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Introductory Chapter: Patient Safety is the Cornerstone of Modern Health-Care Delivery Systems

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http://dx.doi.org/10.5772/intechopen.83842

1. Introduction

Patient safety (PS) is inextricably linked to quality of care. In the value-driven paradigm of modern health-care systems, focus on these critical elements is required for institutions wishing to stay relevant and competitive [1–5]. This is the fourth and final volume of the **Vignettes in Patient Safety**. The previous three volumes featured a total of 31 chapters, covering a multitude of topics in PS and related fields. Discussed among a variety of concepts were PS education, institutional culture, application of evidence-based practices, handoff communication, disruptive behaviors, fatigue and burnout, team collaboration, and a plethora of discipline-specific topics [5–7]. The current book adds eight additional chapters, including in-depth discussions on communication, medication errors, patient safety culture, alarm fatigue, radiation safety, complications of intravenous therapy, as well as health-care policy and operations.

What has become clear over the course of the four volumes of the **Vignettes in Patient Safety** is that, despite continuous long-term efforts by health-care systems to enhance PS, numerous opportunities for improvement remain. In fact, we are all too often faced with the reality that our still limited knowledge of various gaps in safety, including any associated errors and consequences, can affect patient quality of life, the overall trust in our health-care systems, as well as health-care expenses overall [5, 8, 9]. Slowly and methodically, our understanding of how individuals, teams, and systems can more effectively prevent errors continues to evolve. With the advent of electronic medical records, the ability to capture critical events and their timing made it possible to construct root cause analyses more effectively and accurately,



further accelerating our understanding of various "gaps in safety" and corresponding "failure modes" [10–12]. It is hoped that these incremental steps will collectively help reduce both the frequency and impact of medical errors and hopefully lead to better mitigation strategies and the ultimate attainment of the elusive "zero incidence" goal [13]. Some examples of early successes include the growing evidence that adverse outcomes are becoming less common across different areas of care, likely due to a combination of better training and more effective processes and procedures becoming integrated into existing safety systems [11, 14–16]. Concepts such as "failure to rescue" and "never-events" serve to focus teams on minimizing relatively infrequent, but often catastrophic events (e.g., hospital acquired infections; delays in therapy for critical diagnoses such as stroke, sepsis, acute respiratory failure, or acute myocardial infarction) [17–20]. Again, the ultimate goal is to simultaneously achieve 100% readiness and 0% incidence for any such occurrences.

The evolving role of public reporting of quality and safety data, including various clinical metrics and outcomes, will provide a powerful stimulus for developing processes and systems that will make patient care both safer and more efficient [21, 22]. However, without proper organizational and individual context, exclusive attention to such metrics will not inherently result in better or safer care [23–25]. For example, a study looking at 28 strategies to improve "door-to-balloon time" (a commonly utilized quality metric in cardiovascular medicine) across 365 hospitals demonstrated that despite several strategies being associated with substantial reductions in "door-to-balloon time," only a minority of institutions was actually utilizing these proven approaches [26]. It is therefore critically important to evaluate PS systems in a comprehensive and multifactorial fashion, maintaining open and constructive stance on exploring "what is going right", "what has gone wrong", and "what might go wrong."

2. Integrative approach to patient safety

The success of patient safety initiatives and corresponding systemic implementations is heavily dependent on the thorough understanding of the overall framework within which structures, processes, and outcomes dynamically interact in health-care [27]. With that knowledge, it is important to integrate key processes in order to increase organizational efficiency and effectiveness. Examples of successful interventions that span across different domains of the health-care matrix include checklists, standardized handoff protocols, intense analyses/sentinel event reviews, and institutional safety and quality improvement projects [5, 7, 28].

Using specialized processes, such as the plan-do-check-act (PDCA) quality improvement cycle, modern PS protocols and approaches continue to evolve and become increasingly more optimized [29]. Organizations must continue to transform PS systems into more horizontal, cross-disciplinary platforms that function in a nonpunitive, fair, respectful, and inclusive fashion [30, 31]. Determinations regarding the importance and relevance of any constructive input should not be based on hierarchical considerations, but rather on the informational content being communicated [28, 32, 33]. The end goal is to hard-wire quality and safety improvement

into the fabric of health-care operations, both clinical and nonclinical [33]. To paraphrase, there should be a constant emphasis on ensuring that dedicated institutional processes are focused on making it easy to "do the right thing" and harder to "do the wrong thing." The use of checklists helps facilitate just that. Standardization of the process by incorporating all critical steps into an easy-to-follow framework provides a potent fail-safe measure to prevent both human and systemic errors [34, 35].

Of importance, continuous real-time review of patient safety and quality processes must be performed to ensure that all active implementations are being monitored for proper functioning, as well as any unintended consequences or down-stream problems, for either the patient or the health-care system [29, 36, 37]. This can be accomplished through conducting regular performance improvement initiatives, hiring dedicated staff to track and report on different quality measures, and building robust systems to ensure not only that safety and quality are being upheld but also to resolve any issues as they arise [7, 38]. For example, there are numerous initiatives to reduce the incidence of deep vein thrombosis and pulmonary embolisms [39–41]. Clearly, such initiatives are intended to address a substantial and highly complex set of PS issues. Yet, it is critical for clinicians to avoid "blindly" following protocols and guidelines that rely solely on "guaranteeing" that every patient is receiving "standard of care" anticoagulation prophylaxis while failing to consider the potential impact of anticoagulation on bleeding and related complications. Similarly, patients who are fully ambulatory are much less likely to benefit from antithrombotic prophylaxis than patients who are tethered to their beds and unlikely to ambulate for three or more days. Finally, clinicians must always be sensitive to the impact of therapeutic anticoagulation under circumstances where risks outweigh benefits of such intervention [42]. Use of clinical judgment is imperative in such situations in order to determine the necessity, applicability, and appropriateness of any evidence-based protocol or guideline.

3. Gradual and sustainable culture change

Patient safety culture depends heavily on institutional ability to create an environment that welcomes honest disclosure and constructive, nonjudgmental feedback [43]. It has been shown that more positive PS culture correlates with fewer adverse health-care events [44]. A change in culture is no easy feat, but it is instrumental in the development of an environment that does not penalize human error (**Figure 1**). It has been suggested that although humans certainly contribute to adverse events, faulty organizational systems are more likely to be at the root of many of these errors [45]. This suggests that a more fundamental change is needed to affect the safety and quality of care delivered within the health-care system. It has been pointed out that institutions fully committed to a culture of patient safety have seen reductions in medical errors [45]. This involves integration of "error management strategies" to analyze the causes of error and instituting mechanisms of prevention [46]. Buy-in from administration as well as other leadership is integral to the process of adoption of a patient safety culture. Without engagement from leadership, it will be difficult to transform existing organizational "patterns and habits". Hospital leadership must set PS as a priority, even

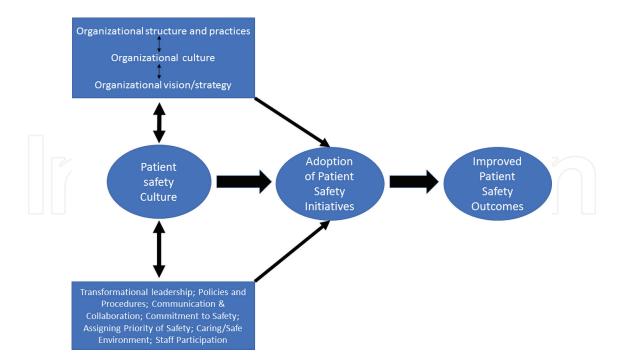


Figure 1. The relationship between institutional culture of safety and improved patient outcomes involves the presence of key foundational factors coupled with effective adoption of patient safety initiatives and the fostering of constructive feedback.

placing it above clinical productivity [45]. Institutional leaders are instrumental in creating a culture of honest disclosure, support, and constructive feedback. When errors occur, root cause analysis ensues to understand which specific systemic factors may have been contributory. The natural inclination to point fingers and blame a specific person or persons for making a mistake is discouraged. Adjustments to the system are then implemented to prevent the reoccurrence of the specific error in question. This includes sitting down with the individuals involved and addressing what went wrong and what needs to be done to prevent similar errors in the future. An action plan may include instituting failsafe mechanisms within the system to prevent performance of certain harmful actions. Development of a patient safety culture depends heavily on organizational structure and priorities, transformational leadership that can trickle down to other stakeholders as well as effective communication amongst all parties involved. Taken collectively, all of the above interventions act synergistically to help create and reinforce a culture of patient safety.

Once safe systems are in place, their preservation becomes critical. In addition, the long-term goal then transitions into permanent culture change that hopefully becomes a source of pride for both employees and the organization [7, 28]. Once a culture of safety is achieved, other aspects of institutional change can occur, including alignment of goals, especially between clinicians and administration. By association, one can also expect improved employee morale, enhanced quality of care, and other positive manifestations of a well-functioning organization. As a word of caution, the same can also occur "in reverse," where negative influences can insidiously and gradually erode various positive elements and influences within the institutional culture [7, 47–50].

4. The challenge of habits: The art of learning and unlearning

A culture of safety represents a complex system of behaviors and hardwired procedures, designed to synergistically create a safe, reliable and efficient, high-quality clinical environment [51, 52]. The creation of such a sophisticated institutional cultural milieu requires all stakeholders to commit to unprecedented amounts of commitment and flexibility [51-53]. In many cases, the organizational transition process can span years and require the replacement of "bad habits" with positive behaviors—a difficult undertaking given the inherent human tendency to resist change when having to "unlearn things" [54]. So how do we change bad habits, motivate people to "do the right thing", and sustainably instill safe and productive behaviors? To motivate individuals, we must first recognize why and how people are influenced. In his book Drive: The Surprising Truth About What Motivates Us, Daniel Pink points out that historically our good behavior has been incentivized with rewards and our bad behaviors reprimanded [55]. This carries the unintended consequence of undermining an individual's motivation. He suggests humans have a strong inner-drive to be autonomous, self-determined, and connected. We all seek the trifecta of attaining autonomy, mastery, and purpose in both our work and our lives. Upon achieving these elements, people will take on greater responsibility, believing they are effecting positive change. With this sense of autonomy and purpose comes increased self-esteem, confidence, and motivation to go beyond what is merely required. The pursuit of mastery naturally follows [55].

5. The importance of anonymous event reporting in maintaining patient safety

In many countries, incident reporting in health-care has become a well-accepted method of improving overall patient safety [56]. Strategic collection of adverse events and "near misses" from across our care delivery platforms allows safety specialists to efficiently analyze each event, identify potential underlying factors, and implement action plans based on this knowledge to help reduce systemic risk levels in the future [5, 7]. However, in the United States, medical errors continue to be significantly underreported, as exemplified in a study of over 1600 hospitals which concluded that substantial proportion of facilities lacked adequate event reporting systems [57].

The overarching question then becomes, which components comprise a thorough, accurate, and effective reporting system design within health-care? Specifically, published studies identify several factors that are essential to constructive "incident reporting". These factors include: staff willingness to report incidents, removal of barriers to incident reporting, the overall culture surrounding reporting, classifying and monitoring the number of incidents reported, taxonomies for various types of patient safety events, and the constitution of incident reporting systems [58–60]. Moreover, one of the greatest challenges that exist with regards to the incident reporting process is determining a way to create a "no blame" culture and balancing team accountability versus individual responsibility [58–60].

Presently, reporting systems within health-care tend to place greater emphasis on collecting reports than on conducting advanced analyses and identifying learning opportunities that can be gleaned from the available wealth of information [61–63]. One study suggests that systems should focus on providing health-care professionals with feedback pertaining to incidents that occurred, including any action(s) taken, to then serve as an integral part of the cycle of continuous improvement and the creation of a culture of safety [64]. Health-care workers who feel protected by employers after disclosing an incident, primarily through anonymity, generally are more likely to report the event through established mechanisms, and the reported event can then be utilized as a constructive example for all staff in regards to reducing risks and embracing PS measures. In summary, appropriately structured, anonymous event reporting programs have contributed to significant changes in practices, including new care processes, constructive behavioral changes, as well as more realistic risk perception and awareness of the importance of a culture of safety.

6. Topics in the current book

The current text contains some unique and perhaps under-appreciated topics. Beginning with "anatomy of medication errors", there are unique chapters on patient safety culture in primary care practices, PS perspectives in the context of health-care operations and risk management, alarm fatigue, the importance of air filtration systems, and even medical radiation safety (both diagnostic and therapeutic). Although seemingly diverse and unrelated, the common thread among the chapters of this final volume of **The Vignettes** is the continued demonstration of the critical importance of teamwork within our increasingly complex health-care systems. Again highlighted are the key elements of communication, collaboration, and coordination [65–67].

7. Conclusion

As our Editorial Team's journey through the four volumes of **The Vignettes in Patient Safety** comes to an end, we hope that our primary goals of increasing awareness and providing clinically applicable solutions toward enhancing PS have been accomplished satisfactorily. In addition, what both the editors and authors have recognized is how many more opportunities there are to better understand the challenges of creating and preserving an institutional culture that is truly focused on patient safety. Without a doubt, and unfortunately, there could be many more volumes on this topic to help illustrate how complex the current PS environment has become—and how many opportunities for improvement still exist. It is easy to become discouraged when one reads and analyzes PS vignettes throughout the four volumes, realizing that it is sometimes only by accident and luck that satisfactory clinical results are achieved. At the same time, one must appreciate and be amazed at - especially given the complexity of modern health-care environment - how much more frequently things go right and patients get better.

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