

Introduction

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Fifty years ago, Abraham Maslow stated that if you only have a hammer, you tend to see every problem as a nail. This analogy applies equally well to health care as to other aspects of life. Fortunately, over the last few decades, health care—and laboratory medicine in particular—have seen the emergence of numerous strategies and tools to improve patient safety and quality of care. In 1946, when Dr. William Sunderman developed the first proficiency testing service under the auspices of the American Society of Clinical Pathologists (ASCP; now American Society for Clinical Pathology), the predecessor to the College of American Pathologists (CAP) proficiency testing program that we know today, the laboratory had very limited tools to improve quality.^{1,2} This chapter discusses the many tools that now exist in the laboratory professional's toolbox that can be applied to improve patient safety.

Any set of tools must be considered as a framework for strategies that can be brought to the table when solving problems. Depending on the specific scenario or scenarios involved, multiple approaches may be needed and specific tools adapted to effectively meet a particular challenge or question.

Current State of Patient Safety in the Laboratory

Medical errors are, for the most part, preventable; however, many patients experience significant morbidity and mortality as a result of medical errors in US hospitals. It is estimated that medical mistakes affect approximately 10% of hospitalized patients and cause hundreds of thousands of preventable deaths in hospitals each year.³ When these adverse medical events are analyzed, the findings show that the system is faulty, rather than the personnel involved.³ The adverse events stem from errors in prevention, diagnosis, and medication management.⁴⁻⁶ Further breakdown of the diagnostic errors revealed that 50% were caused by failure to use indicated tests, 32% were due to inappropriate action based on test results, and 55% were the result of an avoidable delay in diagnosis.^{5,6}

In September 2015, the Institute of Medicine (IOM) released an important report, *Improving Diagnosis in Health Care*,⁷ which specifically acknowledged that diagnostic errors in health care have received very

little attention even in the wake of the landmark IOM report published in 2000, *To Err Is Human*.⁸ The 2015 report highlighted three specific themes:

- Diagnostic error has received relatively little attention in the last 15 years, in part because diagnostic error is underappreciated and data on diagnostic error is sparse.
- Partnering with patients and improving communication are critical to reduce diagnostic errors.
- Reducing diagnostic error requires teamwork and systems improvements, consistent with the messages from the initial IOM report.

Improving Diagnosis in Health Care calls on the medical profession—and the diagnostic medical communities in particular—to hone our tools and skills to better recognize, understand, and learn from diagnostic errors.

Patient safety initiatives involve a fair reporting and learning culture, where stakeholders understand the system and the processes that result in medical errors. From several studies, it is known that most medical errors occur outside the laboratory during the preanalytic and postanalytic phases. For the purposes of this chapter, the term *laboratory medicine* encompasses the medical subspecialties of molecular and genetic diagnostics, microbiology, transfusion medicine, clinical chemistry, anatomic pathology, and hematopathology. The analytic phase had the lowest frequency of errors (13.3%-15%).⁹ In comparison, in the preanalytic and postanalytic phases, the frequency of errors occurred at 61.9% to 68.2% and 19.8% to 23.1%, respectively.⁹ A recent cross-sectional study conducted at a teaching hospital showed similar high results for errors in the preanalytic phase of the total testing process at 65.1%, but postanalytic errors only occurred at 11.7%,⁴ and analytic errors occurred at 23.2%, higher than previous publications on patient safety errors in the laboratory.⁴

In 2003, it was estimated that approximately 7 billion laboratory tests were performed annually in US laboratories.⁶ Although laboratory medicine is only a small part of the hospital budget, it influences 60% to 70% of all critical decisions that affect downstream patient care.¹⁰ Given this, patient safety can be affected adversely by laboratory processes such as sample misidentification, specimen quality, analytical quality, and laboratory results reporting. To date there have

Introduction

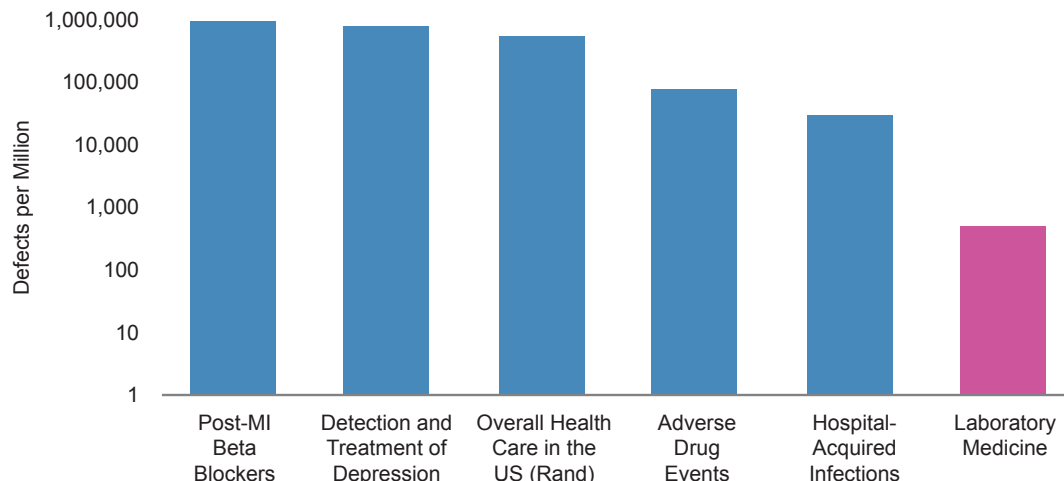


Figure 1-1. The laboratory has the lowest defects per million than the rest of health care (modified from Leape³). MI, myocardial infarction.

been many important studies that address patient safety in the laboratory. Some initiatives reviewed include more awareness of patient safety errors, institution of quality indicators and guidelines, and technological advances.⁹ Among other challenges, ones that significantly impact laboratories and their processes are the following:

- Consolidation of hospital laboratories
- Delivery of services in a wide variety of settings
- Downsizing and shortage of laboratory personnel
- Decreased Medicare and other third-party payer reimbursements
- Alternative-site testing through options such as point-of-care testing
- Focus on test cost reduction and other financial incentives¹⁰

The understanding of the strengths and weaknesses of patient safety in the laboratory would not have occurred without important achievements that have brought patient safety to the forefront of health care. And now, with the publication of *Improving Diagnosis in Health Care*, we have been recharged to delve deeper into learning and implementing procedures that will enhance patient safety through improved laboratory processes and workflow.

The Evolution of Patient Safety Culture

During the early 1990s, the public developed a consciousness about patient safety. The Harvard Medical Practice Study I, published in 1991, was among the first studies to explore this topic and was the springboard for discussion in health care organizations.¹¹ The study's objective was to develop reliable estimates of the incidence of adverse events in hospitalized

patients. The study showed that 3.7% of hospitalized patients suffered disabling injury caused by medical mismanagement rather than their underlying disease.¹¹ The study performed a retrospective review of 30,121 patient records from 51 nonfederal New York hospitals. It showed that in the 3.7% of adverse events, 70.5% resulted in less than 6 months of disability, 2.6% resulted in permanent disability, and 13.6% resulted in death.¹¹ Although the study first showcased the incidence of adverse events in hospitalized patients, public outcry and calls for change came with the publication of *To Err is Human: Building a Safer Health System* by the IOM in 2000.⁸ The report noted that as many as 48,000 to 98,000 Americans died from adverse medical mistakes each year. In addition, the report asserted that the medical errors resulted from faulty systems rather than people, and proposed non-punitive means to discover and ameliorate problems in health care system infrastructures. Subsequently, the IOM published *Crossing the Quality Chasm* in 2001.¹² This report highlighted that marginal reforms would inadequately address systemic flaws. The premise for changing systems is to improve patient safety by reducing loss of life and decreasing the overall economic burden caused by morbidity and mortality. And now *Improving Diagnosis in Health Care* confirms these findings. They state that 5% of US adults who seek outpatient care will experience diagnostic errors (inaccurate or delayed diagnosis), that diagnostic errors are the leading type of paid medical malpractice claims, and that most people will experience at least one diagnostic error during their lifetime, at times with devastating consequences.⁷

Patient safety improvement or quality improvement in health care was an emerging concept in the 1990s, but quality improvement as an approach to analyze performance and systems was conceptualized

and actualized in the 1940s. It was initially used in the manufacturing industry by Joseph Duran and W. Edwards Deming to:

- Decrease production variation and error
- Increase reproducibility and reliability of the production process
- Improve production quality
- Decrease production cost¹³

In addition to manufacturing, health care organizations have utilized quality improvement tools from other industries, such as the aviation and nuclear power industries.

In the interim between the 1940s and 1990s, various health care agencies were established, such as The Joint Commission (originally the Joint Commission on Accreditation of Hospitals; 1951), IOM (1970), Accreditation Association for Ambulatory Health Care (AAAHC; 1979), the Agency for Healthcare Research and Quality (AHRQ; originally the Agency for Healthcare Policy and Research; 1989), and the Institute for Medical Quality (1995). In addition to the creation of various government, research, and accreditation agencies, Avedis Donabedian published his concept regarding how to effectively evaluate quality of medical care by dividing health care measures into three major domains: structure, process, and outcome. Furthermore, in his article on quality he described the seven pillars of health care quality: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity.^{13,14}

The work and findings of these regulatory and research agencies have led to numerous initiatives and changes that target the improvement of clinical and laboratory services in health care organizations.

Patient Safety Initiatives

Given the thousands of near misses every day and the many adverse events leading to injury, disability, and death, various initiatives have been implemented by many health care agencies, including the AHRQ and the National Patient Safety Foundation. Proposed initiatives to improve the culture of safety must take into account the following:

- Health care is a high-risk endeavor.
- Estimates on patient harm may be incorrect or underrepresented because of the methodologies used to collect the data.
- Patient health information is incomplete with the slow phase-in of electronic medical records because some hospitals only have inpatient admissions in their electronic medical record, while others only have outpatient admissions.
- Detection and analyses of adverse events and near misses should be an organizational commitment.

- A nonpunitive reporting environment that balances event reporting with disciplinary actions is ideal.^{7,8,12}

Past initiatives include the National Patient Safety Goals by The Joint Commission, the Patient Safety Improvement Corp by AHRQ and Veterans Affairs, and Never Events by National Quality Forum (NQF). These initiatives vary in focus. Some focus on the reduction of events that lead to medical errors, others on the creation of assessment tools to reduce errors, and others on the establishment of standards for the provision of safe and high-quality health care. For example, in 2003, the NQF suggested 30 safe practices that would reduce error if implemented in clinical care settings. In 2006, for each safe practice, the NQF provided implementation approaches and measures for assessing the practice.

A shortcoming of many of these initiatives is the focus on clinical practice improvement and not on the improvement of laboratory services within the context of clinical medicine. In addition, in managed health care settings, laboratory medicine is often an afterthought because it contributes far less than 5% of total health care costs.¹⁰ However, a change of focus must occur because laboratory medicine is deeply intertwined with clinical practice in the provision of quality health care. Even in managed health care settings, laboratory medicine plays a crucial role in ensuring that the appropriate care is provided at the appropriate time and setting. Furthermore, high-quality health care requires that the services rendered are cost effective and that effective management controls are in place. The Centers for Disease Control and Prevention (CDC) conceptualized and promulgated the “total testing process,” a cyclical process for assessing the quality of laboratory services.⁶ Among issues identified is the lack of standardization within laboratories in their request for patient-specific information. Inadequate collection of historical clinical information can lead to inappropriate interpretation of laboratory findings. In addition, preanalytic variables and postanalytic variables can significantly impact the overall quality of laboratory services, leading to erroneous laboratory results or inappropriate interpretation of reported results. Medicine is not practiced in a vacuum, and given the complexity of health care, it is important to note that all phases along the laboratory testing continuum provide opportunities for improvement, similar to other clinical services.¹⁵ Examples by organizations that include laboratory services in their guidelines include the AHRQ’s *20 Tips to Help Prevent Medical Errors*, in which patients are asked to become partners in their own health care safety by asking for their test results.¹⁶ Another initiative that focused on

patient safety put forth by the The Joint Commission is the National Patient Safety Goals. These include using at least two patient identifiers and emphasize timely delivery of critical test results to the appropriate clinical personnel.¹⁷

Although often taken for granted by many organizations, laboratory services have played a long-standing role in the provision of quality patient care. Since the 1940s, laboratories across the United States have examined their work processes and have reduced errors through appropriate training of qualified personnel, instituting quality control procedures for analytic testing and encouraging voluntary proficiency testing programs. Assessments of laboratory quality show that patient safety enhancements occur with the following system changes:

- Evaluation of individual errors as system failures
- Creation of a just culture and not a punitive one
- Increase in transparency for errors and operations
- Patient-centered and not provider-centered care
- Teamwork focus
- Increased accountability by all health care team members^{3,18}

The provision of high-quality health care also includes garnering support from all levels of the organization and active involvement on the part of these individuals. Patient safety needs to be a priority from the top down. The executive team must provide training and support for those who interact with patients. In order for the multidisciplinary care teams to be effective in reducing risk, they need to have the knowledge and tools to implement strategies that will work.¹⁹ The safety culture improvement employs the “just culture” contextual model, which requires individuals to be held accountable for mistakes but are not blamed for them.¹⁹ By facilitating better communication and teamwork among health care providers, this model helps to improve patient safety.

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