



# System Safety in Healthcare

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## Using System Engineering Principles to Decrease Preventable Deaths

The popular theory that human error, such as making the wrong diagnosis, operating on the wrong body part or administering the wrong medication, in itself causes harm to patients may not always be completely true. According to system safety theory [Ref. 1] and the “Swiss Cheese” theory of healthcare [Ref. 2], at least two things have to go wrong for harm to occur. Usually, the primary cause is a poorly designed care system that allows human errors to happen. Each weakness in the system is called a “hazard.” A human error is a trigger event that finally results in the harm. Therefore, human error is a symptom of a poorly designed system, not necessarily the primary cause of harm. Using the analogy of a gun, the loaded gun is a hazard, while pulling the trigger can result in harm. If the gun is not loaded, the trigger (human error) is not an issue.

### Current Practices in the Development of Robust Systems

Problem solving starts with a series of questions. The answers lead to hypotheses testing. We call it the scientific method or evidence-based practice. But this practice is sometimes time consuming, and does not always address all the causes of system failures. The health care system involves the integration of interactions among clinical care staff, processes, detailed procedures, electronic medical records, patient participation, facility design, environment and anything else that can influence the safety and reliability of care.

System requirements can be flawed. They sometimes fail to identify the key components, including what the system “shall not do.” For example, in a California hospital, a radiology technician was delivering a high dose of radiation to a patient as a part of a therapeutic requirement. He forgot to turn down the level of radiation. For six months, many patients were harmed from high radiation. The system requirement was obviously flawed by depending on the memory of the technician to select the right levels of radiation, rather

than using an automatic reset to a safe radiation level after each use. The system did not specify that “patients shall not get the wrong level of radiation under any circumstance.” One could say that hospitals are not doing enough to prevent harm to patients because of a lack of systems-based thinking.

Another problem is called “groupthink.” While breaking down the process into meaningful questions, team members often tend to agree with each other in the interest of time and cohesiveness. They may fail to challenge assumptions and the soundness of improvements.

### Are We Creating Effective Systems to Prevent Errors?

Recent research indicates that more than 250,000 deaths each year due to medical error occur in the United States alone. What is of more concern “is that a profession dedicated to making us better is doing the exact opposite (albeit by accident), resulting in patient deaths.” [Ref. 3]

Hospitals are still far from being highly reliable. Medical education usually does not cover the theory of reliability. The Institute of Healthcare Improvement (IHI) has taken the initiative to apply industry methods of system reliability to healthcare systems. It defines reliability as “failure-free performance over time.” This definition is simple enough to be understood by anyone. The aim is to have no failures over an extended time period in spite of variability in the patient environment [Ref. 3].

### What Can be Done to Revolutionize the Change?

Some hospitals and healthcare leaders currently experience serious safety failures as routine and inevitable parts of their daily work. To prevent the harm that results from these failures — which affects millions of Americans each year — major changes involving leadership, safety culture and robust process improvement are necessary. This framework needs to be designed to help

hospitals make progress toward high reliability. High levels of safety need to be maintained over long periods of time, and must be comparable to or higher than those demonstrated by the commercial air travel, nuclear power and amusement park industries. Understanding these challenges involves the realization that human error is inevitable. Although we cannot eliminate human error, we must design safer systems to mitigate its frequency, variability and consequences. Additional literature recommends strategies to reduce death from errors in medical care. These strategies include:

- Making errors more visible when they occur so their effects can be intercepted
- Having remedies at hand to rescue patients
- Making errors less frequent by following principles that take human limitations into account [Ref. 3]

A process improvement program will incorporate a system to capture and track the data associated with medical errors, which will, in turn, drive the creation of better practices to improve patient safety. Sadly, there is less room for innovation in the business of health. The high-litigation environment sometimes discourages openness that would allow errors to be seen as opportunities for growth.

### System Engineering: The Most Effective Tool

We need to use systems engineering approaches from high-performance industries in healthcare if we want to make dynamic improvements. In 2005, the National Academy of Engineering (NAE) and the Institute of Medicine (IOM) highlighted the need for a systems approach to the healthcare system and the application of systems engineering tools to improve healthcare [Ref. 4].

### References

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Systems engineering uses a variety of methods to model, analyze, predict, improve and optimize the performance of complex systems, sometimes supported by informatics to harness information in new and innovative ways. Each IOM dimension of the care system — efficiency, effectiveness, safety, access, equity and patient-centeredness — can be improved by systems engineering.

Despite the NAE/IOM's recommendations, only narrowly focused efforts to implement these recommendations have occurred, and no substantive systems approach has gained traction or success [Ref. 4]. The authors of this reference, written in 2013, add, "As a result, we contend that the health care system has not been addressed from a systems perspective at all."

Later in May 2014, the President's Council of Advisors on Science and Technology (PCAST) wrote a report [Ref. 5] stating that systems engineering, widely used in manufacturing and aviation, is an interdisciplinary approach to

analyze, design, manage and measure a complex system, but in spite of excellent examples, systems methods and tools are not yet used on a widespread basis in U.S. healthcare.

Bottom line: Healthcare will take years to improve systems in which human errors should not result in patient harm. According to the world quality guru Dr. Edward Deming, 85 percent of the responsibility for good systems belongs to senior management, *not to doctors and nurses*. But we believe that the responsibility belongs to all of us. We all play a role and should make every effort to contribute to making our healthcare system better. ●

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