many subsequent ethical decisions therefore flowed from this early articulation that a seminal moment had come that would test leadership's adherence to institutional values and justification of public trust.

From this moment, the CEO of Catholic Medical Center felt that his role was to champion institutional mission and values in the face of a challenge. This role conception fits the understanding of

moral leadership outlined by Chervenak and McCullough in 2001:¹⁰ that neither competent management skills nor protecting the organization's economic interest qualify as moral leadership. A moral healthcare executive's primary responsibility is to lead the organization toward the goal of fulfilling the organizational and professional moral foundation of excellence in patient care. Had the CEO instead pursued more pedestrian priorities, such as to aggrandize his own power in the institution, to appease the interests of key allies in the organization, or shield the institution from bad press, Catholic Medical Center's responses to the discovery of potentially contaminated neurosurgical instruments may not have been as admirable or effective.

Public statements of importance and urgency of mission are important, but must be followed rapidly by the appointment of a specific team who feels personally accountable for the success of the plan. Examples in the Catholic Medical Center response include appointment of the chief compliance officer to a key leadership position, and the identification of a skilled patient navigator to interface with concerned patients recently notified of a potentially lethal exposure. Calling upon individual team members to align their personal execution of the CJD contamination event response plan was key to ensuring that the plan was enacted effectively. Attention to such logistical details such as the creation of a high-performance team whose skills, values, and mission are aligned¹¹ can be crucial to the conversion of ethical talk into ethical action. The prioritization of timely responses, such as communicating to the patients and the press before a final autopsy evaluation of the source patient, was key to averting the appearance of foot dragging, which could have led to undermining public trust.

Following the problem articulation, leadership opted for transparency and collaboration. Both are critical. In so doing, Catholic Medical Center was able to engage regional and even national expert support, and to show the integrity of their actions to the public. Examples include strong collaboration with news outfits and state public health agencies. Such collaboration can entail explicit recognition of the ego-driven temptation to hide the problem.

When the next realization of an ethical challenge arises, it can be tempting to develop a short-term plan that gives the appearance of rectitude but is not followed by sustained engagement in patient-centered action. Therefore, the enactment of a root cause analysis that resulted in sustained systems redesign helped protect future patients at Catholic Medical Center from similar risks. This exemplifies the learning health system in which new evidence is mobilized to redesign systems of care that work better for patients.¹² A key feature of such continuous system change activities is the use of ongoing assessment strategies that ensure that change improves the quality of clinical care in a durable fashion over time.¹³ Therefore, the development of a long-term patient follow-up plan and sustained interactions between Catholic Medical Center and patients, for example, as news reports evolved, was essential to the delivery of ethically mandated care in the wake of the CJD contamination event. The articulation of a long-term timeline with concrete deliverables through the application of quality improvement thinking, methods, and assessments tools was a key approach to ensuring sustained engagement and organizational success.

The sustained enactment of plans to ensure ethical care for people potentially affected by the CJD contamination event requires continuing institutional will.

The CEO of Catholic Medical Center stated he knew “I had to be steadfast to the organization’s values and my moral character no matter what we find or what distractions take place.” He resolved personally that the organization would focus on what was right for patients even if, for example, bad press or legal complications arose, and planned in advance of his ethical response to such potentialities. By succeeding in preserving the moral foundation of Catholic Medical Center over other considerations, he brought acknowledgment to a public expectation; a true service mission.

Conclusions

The Catholic Medical Center response to the discovery of potentially contaminated neurosurgical instruments exemplified many facets of ethical leadership, including signaling that a defining ethical moment had occurred, forming a high performing team, communicating transparently, and creating a learning health system to prevent similar ethical problems in the future.

Notes

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