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# Introductory Chapter: The Decades Long Quest Continues Toward Better, Safer Healthcare Systems

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Additional information is available at the end of the chapter

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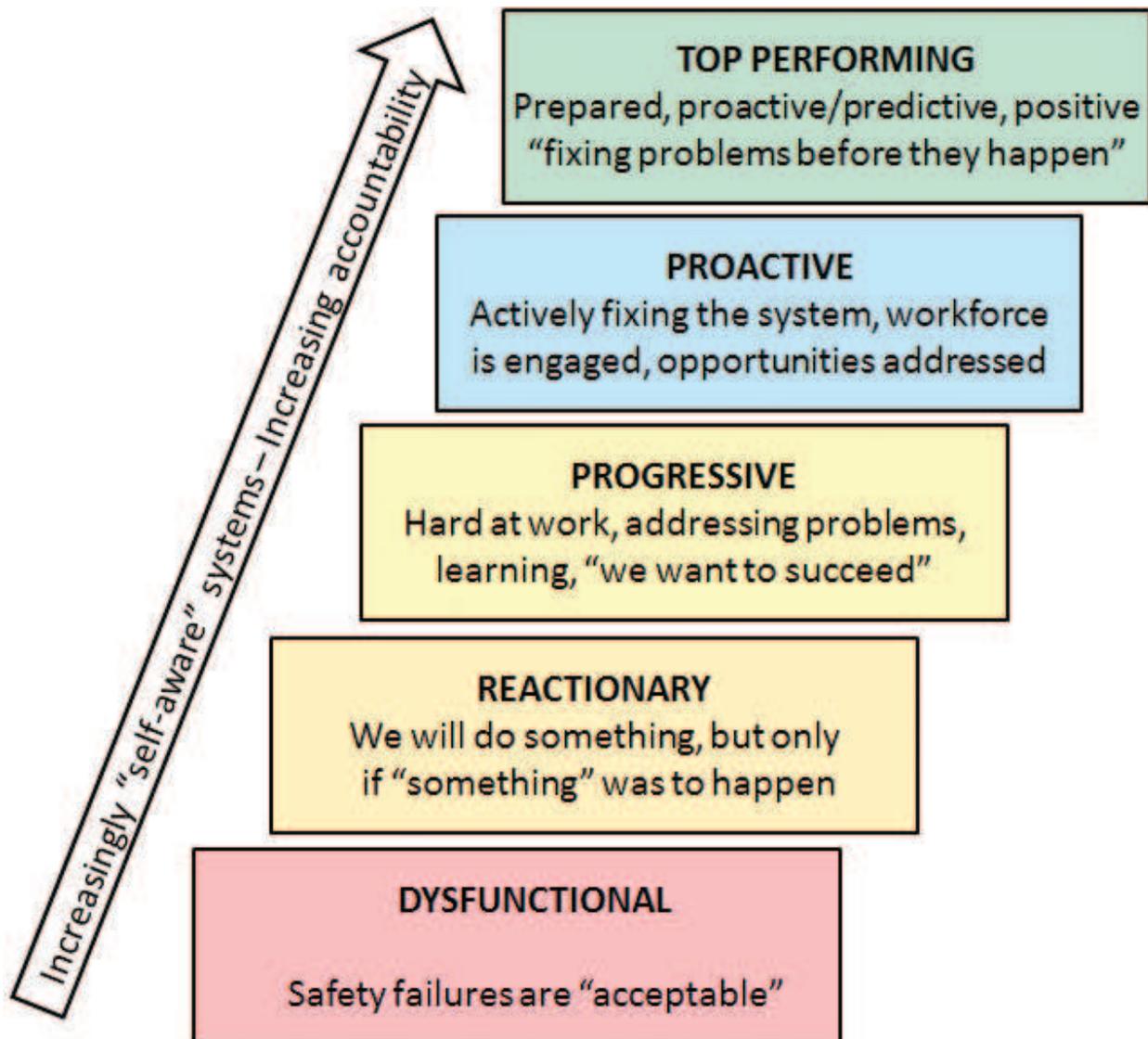
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## 1. Introduction

As the Editors of *Vignettes in Patients Safety*, it is our pleasure to introduce the reader to this collection of problem-oriented, clinically focused chapters discussing various topics in one of the most important areas of healthcare. Each chapter in this collection will feature a clinical vignette, followed by an in-depth discussion of patient safety topics related to the corresponding clinical scenario. Vignettes described throughout this work constitute a blend of previously reported, publically available experiences related to actual patient safety events and carefully crafted, highly realistic scenarios that were designed specifically to fulfill the didactic goal of each respective chapter.

The teachings of Hippocrates, a Greek physician, constitute the conceptual foundation of modern science, art, and practice of medicine [1]. For centuries, enhancements in patient safety were based on educational, technological and methodological progress combined with largely reactive, safety event-based response [2]. As the critical mass of available evidence irrefutably demonstrated the relationship between preventable iatrogenic harm and the associated morbidity and mortality, the medical community began to address the problem in a more organized, proactive fashion [2]. As the movement of patient safety and advocacy gained momentum, the way we understand and practice medicine began to slowly transition, with the parallel developments gradually morphing into a new synthetic state, including the emergence of institutional safety champions and evidence-based, peer-reviewed scientific contributions. In effect, the way we practice medicine and design our medical systems and institutions began to evolve so as to incorporate “patient safety thinking” as one of the fundamental and essential components of the overall paradigm [3]. No longer could physicians continue to practice in the “silos” of their specialty or individual practices and expect that if they performed at a level consistent with the standard of care, then an excellent outcome is to be expected. Everyone must be taught to recognize that they have active ownership in their patients’ care and should be held accountable to that end. Additionally, with the growing emphasis on team-based

care with shared decision-making or governance, any adverse events no longer “inherently reflected” the patient’s medical/surgical condition, co-morbidities, or represented a “justifiably unavoidable” complication. Instead, every event in any way related to patient safety and care quality began to be viewed more as a potential opportunity for learning and continuous quality improvement. This then led to further increases in awareness, better understanding of how medical errors happen, and finally the application of the resulting knowledge toward re-designing our patient care delivery systems so that they become increasingly safer and more reliable [2, 4, 5]. The evolution of patient safety within healthcare systems, from highly dysfunctional to high functioning, is outlined in **Figure 1**. Clearly, such institutional evolutionary developments do not occur overnight or without substantial efforts and champions/advocates. The transitioning of institutional culture and climate to a model that embraces patient safety must be grounded in teamwork, effective communication skills and tools, and an environment of professionalism and mutual respect among leadership and healthcare providers [2, 6, 7]. At



**Figure 1.** Evolution of patient safety over time. The ultimate goal of all modern healthcare institutions is to create a top-performing, “self-aware”, proactive patient safety environment.

the very least, a focus of this text will be a focus on establishing effective team communication. Breakdowns in communication, at all levels of the healthcare delivery process, are without a doubt the leading cause of adverse events and lapses in patient safety [8]. Numerous chapters in this text will not only illustrate how such communication problems occur, but also provide a framework establishing effective checklists and proper team communication approaches.

Although subjectively easy to conceptualize and superficially intuitive, patient safety is a much deeper and more extensive topic than it might seem to individuals with limited or no experience in this important area of expertise [9, 10]. As Emanuel et al. [3], astutely point out, the discipline of “patient safety” is multi-faceted, and the corresponding definition encompasses the rationale (the “why”) for its existence, its nature, its focus of action, its operational premises (e.g., evidence-based, high-reliability design, change management), and those who practice this specialty (e.g., health care workers, patients, and safety advocates). In addition, the same authors identify four key domains within patient safety, each of which centers on different actors and their roles—providers, patients, therapeutic interventions, and methodologies [3]. A commitment to patient safety is often synergistic with a commitment to clinical excellence, focus on quality of care, and improved patient outcomes. This is because of the inherent overlap between many of the involved concepts and processes.

## 2. Definitions: the roadmap to standardization in patient safety

A patient safety book without a well-defined set of mutually agreed upon terms and conventions would be akin to translating a written work between multiple languages and dialects. Consequently, in an attempt to optimize efficiency of the *Vignettes in Patient Safety*, the authors decided to standardize definitions as much as feasible, without of course imposing on, or censoring our contributors and authors. This section of the introductory chapter provides the reader with key definitions and basic concepts that will establish the foundation for the remainder of this written work. What follows is a glossary-like, alphabetical bullet-point collection of key concepts and definitions that collectively provide the framework within which all the other chapters will be constructed. The following list has been compiled from several authoritative sources [2, 11–13]:

- Active error—an error associated with ‘front-line’ operations of a complex system; effects of an active error are apparent shortly after the occurrence.
- Active failure—an action (or process) during the provision of direct patient care that fails to achieve the expected aim, either by omission or commission.
- Adverse event trigger—a set of circumstances that strongly correlates with the occurrence of an adverse event; an adverse event trigger usually initiates the subsequent investigation to determine the exact nature of the occurrence; many, but not all triggers are subsequently confirmed to be tied to an adverse event.
- Adverse healthcare related events (AHRE)—adverse occurrences that occur within the healthcare environment/system; the authors use this broad “umbrella” term to define all occurrences in general fashion.

- Cause—a factor that contributes to a safety event, clinical result or outcome.
- Causation—the act by which an effect is produced; involves causal relationship between the act and the effect.
- Computer physician order entry (CPOE)—clinical system that relays actionable data from healthcare practitioners (e.g., physician, nurse practitioner, physician assistant) to various components of the healthcare system/facility (e.g., laboratory, diagnostic imaging, patient transportation, etc.).
- Contributing factor—similar to a cause; an antecedent factor to an event, effect, result, or outcome.
- Culture of safety—an integrated pattern of organizational and individual behavior; a culture of safety is based on shared beliefs and values, with focus on minimizing patient harm during the process of care delivery.
- Electronic health record (EHR)—clinical data management systems that go beyond simple storage of patient’s clinical data, additionally focusing on the patient’s total health management in a much broader sense.
- Electronic medical record (EMR)—clinical data management systems that contain a patient’s clinical data; some experts consider EMR to be a subcomponent of EHR.
- Error of commission—an error which occurs as a result of an action taken.
- Error of omission—an error which occurs as a result of an action not being taken.
- Evidence-based guideline—consensus recommendations for approaching frequently occurring health management problems aimed at reducing practice variability and improving patient outcomes.
- Failure mode and effects analysis—a risk assessment methodology based on simultaneous analysis of failure modes, associated consequences, and other factors directly or indirectly related to a specific circumstance.
- Harm—permanent or temporary impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting from an associated intervention.
- Human factors—the study of the interrelationships between humans, their environment, their tools and processes; the intent of human factors research is to design efficient, human-centered processes that lead to improved safety and reliability.
- Incident—an event or circumstance which could have, or has resulted in unintended and/or unnecessary harm to a person; in many cases incidents lead to complaints or loss/damage.
- Just culture—critical element of a safe culture, a just culture reconciles professional accountability and the need to create a safe environment within which error reporting is performed in a constructive, non-punitive manner; just culture is designed to balance the need to learn from errors and the need to institute disciplinary action.

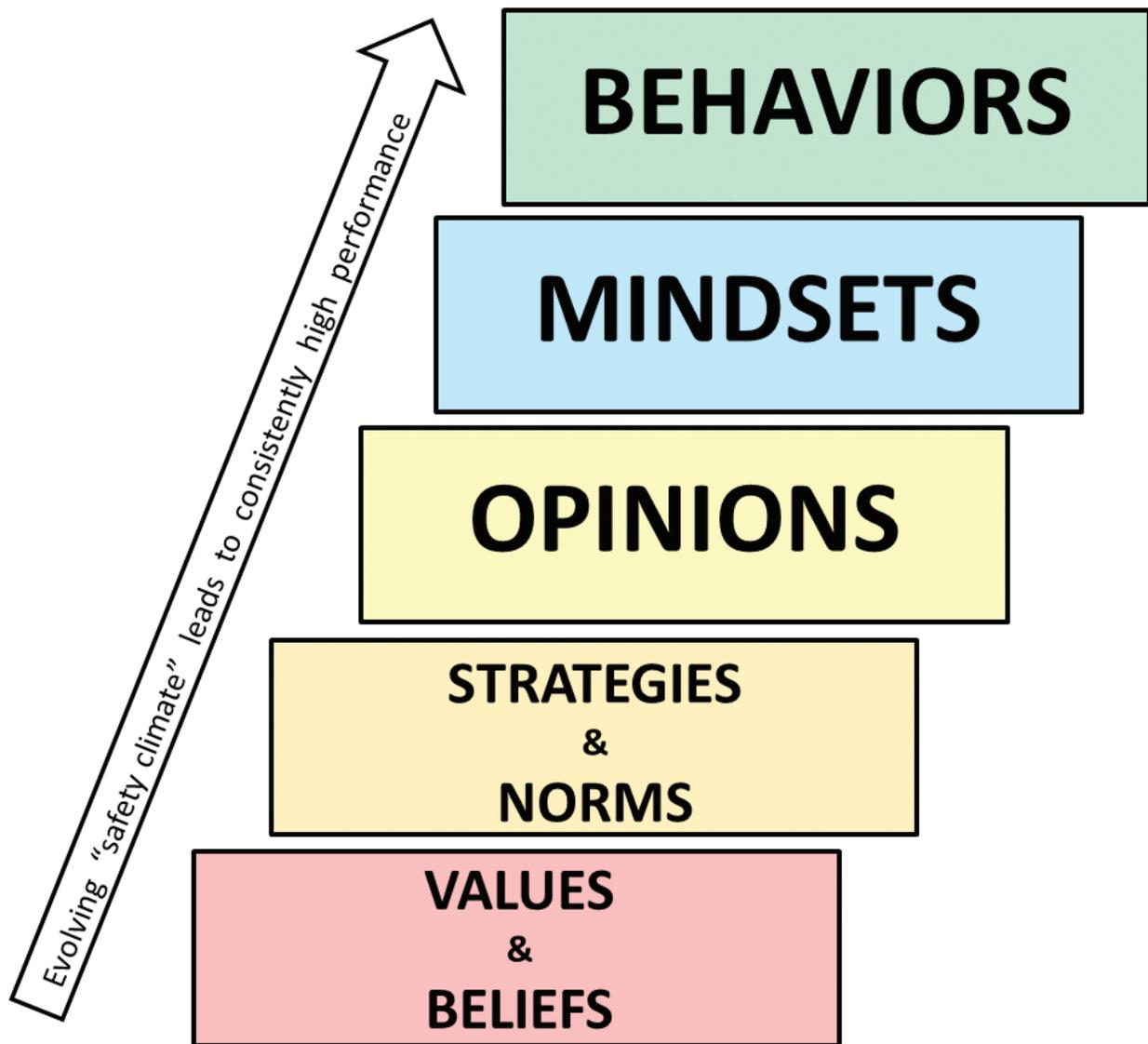
- Lapse—an error which results from some failure in the execution and/or storage stage of an action sequence; most commonly, lapses are internal events that involve failures of memory/recall.
- Latent errors—errors associated with faulty system design, deficient organizational structure(s), inadequate training or maintenance; latent conditions may be present in a “dormant state” until such time that a confluence of factors leads to the emergence of an error (e.g., safety violation) within an organization or system; in theory, latent errors should be preventable through better system design and proactive surveillance.
- Mandatory reporting—event reporting system that requires reporting of all suspected patient safety occurrences; non-compliance may carry negative consequences to individuals who are aware but fail to report an event.
- Negligence—occurs when care provided fails to meet the standard of care reasonably expected of an “average practitioner” under similar circumstances/conditions.
- Observation method—an active approach to error surveillance; monitoring is conducted by a trained observer who identifies errors (or potential errors) and provides corresponding feedback.
- Patient safety evaluation system (PSES)—the collection, management, or analysis of information for reporting to (or by) a patient safety organization (PSO).
- Patient safety indicators (PSI)—a set of measures that screen for adverse events that patients may experience as a result of exposure to the healthcare system. These events are likely amenable to prevention by changes at the system or provider level.
- Patient safety organization (PSO)—an organization or a component of an organization that meets specific criteria outlined in the Patient Safety Rule of the Federal Department of Health and Human Services. PSO’s primary responsibility is to carry out activities that improve patient safety and healthcare quality.
- Potential error—circumstances or events that have the capacity to result in error; sometimes also referred to as “near miss” or “close call”.
- Preventable adverse event—an adverse event that would not have occurred if the patient had received established standard of care management appropriate for the specific clinical circumstance.
- Reckless behavior—an action taken by an individual who knows that there is a risk, is willing to take that risk, and decides to proceed regardless of that risk; at times, the individual may be unaware of the risk, due to a variety of factors such as lack of experience or knowledge.
- Risk assessment—the process designed to help the organization understand the range of risks associated with specific actions/decisions, both quantitatively and qualitatively; risk assessment also includes the determination of the probability that an adverse event could occur, given specific conditions.

- Root cause analysis (RCA)—a structured method used to analyze serious adverse events. Initially developed to analyze industrial accidents, this paradigm is now being applied in patient safety. The RCA terminology may vary, with some institutions utilizing alternative names for essentially the same process.
- Safety “slip”—an error which results from failure in the execution of an action sequence; also defined as observed action “not as planned”, often associated with failures related to inattention or misperception.
- Safety violation—a deliberate deviation from practices considered necessary and proper to the maintenance of the safe operation of a potentially hazardous system.
- Sentinel event—any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient’s illness.
- System—a set of interdependent variables/elements that interact to achieve a common aim; healthcare systems consist of both human and non-human elements.
- The Joint Commission—the Joint Commission is a US-based non-profit, tax-exempt organization that accredits more than 21,000 health care organizations and programs in the United States and beyond.
- Voluntary reporting—a system in which notifications of patient safety occurrences are voluntary and not mandated by the organization.

### 3. Overview of strategies to reduce adverse healthcare-related events

This section will provide an overview of general strategies that have been utilized to reduce adverse healthcare related events. Although a complete discussion of effective approaches in this domain is beyond the scope of a single book section or chapter, we hope that throughout the entire *Vignettes in Patient Safety* series, the reader will find a comprehensive body of evidence-based, clinically relevant information that will help facilitate effective implementation of the approaches outlined below.

Perhaps the most important and fundamental prerequisite to safer healthcare is the ability of our system to examine and modify itself in a bias-free and efficient manner. To avoid bias, every component of the system should be conditioned to report actual and potential safety events in real-time, and for those events to be analyzed in a non-judgmental fashion, focusing on opportunities for improvement. The ultimate goal is to change mindsets and behaviors across the entire organization or system (**Figure 2**). Finally, any opportunities for improvement identified must be implemented in a way that further optimizes the healthcare delivery process and minimizes any associated disruptions [14]. An important component of such process improvement projects is to not to judge the people or circumstances surrounding any particular AHRE, but rather to explore the “who, where, what, when, why, and how” regarding the care delivery process and how lapses in any step of the provision of care might have impacted the outcome of the patient.



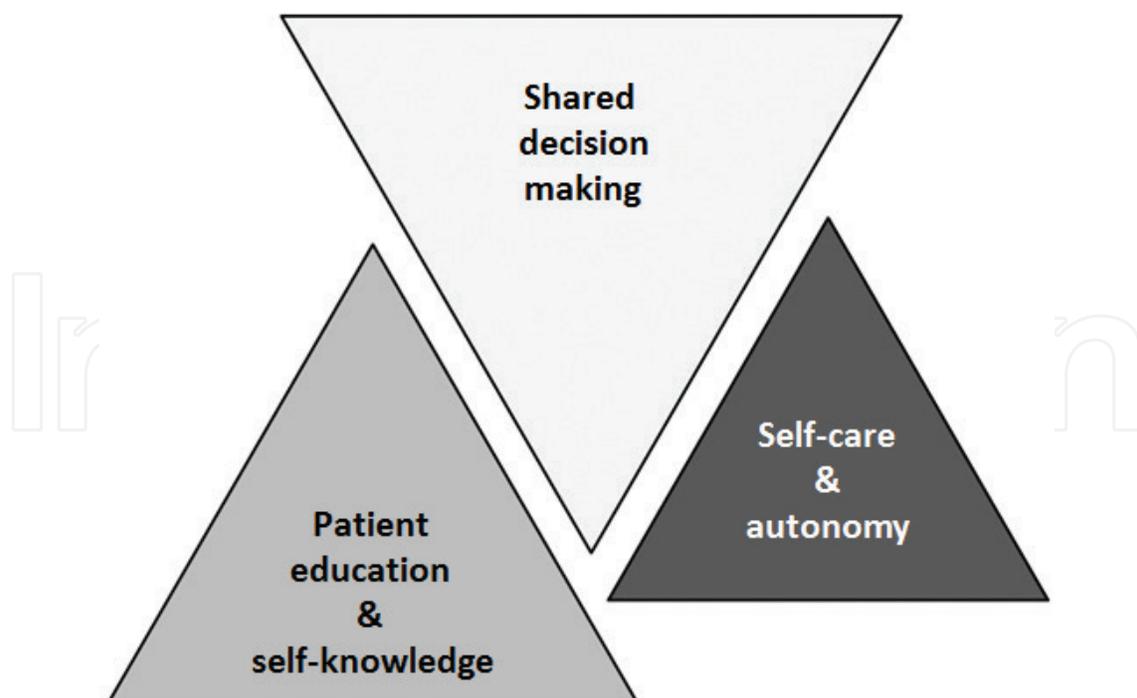
**Figure 2.** Organizational change starts with values and beliefs, which after being transformed in to norms and strategies lead to the formulation of opinions, mindsets, and finally manifest as a set of organizational behaviors.

In general, several strategies have been employed to help reduce the incidence of AHRE [15]. The gradual and incremental introduction of various checklists and corresponding "hard stops" was the initial step toward the now universal acceptance of patient safety as the primary component of all care-related decisions [2]. The subsequent evolution of objective, non-judgmental methods of analyzing patient safety occurrences, such as the RCA helped facilitate the collection of otherwise unobtainable information required to guide subsequent improvements in processes and practices of healthcare delivery [2, 14]. This can be compared to the gradual development of "institutional meta-cognition" or institutional "self-learning", where all components of the increasingly complex healthcare system become more and more aware of opportunities for improvement [16]. In turn, we are then better able to learn what works, what does not work, what matters most, and what healthcare customers (e.g., the public) expect [2, 17–19]. As a result, we are able to provide our patients with better, more effective, and safer treatments.

However, in order for various quality and safety measures to be effective, there must be champions and advocates who will promote and encourage what might be inherently perceived as “administrative challenges” to physician autonomy. Everyone must be engaged and supportive of the collective goals—even if difficult changes in practices and routines are required for the collective good. An important part of the overall evolution toward a safer healthcare system is the reduction in quality and safety variability across institutions [20].

Perhaps the most important recent development is the system-wide implementation of electronic medical record (EMR) systems with hardwired approaches and procedures to reduce known patient safety occurrences. As an immediate benefit, EMRs are able to facilitate the collection of real-time, actionable quality and safety data [20]. In fact, many EMR systems are starting to incorporate feedback mechanisms, checklists, support tools (like medication dosing calculators) and alerts to reduce the risks to the patient from inadvertent errors.

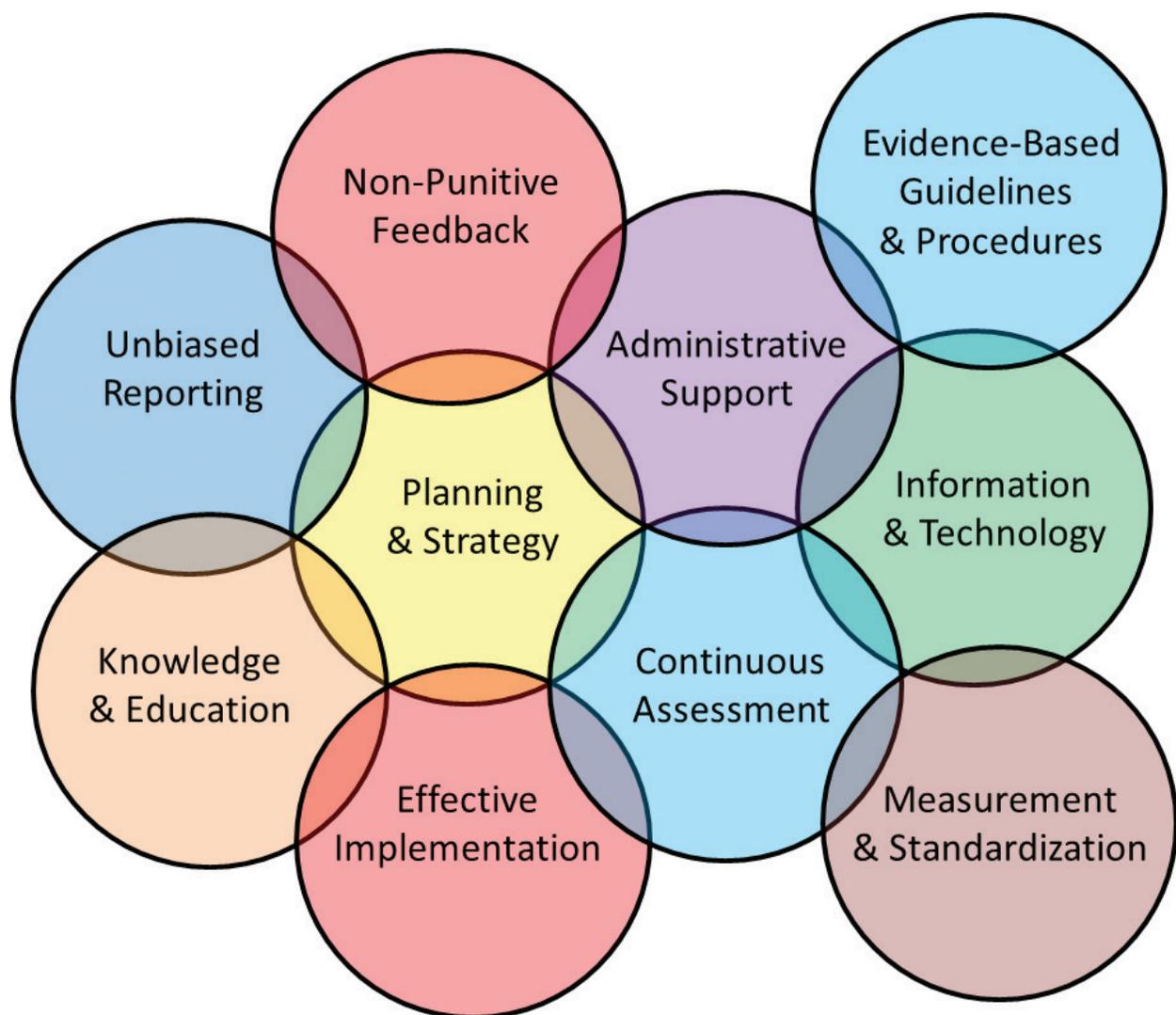
Another critical realization was that majority of AHRE are not the result of an error attributable to a single person or factor, and instead tend to represent a confluence of two or more co-occurrences [21]. In addition, active and informed participation of an empowered patient is critical to the effective implementation of healthcare safety measures (**Figure 3**) [22]. Finally, the emergence of organizations dedicated to ensuring system-wide maintenance of appropriate quality and safety standards via accreditation-based mechanisms provides a valuable enforcement capability in cases where institutional self-improvement fails to correct critical issues related to patient safety and quality of care [23–25]. This discussion will be continued by the Editors in the closing chapter of this book cycle.



**Figure 3.** Factors involved in empowering patients to participate in the healthcare safety process. Successful implementation of these concepts requires excellent interpersonal communication skills, appropriate resources, and targeted educational efforts.

#### 4. Foundations of evidence-based progress

Objective monitoring of progress must incorporate specific components that qualitatively and quantitatively measure diverse parameters related to the healthcare delivery process. In order to ensure such continuous and accurate assessment, the development of robust evidence-based tools is required [2, 26]. In this context, an increasing number of institutional and systemic initiatives are working synergistically toward the common goal of providing real-time monitoring and actionable feedback. Such feedback can then be used in formulating concrete solutions for specific patient safety and care quality-related issues. Given the ever-increasing complexity of the modern healthcare environment, an intricate matrix of closely inter-related components must be taken into consideration (**Figure 4**). Many Institutions equip providers with access to real-time and historical data to track outcomes and complications. Such computer-based dashboards and report-generating tools can be provider specific or reflect the data for an entire Institution [27–29]. Real-time access to



**Figure 4.** The ever-increasing complexity of the modern healthcare environment requires closely coordinated actions by multiple stakeholders, at various organizational levels.

quality and outcome data thereby allows to immediate identification of potential adverse trends, or the hopefully positive response to interventions [30, 31]. While no reporting system is perfect and often physicians might criticize that they are being inherently personally linked to adverse events, in a culture of shared accountability, any limitations in the data collection and the reporting process will clearly be acknowledged and used to improve our understanding of overall trends. High performing institutions might look at relative event occurrences, changes in events over time, or compare own outcomes to similar “like” institutions [32, 33]. Individuals clearly should not be identified outside of established peer-review quality initiatives.

Notable initiatives that have been shown to enhance patient safety include the evolution of venous thromboembolism prophylaxis, reduction in perioperative cardiac events in non-cardiac surgery patients, marked reduction in catheter-associated bloodstream infections, ultrasound guidance to reduce morbidity associated with central venous catheter placement, and the reduction of drug-related errors through the use of technology-based solutions [26]. The use of radiofrequency identification and tagging now allows real-time tracking and analysis of complex hospital-based processes, including real-time monitoring and various patient safety interventions [34, 35]. Of course, there are many other evidence-based success stories in the area of patient safety, many of which will be described throughout this book. The reader is encouraged to critically evaluate the information he or she is exposed to, synthesize the available evidence, and formulate their own understanding of each area, topic and/or specific issue.

While many of the initiatives can result in substantial and objective improvements, there must be a continuous “watchful eye” for any potential adverse consequences of any changes within an institution’s quality and safety paradigm. A failure to recognize any adverse consequences associated with system-based changes has the potential to result in a constellation of problems that might be inherently worse or more challenging than the initial problems that were being addressed. An effective leadership team must always be mindful of some of the consequences a particular action and formulate plans to manage them effectively, safely, and in a timely manner. These issues are discussed further in the next section.

## 5. A word of caution

In any system-based paradigm, even a small change can have profound implications, both intended and unintended [2]. Given this, any new patient safety initiative should ideally be piloted first, then implemented across a variety of settings in search of further process-specific opportunities for improvement, then finally “rolled out” on a wider scale. Throughout the entire process, continuous re-assessment and system-based learning should be continued. Within this context, we must remember that the lack of meta-cognitive approaches at the systemic level may lead to more harm than benefit. In other words, if decision-makers in the area of healthcare quality and safety are unaware of how the system “responds” to changes within its different subcomponents, major errors are bound to occur that may unintentionally result in increased levels of harm.

Another major consideration in the general area of knowledge application is a common tendency to generalize specific research results across patient populations and/or clinical settings [36–38]. The main danger of making generalizations between heterogeneous settings and populations is

the risk of misapplication of interventions where the risk-benefit equation shifts toward unfavorable patient outcomes despite the best of intentions by the involved providers [38, 39]. The lack of awareness of many of the dangers of misapplication of medical knowledge in clinical practice is due to a combination of deficient medical school curricula and lack of adequate emphasis on continuing education in this critical (and yet neglected) area of practice. Among considerations that should be taken into account when applying evidence-based guidelines are factors such as pathophysiologic differences between patient populations, heterogeneous response(s) to various treatment(s), socio-economic factors (e.g., patient ability to adhere to treatment), provider-related factors (e.g., the ability to adequately monitor efficacy of treatment), the presence or absence of various comorbid conditions, the source of the evidence or guideline, and a plethora of other factors [38].

## 6. Disclaimer

This book is a collection of case vignettes that are intended to provide a context for each chapter's problem-based didactic goal(s). While each case might reflect or potentially resemble a specific patient's experience, each vignette was written to insure that no patient-specific identifying information was provided. Even though each author (or authors) were required to describe a case in the context of their chapter—other than previously published, referenced, and publically available reports, such cases do not inherently reflect experiences which directly involved the authors and/or their patients, nor do individual chapter vignettes reflect the actual care (or potential lapses in care) at the institutions at which the authors practice or have previously practiced or trained. In other words, any resemblances to a specific patient, their management, and outcomes are purely co-incidental. Moreover, if any previously published patient safety experiences were utilized by chapter authors, such existing sources were clearly referenced and were treated as scientific contributions intended to enhance future scientific work dedicated to enhancing patient safety.

Furthermore, while each chapter was focused on presenting a specific problem, or set of problems, related to patient safety—or potential lapses in, or deviations from, the standard of care, it is critical that individual outcomes must be evaluated on a case by case basis. Any adverse outcomes encountered in the context of following the guidelines and principles outlined in this text do not inherently reflect deviations in the standard of care or a violation of best practices—and conversely, adherence does not imply that a specific standard of care was met. Appropriate institutional guidelines and peer-review processes must be considered whenever there are real or perceived lapses in patient care and each healthcare provider is obligated to use their experiences, training, and judgment when applying evidence-based practice guidelines and protocols to an individual patient.

## 7. Conclusion

In this introductory chapter, we presented key concepts and definitions that provide a framework for the remainder of this written work. We also outlined fundamental strategies, challenges, and opportunities related to progress in the rapidly evolving area of patient safety.

We then concluded the chapter with a call for all healthcare providers to embrace the enmeshment of quality and safety into their daily routines and the way they practice. Words of caution are also provided, especially related to the potential for misapplication of evidence-based guidelines when improperly implemented or not designed for an intended patient population. We hope that the *Vignettes in Patient Safety* will provide the reader with a wealth of knowledge that can be employed to make healthcare systems around the world better and safer. Our discussion will further continue in the second volume of this book cycle.

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