

# Patient Safety: Evolving from Compliance to Culture

## Introduction

Hospital-acquired infections. Adverse drug events. Pressure ulcers. Falls. Patient safety is top of mind among patients, providers, payors and policy makers, not to mention quality organizations and the media. No one in healthcare comes to work to harm a patient. Yet providers and patients are put in situations where something can go wrong because modern healthcare and the healthcare system are so complex.

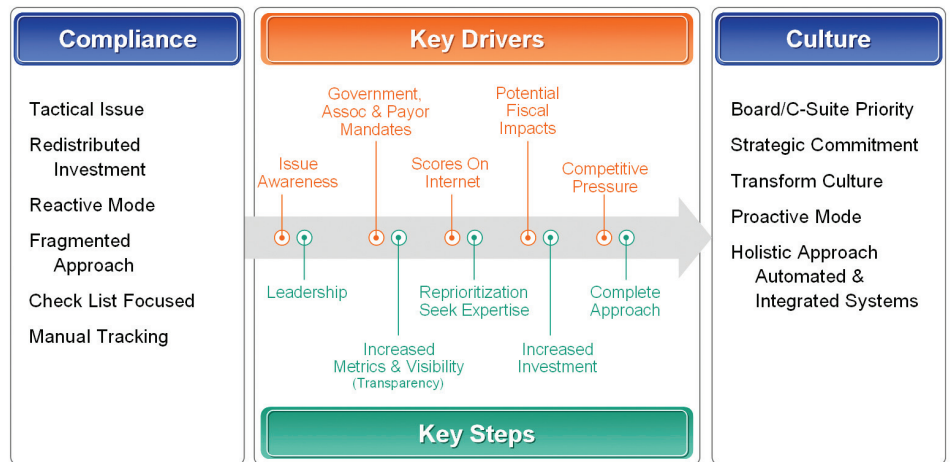
Any examination of patient safety invariably begins with a reference to the Institute of Medicine's (IOM's) landmark report *To Err Is Human: Building a Safer Health System*.<sup>1</sup> Controversial when released in 2000, the report's findings are all too familiar now, and more widely accepted. The headline-grabbing finding was that more than 2 million serious medical errors occur annually, accounting for between 44,000 and 98,000 deaths, making them the fourth leading cause of death in the United States. Subsequent IOM reports drove home the messages in the first report. They also introduced the importance of leadership, culture, the work environment and process design, while calling for a national health information infrastructure that captures patient safety information as a byproduct of care and uses this information to design increasingly safer delivery systems.

## From Compliance to Culture

With so much pressure being brought to bear from so many quarters, the much heralded "tipping point" needed to reinvent healthcare may be upon us. When the focus is purely regulatory compliance, patient safety is relegated to a tactical role. Particularly before the Joint Commission switched to the current, unannounced survey methodology in 2006, patient safety was part of the overall presurvey "fire drill," with a return to business as usual once the surveyors left. Like U.S. healthcare overall, the focus has been reactive rather than proactive — performing often heroically in discrete, vertical episodes of acute, (expensive) intervention rather than transforming the system to excel at prevention, wellness and disease management. Likewise with patient safety — an ounce of prevention is worth a pound of cure.

Providers face ever greater demands to track and report safety and quality performance in order to receive accreditation, secure higher rates of reimbursement and help consumers make informed choices. The result is a shift from regulatory compliance to culture as mission.

## Managing the Evolution from Compliance to Culture



The chart above depicts the shift from regulatory compliance to culture as mission, plus the drivers and key steps as healthcare organizations move along the continuum from a compliance-driven organization to an organization driven by a culture of patient safety.

### Patient Safety Drivers

Increased awareness of the issue of patient safety both within the healthcare industry and among policy makers, politicians and the media, coupled with the rise of consumerism, pay for performance and the increased transparency and publication of safety scores, have all resulted in increased pressure on healthcare providers, their management and staffs to improve patient safety and outcomes.

While the preceding drivers have certainly encouraged providers to improve patient safety, they pale when compared with pending reimbursement changes. In May 2006 the Centers for Medicare and Medicaid Services (CMS) announced that it is reviewing its authority and working with Congress to reduce or eliminate payments for what the National Quality Foundation calls "never events," and to provide more reliable information to the public when these situations occur.<sup>ii</sup>

Beginning in October 2008, CMS will no longer reimburse for hospital-acquired infections (HAIs). In one of the most comprehensive reports to date, the Pennsylvania Health Care Cost Containment Council found that patients in Pennsylvania who developed HAIs in 2004 incurred hospital charges that were more than seven times higher than those who did not.<sup>iii</sup>

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### Key Steps to Safety

Launching a comprehensive patient safety initiative and keeping it alive involves strong leadership from the top down. As the Institute for Healthcare Improvement (IHI) recommends in its 5 Million Lives Campaign, organizations must get “boards on board” by educating members on key issues to ensure patient safety initiatives are included in strategic plans and adequately funded. It also means continued attention from senior executives to overcome skepticism from staff inured by a steady diet of fleeting initiatives. Committed leaders likely have a percentage of their pay tied to patient safety performance. They make frequent safety walkarounds to determine where the next error is likely to occur, and they personally call or meet with the people involved when one does.

Yet patient safety efforts have been slowed by a punitive culture that focuses on action after an incident rather than on creating a “just culture” that recognizes the difference between human error, at-risk behavior and reckless actions.<sup>iv</sup> An approach that appropriately addresses these three types of actions fosters a culture of accountability in which caregivers feel safe speaking up about unsafe practices and recommending changes.

A closely related key to success involves embracing disclosure to patients and families when errors occur. Such disclosure – to patients, families, staff and the community (including board members and the media) – is still new to an industry in which physicians are all but trained to believe they are infallible and fear of legal repercussions dominate practice. However, many organizations are now adopting best practices for disclosure, thanks to the efforts of Lucian Leape, M.D., and others, whose research has found that disclosure does not increase the odds of litigation and in many instances reduces them.<sup>v</sup>

Data fragmentation and siloed operations have also made taking a holistic view nearly impossible. Only recently have a handful of organizations that employ sophisticated analytics tools that tie clinical outcomes to financial outcomes been able to assess the true cost of medical errors and to recognize patient safety as a business driver.

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### **The Ideal “End State”**

What, then, do the most patient-safe organizations look like? For starters, they are committed to building a culture of safety, from the top down. All employees understand that patient safety is their responsibility. Patient safety is a core strategic principal of the organization, not a tactical initiative du jour. They have invested in electronic health records (EHRs) that accurately identify and track a patient from the physician practice across the healthcare continuum. They use pharmacy automation and clinical information technology (IT) including computerized physician order entry (CPOE), bar-code point-of-care medication administration (BPOC) and electronic charting. These solutions have been implemented only after processes have been carefully redesigned based on evidence-based practice, with much of the evidence embedded in that technology to support clinical decision-making. They employ alerts, reminders and tools that help clinicians organize their day and prioritize tasks to ensure all patients receive all the care prescribed. In short, they have taken a systems approach and have hardwired patient safety, making it easy for caregivers to do the right thing and difficult for them to do the wrong thing.

These organizations also expect patients to take a vested interest in their care, ensuring they are properly educated about necessary steps for recovery and empowering them with at-home technology that enables them to proactively manage and monitor their progress.

At the managerial level, end-state organizations monitor compliance with expected behavior and associated outcomes using scorecards that enable managers to determine root causes of variances and quickly take appropriate action. At the executive level, the organization has a patient safety officer who reports directly to the CEO or who is part of a centralized C-level quality office.

At the board level, members with backgrounds from industries employing safety and quality initiatives, who well understand the relationship between patient safety and financial goals, can offer meaningful guidance. They begin each meeting by reviewing a balanced scorecard that offers a holistic view of the organization, and they openly discuss with clinical leadership specific cases in which errors have occurred.

### **A New Framework for Patient Safety**

Definitions of patient safety abound, some rooted in medication safety, others buried in a larger definition of quality. Many are too vague or overly academic. Yet, there is still no commonly accepted industry definition of patient safety beyond the general notion from the Hippocratic Oath to “First, do no harm.” A comprehensive definition is sorely needed, along with an appropriate

framework within which to address and implement a comprehensive solution. McKesson proposes the following definition:

*Patient safety is the sustained, proactive process of identifying, avoiding and rapidly resolving errors, omissions, mishaps and miscommunications that could affect a patient's healing, health or well-being at any point, at any time, in any care setting.*

This definition sets the stage for the following framework, which represents patient safety across the entire healthcare continuum and is designed to help leaders communicate all of the necessary components of a comprehensive patient safety program. Such a program must have broad initiatives and integrated solutions for each of the identified areas. This framework can help guide their implementation.

### Patient Safety Framework



As illustrated above, culture, information safety and communications safety are the joists, girders and struts that support the entire framework.

**Information safety** refers to the availability of secure, up-to-date, complete and accurate medical records for every patient. Those records must be permanent, portable and trustworthy, with longitudinal data on allergies, medication history and so on. The information must move with the patient across settings so that all providers – including retail pharmacists – are aware of the patient's current and past condition, ongoing treatments and possible changes or complications that should be monitored closely.

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**Communications safety** refers to the sharing of relevant, real-time information to all authorized, interested parties, with particular focus on the need to improve hand-off communications. According to the Joint Commission, breakdowns in communication remain by far the root cause of most sentinel events.<sup>vi</sup> “Substantial and ubiquitous deficits” in discharge communication between hospital-based providers and primary care physicians resulting in “suboptimal patient care” have also been called out recently.<sup>vii</sup>

**Medication safety** refers to an end-to-end medication management strategy designed to ensure the “five rights” — that the right patient receives the right medication in the right dose at the right time via the right route. Medication safety requires a comprehensive solution that helps ensure safety at each stage where errors can occur — prescribing, transcribing, administering, dispensing and monitoring. More broadly, medication safety involves safeguarding the integrity of the distribution supply chain, to ensure that life-saving drugs are available when and where needed.

**Diagnostic safety** refers to the gathering and interpretation of data supporting or leading to optimal care planning and treatment. In an area second perhaps only to genetics (where the explosion of available information threatens to overwhelm the capacity to make sense of it), image management is not just a safety issue but a liability issue. A single lab slide can hold 30 gigabytes of data. How do the laboratorian, radiologist and physician decide what to look at and what to act on? And how do providers defend themselves when accused of misdiagnoses because they failed to run the appropriate tests? Strategies to promote evidence-based diagnosis are essential.

**Treatment safety** refers to the accurate capture, recording, executing and sharing of data to support optimal care delivery. Treatment safety also means electronic capture of the treatment that occurs to the permanent patient record for all the care team to see and preventing the objection, “If you didn’t document it, you didn’t do it.” And if the other care team members or the next shift can’t see that someone provided a treatment, that treatment can’t be considered in light of patient status or, perhaps worse, it might be done again.

**Environmental safety** refers to a very broad view of the patient’s environment. It requires that caregivers identify patients who are at risk of falling and follow appropriate protocols, and that they follow strict hand hygiene rules and other protocols to prevent surgical site, central line and other preventable infections. Environmental safety also ensures that appropriate levels and mix of staff are on hand to care for patients based on their acuity, and that staff have ready access to supplies. Evidence-based building design will also play a large role here, particularly given the unprecedented construction boom in healthcare.

## On the Path to Patient Safety

What can be done to replicate a patient safety model industrywide? At McKesson we're passionate about taking a leading role in improving patient safety in our nation's healthcare system. As the nation's oldest and largest healthcare services company, with pharmaceutical wholesaling roots dating back 175 years, we provide pharmaceuticals, medical supplies, information systems and technologies that enable caregivers across the continuum to make healthcare safer while reducing costs. We believe this new framework of information, communication, medication, diagnostic, treatment and environmental safety has the potential to unite the entire care team in its ongoing quest to provide the safest, best possible care for its patients.

<sup>i</sup> *To Err Is Human: Building a Safer Healthcare System (2000)*. Institute of Medicine: National Academies Press. <http://www.iom.edu/CMS/8089/5575.aspx>

<sup>ii</sup> CMS Fact Sheet: Eliminating Serious, Preventable, and Costly Medical Errors - Never Events, May 18, 2006  
<http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=1863&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date>

<sup>iii</sup> Pennsylvania Health Care Cost Containment Council, "Hospital-Acquired Infections in Pennsylvania." November 2006. <http://www.phc4.org/reports/hai/05/default.htm>

<sup>iv</sup> Model developed by David Marx, JD, president, Outcome Engineering.  
<http://www.justculture.org/>

<sup>v</sup> When Things Go Wrong: Responding to Adverse Events: A Consensus Statement of the Harvard Hospitals. Massachusetts Coalition for the Prevention of Medical Errors: March 2006.

<sup>vi</sup> <http://www.jointcommission.org/SentinelEvents/Statistics/>

<sup>vii</sup> Kripalani, S., MD, MSc, et al. "Delays and Lack of Communication to Primary Care Physicians Common After Hospital Discharge." *JAMA*. 2007;297:831-841

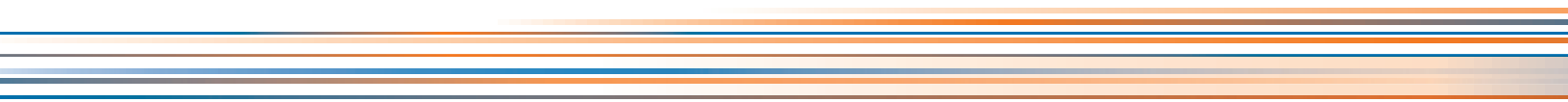
**McKesson Provider Technologies**

5995 Windward Parkway  
Alpharetta, GA 30005

<http://www.mckesson.com>

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