Diagnosis and High Reliability

Since the 1990s, patient safety experts have aspired to principles of “high reliability” that have resulted in excellent safety records in other hazardous industries, such as aviation and nuclear power. Those principles describe characteristics of organizational and workforce culture that must be adapted for application in specific workplaces and have not been easy to define and implement in healthcare. As research and improvement efforts focus on diagnostic error, some are asking how principles of high reliability can be applied to diagnosis.

Human Error

When Lucian Leape, MD, (with the help of a Harvard librarian) discovered the study of human error in the early 1990s, he found something he had sensed was missing from his research. While Leape had begun to quantify the incidence of medical errors and harm to patients, he hadn’t found anything in medical research about why these errors occurred and how to prevent them.

In “Error in Medicine,” Leape applied lessons learned in the study of human error, cognitive psychology, and human factors engineering to the practice of medicine, lessons that still provide a framework for error prevention today. Leape noted the paradox of universal expectations of flawless performance versus the experience of most physicians, who knew that they sometimes committed errors. There was little awareness in medicine that human error is unavoidable and that systems contribute to the occurrence of errors and to the opportunity for those errors to cause harm. In fact, that understanding of human error ran counter to the traditional “heroic” view of medical education that physicians are solely responsible for patient outcomes.

High Reliability

Acceptance of the inevitability of human error and the critical dependence of systems on performance leads to the need for a deeper understanding of systems. Weick points out that it would be a mistake to limit our concept of “systems” to those that are “mechanical, orderly, designed, impervious to improvisation, stable, and routinized,” adjectives that run counter to most experiences in healthcare and counter to conditions found in examples of high reliability organizations (HROs). Although these organizations’ systems include hazardous workplaces and materials—nuclear fuel, aircraft carriers, munitions, jet planes, dangerous chemicals, and so on—and rely on orderly, smooth-running systems, the crux of reliable, safe performance is in the human relationships and culture of the workplace.

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and things that “just don’t seem right” may be important indicators that trouble is brewing, which left unattended may blow up into a crisis. Staying alert to unexpected conditions and events on a small scale and sharing those observations with co-workers turn out to be more important than strict adherence to policies and procedures.

Weick and Sutcliffe provide a list of five principles that constitute the challenge of high reliability, which Weick describes as the “continuing struggle for alertness” that high reliability organizations face every day.\(^{[19]}\)

- **Preoccupation with failure.** Constant awareness of the potential for errors and adverse events, not as exceptions to the rule but as an underlying assumption.
- **Reluctance to simplify interpretations.** To simplify is to remove information, which may promote efficiency but also may increase vulnerability to the unexpected.
- **Sensitivity to operations.** Sometimes referred to as situation awareness, this sensitivity informs daily work and honors the importance of supporting frontline workers and caregivers.
- **Cultivation of resilience.** Resilience, which can be taught and practiced, allows for rapid response to unexpected events.
- **Willingness to organize around expertise.** Hierarchies and command structures may be barriers to reaching the individual(s) who hold the answer to certain problems. High reliability cannot afford to defer to authority instead of turning to expertise needed in the moment.

These principles describe an organizational culture that expands on what the patient safety community refers to as a “culture of safety”: an approach that encourages personal accountability while avoiding blaming errors on individuals, reporting mistakes and near misses, and communicating respectfully and transparently with co-workers, patients, and their family members.

### Applying High Reliability to Healthcare

One good example of how principles of high reliability can be successfully applied in healthcare is in the clinical laboratory.\(^{[4]}\) Combining improved instrumentation with principles of continuous quality measurement and improvement (with added incentives from the Clinical Laboratory Improvement Amendments\(^{[5]}\)), the analytical phase of laboratory testing has achieved exceptionally high levels of quality for some tests, now in the range of 1 error per 100,000 (Figure 1).\(^{[4]}\) This is a remarkable accomplishment, in view of data from the mid-twentieth century that half of all laboratory test results were unreliable. Laboratory-related errors are still a problem, but now mostly in the pre- and post-analytical phases of the testing process, the steps involving test ordering and interpretation. Overall, the rate of laboratory-related error is in the range of 1 to 5 errors per 100 test requests, similar to the error rate in diagnostic radiology.

### …and to Diagnosis

With estimates that 1 in every 10 diagnoses is wrong,\(^{[6]}\) the process of clinical diagnosis is at the opposite end of the quality spectrum from high reliability. Mark L. Graber, president of the Society to Improve Diagnosis in Medicine, compares characteristics of high reliability with the state of diagnosis in healthcare and finds more differences than similarities (Figure 2, p. 3).\(^{[7]}\) These disconnects, however, reveal opportunities for improvement that may benefit from the study of high reliability. A more ideal state can be imagined in the future for each of these dimensions:

- **Ownership:** One can imagine healthcare organizations tracking and improving diagnostic quality, just as the clinical laboratory has done over the past several decades. Professional societies could take ownership of specific diseases, set performance goals, and establish standard methods for quality tracking.

- **Integration:** Someday there will be feedback pathways that allow all providers engaged with a single patient to share diagnostic outcomes. Developing expertise requires regular, high-quality feedback, a process that is currently absent from the silo-entrenched healthcare system. Patients and families will be accepted as experts and make unique contributions to high reliability.
Conway observes, “Patients and families know how the system connectivity works and doesn’t because it’s their world.”

Priorities: Given the current movement towards transparency and public reporting, quality will become ever more important and marketable. One can envision a day when quality trumps productivity-related compensation.

Equivalent actors: To a large extent, all airline pilots are equivalently competent. Someday competency in medicine will both be measured and required, or healthcare will be able to take advantage of intelligent software that helps accomplish this. Models already exist for decision support software that assists in equalizing and improving patient management in certain areas.

Measurement: Someday healthcare providers and their organizations will routinely measure and report the quality of diagnostic services; performance improvement requires measurement.

The Joint Commission has also endorsed high reliability as a pathway to improvement in healthcare. According to Mark Chassin and Jerod Loeb, there are three major principles healthcare needs to adopt to achieve high reliability:

- Commit through leadership investment to the ultimate goal of zero patient harm.
- Incorporate best principles and practices of a safety culture throughout the organization.
- Adopt and deploy the most effective process improvement tools and methods throughout the organization.

Although these principles may be easier to enunciate than to realize, many healthcare organizations are now dedicated to adopting them. The diagnostic error community may find that discussing how the principles of high reliability relate to the diagnostic process leads to deeper understanding of the role of systems, vulnerabilities in the process, and opportunities for improvement. There is no part of the quality puzzle that has more to gain from this exploration than the problem of diagnostic error.

References

Large Study Finds Diagnostic Error Rate Tops Five Percent in Outpatient Care

The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. Singh H, Meyer AND, Thomas EJ. BMJ Qual Saf Published Online First: 5 May 2014. doi:10.1136/bmjqs-2013-002627

“You can’t manage what you can’t measure,” as the saying goes. In efforts to reduce diagnostic error, measurement is a challenge for many reasons: definitions of diagnostic error are evolving, the presentation of diagnostic errors is complex, and methodologies used to measure these errors in the past were limited at best, especially for outpatient settings. This new study synthesizes data from 3 prior observational studies of different populations to estimate the rate of diagnostic error in outpatient care. Two of the studies used electronic “triggers,” or algorithms, to detect activity that indicates diagnostic errors: 1) unexpected return visits to primary care or 2) lack of appropriate follow up for abnormal findings related to colorectal cancer. The third study evaluated diagnoses of lung cancer. Findings of diagnostic error were confirmed in all three studies through chart review. The authors combine results from the 3 studies and estimate that the rate of outpatient diagnostic errors in the U.S. is 5.08%. Extrapolating that rate to all U.S. adults, the authors estimate that 12 million people experience a diagnostic error each year. Based on their earlier research, they estimate that half of them, or 6 million adults in the United States are harmed each year by diagnostic error. The authors believe that this is the largest sample size used so far to measure diagnostic error in routine outpatient care. All who are engaged in understanding and reducing diagnostic errors will find the results, as well as the authors’ definitions, methods, and discussions, helpful. The article is available through Open Access from the publisher.