Spotlight on CERTs Research: Health IT and Patient Safety

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The CERTs program

The Centers for Education and Research on Therapeutics (CERTs) program is a network of research centers established in 1999 by the United States federal government to add to the evidence base on the safety and effectiveness of therapeutics—a broad category that includes drugs, medical devices, and biological products, such as vaccines. The CERTs program generates new knowledge and produces practical tools and educational materials. The program is supported by the Agency for Healthcare Research and Quality (AHRQ), in consultation with the Food and Drug Administration (FDA). Since the program’s inception, the number of CERT centers has varied from as many as 14 to the 6 active in 2012.

This article highlights recent CERTs research on the use of computerized information systems in health care settings. More than a decade ago, the Institute of Medicine (IOM) estimated annual deaths in the US due to medical errors in hospitals at between 44,000 and 98,000 a year.1 In order to prevent medical errors and keep patients safe, computerized physician order entry (CPOE) systems have been implemented in many different care settings over the past decade. CPOE systems support physicians and other health care professionals in ordering medications, lab tests, and imaging services, as well as more routine patient care tasks. Some CPOE systems have been shown to improve medication safety, while for other systems results have been more mixed.2,3 As CPOE systems transmit information electronically, these data can also be scrutinized for errors and safety issues as orders are being keyed in or, alternatively, as they are received by the pharmacy, lab, or other ancillary departments. CPOE systems provide another advantage: decision support tools that offer providers standard dosages, protocols, and care guidelines.

The US is now offering substantial financial incentives to encourage hospitals and doctors’ offices to adopt electronic health records (EHRs), as well as computer systems for entering prescriptions and physicians’ orders.4 The Health Information Technology for Economic and Clinical Health Act (HITECH) authorizes the Centers for Medicare and Medicaid Services (CMS) to make payments to health care providers and hospitals that demonstrate meaningful use of certified EHRs. Private sector entities are also offering initiatives to improve patient care that include assessments of whether CPOE systems are in place. The Leapfrog Group, made up of more than 100 large employers, conducts a voluntary hospital quality and safety survey; the results form the basis of incentive and reward programs designed to influence consumers’ choices in the health care market.5

The incentives are having an impact. The Office of the National Coordinator for Health Information Technology (ONC) in the US Department of Health and Human Services reports that as of December 2011, more than 1,500 EHRs—about 1,000 ambulatory and 500 inpatient—have been certified by one of 6 private-sector authorized testing and certification bodies, up from 300 certified EHRs at the start of 2011. The ONC reports that 154,362 eligible professionals and 2,868 eligible hospitals have registered with the EHR incentive programs. More than 20,000 eligible professionals and 1,200 hospitals have already received their incentive payments from CMS, totaling $1.8 billion thus far.6

While hospitals and physicians’ offices are increasingly adopting computerized information systems, the systems are still relatively new, and research reviewed below
suggested they need to be improved to optimize their benefits. CERTs program researchers have found troubling gaps in these systems that point to how they can be improved in the near term, and also to the need to constantly evaluate and refine them. This work includes the development of practical, real-world tools to assess and improve the performance of these systems.

Improving tools to prevent medication errors

University of Arizona

The Arizona CERT, a program of the Critical Path Institute in collaboration with the University of Arizona College of Pharmacy, has conducted research suggesting that clinical decision support (CDS) systems—software programs pharmacies and others use to prevent harmful drug-to-drug interactions (DDIs)—do not perform as well as they should. Arizona CERT researchers studied 64 pharmacies in Arizona and found that only 28% of pharmacies’ CDS software programs identified potentially dangerous DDIs. Investigators tested the pharmacies’ CDS systems using prescription orders for a fictitious patient with 18 different drugs, which posed 13 clinically significant DDIs.

This work led Arizona CERT researchers to develop a tool that allows pharmacies and other organizations to test their CDS systems to determine if significant gaps or problems exist. The tool consists of a set of steps for creating a test patient profile, entering medication orders for the test patient, and then assessing how the system responds. The tool can be customized to look specifically for DDIs that reflect prevalent local patient safety issues. Beyond providing a check of how well the current software system is identifying potential DDIs, implementing the tool also creates an opportunity to evaluate a pharmacy’s other means of preventing DDIs, such as policies and staff training. Arizona CERT researchers have published detailed instructions on how to use this tool to evaluate the performance of CDS software programs.

University of Pennsylvania

The effectiveness of CPOE systems has been shown to be highly variable, a finding supported by CERTs research. In particular, striking the right balance in creating effective medication alerts has been a major challenge. Researchers at the University of Pennsylvania CERT conducted two randomized clinical trials in 2006 and 2007 that assessed how electronic alerts led to prescribing changes when concurrent medications were contraindicated. One study evaluated the effect of a hard-stop alert to prevent concurrent prescribing of warfarin with an antibiotic. With one group of physicians, researchers tested an alert that prescribers could not override, and that blocked the second order from execution unless the provider acknowledged the patient had a specific condition that required concurrent therapy or the provider contacted the pharmacy to bypass the alert. Meanwhile, a control group experienced the standard practice of being allowed to place the concurrent orders but receiving a call from a pharmacist. While the alert was extremely effective in preventing concurrent prescribing, the study had to be terminated early because of unintended consequences—the alert was so effective that it caused treatment delays for patients who required immediate drug therapy.

The other Pennsylvania study evaluated a customized CPOE alert requiring an affirmative response for preventing concurrent orders of warfarin and nonsteroidal anti-inflammatory drugs (NSAIDs). When researchers compared it to a standard passive CPOE alert with no response required, they found that the customized alert did not decrease concomitant prescribing of these two drugs. Despite the robust study design, it was difficult to determine why the customized alert was not more effective; it may have been too similar to the standard alert, or physicians may have made complex risk-benefit calculations to determine whether or not to accept the alert that could not be accounted for in the study.

These University of Pennsylvania studies exemplify the need for evaluation and monitoring of CPOE alerts; not all new CPOE alerts are effective in reducing concurrent prescribing, and those that are may have unintended consequences that impact the safety of patients and negate the primary intent of these tools.
Supporting Nursing’s Role in Preventing Failure to Rescue

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In 2011, the HealthGrades Patient Safety in American Hospitals Study reported a rate of approximately 100 deaths per 1,000 surgical inpatients from serious, yet treatable, complications.1 In another research study, vital sign abnormalities and declines in physiological status occurred up to eight hours prior to an unexpected inpatient death, indicating missed opportunities for early intervention.2 As an example, infection leading to sepsis is a known, and in many cases treatable, complication of surgery, yet the HealthGrades® study reports that between 2007 and 2009 over 5,000 Medicaid beneficiaries died from postoperative sepsis.1

When the health care team does not recognize or fails to respond appropriately to the early signs of a hospital-acquired complication that leads to a patient death, the result is failure to rescue. Registered nurses, as the primary bedside care provider, play a prominent role in maintaining patient safety by recognizing the early signs of potentially lethal complications or other unanticipated physiological events. Hospital administrators are responsible for maintaining an environment that promotes nurses’ ability to play this role: by reducing nurse-to-patient ratios, employing greater numbers of BSN-prepared nurses, and providing adequate training for novice nurses.

Background

Failure to rescue was introduced as a patient safety and hospital quality indicator by Silber et al in 1992 to help hospitals distinguish between the ability of an institution to prevent complications in surgical patients and its ability to rescue patients after a complication developed. The failure to rescue rate was defined as the number of patients with an adverse occurrence who died out of the total number of patients who had an adverse occurrence.3 Adjusted mortality rates on their own are not reliable patient safety indicators because patient severity of illness varies widely among hospitals—larger, urban hospitals generally have higher adjusted mortality rates because they treat the most severely ill and injured patients.

Early detection of serious or potentially fatal clinical complications relies heavily upon registered nurses, who are the professionals providing the vast majority of direct patient monitoring and care at the bedside, and therefore are the ones most likely to notice early signs of patient deterioration. The intersection of failure to rescue and nursing practice was brought to the attention of the nursing profession in several large, multihospital studies. Needleman et al found that hospitals reporting more hours of

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patient care provided by registered nurses coupled with employing a greater proportion of registered nurses were associated with lower rates of failure to rescue in both medical and surgical patient populations.4 Aiken et al found that hospitals with more baccalaureate prepared nurses, lower nurse-to-patient ratios and better nursing practice environments had lower rates of failure to rescue.5,6

Surveillance and detection of serious complications among hospitalized patients is only the first step in preventing failure to rescue. In an attempt to improve the health
care team response to potential failure to rescue situations, hospitals nationwide have instituted rapid response systems. These systems consist of a small team of experienced clinicians who are called to the bedside when nurses identify institutionally defined criteria such as low or high blood pressure, heart rate, and/or respiratory rate, or when nurses, patients, or family members are concerned about the patient’s condition. The goal of the rapid response system is to provide early evaluation, triage and intervention to prevent injury, cardiac arrest, unplanned intensive care unit transfers, or death. However, it is unclear whether the initiation criteria for a rapid response team call are in fact the earliest signs of these complications. For instance, many protocols use a systolic blood pressure of less than 80 mm Hg as a trigger, yet in many cases this parameter may represent late stages of decompensation, rather than early stages of shock. One study found that experienced nurses appropriately initiated the rapid response system because of subtle changes from patient baseline, rather than relying solely on institutional criteria.

Another proposed solution for preventing failure to rescue is automated early warning systems that trigger alerts when electronic documentation matches rapid response system activation criteria. However, these early warning systems and the criteria from which they are derived are being implemented without strong evidence of their validity, reliability, and usefulness.

Nursing research on failure to rescue has focused primarily on nurse staffing, skill-mix, and the characteristics of hospital environments that promote the ability of nurses to prevent death from serious, treatable complications. However, there are many individual nurse behaviors and actions that can impact whether a serious complication is detected or not. Frequent observation, assessment and collection of vital signs are not sufficient. Nurses must have a broad understanding of the patient’s medical history, have adequate knowledge of disease presentation and expected course, identify subtle deviations from what is expected of the disease process, anticipate complications, and situate findings within an understanding of patient baseline and trends.

Learning more through research
In an effort to identify and distinguish between the individual factors that help nurses successfully detect and intervene in the face of adverse complications and those factors that consistently lead to failure to rescue, a study titled “Identifying the Cognitive Dimensions of Failure to Rescue” has been funded by the National Patient Safety Foundation (2009 NPSF Board Research Grant; A. Doig, Principal Investigator). In this study 60 novice and experienced hospital nurses were observed as they monitored acutely ill patients in a high fidelity simulated acute care environment. Three patient care scenarios were developed for the study using interviews with 9 experienced nurses which were then validated by three nurse educators. Each scenario included the presence of a complication that was not directly related to the patient’s primary diagnosis, but could be anticipated and detected given the data presented to the nurse by the medical chart, vital signs, physical assessment and communication with the patient. Each complication was characterized by risk factors, laboratory data, vital signs and physical assessment findings and the presence of physiological trends (e.g., decline in blood pressure). After nurses completed the three 20-minute simulations, an in-depth interview was used to capture the thought processes underlying nurses’ observed statements and behaviors during the scenarios.

The goal of the analysis will be to compare and contrast observed behaviors and thought processes between successfully detected events and potential failure to rescue situations. Successful and unsuccessful patient surveillance strategies used as the basis for clinical decision-making will also be examined. Preliminary findings are that the detection and identification of hospital-acquired complications and likelihood of taking appropriate action is associated with a nurse’s lack of preconceived assumptions regarding
Brigham and Women’s Hospital

In work carried out in a national sample of hospitals, researchers at the Brigham and Women’s Hospital CERT in Boston recently used simulated medication orders to assess how well hospitals’ computerized information systems detected medication errors that would lead to serious safety concerns. Nationwide, 62 hospitals volunteered to test their systems’ abilities to detect medication errors using the simulation tool. The research found that the hospitals’ CDS systems detected only 53% of the orders that would have resulted in fatalities.11 As the authors noted, “It is important to ascertain whether actual implementations of computerized physician order entry are achieving goals such as improved patient safety.”11(p655)

Brigham and Women’s CERT researchers have also examined electronic prescribing systems in outpatient settings to learn more about errors and how to prevent them.12 Researchers analyzed 3,850 computer-generated prescriptions from a pharmacy chain in three states in 2008. Clinicians reviewed the prescriptions to find and categorize medication errors. They found that about one in 10 prescriptions had errors; about one-third of the errors were potentially harmful adverse drug events. Error rates varied substantially (5% to 38%) depending on the type of electronic prescribing system used.

The error rates they found in e-prescribing systems were consistent with error rates for handwritten prescriptions. The authors suggested specific ways to improve e-prescribing systems, such as adding forcing functions that would require prescribers to enter certain information (eg, drug dose or frequency), decision support that is drug-specific, and a calculator function. They also suggested interventions to ensure that the system that providers are using is designed and implemented to minimize errors. These include careful selection of the system vendor and adequate training for system users. The authors noted, “When implementing any computer-based intervention, the benefits of reduced errors and improved patient safety must be weighed against the cost of physician resistance to using an inflexible system while under significant pressure.”12(p6)

Linking electronic systems to maximize patient safety

University of Illinois at Chicago

In order to minimize medication errors, ideally, computerized information systems that contain patients’ lab test results and those that contain their current prescriptions should be connected and compared, so that patients do not begin taking a medication that is contraindicated by a recent lab test result and so that doctors can use lab test results to monitor and adjust dosages. Researchers at the University of Illinois at Chicago (UIC) CERT connected patients’ lab test results with their prescriptions and alerted prescribers to results that would impact their decision to prescribe a medication.

To do this, researchers used an expert consensus process to develop a set of 24 “high-yield pairs” of medications and laboratory test results. They evaluated these pairs to determine the best laboratory test result thresholds and times for alerts. Getting this balance right is crucial for patient safety. Their research evaluation showed variations in the best alert times and cutoffs for test results, depending on the pair studied.13

The next step in this work involved programming these 24 drug-and-laboratory-test pairs into the clinical computer system at the University of Illinois hospital to give pharmacists and physicians daily alerts about patients’ chronic kidney disease when they ordered a gadolinium-based contrast MRI. The use of gadolinium increases the risk that patients with chronic kidney disease will develop severe complications. In May 2007, the FDA ordered a black-box warning for MRI contrast agents containing gadolinium, stating that they...
increase the risk that patients with chronic kidney disease will develop a condition that involves thickening of the skin, organs, and other tissues (nephrogenic fibrosing dermopathy/nephrogenic systemic fibrosis), for which there is no known treatment. CERT researchers assessed how the new alert affected order cancellation rates. They found that the alert reduced orders for gadolinium-enhanced MRI for patients with impaired kidney function, but physicians continued to override the warnings and order them.¹⁴

Looking forward: We can do better

As the US health care system continues to adopt electronic systems at a rapid pace, it is critical that health care researchers evaluate these systems’ performance in terms of patient safety. Although implemented to improve patient safety, computerized information systems may be implemented too quickly and with too little support and training for clinicians, leading, paradoxically, to mistakes that compromise patient safety. To ensure that patient safety remains the top priority, the electronic systems used in health care settings must be rigorously evaluated and, if found to be flawed, repaired and improved. New software systems in health care settings have great potential to improve patient safety if they are designed and implemented carefully. Despite the growth of electronic systems for medical records, prescriptions, imaging, and lab results, interconnecting these systems to consolidate patient information is a potential safety measure that remains largely untapped.

Recognizing the need for guidance during this period of transition to electronic medical systems, the Office of the National Coordinator for Health IT tasked an IOM committee with exploring ways to make health IT–assisted care safer. In 2011 the committee issued the report Health IT and Patient Safety: Building Safer Systems for Better Care.¹⁵ An essential approach, the report states, is “for both the public and private sectors to acknowledge that safety is a shared responsibility.”¹⁵(p125) The CERTs program, which brings together public and private partners to carry out its mission of public interest research, will play an essential role by assessing existing systems and identifying key areas for improvement going forward. NPSF

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the patient’s status, use of medical chart data including patient history and laboratory findings, and focus on physiological trends. For instance, during the scenarios fewer than 50% of the nurses recognized the clinically significant drop in the patient’s blood pressure that had occurred between the previous shift and when the first set of vital signs were taken. Most nurses focused on a common subset of physical assessment findings; therefore, the amount of data they collected during their physical assessment was not associated with detection of these complications. The results of this study will be used to develop an approach to clinical training that promotes the early detection of and response to situations that have a high potential of leading to failure to rescue.

Improved future

Addressing the patient safety issue of failure to rescue will not be accomplished by assigning blame to clinicians. Research to date has shown that there are significant health care system issues that make failure to rescue more likely to occur. Employing greater numbers of baccalaureate-prepared nurses and providing them with opportunities for increased patient surveillance by reducing nurse-to-patient ratios will likely result in an increase in the detection of subtle patient changes, and appropriate and timely intervention. Improved training with evidence-based programs for nurses addressing the recognition of and response to life threatening complications may also decrease the occurrence of failure to rescue. NPSF

References


Report Highlights NPSF-Funded Patient Safety Research

NPSF has published an updated report documenting patient safety research projects supported by its research grants program, highlighting the accomplishments of grant-funded investigators and the program’s contribution to the field of patient safety. The report provides a summary of each project funded to date along with a list of publications and presentations directly or indirectly resulting from NPSF-funded research. Download the report at www.npsf.org/wp-content/uploads/2012/05/NPSF_Research_Grants_Summary_2012_web.pdf
The National Patient Safety Foundation has awarded grants totaling nearly $200,000 to support new research in patient safety. The two grants will support projects led by Alicia Arbaje, MD, MPH, of Johns Hopkins University School of Medicine, and by Mary Beth Happ, PhD, RN, FAAN, of University of Pittsburgh School of Nursing.

Dr. Arbaje’s project, “Identification and Validation of Risks to Patient Safety during Care Transitions of Older Adults Receiving Skilled Home Healthcare Services after Hospital Discharge,” will focus on improving safety of care during the posthospitalization period for older patients who require skilled home health care (SHHC) services after hospital discharge. Errors during such care transitions are common, and older adults who require SHHC services (such as nursing or physical therapy) after hospital discharge appear to be particularly high risk of experiencing suboptimal outcomes, including early rehospitalization.

The study will use an approach based on principles of human factors and systems engineering to investigate threats to patient safety during care transitions and to develop sustainable interventions. In order to identify factors that contribute to unsafe care transitions, the researchers will conduct direct observations of the SHHC admissions process from the hospital to the patient’s home as well as semi-structured interviews of older adults, caregivers, and SHHC providers. The researchers will then develop and pilot test an innovative index that will enable SHHC agencies to identify older adults at high risk for suboptimal care transitions and target them for intervention during the hospital-to-SHHC transition.

By focusing on transitions to the SHHC setting, this study will begin to fill important gaps in research and provide evidence to support interventions that address care transition risks in this setting. Study findings have the potential for applicability to a broader group of patients discharged from hospital to home and requiring complex care.

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The project will consist of 2 related studies designed to address the problem of distraction and interruption as a potential source of error in adult critical care settings. In the first of the two studies, the researchers will analyze video recordings of nurses providing bedside care in order to characterize types of interruptions and describe nurses’ strategies for managing interruptions. In the second study, the researchers will augment these findings through qualitative analysis of real-time observations and focus-group interviews with nurses working in the same types of critical care settings as were observed in the first study.

Findings of this research project are expected to help to improve critical care patient safety by providing a more complete understanding of distraction and interruption during bedside care; identifying strategies for preventing and managing nurse disruption and interruption in the ICU; and providing practice-based evidence for the development of a program to improve clinicians’ safe management of distraction and interruption.

Dr. Happ is the recipient of the NPSF Board Grant, which is supported in part by generous contributions from NPSF Board members.

The National Patient Safety Foundation’s Research Grants Program seeks to stimulate new, innovative projects directed toward enhancing patient safety in the United States. The Program’s objective is to promote studies leading to the prevention of human errors, system errors, patient injuries and the consequences of such adverse events in the healthcare setting. Since 1998, the National Patient Safety Foundation Research Program has supported 38 research projects with nearly $3.8 million in grant funding.
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Reserve Now for Lucian Leape Institute Forum & Gala

Once again, the Lucian Leape Institute offers its annual Forum & Gala, on September 13, 2012, in Boston, Massachusetts, providing an afternoon of dialogue with members of the Institute followed by an evening of networking at a reception and dinner.

The afternoon Forum will take place at the Westin Boston Waterfront, where interactive discussion will be led by the Leape Institute members. As thought leaders in the ongoing work of patient safety improvement, the members will offer insights into their work and will also actively seek attendee reaction and perspectives. Topics will include the transformative concepts already identified by the Institute, with special focus on the restoration of joy and meaning to health care work as well as safety of the health care workforce.

The evening Gala will feature a reception and dinner at The State Room overlooking Boston’s skyline and harbor. The distinguished keynote dinner speaker this year is Donald M. Berwick, MD, MPP, FRCP, Former President and CEO of the Institute for Healthcare Improvement, and Former Administrator of the Centers for Medicare and Medicaid Services.

Seating for this event is limited. To make reservations, visit www.npsf.org. For more information, email info@npsf.org.
NPSF Welcomes Members of the AHA-NPSF Comprehensive Patient Safety Leadership Fellowship

The AHA-NPSF Comprehensive Patient Safety Leadership Fellowship, now in its twelfth year, is an intensive learning program designed to help health care professionals gain knowledge and skill in leading patient safety, quality, and performance improvement initiatives in their organizations. The year-long program culminates with the completion of an Action Learning Project demonstrating the Fellow’s ability to apply the concepts learned.

The AHA-NPSF Comprehensive Patient Safety Leadership Fellowship is sponsored by the American Hospital Association and the National Patient Safety Foundation, in partnership with the Health Research & Educational Trust, Health Forum, the American Society for Healthcare Risk Management, the American Organization of Nurse Executives, and the Society of Hospital Medicine.

For more information, visit http://www.hpoe.org/fellowships/PSLF/index.shtml.

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