Safe Use of Electronic Health Records and Health Information Technology Systems: Trust But Verify

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Objectives: We will provide a context to health information technology systems (HIT) safety hazards discussions, describe how electronic health record—computer prescriber order entry (EHR-CPOE) simulation has already identified unrecognized hazards in HIT on a national scale, helping make EHR-CPOE systems safer, and we make the case for all stakeholders to leverage proven methods and teams in HIT performance verification.

Methods: A national poll of safety, quality improvement, and health-care administrative leaders identified health information technology safety as the hazard of greatest concern for 2013. Quality, HIT, and safety leaders are very concerned about technology performance risks as addressed in the Health Information Technology and Patient Safety report of the Institute of Medicine; and these are being addressed by the Office of the National Coordinator for HIT of the U.S. Dept. of Human Services in their proposed plans. We describe the evolution of postdeployment testing of HIT performance, including the results of national deployment of Texas Medical Institute of Technology’s electronic health record computer prescriber order entry (TMIT EHR-CPOE) Flight Simulator verification test that is addressed in these 2 reports, and the safety hazards of concern to leaders.

Results: A global webinar for health-care leaders addressed the top patient safety hazards in the areas of leadership, practices, and technologies. A poll of 76 of the 221 organizations participating in the webinar revealed that HIT hazards were the participants’ greatest concern of all 30 hazards presented. Of those polled, 89% rated HIT patient/data mismatches in EHRs and HIT systems as a 9 or 10 on a scale of 1 to 10 as a hazard of great concern. Review of a key study of postdeployment testing of the safety performance of operational EHR systems with CPOE implemented in 62 hospitals, using the TMIT EHR-CPOE simulation tool, showed that only 53% of the medication orders that could have resulted in fatalities were detected. The study also showed significant variability in the performance of specific EHR vendor systems, with the same vendor product scoring as high as a 75% detection score in one health-care organization, and the same vendor system scoring below 10% in another health-care organization.

Conclusions: HIT safety hazards should be taken very seriously, and the need for proven, robust, and regular postdeployment performance verification measurement of EHR system operations in every health-care organization is critical to ensure that these systems are safe for every patient. The TMIT EHR-CPOE flight simulator is a well-tested and scalable tool that can be used to identify performance gaps in EHR and other HIT systems. It is critical that suppliers, providers, and purchasers of health-care partner with HIT stakeholders and leverage the existing body of work, as well as expert teams and collaborative networks to make care safer; and public-private partnerships to accelerate safety in HIT. A global collaborative is already underway incorporating a “trust but verify” philosophy.

Key Words: patient safety, health information technology, computerized prescriber order entry (CPOE), electronic health records, leapfrog group

Trust But Verify

In 2011, the Institute of Medicine (IOM) released a report on Health Information Technology (HIT) and Patient Safety that clearly articulated the significant risks to patients; provided useful conceptual models; and made recommendations including verification of HIT performance; it also cited the use of existing methods such as Texas Medical Institute of Technology’s electronic health record-computer prescriber order entry (TMIT EHR-CPOE) flight simulator. Late in 2012, the Office of the National Coordinator for Health Information Technology (ONC) of the Department of Health and Human Services issued an action plan for public comment acknowledging the IOM report and included recommendations that would “leverage existing federal agency authorities and private sector safety programs to increase knowledge about health IT safety among health care professionals and improve health IT safety.”

A recent poll of a national patient safety audience conducted by TMIT at one of its monthly global webinars revealed that safety of the electronic health record (EHR) system was the top hazard of concern for 2013 out of 30 carefully identified hazards in the areas of leadership, practices, and technologies, by an overwhelming margin. Of the 221 organizations, 76 responded to the poll and “Patient/data mismatches in EHRs and health IT systems” generated the greatest score; 89% of the respondents voted it 9 or 10 out of 10. The potential hazard that was ranked second was “Interoperability failures with medical devices and IT systems;” 65% of the respondents voted this potential hazard a 9 or 10. A follow-up poll in January of 2013 reconfirmed that HIT hazards were of top priority. In this webinar of more than 590 organizations with an estimated audience of more than 1800 attendees, the HIT hazard was reconfirmed as of the highest critical importance for 2013.
There is growing dissatisfaction in hospital boardrooms with the results of investment in HIT. The pressure on all health IT stakeholders is only increased by the 2013 release of a RAND study and its amplification by the general press that the $81B savings projected for U.S. health care by an earlier 2005 RAND study has not yet been delivered.\textsuperscript{7,8} The dramatic cost savings we were promised by the HIT vendors have also been unfulfilled. In his 2013 Health Affairs article, Kellerman reported, “In our view, the disappointing performance of health IT to date can be largely attributed to several factors: sluggish adoption of health IT systems, coupled with the choice of systems that are neither interoperable nor easy to use; and the failure of health-care providers and institutions to reengineer care processes to reap the full benefits of health IT.” It is felt that many of the potential savings will accrue only when strong decision support is implemented and confirmed to be working, which underscores the importance for verification of performance.\textsuperscript{7,9}

In this paper, we will provide a context to the discussion of HIT hazards; describe how the concept of simulation as a way to verify performance has already been successfully applied at a national scale to identify unrecognized hazards in HIT systems and has helped health-care organizations improve their EHR-CPOE systems; and make the case for all stakeholders to partner with existing teams which have proven methods in HIT performance verification.

The TMIT EHR-CPOE flight simulator has been used by hundreds of inpatient EHR systems across the United States and United Kingdom to verify quality in and improve HIT systems. See Table 1 for a description of this tool. We propose that government agencies work with an existing collaborative network of experts and care providers within the health care ecosystem who already have years of experience developing such surveillance methods and have significant global momentum. Using approaches like this can help organizations and providers in all settings, and “raise all the boats,” by ensuring that the most important warnings are included.

Verification of the performance envelope of such systems is critical because this can save lives, save money, and create new value in the communities we in health-care serve. The performance gaps in care, such as preventable adverse drug events (ADEs), will only be closed by conscious and verifiable improvements at the intersection of leadership, practices, and technologies using standardized measures and methods.

\textbf{TABLE 1. EHR-CPOE Flight Simulator Tool Procedure} 

\begin{tabular}{|l|}
\hline
Seven Steps in Use of the TMIT EHR-CPOE Simulator Tool \\
\hline
1. Register for the CPOE evaluation. \\
2. Download test patient information (e.g., age, weight, allergies, lab values). \\
3. Download test orders. \\
4. Enter orders into CPOE application. \\
5. Enter and submit results. \\
6. Scoring. \\
7. Reporting. \\
\hline
\end{tabular}

The evaluation tool is an entirely remote, web-based, reliable, and easy-to-implement evaluation process that can be accomplished in a matter of hours. It provides unlimited access and scalability; and simulated patient scenarios can be updated as hazards change over time.\textsuperscript{12}

Captain Sully Sullenberger, who performed the “miracle on the Hudson” landing just over 4 years ago, readily admits that without many hours of simulator time verifying his competencies, he would never have had the ability to perform as he did on US Air Flight 1549.\textsuperscript{10} Thousands of hours of scenario simulation by engineers refined the aircraft systems that supported him. All high-hazard industries use simulation and performance verification routinely after deployment of information technologies to ensure safety…except one: health care.

\textbf{“TRUST BUT VERIFY”} 
\textbf{THE VALUE PROPOSITION} 

The value proposition for HIT performance verification using EHR-CPOE as the example is provided below. An innovation development framework used by innovation teams to communicate the value of a solution, product, or service is used. The value proposition is organized by a structure of “Claim, Evidence, Message, and Offering” (CEMO). The short, memorable claim statement is backed by statements of evidence that support a message to decision makers and an offering made by the solution team as a mechanism for action.

\textbf{Claim} 

The assertion that HIT systems are safe “out of the box” is simply inaccurate. Performance must be verified in a proven and transparent way; we will pay a terrible price in lives and dollars without it.

\textbf{Evidence} 

The 3 Whys: “Why do it?”, “Why now?”, and “Why do it with existing successful teams?”

- **Why Do It?—Verify Performance:** If we do not verify performance of safety systems such as EHR-CPOE, we risk harming patients and put our health systems and caregivers at new risks. Merely adopting EHR systems will not lead to significant improvements in patient safety if the key decision support is not included. But even the leading vendors do not include comprehensive decision support as part of their base packages. Thus, adoption of even the best vendor applications does not guarantee high levels of performance with respect to safety. In fact, low-cost systems may out-perform the high-end systems if deployed properly. Performance improvement and assurance of safety is impossible without real-world measurement of the same scenarios that harm patients with actual operation of these systems.\textsuperscript{11}

- **Why Do It Now?** The Institute of Medicine; Office of the National Coordinator of HIT of the United States federal government; leaders of health-care systems; and now even the public through the lay press are becoming aware of the hazards we are encountering at a time with the experts agreeing that we have 30% to 50% waste in the health-care industry. Employers, payers, and consumers are going to be voting with their feet and their wallets and will no longer tolerate harm, waste, and waste because of harm. Time is of the essence.

- **Why Do It With Existing Successful Teams?** The TMIT EHR-CPOE Flight Simulator, as described below, is the example of an innovation that took years to develop, has an unlimited scalability, and is being implemented by experts in an established network who are drawing on communities of practice that would take many years and dollars to duplicate. To start over has an unacceptable cost of preventable harm and cost.
**Message**

The message for leaders from all sectors is “join the global collaboration network and emphasize speed to impact.” Do not reinvent a broken wheel when the cost of entry is so low—sharing and learning together. We need to stand on the shoulders of others.

**Offering**

The existing team of experts and collaborating hospital systems is inviting governments, suppliers, providers, purchasers, and consumers to the collaborative network. The “all teach/all learn” maxim, pioneered by Dr. Don Berwick and others, will be expanded upon to include “all share” data to drive HIT performance improvement.

**THE PERFORMANCE GAPS**

The performance gaps in health-care quality and safety are becoming very clear to all stakeholders. Preventable harm due to errors; and overuse, underuse, and misuse of care services in testing, procedures, integrated care, and medication management are having dramatic implications on the health and wealth of many nations, and the employers who are the lifeblood of their economies and are now moving market share to safe harbors of care.13-15

We will use medication management and prevention of adverse drug events to illustrate how simulation and performance verification of EHR and HIT systems with CPOE performance can have significant impact on our understanding of such systems; however, we recognize that this is just one clinical area of many that can be improved.

In 2002 the National Quality Forum designated medication errors resulting in harm as “never events”—events that never should happen. Increasingly, hospital data on “never events” is being made available in public reporting, and payers are moving toward not reimbursing for care that results from a never event.7,16

The authors of this paper, along with scores of experts, helped establish the National Quality Forum Safe Practices for Better Healthcare, with specific emphasis on medication management, and found it was very helpful to address the clarity of “error without harm” and “error that causes harm.” Furthermore, the frequency, severity, cost, and impact of improvement through leadership, practices, and technologies innovations provided a framework all stakeholders can use to understand how to deliver better care.18

**Medication Systems and Processes**

It is very helpful to understand where harm and where error occurs in medication management systems. Adverse Drug Events (ADEs) that cause harm and errors can have very different implications, and it is always important to make sure to prioritize preventable harm. Almost half of all medication safety problems occur at the ordering stage of medication use.19-21

**Reporting Versus Automated Surveillance**

It has been well established that detection of ADEs and potential adverse events by self-reporting fails to catch the majority of errors and potentially harmful events; thus it is critical that technologies be used to understand the scope of the gap in performance we can close. For example, most hospitals use voluntary reporting and administrative codes to track medication safety problems; studies have shown that these systems miss more than 90% of actual adverse events.22-24

**Frequency and Severity of ADEs**

It is estimated that more than 5 million Americans are harmed and thousands lose their lives in America due to ADEs each year. In the acute-care inpatient environment, the frequency of ADEs is 7–15 ADEs per 100 admissions.19,25 While many of these are of low severity, a very important proportion are severe or life-threatening and some do result in death.19 Although less well understood, medication safety in the ambulatory setting is also important, and the majority of care is typically delivered in the ambulatory environment. Worse, ADEs may occur in as many as one in four patients in the outpatient environment.19,26 Only about 50–60% of prescriptions are filled27,28, and adherence by patients of the 1.8 billion prescriptions that are filled is likely less than 50%—either taking the medication improperly or lack of persistence such as not fully finishing a course.

**Cost of ADEs**

The fully loaded cost of ADEs to a health-care organization in the inpatient environment is hard to determine and depends on whether patients are in community or academic settings.

The approximate cost of ADEs in community hospital inpatient care has been reported to be $3000 in 2006 dollars, and $3702 in 2012 dollars, using medical cost inflation forecast factors.25

Academic institutions have been found to have a cost from all ADEs of $2013 in 1997 dollars, and $3559 in 2012 dollars.21 Bates found that preventable ADEs in 1997 cost $5857, which is $10,355 in 2012 dollars, and found all ADEs cost $3244 in 1997, which is $5728 in 2012 dollars.29 The cost of ADEs in ambulatory care environments is $1310 in 2005 dollars, and $1616 in 2012 dollars.30

**Impact of Improvement—Optimizing the Leadership-Practices-Technology Envelope**

The potential to reduce medication errors and medication-related adverse events has been well documented in certain settings; however, the ability of front-line health-care systems to generate high impact has been daunting.31 It is very easy to fall into the trap of magical thinking regarding technology—that buying an expensive system will fix an ADE problem overnight without serious care process re-engineering.

Even highly computerized hospitals have ADEs, which may continue to occur after implementation of CPOE and related computerized medication systems that lack decision support for drug selection, dosing, and monitoring.32

Experience in medication management, imaging, laboratory, intensive care, and surgical services has shown that high performance is delivered when leaders are engaged in ensuring that best practices are adopted and that optimizing technologies are enabling those best practices. As used in the NQF Safe Practices, the “4 A Innovation Adoption Model” has been very successful at systematically addressing performance gaps and risk identification and mitigation.33-35

**Awareness, Accountability, Ability, and Action**

All hospitals must be aware of the gaps; the right teams and people must be accountable for changing workflow and behaviors to close them; leaders must invest in those who need the new abilities to close them; and finally the line-of-sight actions must be taken that, in aggregate, will close the gaps and sustain the gains.

In the case of medication management, leaders must make sure that the performance envelope can be improved through the many technologies used to minimize adverse drug events. They
act at varying points along the medication management process. For instance, wireless physician order entry, robotic dispensing, pharmacy information systems, bar-coding, and automated surveillance are critical. Yet interoperability is in its infancy. The interoperability of systems in a typical instrument-rated airplane cockpit is standard and critical to basic operation; yet, such interoperability in health-care information systems is missing as well as innovation and collaboration between technology vendors, and between the vendors and caregivers.

Although slow, the good news is that the inpatient use of CPOE in the United States has grown to over 34% overall, with more than half of hospitals with more than 300 beds having adopted the technology.36

**CLOSING THE GAPS: LESSONS LEARNED FROM HARMONIZATION AND SIMULATION**

Many of the successes in health-care improvement that we often cite today were thought of as “mission impossible” when innovation teams embarked on their journeys. Examples include the launch of the Leapfrog Group Safe Practices survey of the NQF Safe Practices in 2004 and survey simulation to prepare hospitals for submission; synchro-harmonization of the National Quality Forum Safe Practices for Better Healthcare updates across major health-care stakeholders; industry-wide harmonization of the health-care-associated infections best practices in a Healthcare-Associated Infection Compendium; and the development of the TMIT EHR-CPOE Flight Simulator. They provide context to the issue of HIT performance verification and simulation as well as background to the medication management area that is the focus of this paper.37

**Synchro-harmonization—Mission Impossible!**

- **The First Three Leaps of The Leapfrog Group:** The original Leapfrog Group launch of requirements of hospitals in 2001 made adoption of CPOE one of their three requirements, or what they called “leaps.” The problem was that there were few commercially available systems, and the other two leaps were very difficult to adopt across the nation as well. For instance, one of the other leaps required hospitals to ensure that board-certified critical-care physicians staff every intensive care unit. The problem was that full-scale fulfillment of this requirement across the United States would have required 10 times the number of board-certified critical-care physicians that existed in America at that time. The program had modest adoption and significant resistance by hospitals.
- **Leapfrog Survey of NQF Safe Practices:** In 2003, C Denham and TMIT, who had developed a collaborative network of 1700 hospitals, were asked to lead expansion of the Leapfrog Group survey to measure hospital performance against 27 safe practices released that year by the National Quality Forum (NQF). The NQF is a public–private partnership that uses a congressionally approved consensus process which, if followed properly, makes its measures and practices easily deployable by federal agencies as standards if they decide to use them.38

Denham agreed to lead and fund the program through the Denham Family Fund as philanthropy in order to avoid any real or perceived conflict of interest that might arise were it funded by any other sources. TMIT developed the survey; a weighting system with a team of global patient safety leaders; and a relative national ranking system; and field-tested it with scores of hospitals, then launched it across the nation through town hall and webinar sessions in 2004.

- **The “4 A Innovation Adoption Model”:** The “4 A Innovation Adoption Model” of awareness, accountability, ability, and action was used as a framework in the Leapfrog survey so that hospitals would earn points out of a 1000-point universe. After the survey was deployed, hospitals were ranked by quartile. More than 1200 hospitals were recruited to submit to the survey the first year, representing more than 40% of the care in America, as many of the hospitals were large centers with high patient volume. Few thought hospitals would voluntarily expose their patient safety weaknesses in this way. The participation by hospitals proved the skeptics wrong and the mission of transparency was proved possible, not impossible.35,39,40
- **NQF Safe Practices 2006, 2009, and 2010 Updates:** With the success of the Leapfrog Group survey and the powerful impact transparency and purchasing pressure had on increasing adoption of the NQF Safe Practices, Denham was asked to co-chair the NQF Safe Practices Maintenance Committee. He proposed to synchro-harmonize the practices with the patient safety requirements and measures of The Joint Commission, the Centers for Medicare & Medicaid (CMS), the Agency for Healthcare Research and Quality (AHRQ), The Leapfrog Group, NQF, and elements of the Institute of Healthcare Improvement’s (IHI) successful 100,000 Lives Campaign. This was thought by many to be another mission impossible. Through the same philanthropic family fund, TMIT provided work teams from its collaborative network of hospitals and 500 subject-matter experts. Members representing the organizations above were appointed to the NQF committee and were led to synchro-harmonize the specifications of the safe practices with a unanimous consensus Modified Delphi multivoting method to ensure 100% synchro-harmonization. The committee was inspired to provide a unified set of standards across certifying, quality, and purchasing organizations for the very first time in health-care history.

The “4 A Innovation Adoption Model” became the backbone of Safe Practice 1: Culture of Safety Leadership Structures and Systems, which defines the responsibilities of leaders of hospitals and health-care organizations. The CPOE safe practice, and ultimately the CPOE Flight Simulator standard, was one of the elements. A patient engagement chapter was added to the program, and patient and family engagement elements were added to each practice with input from a formal collaborative team of consumers who have now become national safety authorities in their own right.41 The impossible became the inevitable in 2006, and the process became easier with every update. Were it not for the personal commitment made by the leaders of The Joint Commission, CMS, AHRQ, Leapfrog, NQF, and IHI, the “mission impossible” would have failed. There were no contracts or legal documents—the effort was fueled by trust, goodwill, and the desire to help patients.18,42–45

- **Healthcare-Associated Infections Compendium Synchro-harmonization:** Led by Dr. David Classen, who applied the synchro-harmonization principles used by the NQF Safe Practices and Leapfrog Group Survey teams at TMIT, the very first Healthcare-Associated Infections Compendium was created through a broad range of specialty organizations such as the Infectious Disease Society of America (IDSA), Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), The Joint Commission, AHRQ, CMS, Leapfrog, NQF, IHI, and the Centers for Disease Control (CDC). This document became a major expert and evidence resource for the 2010 NQF Safe Practices and again proved the incredible value of servant leadership and consensus-driven collaboration.37
Simulation and Performance Improvement

- **Survey Simulation—Safe Practices**: Since the Leapfrog Group survey was funded by TMIT who owned the copyright, TMIT was able to host an identical web-based version of the Leapfrog survey and deployed it to allow all hospitals to use it as a simulator. They could confidentially access it and run various scenarios of responses, which they might formally submit in order to identify what areas of performance improvement they could fund and act upon to improve their score. TMIT produced an educational program to help safety and quality leaders develop an internal business case they could use to present to their leadership and increase funding for their patient safety programs. This was extremely successful, and a number of states developed state-wide programs in which their hospitals would “fly” on the survey simulator and run improvement scenarios. States included Iowa, Oregon, Illinois, and Alabama. TMIT encouraged hospitals to formally submit to the Leapfrog Group by using the TMIT simulator to ready themselves for formal submissions. For certain state programs, TMIT required submission to Leapfrog as a condition of participation after each hospital used the TMIT survey simulator for 1 year.

- **Challenges from the Market**: Many hospitals challenged the honesty of their local competitors regarding their Leapfrog scores, so TMIT undertook a nationwide random audit of hospitals that had submitted the survey, using a 30- to 90-minute line-item interview of safety officers from submitting hospitals regarding every answer they provided. More than 20%, or 260 hospitals of the 1267 organizations, were carefully audited. Findings from interviews with leaders (the CEO or his or her designee, typically the safety officer or quality leader) revealed that fewer than 10 hospitals were found to have submissions of any type that would have changed their score. About half would have had a slight increase in their score and half would have had a slight decrease in their score. If anything, the interviewers found the hospitals very hard on themselves and were conservative in interpretation of the questions. No frank fraud was found of any kind. These findings revealed a surprising level of honesty, with respondents verifying the value of national self-reporting surveys, and likely reflected the gravity hospitals attach to their leadership and increase funding for their patient safety efforts. TMIT undertook a nationwide random audit of hospitals in identifying CPOE performance gaps. The great value to hospitals and to safety was that they could use their score to foster organizations that are implementing CPOE with appropriate decision support about alerting levels; these alerting levels need to be carefully set to avoid over-alerting and under-alerting.

- The CPOE safe practice and simulator were developed to provide organizations that are implementing CPOE with appropriate decision support about alerting levels; these alerting levels need to be carefully set to avoid over-alerting and under-alerting.

- Thanks to the front-line work of Metzger, Welebob, Clasen, and Bates working with many clinical collaborators, hospitals are now able to test their CPOE systems against the TMIT EHR-CPOE Flight Simulator. The CPOE performance verification work was initially funded as a research project. Later partial funding was provided by AHRQ; however, when no funding was available, TMIT stepped in and funded the development and transformation to what the current version has become today.

- The Simulator has been provided by TMIT to the Leapfrog Group for its Inpatient CPOE Testing Standards so that consumers and health-care payers can use it to identify high-performing organizations.

- **IOM Endorsement of CPOE Flight Simulator and NTSB for Health Care**

  - **IOM Endorses EHR-CPOE Flight Simulator**: The IOM 2012 Report on HIT and Patient Safety made a number of recommendations and used a very powerful concept termed sociotechnical model to describe the very important dimensions that are important to safe HIT adoption. It called for routine safety testing of deployed EHR systems and used the TMIT EHR-CPOE flight simulator which TMIT provides to the Leapfrog Group as an example.

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<tr>
<th>TABLE 2. Operational Risks of HIT Performance</th>
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<td><strong>Computer Prescriber Order Entry (CPOE)</strong> is a required feature for Meaningful Use incentives as part of the HITECH section of the American Recovery and Re-investment Act of 2009.</td>
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www.journalpatientsafety.com | 181
• IOM Endorses NTSB for Health Care: The same 2012 IOM report cited above called for the creation of a National Transportation Safety Board (NTSB)-like organization to collect information and investigate accidents related to HIT safety problems. Although not directly pertinent to the discussion of this paper, such an approach will be very valuable to applying the sociotechnical model concept and for future development of more refined simulators tasked with providing scenarios of preventable harm that can be avoided through HIT systems (Table 3).52

Office of the National Coordinator of HIT
• In response to the IOM report in December of 2012, the Office of the National Coordinator (ONC) of HIT has created a plan to implement the IOM HIT and Patient Safety Report recommendations. The draft plan prescribes a list of actions that are organized under three strategies:
  
  A. Learn: Increase the quantity and quality of data and knowledge about health IT safety
  B. Improve: Target resources and corrective actions to improve health IT safety and patient safety
  C. Lead: Promote a culture of safety related to health IT

• The proposed federal plan acknowledges the importance of “live testing to ensure safety features are functional in live environments and that developers address safety complaints,” as articulated in the ONC Fact Sheet.53 ONC will leverage ONC-Authenticated Accrediting Bodies (ONC-ACBs) for surveillance and ONC certification. As stated in our conclusion, we recommend that the ONC and certifying bodies work with existing expert teams and collaborate on solutions such as the TMIT EHR-CPOE Flight Simulator.

• Several organizations have responded to this ONC plan and suggested that post-deployment testing should use existing standards wherever possible, such as the NQF Safe Practice for CPOE that includes use of the flight simulator.5

SUCCESS REQUIRES GLOBAL TEAMS
FOCUSED ON HIT SAFETY

Patient safety accidents; waste because of harm; and the consequences of overuse, underuse, and misuse of care services are at crisis proportions and threatening the very financial security of many countries. To repeat a phrase we have used previously, it is time to learn global, act local, and be vocal.54

Progress in patient safety and especially HIT safety is entirely too slow as recognized by global safety leaders such as Wachtler, in 2009,55 when he looked back at the decade since the original IOM report “To Err is Human.”56 We can no longer expect any one stakeholder alone to solve the challenges of growing HIT risk. This demands that global multidisciplinary teams work on HIT innovations, performance verification, and scenario development.

In the case of the TMIT EHR-CPOE development team, a long-standing, seasoned, cause-driven expert group that is focused on saving lives, saving money, and creating value in communities has been established, although it is but one example.

Over 30 years, through support of extraordinary experts and partners, TMIT has helped fund and establish the beginnings of a global collaborative network, learned how to synchronize and harmonize standards, and developed low-conflict mechanisms to fund education, R&D, and performance improvement at healthcare organizations with financial fuel from industry. In light of the slow progress in patient safety and HIT improvement, TMIT will launch an analog to the Commercial Aviation Safety Team (CAST) initiative described below that reduced airline fatalities more than 80% over a decade. This effort will leverage learning from CAST leadership and call on experts and organizations from around the globe to tackle these serious problems. It will raise funds to drive innovation and seek to partner with government and private sectors.52 It will create an “integration innovation accelerator” that will rapidly assess, help secure funding, and accelerate adoption of high impact performance solutions built on an existing model that TMIT and its affiliate, HCC Corporation (HCC), have successfully employed since the mid-1980s. Innovators will reduce risk; providers will be funded to improve education, clinical care, and research. A conflict-safe harbor will be created to allow collaboration between trading partners. Patients and families will be safer.

A GLOBAL PATIENT SAFETY TEAM

• The GreenLight Network: The GreenLight Network is a group of collaborating health systems and more than 500 experts that are part of the TMIT Research Test Bed. Core leaders come from organizations such as the Brigham and Women's Hospital and its Center for Patient Safety and Practice; the Mayo Clinic; Cleveland Clinic; Johns Hopkins; Vanderbilt University Medical Center; Ascension Health System; and Catholic Healthcare Partners. All have been featured in two consumer documentaries seen on the Discovery Channel and will continue to be featured in a series of future films. Many have been contributors to Leapfrog Group Surveys; NQF Safe Practices development; Healthcare-Associated Infections impact calculators; and proper use of imaging and testing, including the now-global framework called the “5 Rights of Imaging®.” Each will play a unique role and most will be contributors to medication management best practices and development of the CPOE Flight Simulator and an expanded array of HIT high impact solutions for use in both adult and children's hospitals.57

• World Health Organization (WHO): The WHO has made medication management a top priority, according to Dr. Edward Kelley, Head, Strategic Programmes and Coordinator of WHO Patient Safety, whose group will be collaborators on the global team. At a recent global conference, Dr. Kelley stated that recent data have shown that in some countries “over 70 percent of patients’ medication histories have errors.” (Edward Kelley, PhD, Oral Communication, January 13, 2013, Patient Safety and Technology Summit)

• Learning from Aviation: As cited in a recent article addressing the need for a National Transportation Safety Board for health care, “a study of airline accident probability was undertaken in 1993 by the Boeing Commercial Airplane Group that forecast the loss of one airliner every week by 2010. It forecast a growth of the global airline fleet and found that unless emphasis was placed on prevention in addition to just understanding the cause, the losses of airliners would be unacceptable.” In 1997, the White House Commission on Aviation Safety and Security report challenged government and the airline industry to reduce the accident rate of air travel by 80%. The National Civil Aviation Review Commission recommended that the FAA and industry work together to develop a comprehensive, integrated safety plan to implement many existing safety recommendations and develop performance measures and milestones to assess progress in meeting safety goals. They found that aviation safety needed to be addressed worldwide, not just in the United States. The Commercial Aviation Safety Team (CAST) was formed in...
TABLE 3. A Safety Timeline—Context for HIT and EHR-CPOE Flight Simulator

1999:
• **IOM Report: To Err is Human**: One of the most frequently cited reports in health-care history, it served to wake up the healthcare industry.

2000:
• **Leapfrog Group Formed**: In response to the gridlock between providers, payers, and government, it developed “leaps” to leverage market forces.

2001:
• **IOM Report: Crossing the Quality Chasm**: Provided a lasting and powerful framework with focus on evidence-based medicine, systems, and patient-centeredness.
• **EHR-CPOE Flight Simulator Work Begins**: Initial experimental work was funded as a research project and led by D Classen.
• **Leapfrog Group Announces First Three “Leaps”**: Including adoption of CPOE as a leap, they put focus on the important technology solution.

2002:
• **NQF Releases Serious Reportable Events Report**: Medication errors are recognized as some of the most common adverse events.

2003:
• **NQF Releases Safe Practices for Better Healthcare**: An evidence-based set of practices was formally made NQF-Endorsed Measures®.

2004:
• **Leapfrog Surveys All NQF Safe Practices**: All practices were surveyed, with Leadership Structures and Systems commanding 300 of 1000-point weight, recognizing leadership as critical to optimizing culture vital to safety.

2005:
• **TMIT Supports NQF Safe Practices Update**: Practices are synchro-harmonized across NQF, CMS, Joint Commission, AHRQ, the Institute for Healthcare Improvement, and the Leapfrog Group.

2006:
• **TMIT Updates Leapfrog Survey**: Survey updated to synchronize with NQF.

2007:
• **TMIT Funds NQF Development and Maintenance of Practices**: NQF Safe Practices are updated and new safe practices are developed.
• **TMIT EHR-CPOE Simulator Released**: Deployed for testing in field.

2008:
• **TMIT Funds NQF Development and Maintenance Practices**: Work establishes basis for 2009 update.
• **TMIT AHQR Funding**: CPOE Simulator patient order sets updated.
• **Hospital-Acquired Conditions (HACs) Established**: Future of reimbursement impact for certain conditions established.

2009:
• **NQF Releases Safe Practices for Better Healthcare Report 2009 Update**: TMIT – CPOE Adoption becomes SP #16 and Simulator is added as Example Implementation.
• **TMIT Completes CPOE Simulator Order Sets**
• **Leapfrog Begins Public Reporting of CPOE Simulator Results**
• **American Reinvestment and Recovery Act Passed**: Meaningful Use incentives established impacting HIT adoption.
• **Patient Protection and Affordable Care Act Passed**

2010:
• **NQF Releases Safe Practices for Better Healthcare Report 2010 Update**: CPOE Adoption is established as Safe Practice 16, including TMIT EHR-CPOE Flight Simulator component.

2011:
• **TMIT Undertakes Full Re-design of EHR-CPOE Flight Simulator**: Total system updated and entirely new design funded by HCC.
• **NQF Serious Reportable Events 2011 Update**: Medication error remains as a serious reportable event.

2012:
• **TMIT High Performer Webinar Confirms HIT as Top Safety Hazard for 2013**: 30 high-hazard areas in leadership, practices, and technologies were reviewed and polled—HIT ranks as top hazard for 2013.
• **ONC Health Information Technology Patient Safety Action and Surveillance Plan Release for Review**: ONC addresses postdeployment measurement of performance through ONC Authorized Certification Bodies.

2013:
• **TMIT Reconfirms HIT as Top 2013 Safety Hazard**: The January 2013 TMIT High Performer Webinar reconfirms December 2012 results of HIT as top safety hazard for 2013 with quality and safety leaders.
• **HCC-TMIT Clinton Global Initiative Commitment**: Commitment to a Global Patient Safety Guidance System including the development of the EHR-CPOE tool is made emulating the CAST program undertaken for airline safety in the 1990s. An accelerator model established to access resources for R&D.
1998. Remarkably, this cross-industry group reduced American fatalities by 83% over 10 years.

The National Transportation Safety Board (NTSB), formed earlier, is an independent agency of the U.S. government, established by Congress primarily to investigate all significant transportation accidents in the United States for the purpose of learning lessons from significant accidents and applying those lessons through specific recommendations to prevent repeats. The NTSB routinely issues so-called “Blue Cover Reports” as end-of-investigation public releases containing the fruit of their investigatory and analytical labors. It is the standard format of these reports and the intellectual rigor of the presentation methodology inherent to them that could be of great benefit to American health care.52,58,59

- **A New CAST of Characters for Healthcare**: The CAST strategy was to adopt an integrated, data-driven strategy to reduce the fatality risk in commercial air travel. The CAST model identified the top safety areas through analyzing accident and incident data; charting joint teams of experts to develop methods to fully understand the chain of events leading to the accidents; and identification of and implementing high-leverage interventions or safety enhancements to reduce the fatality rate in those areas. A GreenLight Network Team has been formed to leverage the learning from CAST and is developing the plan described below to take the same approach on a global scale.58 In a 2009 article entitled Reducing Health Hazards: Lessons from the Commercial Aviation Team Pronovost et al addressed four lessons for health care: to standardize work processes, use checklists to ensure that patients receive evidence-based interventions consistently, improve teamwork and communication to reduce errors, and use robust scientific methods in collaborative efforts to identify and mitigate risks. A number of efforts inspired by the first three aviation lessons are under way in hospitals with dramatic impact.60-62 The Keystone project and its global spread, led by Pronovost, have saved thousands of lives and many millions of dollars and is the best example.63,64 Pronovost recommends that the fourth lesson above, “so masterfully demonstrated by CAST, is one that the health care field should also emulate.” The strategy that a new health-care team will undertake, described above, will be to learn from the CAST team and their lessons and to apply this fourth lesson of developing and using the most robust scientific methods through collaboration across collaborative networks, leveraging communities of practice to identify and mitigate risks. High frequency, high severity, and highly preventable adverse events will be targeted first.

- **Documentaries Targeting Centers of Gravity**: Awareness building limited to care providers regarding patient safety issues and risk has failed. However, history has shown that when “centers of gravity” or leverage points in a market are surgically targeted with initiatives that can change behaviors, ecosystems can be disrupted. Centers of gravity in supplier, provider, and purchaser elements of the health-care value stream have been targeted with documentaries communicating a call to action and distributed as continuing education programs. GreenLight Network organizations have been featured in two Discovery Channel documentaries - Chasing Zero: Winning the War on Healthcare Harm65 and Surfing the Healthcare Tsunami: Bring Your Best Board,66 which targeted health-care governance leaders and their unrecognized and continuous opportunity to have immediate impact. The EHR-CPOE Flight Simulator was featured in the second film and HIT safety will be again addressed in the next film, Healing Moments: Loved Ones Caring for Loved Ones, which will focus on caregivers and families. The entire series is being converted into continuing education programs on an ongoing basis. The Choosing Wisely Campaign® and best practices, led by soon to be more than 35 medical societies, will be captured in another documentary and training program entitled Choosing Wisely: Critical Conversations. It will deliver health-care education content, inform consumers, and be another call to action. The Campaign is a global example of high impact leadership. The documentaries’ initiatives will reinforce the global HIT Plan by targeting centers of gravity or leverage points in the system that can drive high impact improvement.

- **Education and Continuing Education Programs**: All stakeholders will need new knowledge and competencies. The industry globally has recognized that knowing is not enough to drive the critical changes we need to avert preventable harm. Learning programs are being offered to train administrators and caregivers, such as the LEAD Healthcare program,67 to address leadership, practices, and technologies. Governance board-specific training is being provided through the CareBoards® program.68 And, since the majority of health-care decisions of a family unit are made by women, consumer training in patient safety is being offered through the CareMoms® program,69 addressing the needs of what we call the Chief Family Officer.

- **Incubation and Acceleration of Innovations**: Conflict of interest and competitive forces between trading partners have made it very hard for the multiple stakeholders in health-care to collaborate. The crisis in care and patient safety, especially in HIT, demands that new ways be found to assemble the resources to collaborate and accelerate integration innovation. The plan summarized in Table 4 includes utilizing a “network accelerator” approach to assemble resources from the private sector to invest in innovation, help fund research and development, and gain from the success of accelerated adoption of innovations. The funding will help fuel education, research, and performance improvement by caregivers in the GreenLight Network. It will help disseminate innovations in leadership, practices, and technologies to the global market.

- **Clinton Global Initiative (CGI)**: CGI is a non-partisan organization that convenes global leaders to devise and implement innovative solutions to the world’s most pressing problems. Its members are primarily corporations, non-government organizations, and government leaders which work through and with CGI to maximize their efforts to create positive change.

The partner organizations make a commitment to generate global impact. TMIT and the private philanthropy supporting it are committed to drive global spread of Patient Safety Health Information Technology best practices and have made this a component of their CGI commitment. The intellectual property of the CPOE Flight simulator will be leveraged by TMIT and HCC to support this effort and help government agencies and purchasing organizations use it as a national standard.73

**NO MONEY OR TIME TO WASTE**

“Trust but verify” is the maxim that must be followed by all stakeholders to ensure that health information technologies such as electronic health records and innovations like CPOE can succeed.

The industry has been in love with technology and technology stories for years. However, it has been sobering to find that EHR and CPOE technologies are not performing safely or delivering anticipated savings off the shelf.
TABLE 4. A Global Research, Development, and Improvement Plan

A global research and development plan is under way that will leverage the best concepts, tools, and resources available to address high-hazard safety risks based on their frequency, severity, preventability, and cost to pursue a calling to save lives, save money, and create value in the communities we serve. High-hazard areas of leadership, practices, and technologies will be targeted.57

Expanding Across Care Settings and Care Processes:

• **Acute Care to Ambulatory:** The development and improvement effort is expanding from the TMIT EHR-CPOE Flight Simulator for medication management from acute-care hospitals to ambulatory care and then to pharmacies. It will expand from providers to assisting suppliers and eventually to improve consumer-centered mobile devices and address medication gaps in compliance/adoherence of medication use.

• **From Providers to Suppliers and Purchasers:** The team will redesign the tool and develop new tools to support performance improvement of not only providers of care but to help suppliers of technology and the purchasers of care. It will enhance performance to meet the needs of accountable care and direct contracting with employers.

• **From Medication Management to Imaging and Laboratory:** The success of performance verification in medication management is a platform of competency that will be leveraged to deliver the same results in proper ordering and delivery of results in the areas of imaging and laboratory where overuse, underuse, and miss-use cause harm.52

**Global Collaborative Network of Communities of Practice:**

• **Collaborative Network:** TMIT is continuing to build its global collaborative network of suppliers, providers, and purchasers that provides a collaborative base for information-sharing among communities of practice with it for rapid-cycle learning and optimization of safe HIT implementation. It will work with Patient Safety Orgs. and Quality Improvement Orgs.57

• **Communities of Practice:** Specific topical areas of hazard will be studied to identify opportunities to improve performance improvement in health information technology. They complement others addressed in prior papers that were undertaken by the National Light Network.87

• **Global Patient Safety Forum:** Summits, webinars, and continuing education—global summits, face-to-face meetings of leaders, and global webinars—will continue to be used by the team to implement the plan explained below. Meeting outputs will be produced to provide synchronous and asynchronous learning opportunities.70

**Synchro-harmonization of Key Stakeholders:**

• **Quality, Certifying, and Government Organizations:** As in the process undertaken with the Leapfrog Group surveys and NSQF Safe Practices, organizations such as The Joint Commission, CMS, Leapfrog, AHRQ, NCQA, and others will be invited to collaborate to learn from their networks.70

• **New Certifying Organizations:** The U.S. Department of Health and Human Services (HHS) released its “Health IT Patient Safety Action and Surveillance Plan” on December 21, 2012, and is currently in the review process. It recommends that ONC-Authorized Certification Bodies conduct surveillance which focuses on capabilities that pose the greatest potential risk to patient safety, as well as focus on complaints that developers receive related to those capabilities.5 The development team will plan to collaborate with any future bodies verifying performance of HIT.

• **Scorecard, Payers, and Purchasers:** As noted above, TMIT plans to provide the EHR-CPOE Flight Simulator results and variations of the tool to scorecard organizations as it has provided to The Leapfrog Group in order to drive transparency and help the market reward quality and safety, as well as to drive rapid improvement.

• **Innovation Accelerator:** A program will be established to secure funding for innovations in a low conflict environment of transparency that will fuel research and rapid improvement.

**A Formal Strategic Plan:**

• **Leadership-Practices-Technology Performance Solutions Framework:** The focus on the performance envelope of leadership, practice, and technology tactics will be used as an overarching framework for the HIT global R&D initiative that will address HIT hazards and opportunities for improvement of interoperability. The best practices of CAST52

• **A "4 A Innovation Adoption" Approach:** Accelerating innovation adoption is very difficult. As we addressed in the NQF Safe Practice 1: “Leadership structures and systems must be established to ensure that there is organization wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served.” The team will use this framework to address identification and mitigation of risks and hazards in HIT adoption, and in the design of simulation and surveillance systems to prevent patient harm.33

**Patient-centered Outcomes Focus:**

• **Consumer-Directed Healthcare:** The trend of “accountable care” replacing fee-for-service payment is contributing to and will be complemented by consumer-directed care, as more and more risk is passed on to families who will have to be informed to make value choices with their shrinking funds. This will be one dimension of the development plan.

• **Network Broadcast and Internet Documentaries:** One consumer documentary a year will be produced, building on the success of Chasing Zero65 and Surfing the Healthcare Tsunami66 seen on the Discovery Channel that will generate a library of awareness building assets and multimedia for training. Healing Moments: Loved Ones Caring for Loved Ones will be the third documentary of the series. The Choosing Wisely Campaign67 and best practices led by 35 medical societies will be captured in a documentary and training program entitled Choosing Wisely: Critical Conversations that will target provider education and informing consumers. The CareBoards68 and LEAD Healthcare programs will offer continuing education credits and certification to those taking the training.67,68

• **Chief Family Officers—Our Greatest CFOs:** Globally, women are the key health-care decision makers. They are the most important CFOs of the future—the Chief Family Officers. TMIT will be providing training programs that will help families optimize patient safety. The CareMoms program and training through CareUniversity are providing multimedia output to help protect families.69

• **The Future is Mo-So-Clo:** The future of information systems will be Mobile technologies, Social Media, and leveraging Cloud services, whether they are Infrastructure-as-a-Service (IaaS), Platform-as-a-Service (PaaS), or Software-as-a-Service (SaaS). Focus will be on these dimensions and new horizons.71

• **An Integrated Dashboard—CareScore:** Existing scorecards provide consumers with grades or scores from retrospective, publically-available data, are confusing when they conflict, and most do not measure vital systems. Worse, providers can’t use them for performance improvement. The team will release a synchro-harmonized dashboard of scorecards providing a guidance system for patients; purchasers comparing value; and employers undertaking direct contracting with providers. It will include input from the TMIT EHR-CPOE Simulator and systems/ethics indicators that drive care value.72
The need for attention to the socio-technical model and issues of the performance envelope defined by leadership, practices, and technologies has become clear.9

**Great Opportunities for Key Stakeholders**

There are enormous untapped opportunities to generate great speed-to-impact if the key stakeholders work together with seasoned teams who have solutions and are all ready to openly collaborate. President Bill Clinton, at a recent Patient Safety and Technology Summit (the first time ever that a former president participated in a patient safety meeting), shared a message of the power of collaboration. He challenged the audience to believe that the future will be led by those who develop collaborative networks.74

- **Government Entities:** Our recommendation is not to waste taxpayers’ time or money by starting over, but to further develop systems that already exist and can be made available as national standards through collaboration. For instance, typical certifiers do not have an existing solution, a collaborative network, communities of practice, front-line clinical knowledge, or technical experience with an EHR-CPOE simulator such as the one endorsed by the IOM. The TMIT EHR-CPOE team is ready to work with ONC certifiers, Patient Safety Organizations (PSOs), and Quality Improvement Organizations (QIOs) to accelerate HIT safety. Duplication and starting over will have an enormous price...in lives and dollars.

- **Hospital and Health System CEOs and Teams:** It is impossible for CEOs and governance boards to delegate away the risk of adoption of HIT. The threat is real, large, and systemic, and will require new resource allocation to risk identification and mitigation that is not in budgets today. This will require personal engagement by great leaders.

- **Governance Leaders:** It is not necessary to have all the answers; however, it IS necessary, in fact critical, that governance leaders representing the community ask the right questions of administrative teams that report to them. One simple question: are our Health Information Systems such as EHR and CPOE safe? And if the answer is “yes,” how do you know? If the answer is “no” or “I don’t know,” prepare to write some checks and spend some time asking questions until the answers regarding safety are a strong “yes.” Your communities and their families are counting on you.

- **CFOs and Finance Leaders:** The accountable care movement will turn existing profit centers into cost centers overnight. The mantra of “no margin-no mission” is being replaced with “no outcome-no income.” Blind cost-cutting is a sure way to perish in accountable care, where verifiable value will rule. Finance leaders will need to develop new return-on-investment (ROI) models of the fully loaded savings they will generate by reducing the very risk that used to be passed on to consumers, payers, and employers.75

- **Quality Leaders:** It can be said that working with physicians to make care safer is like going to war with a circus troop. Care is fragmented and driven by individual, self-absorbed performers who are uninterested in their support systems until they fail. Non-IT quality leaders need to weigh in on risks that are keeping them up at night and argue their case for new resources. They will have to call on the better angels of their leaders to ensure proper funding of risk prevention. They will have to communicate the moral imperative.

- **CIOs and Health Information Technology Leaders:** In the early stages of digital transformation, we said that IT leaders were 10% “I” and 90% “T” as they were absorbed by and completely dedicated to “go-live” milestones and then to keeping technology systems up and running. Their priorities will change dramatically now that systems are part of core work process. Clinicians will truly demand their IT leaders become 90% “I” and 10% “T,” for it is the clinical decision support and information we capture and synthesize that will generate better care. The real savings and safety that can fulfill the promise of HIT lie in the proper generation of accurate patient information processes. Our best CIOs and their teams are going to have to become collaborative champions and great communicators to help us do this.76

  - **To Practicing Physicians:** For those in the USA and other countries where fee-for-service private practitioners still prevail, it will be important to move from being passive beneficiaries of the ecosystem, where they have thrived to being actors and champions for their patients and protectors of their families. It is a golden opportunity for dedicated physicians to step up. Many are. The Choosing Wisely campaign is an example. It will be more than 35 medical societies strong by mid-2013, and is an extraordinary role model of leadership by physicians to curb overuse and misuse of testing.13

  - **To Health Information Technology Suppliers:** Our HIT companies have done a terrific job in one of the most complex industries at one of the most challenging times the global economy has known. They must weather the storms of criticism for not delivering savings from the press and studies reflecting early performance. They must also make sure that they dedicate their energy to delivering the clinical decision support systems we need by working with collaborating teams who put safety first. They will become 90% “I” and 10% “T” just like the leaders who implement their systems.76 The extraordinary financial success of these companies is not lost on anyone. It is time to invest the fruits of their labor in making their system safe and delivering savings now that they are hardwired into our process of care. We must solve the challenges of clinical decision support, safety functions like CPOE, and interoperability.

The use of standardized measurement systems for HIT has been shown to work in measurement of the performance of EHR-CPOE systems. It is time to use this approach with as many health information systems as we can to ensure patient safety. It works.

President Reagan may have popularized the concept of “Trust But Verify”; however, his resolve to maintain it through the most complex of negotiations, and acknowledged by Mikhail Gorbachev, is what health-care leaders must do...“repeat that at every meeting.”

**Trust But Verify... Use It at Every Meeting**

This is what has to be done at every meeting between man and machine; at every meeting between HIT vendors and providers; and even at meetings between patient families and their caregivers, if we are to make health care safer.

**REFERENCES**


Jan 1, 2014

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We want to acknowledge you and your institution for your current efforts in patient safety. We hope you enjoy this article and find it useful in your future work.

Sincerely,

Charles R. Denham, M.D.
Chairman