Clinical Patient Safety—Achieving High Reliability in a Complex System

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Abstract. Since the 2001 Institute of Medicine Report which estimated that 44,000 to 98,000 patients die each year as a result of healthcare error. This report in effect launched a global patient safety movement, with many proposed regulatory, research and administrative solutions. Patient safety areas of focus such as work complexity, teamwork and communication, technology, and evidence based practice provide a basis for understanding healthcare error. Reliability concepts are the goal of healthcare organizations; and applications such as simulation theory provide means to achieve this status. The translation of research into practice is the foundation of organizational patient safety. Understanding and awareness of patient safety issues has increased; however, significant work to improve patient care outcomes remains.

Keywords: patient safety, culture, work complexity, human factors, education, root cause analysis, failure mode event analysis, simulation, high reliability organization.

1 Introduction

The landmark 2001 Institute of Medicine report *To Err Is Human: Building a Safer Health System,* estimated that from 44,000 to 98,000 patient die every year due to healthcare error. (1) This attention has driven a variety of important patient safety related solutions that include regulatory requirements, error reporting systems, and technology. Five years after this report, improvements, particularly in the area of regulatory standards, have been achieved. However, significant barriers remain. These barriers include complexity, individual, professional autonomy, fear, hierarchical authority structure, diffuse accountability, lack of leadership, difficulty of measuring patient safety and reimbursement structure. (2) This paper will explore the current state of patient safety knowledge, and identify challenges and a direction for future multidisciplinary patient safety research, design, and collaboration.

2 Patient Safety Areas of Practice

To create a reliable healthcare environment, an understanding of theoretical patient safety is necessary to understand, interpret and formulate patient safety solutions. Patient safety areas of practice may be grouped in the following broad categories.

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2.1 Work Complexity

Understanding the work environment is a key to understanding patient care error. Work complexity, which is really the study of the healthcare environment from the frontline perspective, is related to human factors engineering. The healthcare environment is highly complex, involving multiple people, products, equipment, interruptions and patients. The needs and conditions of patients may change dramatically within a short period of time. Researchers in nursing and other disciplines have determined that this complex, rapidly changing and unpredictable environment causes a series of small latent failures or gaps, which may cause or contribute to patient care error. (3) For example, a surge in patient admissions increases the workload of a nurse. Unless the surge is addressed by staffing, the nurse must juggle additional information and a critical piece of information may be missed. Human factors concepts, such as the impact of labeling on healthcare provider performance, are an integral part of understanding the work environment.

2.2 Technology

While technology has provided many solutions to patient safety, it may also provide unintended consequences. (4) Technology is only as good as the culture in which the technology is used. Technology must be developed, implemented and analyzed with the assistance of the frontline staff that uses the particular technology. The work environment must be evaluated prior to technology implementation.

2.3 Communication and Teamwork

Collaborative relationships between healthcare providers are key to understanding error providing good patient outcomes. The JCAHO Sentinel Event database identifies communication as a root cause in most serious reported healthcare error regardless of the type of error. The Health Work Environment Standards by AACN are evidence based interventions based on the “Silence Kills” study. This study showed that in most healthcare environments, staff members do not speak out regarding patient safety issues for a variety of reasons. (5)

2.4 Evidence Based Practice

Evidence based practice is defined as the conscientious use of current best evidence in making decisions about patient care”. (6) Many decisions made in healthcare are not based on evidence, even when evidence exists. (7) This failure to translate research into practice may be the result of difficulty translating evidence into practice, or the result of leadership style. Evidence based practice should be required for every healthcare decision.

3 Reliability and Healthcare

Reliability is the measurable capability of a process or procedure to perform its intended function in the required time under commonly and uncommonly occurring

conditions (8). High reliability organizations are those that, even with highly complex and dangerous activities, have very few errors. Examples of high reliability organizations include nuclear power plants, aircraft carriers, and air traffic control systems. High reliability organizations exhibit harmony, balance and a sense of purpose with all aspects of the given process or product to produce a reliable result.

Healthcare is even more complex than the examples listed above. An aircraft carrier focuses on landing one aircraft at a time. Manufacturers are able to standardize parts and processes on the assembly line. In contrast, healthcare practitioners manage the arrivals, transfers, and departures of highly individual patients with very different needs on any given day. When the individual practitioner practice, process, and products are factored into patient needs, the result is fantastically complex care. The challenge for all of us, as healthcare professionals, is to convert healthcare into high reliability organizations.

It is one thing to study high reliability organizations, but quite another to introduce reliability into practice. There are four elements present in every high reliability organization. These elements are:

- Systems, structures, and procedures conducive to safety and reliability are in place
- A culture of safety permeates the organization
- Safety and reliability are examined prospectively for all the organization's activities; organizational learning by retrospective analysis of accidents and incidents is aggressively pursued
- Intensive training of personnel and teams takes place during routine operations, drills and simulations (9)Aspects of all these elements are present in every organization, service and academic. Healthcare organizations wishing to decrease error need to address every element in depth, implementing the latest evidence in each area.

3.1 Systems, Structures, and Procedures Conducive to Safety and Reliability Are in Place

To provide a safe environment of care for both staff and patient, certain factors must be present. Systems, such as an electronic medical record or the way drugs are distributed in pharmacy, are necessary to run the hospital efficiently. Physical structures, such as the needed equipment, the physical environment or software, are components of the reliable workplace. Additionally, the providers' infrastructure, or organizational structure, is another example of structure needed. Finally policies and procedures for safety—from policies on the actual procedure to regulatory policies are necessary. Some regulatory bodies, such as the Joint Commission for Healthcare Accreditation (JCAHO), as well as government agencies, require baseline system, structures and procedure to ensure patient safety. The JCAHO National Patient Safety Goals are an example of a regulatory required procedure. (10)

3.2 A Culture of Safety Permeates the Organization

A "culture of safety" is a term used to describe a working environment where staff members feel comfortable reporting errors and mistakes without fear of retribution,

where staff may question those in higher authority when a patient safety question arises, and where management values and acts on patient safety information from any source. In a culture of safety, rather than blame the individual practitioner who may have given the wrong medication or procedure, patient care error is viewed as a systems issue. Many in health care fear that non-punitive reporting allows a substandard staff member to stay in the system without taking responsibility. As a result, researchers such as James Reason have suggested the concept of a just culture, where the error is analyzed from both a systems and a personal accountability perspective. There are several surveys, instruments and tools designed to measure a culture of safety.

3.3 Safety and Reliability Are Examined Prospectively for All the Organization's Activities; Organizational Learning by Retrospective Analysis of Accidents and Incidents is Aggressively Pursued

Borrowing from the world of industry, tools such as failure modes event analysis (FMEA) and root cause analysis are used by healthcare providers to learn from error. Although required by some accreditation organizations such as JCAHO, there is a great degree of variability in the application of these tools to the healthcare setting and to what degree the healthcare organization uses these tools. Additionally, the learning from healthcare error is often difficult to disseminate within the organization and to other healthcare providers. The JCAHO Sentinel Event program and various state reporting systems are methods that accrediting bodies and the government have chosen to assist healthcare organizations in sharing and disseminating healthcare error information. (11)

3.4 Intensive Training of Personnel and Teams Takes Place During Routine Operations, Drills and Simulations

Training and simulation has a strong evidence base in healthcare. Like the airline industries that put their pilots and crews through teamwork and simulation exercises, similar training and simulation exercises have been developed in some regions of the nation. There are three types of simulation and training. The first is using equipment or props to perform a task. Examples are anchoring a foley catheter, mock codes or starting an intravenous line. A second type of simulation is a simulation of a particular procedure or scenario, using high tech simulated patients. These patients may be used in a variety of circumstances and scenarios, such as performing a cardiac catheterization or simulating a process such as anesthesia in the operating room. This type of simulation may be done individually or with teams. Lastly, simulations may be computer based. Much like video games, these simulations can teach the operation of equipment or any number of processes or procedures.

Simulation and training is important to both professionals and students. Moving from the old model of "see one, do one", simulation and training provides learning and practice on virtual patients rather than very real patients. Additionally, the concept of teamwork training is a concept very important to healthcare. Sentinel event data, both internal and external, indicates that communication is a root cause of almost every adverse event. Learning how to communicate and work in teams not

only raises awareness, but also teaches essential skills. Simulation and teamwork training also can mimic work complexity. Traditional training teaches a perfect procedure in a perfect environment, which happens infrequently in the real environment.

Simulation and training provides a basis for service and academic research. Simulation and training were adopted primarily through comparisons to military and airline training—high-risk technical operations. Although simulation is used by academia and service to increase performance, there is not a great deal of evidence in the literature to show outcome measures.

4 Designing and Implementing Patient Safety Programs

4.1 Leadership

Leadership is a requirement of an effective patient safety program. Diffuse accountability has been cited as a barrier to patient safety solutions. Programs such as the Institute for Healthcare Improvement 5 Million Lives Campaign have targeted governance as a key element in the success of patient safety.

An excellent example of nursing leadership that produces quality outcomes is the American Nurses Credentialing Center (ANCC) Magnet Recognition Program®. This program was developed by to recognize health care organizations that provide nursing excellence. A Magnet facility is marked by a professional environment guided by a strong visionary nursing leader who, through shared governance with the staff, creates an environment that embodies quality and patient safety. (12)

4.2 Framework

Each healthcare organization or should have a framework or plan that not only describes patient safety in that organization, but also provides measurable goals, objectives, measurement and evaluation. The patient safety framework or plan should include not only regulatory goals, but also areas of priority for that particular organization. Due to a lack of standardization and many patient safety approaches, not every patient safety plan will look the same and some organizations do not have such a plan. However, to make patient safety improvements, the identification of baseline status and direction is essential.

4.3 Performance Improvement and Outcome Measurement

Healthcare organizations and providers may choose several different methods, most based on industrial applications to execute patient safety performance improvement activities. Common performance improvement tools include the Plan Do Study Act method, lean 6 sigma and 6 sigma. Culture assessment is another common way to measure safety.

Outcome measurement is a challenge for healthcare organizations. Benchmarking or comparison data is not readily available due to litigation concerns in regard to patient error. Thus, there is no standard for a medication error rate, for example. Organizations use statistical analysis such as statistical control charts to track error internally.

Denominators are frequently an issue in obtaining rates in patient care error. Rates per 1000 patient days are commonly used as some indication of unit or hospital activity.

Benchmarks and comparative data are emerging. The ANCC Magnet Program has comparison data available for falls and skin problems; regional and professional collaborative also have comparison data. There are some studies in the area of staffing and patient care error. Electronic medical records are providing information and simultaneous data collection for some patient safety issues.

5 Education

The IOM noted in 2001 that educational institutions, among other stakeholders, must improve the environment to prepare the workforce for a complex health environment, and recommended a multidisciplinary summit review the state of education in light of the current complex health environment. (IOM (2001) p.5) The *Health Professions Education: a Bridge to Quality* was published in 2003. The report noted "[a]lthough there is a spotlight on the serious mismatch between what we know to be good quality care and the care that is actually delivered, students and health professionals have few opportunities to avail themselves of coursework and other educational interventions that would aide them in analyzing the root causes of errors and other quality problems and in designing system-wide fixes." (13) The Purdue vision was a practice doctoral program that would address the complexity of the health-care system; the information, knowledge and technology explosion; spiraling costs; and the need for a systems approach to create new models of care and solve existing health-care dilemmas. Launched in 2003, the Purdue Doctor of Nursing Practice Program is an example of educational design that has incorporated patient safety and systems thinking into the curriculum.

6 Challenges for the Future

Although much progress has been made in patient safety, challenges remain. Following is a summary of significant challenges:

- Utilizing patient safety concepts, such as work complexity and human factors, to plan, design and redesign healthcare and healthcare products, equipment and education.
- Working with industries including but not limited to healthcare in order to provide quick implementation of safety methods and research.
- Providing, in conjunction with healthcare and industry, tools and methods that can be standardized to measure patient safety outcomes.
- Disseminating evidence based practice and research quickly and efficiently.
- Utilizing evidence based practice to make educational, administrative, and technical healthcare decisions.
- Integrate high reliability concepts into healthcare administration, education and product design.

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