Key Learning from the Dana-Farber Cancer Institute’s 10-Year Patient Safety Journey

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Overview: The tragic chemotherapy overdoses to Betsy Lehman and Maureen Bateman, which were discovered at the Dana-Farber Cancer Institute (DFCI) in February 1995, are well known to the cancer community and the public. With 2004 to 2005 marking the 10-year anniversary of these events, DFCI leadership assessed its patient safety learning. The six most critical elements of learning were as follows: the responsibility and power of all leadership to drive patient safety after the overdose and thereafter; the need for relentless vigilance every day to safety, risk, error, near miss, and harm at all levels of the organization by all staff; the responsibility of addressing the multiple victims of error, including the patient, the family, and the staff; the power of partnership in patient-centered and family-centered care; the crucial role that the design of systems and application of technology play in support of safe practice by excellent, not perfect, staff; and the synergy of interdisciplinary practice and team work. The organization remains excellent (not perfect) and vigilant in closing the gap through ongoing priorities and by reassessment of how the journey could be enhanced.

The tragic chemotherapy overdoses to Betsy Lehman and Maureen Bateman, which were discovered at the Dana-Farber Cancer Institute (DFCI; Boston, MA) in February 1995, are well known to the cancer community and the public. These errors and the resulting organizational journey have been the subject of presentations and publications.1-6 The year of 2004 to 2005 marks the 10-year anniversary of these events and the 5-year anniversary of the Institute of Medicine’s seminal publication To Err is Human: Building a Safer Health System,7 which is a publication that referenced Betsy Lehman’s death. This is an appropriate moment for DFCI leadership to assess their quality and patient safety learning throughout these years.

KEY LEARNING FINDINGS

The learning of the organization is substantial. The six most critical findings are briefly noted in the following sections and in the cited publications.

Leadership

Foremost is the engagement of all leadership, including trustee, clinical, academic, and administrative. Leaders must personally lead and be accountable for the ongoing patient safety program, setting expectations for superior performance, modeling the way, and mobilizing the effort. This would be done in the same way and with the same emphasis that they lead and are held accountable for strategic planning, human resources, financial management, clinical practices, and fund raising. Leaders must ensure interdisciplinary incident review focused on the why rather than on the who. Patient safety, error, and harm must be transparent and discussed honestly with the board of trustees and throughout the organization. Safety should be an integral component of meetings of the board, medical staff, and executive leadership, as well as all organizational forums. Especially in times of enormous demands and complexity, leaders bring focus and assure effective prioritization. Organizational researchers have noted that the primary task of leaders is not making decisions but creating an environment and establishing a set of conditions that informs excellent decisions that people are able to make for themselves.8 It is difficult to consider this in world-class academic institutions attracting leaders with considerable experience and impressive credentials. Yet, processes that include active and disciplined listening from, and engagement of, staff at all levels across organizations may produce superior results. We have learned that leaders do not have all the answers and should not worry alone. Leaders have the collateral opportunity to drive patient safety and use it in setting the vision, providing the will, declaring the current state unacceptable, and executing change. In 1995, at a time when it was the exception and not the rule to disclose preventable medical error causing serious harm and death, it was leadership’s acceptance of their moral responsibility and accountability to the patients, family members, the institution, and its staff that began this extremely high-profile and painful period of discovery, assessment, and improvement. In the process, through a partnership among leadership, patients, family members, and staff, the extraordinary potential was seized, much was reaped, and much more is still to be realized.9-13

Vigilance

There must be a preoccupation with the possibility of error and constant vigilance to safe practice. Risk, error, near miss, and harm must be persistently sought out. All staff must be aware of and avoid the arrogance of excellence and the normalization of deviance, and above all, they must be looking for trouble. Root cause analyses (RCA) conducted after incidents must be timely, with systematic follow-up to assure intended improvements are made and disseminated broadly, along with associated learning. Mechanisms should exist to educate all levels of the organization to build on RCA results with specific emphasis on the often forgotten direct-care staff.

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Elements of this article have been presented extensively via lecture over the 10 years and in cited publications.

Authors’ disclosures of potential conflicts of interest are found at the end of this article.

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It is critical for an organization to know its incidence of error. This sharpens the focus of efforts and allows accurate communication on an institutional level and, publicly, on the realities of practice. Patients know that errors happen. They are looking for evidence that the organization knows it and is doing something about it. In that spirit, in November 2004, DFCI publicly released 8 years of data and trends on medication events reaching outpatients and causing harm (Fig. 1). The public response was favorable; accountability was underscored. In one of the first studies to examine chemotherapy errors in ambulatory care patients with cancer, researchers at DFCI and Brigham and Women’s Hospital found that approximately 3% of the outpatient chemotherapy orders studied contained mistakes. There was a favorable public response to the study, to the release of the results, and to the low incidence reported. At the same time, errors continue to occur; this underscores the need for continued vigilance.

Whether the result of RCAs or daily improvement processes, the focus must be on systems rather than individuals. There must be a feeling of deep, shared accountability by all involved, with efforts directed proactively on continued process improvement rather than reactively to what has happened.

Patient-centered and Family-centered Care

The errors that affected Betsy Lehman and Maureen Bateman raised significant questions as to how the voice of patient and family was heard and respected. Embraced was patient-centered and family-centered care, which is defined as follows by the Institute for Family-Centered Care:

- people are treated with dignity and respect;
- health-care providers communicate and share complete and unbiased information with patients and families in ways that are affirming and useful;
- patients and family members build on their strengths by participating in experiences that enhance control and independence; and
- collaboration among patients, family members, and providers occurs in policy and program development and professional education, as well as in the delivery of care.

Patients are treated as partners in care design, delivery, assessment, and improvement. Through adult and pediatric patient/parent and family advisory committees (PFACs), participation includes serving on institutional committees such as the board of trustees quality, patient safety, strategic and building planning, operating, disease center, and patient education. The PFACs are engaged throughout every clinical renovation process. They are full partners in Joint Commission on the Accreditation of Healthcare Organizations surveys and all leadership search processes, teach in customer service training programs, and present at new employee orientations. Educational efforts in which they take a lead role include a quarterly newsletter for all patients and families, patient resource centers, and advocacy groups. With the interdisciplinary team and with confidentially respected, the PFACs make clinical rounds on inpatient and outpatient units and interview patients one on one.

Patients and family members deserve our respect and are to be listened to at all times. They can tell us things that we do not know, can make significant contributions to improving our prioritization and work processes, and are critical in answering the question of whether a change is an improvement. DFCI could not have taken the journey, achieved the successes, or have as clear a sense of what remains to be done without the active participation of our partners — the patients and families.

Victims

Patients, families, and hospital staff can all be injured by, and see themselves as victims of, medical error. Errors do not distinguish organizations; they happen everywhere. Organizational response to error can be a distinguishing characteristic. Errors do not erode trust; the response of staff and organizations to the error can, however. Oncology patients and their families have enormous respect for the care and caring received in great organizations from exceptional people. Patients and families want and deserve an explanation of what happened, why, and what is being done to prevent similar events. They deserve an apology and the truth. Furthermore, although there are risks to disclosure, far greater risks are associated with having known something and not disclosed it. DFCI has practiced disclosure of medical error for 10 years. Positive, healing outcomes are realized for the patients, families, staff, and organization.

DFCI became acutely aware that clinical staff are also injured by, and see themselves as victims of, medical error, experiencing distance, shame, and blame from their organization, colleagues, and external regulatory agencies. DFCI learned that its responsibility is to nurture a supportive, fair, and just working environment and one that values objective and explicit decision rules for determining accountability and culpability subsequent to an
Systems

Oncology systems are too complex to expect merely extraordinary people to perform perfectly 100% of the time. No matter how strong the team and its individuals are, they are human and make mistakes. Leadership has a responsibility to put in place systems and the concomitant resources to support safe practice and to mitigate the chances of error reaching patients and causing harm. These systems must be developed with strong clinical leadership, with a safety-over-convenience orientation, and they must be implemented by and for all. Safe practices are not electives. As noted by Berwick,24 “Every system is perfectly designed to achieve the results it gets.” Practice will be safe and error mitigated in the right system under the right design.

These systems include electronic medical record, computerized chemotherapy, and medication order entry. Standing order sets and templated standardized chemotherapy regimens, which include essential ancillary medications and intravenous fluids (preprinted if computerized order entry is not available), can have a significant safety effect on oncology care.25 Handwritten orders and free format carries many forms, a bias toward teamwork, and a predilection toward shouldering the burden of improvement, rather than blaming external factors.”

CURRENT AREAS OF FOCUS

The DFCI’s journey is not done. Current efforts include mitigating risks of new technology, improving medication safety through patient engagement, developing intensive infection-control strategies, further improving systems by introducing bar coding, implementing high-performance teamwork and communication tools, initiating a web-based incident reporting system, analyzing diagnostic errors, and continuing to work to support patients, families, and staff at the sharp end of error.

WHAT COULD HAVE BEEN DONE BETTER?

In the 10-year assessment, DFCI a number of areas where could have done better were identified, including ongoing attention to measurement of outcomes, utilization of a framework or systematic approach to guide and integrate the work, greater engagement of rank-and-file medical staff and those on all frontlines, and integration of clinical research into the overall institutional patient-safety program, publications, and patient-safety research.

Interdisciplinary Practice and Teamwork

Ten years ago, DFCI found exceptional physicians, nurses, pharmacists, and other health-care workers individually managing the complex care of patients with cancer; there was little emphasis on team. Cancer care requires high-performance interdisciplinary teams led by a physician and a nurse. Interdisciplinary collaborative practice models must exist in all levels of leadership, including the practices, clinics, and programs. The leaders and team have to be supported and oversee all aspects of care for each microsystem and must be held responsible and accountable for quality, service, and financial and outcome targets.30 Berwick31 stated the charge to all of us as follows: “This requires a workforce capable of setting bold aims, measuring progress, finding alternative designs for the work itself, and testing changes rapidly and informatively. It also requires a high degree of trust in
A CULTURE OF SAFETY

There are dramatic differences between where DFCI was in 1995 and where it is in 2006. Two notable examples are the evolution in how it assesses medical error and overall quality (Table 1) and how it responds to specific medical errors (Table 2). We realize that a culture of safety must be imbedded in the real work and the policy decisions of the organization. It cannot be contrived or simply declared to exist. The culture of safety on which DFCI is building has emerged from its daily approach to safety and its response to every error or potential error.

The culture:
- is based in trust, respect, human rights, repentance, and forgiveness;
- is patient and family centered;
- engages and holds accountable leadership at the top and leadership at the frontline;
- enables and motivates the highest levels of staff performance;
- acknowledges the high-risk, error-prone nature of health care;
- ensures individual and shared acceptance of responsibility and accountability for safe delivery of quality care, risk reduction, and care outcomes in a systems-based approach;
- encourages and facilitates reporting and open communication about safety concerns in a fair and just environment;
- ensures organizational structures, processes, goals, measures, and rewards are aligned with improving patient safety;
- learns from errors;
- shares stories of safety.

RELEVANCE TO THE CANCER COMMUNITY

Through journal articles, educational meetings, press reports, and interactions the staff at DFCI have with the national cancer community, it is clear that opportunities to improve patient safety can be found throughout oncology. In medication safety alone, data published by U.S. Pharmacopeia CAPSLink\textsuperscript{32} for 1999 to 2003 show that errors continue to reach patients with cancer, causing harm and death; voluntary reporting systems dramatically understate actual incidence.\textsuperscript{33} The sentinel alert issued by the Joint Commission on the Accreditation of Healthcare Organizations in 2005\textsuperscript{34} points urgently to the need for systems to support safe practice with vincristine and with oncology practice overall. In the peer review literature, there are few reports of the incidence of error and harm in oncology inpatient and ambulatory care; there are relatively few articles on issues, solutions, and priorities in oncology safe practice overall. At the same time, educational sessions organized by the American Society of Clinical Oncology, the National Comprehensive Cancer Network, the Oncology Nursing Society, the American Society of Therapeutic Radiation Oncology, and many other organizations offer important findings and practice innovations to reduce error and improve patient safety. All of us in the cancer community must accelerate our work individually and collectively to increase the opportunities to share learning, evidenced-based research, and innovative practice.

CONCLUSION

DFCI appropriately carries the burden for the death of Betsy Lehman and the suffering of Maureen Bateman, but carrying the burden is not enough. There is the responsibility to learn everything possible to prevent similar tragedies from happening again. Through hard work and a partnership of trustees, leaders, clinicians, staff, volunteers, and patients and families, DFCI seeks to fulfill that responsibility. In that journey, DFCI found the enormous power that comes to an organization when an institution considers its vision along with the realities of practice (including error, near miss, suffering, harm, and death) and uses the resultant creative tension to take an organization to a different and much better place. It is a journey all must take for those who depend on them, for their organizations, and to inform the practice of others.

Authors’ Disclosures of Potential Conflicts of Interest

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