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Vignettes in Patient Safety

Volume 3

Edited by Stanislaw P. Stawicki and Michael S. Firstenberg

VIGNETTES IN PATIENT SAFETY - VOLUME 3

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Meet the editors

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Preface

Modern healthcare continues to evolve. With the shift away from primarily quantitative measures of performance, the new landscape of quality and value-based metrics became the hallmark of the ongoing paradigm shift. *The Vignettes in Patient Safety* book series is an attempt to highlight some of the prevailing healthcare trends, focusing on highlighting the increasingly complex matrix of multidisciplinary teams, rapidly evolving treatments, technological advancements, regulatory requirements, and ever greater patient (consumer) expectations.

The third volume of *The Vignettes* is the most successful tome in the current series. This is both a testament to the importance of the topic and a reflection of the high quality of work published in the earlier volumes. The favorable response of our readership also corroborates the growing importance of patient safety as an essential component of the modern healthcare landscape. In fact, the permanency of the "quality and safety" mindset is slowly becoming the long-sought reality throughout our clinics, hospitals, and operating rooms.

Despite many important advances in our collective understanding of patient safety, a tremendous amount of work remains before the ultimate goal of "zero incidence" is achieved across the entire spectrum of the so-called "never events" that continue to affect our healthcare systems. Topics discussed in the current book include fundamental principles of the performance improvement process, the application of levels of scientific evidence in clinically relevant contexts, assessment of patient safety culture in a primary care setting, patient safety education, and a number of different patient safety scenarios.

It is our goal as editors of *The Vignettes in Patient Safety* to introduce new concepts and clinical scenarios that will enrich the cumulative value of the entire book series. Volume 3 follows this important principle as well, adding important information regarding teamwork and communication, the "Swiss cheese" model of medical error genesis, transfusion-related patient safety issues, errors involving pathology labeling and reporting, operating room fires, and various dangers associated with intrahospital patient transfers.

The editors of *Vignettes in Patient Safety* would like to thank all of the individuals involved in bringing this important work to fruition. We also want to thank our friends and family who supported our efforts for their patience and understanding during the entire process of book preparation, editing, and readying the content for publication. In addition, we formally acknowledge and express our appreciation to all of the authors that have committed their valuable time and effort to making this third tome of *The Vignettes* a success. Their contributions, especially in the context of an open source publication model in which the authors support the expenses of a publication, clearly reflect their dedication to the primary objectives of this text—and the passion to share and promote this work's important message. Finally, we must recognize the important role of various departments and institutions

that directly or indirectly contributed to this publication, both through their support of faculty time and effort, and through generous contributions to the open access publication process.

As we embark on planning the next volume of *The Vignettes in Patient Safety*, we hope that the content of the first three tomes of this cycle will provide our readers with an important and actionable foundation for better understanding of key patient safety concepts (and their clinical application). We also hope that members of our audience may consider contributing novel, high-quality content to this and other projects in the area of patient safety. After all, sharing one's knowledge and experiences, with the goal of helping others and making a difference, constitutes the highest form of giving.

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Chapter 1

Introductory Chapter: Medical Error and Associated Harm - The The Critical Role of Team Communication and Coordination

Alyssa Green, Stanislaw P. Stawicki and
Michael S. Firstenberg

Additional information is available at the end of the chapter

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1. Introduction

Healthcare safety is among the most important considerations when designing, building, and managing modern patient care facilities and systems. Among many reasons why healthcare systems have not inherently "evolved into safety" were the combination of provider individualism and the lack of early recognition of the importance of effective communication and coordination as the primary method of ensuring maintenance of safety standards throughout the entire patient care continuum [1]. The first two volumes of the *Vignettes in Patient Safety* focus on the development of patient safety champions [2] and the continued quest toward "zero error" performance across modern health systems [3].

As our clinics, hospitals, and more recently growing networks of facilities began to aggregate providers from diverse disciplines and training backgrounds, the need for better coordination and communication to ensure safe and seamless patient care became apparent [3, 4]. Growing teams of highly trained individuals who work together, yet may not know each other, became the reality of healthcare systems that require the performance of multistep tasks of great complexity [5, 6]. In this introductory chapter, we will discuss how team communication and appropriate coordination of care are instrumental to ensuring and improving patient safety, as well as to the overall functioning of the patient safety matrix across healthcare organizations (**Figure 1**).

The Institute of Medicine (IOM) defined six key measures to improve the overall quality of our healthcare system, including safety, effectiveness, timeliness, efficiency, equity, and focus on the patient [7]. The concept of patient safety has been an active area of opportunity for

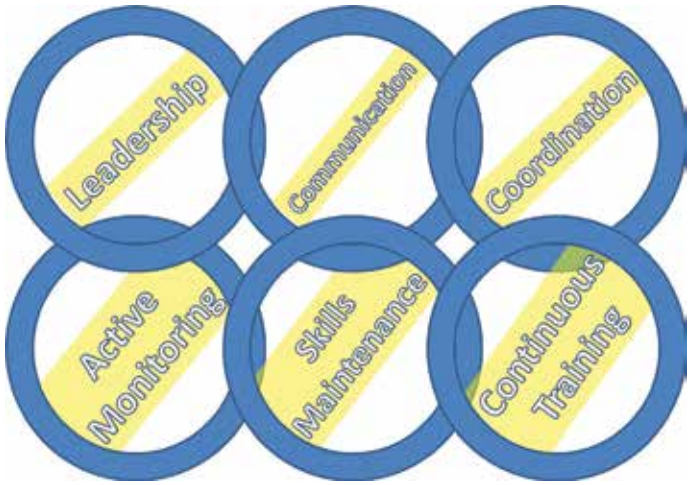

Figure 1. Idealized diagram summarizing key components of patient safety matrix in health care. Only selected components are listed, emphasizing the importance of good leadership, communication, and team coordination, in addition to other domains previously discussed in the *Vignettes in Patient Safety*.

hospitals [8] and clinicians, especially with the advent of objective scorecards and pay-for-performance measures [3, 7]. Patient safety began to transform into its current, more structured format in the early 1990s as it became increasingly apparent that hospitals were not as safe as previously thought and patients undergoing treatment at our healthcare facilities were shown to be at substantial risk of adverse events [4, 9]. The field of healthcare quality and safety encompasses numerous factors, most of which have been discussed in previous volumes of this series, including topics like leadership and organizational culture [3]. In this volume we will explore in greater detail key patient safety concepts in the context of team communication and coordination. It is only through appropriately coordinated work as a team, using proven communication techniques, that we can bring tangible benefits to new and existing healthcare platforms, making care delivery safer, and establishing greater trust in the current system [10–13]. Our exploration will emphasize the importance of teamwork in achieving the goals of the IOM and ultimately creating a universal and standardized environment and a culture safety (**Figure 2**).

Historically, the practice of medicine has revolved around a personal interaction between the patient and his or her healthcare provider [14]. This viewpoint has permeated the cultural and organizational perceptions within medicine, thus heavily influencing and shaping the delivery (and effectiveness) of care [15, 16]. Even with the changing institutional and work dynamics within the healthcare system, this individualistic paradigm continued to prevail, with physicians treating patients at the point of care, characterized by only limited collaboration and coordination with other healthcare professionals [17, 18]. The transition from a physician-centered system to a more patient-centered system required a paradigm shift that inherently led to increased care complexity and the need for better coordination and communication across multidisciplinary teams [7, 19, 20]. There is ample evidence linking adverse healthcare events

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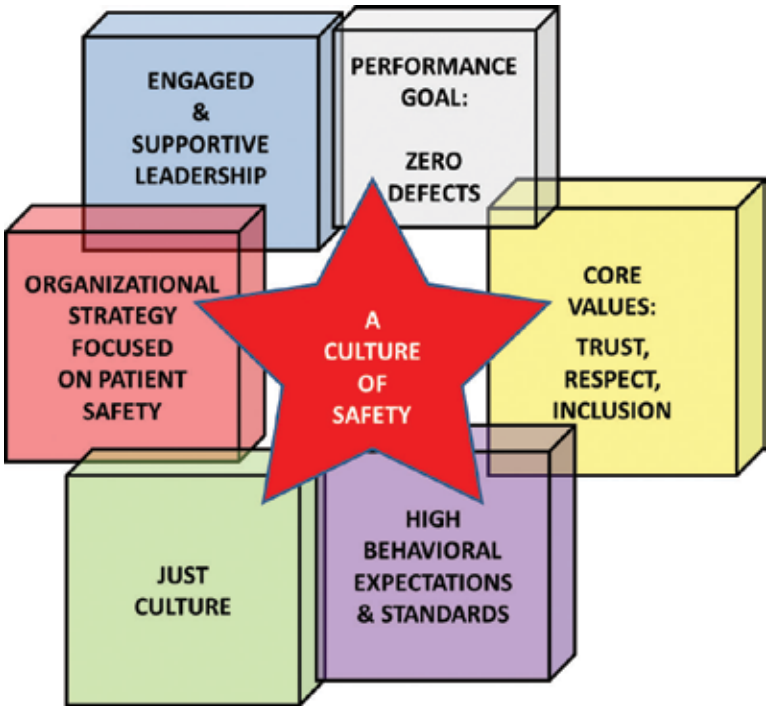

Figure 2. Key components necessary for the creation of institutional culture of safety.

with inadequate team communication and/or coordination, highlighting the critical nature of "teamwork" as opposed to the more traditional and flawed "individual blame" culture [4, 5, 21, 22]. Patient safety literature also indicates that teamwork is key to establishing and maintaining patient safety, and issues related to lack of collaborative approaches and/or communication often contribute to poor quality and safety record [21, 23, 24]. Support for constructive and collaborative thinking must permeate all levels of the organization [3, 4]. At the same time, we must recognize that effective teamwork and collaboration are not going to be inherently easy within a dynamic, complex, and unpredictable environment of modern healthcare systems. However, the above limitation should not serve as a perpetual excuse for failing to improve the current status quo, as proven by other high performance or high-stakes industries that have successfully adopted effective quality, safety, and reliability models [4, 25, 26].

Throughout the *Vignettes in Patient Safety* series, we continually emphasize the importance of teams, communication, and the presence of dedicated champions critical to promoting a culture of safety throughout our institutions. In an attempt to present the reader with practical information and actionable knowledge, we also focus on clinically relevant elements of implementing effective team approach including strong leadership and communication and describing key aspects of a robust organizational culture of safety. This volume of *The Vignettes* will be specifically devoted to the importance of team communication and coordination as inextricable elements of a safe and efficient modern healthcare environment.

2. Patient safety and teamwork

Patient safety can be defined as a discipline or characteristic of a healthcare system that focuses on the application of safety science methodologies to minimize the incidence and impact of adverse events, with the ultimate goal of creating a trustworthy and highly reliable healthcare delivery environment [9]. The critical importance of patient safety has been well established across the full spectrum of modern healthcare settings, including the more recent introduction of patient-centered care and quality-based reimbursement paradigms [3, 27, 28]. As the care delivery paradigm continues to evolve, we must strive to learn, grow, and make sustained improvements across all domains of practice, from the most mundane to the most complex ones. Because the focus on patient safety has its genesis in the combined desire and duty to "do the right thing" in conjunction with the realization that there is an unacceptably high prevalence of avoidable adverse events, we must all join forces and make the effort to meaningfully contribute at the personal, team, and institutional levels [3, 29, 30].

For any meaningful change in practice (and thus organizational culture) to occur, a shift in mindset must be embraced at both individual and institutional levels [31]. In the past, there was a widely held belief that "well-trained and conscientious" providers generally do not commit errors and that most errors occurred because of "carelessness and incompetence" [9, 32]. Consequently, punitive approaches to error identification and correction prevailed, creating an environment of "fear, secrecy, and nondisclosure" [4, 9]. The resultant "culture of blame" gradually gave way to a more in-depth understanding of medical errors, with increasing realization that only a minority of errors are clearly attributable to a single individual or factor [3–5].

Research into human factors provides evidence that in great majority of cases it is not "the individual" who is to be blamed, but rather the error results from imperfections within the organization's systems, training, equipment, and/or management [9, 33, 34]. This sparked a transition toward system-based thinking and adoption of error management, an effective method used in aviation, into health care as a way of introducing a more sustainable paradigm change [3, 4, 35]. Subsequent identification and improved understanding of various "failure modes" such as "latent failures" that may be "hidden" within an otherwise highly efficient and safe environment [35] gave us further insight into phenomena "we did not know that we did not know." Among various areas of scrutiny, it became apparent that the largest number of opportunities for improvement resided within the general domains of "team communication" and "team coordination" [36, 37].

For the purposes of our discussion, a team is described as one or more individuals working together toward a specific, shared aim [21]. This highlights the importance of any verbal or written communication between providers and caretakers where at least two individuals are involved, regardless of how trivial such communication may seem at the time. Also, integral to the team context, each individual has a special role to play within their own area of knowledge and expertise [21]. Inherent to effective teamwork, individuals should be willing to share their resources, communicate and coordinate closely in order to provide the very best care and experience for the patient from every conceivable standpoint, including clinical outcomes, quality, and safety [21]. Of note, the above statements describe nearly every team-based microsystem within the modern healthcare construct.

It seems that coordination and collaboration should be occurring intuitively in a high-performing medical system. However, breakdowns in communication, an essential element in care coordination, were found by The Joint Commission to contribute to 70% of adverse events [32], with a large proportion of these events resulting in mortality [38]. Teamwork is paramount not only to the development of a safe patient environment but also to improved patient outcomes, enhanced quality of care, and greater provider satisfaction [32, 38]. Inefficient team structure and poor functioning have been implicated in inferior quality of care and worse safety performance [21]. Given the complexities of modern healthcare environment, including the diversity of roles and increasing degree of specialization within essentially every area of practice/expertise, the above considerations become even more urgent [39, 40]. Consequently, the concurrent presence of well-choreographed coordination, communication, and teamwork is no longer optional in the interprofessional environment of modern health care, at all levels of every organization [40].

3. Effective team communication and coordination: "Together Everyone Achieves More"

When people work together toward a common goal, remarkable achievements are possible. There are, however, important team-specific considerations. With the growth of team size and complexity, so does the potential for errors. Essential to reducing the number of errors is the presence of robust, often redundant feedback mechanisms [4, 41, 42]. In addition to improving safety and effectiveness of teams, properly structured teamwork may also help improve staff well-being and morale [21]. Consequently, targeted restructuring of microsystems and processes toward a more team-based approach can bring about important benefits and synergies [21]. Finally, thoughtful implementation of interventions that foster shared decision-making, planning, and problem-solving can also be effective in improving both clinical outcomes and patient safety [32].

Although healthcare professionals tend to be aware of the importance of teamwork, communication, and coordination, this awareness does not universally translate into appropriate or optimal behavioral manifestations [21]. As a result, breakdowns in teamwork—rather than lack of knowledge or clinical skills—continue to contribute to a significant proportion of adverse healthcare events [21]. Thus, the importance of working effectively within a complex team-based environment cannot be overstated, with evidence from one observational study conducted in the pediatric surgical setting demonstrating that "…effective teamwork was associated with fewer minor problems per operation, higher intraoperative performance and shorter operating times" [21]. If coordinated teamwork and communication are so important to ensuring patient safety, what are some of the more common failure modes and more importantly the associated barriers?

4. Barriers to communication, collaboration, and care coordination

Without effective communication between care providers, healthcare teams, and their patients, considerations given to safety measures are more likely to be insufficient, often

creating adverse outcomes in both unexpected and unpredictable ways [6]. There are several important barriers to collaboration, coordination, and communication, as outlined in the current section. Within the highly complex and dynamic modern healthcare organizations, each individual must organize and coordinate the necessary care in accordance to their unique, specialized, and highly valued training, expertise, and patterns of practice [43]. Consequently, this inherent systemic heterogeneity is a strong determinant of breakdowns in team function, beginning with differences in the level and type of training and ending with vast and often non-overlapping skill sets that are neither universally understood nor well communicated across the involved group. For example, nurses and doctors are trained to communicate very differently. Nurses tend to be more detailed and emphasize gathering, collecting, and communicating highly granular facts [44, 45]. On the other hand, physicians are taught to interpret these facts, make a diagnosis, and communicate their conclusions without necessarily relating all of the details that led to the formulation of associated clinical plans [44, 45]. An important consideration in this general context is the potential difference in perceptions related to communication among different group members [45, 46].

Another barrier to effective collaboration and communication is the persistence of hierarchical systems that place various team members at different levels of the team decision-making process, often based on specialty, expertise, politics, and other arbitrary factors [47]. Instead, approaches that embrace the fact that each individual brings a unique perspective and breadth of knowledge to the team should be encouraged and appear to be of great importance to improving patient outcomes and promoting a culture of safety [3, 4]. Inviting input and open discourse from the entire team can both improve the delivery of care and reduce the possibility of critical safety steps being missed. Mutual respect, appreciation, acknowledgement, and constructive reflection within the team must be encouraged and should constitute the foundation of sound organizational culture [48, 49]. Great emphasis also needs to be placed on valuing different perspectives, regardless of how divergent individual views may be, through respectful discourse and acknowledgment of key differences. In health care, each member of the team inherently believes that he or she is doing what is truly best for the patient. Respect for differing opinions is an important part of avoiding unnecessary "ego contests" that may be detrimental not only to the team dynamic but also to patient safety and outcomes.

There are several other potential barriers to communication and collaboration that are worth mentioning. Intimidation and disruptive behavior both can interfere with effective coordination of care. There should be "zero tolerance" for these phenomena because they can lead to the development of a hostile work environment and result in fear of communicating or reporting medical errors (e.g., unwillingness to speak up). Any evidence of intimidation or retribution should be a basis for disciplinary action, up to and including termination of employment. Disruptive behavior has been associated with preventable adverse events and adverse patient outcomes [50], and it can distract team members from focusing on effective communication and the performance of essential functions of their job [32, 51]. In summary, it is critical that these two major, yet uncomfortably under-recognized barriers to effective team collaboration and communication be identified and aggressively addressed at all levels of healthcare institutions.

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5. Overcoming barriers to communication, collaboration, and coordination of care

Much like effective communication, highly structured coordination is important to ensuring that established patient safety mechanisms continue to function properly. All team members should be "on the same page" in terms of their understanding of the group's function and purpose. Yet, as we discussed in previous sections, this can be challenging at times due to the abovementioned barriers. In this context, resistance to change may be responsible for the reluctance of both people and institutions to embrace better ways of doing things. Such resistance can persist within clearly dysfunctional teams despite unequivocal evidence demonstrating successful culture shift within other high-stakes industries such as aviation and banking [52]. Identification of problems in the current patient safety paradigm must begin with clear and unambiguous definitions. For example, there are different categories of suboptimal communication, including poorly timed, misdirected, incomplete or inaccurate information exchanges, as well as ineffective communication due to lack of follow-through [32]. The latter type is thought to be a leading cause of medical error and patient harm in the acute care setting [32]. As outlined throughout the *Vignettes in Patient Safety* cycle, the goal of effective communication should be to ensure that everyone's understanding of the situation at hand is clear and that all participants are communicating in an organized, methodical fashion. This can be accomplished by standardizing the approaches which we use to relate critical information within and between healthcare teams. Thus, efforts to disseminate universally agreed upon clinical communication tools across our organizations will be of pivotal importance (as well as the efforts to educate all stakeholders accordingly). Multidisciplinary rounds are a great platform for coordinating care, ensuring that "everyone is on the same page," fostering open communication and collaboration among different disciplines, and providing a troubleshooting forum for any problems that may arise [53].

Standardized team training is important to ensuring a sustained ability of our institutions to function at high-performance levels. Such training programs increasingly take into consideration the human performance science and are designed to mitigate errors and patterns of errors that commonly occur when human beings operate under high levels of stress [54]. Targeted training in leadership, decision-making, briefings, and cross-checking, as well as monitoring, reviewing, and modifying plans under stress, is integrated into the curricula [54]. Simulation constitutes another important aspect of team training. It provides an opportunity to practice various techniques and scenarios in a controlled, highly structured environment. It facilitates real-time feedback and thus creates an opportunity to proactively improve team attitudes and behaviors.

6. The importance of organizational culture and leadership

Good leadership is paramount to organizational success. Rapidly evolving modern healthcare environment requires leaders to be highly flexible and well-versed in change management skills, with focus on the delivery of high-quality, safe patient care. The establishment

of a culture of safety is critical to the leadership's ability to bring about institutional change, enhanced quality of care, and ultimately better patient outcomes [3, 4, 8]. Moreover, healthcare leaders must make patient safety a top organizational priority [8], and through such prioritization, a positive "trickle-down" effect will help gradually facilitate the desired institutional transformation. High-reliability organizations (HRO) can be defined as being able to successfully implement changes required to make them more efficient, safer, and cost-effective. This, in turn, exemplifies the "big picture" view of value-driven health care.

Organizational culture defines the parameters of the work environment. For each healthcare institution and system, poorly managed variability within and between individuals, teams, departments, etc. has the potential to create a dangerous mix of both active and latent systemic contributors to patient safety events. In order to reconfigure the culture of an organization, not only does it takes broad-based staff buy-in but also effective leaders who are able to inspire individuals and teams to pursue both personal and operational excellence.

7. Synthesis and conclusions

Patient safety is a dynamically evolving discipline, with many challenges and opportunities along the journey to operational excellence, just culture, and sustained "zero defect" performance record. The overarching theme of this chapter and this book is that effective teamwork requires the investment of significant amounts of time, effort, and energy by all stakeholders. Modern healthcare requires safe and efficient teamwork, which in turn requires intensive training and education. Most people find it challenging to work with large, complex teams and are often unaware of the various barriers to effective communication and coordination required to thrive in such environment. The creation of team-based healthcare systems must begin with breaking "old habits" and proactive advocacy for the adoption of modern, evidence-based approaches. Beginning with institutional leadership's vision and strategy, trust and respect are fostered to help encourage positive behaviors and implement just culture. The ultimate goal of "zero harm" must always remain the top priority within the safer and more efficient healthcare systems of tomorrow.

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Chapter 2

Defining Adverse Events and Determinants of Medical Errors in Healthcare

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Additional information is available at the end of the chapter

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Abstract

The concept of error typically regards an action, not its outcome, and its meaning becomes clear when separated into categories (medical error, nurse perceptions of (medication) error, diagnostic error). One wrong action may or may not lead to an adverse event either because the abovementioned action did not cause any serious damage to patients' health condition or because it was promptly detected and corrected. The concept of error, on the contrary, which is used alternatively in the study, refers to the adverse outcome of an action. The responsibility for the emergence of errors in healthcare systems is shared among the nature of the healthcare system that is governed by organizational and functional complexity, the multifaceted and uncertain nature of medical science, and the imperfections of human nature. Medical errors should be examined as errors of the healthcare system, in order to identify their root causes and develop preventive measures. The main aims of this chapter are the following: (1) to understand medical errors and adverse events and define the terms that describe them; and (2) the most excellent way to comprehend how medical errors and adverse events occur and how to prevent them. Moreover it makes clear their classification and their determinants.

Keywords: medical error, adverse event, mistake, patient safety, culture of safety, error of omission, negligence, harm, injury, definition, etymology, determinant(s), cause(s), risk factor(s)

1. Introduction

Early studies on patients' safety in the 1950s considered medical errors largely "inevitable diseases of medical progress" [1], and scientific literature often referred to them as "the price paid for modern diagnosis and treatment" [2]. Patients' insecurity regarding the quality of

services provided grows constantly, as mortality and morbidity caused by medical errors demonstrate increasing trends throughout the ages, particularly in countries with deficient social and scientific maturity. In developed countries, one in 10 patients experiences adverse events during hospitalization, according to World Health Organization (WHO). These events could have been predicted and prevented. Moreover, the risk in developing countries is 20 times higher, compared to developed countries [3]. Two categories of errors, which are mentioned subsequently, are the most reported the latest years.

"Communication errors" between healthcare professionals could negatively have an effect on patient safety throughout routine care and even more so during emergency care and in code situations. Training and recent procedures have been established to decrease communication errors [4].

"Wrong-site procedures" are a high-impact, low-frequency "never event" that exists all through procedural specialties. Effects of "Wrong-site procedures" are significant, starting with the psychological and physical harm to the patient. Moreover, the affected patient's loved ones are likewise highly likely to suffer emotional effects of having been, not in a direct manner, unprotected to a wrong-site event [5].

2. Actions and omissions which are associated with errors in healthcare

In an attempt to create a glossary of terms regarding patient safety, the EU Patient Safety and Quality of Care Expert Group accepted Reason's definition of error, which identifies two types of errors (**Figure 1**) [6].

According to Reason [6], errors are separated into "active" and "latent" errors. In "latent errors," effects occur later, and they are attributed to poor planning, increased workload, poor organization, and inadequate training of the personnel; in "active errors," effects are direct and may be detected instantly upon occurrence [6]. The terms "active failures" and "latent conditions" or "latent failures," the definitions of which are presented subsequently, are also frequently used:

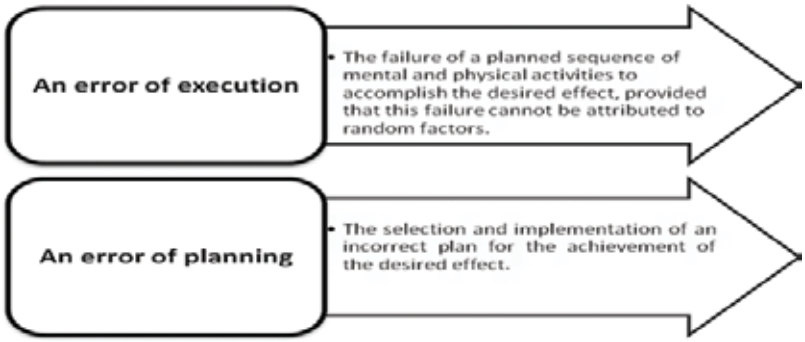

Figure 1. Types of errors by Reason. Source: Reason [6].

i. "Active failures": direct failures, unsafe acts carried out by people in direct contact with the patient or the system [7]. The effects become apparent almost instantly or at least within a few hours. These errors are often referred to as "errors on a knife-edge" [8]. It is true that people being on a "knife-edge" make errors, but this is only one part of the truth—and not even the most crucial.

ii. "Latent conditions or latent failures": latent conditions, inevitable inner pathogenic "micro-organisms" of the system that lead to errors. They arise from decisions taken at the strategic level and, thus, by the top management. Consequently, they are associated with the organization's structure, design, planning, training, forecasting, budget, resource allocation, etc. Latent conditions are manifested in two ways. The first way is by influencing working conditions so that the employees are prone to errors (e.g., time pressure, understaffing, lack/shortage of equipment, etc.) and the other way is by creating gaps in various organizational "defense levels" (e.g., unreliable alarm systems, design and construction defects, etc.). As the term suggests, latent conditions may remain ineffective inside the system for many years, and when combined with "direct failures," it may lead to the occurrence of several and different adverse events [6].

The difference between "direct" and "latent failures" lies, on the one hand, on timing, and, on the other hand, on the level of the system they will manifest. In "direct failures," people's actions have immediate effects, whereas in indirect failures, the effects may not be obvious or appear much later and only provided when they are combined with other direct failures. As a result, professionals being on a "knife-edge" are easier to blame. This may also be attributed to the fact that the detection of the root causes is rather hard and is often related to the organizational level. "Direct failures" usually occur to those who are directly related to the patient, whereas indirect failures are mostly associated with the organizational and administrative level. "Indirect failures" may be "transferred" along organizational and departmental pathways in the workplace (e.g., in an operation room (OR), etc.), locally generating the conditions that favor the occurrence of errors and misconducts.

Reason [7] compared the "individual's approach" to the effort made by an individual trying to kill a mosquito that bit them and the "system approach" to the effort to drain the swamp wherein mosquitoes procreate. "Individual approach" focuses on the errors of the employees, for example, by blaming them for carelessness. It is, however, a fact that errors are not realized only by incompetent but also by very competent healthcare professionals, and they are often the most competent professionals, who make the worst errors. "System approach" focuses on the conditions under which the employees perform their duties. This approach is mainly adopted by organizations that require highly reliable services (e.g., aviation), and it is considered the most appropriate by the scientists who have dealt in depth with errors in the healthcare sector [7, 9].

Based on previously mentioned definitions of errors, Reason [6, 7], focuses on the process design and implementation and not on the outcome and the consequences, thereof taking into consideration the fact that those psychological, physical, and technical failures abet to the conduction of an error. He, however, overlooks the errors caused by omissions (error of omission) [6, 7].

In contrast, Leape [10] refers to errors attributed to actions or omissions but overlooks the actions based on design errors, unless they lead to adverse effects. Reason's and Leape's definitions are subjected to several limitations. Although an action may be mistaken or the plan for the accomplishment of the desired effect may not be appropriate, errors or omissions must not be always blamed for adverse events in the healthcare sector, since there are other factors that contribute to them, such as an unexpected allergic response to a new medication treatment.

An equivalent definition of error, similar to the one provided by Reason [6], is the definition by the Institute of Medicine (IOM)[1] in the United States in 1999, in a published report, regarding errors in the healthcare sector. Therewith, a "medical error" is defined as the failure to complete a planned action or the use of ineffective planning for the accomplishment of an objective [11].

In a report published in 2000 regarding medical errors and patients' safety, Quality Interagency Coordination Task Force (QuIC) in USA attempts a conceptual clarification of error in the healthcare sector expanding the definition that was provided by the IOM the previous year. According to this definition, "error" is defined as the failure to complete a planned action as expected or as the use of incorrect/poor planning to achieve an objective. According to the same report, "medical errors" may also refer to processes, practices, and equipment [12].

In order to understand the concept of error in the healthcare sector more accurately this time, Reason [13] defined error as the variations in the provision of healthcare that may cause harm to the patient. Other definitions concerning medical errors, which were published recently, are presented in **Table 1**.

Zhang et al. (2002) [14]	"Medical error" occurs when a healthcare provider chooses an inappropriate method to improve a patient's health status or fails to apply the appropriate method correctly in order to improve a patient's health status
National Patient Safety Foundation (NPSF) (2003) [15]	"Medical error" is the unintended outcome, caused by a certain defect in healthcare provision. Moreover, errors in the healthcare sector may be divided into "errors of practice" (wrong action), "errors of omission" (lack of the correct or appropriate action), and "errors of execution" (performance of the correct action executed wrongly)
Grober and Bohnen (2005) [16]	"Medical error" is an action or omission throughout the design and execution of a healthcare provision process that causes or is likely to cause adverse events
Kyritsi (2009) [17]	"Error" is any unintended event that poses a threat to patient's safety or any deviation from the rules and the established practices in the workplace
Raftopoulos (2009) [18]	"Error" is an action that fails to achieve the intended outcome, which may be analgesia, muscle relaxation, or any other recession of unpleasant symptoms
Kapaki (2015) [19]	"Medical error" refers to a healthcare professional's action or omission during the planning and implementation of healthcare provision, which contributes or could contribute to the further impairment of a patient's health status on the one hand and the healthcare provision system on the other

Table 1. Additional definitions of medical errors.

[1]Institute of Medicine (IOM) has been renamed to National Academy of Medicine (NAM).

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3. Adverse events in healthcare

A previous literature review includes research on patient safety issues that mainly focus on adverse outcomes from the practice of medicine, adopting definitions of medical errors and related terms based on the adverse outcomes of medical practice [20–24]. This could be explained by the basic medical principle of Hippocrates, which is summarized in three words: "Primum non nocere" or "First, do no harm" [10, 25]. Moreover, the definition of patient safety dictates an outcome-based approach of medical error.

"Patients' safety" is defined as avoidance, prevention, and improvement of negative effects or injuries caused to patients during healthcare provision [26]. IOM defines "patient's safety" as freedom from random harm [11].

In his study "Hazards of Hospitalization," Schimmel [27] argued that the evaluation of undesirable effects resulting from healthcare provision, as well as the registration of their frequency, is necessary regardless of the severity of the effects. It is also paramount that an overall risk assessment is realized, regarding the patients' exposure to polypharmacy and complex procedures during healthcare provision. Within this context, he introduces the term "noxious episode" for the first time.

"Noxious episodes" are all the unpleasant events, the complications, and the misfortunes caused by acceptable diagnostic and therapeutic measures executed in the healthcare unit [27].

The term "potentially compensatable event" was introduced for the first time in 1977 in the study titled "The California Medical Insurance Feasibility Study," defining it as an event that occurs during healthcare provision and leads to disability or prolonged hospitalization [28].

Four major researches regarding errors in the healthcare sector were published in the 1990s, emphasizing the term "adverse event." According to "Harvard Medical Practice Study" [20, 21], "The Utah and Colorado Medical Practice Study" [22], "The Quality in Australian Health Study" [23, 24], and the study of IOM in US "To Err is Human: Building a Safer Health System" [11], an "adverse event" is defined as a localized damage or complication caused to patients by medical care that does not result from patient's impending disease and leads to patient's disability, prolonged hospitalization, or even death.

"An adverse or undesirable event" refers to an outcome of a process, whereas an error characterizes an action itself. This means that an error may cause an adverse event or not, either because this action caused no harmful effects and the patient did not experience any symptoms or because it was detected on time and was prevented. An error constitutes a necessary but not sufficient cause of an "adverse event." This is explained by the fact that "adverse events" do not always result from errors or omissions; they may also arise from appropriate actions with "adverse effects" (complications) that were either unknown at the time the action was taken or they were known and expected but could not be prevented (e.g., adverse drug events, etc.) [29].

Leape [10] classifies "adverse events" into three categories as shown in **Figure 2**.

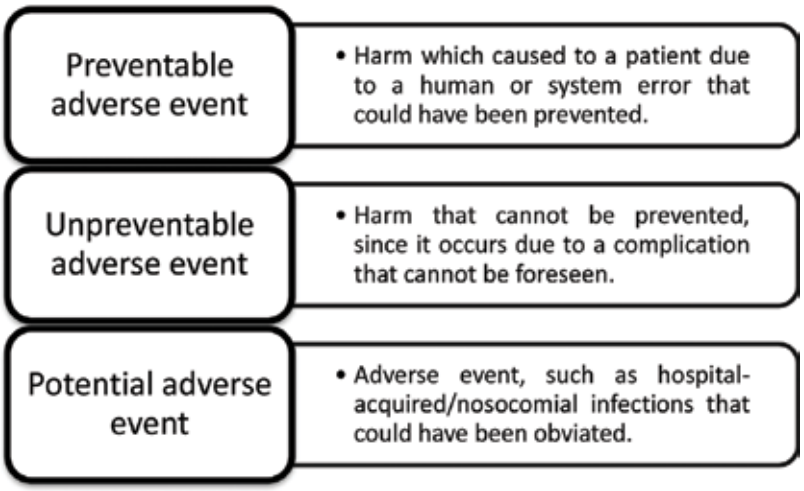

Figure 2. Adverse events classification by Leape. Source: Leape [10].

Literature also makes frequent reference to "adverse events," the severity, and criticality of which could have been significantly limited, provided that different actions had been followed (ameliorable adverse event) [30].

In addition to the conceptual clarification of the term "adverse event," studies, such as the Harvard Medical Practice Study [20, 21] and the Utah and Colorado Medical Practice Study [22], introduced the term "negligent adverse event" for the first time as a subcategory of the "preventable adverse events," which, however, meet the legal criteria defining negligence.

Other than words such as "mistake," "error," and "adverse or undesirable event," literature regarding patient safety issues also makes frequent use of several relevant terms without any clear and distinct conceptual differentiation. According to Cook et al. [31], it is a fact that the approach of patient safety issues is not the same among all healthcare professionals.

4. Other terms used in literature

Another term similar to "adverse event" that ranks second in terms of incidence is the term "sentinel event." The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (2003) defined it as an unexpected event that involves death, serious physical or psychological damage, or risk of those. Serious physical or psychological damage refers to the loss of a body part or a function, whereas the risk of such damages refers to any variation of the procedure, the revision of which would entail the risk of serious medical error occurrence or would pose a threat of an adverse event. The term "sentinel," is interpreted as a guard or a watchman and is used for events that require immediate investigation and handling [32]. Such events are as follows:

i. any event that led to amputation of a human body part or loss of function, not related to the underlying disease; and

ii. events such as suicide, rape, delivery of a newborn to the wrong family, violent abduction of a patient, surgery on the wrong body part of a patient, etc.

The terms "close call" or "near miss" are almost identical and refer to certain actions or situations, which could have caused an "adverse event" but were timely detected and prevented or randomly prevented [33].

A term that is often used when referring to "adverse drug events" is that of "side effects," which regard the known effects of a drug and are different than those for which the drugs were originally designed [34].

"Iatrogenic injury" or "illness" is another term, which refers to undesirable effects that result, partly or entirely, from the medical process or medication treatment and do not constitute a direct or an indirect complication of the patient's initial state or the disease. This term is similar (or identical) to the side effects. The difference between "iatrogenic injuries" and "side effects" is that the first are not known and therefore they are totally unexpected. Furthermore, they are not caused due to technical failures, and therefore they do not constitute a criminal offense. This term is not also different from an "adverse event" [35].

The term "incident" occurs frequently in cases relating to patient safety, and it is used as a general term until the moment the event has been classified [36]. It characterizes an event that has already led or could lead to an artless injury and patient complain, and loss or damage [37]. The National Research Council (NRC) defined "incident" as an event that could be considered an accident, if it had taken place under slightly different circumstances. A critical event regards an event that leads to serious damage or even death [38].

The concept of "error" is often confused with the concept of "injury". WHO defines "injury" as tissue damage caused due to a factor or under certain circumstances? "Errors" become noticeable when they cause a certain "adverse event" or "injury" to the patient and influence health outcomes in a negative way [34]. Leape [10] argues that most "errors" do not lead to "injury".

The term "harm," which is typical of the body's structural or functional impairment and the resulting negative effects, is also frequently used in the study [34].

The term "hazard" has the meaning of risk factor and refers to anything that causes damage. A "hazard" is also defined as a factor, a situation, or an action, which may lead to or increase risk. In his article titled "The hazards of hospitalization" published in 1964, Schimmel refers to the terms "hazard," "adverse reaction," "adverse episodes," "incidence," and "risk" and categorizes reactions into those caused by diagnostic or therapeutic interventions that occurred in the hospital and those resulting from physicians' or nurses' errors of negligence [27].

5. Determinants of medical errors

The first study regarding "errors" in the healthcare sector was conducted in 1960 at a New York City hospital and indicated that 60% of the "errors" are caused by healthcare professionals' negligence [39].

This study was followed by Vincent's research effort in 1989, which regarded the underlying causes of "errors" in the healthcare sector and classified them into the following categories [40]:

i. individual characteristics of health professionals that commit the errors,

ii. temporary situations such as the consumption of pharmaceutical preparations and alcohol by health professionals,

iii. organizational factors, and

iv. patients' characteristics.

In his development of organizational accident causation model (Swiss cheese model applied to clinical events), Reason [6] suggests that a factor may cause more than one "error" and one "error" may be attributed to more than one factor. In the event, however, that no efforts are made in order to improve the overall factors causing the errors and address errors on an individual basis, no progress will be made and new errors will continue to arise. Reason grouped the factors that influence clinical practice negatively into five levels [6, 40].

In 1995, Leape et al. published one of the largest studies regarding "errors," which constituted a key presumption for the need to study organizational factors that contribute to the occurrence of "errors" [9]. The study examined the weaknesses of the system that led to the emergence of 334 errors. The authors attempted to answer three major questions: (1) why did the error occur, (2) which was the basic cause of the error, and (3) what were the system's weaknesses. According to the findings of the study, the weaknesses of the system may be categorized as listed in **Table 2**.

A similar classification of "error determinants" was also attempted by Helmreich in the "The university of Texas Threat and error management model" in 2000. Helmreich distinguished between the organizational factors, the individual factors, and factors regarding teamwork and the patient [41].

Carver and Hipskind [43] confirm that a medical error is an "avoidable adverse effect" of medical care, whether or not it is substance to the patient. Among the difficulties that usually happen throughout providing healthcare are adverse drug events and irregular transfusions, incorrect identification of an illness, under- and overtreatment, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and incorrect patient identities. High error rates with important effects are most probable to happen in intensive care units (ICUs) [42], operating room (OR), and emergency departments (EDs). Furthermore, "medical errors" are connected with unused procedures, immediate necessity, and the seriousness of the medical condition being treated [43].

The responsibility for the emergence of errors is apportioned among the nature of the healthcare system that is characterized by organizational and functional complexity, the multifaceted and uncertain nature of medical science, and the imperfections of human nature [44, 45].

5.1. Factors related to the nature of the healthcare system

According to the theory of physical accidents, which was formulated for the first time in 1984 by the sociologist Charles Perrow, accidents are inevitable; therefore, they occur naturally,

Weaknesses of the system	Clarification
Dissemination of pharmaceutical knowledge	A set of interpersonal interactions and relationships is established between theoretical researchers, pharmaceutical industry, journalists, practicing medical professionals, and prospective patients such that researchers' involvement with the development of new drugs is inevitably a procedure in which a number of "goods" become fungible
Control of medicine dosage and patient's identity authentication	A considerable number of nursing tasks entail an extent of risk, and medication administration possibly carries the most extensive risk. Nursing stuff has followed, in the customary way, the five rights of medication administration (patient, drug, route, time, and dose) to help prevent errors
Availability of information regarding the patient	Instructions of language usage in medical settings could be efficacious in classifying and giving attention to language barriers and would enhance knowledge of health inequalities
Copy of the instructions	A medication order is written instructions provided by a prescribing practitioner for a particular medication to be administered to an individual. The prescribing practitioner may also give a medication order orally to a licensed person such as a pharmacist or a nurse
Allergic reactions	As a whole, medications have the possibility to provoke side effects, but only about 5–10% of adverse reactions to drugs are allergic. Allergy indicators are the outcome of a chain reaction that begins from the immune system. Your immune system controls how your body protects itself
Medication order tracking	Hospital sector has long faced challenges connected with getting, written by hand, medication orders from the prescriber to the pharmacist
Intra-hospital communication	There is notable dialog of, and investment in, information technologies, communication systems receive much less attention and the clinical adoption of even simpler services like voice mail or electronic mail is still not ordinary in a considerable number of healthcare services
Use of devices	Adverse Device Effect (ADE): adverse event connected with the use of an investigational medical device
Dosage standardization and administration frequency	One more plan to decrease "medication error" is drug dosage standardization. Standard doses minimize the interpatient variation of drug dosages
Standardization of medical products distribution process within the department Process standardization	Standardization is a significant term in the healthcare industry. With hospital budgets getting tighter, standardization is perfect for operating under cost constraints. But the negativity connected with the term makes it not easy for providers and hospital management to encourage standardization to clinical end users
Patient transport process	Patient transportation is a considerable action in healthcare with important resource consequences for healthcare systems. Much attention has concentrated on the emergency transport of acute- and critical-care patients
Conflict resolution	There are four widespread sources for interpersonal conflict: personal differences, informational deficiency, role incompatibility, and environmental stress. There are five frequent responses used in dealing with conflict: forcing, accommodating, avoiding, compromising, and collaborating. Managers on healthcare sector should become comfortable with using all of these approximations
Preparation of intravenous solutions by nurses	
Staffing and work allocation	Allocation of nursing time to patients at an educated guess influences quality and carefulness of nursing acts and evaluations. Also, there may be skill-mix issues
Feedback following the emergence of unintended events	The healthcare sector has an obligation to guarantee that their staff is skilled enough and confident in dealing with all particular kinds of feedback in a way that is individually centered

Table 2. The weaknesses of the system.

since they constitute inherent features of complex systems. The more complex a system is and the stronger the bonds between the individual elements of the system are, the more complicated and unpredictable are the consequences from a possible error. Perrow uses the term "accident" in order to describe a fact that entails damage to a given system that disorganizes the consecutive or future outcome of the system [46]. Perrow's theory is also supported by Reason in 1990, who argues that complex systems entail unfavorable developments. This is the reason why complex systems provide multiple methods for error detection and recording [6].

Another key factor that determines errors in the healthcare sector is technology. Problems often arise from human interaction with technology, or insufficiency, or poor maintenance of the technological equipment. This fact is proven in a study by Taxis and Barber [47], in relation to intravenous (IV) medication errors, where 79% of errors are associated with the lack of knowledge regarding the drug preparation and administration and machinery operation (e.g., pumps). According to the results of a current study, the unforeseen potentially fatal events within 24 h of admission from the ED could be a helpful trigger tool to recognize "preventable adverse events" with grave harms to body in ED [48].

5.2. Factors associated with the healthcare professionals' human nature

"Medical and nursing errors" are human errors committed by persons acting in a certain capacity (physicians, nurses), in a certain environment, and under special conditions. Human intelligence is not infallible; therefore, the resulting action cannot be infallible. Causes associated with the human factor contributing to the emergence of errors in the healthcare sector are the following.

5.2.1. Professional burnout

The term "professional burnout" was used in literature for the first time in 1974 by Freundenburger. In one of his articles, he described the psychosomatic symptoms that appeared in healthcare professionals occupied with mental illnesses [49]. In 1982, Christina Maslach described this phenomenon as "a syndrome of mental and physical exhaustion, where an employee loses interest for the patients, ceases to be satisfied from his/her work and performance, and forms a negative opinion about his/her self" [50]. According to Maslach and Jackson [51], the three most important components of burnout are the emotional burnout, depersonalization or cynicism, and the sense of ineffectiveness (lack of personal achievements).

According to international studies, the factors relating to "professional burnout" are categorized into factors relevant to the working environment, individual factors, and personality factors. Workload [52–55], high stress levels [56–59], conflicts with colleagues superiors or relatives [59, 60], social support from colleagues and superiors [52, 55], job satisfaction [59, 61, 62], balance among work family and personal development [53, 55], sense of control [53], organizational support [55, 63], autonomy [52, 53], inadequate time to study [52, 62], sufficient staffing [63–65], training in communicational skills [58], and salaries [52, 53] are among the factors relating to the working environment, which are systematically highlighted as closely linked to a professional burnout caused at physicians and nurses.

With regard to individual factors, demographic parameters reveal that age appears to be systematically associated with "professional burnout," with the younger employees exhibiting it to a larger degree [52–54, 58]. In relation to gender, the findings are contradictory [54, 66–69] although studies reveal that higher levels of professional stress for women are systematically encountered [66, 67]. Marriage appears to have a protective effect on the occurrence of "professional burnout" in women. Support provided by husbands or wives as well as work life balance are also among the factors that systematically demonstrate negative correlation with "professional burnout" [54].

Among the personality traits systematically associated with "professional burnout" are empowerment [70], empathy [70], tolerance to stress [71, 72], sense of effectiveness [54], and mental well-being [73].

The effects of "professional burnout" on physicians and nurses are manifested not only on the individual level but also on the organizational, thus affecting the quality of the healthcare provision at the organization in which they are occupied. "Professional burnout" may also cause physiological symptoms to employees either in the form of plain discomfort or more serious health problems, emotional problems such as the feeling of discouragement, low self-esteem and self-confidence, behavioral symptoms such as coldness, indifference, lack of care interest and respect for the patients, and psychiatric disorders such as stress and depression. There is also evidence that "professional burnout" may influence individuals' satisfaction regarding life in general, their social and personal life and may also be contagious to other health professionals (colleagues or trainees) [74].

The effects of professional burnout expand, as previously mentioned, to the healthcare provision organization, increasingly slowing the implementation of the employees' project, leading to absences and reduced performance. It has also been associated with an increased intention of the personnel to leave employment/retire [53, 64, 75]. "Early" retirement of physicians and nurses intensifies the already existing problem of staff shortage contributing to the lower quality of offered services, since insufficient staffing is associated with patient mortality, adverse events, and the quality of services provided, as substantiated by the existent literature [64]. The retirement of the aforementioned health professionals also has a financial impact to the organization, as the latter bears a large cost for their replacement [11].

Shanafelt et al. [62] examined the relationship between burnout in medical residents and their opinion regarding their practices regarding healthcare provision to patients. On the one hand, according to the findings, 76% of the physicians who participated in the study suffered from professional burnout. On the other hand, "burnout physicians" were more likely to report "inappropriate patient healthcare practices," such as inappropriate behavior toward patients, omissions in diagnostic treatment, and medication errors at least on a weekly or a monthly basis, in comparison to those that did not suffer from a professional burnout [62].

5.2.2. Workload

Workload has been directly associated with the emergence of errors during clinical practice and is mainly attributed to the lack of personnel [47, 64, 76, 77]. Understaffed healthcare units

in combination with workload are likely to endanger patient's safety [76]. A study conducted in 1998 in Australia by Beckmann et al. has shown that lack of personnel is associated with increased medication errors, inadequate patient supervision, equipment preparation, and omissions in documentation of medical and nursing care [78]. Similar were the findings of a study by Giraud et al., in 1993, which identified heavy workload as the main cause for an increasing rate of errors [79]. In a study realized by Blendon et al. [80], the physicians participating in the research argued that the main cause of errors in clinical practice is the lack of nursing personnel.

In their research published in 1995, Roseman and Booker demonstrated the correlation between workload and the errors in healthcare, quantifying workload with the use of nine indexes. It was found that three out of nine workload indexes that were examined (number of patient days per month, number of emergency shift staff, and overtime of permanent nursing staff) could significantly predict the risk of medication error. More specifically, the number of errors increased as the number of patient days and the number of emergency staff's shifts increased, whereas it decreased as the number of overtime of the permanent nursing staff increased. The latter is reasonable, since permanent nursing staff is better trained and oriented in a specific department compared to emergency staff [81]. According to the findings of Mayo and Duncan's study [82], the interruption of nurses by a relative or another healthcare professional during the preparation of medication is ranked second among the factors that cause the emergence of errors. However, a study by Osborne et al. [83] ranks the same factor as fourth.

5.2.3. Lack of knowledge and experience

According to a study realized by Arndt [84], regarding the effects of errors on nurses' psychology, the respondents reported that errors were caused by lack of knowledge regarding medicine administration. In a study by Taxis and Barber [47], regarding intravenous medication errors, 79% of errors were related to lack of knowledge regarding medicine preparation, administration, and machine operation (pumps), and 15% were related to heavy workload and often interruptions. Blais and Bath [85] identified three categories of errors relevant to the calculation of drug dosage: mathematical, conceptual, and measurement errors. In Osborne's study [83], 5.3% of errors are caused by wrong calculations. The experience of healthcare professionals constitutes another factor regarding errors. In his study, Walters [86] mentions that there is a statistically important relation between the number of errors made by nurses with a greater working experience (less errors) and the errors made by professionals with less working experience (more errors). Due to the lack of experience, newly recruited healthcare professionals are the first to blame when an error occurs. In several occasions, however, newly recruited in the unit are hesitant and lack initiatives out of fear of making an error that may have adverse effects on patients' health status. On the other hand and according to the study, the most experienced professionals are those that indeed make fewer errors compared to beginners [87]; however, they may commit errors with very serious consequences for patients' health status [7].

5.2.4. Communication difficulties among healthcare professionals

Communication among healthcare professionals constitutes an important factor not only for preventing but also for making errors [76]. In a study by Taxis and Barber [47], regarding

IV medication errors, 16% of the errors are associated with poor communication among healthcare professionals, whereas in a study by Blendon et al. [80], physicians argue that poor communication among professionals causes errors at a level of 39%. In the same study, the citizens, who were also included in the study responded that poor communication among healthcare professionals promotes errors at a level of 67%. Mayo and Duncan [82] also believe that conversations between nurses and supervisors regarding errors that are considered a "taboo" are necessary. Interprofessional cooperation between physicians and nurses is also of significant importance. The fact that is of particular importance in Arndt's [84] study is that some physicians had a good communication and cooperation with the nurses, and often after evaluating the error and provided no serious damage was caused to the patient, they covered up for the errors realized by the nurses. According to Helmreich [41], the risk of errors in surgeries increases when there are problems in communication, information transmission, leadership, interpersonal relationships, and conflicts. Van Cott [88] generally indicates that a high rate of errors results from communication problems, oral or written, which can be prevented provided appropriate training is present. Cooke and Salas [89] highlighted that in a stressful environment, people tend to fail to express orally what they mean. Even if they do manage to express it orally, it is not certain that the intended recipients will hear it. Even if they hear it, it is not certain that they will understand it. Finally, even if they do understand it, it is not certain that they will act accordingly. It is for this reason that confirmation should be required, in order to prevent a gap between the abovementioned steps [89].

5.2.5. Environmental conditions

Roseman and Booker [81] examined the association between "medication errors" and daytime, the latter being an environmental specificity regarding a particular geographical area. The study was conducted in Anchorage in Alaska, where daytime is gradually changing from 5.5 h in December to 19.5 h in June. This change in daytime throughout the year leads to mood disorders called "Seasonal Affective Disorder (SAD)," which is characterized by a recurring depression in the fall or in the winter that normally resolves in the spring. More than half of the errors occurred in the first quarter of the year, and, more specifically, 22% of the errors occurred in February and 29% in March. This finding is considered significant; however, further research is required [81].

5.3. Factors associated with the nature of medical science

Other than the error factors that are associated with the healthcare system per se and the factors related to the human nature, there are also factors related with the uncertain and multifaceted nature of medical science. Every medical action initially affects the bodily integrity and secondarily the patient's personality and privacy. Every medical and nursing intervention poses threats, which according to the law of probability will eventually be realized. Medicine and Nursing are empirical sciences, and the uncertainty factor lurks in every stage of healthcare provision (prevention, diagnosis, treatment, research). Patients and their relatives are not trained to identify the finite limits of the medical science in the case of aggressive diseases and death [90, 91].

6. Clinical vignette

Eighty-year-old Denisa Conolly used to wake up during the night with symptoms of dyspnea and wheezing. Her physician diagnosed her with asthma and prescribed albuterol, an asthma bronchodilator. Two days later, Mrs. Conolly was admitted to the hospital at the Coronary Care Unit (CCU) suffering from a heart attack. In his letter to the Head of Medical Services, the cardiologist reported that a diagnostic error had been realized by Mrs. Conolly's physician regarding the abnormal congestive heart failure and had administered treatment for asthma. The cardiologist reported that treatment might have accelerated the heart attack.

7. Conclusion

There is an urgent need to develop a commonly accepted definition of the "medical error" among the scientific community, which will contribute to further research regarding "error phenomena" in healthcare, facilitating data collection, synthesis, and analysis, avoiding the usage of terms with a similar meaning. Furthermore, it will contribute to a better quality control of the offered healthcare services and will also serve legal and insurance purposes. As every "human error," "medical errors" do not constitute unpredictable situations but the outcome of aggregated risk factors. The analysis of errors allows early identification and change of the conditions that favor such errors. The causes of errors in healthcare are not unambiguous or independent from each other.

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Competing interests

The authors affirm that they have no competing interests.

Abbreviations

CCU	Coronary Care Unit
ED	Emergency Department
EU	European Union
ICU	intensive care unit
IOM	Institute of Medicine

IV	intravenous
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NPSF	National Patient Safety Foundation
NRC	National Research Council
OR	operation room
QuIC	Quality Interagency Coordination Task Force
SAD	Seasonal Affective Disorder
WHO	World Health Organization

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Chapter 3

Adverse Events in Hospitals: "Swiss Cheese" Versus the "Hierarchal Referral Model of Care and Clinical Futile Cycles"

Michael Buist

Additional information is available at the end of the chapter

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Abstract

The James Reason 'Swiss Cheese' model of adverse event causation has been the predominant principle in the determination and prevention of health-care-associated adverse events for the last 20 years. This model was developed to understand the causation of large-scale organisational and industrial accidents. In principle, it looks for holes in the defence layers of a large organisation that are largely administrative and not the fault of individuals that may be directly involved with the accident. This model has limitations when applied to health care, where most of the errors or accidents are individual technical or competency deficiencies within a background of an ever-changing micro socio-cultural environment. As such, using 'Swiss Cheese' methodology, there has been an over reliance on looking for system issues in health care that has led to a decreased focus on the individual performance of the health-care professional and avoidance of difficult cultural workplace issues. Clinical futile cycles (CFCs) are a model of adverse event causation that primarily focuses on the interaction between the immediate health-care professionals and patients and between health-care professionals. This focus allows for interventions that address issues such as clinical competency and the culture of the health-care environment.

Keywords: clinical futile cycles, health-care adverse events, Swiss cheese

Clinical vignette

Mrs. M, a fit 69-year-old, underwent an uncomplicated elective laparoscopic cholecystectomy [1]. The next morning (Day-1), upon review by the surgical team, it was decided that she should remain for

overnight observation due to some shoulder tip pain and nausea. That afternoon, she was transferred without the consultation of the surgical team from the surgical ward to a low dependency rehabilitation unit. By the following morning (Day-2), she was tachycardic, diaphoretic and had a distended abdomen. The ward medical officer reviewed Mrs. M and prescribed intravenous (IV) fluids and analgesia, ordered blood tests, and requested an urgent surgical review. The surgical team then saw Mrs. M as part of their usual morning ward round, and she still had generalised abdominal tenderness and abnormal vital signs. An abdominal X-ray and CT scan were ordered.

Mrs. M continued to deteriorate over the day. Another set of abnormal vital observations was taken sometime after the ward round, yet no doctor was informed. Mrs. M was seen by the two interns attached to the surgical unit. They were called to review her in the CT room due to concerning vital signs and contacted their registrar for assistance. They prescribed IV therapy and analgesia following their registrar's phone advice.

Upon discussion of the CT results between the consultant and registrar midday, it was decided that Mrs. M was to return to theatre later that day for explorative laparotomy, and then to transfer to ICU for post-operative observation. Mrs. M was therefore assessed by the intensivist on-duty who diagnosed peritonitis and renal failure, and prescribed triple antibiotics and rapid IV fluid therapy, and strict monitoring of fluid balance. She was concurrently seen by the anaesthetist on-duty for pre-anaesthetic assessment. As Mrs. M had single IV access, only one antibiotic was administered by the time she was called to the operating room.

Once in the operating theatre, surgery was delayed by an hour and ten minutes when Mrs. M becoming profoundly hypotensive upon anaesthetic induction. A bile leak was found intra-operatively and the abdomen lavaged. It was not discovered until her arrival in ICU later that evening that Mrs. M had only received one of the three prescribed antibiotics. By then, Mrs. M was severely septic, requiring inotropes, dialysis and mechanical ventilation. A second laparotomy, 2 days (Day-5) later found widespread bowel and hepatic ischaemia, and Mrs. M died the next day of multi-organ failure (Day-6).

Analysis of case

The death of Mrs. M, a fit 69-year-old lady, who underwent an elective procedure, is a classic case of clinical futile cycles (CFC) [1–3]. This term has been borrowed from biochemistry where two (or more) always on enzymatic systems change one chemical to another and then back to the original chemical with no net output but the use of much energy. In Mrs. M's case, there was certainly a lot of clinical activity from all levels of the medical and nursing hierarchy; yet, the net outcome was a preventable death. The ward doctor on day 2 did all the right things, IV fluids, ordered labs, and requested an urgent surgical review. The surgical team certainly had this patient on the radar, performed a CT scan, and got the theatre organised and the post op ICU bed. The surgical registrar gave good instructions over the phone and the consultant agreed with all of the above and undertook the re-operations.

However, if we 'scratch the surface' a bit more in this case sadly, Mrs. M found herself in the midst of an unintended CFC:

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- nurses, doing the right thing, taking the observations and notifying the medical staff,
- interns with little knowledge and even less experience (too much time at med school learning ALS and CPR, but not enough time with real sick patients) of acutely deteriorating patients and certainly not enough emotional intelligence to manage all the players in a clinical scenario like Mrs. M's,
- a surgical registrar who would have all the competencies, but is too busy to attend the patient and direct the care at the bedside and instead delegates tasks to the interns above by phone and
- a consultant surgeon with the skill and ability to fix the problem but most commonly employed only on a sessional basis, so often not actually there in the hospital in question.

So, at four levels above in the traditional hierarchal referral model of care, everyone is doing the right thing. CFC is the explanation for all this activity, whilst appropriate for the individual practitioner concerned was not sufficient to get Mrs. M to theatre more urgently to have the problem fixed. In addition to the CFC, we have become accustomed to the naïve expectation that some sort of track and trigger system (Medical Emergency Team, Rapid Response System) will fix the problem by getting the patients deterioration alerted. However, that is all they do. The rest is up to the clinicians on the ground to make the right diagnosis, determine the level of severity of the condition, initiate management, notify the right people and with all pressures of the job to do this in a timely fashion to prevent patient catastrophe [4, 5]. All too often, it is only patient physiological reserve that defends patients from a system of care that is designed to fail them.

1. Introduction

The first chapter in this series of Patient Safety Vignettes [6] gives an overview of adverse events in health care and provides a standardised glossary of the various definitions that are used. An adverse event is defined as an injury resulting from a patient's medical management rather than a consequence of the patient's underlying medical condition or conditions [6–10]. Adverse events are common and costly to both the affected patients and the health-care system [6, 11–18]. In the last two decades, the incidence, aetiology and outcomes from adverse events have been documented mostly in the hospital setting [6, 11–23]. Taking these studies together, approximately 10% of hospital patient admissions have some sort of adverse event. Of these, half result in no long-term harm to the patient. However, 10% (of the 10%, i.e., 1% of all hospital admissions) of the affected patients suffer significant harm such that they either die of or are left with some sort of permanent disability as a result of the adverse event (**Table 1**) [37]. In 1995, the cost of adverse events to the Australian health-care system was estimated at $2 (AUD) billion dollars [8]. Attempts to reduce the incidence of adverse events and make hospitals safer have been largely unsuccessful [38–41]. Like other diseases and conditions, an understanding of the underlying aetiology or 'pathophysiology' of adverse events is important for the development of preventative strategies. To date, the predominant

Study (year of study)	Methodology	Setting	Sample	Incidence (%)	Outcome death	Outcome permanent disability	Preventability	Negligent care	Cost (annual)
California medical association (1977) [24]	Random sample retrospective case note review			4.2	N/A	N/A	N/A	19.1%	
Harvard medical practice study (1991) [25, 26]	Two-stage random sample retrospective case note review	51 acute-care New York State hospitals	30,121	3.7	13.6%	2.6%	58%	N/A	N/A
Utah and Colorado study (1992) [27]	Random sample retrospective case note review	28 general hospitals	15,000	2.9	6.6%	8.5%	53%	30%	
Quality in Australian Health Care Study (1992) [28]	Two-stage random sample retrospective case note review	28 acute-care hospitals of different sizes in 2 Australian states	14,179	16.6	4.9%	8.9%	51%	N/A	$2 billion (AUD)
New Zealand public hospitals (1998) [29]	Two-stage random sample retrospective case note review	13 general acute hospitals	6579	11.2	15% for both categories		N/A	N/A	
United Kingdom (1999) [30]	Random sample retrospective case note review	2 acute-care London hospitals	1014	11.7	8.2%	6.3%	N/A	N/A	
Canadian health care study (2000) [31]	Two-stage random sample retrospective case note review	1 teaching, 1 large community and 2 small community hospitals	3745	7.5	20% for both categories		36.9%	N/A	
Brazilian hospitals (2003) [32]	Random sample retrospective case note review	3 teaching hospitals in Rio de Janeiro	1103	7.6	N/A	N/A	66.7%	N/A	
Dutch hospitals (2004) [33]	Three-stage random sample retrospective case note review	21 acute-care hospitals	7426	5.7	12.8% for both categories		40.3%	N/A	

Study (year of study)	Methodology	Setting	Sample	Incidence (%)	Outcome death	Outcome permanent disability	Preventability	Negligent care	Cost (annual)
Italian acute care hospitals (2008) [34]	Two-stage random sample retrospective case note review	1 acute-care hospital	1501	3.3					
Portuguese hospitals (2009) [35]	Two-stage random sample retrospective case note review	3 acute-care hospitals in Lisbon	1669	11.1	10.8%		53.2%		Euro 470,380 Direct costs
Swedish Hospitals (2009) [36]	Three-stage random sample retrospective case note review	28 acute-care hospitals	1967	12.3	3.0%	9.0%	70%	N/A	63,0000 hospital bed days

Table 1. Epidemiology of adverse events.

theory to explain adverse events in health has been the 'Swiss Cheese' model developed by James Reason from his analysis of large-scale industrial and organisational accidents [42]. In this chapter, we examine the theory and, in particular, its limitations when applied to hospital systems, with specific reference, to the 'deteriorating patient', the final common pathway for most adverse events when patients suffer harm. We then propose an alternative called CFC within the traditional hierarchical referral system of care, to explain hospital setting adverse events which takes into account some of the unique cultural systems that exist in health care, but in hospitals in particular [43, 44]. Finally using this model, we then propose some fundamental reforms for the prevention of these adverse events in hospitals.

2. The 'Swiss cheese' model of health care and hospital setting adverse events

James Reason in his book 'Managing the Risks of Organizational Accidents' states that organisational accidents, as opposed to individual accidents, are predictable events [42]. An individual accident is one in which a person or a group of people makes an individual slip, lapse or error of judgement with the net result being an adverse outcome either to the person or the people who erred, or to the person or people in the immediate vicinity. As such, there is usually a relatively tight, simple explanation for cause and effect in an individual accident. On the other hand, organisational accidents have 'multiple causes involving many people at different levels of an organization' [42]. These events, whilst usually infrequent, are often catastrophic. Analyses of such organisational accidents often reveal that the defences an

organisation has to prevent such catastrophes are breached by a unique series of sequential hazards that play out in an environment of latent conditions, the so-called 'Swiss Cheese'. It follows that one can decrease the incidence of these organisational accidents by increasing the number of defences (more cheese slices) and/or by shrinking the size of the holes in each of the defences (**Figure 1**).

In 2008, Palmieri et al. published their 'Health Care Error Proliferation Model' of adverse health-care events [45]. This model takes the 'Swiss Cheese Model' and specifically adapts the various factors that exist in health care. Most notably, they place clinician vigilance as a key defence at the sharp end of the actual adverse event, in the form of clinical improvisation and localised workarounds. This clinician vigilance repairs gaps produced by actions, changes and adjustments that are made at the blunt end of the health-care organisation with its administrative and therefore higher level, layers of defence. A good example of this is the use of high-definition mobile telephone devices in rural and regional settings that allow almost an immediate transfer of clinical information to an appropriate clinician at a referral centre. However, this clinical workaround and improvisation is clearly at odds with most organisations' patient privacy policies that have been developed at the blunt administrative end of the organisation.

Having for the most part accepted the Reason 'Swiss Cheese' model of adverse events and adapted variations, most hospitals' response to adverse events has been to increase defences at the blunt end of the health-care organisation's administration [46]. These defences, in the hospital, take the form of dedicated quality and safety units and committees, electronic event-reporting systems and the development of appropriate standards linked to hospital accreditation [46]. The aim of each of these blunt end defence layers is to continually decrease the size of the holes in each defence layer, by more audits, meetings and root cause analysis projects combined with the use of the quality improvement cycle. Inevitably, what are generated are recommendations, guidelines and more policy and procedure.

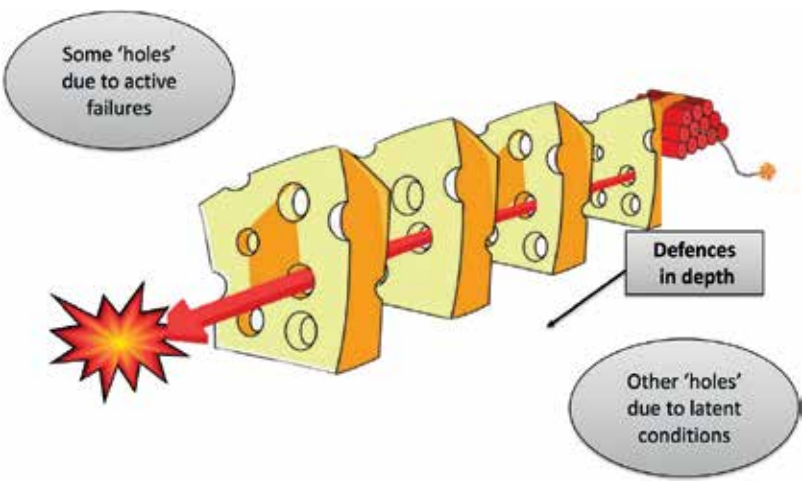

Figure 1. The reason 'Swiss cheese' model [37] (with kind permission from Ashgate Publishing).

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The 'Swiss Cheese' model does explain well some types of hospital adverse events, in particular patient falls, wrong-side surgery and medication errors. In the case of medication errors, the root cause analysis of these events often highlights holes in the 'Swiss Cheese', such as poor transcription of medication prescriptions and failure to do appropriate checks [47]. In the case of patient falls, there is failure to identify the 'at risk' patient and put appropriate preventative strategies in place. Fixing the holes or at least reducing the size of them can reduce the incidence of patient falls and medication errors. This can be done by and large with top-down policy and procedure and ensuring implementation of such [47]. The best example of this has been the reduction in the incidence of wrong-side surgery, with the implementation of time-out, with completion of a check list before surgery [48]. The Reason 'Swiss Cheese' model gives good explanation of the adverse event when there is a relatively tight temporal relationship, between the adverse event and the preventative strategies. The adverse event in these circumstances is itself evidence that a mistake or error was made. There is usually a series of clear errors with the 'Swiss Cheese' model that can be identified. This model then allows for preventative strategies to be implemented, and with the increasing move back to professional responsibility for compliance, in theory, at least the Holy Grail of the perfectly safe hospital should be attainable.

However, most adverse events in hospital, particularly the more serious ones, often do not have such clear errors with a tight temporal relationship with the adverse event and the contributing errors. When the temporal relationship between the adverse event and the preventative strategies is not so tight, hospital cultural factors start to be more significant, and the potential for policy and procedure to help is much less so, simply because it can be and often is ignored.

3. Problems with the 'Swiss cheese' model: why are hospitals different from other industries?

There are three fundamental problems with the application of the 'Swiss Cheese' model to adverse events in hospitals. First, in the hospital, the distinction between individual and organisational accidents is not clear. The entire premise of the 'Swiss Cheese' model was the investigation of causation factors of large industrial accidents as opposed to individual accidents. In the hospital, we do not have large-scale accidents but, instead, multiple little accidents or adverse events daily, if not hourly, and in almost every setting. The study on the causation of adverse events in hospitals overwhelmingly points to failures at the sharp end of care delivery to the patient by frontline staff. Analysis of the causative factors associated with the adverse events in The Quality in Australian Health Care Study found that cognitive failure was a factor in 57% of these adverse events [49]. In this analysis, cognitive failure included such errors as failure to synthesise, decide and act on available information; failure to request or arrange an investigation, procedure or consultation; lack of care or attention; failure to attend; misapplication of, or failure to apply, a rule, or use of a bad or inadequate rule [49]. In a two-hospital study from the United Kingdom that looked at 100 sequential admissions to the intensive care unit (ICU) from ward areas, it was found that 54 had sub-optimal care on the ward prior to transfer [50]. This group of patients had a mortality rate of 56%. Some of the

sub-optimal treatment factors included failure to seek advice, lack of knowledge, failure to appreciate clinical urgency and lack of supervision [50].

The adoption of the Reason 'Swiss Cheese' model for organisational accidents has led the whole Quality and Safety industry, and in particular hospitals, looking for system solutions to what can be explained by individual competency and micro-environment cultural issues at the patient interface. In particular, a major rationale of Reason's philosophy is to avoid individual accountability for errors and the culture of blame and shame. Nearly 20 years ago, Reason himself noted the folly of this approach in medicine when he stated, '*It is curious that such a bastion of discretionary action as medicine should be moving towards a 'Feed Forward' mode of control when many other hitherto rule dominated domains – notably railways and oil exploration and production – are shifting towards performance-based controls and away from prescriptive ones'* [42]. When Reason talks about human contribution to organisational accidents, he describes two schemas of control [42]. A 'Feed Forward' control system is one where human performance is determined by rules and procedures as determined by an organisational standards and objectives (**Figure 2**). In this schema, occasional accidents and incidents are analysed and then fed back into either an alteration of an existing rule or a procedure or the creation of a new one. At the other end of the control spectrum, there is the model where organisational output is largely determined by individual human performance (**Figure 3**). The basis for this model is that, in the first instance, the humans are generally highly trained and that performance is controlled by continual performance reinforcement against a known or a standard comparator. The best example of this, in hospitals, is specialist medical practice. To even start specialist training, there have been many years of training and experience (medical school, house officer jobs and pre-specialty registrar placements) followed by a period of mentoring and in essence apprenticeship to learn the specialty to the known standard of the comparator, the standard of practice as maintained by the specialty colleges. Taking these two schemas, one can immediately see the trouble with health care in hospitals. It is a large industry with community and political expectations that are more congruent with the 'Feed Forward' schema, but yet with most of the actual clinical activity being undertaken by the 'Human Performance' schema.

Thus, what we have seen in the construction of hospital adverse event defences is an over-reliance on the administrative blunt end of the organisation, in terms of policy and procedures,

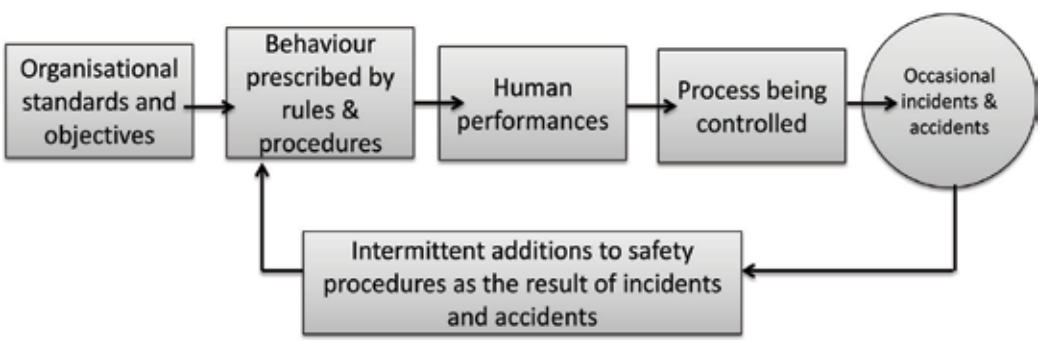

Figure 2. The reason 'feedforward' process control system [37] (with kind permission from Ashgate Publishing).

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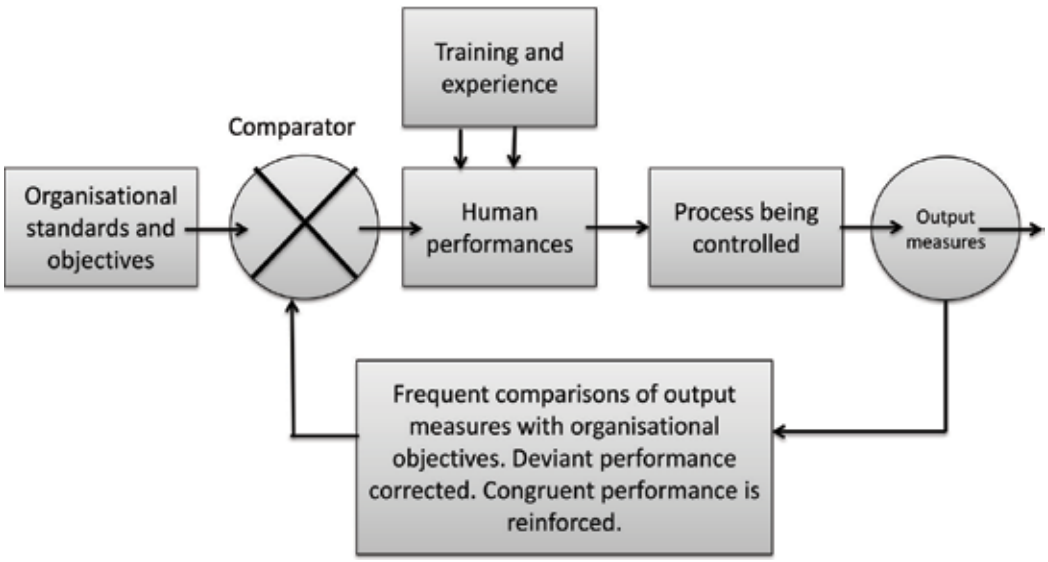

Figure 3. The reason feedback process control system [37] (with kind permission from Ashgate Publishing).

with the assumption that the health-care professionals at the patient end are competent and will be compliant. The shift to looking for hospital-wide problems has come at the cost of avoiding the issue of individual professional accountability and associated issues, most notably the education and certification of health-care professionals. In Australia and the United Kingdom, several studies indicate that the medical undergraduate syllabus does not provide graduates with the basic knowledge, skills and judgement to manage acute life-threatening emergencies [51–53]. These studies identified deficiencies in cognitive abilities, procedural skills and communication. Despite this, undergraduate and postgraduate curricula have been slow to embrace a patient safety culture [54–56].

The second fundamental problem with the 'Swiss Cheese' model and the Palmieri variation of this are that they are overly simplistic and do not take into account the complexity of the patient and the hospital system. When a patient enters a hospital system, they enter a system where they will be exposed to a variety of hazards which, in turn, have numerous defences in place to prevent an adverse patient outcome. Operations, anaesthesia, medical interventions and procedures, drugs and fluids and even oxygen therapy constitute the hazards. Most defences in health care are reliant on the competence of the health-care professional and as such are 'soft'. 'Hard' defences are those that are impossible to overcome, for example in anaesthesia where the administration of hypoxic gas mixtures is physically prevented. The soft defences, in health care, include treatment policies and procedures, manual alarm systems, and ad hoc hierarchical and lateral human checking systems. Soft defences are very reliant on the training and education that health-care workers receive and the culture of compliance. Superimposed on these layers of hazards and defences that confront a patient, there are the latent conditions that exist, most obviously within the patient, but more insidiously within the hospital as an organisation. A patient's past medical history, family history, social

history, associated co-morbidities, drug regimen and allergies largely constitute their latent conditions. These conditions and their relation to the current presenting complaint that brings the patient into the hospital system are territory that individual health-care workers are usually extremely well trained in and familiar with. Hospital latent conditions are not so explicit, particularly to the patient or the frontline health-care worker. They are made up of a complex matrix of production and cultural imperatives such as the financial operating environment, political and societal imperatives, medico-legal and insurance concerns, compliance issues imposed by various regulatory bodies (often with associated financial incentives or disincentives) and workforce and work-practice issues. Thus, in the hospital system, unlike any other industry, we have a high degree of ever-changing complexity, complex patients and a complex system where adverse events are essentially prevented by a whole host of predominantly soft defences [57]. The 'Swiss Cheese' model is a static model with fixed defences in terms of the layers and the size of holes in each layer. This translates well into most industries, but in health care, the complexity is dynamic and ever changing, the number of holes and layers change with every patient and each and every different health-care professional.

The third problem with the 'Swiss Cheese' model is that adverse events in hospitals occur so insidiously that they become normalised into the operating behaviour and practice of the organisation. This is distinct from large-scale industrial accidents, where the impact of the event has a high degree of face validity, primarily due to the immediacy and scale of the event. Therefore, in terms of numbers, patient adverse events may constitute a crisis. However, to the individual practitioner or even hospital, these events may not appear to be a problem. On the whole, such events are infrequent and occur over a long time frame. For example, The Quality in Australian Health Care Study looked at a random sample of 14,179 admissions to 28 hospitals in two states of Australia in 1992 and documented 112 deaths (0.79%) and 109 cases where the adverse event caused greater than 50% disability (0.77%) [14]. Seventy per cent of the deaths and 58% of the cases of significant disability were considered to have had a high degree of preventability [49]. Thus, for the individual clinicians, treating departments and units, and even the 28 study hospitals themselves, their actual experience of these outcomes over the year would be minimal (one or two cases) [14].

The 'Swiss Cheese' model gives a poor explanation of the multitude of insidious individual accidents that occur in hospitals and is too simplistic for the complexity of most patients and the complex matrix of health care that is provided in a hospital. Most importantly, the focus on system issues whilst valid and important has detracted from what is really needed: focussed attention on clinical competence and accountability at the patient interface.

4. CFC and the traditional hierarchical referral model of care

The term 'Futile Cycle' is a term used in cell biology and biochemistry to explain the conversion of one substance to another and back to the original substance by two always on enzymatic pathways. However, despite the enzymatic activity and energy utilisation, there is no net output or gain from this energy-consuming and active process. This is exactly what we see with hospital patient adverse events and in particular the deteriorating patient, a lot of clinical activity, none of which effectively alters the trajectory of the patient towards the adverse event. The clinical activity

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occurs in a traditional hierarchal referral model of care that by its very nature is often either unresponsive or slowly responsive and where the exhaustive policy and procedures are often ignored.

In the hospital, the CFC usually starts with the most junior level of the 'traditional hierarchical referral model of care', at the bedside with the interaction between the junior nurse and the patient (**Figure 4**). With a clinical abnormality, be it an observation, a wrong drug order or a procedural failure, the junior nurse must make a decision as to the significance of the abnormality and the importance of reporting it to a more senior team member, either a senior nurse or the most available (usually junior) doctor. However, that decision to escalate the issue can be influenced in the workplace culture that exists in the particular micro-environment of that bedside and that ward at that time [58]. If the concern or abnormality is escalated, it is to the next person in the care hierarchy of the team looking after that patient. This is often the junior doctor who then needs to attend, assess and then also make a decision about whether or not to escalate the issue to the next person in the hierarchy. This is important because, for the most, the junior doctor does not have the skills or emotional intelligence to appropriately manage many of these clinical abnormalities [51–54]. If the issue is escalated, it is often to a middle-grade doctor, one who is often a specialist in training and who as such may be difficult to find. Unlike their juniors, usually this grade of doctor does have the technical and clinical abilities to deal with the particular issue. However, they are often over-committed with clinics, operating theatre, but more importantly often see themselves more like the consultants they aspire to be rather than a junior doctor having to deal with patient problems on

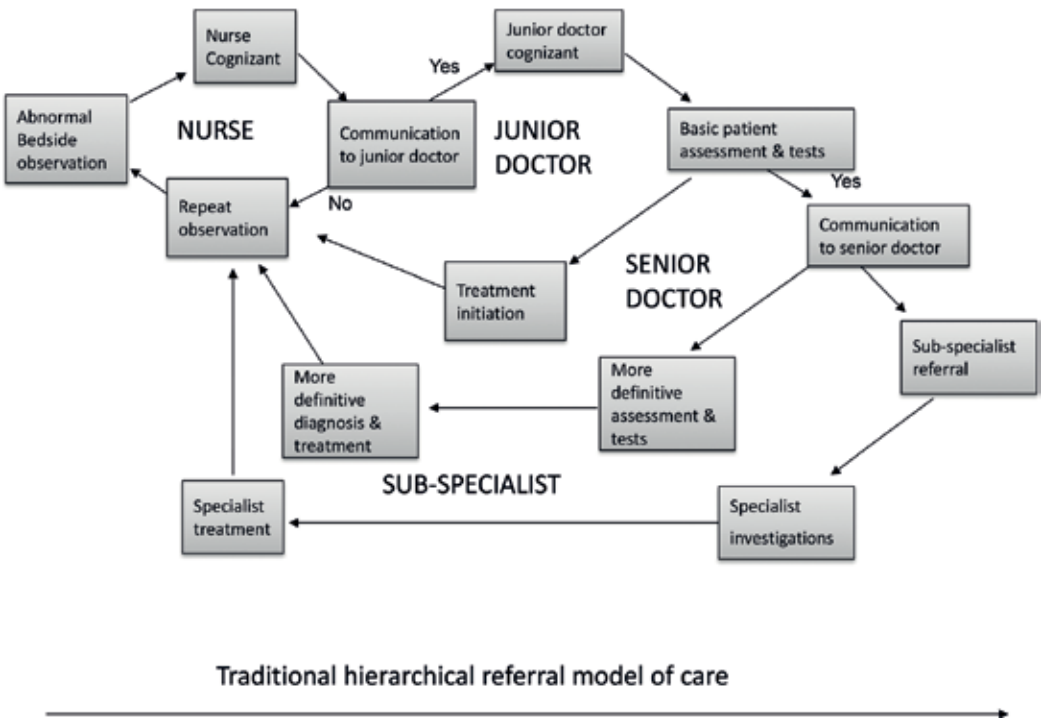

Figure 4. Clinical futile cycles [38, 39].

the ward. In addition, this grade of doctor is diagnosis–focused and often we see them giving instructions to their juniors (usually appropriately) to organise specialised investigations and other speciality consultations. There is nothing wrong with this, except for the fact that it is time-consuming [59].

In support of the CFC model is the study that has looked at the causation of adverse events in hospitals [13, 37, 49, 50]. All these studies can assign almost all causation to three human factor issues at the patient interface: competency, cognition (or failure thereof) and culture. Perhaps, the most disturbing example of this was described in the MERIT study, a randomised cluster control study of Medical Emergency Teams (MET) [60] in 23 Australian hospitals (including private and rural hospitals) in 2002. In the nearly 500 cardiac arrests that occurred during the study, in more than a third of instances staff took abnormal (that broached MET activation criteria) patient observations in the 15 min prior to the cardiac arrest, but did not activate an emergency response. The first thing of note with this phenomenon was that the incidence of not calling for help in an abnormal patient situation was high at 30% in the intervention hospitals and 40% in the control hospitals. Put in another way, in the average Australian hospital in 2002, if a patient had documented abnormal signs, in the 15 min before a cardiac arrest, in up to 40% of the time the staff did nothing about this. Another thing of note with these findings is that in intervention hospitals that had an intense education process on the new MET activation policy and procedure, the incidence of calling for help was only 10% greater than the control hospitals [60]. It is here at the bedside with the pre-cardiac arrest patient that the staff are trapped in a CFC, unable to get out of it due to either clinical incompetency (not able to recognise and act for the pre-arrest patient) and/or culture, whereby calling for help maybe considered not the norm in that ward, on that shift at that time [4, 5, 61–64].

The 'Swiss Cheese' response when RRS fails at the sharp end, for whatever reason, the response is to assume policy and procedure failure, despite the fact that there is no direct evidence for the benefit of Rapid Response Systems (RRS) [62–64]. However, it is well documented that there may be problem with the face validity of RRS due to the very low specificity of the activation criteria [65–67]. Furthermore, there may be problems around staff competency or cultural issues around staff losing face by calling for help. As a result, rather than trying to understand or deal with this very real issue of face validity, possible competency issues and probable cultural issues, the administrative response, all too often, is just to alter the policy and procedure and make the activation criteria mandatory for the bedside staff [68].

5. Using CFC to safety proof health from the sharp end back

If we accept the model of CFC, it becomes immediately apparent that no amount of activity away from the sharp end of the health-care adverse event will help, least of all the generation of a more policy and procedure. Instead, we need to focus attention on the health-care professional and the immediate socio-cultural environment in which they work [69].

Dealing first with the health-care worker, the selection of these individuals to undertake their chosen vocation is invariably done by consideration of various personal attributes, in the case of medicine academic achievement and individual performance in tests [69–73]. This process

and subsequent education takes no account of the fact that as soon as these people graduate, they will be working in a team environment.

The clinical care we deliver (and receive) is a function of the education and capability of our students who will eventually be our doctors and ultimately clinical leaders and decision-makers. What we teach and practise best is the point-of-care medicine and clinical interventions. Therefore, it is no surprise that what we examine and what students focus on are specific point-of-care clinical assessments and interventions [74]. This is best represented by the objective, structured, clinical, examination system (OSCE) that is now a widespread and common form of summative assessment [75]. In the OSCE, candidates undertake clinical assessment tasks at a number of specific stations for 5–8 min. Each station has a structured 'score card' that students must address to get the points. This system of examination in no way gives any indication on a student's ability and competency to comprehensively take a history, perform a physical examination, synthesise these findings into a meaningful problem list and finally and actually least importantly come up with a diagnosis [76]. It has got to the point now in the undergraduate curriculum that the clinical process of whole patient assessment is variably taught and certainly not examined, in a sufficiently stringent manner to motivate students to spend long hours doing patient histories and examinations. Having competent health-care professionals spend time with and understanding our patients is the single biggest step to making health care safe.

Second, priority needs to be given to the core business of hospital care, the interaction at the bedside and clinic between the patient and the various health-care professionals [4, 5, 61]. Clinical futile cycles give a practical platform to understand this culture. We need to accept that an abnormal or an inappropriate workplace culture is at the heart of every major inquiry into poor hospital care [77–82]. Every report into these enquiries recommends change. Yet, 30 years on from Bristol [81], we have mid-Staffordshire [80]. So, what have we really learned from the reports and thousands of pages of recommendations? Nothing. We need a different strategy: one that puts the patient and their well-being first. This should be followed by the implicit understanding that our core business is that of interaction with the patient from the most basic and junior levels. The bedside health-care team needs to be trained, credentialed and supported to deliver better health care, not as individual players, but as members of a team.

6. Conclusion

Despite the hundreds of millions of dollars spent on patient safety, we have very little to show for it except the fact that we know that the problem is real, common and universal to all health-care settings. In this chapter, we propose that the reason why we have not been able to improve patient safety is because we really do not understand what is going on at the point of clinical intervention.

The organisational response is based on mandated requirements, which look at system and operational issues. Rarely do we focus on the quality of the judgements made by the individual clinicians involved in adverse events and usually never do we question the clinical culture in which these events occur.

CFC provides an alternative framework to help understand adverse events and patient safety breaches, by forcing us to ask the question, 'they or she/he, knew that there was a problem, or that there might be a problem, why didn't they do something about it?' The question needs to be put to all the involved clinicians regardless of where they sit in the traditional clinical hierarchy. The answer to the question will usually fall into one of three broad categories, first those involved simply did not know what was going on, second, they did know what was going on and they tried to do something about it, and third they did know that there was a problem and for whatever reason did nothing. The answer to this one question then allows for appropriate interventions at the health-care workplace. If the involved individuals were simply oblivious to the situation, then retraining, re-credentialing and recertification are required for those clinicians. If the problem was recognised and attempts made to ameliorate it, then the more traditional root cause analysis should shed light on the issues that need resolution. Lastly, if the problem was recognised and nothing done, then cultural issues are at play. These may range from the obvious (e.g., an overall culture of not calling senior clinicians at night about problems) to more serious issues of workplace bullying and harassment (e.g., senior clinicians when called overnight about problems, being rude, belittling the caller, blaming and side-stepping the problem to avoid coming in after hours).

CFC also provides us with a term or a condition that describes the 'brain freeze' state of mind that can occur in stressful clinical situations. For the individual clinician, recognising and knowing that they have a moment of 'brain freeze' and that they are stuck in a CFC is the first step to getting out of that situation. The best way out is quite simply to ask for help, or to take time-out to reassess the problem.

In summary, we need to divert some of those hundreds of millions of dollars, away from committees, the quality and safety units, organisational and government mandatory-reporting systems back to understanding the core business of health care, the intervention between clinician and patient. Perhaps, then we will get the significant cultural change that needs to occur (and has occurred in other industries) that puts the saying 'first do no harm' at the centre of all clinical interactions.

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Chapter 4

Fact versus Conjecture: Exploring Levels of Evidence in the Context of Patient Safety and Care Quality

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Additional information is available at the end of the chapter

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Abstract

Evidence-based medicine (EBM) can be defined as the integration of optimized clinical judgment, patient values, and available evidence. It is a philosophical approach to making the best possible clinical decisions for individual patients. Based on objective evaluation and categorization of methodological design and data quality, all existing literature can be organized according to a hierarchy of "evidence quality" that helps determine the applicability and value of scientific findings in terms of clinical implementation and the potential to change existing patterns of practice. In terms of general categorization of scientific impact, randomized controlled trials (RCTs) are placed on top of the hierarchy, followed by systematic reviews of randomized controlled trials (RCTs), quasi-randomized designs, observational studies including retrospective case series, and finally case reports and expert opinion. Each study design is susceptible to certain limitations and biases, highlighting the importance of both clinical and scientific acumen of the interpreting provider. Such approach is critical to determining the value and the applicability of study recommendations in everyday practice. Evidence-based practice (EBP) has become one of the fundamental components of modern medicine and plays an indispensible role in the development (and improvement) of patient care and safety worldwide. Furthermore, organizations that create guidelines and policies for the management of specific conditions, often base the content and strength of their recommendations on the quality of evidence available to expert decision-makers. Therefore, understanding the "state of the science" upon which those recommendations are based will help guide the medical practitioner on "if, when and how" to apply evidence-based guidelines in his or her everyday medical or surgical practice. This chapter focuses on clinically relevant application of levels of scientific evidence (LSE) and the corresponding levels of clinical recommendation (LCR) in the context of care quality and safety.

Keywords: evidence-based medicine, levels of evidence, levels of recommendation, meta-analysis, randomized controlled trial, case-control study, cohort study, case reports, expert opinion, medical decision making

1. Introduction

Evidence-based medicine (EBM) is a scientific approach to clinical problems, intended to help clinicians make the best possible decision for their patients, and the "best decision" being defined as one that incorporates the relevant evidence applied through the expertise of a practitioner while preserving patient autonomy and safety [1, 2]. At its core, EBM combines two fundamental principles. First, evidence by itself is never sufficient to make a clinical decision and should be combined with clinical expertise and adapted to each patient's unique case. Second, practitioners need to be aware how much confidence can be placed in a particular recommendation, thus creating the need for establishing pre-determined levels of scientific evidence (LSE) to help guide the decision-making process [2].

During the past two decades, the introduction of EBM has contributed to a dramatic shift in clinical practice patterns [3–5]. Wide-scale implementations of EBM principles across institutions formed a foundation for better and more streamlined decision making among physicians, contributing to gradual improvement in both patient safety and quality of care [6, 7]. Perhaps just as importantly, such paradigms led to an increased ability for individuals and systems alike to undergo self-evaluation and self-improvement [8, 9]. As the overall quantity and quality of available clinical scientific evidence increased over time, applications of this knowledge led to enhancements in various clinical processes, directly and indirectly improving the safety record of healthcare institutions that embraced EBM-based models [10, 11].

Any experimental observation suggesting a relationship between two clinical variables constitutes some form of scientific evidence. The "strength" of that evidence is determined by the total number of measurements, the degree of any observed correlation, ability to reproduce results, as well as the methodology used to collect and analyze information [12–14]. It is important to note that the availability of multiple sources of information in a specific area may allow for cross-correlation of results and greater decisional confidence when making recommendations. It then behooves clinicians to understand both the strength of recommendations, which is inherently variable due to heterogeneous methodological approaches, and the applicability of results to a particular patient which is derived through a deeper understanding of how the evidence was obtained [2, 15]. Based on the quality of study design, estimated level of bias, overall validity, and clinical applicability, standardized definitions of "levels of evidence" were introduced to help reduce errors and to make better, more consistent clinical decisions [4, 16]. **Tables 1** and **2** demonstrate commonly utilized levels of scientific evidence and grades of recommendation, respectively [17]. Grades of recommendation (GOR) are discussed in more detail in subsequent sections of this chapter.

Currently, the best available evidence in any particular clinical area is heavily dependent on the issue being researched, the difficulty of obtaining adequate data (which may be based on the

LSE	Type of supporting scientific data
Ia	High-level evidence derived from meta-analyses of RCTs
Ib	Scientific evidence obtained from at least one high-quality RCT
IIa	Evidence obtained from at least one well-designed, non-randomized CT
IIb	Evidence obtained from at least one well-designed, quasi-experimental study
III	Evidence based on well-designed observational (e.g., case-control, correlation, or comparative) studies
IV	Evidence based on documented opinions of experts, committees of experts, and/or clinical experiences of opinion leaders in a specific topic area

CT, clinical trial; LSE, level of scientific evidence; and RCT, randomized clinical trial.

Table 1. Broadly accepted classification of levels of scientific evidence.

Grade	LSE	Corresponding recommendation
A	Ia, Ib	Grade A recommendations require at least one RCT as part of the overall scientific evidence. In addition, good overall data quality and consistency of results must be present
B	IIa, IIb, and III	Grade B recommendations require methodologically sound CTs (that are not RCTs) as part of the overall scientific evidence used during the formulation process. Grade B recommendations are based on the most heterogeneous grouping of evidence (IIa, IIb, and III)
C	IV	Grade C recommendations are usually built upon a careful compilation of expert opinions and/or clinical experiences of respected opinion leaders in a specific topic area. In global terms, Grade C recommendations indicate the absence of high quality clinical studies (e.g., suitable CTs or RCTs)

CT, clinical trial; LSE, level of scientific evidence; and RCT, randomized clinical trial.

Table 2. Grades of recommendation, from highest (A) to lowest (C), are primarily based on the level of available scientific evidence.

prevalence, incidence, or even our understanding [or lack thereof] of a particular disease), and the type of scientific question being asked (e.g., clinical prognosis, treatment effectiveness, and risk-benefit assessment) [4, 18–20]. However, when it comes to issues of therapy or treatment, randomized controlled trials (RCT) and systematic reviews of RCTs are generally considered to be the "gold standard" with the highest internal validity and least amount of bias [14]. On the opposite end of the spectrum, non-systematic observations, ideas, and editorial opinions made by individual clinicians are considered to be the weakest form of supporting evidence in the context of formulating subsequent recommendations [3, 21]. The hierarchy of LSE, broken down by the type of research endeavor, is presented in **Figure 1** [9, 22].

The practice of EBM provides clinicians with a clear, concise course of action, encouraging the formulation of a relevant clinical question, finding and critically assessing the best available evidence, and applying pertinent results into clinical practice with the fundamental goal of improving patient outcomes, safety, and overall quality of care [23–25]. As outlined in **Table 1** and **Figure 1**, available evidence may range from an RCT to isolated observations or opinions of single individual. While all existing evidence is not considered equal, it is critical to

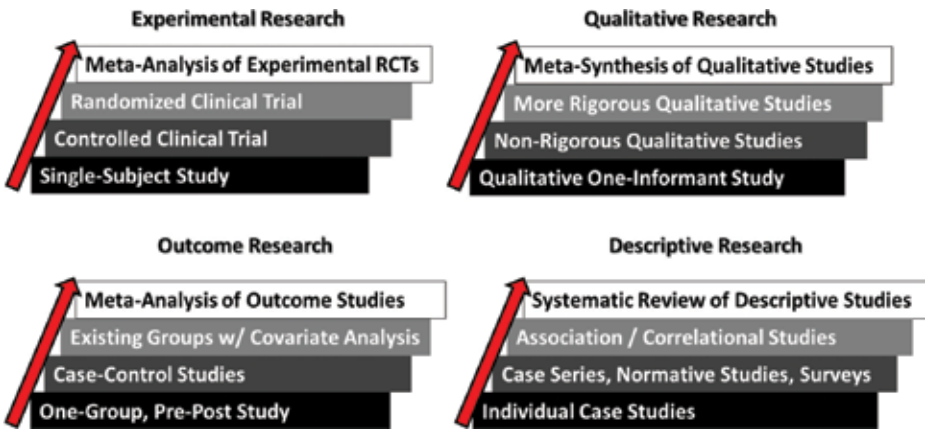

Figure 1. Levels of scientific evidence according to different types of study. For each category of research (e.g., experimental, qualitative, outcome, or descriptive), the red arrow indicates the increasing level of scientific evidence, manifested through greater internal, external, and quantitative result validity. Modified from Tomlin and Borgetto [22].

understand that all LSEs are important and have their own intrinsic value that corresponds to their level of clinical relevance and overall impact on patient care [26].

In this chapter, we outline different LSEs and associated study designs, followed by a detailed discussion on implementing clinical research findings in the context of GOR. Finally, we consider adaptation of evidence-based practice to improve both quality of care and patient safety across our health systems.

2. Levels of evidence: the importance of study design

Therapeutically relevant clinical research evidence can be broadly categorized into studies of an observational nature and those that have a structured experimental study design [4, 27]. Experimental studies, which include randomized controlled trials (RCTs) and methodologically sound meta-analyses of RCTs, are positioned at the top of the hierarchy (**Figure 1** and **Table 1**) [3]. Although nomenclature may change across different categories of research (e.g., experimental, qualitative, outcome, or descriptive), the fundamental premise of LSE stratification remains the same—an organized progression from "low to high" along the spectrum of internal/external scientific validity (and repeatability) [28–32].

Bias in a study design can confound results of an investigation and lead to misrepresentation of the true implications of the intervention/treatment being studied [33]. An RCT is a clinical trial design intended to minimize bias by randomly allocating study participants to two or more interventions or treatment "arms" [14, 34] and often "blinding" patients and investigators from knowing which intervention an individual is receiving. Within this paradigm, each treatment arm may represent a different drug, device, or a procedure. It may also represent different ways of applying or using a process, device, a procedure, or a placebo. By limiting any opportunity for patients, clinicians, or investigators to choose which arm of the trial the

participants will be assigned to, RCTs effectively minimize bias through the process of randomizing both known and unknown prognostic variables [4, 18, 35, 36]. The above-mentioned "blinding" process thus allows a "less biased" estimate of the treatment effect that has enabled RCTs to revolutionize medical research, achieving the status of "gold standard" for therapeutic research and holding the top position in the EBM hierarchy of LSEs (**Table 1** and **Figure 1**) [37, 38].

Results from RCTs, although considered the most robust and reliable form of evidence, are not always easily translatable or applicable across diverse clinical settings. Moreover, not every medical decision requires data from an RCT [39]. Implementation of RCT findings may be challenging at a single-institution level, primarily because of procedural, work-flow, and other institution-specific factors [2, 40].

Well-designed observational studies are recognized as level IIa, IIb, or III evidence (**Table 1**) and generally are easier to conduct than an RCTs, but still provide meaningful clinical evidence [37, 41]. Additionally, observational studies may lay the foundation for the definitive RCT to be conducted. Cohort and case-control studies are the two primary types of observational studies that can demonstrate important associations between exposure and disease [37]. Placed slightly above case-control studies on the LSE hierarchy, cohort studies can be both prospective and retrospective in nature [37, 42]. Prospective cohort studies observe two groups of populations—one group with the risk or prognostic factor of interest and the second group without [9]. These populations (or groups) are followed over a variable period of time to observe the development of a disease or a specific outcome among those with the risk factor and those without. Prospective cohort studies can be tailored to collect data regarding exposure to any specific or rare disease and can be designed to observe multiple outcomes for any given exposure or intervention [37, 43]. Retrospective cohort studies, on the other hand, are historic in nature and look in to the past to analyze disease development within a specific group of subjects based on their known (or declared) exposure status. Retrospective cohort studies are more economical to conduct compared to prospective studies and take a shorter amount of time to complete, although the results from such studies may be incomplete or inaccurate [37, 44, 45]. They may also have advantages in terms of utilization of large national data sets to help analyze and derive relationships that may answer or pose new clinical questions.

In contrast to cohort studies, case-control studies recruit subjects based on the outcome of interest at the outset of the study [46, 47]. Subjects with a specific outcome are categorized as "cases" and subjects without the specific outcome are categorized as "controls" [47]. Retrospective data regarding the presence of exposure to single or multiple risk factors are then collected from both groups, typically by conducting interviews, surveys, or collecting chart data. Based on the collected data, strength of association between disease and exposure may be determined and provided in the form of odds ratio or relative risk [4]. Case-control studies can provide valuable information about rare diseases or those ailments that have a prolonged latency period [4, 37, 44, 45].

Case series, case reports, and expert opinion constitute the lowest quality evidence on the overall hierarchy of LSE, are inherently retrospective in nature, and most often feature no

control or comparison groups (or cases) [48]. These reports are usually narrow in scope, describe a single population subgroup, and are often based on the experiences of an individual researcher or a single institution. The above-mentioned factors render data within the latter LSEs less reliable, possibly difficult to reproduce, and often non-generalizable when applied to a larger (or different) population. Such studies, however, can provide useful information on rare diseases or unique presentations and complications associated with particular interventions or procedures [4, 49–51].

The practice of EBM requires deep and critical analysis of the entire body of available evidence in a specific area, with more fragmentary assessments being considered improper and inadequate [15, 52]. Systematic reviews are a key component of evidence-based health care, and are defined loosely as "secondary analyses" of a large collection of reported results from individual studies for the purpose of integrating the overall findings [53, 54]. Systematic reviews essentially use data from individual studies (most often RCTs) and "pool" these data together to draw a more robust conclusion regarding the effect of the intervention being researched on specific clinical outcome(s) [4, 19, 55]. The primary aim of systematic reviews is to determine whether an effect exists and if that effect is negative or positive in relation to a specific clinical approach or intervention vis-à-vis a pre-defined outcome [54]. By "pooling" data and results from multiple studies, well-designed systematic reviews can answer questions that cannot be sufficiently answered by any individual study [56]. In addition, this approach clearly demonstrates any discrepancies between apparently conflicting studies. Finally, systematic reviews can also be used to generate new hypotheses [54, 57].

Having described the different levels of evidence, it is important to note that the LSE hierarchy is not "set in stone" and a number of factors determine the validity and strength of any particular research study and consequently the evidence. Key elements within study methodology, such as patient inclusion or exclusion criteria, play a critical role not only in determining the level of evidence attributable to any particular finding but also the applicability and translatability of study results to any particular patient or institutional setting. The recognition of inherent biases based on the study setting, financing source(s), and the appropriateness of the statistical analysis plan is important when determining the validity of results. Subsequent sections of our chapter will provide a practical discussion on the practical application of LSEs in the clinical arena, focusing specifically on patient safety and quality of care as well as the role of different grades of recommendations (GOR's) in understanding the implementation of evidence in a particular setting or situation.

3. Levels of scientific evidence: clinical applications and examples

In order to better understand how LSEs are relevant to GORs and EBM, some practical clinical examples are provided below to help clarify these important scientific relationships and associations. Further discussion of GORs and implementation paradigms for clinical scientific evidence (e.g., 5A's, P-D-C-A, **Figures 2** and **3**, respectively) will then follow, with focus on fostering organizational excellence and a culture of safety [58–60].

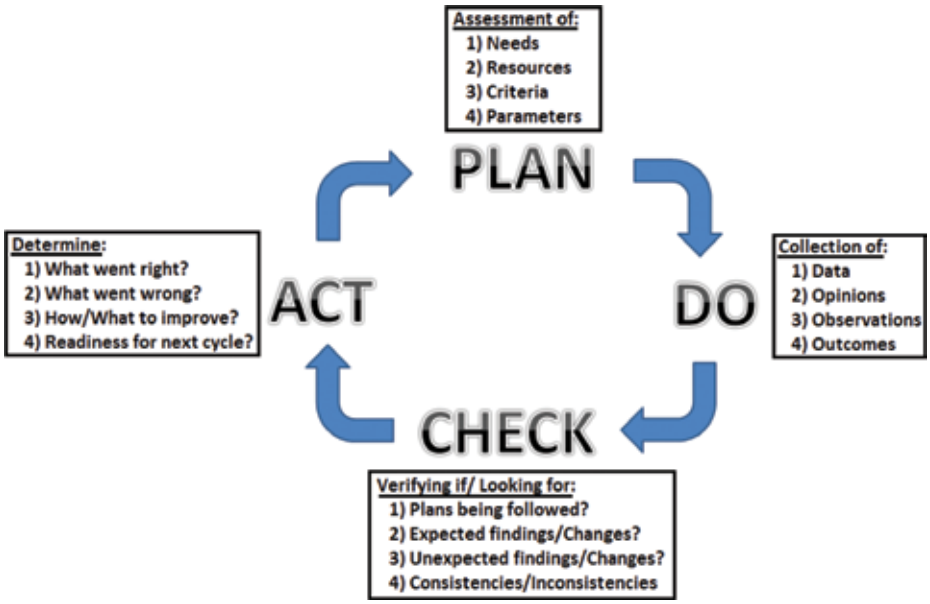

Figure 2. Schematic representation of the PDCA (Plan-Do-Check-Act) cycle. Each iteration of the cycle involves a number of procedural checkpoints, with specific sets of associated tasks and critical questions.

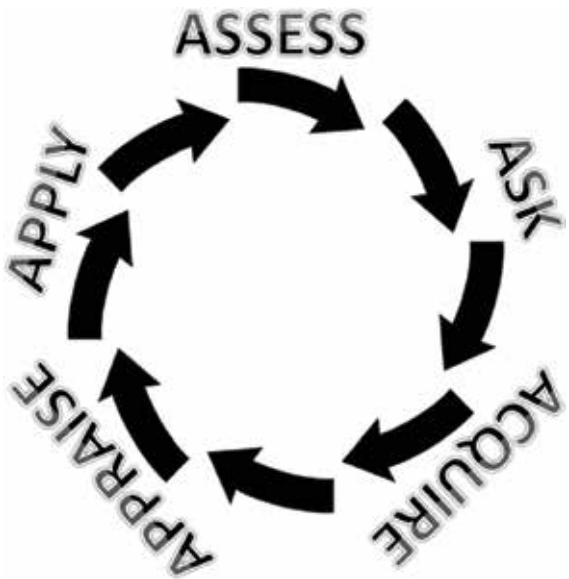

Figure 3. The evidence-based medicine cycle begins with *Assessment* (e.g., determination of need for a new cycle/process). This is followed by *Asking* pertinent questions (e.g., reasonably answered and searchable issue) and *Acquisition* of data (e.g., existing literature and targeted *de novo* gathering of information). The next step is the *Appraisal* (e.g., critical evaluation of all available data in the context of the primary question and the quality/levels of evidence), and finally, *Application* of the newly synthesized evidence into existing institutional/patient care matrix. Based on the overall outcome of the currently completed cycle, as well as the institutional needs and areas of focus, the determination of "if/when" to begin next cycle is made [143, 148].

Our discussion will begin with a relatively recent account of clinical investigations into a hypothesized association between silicone breast implants and lymphoma [18, 61–64]. Given the growing number of anecdotal case reports regarding observations of lymphoma following silicone breast implantation, several retrospective cohort studies with large numbers of subjects were conducted, including many years of follow-up data [18, 65–67]. An association was reported in some studies, but no statistically significant conclusion could be drawn, suggesting that in order to demonstrate any linkage between silicone breast implants and lymphoma, a greater LSE will be required. When a high-quality systematic review was performed by combining data from all retrospective cohorts, no significant association was shown between silicone breast implants and the development of lymphoma [63]. This particular story highlights the importance of LSEs and the potential for patient harm (economic, physical, and psychological) when available data are insufficient to make specific clinical management recommendation(s) [68, 69]. At the same time, one might also make an argument that further research is required to increase the certainty of the relationship between variables under scrutiny, but this approach may not be feasible for very rare conditions or occurrences due to various ethical, patient safety, and statistical considerations [18].

Another example where ethical, financial, and patient safety considerations preclude the conduct of any prospective, randomized research is the area of retained surgical items (RSI) [56, 70]. The retention of surgical instruments is an extremely rare complication, and thus, any study of methods to prevent this dreaded occurrence would need to be prohibitively large to have the power to show a statistically significant advantage of any particular approach over another. At the same time, justification for prospectively comparing specific interventions or the differential application of protocols/procedures related to RSI risk is ethically questionable at best. Consequently, a meta-analytic study of all existing case-control reports on the topic of RSI was performed, effectively demonstrating that pooled data from three source studies identified potential risk factors for RSI that were not apparent from each individual study [56]. While source reports individually suggested that between 3 and 6 variables may be associated with greater incidence of RSI [70–72], the combined report showed that 7 of 11 potential risk factors were significantly associated with elevated odds for RSI [56]. The above exercise in knowledge synthesis shows that carefully implemented meta-analytic approaches can result in better understanding of an important area of patient safety.

Moving to a different patient safety topic, case-based experiences from the 1950s led physicians to avoid epinephrine injections during hand/finger procedures due to concerns for ischemic complications [18, 73]. Despite the absence of higher level of evidence, avoidance of digital epinephrine injections was widely practiced and taught during that time. Eventually, a comprehensive review of literature between the years 1880 and 2000 was performed, highlighting 48 cases of digital infarction, 21 of which involved epinephrine injections [73]. Subsequent to that, a number of cohort studies were published, reporting no significant association between digit ischemia and local epinephrine injections [74–76]. Based on the conclusions drawn from studies with higher LSE, the original hypothesis was rejected [18]. This example demonstrates how observational and case studies may be inherently biased and that higher levels of scientific evidence must be available before making any definitive conclusions, accepting evidence as fact, and implementing evidence-based recommendations [18].

In contrast, even well-conducted RCTs are sometimes unsuccessful in swaying medical practice. The University Group Diabetes Program trial, a methodically sound RCT conducted in the late 1960s found lack of efficacy of an anti-diabetic drug tolbutamide compared to diet alone in prolonging life. Furthermore, the study suggested that tolbutamide is less effective than diet alone or diet with insulin as a modulator of cardiovascular mortality [77, 78]. Despite relatively high LSE presented in the study, tolbutamide prescriptions increased, as debate over the trial's interpretation continued for more than a decade [78–80]. Similarly, the Antihypertensive and Lipid-Lowering treatment to prevent Heart Attack Trial (ALLHAT) showed that thiazide diuretics were as effective as modern (and much more expensive) calcium-channel blockers and angiotensin-converting-enzyme inhibitors in treating hypertension [81]. These finding were questioned by pharmaceutical companies, and after an initial resurgence of thiazide prescriptions following the trial's publication [82], the sales of newer antihypertensive agents increased [38, 83–85].

All of the above examples show that no single study can provide definitive answers or understanding of therapeutic response, diagnostic test efficacy, or disease-specific risk factors. The struggle continues between the forces of clinical habit, third-party interests, and objective evidence. Policy-makers, opinion leaders, and providers must embrace both open-mindedness and the value of unbiased research in guiding EBM and evidence-based recommendations [86–88]. Likewise, all healthcare providers must be well versed in both the definitions and the application of the concepts of LSE, GOR, and EBM and must recognize that there are multiple factors at play when deciding which evidence is best and how to apply this evidence [87–89]. It has been proposed that misapplication of clinical scientific evidence may be one of the key barriers to sustainable improvement in healthcare quality and safety in a highly complex system with increasingly constrained resources [87, 89, 90].

4. Important limitations

Recommendations from various expert groups are based on different LSEs, ranging from randomized controlled trials to so-called expert opinions, and all come with their own set of limitations that should be considered when transforming research findings into clinical practice. After defining and discussing important aspects pertaining to different LSEs, we will now touch upon some of the pitfalls associated with implementing and following EBM in every day practice.

Introduced as an effort to reduce bias and improve the accuracy of evidence, RCTs have expanded medical knowledge and transformed clinical practice [3]. While RCTs are considered to provide the most internally valid evidence, not all RCTs are methodologically sound and often offer only partial answers. In their "Evidence Based Medicine Manifesto for Better Healthcare," Heneghan et al. [91] state that "too many research studies are poorly designed or executed. Too much of the resulting research evidence is withheld or disseminated piecemeal. As the volume of clinical research activity has grown the quality of evidence has often worsened, which has compromised the ability of all health professionals to provide affordable, effective, high value care for patients" [91]. In addition, RCTs are very challenging to execute,

are costly, and have long latency periods. This may have important implications during study design, especially when establishing appropriate inclusion criteria or standardizing experimental interventions [3, 4, 18, 38]. Limitations and challenges associated with RCTs have forced physicians to look into alternate study designs that are easier to conduct, take less time to complete, are less expensive, and yield similar results to RCTs [2].

Perhaps the most commonly employed tool that allows researchers quickly and effectively leverage the wealth of existing evidence from various RCTs is meta-analysis [88, 92, 93]. Having said that, systematic reviews including meta-analyses can generate secondary evidence that is only as good as the cumulative evidence provided by primary source studies [15, 52]. Therefore, the validity of evidence from systematic reviews is largely based on the RCTs included, and meta-analyses cannot ameliorate any biases present in source studies [15]. Moreover, systematic reviews and meta-analyses rely solely on published data and evidence, some of which may be published in obscure journals and not easily accessible. In addition, some of the reported data may be limited in scope, with heterogeneous reporting of outcome parameters. This phenomenon is called publication bias, and in order to minimize such a bias, researchers are advised to search literature thoroughly and methodically as well as maintain contact with both study authors/investigators and other experts in the field [15].

Observational studies, including case-control and cohort designs, come with their own set of limitations and biases [94, 95]. Case-control studies draw a comparison between individuals with a condition or disease (cases) and those individuals in whom the condition or disease is absent (controls), optimally in a fixed ratio of cases and controls (e.g., 1:2, 1:3, or 1:4) [14]. Since both groups are compared with respect to their past and present exposures, most of the information provided relies on recall and may end up being incomplete or even untrue [47]. In addition, validation of the collected information may be extremely difficult or not feasible, and a detailed study on the mechanism of the researched disease is rarely possible. On the other hand, cohort studies select a group of individuals with certain characteristics and follow them over a long period of time for the development of a particular disease or outcome of choice [96]. Since cohort studies are usually conducted over extended periods, key challenges include high study costs and ensuring adequate follow-up over a long period of time. Moreover, a sizable group of subjects is required to adequately investigate a rare disease and control of peripheral variables may be incomplete, resulting in increased bias [4, 37, 44, 45]. Finally, it is difficult to accurately account for changes in medical treatment over time, resulting in the emergence of "temporal bias".

Unsystematic personal observations, prior to the introduction of EBM, have carried great weight in shaping both medical education and practice [15]. We now have a much better appreciation of how these observations may be inherently biased and how much progress was forfeited by perpetuating a system of subjective opinions in our current era of less biased, objective scientific investigation [4]. Although the different limitations of various LSEs discussed above may seem considerable, one must remember that they are dwarfed by the potential harm resulting from unrestricted, non-evidenced practice of yesterday. As long as practitioners and champions of healthcare quality and safety use a healthy degree of informed caution when interpreting published evidence and clinical data, continued progress can be made toward a better and safer, evidence-based medicine of tomorrow [2, 8].

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5. Evidence-based practice: focus on quality and safety

The practice of EBM is essential for making safe and effective clinical decisions and is also crucial to promoting quality improvement and ensuring continuous focus on patient safety in healthcare organizations [10, 25, 97]. Research is the foundation of the practice of EBM. It helps drive enhanced health outcomes, promotes standardized approaches to care, and facilitates cost reduction in a resource-limited healthcare system [98–101]. Evidence for beneficial effects of EBM continues to accumulate in a diverse number of allied health and medical areas of specialty, including surgery, critical care, primary care and preventive medicine, internal medicine and subspecialties, obstetrics and gynecology, as well as nursing, hospital administration, health information technology, quality, and patient safety [102–106]. EBM can also be formulated from patient-reported outcomes using established clinical processes such as The Joint Commission Core Measures [107]. In addition, the Agency for Healthcare Research and Quality (AHRQ) developed a series of quality indicators designed to standardize evidence-based care medicine for preventing in-hospital complications that may result in penalties under the auspices of value-based purchasing program [108]. Often, performance in standardized quality indicators can be used to benchmark quality and safety performance in various patient populations [108]. Preoperative prophylactic antibiotics, bowel preparation, and deep vein thrombosis prophylaxis are examples of evidence-based best practices that have been defined and protocolized by organizations and initiatives like Centers for Medicare & Medicaid Services (CMS) and the Surgical Care Improvement Project (SCIP) [109]. Similarly, checklists have revolutionized healthcare across increasing number of settings, as documented by multiple studies demonstrating lower mortality, postoperative complication rates, and enhanced adherence to patient safety procedures [110–115].

Patient safety research focuses on the identification of safety issues (e.g., patient safety gaps) and their subsequent remediation through the study and implementation of new practices and policies [113, 116]. Despite ample descriptive evidence, the implementation of safety practices remains an underresearched subject, with much work remaining before achieving "zero incidence" goals across many adverse event types [9, 117]. Perhaps more troubling is the observation that the gap between research findings and implementation across various clinical settings may indeed be widening [102]. There is an estimated lag time of approximately 17 years from research to implementation in clinical practice [118, 119]. It stands to reason that a better process is required for this much needed translational process to occur more efficiently. For example, since the mid-1800s, the importance of hand hygiene has been a widely accepted fact, as numerous studies have confirmed the significant benefit of this practice. Despite the presence of widespread awareness and institutional guidelines, compliance among healthcare workers and doctors in particular remains low [120, 121]. Dissemination and application of evidence-based safety practices is often met with multiple obstacles and/or outright resistance, both at the individual and organizational levels [8, 106]. In one systematic review of 23 studies of stand-alone teaching of EBM principles in a postgraduate education setting, it was noted that although knowledge increased, behaviors, attitudes, and skills did not change; and a system of interactive teaching strategies was recommended [122]. Development of effective policies based on carefully vetted research evidence constitutes another major barrier to the

actual implementation of evidence into practice, especially within organizations where expert opinion and hierarchical decision-making impose "glass ceilings" toward evidence-based approaches. Moreover, numerous methodological and ethical complexities make research in clinical safety particularly challenging, as patients cannot be subjected to blinding or randomization [102].

It is important to reiterate that EBM is not purely about conducting RCTs and implementing their context-appropriate results into clinical practice. Evidence-based medicine extends to critical decision-making regarding treatment and practices that stem from carefully and thoughtfully considering and weighing "best evidence" [123–125]. Well-designed case-control and cohort studies can prove to be equally effective tools and should be considered for areas where RCTs are simply not feasible or impractical. Lastly, it is every practitioner's obligation to provide the best available care for their patients and that will continue to be driven by the increasing wealth of available literature [126], hopefully characterized by better LSEs and overall quality of both methodology and data. Practitioners and champions of patient safety must therefore be encouraged to thoroughly search and evaluate published research and thoughtfully consider "best evidence" in an unbiased, holistic manner before committing to any clinical decisions or programmatic implementations.

Clinical pathways and guidelines are used by practitioners to provide a framework of care for specific patient populations to improve outcomes [107]. Clinical guidelines are evidence-based care recommendations for defined populations and assist the clinician in decision-making regarding the patient care plan. Clinical pathways are used to implement the guidelines into practice and represent what has been determined to be the best evidence-based care for most patients [127]. They are typically a written tool and may be facility specific with an overarching goal of minimizing variability and optimizing outcomes. Rotter et al. [128] reviewed 27 studies involving 11,398 participants. Twenty of those studies compared clinical pathways with usual care. Their review identified a reduction in complications and improved documentation. Most studies also reported significant reductions in patient length of stay and thus a favorable impact on associated costs [128].

6. Grades of recommendation

It has long been known that clinical practices based on scientific evidence can only be "as good as" the underlying evidence and judgments [124]. Parallel to the assessment of LSE discussed in previous sections of this manuscript, the need arose for the ability to grade the corresponding recommendations—a necessary step for reconciliation of all of the components of, and internal consistency of, EMB practices [124]. Grading of recommendations has been pioneered by the Scottish Intercollegiate Guidelines Network (SIGN), with subsequent worldwide embrace and adoption of this powerful healthcare quality improvement paradigm [129, 130]. As outlined in **Table 2**, recommendations are graded on a scale from A (highest) to C (lowest), with the overall goal of careful consideration and weighing of objective and

High	High level of confidence regarding the true effect being close to that of the estimate of the effect
Moderate	Moderate level of confidence regarding the effect estimate. In other words, the true effect is likely to approximate the estimate of the effect, but non-trivial possibility exists of a "substantial difference"
Low	There is low overall confidence that the effect estimate reflects the true effect. In other words, the true (actual) effect may be substantially different from the estimated effect
Very low	There is very little confidence that the effect estimate reflects the true effect. In other words, the true effect is likely to be substantially different from the estimated effect

Table 3. Quality of evidence assessment definitions, as utilized in the GRADE approach [138].

subjective components of both the available evidence and its corresponding interpretation. It is important to note that different other GOR paradigms have been devised, with the topic being so vast as to warrant its own dedicated chapter and/or book [124]. Finally, another matter that is beyond the scope of the current discussion is the advent of various reporting requirements for different types of studies. The reader is referred to external resources for additional information on this important and increasingly complex subject [131–134].

Another important development in the area of translating evidence into practice was the introduction of the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach [135, 136]. In the GRADE paradigm, evidence is assessed in terms of both its certainty (e.g., quality) and strength of the corresponding clinical recommendation(s) [135, 137]. In terms of practical applicability of the GRADE system, quality of evidence and the corresponding definitions are provided in **Table 3** [138]. A multi-tiered system, examining specific evidence-related factors and criteria in the context of their influence on the direction and strength of the recommendation, is then employed to help with clinical implementations and translations of research data [139]. Since its introduction, the GRADE paradigm provides a well-organized and objectivized framework for evaluating the relative importance of research outcomes and alternative clinical approaches, and summarizing evidence for systematic reviews and clinical practice guidelines [139].

7. Synthesis: putting evidence to work, one improvement cycle at a time

The entirety of our previous discussion revolved around the levels of scientific evidence, various aspects of their interpretation and implementation, as well as grades of recommendations outlined in the overall context of EBM-based discussion. At this point, it will be important for the reader to become familiar with some of the methodologies employed in healthcare quality and patient safety improvement efforts. It is critical to emphasize that these approaches not only rely on EBM for planning and assessment but also help modify our existing EBM patterns through a continuous process improvement cycle. While evidence-based medicine has focused on providing the most recent evidence-based care for patients, quality improvement has focused more on the way we provide that care [140]. The evidence must be reviewed to ensure that it is indeed the right care while there also needs to be a clinical improvement

process to implement the change or evidence-based care. The two most common formats used in the areas of healthcare quality improvement and patient safety are the PDCA (or Plan-Do-Check-Act, **Figure 2**) and the 5A's (Assess-Ask-Acquire-Appraise-Apply, **Figure 3**) methodologies [141–147]. The goal of these performance improvement approaches is to achieve the desired results and continue on to another part of the process [107].

8. Conclusion

Evidence-based medicine continues to evolve into a practical way of integrating feedback from process outcomes and research results into clinical practice, assisting practitioners globally in providing optimal care for their patients. Understanding the different levels of evidence and the strength of recommendations is an integral component of EBM and helps guide decision making, but must consistently be interpreted in the context of sound clinical judgment and a strong therapeutic relationship with our patients. Champions of patient safety and care quality should be familiar with and comfortable in the application of the above concepts in their everyday practice. In addition, excellent knowledge of established standards for reporting evidence, as well as key methodologies used in the process of guideline implementation, will help guide clinicians toward providing the highest quality, safest possible care to their patients. It is crucial to understand that no single study should be accepted as "fact" nor should any study be disregarded based purely on its LSE. Instead, deliberate efforts should be made to critically analyze recommendations and apply them judiciously, after careful consideration of all available evidence has been made in the context of each specific clinical situation and setting. It is essential that healthcare institutions undergo a cultural transformation to ensure that evidence-based safety practices are introduced, effectively implemented, and allowed to achieve their full potential and intended impact [101].

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Chapter 5

Patient Safety Culture in Tunisia: Defining Challenges and Opportunities

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Abstract

Background: Although adverse events in health care have been a center of attention recently, patient safety culture in primary care is relatively neglected. This study aimed to provide a baseline assessment of patient safety culture in the primary healthcare centers and explore its associated factors.

Methods: This is a multicenter cross-sectional descriptive study. It was conducted in the center of Tunisia over a period of 4 months. It surveyed 30 primary healthcare centers, thus 251 staff members. It used the French-validated version of the Hospital Survey on Patient Safety Culture questionnaire.

Results: The total number of respondents was 214 participants with a response rate of 85%. The dimension of "teamwork within units" had the highest score (71.47%). Though, three safety dimensions had very low scores, which are "frequency of event reporting," "on-punitive response to errors," and "staffing" with the following percentages 31.43, 35.36, and 38.43%, respectively. As for associated factors, the dimension of "Frequency of reported events" was significantly higher among professionals involved in risk management committees ($p = 0.01$).

Conclusion: This study demonstrated that the level of the patient safety culture needs to be improved in primary healthcare centers in Tunisia. As well, the results obtained highlight the necessity of the implementation of quality management system in primary healthcare centers.

Keywords: patient safety culture, patient safety, primary care, risk management

1. Introduction

Adverse events (AEs) still remain as a global challenge and no country has yet overcome all of its patient safety problems [1]. So, many studies have shown the severity of these accidents, in terms of cost, frequency, and serious consequences [2]. The overall incidence of AEs in various high-resource countries varies between 2.9 and 16.6% [1]. The situation is more difficult and serious in low-resource countries with higher risk of patient harm due to the limitation of resources and lack of adequate infrastructures [1, 3]. In Tunisia, a study conducted in Sousse showed that the rate of AEs is 11.3% [1].

As for the area of primary healthcare, which provides the first contact for the patient [2], it goes without saying that quality and patient safety are vital goals and challenges [3]. In fact, errors and AEs are common in the outpatient setting [4, 5]; it has been identified that a significant proportion of safety incidents caught in hospitals had originated in the earlier levels of care [3]. Actually, a study in Spain deemed that 64.3% of AEs in primary care are preventable [5]. As a result, the World Health Organization (WHO) Safety Program has initiated the "Safer Primary Care" project, whose goal is to advance the understanding and knowledge about the risks to patients in primary care and the magnitude of the preventable harm due to unsafe practices in these settings [6].

Furthermore, in order to enhance primary care safety, the National Patient Safety Agency developed a best practice guide that describes how to "build a safety culture" as the first of the seven key steps for primary care organizations to protect the patients they care for [3]. Indeed, the success of any intervention with the ultimate goal of securing care and reducing AEs must go through the development of a patient SC with healthcare workers [4].

Nieva and Sorra defined patient safety culture (PSC) as the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to the style and proficiency of an organization's safety management [7].

However, undertaking a baseline assessment of PSC of the organization is the first step to start with in building safety culture [3]. Actually, assessing allows healthcare institutions to identify their strengths and weaknesses in terms of patient safety and to provide a clearer view of the aspects that require attention [8, 9].

Several studies found in literature that have been interested to PSC in primary healthcare centers (PHC) and reported variations between countries [2, 3, 9–11]. To our knowledge, there is currently no study that investigated PSC in PHC in Tunisia. We conducted this study to respond to the following research questions: "What is the level of PSC in Tunisian PHCs? And what are the PSC's associated factors?" Therefore, our objectives were to assess PSC through exploring perceptions and attitudes of professionals in the PHC of the healthcare centers in Sousse (Tunisia) and to determine PSC's associated factors.

2. Methods

2.1. Design, settings, duration, and participants

A cross-sectional multicenter study was conducted from January to April 2016 in the PHC in the Tunisian center (Sousse, Kasserine, and Kairouan). These structures were chosen

because they were partners of the Faculty of medicine of Sousse, and therefore, they were responsible for mentoring future family doctors.

All PHC of these listed cities were included in the study (n = 30) and all the healthcare providers in them (physicians, healthcare technicians, and nurses) were invited to participate in the study (n = 251). Workers who are not involved in healthcare practices and those with less than 1-month experience were excluded.

2.2. Measures

The current study used the French version of Hospital Survey of Patients' Safety Culture (HSOPSC) questionnaire, which was translated and validated by the Coordination Committee of the Clinical Evaluation and Quality in Aquitaine (CCCEQA). Internal consistency reliability was of 0.88 for the questionnaire, Cronbach's alpha values varied between 0.46 and 0.84 in 10 dimensions [12].

Ten PSC dimensions were explored by the French version through 45 items. Dimensions were about: overall perception of patient safety (D1), frequency of events reported (D2), supervisor/manager expectations and actions promoting patient safety (D3), organizational learning-continuous improvement (D4), teamwork within units (D5), communication openness (D6), nonpunitive response to error (D7), staffing (D8), management support for patient safety (D9), and teamwork across units (D10). The survey also examined staff perception of patient safety quality (1 item), the number of AEs reported during the last 12 months (1 item), and characteristics of participants (6 items). A Likert scale of five points was used to explore professionals' patient safety culture perception.

2.3. Data collection, ethical consideration, and analysis

This study was approved by the common ethics committee of the High School of Sciences and Techniques of Health of Sousse and the university hospitals of Sousse. Administrative authorizations have been obtained from heads, head chiefs, and PHC directors.

A self-reported paper-based questionnaire was distributed to the participants that accepted to take part in the study. The study purposes, outcomes, and instructions were explained to participants. They could freely and anonymously fill in the questionnaire and return their responses directly to the investigator. According to the user guide of the French version of HSOPSC questionnaire, if none of the dimensions' sections was entirely filled, the questionnaire would not be taken into account. Also, if less than half of the items in the questionnaire have been completed, or the same answers were given to all the items, the questionnaire would be illegible and excluded.

2.4. Data analysis

The data analysis was conducted using SPSS version 20 and Epi info 6 for windows. Descriptive statistical analysis such as frequencies and percentages of positive responses for each item and dimension were used to examine healthcare professionals' perceptions about PSC. Items were worded in both positive and negative directions. For items with a positive formulation, answers "Strongly Agree/Agree" or "Most of the time/Always" were considered positive. For items with a negative formulation, the answers "Strongly Disagree/Disagree" or "Never/Rarely" responses were considered positive for PSC.

The chi-square test was also used to examine the association between total score of PSC dimensions and participants' demographic and professional variables such as gender, age, professional title/specialty, work experience, region of the PHC, and participation in risk management committees. Statistical significance was defined at $p \leq 0.05$.

3. Results

3.1. Characteristics of the participants

In total, 214 professionals provided survey feedback (85%). Seventy six (35.5%) participants were general practitioners, 92 (43%) were nurses, and 46 (21.5%) were technicians and midwives. As for gender, the majority of respondents 154 (72%) were female with a sex ratio of 0.39. More than half of the professionals (67.8%) had a work experience of more than 10 years (**Table 1**).

Characteristics	n	%
Professional title/specialty		
General practitioners	76	35.5
Healthcare technicians	46	21.5
Nurses	92	43
Total	214	100
Gender		
Females	154	72
Males	60	28
Total	214	100
Age		
>40years	124	58.2
≤40years	90	41.8
Total	214	100
Work experience		
<10 years	69	32.2
≥10 years	145	67.8
Total	214	100
Participation into risk management committees		
Yes	34	15.9
No	180	84.1
Total	214	100

Characteristics	n	%
The district of the primary healthcare center		
Urban	164	76.6
Rural	50	23.4
Total	214	100

Table 1. Characteristics of participants.

3.2. The staff perception of patient safety quality and the frequency of reported AEs

Staff perception of patient safety quality in the PHC was ranked as good in 59.3% and poor in 15.9%. Regarding reported AEs, 75.2% of the participants declared that they did not report any event in the last 12 months (**Table 2**).

3.3. PSC dimensions

Concerning "overall perception of safety," it had a score of 52.45%. The percentage of positive responses was the highest for "teamwork within units" (71.47%), so this dimension was a potential area for improvement. The lowest scores were for "frequency of event reporting" (31.43%) and "nonpunitive response to error" (35.36%). Results of all dimensions are shown in **Table 3**.

3.4. Factors associated with PSC in PHC

All dimensions of PSC have not been significantly associated with professional title, gender, work experience, the region of the PHC, and participation to a risk committee, except for the

	n	%
Staff perception of patient safety quality		
Excellent	12	5.6
Very good	40	18.7
Good	127	59.3
Poor	34	15.9
Failing	1	0.5
Number of events reported		
No event reported	161	75.2
1–2	29	13.6
3–5	9	4.2
6–20	8	3.7
More than 20	7	3.3

Table 2. Staff perception of patient safety quality and number of reported adverse events during the last 12 months.

Items of patient safety culture dimensions in the primary healthcare centers	Average positive response (%)
D1: Overall perceptions of safety	**52.45**
Patient safety is never sacrificed to get more work done	61.2
Our procedures and systems are good at preventing errors from happening	57
It is just by chance that more serious mistakes do not happen around here	53.3
We have patient safety problems in this facility	38.3
D2: Frequency of events reported	**31.43**
When a mistake is made, but is caught and corrected before affecting the patient, it is reported…	33.6
When a mistake is made, but has no potential to harm the patient, it is reported…	28
When a mistake is made that could harm the patient, but does not, it is reported…	32.7
D3: Supervisor/Manager expectations and actions promoting patient safety	**51.25**
Manager says a good word when he/she sees a job done according to established patient safety procedures	54.7
Manager seriously considers staff suggestions for improving patient safety	51.4
Whenever pressure builds up, my manager wants us to work faster, even if it means taking shortcuts	49.1
My manager overlooks patient safety problems that happen over and over	49.8
D4: Organizational learning and continuous improvement	**45.01**
We are actively doing things to improve patient safety	64.5
Mistakes have led to positive changes here	58.9
After we make changes to improve patient safety, we evaluate their effectiveness	72
We are given feedback about changes put into place based on event reports	10.3
We are informed about errors that happen in the facility	34.1
In this facility, we discuss ways to prevent errors from happening again	30.3
D5: Teamwork within units	**71.47**
People support one another in this facility	68.2
When a lot of work needs to be done quickly, we work together as a team to get the work done	80.8
In facility, people treat each other with respect	70.1
When one area in this unit gets really busy, others help out	66.8
D6: Communication openness	**44.56**
Staff will freely speak up if they see something that may negatively affect patient care	53.3
Staff feel free to question the decisions or actions of those with more authority	29.9
Staff are afraid to ask questions when something does not seem right	50.5
D7: Non-punitive response to error	**35.36**
Staff feel like their mistakes are held against them	34.6

Items of patient safety culture dimensions in the primary healthcare centers	Average positive response (%)
When an event is reported, it feels like the person is being written up, not the problem	42.1
Staff worry that mistakes they make are kept in their personnel file	29.4
D8: Staffing	**38.43**
We have enough staff to handle the workload	50.5
Staff in this facility work longer hours than is best for patient care	19.6
We work in 'crisis mode' trying to do too much, too quickly	40.2
D9: Management support for patient safety	**50.22**
Management provides a work climate that promotes patient safety	47.2
The actions of management show that patient safety is a top priority	55.1
Management seems interested in patient safety only after an adverse event happens	41.6
Units work well together to provide the best care for patients	57
D10: Teamwork across units	**44.23**
There is good cooperation among units that need to work together	49.5
Units do not coordinate well with each other	41.6
It is often unpleasant to work with staff from other units	39.7
Things 'fall between the cracks' when transferring patients from one unit to another	36
Important patient care information is often lost during shift changes	59.8
Problems often occur in the exchange of information across units	38.8

Table 3. Scores and items of the 10 dimensions of safety culture (n = 214).

dimension of "Frequency of adverse events reported," which was significantly higher among professionals involved in risk management committees (p = 0.01).

4. Discussion

Recently, patient safety in primary care has been given increasing attention [12]. Due to the fact that many studies who have investigated the quality of care in primary healthcare settings, have detected a high level of AEs leading to miserable and lethal consequneces [14, 15].

Moreover, it is directly accessible to patients and consists of several professions such as general practice, dental care, physiotherapy, and midwifery. Indeed, this study is the first to assess PSC in Tunisian PHC. It was carried out in urban and rural PHC of the listed cities. A high participation rate (85%) (n = 214) was acceptable and run counter to the results from previous studies [13, 14].

The dimension of "overall perception of patient safety" had a score of 52.45%. This reflects the lack of security of care in these PHC and the need to implement corrective measures to increase awareness of this issue among professionals.

Our results reveal that the dimension of "teamwork within units" had the highest score (71.47%) and this statement was similar to what was found in literature [2, 9, 13, 14]. However, it was developed in almost all the studies in PHC [2, 9, 11, 13] and this may be due to the fact that PHC are small buildings with less staff compared to hospitals and an unsophisticated environment, which are the factors that encourage teamwork [15]. Actually, teamwork is known as a dynamic process of healthcare professionals with complementary backgrounds and skills sharing common health goals and exercising concerted efforts in patient care through interdependent collaboration and shared decision-making through open communication, which is critical to teamwork [16].

Concerning the dimension of "communication openness," it was an area of concern in studies in Kuwait and Turkey [2, 9]. Responses have shown that professionals were not encouraged to express disagreement or to say alternative viewpoints. In a recently published study, only 28% of the staff members dared to speak with their superior regarding their concerns about the risk of a planned measure while the other staff members remained silent. In nearly 90% of the cases, the silence led to a near miss [17–19].

As a matter of fact, openness, in general, is found to be a problem in low-resource countries. Disagreement and criticism against supervisors or team members are frequently interpreted as blame or as a fight against them and may lead to loss of personal relationship or career, so most employees tend to avoid it [3].

According to literature, failures in teamwork and communication lead directly to compromised patient care, staff distress, tension, and inefficiency, make a substantial contribution to medical error [21].

Results of the current study show that all safety culture dimensions are potential areas for the improvement but with prioritization; there are three safety dimensions with very low scores and need to be considered of high priority. These dimensions are "frequency of adverse events reported" (31.43%), "nonpunitive response to errors" (35.36%), and "staffing" (38.43%). These results go hand in hand with several studies [9, 17].

Patient safety is a center of interest in healthcare, internationally, and error reduction can be improved by reporting and learning from errors [22]. A very low positive response for event reporting is expected in primary care because it is known to lack standardized reporting systems and reporting culture [20, 24]. Although primary care may imply lower risks compared to hospitals, the large volume of contacts in this sector suggests that safety incidents can be expected to occur [23].

Also, this underreporting can be explained by the fact that the commission of error is always considered as a lack of skill and rarely seen as a learning opportunity. A number of barriers exist to reporting, including insufficient time to report, lack of feedback, fear of blame, and damage to reputations and patient confidence in a competitive environment [24]. Here, we highlight the dimension of "nonpunitive response to error," which as mentioned above, has the second lowest score.

These two dimensions appear to be closely related to each other because of the "blame and shame" culture and the punitive environment where failure is punished or concealed and people refuse to acknowledge that problems do exist [9, 13].

Actually, we found that among all participants working in 30 different PHC, 75.2% of them declared that they did not report any event in the last 12 months in their facilities. And it is only normal that in this punitive culture, people will not be willing to report AEs due to the fear of blame and obstruction of any possibility to learn from error.

In this study, the only dimension influenced by one associated factor was "frequency of adverse events reported." In fact, participants who were engaged in risk management committees had a significant higher score of this dimension (21.81 vs 40.19%, $p = 0.01$). This finding goes hand in hand with results from the PSC survey that was conducted in operating rooms in Tunisia [17].

Actually, risk management describes a dynamic process that includes all measures for systematic identification, analysis, assessment, surveillance, and control of risks. An effective risk management should not start only after the evaluation of an incident but when failure can still be avoided and damage can be prevented. A successful example of effective risk management is the World Health Organization's safe surgery checklist," which is the most prevalent example of a standardized information exchange aimed at preventing patient harm due to information deficit [25].

This study provides an overall assessment of safety perceptions among PHC staff. Based on its reflections, we recommend a systematic improvement of staff qualification by providing training opportunities and educational interventions to promote a better understanding of the principles of teamwork, help staff acknowledge each other's roles and perspectives, and develop effective communication strategies. Moreover, regarding the underreporting, if incident reporting process is perceived as a supportive and formative opportunity, and where protected time is allocated to discuss incidents, then professionals are willing to participate. That is why it is essential to establish a culture where individuals are supported to identify and report errors without threat of punitive action or blame.

Also, we recommend the implementation of continuous training programs concerning risk management and patient safety guides. As well, we find it useful to introduce a medical curriculum safety culture in the educational programs of undergraduate healthcare professionals. Actually in 2011, the WHO published the "Multi-professional Patient Safety Curriculum Guide" with 11 themes related to patient safety to be integrated into healthcare universities [26].

One of the study's limitations was that the instrument tool used was, actually, developed for use in hospitals setting and not for PHC [16]. The assessment of PSC using a self-administered questionnaire can be associated with a declaration bias. Indeed, self-administered questionnaire may influence the reaction of those who, for fear of reprisal or prosecution, will give social answers that do not reflect reality. Furthermore, HSOPSC does not calculate an overall score of PSC. The validation of such score is complex and raises the problem of choosing the dimensions to be considered and their weightings.

In conclusion, the study findings demonstrate that none of PSC dimensions is developed in our PHC. We highlighted different areas of concern such as "frequency of adverse events reported," "nonpunitive response to error," and "staffing." It also shed the light on the lack of reporting in primary care due to the punitive culture regarding errors.

More attention should be paid to PSC in primary healthcare because changing values and attitudes needs time and motivation through training and improving risk management skills within healthcare providers. Also, as well, the results obtained bring up the necessity of the implementation of quality management system in Tunisian primary healthcare centers.

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Chapter 6

Learning of Patient Safety in Health Professions Education

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Additional information is available at the end of the chapter

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Abstract

The awareness of patient safety became one of the emerging topics over the last two decades. However, in medical curricula, the knowledge of its principles is still facing challenges concerning its proper timing and the suitable methods of instruction. Many studies have shown several trials dealing with the introduction, implementation, and evaluation of patient safety courses in health professions institutions. Moreover, the training of healthcare professionals focuses on the clinical and curative competencies rather than preventive skills. Therefore, the knowledge about patient safety is a necessity for all graduates in health professions careers. Thus the World Health Organization (WHO) have developed a curriculum guide for patient safety to help health professions institutions integrating patient safety principles in their curricula. This chapter will focus on the educational aspects of patient safety topics in health professions education.

Keywords: patient safety, curriculum, healthcare professionals, instructional methods, training

1. Introduction

Healthcare has been improved and developed to cope with the rapid evolution of knowledge. Hospitals, resources, and drugs are also continuously enhanced. Still, there are risks of the human errors which are always inevitable. Safety measures are now included in modern industries to overcome these errors. As the patients are the main customers of the health care system, patient safety is an important issue to maintain developing this system. The essential step towards lowering errors and harms to the patients is educating healthcare professionals about patient safety.

There are many involuntary but preventable adverse events that affect patients and may lead to temporary or permanent harms, including increased admission duration, or even causing the death of patients. These harms are most probably related to health care management system failure regardless of the competencies of the healthcare professionals. They also affect the general people and cause economic problem in both developed and developing countries. These events include diagnostic errors, medication errors, postoperative infections and complications, miscommunication, lack of personal and other identities. The problem may be higher in the developing countries because of the poorer infrastructure and lack of financial resources compared to developed countries [1, 2]. We should know that 80% of these events are system driven rather than individual mistakes. So, in order to reduce these adverse events, there is a need to implement a program incorporated in the healthcare system. This program requires the individual commitment towards patient safety rather than financial resources. We need to foster the culture of patient safety and this in turn will reduce the occurrence and impact of harms.

Patient safety is about reducing the risk of unintentional but preventable harm related to health care system to an acceptable minimum. Patient safety is an attribute of the health care system as well as its relation to the physician skills. To develop a curriculum for patient safety, we must consider the complexity of healthcare system and the involvement of many individuals in the delivery of health services. Nowadays, patient safety is considered as a discipline that applies the safety measures and increases the effectiveness of health care system [3].

Necessary steps are to be followed while developing patient safety curriculum. Identification of the problem and the rationale for implementing such curricula is the first step. Then, assessing the needs of healthcare professionals and formulating objectives and selecting the appropriate content and instruction methods according to these needs are the next steps. Evaluating the implemented curriculum is then conducted for improving the process and taking actions and decisions regarding the other steps.

2. Problem and rationale for implementing patient safety curriculum

Hospitalized patients may be affected by adverse effects. Meanwhile, patients on drugs could be harmed from side effects. Health professions education students should know how to deal with these harms. They should also know the outcomes of miscommunication [4]. Therefore, patient safety is one of human rights issues and a major health problem [1]. In the developed countries one of 10 hospitalized patients is harmed while in the developing countries the rate is higher than that in the industrial countries. A high percentage of these adverse events, reaches 83%, were preventable, while 30% caused the death of the patient [1]. The cost of additional hospitalization, legal actions, infection acquired in hospitals, and disabilities, is estimated in some countries between US $ 6 billion and US $ 29 billion in a year. So, there is a growing attention to the income benefits from improving patient safety [5]. Additionally, international accreditation guidelines and standards recommend teaching and learning skills related to patient safety [6].

As there are many adverse events caused by unfollowing the patient safety measures, training and supervision of the clinical staff, establishing clear guidelines and improving the record keeping are stated as priorities within the prevention strategies. Other causes, as low number of clinical staff and low resources are reported of low priorities [1].

Studies have identified that teaching patient safety to undergraduate students is a necessity, still, there is no either consensus on how to deliver it nor agreed upon priority areas [7, 8]. Even students themselves rated patient safety as important topic that should be included in their curricula [9].

Skilled health care professionals, who are using patient safety principles by intuitive practice, could not transfer it to practice. Meanwhile, the challenges of patient safety principles induction in curricula are mainly that non-academics or who in administrative responsibilities probably are not skilled in teaching and learning such new principles [9, 10].

So, the need of informed, skilled staff constitutes a major problem in delivering such courses. They should have the preplanned changes in their teaching to cope with the current recommendations of teaching patient safety. Another factor that may contribute to the problem is the current deficiency of performance and knowledge of the healthcare professionals regarding patient safety. Thus educational intervention is the main solution to this problem.

3. Healthcare professional needs

Medical educators are interested in introducing patient safety in medical programs, on the other side, there is a little training of the undergraduates' students regarding this topic [11].

Inadequate training and the failure of the clinicians and the assistant staff to follow guidelines and protocols contributed to the adverse events [1]. Students' needs should be assessed concerning the topics to be included in patient safety curricula. The goal-directed patient safety curriculum leads to an opened culture and improving the satisfaction of both patients and students [12].

Many factors contributed to this deficiency of training of the healthcare professionals such as: low recognition by the health professions institutions that integrating the principles of the patient safety in their curriculum is important, lack of familiarity and reluctance of the educators to teach these principles, emphasis of educating treatment rather than prevention of the disease and the perceived role of the teachers as only information provider or an expert [13].

Moreover, educational interventions for the healthcare students proved to enhance the prescription of the medications and the adherence to the guidelines by the physicians [14] .

The target learners' needs differ from one context to another. Previous training and experiences relevant to curriculum, existing proficiency and perceived deficiency of the learners should be assessed to adjust the suitable course. The preferences regarding different learning strategies and resources available to the learners help to conduct a learner-oriented course.

Formulating the rational and assessing the needs of the healthcare professionals are essential steps for formulating objectives and identification of the course content.

4. Formulation of objectives and identification of the content of patient safety curriculum

The main addressed areas into the content of the patient safety include; good communication skills, development of team work skills, improving skills of managing risks and solving problems while a harm was detected for the patient [11].

4.1. Models of patient safety curriculum

I. The Australian Patient Safety Education Framework

It is a model for learning patient safety includes different seven areas with 22 topics and describes knowledge and performance that are required form each personal in the health system in order to provide safe care. Each objective is divided into four levels. Each level includes a category according to the position or the responsibility of each individual.

The seven areas are as follow:

- Communicate effectively: patients and their carers are among the health team. They are considered as a second pair of eyes for a doctor. Communicating effectively will reduce the risk for patients. This area includes involvement of both patients and their carers in their health care, communicating risk, obtaining consent, being honest, and being knowledgeable and sensitive to cultural difference.
- Using evidence: in this area, health care workers should know and apply principles of evidence-based practice in their work and use information technology.
- Adverse events: we cannot reduce errors unless we know causes and nature of errors. Most adverse events are system failure determined rather than professional carelessness or misconduct. In this area individuals should learn how to record errors, to perform quality measure, and to improve performance, managing risks and complains.
- Working safely: this area is about teamwork and knowing roles and responsibilities within the healthcare team. It includes leadership, understanding complex organization, human factor, continuity of care, and managing fatigue and stress.
- Being ethical: health care workers should know and apply ethical codes of practice and maintain their fitness to practice.
- Learning and teaching: health care information expands rapidly and continuously, so health care workers need to continuously update their knowledge and skills, and this requires learning and teaching in the workplace.
- Specific issues: this area is to ensure that the right treatment is delivered to the right patient, and to eliminate wrong procedure and site, and to medicate safely [3].

II. The Canadian Framework (The safety competencies – Enhancing patient safety across the health professions)

This framework is an inter-professional, and it includes six domains which are as follow: contribute to a culture of patient safety; Work in teams for patient safety; Communicate effectively for patient safety; Mange safety risks; Optimize human and environmental factors; Recognize, respond to and disclose adverse events [2]. Each domain contains the needed knowledge, skills, and attitude.

III. Scottish Patient Safety Fellowship

It includes six topics and general aims to be fulfilled.

1. Improvement theory, methods and tools

   a. Theory of profound knowledge b. Model for improvement c. Quality improvement as core business strategy d. Planned experimentation.

2. Leading clinician through change.

   a. From stable delivery model to adaptability and growth within an organization. b. Principles and difference of adaptive versus technical changes. c. Building a compiling case for change. d. Developing a shared vision. e. Sponsorship, champions, alignment and feedback f. compacts

3. Measurement for improvement.

   a. Data, variation, reporting b. Measure for improvement versus research and judgment

4. Communication, presentations and marketing skills.

5. Reliability theory, system, design for safety.

6. Working with people, motivation, team building [15].

IV. WHO patient safety curriculum guide

World Health Organization provided a Multi-Professions Edition of Patient Safety Curriculum Guide to assist the health professions institutions in implementing the curriculum of patient safety. The guide includes some suggested topics, teaching, and evaluation methods for preparing students who have the knowledge, skills, and attitude for improving their clinical practice and patient safety. Each institution after performing a needs assessment, could integrate these topics into its curriculum. A medical guide was produced by the WHO in 2009; the multi-professional edition was developed after consulting dentists, nurses, midwives, and pharmacists. The guide is divided into two sections: part A: Teacher Guide; and part B: patient Safety Topics. The Teacher Guide helps to build the capacity of the educators. It offers information about the efficient instructional methods to teach the topics and suggested techniques for integrating the module into the existing curriculum. The patient safety topics are suggested to be implemented as parts or as a whole [4].

The guide covers 11 topics and includes 16 subtopics which were selected from the Australian framework. The 11 WHO topics are shown in **Table 1**.

The listed topics in WHO guide
Topic 1: what is patient safety?
Topic 2: what are human factors and why is it important to patient safety?
Topic 3: understanding systems and the impact of complexity on patient care
Topic 4: being an effective team player
Topic 5: understanding and learning from errors
Topic 6: understanding and managing clinical risk
Topic 7: introduction to quality improvement methods
Topic 8: engaging with patients and carers
Topic 9: minimizing infection through improved infection control
Topic 10: patient safety and invasive procedures
Topic 11: improving medication safety

Table 1. The eleven topics presented in the WHO patient safety curriculum guide.

1. Topic 1: what is patient safety?

This topic presents the patient safety principles and concepts as a response to the requirement of healthcare professionals aiming to incorporate these principles and concepts into everyday practice [4].

2. Topic 2: what is human factor and why it is important to patient?

Students need to recognize how human factor can be used to decrease adverse events and errors by detecting how and why systems break down and how and why human beings miscommunicate. Using a human factor method, the human-system interface can be enhanced by providing systems and procedures which are better designed. This often involves improving communication, simplifying processes, and standardizing procedures [4].

3. Topic 3: understanding systems and the impact of complexity on patient care

The concept that a healthcare system is made up of different units that provide multiple services and practices should be introduced all healthcare workers. The complexity of health system increases by the existence of relationships between health care providers, patients and their career, supporting staff, administration, and community members. This topic introduce the concept of complex organization to students by using a system approach [4].

4. Topic 4: being an effective team player

This topic includes the fundamental knowledge required to be an effective team member. The importance of effective multidisciplinary teams for improving care and reducing errors. Students need to understand the culture of their workplace and how it influences team dynamics and functioning [3].

5. Topic 5: understanding the learning from errors

The poorly designed systems have contributed to making errors. Students should understand and appreciate happening of these errors to prevent their occurrence in the future. This systems-based approach and knowing the factors contributing to the cause of the errors is better than blaming individuals for their errors [3].

6. Topic 6: understanding and managing clinical risk

Risk management is a process of recognizing, dealing with and preventing risks. Clinical risk management is recognizing the events that could harm the patients and ways to prevent them from occurring again. Information that are emerged form patients' complaints, incidents, legal cases related to health care, can be used to set strategies for clinical risk management [2].

7. Topic 7: introduction to quality improvement methods

Quality management methods have been introduced from industries to healthcare. Students should be able to identify problems, measure the problem, develop strategies to fix this problem, and test whether these strategies worked or not. Knowing how every step in health care process is incorporated into the system is essential [4].

8. Topic 8: engaging with patients and carer

Students should understand and appreciate the role of the patients and their carers in the diagnosis and compliance with treatment. The outcomes of the treatment and the prognosis can be enhanced and the adverse effects could be reduced by the good patient-doctor relationship and communication.

9. Topic 9: minimizing infection through improved infection control

Hospital-acquired infection and healthcare associated infection are major causes of death and disability worldwide. Patients with invasive procedures are particularly predisposed to hospital-acquired infections. How to apply preventative measures and guidelines is crucial to be learned.

10. Topic 10: patient safety and invasive procedures

Miscommunication between healthcare providers before carrying out surgeries leads to perform wrong procedures, in the wrong sites for wrong patients. This is the main source of errors pre operatively.

11. Topic 11: improving medication safety

WHO has defined adverse drug reaction as any harmful response to medication, which is unintended and occurs at amounts used for prophylaxis, analysis or treatment. The main causes of medication errors are induced by low knowledge about the patients or the medication or calculation errors.

Concerning the learning outcomes in patient safety curricula, they should be competency-based and directly linked to the content [9].

To ensure patient safety, the future physician must be prepared to know potential sources of errors and to recognize their own susceptibilities to error. An elective course in the open disclosure of the health care providers, which is communicating with the patients the errors and how it happened, can be introduced. This training of disclosure may decrease the harm of the future patients [16].

The course of patient safety necessities to be more focused. Writing objectives that are specific to the learners, measurable and relevant to their needs, help to focus the content course and essential for planning the appropriate instructional methods of conducting the course.

5. Instructional methods and implementation of patient safety education

Patient safety as a subject is new, generic, multidisciplinary and highly contextual course. It should be based on experiences, and learners should have the opportunity to reflect on their practices.

- Integrated with the existing curriculum.

Although patient safety is a new subject, it has many facets in the existing curriculum and links with basic and clinical sciences. Almost all healthcare curricula have restricted space and time for adding new courses. It is a good approach to review the existing curriculum to identify where to integrate patient safety topics. Thus, it could be vertically integrated into the existing curriculum. Topics of patient safety are generic and could be applied to any specialty. In the existing curriculum, we can find generic areas that are suitable to include patient safety principles e.g. communication skills, ethics, professionalism…etc.

Patient safety is related to all healthcare professionals' clinical practice so it should not be studied in isolation. Topics of patient safety curriculum were designed to be easily integrated into the existing medical teaching, for example, anatomy, pediatric, physiology, etc. Incorporation of all topics is essential for the development of safe heath care providers [13]. Spiral approach is recommended while implementing patient safety curriculum. The curriculum should be spread over the undergraduate level program [17].

- Multi-professional/ Multidisciplinary.

The WHO Multi-professional Patient Safety Curriculum Guide (2011) was established responding to the need for providing harmless care. Being a safe healthcare provider requires different competencies that cover specific knowledge, skills, and attitude. Heath care workers should collaborate together to provide safe service, to guarantee that patient safety learning is delivered in an incorporated way which should be single coordinated, system based, in a team dependent approach, and includes different specialties. Patient safety curriculum includes basic, behavioral and clinical sciences. It is a multi-professional subject needs the repeated application to the workplace settings. It has been reported that

medical students are positive about learning with other students who participated in clerkships of different specialties

- Experiential/ Provides opportunities for application and reflection

The course may include interactive lectures, e.g. problems with inappropriate supervision by a physician, to highlight the relation between theory and practice. Then the students had to reflect on incidents concerning patient safety based on their own personal experience and to complete an incident report card for each of these incidents. The course may also include presentations arranged by the students, which are followed by a 10-minute discussion for each presentation. Assessment of the students includes content, structure and presentation techniques [10].

Most courses in patient safety were introduced by lecturing and discussion which have short terms positive changes but the transfer of knowledge to the practice is low [9]. Learning patient safety could be enhanced by reflection, feedback, portfolio, and critical incident analysis, case discussions with senior clinicians, simulation environments and workshops. So, patient safety courses based on personal experiences and reflections enable students to transfer knowledge into practice and have a high impact on future career [10]. Some studies reveal that students emphasized active learning and experiential activities to reinforce safety principles [18].

- Contextual.

Patient safety is highly contextual, so, students should have adequate professional practices to learn patient safety, in this regard patient safety is best taught once students involved in the health services. However, some behavioral sciences-based subjects could be learned early such as; what is patient safety, what are human factors, and understanding systems modules. Students need to continuously reflect on their practices and apply the learned knowledge and performance to be a safer provider of health care. Using critical cards incidents to help students reflecting on their personal experiences seems to be useful in improving the transfer of knowledge [10].

5.1. Who should teach patient safety?

Advocates of patient safety are usually from administrative nonacademic staff. To integrate patient safety throughout the curriculum we need a large number of academic teachers who often are not familiar with concepts and principles of patient safety. Some of them may practice patient safety principles without being aware of such knowledge. Academic clinicians, administrators, nurses, engineers, behavioral scientists are all involved in teaching patient safety. They should have capacity building through training workshops and seminars. Some schools trained healthcare administrators to deliver patient safety curriculum for undergraduates' students [9].

5.2. Limitations

From the point of view of the tutors who were involved in the implementation of the patient safety curriculum, some recommendations emerged. For example, training of the tutors, and the participation of large number staff in implementation, which will reduce the load on one or two

tutors, are essential. The local support for implementation is also required for allocating more time and resources. They also recommended full integration of the curriculum in the undergraduate years [19]. Cost issues are limited to the time of the teachers and the students when the materials are available and the curriculum topics are provided as in the WHO guide [20].

6. Evaluation and student assessment methods

Evaluating the course content and the process of implementation is an opportunity for further improvement and reforming. Evaluation includes evaluation of the program as well as students' assessment.

6.1. Evaluation approaches

Evaluation of any program is variable and has a direct relationship to the intended learning outcomes (ILOs) of the course. It takes various forms, may be either formative or summative, or even both as conducted in WHO patient safety curriculum guide. In the latter, each school selects the patient safety topics in the Curriculum Guide and has the flexibility to do that with plans on how to incorporate these topics in their existing curricula. Then, formative evaluation is conducted where assess the medical schools' different experiences in using the WHO curriculum guide. The aim of this evaluation was to provide feedback to WHO stakeholders and concerned bodies regarding capacity building, implementation, with suggestions for improvement. This also will help other schools who want to use this guide in the future. On the other hand, in summative evaluation, the scope was to the evaluation of the effectiveness of the curriculum guide to develop patient safety curriculum. Retrospective data emerged form conducted interview while prospective data excluded from pre-and-post surveys of students receiving the courses [4].

Overall, the main aim of the conducted evaluative studies of the Patient Safety Curriculum Guide is to assess its effectiveness for teaching patient safety to both undergraduate and graduate medical students [3]. The results of these evaluative studies will guide others when planning for their curriculum guides and promotes in depth background of successful methods used in introducing patient safety to curricula [10].

6.2. Evaluation steps

Evaluation of the designed course is a necessity. Evaluation involves three main steps, developing an evaluation plan; collecting and analyzing information; disseminating the findings to appropriate stakeholders action [3].

6.2.1. Step 1: the evaluation plan

In the evaluation plan, it is the framework for the process. So, you should first identify what's to be evaluated, who are your stakeholders, the purpose of the evaluation which is closely related to the evaluation questions.

Identification of users of these evaluations is an important step in the evaluation plan. Participants in patient safety courses have sake to provide their own views and participate in the assessment process concerning their own performance and the designed curriculum. These evaluations can provide feedback and be a source of motivation for continuous improvement for learners, faculty, and curriculum developers. An Example for this was the evaluation study of the WHO patient safety curriculum guide, its main aim was assessing the effectiveness of using the guide in teaching patient safety for postgraduate and graduate medical students. Concerning the feedback from this evaluation, it was utilized to guide through future versions of the Curriculum Guide and enhance the understanding of the successful methods of introducing patient safety to curricula [21].

The evaluation results should be publicized as this would be interesting to educators from other institutions that are willing to introduce patient safety principles in their curricula.

After identifying users, we should identify uses of the evaluation, which are generic and specific ones. The generic uses refer to whether the evaluation is used to appraise the performance of individuals, the performance of the entire program, or both. The assessment of learners is closely related to whether they have achieved the cognitive, affective, or psychomotor or competency objectives of a curriculum or not. Meanwhile, it refers to whether an evaluation is used for formative purposes, for summative ones or for both purposes as discussed before. One more thing that should be considered is the specific needs of different users (stakeholders) and the specific ways in which they will put the evaluation to use [21]. Specific uses for evaluation results might include the following: feedback on individual learners' performance to assign grades or detect mastery in certain skills. Feedback on and improvement of program performance is also included in specific uses as the evaluation results could be used to identify parts of the curriculum that are effective and parts that are in need of improvement. Evaluation results may also provide suggestions about how parts of the curriculum could be improved [21].

Identifying resources that will be used, followed by choosing measurement methods, and constructing instruments were also included in evaluation plan.

6.2.2. Step 2: collecting and analyzing data

Data collection methods that were used to evaluate the patient safety curriculum guide ranged from simple methods as getting students' perception about the course after receiving a patient safety teaching, and complex methods such as having faculty to review the conducted whole curriculum. These complex methods involve a varieties of tools such as surveys, interviews, and focus group with students, faculty or administration, observation and other methods. Reported data collection tools by previous studies either were face to face or telephone interviews with key stakeholders: teaching staff, and executives at the involved medical schools. Students' surveys regarding patient safety topics were collected before and after teaching patient safety curricula. The two methods were used to get different data. The pre-teaching ones to get information about students' perceptions and attitude towards patient safety and to test their knowledge of patient safety facts and actions. Meanwhile, the post teaching collected data measures two domains the effectiveness of the topics and the effectiveness of

teaching; through measuring the change of students' perception, knowledge and attitude towards patient safety taught topics after completing the course [4].

Concerning the timing of data collection, it is better to start as early as possible. It is better to start form the first week of teaching and end within three weeks up to two months after completion of the course. This depends on the availability of faculty staff and executives to complete the interviews and focus groups [4].

The survey questions were grouped in four domains as reported in many studies: patient safety knowledge; Healthcare system safety; Personal influence over safety; Personal attitude about safety. The WHO staff has developed questions of patient safety knowledge those were reviewed by the developers of the patient safety curriculum guide [3].

The contents of the interview and students' surveys were developed to collect data for answering four research questions defined for evaluation. These questions proposed for WHO curriculum evaluation guide as follow:

1. Does the curriculum guide contains the necessary as well as sufficient information and topics to allow its effective use in undergraduate training of healthcare professionals?
2. What is the impact upon students' learning of the inclusion of patient safety teaching in the curriculum?
3. In what ways can this curriculum guide be used to support the widespread implementation of explicit patient safety education globally?
4. How could the curriculum guide be modified in the future to best support teaching of patient safety to students in different environments? [3]

One of the reported data collection tools is reflection. Self-reflection has an important role in evaluation and represented a chief activity for a medical or clinical educator. For a reflection to be effective, it may include: experience of teaching or feedback received from others; description of how you felt as a learner and whether you were surprised by those feelings; re-evaluating your experience. Self-reflection will enhance the development of new perspectives in terms of improving the teaching or learning of patient safety approaches and procedures [4].

It is worth mentioning that some studies used a mixed method triangulation design to evaluate their patient safety course. A Course Evaluation Questionnaire (CEQ) completed by participants to assess the overall perceptions and effects of the course and data from incident report cards were used as quantitative measures. Focus groups with participants of the course were used as qualitative tools to get in depth information of the course effect.

During the focus groups, students were asked questions related to their experience with the course, what they believed they had learnt from it, whether they had experienced situations in which patient safety was compromised, if they felt more capable to act safely in their daily practice, and how this feeling was influenced by their environment [10, 22].

Data analysis: data collection may be using any of the previously mentioned tools, may also involve others. They may be just quantitative, qualitative or a combination of both as the case in mixed methods approach.

In either case, there are three interconnected elements to consider in terms of data analysis [23]:

- Data display; which refers to organizing information collected in a meaningful way;
- Data reduction; which means simplifying and in other words transforming the raw information into a more workable or usable form;
- Conclusion drawing; which is closely related to constructing meaning from the data, with respect to the evaluation question(s).

So, by this time, we have developed our evaluation plan, collected our data and analyzed their results. Here comes the stage of disseminating these results to the relevant bodies.

6.2.3. Step 3: disseminating findings and taking action

This is a crucial step that should not be overlooked. In some cases the conclusions and recommendations of evaluations are not acted upon, and as a consequence this will lead that the reached valuable information is not feed-backed in a meaningful way to all relevant stakeholders. In some instances, the results of evaluation are concerned with the quality of patient safety teaching, so these results (e.g. from student questionnaires, peer observed teaching sessions) must be relayed to and discussed not only with administration, but also with the teachers. The key here in education is to provide an effective constructive feedback. Brinko provided an excellent review of best practice on the process of giving feedback for students or colleagues. It is important that any feedback is received in a way that encourages growth or improvement of learners. Meanwhile, If the evaluation focuses on the effectiveness of the patient safety curriculum, any conclusions and recommendations for improvement must be communicated to all who had a share in implementing the curriculum (e.g. at faculty, teacher and student levels).

The dissemination step may be in the form of reports or concerned bodies meetings and its format must be meaningful and relevant. Effective communication of evaluation outcomes, findings and recommendations is a key catalyst for improvements in patient safety teaching and curriculum design [24].

6.3. Used evaluation models

One of the reported evaluation models was evaluation of patient safety initiative using the CIPP which stands for (Context, Input, Process, and Product) model. The framework emphasizes multiple stakeholders' interests (e.g. patients, providers, researchers). In this context, many methods fundamental to formative evaluations were used, including use of logic models to frame the evaluation, use of interview and focus group techniques to collect data, triangulation of results from multiple stakeholders, and feedback about the findings to help to strengthen the program.

In CIPP framework, evaluation emphasizes on documenting what happens in a program including the contextual factors that influenced what occurred. The evaluation shifts its focus according to changes occurring in the program over time, and its intention is to influence

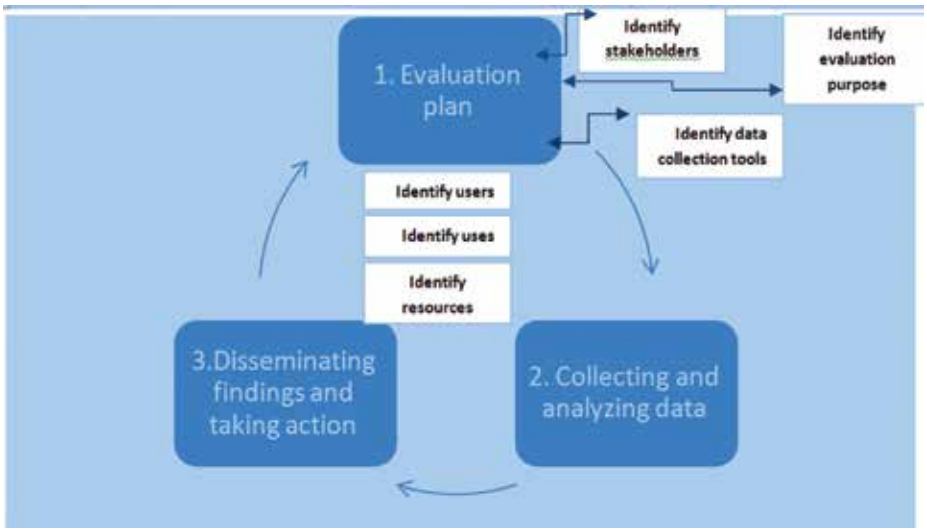

Figure 1. Diagram of the steps of the curriculum guide evaluation.

these changes. In this model, evaluation takes several steps, in the first evaluation year, the context and input aspects of the CIPP model are the main focus as well as early experiences in implementing the initiative. The context and input portions of the evaluation were used to examine the strategic aspects of the initiative, which are the circumstances leading to the development of the patient safety initiative (context) and, the strategies followed to carry out the initiative (input). Thereafter, in later evaluation years, the focus is directed towards the process evaluation addressing the operational aspects of carrying out the activities involved, taking into consideration how these activities contributed or may be contributing to the main goal of improving patient safety curricula. Meanwhile, there is a regular update on the information on context and input to assess how changes in the strategic aspects of the initiative had effect. Finally, the last step is the product evaluation, this is performed by measuring the effects of the patient safety initiative on various stakeholder groups [25].

The steps of the evaluation process for WHO curriculum guide are summarized in the below diagram. Three steps of evaluation are represented: first, evaluation plan which is followed by the second step which is collecting and analyzing data, then the third step of disseminating findings and taking actions (**Figure 1**).

7. The conceptual framework for patient safety curriculum development

In this chapter, we propose some essential steps while developing a curriculum in patient safety for healthcare professionals. In these steps, the developed curriculum is best tailored to the learners' needs.

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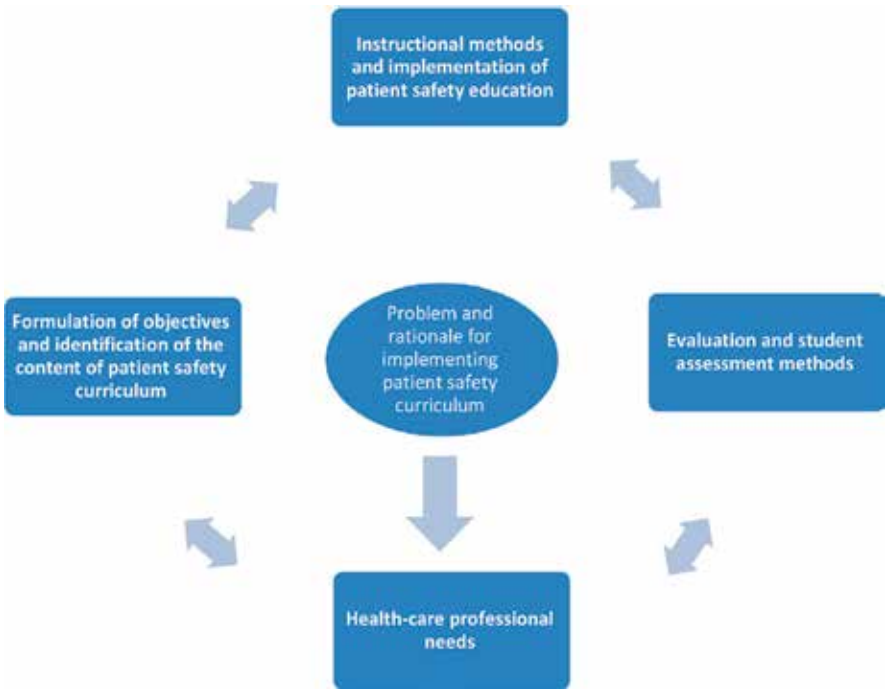

Figure 2. The conceptual framework for patient safety curriculum development.

The topics are selected according to the recourses available and it is better integrated into the whole undergraduate curriculum. The objectives are well-defined, competency-based and directly related to the selected content. The instruction should be practice-based and student-centered. Following this systematic approach maximize the role of the evaluation of students and curriculum in judging the merits of the implemented curriculum. These steps are illustrated in the conceptual framework (**Figure 2**).

8. Conclusion

In brief, patient safety is now of international interest and healthcare providers need to learn its principles. Meanwhile, educational strategies involve learning by doing and reflections are essential to bridge the gap between theory and practice. Therefore, patient safety curriculum should be integrated with all levels and years of education. It should be also multidisciplinary and multi-professional. Students should be involved in the health services and have the opportunity to apply the learnt knowledge and performance and reflect on their practices. The outcomes and impact of the implemented curriculum should be continuously evaluated to ensure that skills of the health professionals regarding keeping a safe environment, for both them and the patients, are acquired and such skills are recognized as other clinical and professional skills. All this will increase the effectiveness of health care system and decrease

the occurrence of adverse events associated with health services. Thus, teaching patient safety is mandatory.

Vignette 1.

Mr. Hassan is 75 years old male. He suffered from hypertension several years ago. He began to complain of numbness of his left jaw 2 days ago. He went to a large hospital, an intern who is still under training performed neurological examination and said he is neurologically free, and he did not recorded his main complain. He decided to go to a private clinic, the doctor measured his blood pressure which was elevated and prescribed him drugs for hypertension and ignored his main complain.

Two days later, Mr. Hassan condition deteriorated, his speech became sluggish and he became delirious and unable to stand steadily, later he became unconscious. Then, he arrived to the emergency and a CT was performed which revealed a cerebral hemorrhage

Vignette 2.

Mr. Ali is 60 years old male, he is diabetic, he had Hyperglycemic coma and transferred to the emergency department. Doctor A examined him and wrote down the exact medication and gave the prescription to the nurse. She was on the last minutes of her shift after 12 hours work time. She gave Mr. Ali the proper medication, and then she left the workplace without informing her teammate. Another nurse saw the doctor note and gave Mr. Ali the same medication again. Few minutes later, Mr. Ali began to sweat and he developed tremors and tachycardia. Then he became drowsy with respiratory distress.

Vignette 3.

Mrs. Samah is 45 years old female. She underwent cholecystectomy. Few weeks after operation, she felt abdominal pain and she went to another doctor who diagnosed her condition as gastroenteritis and prescribed her antibiotics and analgesics. Her condition worsened and she felt sever pain in her abdomen and when she arrived to the emergency she was diagnosed as having acute abdomen. The ultrasound revealed that a part of the intestine was sutured with the previous surgical wound, effusion and adhesion were developed, and the patient had to undergo another operation.

Conflict of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the chapter.

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Chapter 7

Adverse Events during Intrahospital Transfers: Focus on Patient Safety

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Additional information is available at the end of the chapter

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Abstract

Intrahospital transport of patients constitutes an integral part of care delivery in the complex environment of modern hospitals. In general, the more complicated and acute the patient's condition is, the more likely he or she will require both scheduled and unscheduled trips. The purpose of this chapter is to highlight the potential adverse events associated with intrahospital transfers (IHTs), to discuss the interdepartmental handoff process when patients travel within the walls of a single institution, and finally to provide strategies to prevent adverse events from occurring during the IHT process. A comprehensive literature review, covering some of the most recent developments in this area, has been included in this manuscript. Aspects unique to this presentation include sections dedicated to risk assessment, commonly seen patterns of transfers and complications, as well as the inclusion of family communication as a core component of the process. The overall goal of providers and patient safety champions should be the achievement of "zero incidence" rate of IHT-related events. We hope that this chapter provides a small, but significant, step in the right direction.

Keywords: patient safety, intrahospital transfers, transport checklist, critical illness

1. Introduction

Intrahospital transfers, especially those involving high-acuity patients, are inherently complex processes, with levels of direct and indirect risk inextricably tied to a multitude of difficult-to-control factors [1]. Although many diagnostic and treatment modalities are being increasingly "brought closer" to the intensive care unit (ICU) bedside, sporadic IHTs are still necessary

throughout each ICU patient's typical stay [2–4]. In addition, non-ICU patients also require complex, highly coordinated, movement to multiple departments and locations. Interestingly, the non-ICU patient group has been found to constitute the majority of medical emergency calls in a recent study [1].

From the time of initial admission to hospital discharge, a complex meshwork of diagnostic testing in departments separated by considerable distance, and often with multistage trips required to provide life-saving surgical and nonsurgical therapies, combine to create a significant amount patient risk. Frequently this is both poorly appreciated and difficult to manage [5, 6]. Due to this elevated potential for complications, the need for IHTs is frequently questioned due to valid concerns regarding patient safety (PS). Over the past two decades, multiple safety issues surrounding the transfer of patients between different units within hospitals have been identified, described, and investigated [1, 5–7]. Following an introductory clinical vignette, this chapter summarizes key aspects of PS in the context of IHT, focusing on minimizing the risk associated with medically necessary transfers and appropriately managing the risk of unplanned intrahospital transfers. Although our focus will be primarily on the critically ill patient population, most concepts discussed herein apply across all hospital and healthcare settings.

2. Clinical vignette

A 41-year-old female was admitted to the ICU for severe acute pancreatitis secondary to alcohol abuse. During the initial 72 hours, she underwent massive (>12 liters) crystalloid fluid resuscitation. Due to the development of concurrent acute respiratory failure, she required endotracheal intubation on the third hospital day. Portable chest radiograph showed increasing bilateral infiltrates. Overnight, the patient was noted to have increasing oxygen requirements, necessitating a transition to a more advanced mode of ventilatory support. She also experienced worsening agitation, fevers, and progressively decreasing urine outputs. The ICU team suspected that the patient developed necrotizing pancreatitis, and it was decided to obtain a computed tomography (CT) scan of the chest, abdomen, and pelvis. After meticulous planning, the patient and her bedside care team, including primary nurse, ICU resident, and respiratory therapist, proceed downstairs to the CT imaging suite. The brief elevator trip was largely uneventful, with only a self-limited, brief period of tachycardia and hypertension. While in the Radiology Department, the patient became increasingly agitated and difficult to ventilate, necessitating ventilation by bagging. After obtaining non-contrast CT images of the abdomen and pelvis, it was decided that further imaging would carry too much risk. After aborting any further CT studies, the patient was transferred back to the ICU, where she subsequently declined clinically to the point of requiring pharmacological paralysis for worsening respiratory failure over the next 24 hours. The patient eventually recovered but was unable to be discharged to home and required a combined 6-month inpatient and outpatient rehabilitation course before returning to work. Following this incident, important questions arose: Was the respiratory worsening in the CT suite preventable? What measures could have been taken by the team to safely obtain required images without putting the patient's well-being at risk? Were there any warning signs that could have prompted the team to either postpone the CT study or to proceed with more caution?

3. The importance of team communication

As discussed in other volumes and chapters of *The Vignettes in Patient Safety*, the importance of team communication is critical to ensuring the focus on safety throughout the entire healthcare experience of each and every patient [8, 9]. Because IHTs involve high-risk care transitions with complex handoffs between providers, clinical units, and different departments, it is essential that meticulous attention to every single aspect of the overall process is given in order to deliver optimal and safe care [10, 11]. When categorizing various safety occurrences during IHTs of nearly 600 patients involving more than 900 transfers, it was noted that patient care issues contributed to about 45% of total events, followed by poor documentation (32%) and finally various process-related findings (23%) [12].

According to Warren et al. [13], pre-transport coordination and communication are critical to the overall success of the IHT process, including the confirmation of readiness by the receiving department. Whenever care transitions occur, the responsibility for the patient's care shifts to the team that will temporarily assume direct bedside decision-making capacity. In the context of high-acuity ICU patients, such transitions require both physician-to-physician and nurse-to-nurse communication, including detailed review of the patient's most current condition and the associated treatment plan(s) every time patient care responsibilities are transferred [13]. As always, interdisciplinary dialogue and collaboration are critical to successful, complication-free patient outcomes [14, 15]. In this overall context, it is important to remember that significant proportion of IHT-related adverse events may be preventable [16] and that all too often medical emergency responses during IHTs are associated with preexisting "warning signs" of supplemental oxygen use, tachypnea, and tachycardia [1]. The movement of critically ill or injured patients, even in the most complex and austere environments, has been consistently performed by the US Air Force Critical Care Air Transport Teams (CCATTs). Over the preceding 10 years, an en route mortality of less than 1% was achieved only with rigorous training, preparation, and attention to real time and potential obstacles. Following this established model can greatly reduce IHT-related complications [17]. Even with such advanced level of preparation, a 10% incidence of transport-related events did occur and included oxygen desaturations, hypotension, worsening of neurologic status, and declining urine output. However, during 656 patient moves, there was no dislodgement of airway or chest tubes [18].

4. The impact of IHT-related complications: focus on common themes

The cumulative incidence of complications associated with IHT ranges from 22 to 67%, depending on patient characteristics and clinical acuity level [19–24]. Among all occurrences, more severe "critical" incidents take place during 2.4–7.8% of IHTs, depending on the urgency of the transport [25]. Of interest, one study reported that most emergency medical responses in the medical imaging department involved noncritical patients, with 43% occurring during the first day of hospitalization [1]. In critically ill patient population, the most commonly occurring events during IHTs for therapeutic or diagnostic procedures were oxygen desaturation, patient agitation, and perhaps most concerning, unplanned extubation and hemodynamic instability

[21, 23]. Specific risk factors associated with adverse events during IHT include emergent/urgent indications for the trip, the presence of mechanical ventilation, transport for diagnostic procedures, number of infusion pumps, duration of the overall process, and sedation requirement [21–23]. When transported patients require mechanical ventilation, the need for positive end-expiratory pressure (PEEP) ≥6 cm H_2O was associated with increased incidence of adverse events [21, 23, 26].

Unanticipated loss of airway can be catastrophic in the setting of respiratory failure [5]. In addition to the direct threat to the patient's life, hypoxic events pose the risk of exacerbating other critical conditions such as traumatic brain injury or cerebral infarction [27, 28]. Multiple factors can lead to loss of airway, including mechanical dislodgement or kinking of tracheal tubes, oversedation in non-intubated patient, under-sedation in intubated patient, malfunction of medication delivery infusion pumps, among many other possibilities and combinations thereof [29–33].

In a single-institution prospective observational study of 184 patients undergoing 262 IHTs, major complications were noted among critically ill patients undergoing CT scans, including both patient-related and equipment-related incidences [22]. The most common patient-related events included oxygen desaturation, unplanned extubation, unanticipated central line removal, and episodes of hemodynamic instability with increased vasopressor requirement. Equipment-related events included ventilator malfunctions, oxygen supply problems, and battery charge problems involving monitors or infusion pumps [22]. It is important to mention that among major events occurring during IHTs, approximately 40% are cardiac, 30% respiratory, and approximately 25% neurologic in nature [1].

Deterioration of respiratory function during and after IHTs is a known and serious issue that eludes satisfactory solutions [34]. Multiple potential causes include recumbent position for transport, the lack of PEEP valve use during transport "bagging," and inadequate ventilator support with "transport" ventilators. In one report, nearly 84% of post-IHT patients were noted to have a decreased PaO_2/FiO_2 ratio, with the worsening lasting >24 hours in 20% of cases [34]. There is conflicting evidence regarding the association between ventilator-associated pneumonia and IHTs. Although no significant relationship has been demonstrated in one study [22], another report comparing 118 mechanically ventilated patients undergoing IHT with 118 ventilated patients who did not undergo IHT showed that intrahospital transfers were independently associated with ventilator-associated pneumonia [35]. This is certainly very concerning given the potential harm to the patients and the increasingly severe penalties for hospitals reporting healthcare-associated infections [36].

In our review of current literature, few deaths are directly attributed to complications that occur during IHT; however, there continue to be a plethora of potential risks related to the totality of all adverse events associated with IHTs [26, 37]. For example, it has been noted that even the simple act of transferring a patient from their hospital bed to another resting surface (e.g., bed or stretcher) was associated with significant harm, including falls with injuries [38]. Patients requiring medical emergency response during the IHT have been noted to require higher level of care in 70% of cases [1]. Moreover, a correlation may exist between IHTs and longer ICU stays [39], although this requires independent confirmation. Excluding patient

transfers involving escalation of the level of care [40], the best estimate of direct and indirect mortality attributable to IHTs, based on the totality of the reviewed literature, appears to be anywhere between 0 and 3% [1, 6, 16, 41].

5. Team planning and preparation

The success of the intrahospital transport of a critically ill patient depends on the ability of the clinical team to plan the transfer, monitor, and provide any necessary intervention [37]. The degree of collective experience and skill that a transfer team possesses can directly affect patient outcomes. Consequently, the involvement of appropriately trained and experienced medical personnel during patient transfers, especially those involving ICU level of care, is vital to promoting patient safety [22, 42]. The transport team for a critically ill patient should consist of three providers, all possessing critical care experience and training specific to patient transport [22]. It is recommended that this team include a physician with experience in airway management, critical care nurse, and respiratory professional familiar with mechanical ventilation equipment [13, 22, 43]. Collectively, such multidisciplinary team can effectively anticipate potential problems during transport [42, 44]. All members of the transport team should have appropriate training in patient transport and either direct experience or documented observation of patient transport teams [5, 13]. Finally, specialized/dedicated transport teams allow the primary ICU personnel to remain with other patients during time-consuming IHTs while ensuring the availability of expertise required for safe and effective transfer process [42].

When planning an IHT originating from the ICU, the patient's nurse and physician should communicate with the transport team about the patient's condition, known/possible risks, and/or specific needs during the transfer [43]. If the patient has an orthopedic or neurological injury, then a specialist from that field may need to be consulted to prevent the exacerbation of the injury during transfer (e.g., by ensuring that traction or fixation devices are properly operated and configured) [5]. Team planning should include the estimation of total transfer time, preparation for administering any dose- or time-sensitive treatments such as scheduled medications and continuous drips, and ensuring that any drains or wound dressings are functioning properly throughout the entire process [44]. The team should plan the route that will be taken through the hospital and ensure that it will be clear/passable at the time of transfer. The route and time of the transfer should be communicated to the necessary hospital personnel, such as security or respiratory professionals, so that necessary support can be provided to the transfer team [13]. Checklists for pre-, intra-, and post-transfer phases of IHT should be utilized assuring the presence of key patient safety aspects, including medication and equipment availability and functionality [45].

As the length/duration of IHT has been shown to impact patient outcomes, the transport team should be in contact with the receiving department to confirm readiness for immediate testing or procedure upon patient arrival to reduce or eliminate any unnecessary delays at the destination [13, 22, 43]. Not only are such delays problematic from the PS standpoint, they also

preclude transporting personnel from effectively tending to other patients. If the intended diagnostic or therapeutic procedure is lengthy and the receiving team has the personnel and resources to adequately care for the patient, then care can be transferred via direct personnel communication and written documentation of the patient's condition, treatments, and transfer details [13, 44]. If the approximate time spent at the destination is short or that particular department does not have the staff or resources needed to adequately care for the patient, then the transfer team should remain with the patient for the entire duration of the procedure and transport back to the point of origin (e.g., ICU) [43].

Effective navigation of the physical landscape of the hospital, including hallways, building connectors, and elevators requires careful planning and attention to detail. Excellent knowledge of the facility, including any potential construction or maintenance activities, is needed to avoid unexpected delays and/or dangerous backtracking. For example, some multibuilding medical centers feature connecting bridges only on certain floors, and travel on the incorrect level may result in unnecessary delays. It has indeed been noted that a small, but by no means trivial, number of IHTs were complicated by the team becoming either "lost" en route to their destination or unexpectedly "trapped" in an enclosed space, such as an elevator [24]. This is especially important when using battery-operated equipment that provides vital support to the patient. Communication regarding the overall status of the process is also crucial to the safe transport of patients [6, 46]. Finally, providers must be cognizant that while substantial proportion of adverse events involving IHTs occurs in radiology departments, the most susceptible type of diagnostic test appears to be computed tomography (CT, 42% of occurrences) [1].

6. Overview of IHT complication types

At this juncture, we will highlight specific IHT complication groups and types. Because the overall topic is quite vast, we will only "scratch the surface" of the different categories of patient safety events that can occur during intrahospital transfers. Rich referencing will be provided so that the reader can consult with source studies and manuscripts. To further compensate for lack of granularity, we will encourage our readers to think more broadly and to instead apply the principles learned throughout this and the other chapters of the *Vignettes in Patient Safety* cycle.

7. Cardiac and pulmonary complications

As discussed earlier in this chapter, cardiac and pulmonary complications are among the most serious and clinically impactful events during IHTs. This group of heterogeneous occurrences can take multiple manifestations, from acute respiratory failure to permanent cardiac or pulmonary impairment (e.g., pulmonary embolism and its sequelae). It is now well established that IHTs are associated with significant risk of healthcare-associated pneumonia [35]. In fact, the odds of this serious complication increase 3.1-fold among ventilated patients undergoing IHTs during their ICU stay [35]. Moreover, IHTs were associated with increased risk of

thromboembolic phenomena, thus predisposing affected patients to a broad range of both acute and more chronic cardiovascular and pulmonary complications [39]. Cardiac arrests and severe dysrhythmias during IHTs have been reported, and despite their usually grave nature, attributable deaths have fortunately been uncommon [19, 24].

8. Hemodynamic parameter excursions

An extension of the preceding paragraph on cardiopulmonary complications, this section will briefly discuss the potential occurrence of unplanned blood pressure and heart rate gyrations during IHTs. The importance of hemodynamic parameter excursions is highlighted by the fact that approximately one in six patients who experienced adverse events during IHTs had a cardiovascular diagnosis and that nearly 40% of reported events were cardiac in nature [1]. Both high and low blood pressures can have deleterious effects on the patient's clinical condition, and both extremes can be attributable to common factors. For example, elevations of blood pressure can be due to intravenous pump malfunction resulting in interruption of analgesic infusion, yet the same patient during the continuation of the same scenario can then become profoundly hypotensive as multiple doses of analgesic medication are given to compensate for the severe pain that initially led to hypertension. If not promptly treated, severe hypertension can be associated with end-organ damage [47, 48], highlighting the need for immediate recognition and management of unplanned blood pressure elevations during IHTs.

A cause for great concern in the critically ill patient, hypotension is an all-too-common complication during IHTs. This adverse event can occur as a result of multiple inciting events, including malfunctioning infusion pumps (e.g., during active infusion of vasopressor), airway dislodgment (e.g., the presence of acute hypoxia), impromptu medication boluses (e.g., beta blocker or calcium channel blocker administration for atrial fibrillation), worsening sepsis (e.g., immediately following deep abscess drainage), cardiopulmonary factors (e.g., hemodynamic device disconnection), and many other potential causes [49]. It has been noted that hypotension is among key secondary insults that affect outcomes in patients with traumatic brain injury [7]. In addition, episodic hypotension results in intermittent hypoperfusion of vital organs, including but not limited to the heart, kidneys, bowel, and liver [50, 51].

Episodic heart rate gyrations, especially those outside of the generally accepted normal range, can be associated with systemic hypoperfusion [52–54]. These potentially dangerous occurrences can be due to intrinsic cardiac causes (e.g., aberrant conduction pathways) or a plethora of extrinsic factors (e.g., tachycardia secondary to vasoactive medication infusion or uncontrolled pain, bradycardia associated with beta adrenergic blockade or acute vasovagal response). Various commonly used vasoactive infusions and intermittent medications have the potential to contribute to both heart rate and blood pressure gyrations, leading to potentially harmful hemodynamic manifestations [55–57]. In addition, pre-IHT abnormalities in blood pressure or heart rate may be a harbinger of adverse events during the trip. Thus, personnel accompanying the patient during IHTs should conduct close monitoring of vital signs, medication infusion rates, and the functional status of infusion pumps [58–60].

9. Elevation of intracranial pressures

Among patients with traumatic brain injury, IHTs have been associated with significant elevations in both intracranial pressures (ICP) and reductions in cerebral perfusion pressures [61]. As alluded previously in this manuscript, this may be related to contributions from singular or combined factors, including primary hypotension, inadequate analgo-sedation, and unfavorable patient positioning changes during image acquisition (e.g., supine positioning for magnetic resonance imaging [MRI] or CT scan) [7, 61]. When ordering any diagnostic tests that may put patients with traumatic brain injury at risk, providers must always be aware of the potential for unexpected ICP elevations. A common source of technical complications for the patient being transported is the intracranial pressure monitor, usually an external ventricular drain (EVD) [62, 63]. Studies have shown that the EVD catheter may be subject to displacement, removal, or accidental blockage during patient transfer, particularly if the catheter contains a strain gauge rather than fiber optic sensor. The overall rate of catheter disturbance is estimated to be 5%, although these can be replaced or flushed as necessary [62, 63]. Further, all team members must be comfortable with basic therapeutic maneuvers for ICP normalization, including administration of analgo-sedation, mannitol, hypertonic saline, vasopressors, transient hyperventilation, and positional changes (e.g., head-of-bed elevation to at least 30°) [64].

10. Equipment-related events

This heterogeneous group of IHT-related complications spans an entire spectrum from catheter dislodgements and/or kinking to failures of negative pressure wound dressings [5]. In a report of IHTs involving more than 250 critically ill patients, it was noted that a large proportion of unexpected occurrences were associated with some form of "equipment malfunction" [37]. In our review of the literature, common types of equipment failures included "oxygen probe displacement" [37], "physiologic and equipment alarm issues" [5, 22], "tube/drain dislodgement" [6], "loss of intravenous access" [65], "wound dressing integrity issues" [5], "battery-related problems" [22], and "loss of suction" [26]. Because some types of equipment malfunction can result in fatal outcome, appropriate provider/team training and careful planning prior to IHT are mandatory to avoid preventable complications [66–68], especially in patients whose management may be challenging to begin with [69]. Positioning changes can be especially risky for patients with multiple catheters or tubes, where each additional device adds an extra layer of complexity.

11. Risk assessment procedures and protocols

The need for major corrective steps has been reported in over one-third of all IHTs [70]. Coupled with the fact that adverse events of differing magnitude may occur in as many as 70% of IHTs [71], increasingly vocal calls are being made for improving PS during intrahospital trips. Beginning with team debriefing and equipment checks, the entire process should be conducted with utmost attention to the smallest detail. As outlined throughout the *Vignettes in Patient Safety* book

cycle, strict adherence to established PS protocols helps reduce the incidence of adverse events and improves a broad range of associated clinical outcomes [8, 72].

12. Special considerations

Transport of critically ill patients from the emergency department (ED) to the ICU is among the better researched areas within the broader domain of IHTs. The most common adverse events occurring during IHTs of critically ill patients from the ED to the ICU were equipment problems such as oxygen saturation probe failures, monitoring lead and intravenous line entanglements, hemodynamic parameter excursions, and problems related to analgesia, sedation, and paralytic medications [19, 24]. The most common serious adverse events requiring intervention included severe hypotension, declining level of consciousness requiring intubation, and increased intracranial pressure in brain-injured patients [24]. Of note, delays in transport from the ED to ICU can significantly impact patient outcomes, including both increased lengths of stay and hospital mortality [73]. The interdisciplinary nature of the process cannot be overemphasized, and all members of the team must respect each other's expertise and the ever-present potential for mishaps [14].

Another important, yet often overlooked type of intrahospital critical care transport involves patients on extracorporeal membrane oxygenation (ECMO) circuits [74]. While intrahospital transfers involving patients with acute respiratory distress syndrome (ARDS) can be challenging, the addition of an ECMO circuit adds an extra layer of complexity that requires significantly greater amount of team/provider expertise during IHTs [74]. Despite recent advances in device design, including miniaturization and simplification of the overall transport framework, extreme caution is required during any kind of "more-than-minimal" change in patient environs [75–77]. Consequently, providers caring for ECMO patients who require intrahospital transfers during their active therapy period must be able to handle not only the routine "sets of challenges" associated with transporting critically ill patients but must additionally be able to successfully tackle issues specific to ECMO. When examining interhospital ECMO transfers in terms of safety and efficacy, outcomes of patients transported by an experienced ECMO team appear to be comparable to outcomes for non-transported ECMO patients [78]. These data are likely translatable to intrahospital transfers.

13. Improving the safety of IHT

Good clinical practices and common sense provide a solid platform for making IHTs safer, as well as efficient. It is important to note that although our focus on preventing adverse events related to diagnostic and procedural patient trips is centered mainly on the ICU setting, it is well documented that significant proportion of unexpected occurrences may in fact be associated with IHTs involving non-ICU patients [1]. Several tools have been developed to address various safety issues associated with IHTs. Perhaps the most obvious and straightforward tool is the use of patient care checklists [12, 79]. Fanara et al. describe a comprehensive checklist that includes

Equipment and patient preparation
Patient labels
Preparation and equipment adapted to procedure
Sufficient medication, O_2, and electrical reserves
Breathing: Intubation secured and position confirmed on CXR Mechanical ventilation adapted to patient Intubation equipment, bag + valve + mask, suction catheters, and monitors
Circulation: Route for venous access isolated and secured Medication and fluid loading solutions Alarms adjusted and activated
Lines, cables, and drainage tubes
Transport team
Minimum of three escorts available including experienced doctor
Transport organization
Confirmation of timetable for procedure
Transport route clear, lifts, and emergency room available
Operational equipment for continuous treatment at sites of procedure
Clinical stability of patient
Preparation adapted to clinical status of each patient Breathing (as above) Circulation (as above)
Neurological status: GCS, pupils, and ICP
Sedation/analgesia
Breaks stabilized, burns, and wounds protected
Head raised if possible
Systematic check points following transport
A: airway = integrity of ventilation system
B: breathing = bilateral auscultation, insufflation pressure, spirometry, SpO_2, and $EtCO_2$
C: circulation = read monitor, check blood pressure, and isolate injection route
D: disconnect = plug O_2 and electrical supplies into wall socket
E: eyes = monitors are visible to transport team
F: fulcrum = check points of support

CXR = chest radiograph; $EtCO_2$ = end-tidal carbon dioxide; GCS = Glasgow Coma Scale; ICP = intracranial pressure; O_2 = Oxygen; SpO_2 = peripheral capillary oxygen saturation.

Table 1. Checklist for intrahospital transport of critically ill patients. Modified from Fanara et al. [79].

both patient and equipment assessment prior to transport, an evaluation of patient stability during transport, and a complete repeat assessment after the patient is moved (**Table 1**) [79].

Nurses play a critical role in ensuring patient safety during IHTs through both adequate communication and meticulous patient monitoring, as well as managing patient handover protocols [25, 80]. A potentially helpful clinical intrahospital transport tool was described by Brunsveld-Reinders et al. [45]. The tool utilizes a pre-transport, intra-transport, and post-transport checklist in order to ensure proper functioning of equipment; adequate supply of medications, fluids, and oxygen; and continuous patient monitoring [45]. Pre-IHT patient assessment deserves further mention, especially when one considers that among patients who required medical emergency response while in a diagnostic department, nearly 40% of patients arrived receiving supplemental oxygen administration, almost 30% had tachypnea, and approximately one-third had tachycardia [1].

Hemodynamic and other forms of patient monitoring during transport are becoming more advanced, and the availability of clinical data can be leveraged to improve the quality and safety of IHTs. For example, when transporting brain-injured patients, more frequent or continuous neuromonitoring by using intracranial pressure and end-tidal CO_2 determinations throughout the IHT duration has been proposed as a means to reduce both hemodynamic and neurological complications [81]. It has also been postulated that critically ill patients undergoing IHTs be accompanied by an intensivist or experienced attending physician in order to reduce adverse events [24, 37]. This particular aspect may be important for the most critically ill patients, where the impact of even the smallest errors, including omissions during the handover process, may result in major clinical setbacks [46].

Finally, ensuring operational readiness of medical equipment, particularly mechanical ventilators, is crucial during the IHT of critically ill patients [6, 23, 79]. It has been suggested that hospital transport stretchers/beds incorporate key functional components (e.g., high-capacity batteries, monitoring equipment core units, built-in suction pumps) and intelligent sensing instrumentation to prevent the snagging and tangling of leads and lines and discontinuation of critical functionalities [24, 78, 82].

14. Family communication

Transporting critically ill patients is inherently associated with adverse events that have the potential to change the patient's medical condition; thus it is reasonable to treat transports in a manner similar to that of any other medical treatment. In respect of the patient's right to privacy and autonomy as well as compliance with the Patient Self-Determination Act [83, 84], the patient's wishes regarding communicating medical information to family members, the patient's advanced directive, and proxy appointment(s) should be established as part of general consent to treatment. If the patient is not competent to make a determination, then the patient's appointed proxy or next of kin should be consulted to give informed consent for the transport and procedure on the patient's behalf. Majority of patients express wishes that their families be kept informed regarding their condition, and when this is the case, medical personnel have a responsibility to communicate clearly and efficiently with families so that good understanding of key diagnostic and therapeutic issues exists [85]. When a critically ill patient requires potentially risky IHT, families should be made aware of the patient's condition, reasons for transport, and the risks and risk–benefit consideration associated with both the transport and procedure [5].

Medical personnel should communicate with the family before the transport about the projected time, duration, destination, and expected benefit or outcome of the process. Thus, proper expectations can be met, and family members are provided with basic goals and parameters regarding the overall clinical context [86]. Prior to the transport, the patient's proxy or next of kin should be available, and their phone numbers should be obtained by the transport team in case of unexpected events, especially if the patient is not decisionally competent or becomes noncompetent during the transport or procedure. When the patient is stabilized at the destination or returned to the ICU, the patient's proxy and family members should be informed and updated on the patient's condition by a member of the transport team [86–88].

15. Conclusions

Intrahospital transfers are among some of the most dangerous, yet necessary endeavors that hospitalized patients require during the implementation of diagnostic and therapeutic plans. Although the overall risk profile of IHTs depends on patient acuity, other factors are important risk determinants as well, including location and distance between hospital departments, team member knowledge and communication, the complexity of medical management, and the equipment involved. Significant amount of provider/staff training is required to optimize the team performance and minimize the overall risk of an adverse event occurring during an IHT. Healthcare professionals are encouraged to strictly follow the fundamentals of patient safety, as outlined throughout the *Vignettes in Patient Safety* cycle, to help reduce complications and to propagate a culture of safety throughout their clinics and hospitals.

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Chapter 8

Transfusion Error in the Gynecology Patient: A Case Review with Analysis

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Additional information is available at the end of the chapter

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Abstract

Emergency blood transfusion (EBT) is a life-saving intervention which also carries a significant risk of harm in the event of a transfusion reaction. Our chapter starts with a hypothetical case study of a gynecology patient who underwent emergent hysterectomy with severe hemorrhage managed with an emergency blood transfusion. During the aggressive resuscitation, the patient was inadvertently transfused with blood products that had been allocated for another patient. Through this clinical vignette, we review the operational aspects of an EBT and identify sources of transfusion-related errors. We emphasize best practices that can be implemented with the goal of improved patient safety. This chapter offers a concise, practical review of EBT for our readers.

Keywords: transfusion error, massive transfusion protocol, postpartum hemorrhage

1. Introduction

Transfusion medicine is used to manage the bleeding patient. An emergency blood transfusion (EBT) protocol describes how a massive blood transfusion (MBT) can be performed in an effort to compensate for the blood loss of a severe hemorrhage. Not every EBT is an MBT: in a patient with a low cardiopulmonary reserve, moderate blood loss can require an EBT but not the volume of an MBT. Near miss and sentinel events in the hospital setting continue to represent a significant concern for patient safety [1]. In the context of blood transfusions, a "near miss" event includes any error that could cause administration of an incorrect blood product but is recognized prior to the start of transfusion. Failure to recognize the error can result in the sentinel event of acute hemolytic transfusion reaction (AHTR) due to major blood

group incompatibility [2]. AHTR was a leading cause of transfusion-related mortality from 2005 to 2009, second only to transfusion-related acute lung injury (TRALI) [3].

The blood administration process is challenging in a chaotic, often time-sensitive environment that employs high-volume blood transfusions to prevent a hemorrhaging patient from dying. This combination of factors creates a formidable risk to patient safety [1]. Optimal strategies have been developed to standardize the management of blood transfusions in the setting of a severe hemorrhage, irrespective of its etiology.

This chapter describes select best practices and identifies system vulnerabilities that may lead to near misses and sentinel events so as to improve patient outcomes and provide an error-free delivery of blood products. We also review potential solutions that our institution has implemented to decrease the transfusion error risk associated with blood product administration. The case review subsequently underscores how imperative it is to identify the critical steps within the process of blood transfusions so as to prevent error.

2. A case review

A 48-year-old female presented to the emergency room of a busy community hospital with the chief complaint of a syncopal episode. She had a history of heavy menstrual bleeding caused by multiple uterine fibroids. Upon arrival, the patient was actively bleeding per vagina. She was pale, but alert and oriented, was tachycardia at 120 beats per minute, and had orthostatic hypotension.

Her past medical history was significant for a DVT while using combined oral contraceptive pills approximately 20 years before. Her past surgical history included a laparoscopic bilateral tubal ligation. She was scheduled to undergo a hysterectomy later that month secondary to her history of heavy menses and her contraindication to estrogen therapy.

While being evaluated in the emergency room, her initial blood work demonstrated a hemoglobin of 9 g/dL, down from her baseline of 12.5 g/dL. Her gynecologist was consulted who recommended performing the hysterectomy in the acute setting given her ongoing bleeding and contraindication to medical management. The patient agreed and consented for surgery.

On the same day, there was a second patient being admitted for a hysterectomy for endometriosis. The patient was known to have two atypical blood antibodies necessitating cross-matched blood to be prepared. The operating staff and blood bank were in close communication for this patient in an event of a hemorrhage.

The first patient was taken to the operating room where a total laparoscopic hysterectomy was performed. Secondary to the location of her uterine fibroids, the patient sustained a laceration to her right uterine artery upon manipulation of the uterus to better visualize the uterine vessels. During attempts to control this bleeding, a massive blood transfusion (MBT) was initiated using non-cross-matched O negative blood. The gynecologic surgeons were unable to properly visualize and control the source of bleeding and therefore converted to a laparotomy.

Upon arrival of the blood products, the patient was immediately transfused. The surgeons completed the hysterectomy but continued to observe significant and diffuse pelvic bleeding. At this

time, a surgeon noted that the blood being transfused was not O negative blood. The anesthesiologist was alerted and he immediately stopped the transfusion. The circulating nurse called the blood bank to notify them of the error. The blood bank personnel had incorrectly assumed that the MBT was initiated for the patient who had tested positive for the antibodies. The operating room staff removed all blood products from the operating room, and new O negative non-cross-matched blood was sent. By this time, the patient had developed a state of disseminated intravascular coagulation (DIC). With no identifiable active bleeding source, the patient's pelvic cavity and vagina were packed, and she was transferred to the intensive care unit (ICU).

The patient's ICU course included aggressive resuscitative efforts with multiple blood transfusions and ventilator support due to transfusion-related acute lung injury (TRALI). Once stable, the patient was taken back to the operating room for removal of packing and re-exploration where no active bleeding was noted. Fortunately, the patient recovered from her near-fatal injuries, and she was eventually discharged home with a close outpatient follow-up.

3. Discussion

Hysterectomy is one of the most commonly performed surgical procedures in the United States. Symptomatic uterine fibroids are the leading indication for the procedure, accounting for 52% of this procedure. Abnormal uterine bleeding is the indication for another 42% of hysterectomies [4].

Similarly, maternal hemorrhage is a leading cause of maternal morbidity and mortality worldwide. Its incidence varies widely but is thought to occur in 1–5% of all deliveries [5, 6]. This is a concerning fact since obstetric services are provided in 92% of rural hospitals [7]. These smaller hospitals do not have the same resources as their larger urban counterparts to handle severe hemorrhage from a variety of etiologies. For these smaller institutions, developing a standardized plan to manage emergencies such as postpartum hemorrhage is critical [7]. All surgical and emergency services should devise comprehensive approaches that identify, evaluate, treat, and monitor a hemorrhaging patient in order to stop bleeding at earlier stages, reduce the number of blood products transfused, and to reduce adverse outcomes [1]. The case review above demonstrates the need for an institution to establish and practice sound policies for the emergency preparation, transportation, and administration of blood products.

Root cause analysis (RCA) is a process with the primary aim of identifying any factors that may influence the nature, magnitude, timing, and/or occurrence of an error, keeping in mind that more than one root cause can impact an event. Through such a methodical approach, RCA is commonly employed after an occurrence of an error in order to develop and implement preventative strategies to improve future response and outcomes. Through this chapter, we perform a root cause analysis to systematically identify "root causes" of potential errors in the blood transfusion process.

Medical errors fall into one of two broad classes, errors of omission and errors of commission. An error of omission is one that occurs because an action was not taken, whereas an error of commission occurs because an incorrect action was taken [8]. The clinical vignette described

in this chapter is a combination of both types of error. The errors of commission are the blood bank sending the inappropriate blood to the operating room as well as the anesthesiologist administering the wrong blood to the patient. The failure of the blood bank to properly identify which patient was receiving the transfusion as well as the failure of the anesthesiologist to verify that O negative blood was sent to the operating room would be considered acts of omission. These omissions acted in conjunction with the errors of commission to result in a nearly disastrous outcome for the patient involved. Therefore, systems must be in place to combat both of these types of errors in order to keep patients safe in complex medical situations.

Secondary to human error, as many as one in 12,000 blood transfusions are administered to the wrong patient [1, 9, 10]. The serious hazards of transfusion (SHOT) Hemovigilance Program of England reports that mortality risk from transfusion in 2012 was one in 322,580 transfusion blood products while the morbidity rate was one in 21,000 [10, 11]. The transfusion of incorrect blood products, specifically ABO-incompatible blood, with resulting acute hemolytic transfusion reaction is one of the most grave and yet preventable causes of transfusion-associated morbidity and mortality [1, 12].

Transfusion-related acute lung injury (TRALI) is another rare life-threatening adverse event that can present to a recipient of a blood transfusion, as was seen in our patient in the clinical vignette [13]. The incidence is estimated to be approximately one in 5000 transfused units with more recent literature citing one in 12,000 blood products [14]. However, some literature argues that the true incidence is unknown secondary to underdiagnosis and underreporting. Regardless, TRALI rates are affected by patient population with an increased occurrence observed in critically ill patients [13]. As reported by the International Haemovigilance Network, TRALI is one of most common etiologies behind transfusion-related fatalities. Specifically, it remains the leading cause in the United States [13, 14]. The study has cited TRALI-associated mortality ranging from 5 to 8%, but up to 50–60% in critical care patients [13]. Respiratory symptoms typically present within 6 h of a transfusion of any plasma-containing blood products including intravenous immunoglobulin and cryoprecipitate [14]. TRALI is diagnosed based on clinical and radiographic findings indicating new-onset acute lung injury/acute respiratory distress syndrome within these 6 h [13]. Majority of patients require ventilator support with oxygen levels returning to pre-transfusion levels in 48–96 h [14].

Currently, there are two hypothesized theories behind the pathophysiology for TRALI. The "two hit model" is the most widely accepted hypothesis and postulates that TRALI occurs in two steps [14]. The initiating event occurs pre-transfusion and is thought to be related to the clinical condition of the patient such as recent surgery, infection, or burns [14]. This event will result in the activation of the pulmonary endothelium followed by neutrophil sequestration to this endothelium [13–15]. The second step involves the activation of neutrophils adhered to this endothelium. Activation typically occurs by donor-derived antihuman leukocyte antigen (HLA) or antihuman neutrophil antigen antibodies targeting antigens on these surfaces (HNA) [14]. The activated neutrophils then incite endothelial damage which results in capillary leak and pulmonary edema [14, 15]. This second step is postulated to be either immune-mediated or non-immune-mediated. The majority of TRALI is immune-mediated, whereby neutrophil and HLA class I and II antibodies initiate TRALI [15]. However, approximately 15–20% of cases are

non-immune, whereby other biological response modifiers in the transfused blood are believed to be the etiology behind the reaction [14]. These factors include bioactive lipids and sCD40L molecules, both of which are found in stored red cell and platelet components [15]. This may explain why TRALI reactions can also occur in the absence of donor-derived antibodies and why every blood transfusion does not result in TRALI [14]. Another model known as the "threshold model" is believed to support cases, whereby TRALI occurs in otherwise healthy recipients who receive donor blood [13]. This theory postulates that if the second event is significant enough, then a TRALI reaction may occur without the initial clinical event [13, 14].

Given the high morbidity and mortality associated with TRALI, many preventative measures have been instituted in an attempt to limit these adverse transfusion reactions. These aims include decreasing donor-derived antibodies in blood products with elevated levels of plasma. This is done by obtaining blood from male donors as opposed to females with a history of pregnancy [14]. A history of pregnancy places these patients at an increased risk of exposure to anti-HLA antibodies [14]. In addition, blood donor management strategies include the inability of patients who have had TRALI to donate whole blood or apheresis platelets [14].

With strategies in place to reduce these transfusion-related adverse events, there remains an additional complication to the blood transfusion process known as mistransfusion [16]. The SHOT program reported that nearly 30% of mistransfusions were a result of hospital laboratory or blood bank error [11]. These sources of error include the selection of the wrong blood sample for testing, inaccurate blood product labeling, technical errors, or incorrectly selected blood components of the wrong specification [11]. As such, an electronic pre-issuing system within the blood bank should be implemented to further reduce transfusion-associated morbidity and mortality [11]. As a best practice, blood bank staff members should

1. print the blood order request form with patient identifier information, blood product number, blood type, and the name of the ordering physician;
2. prepare the blood products, print a compatibility label with a bar code, and then attach the label to the blood product;
3. using a handheld device, sequentially scan the bar codes and include the staff member identifier, the original blood product label, the newly attached bar code label, and the compatibility report form; and
4. ask an additional blood bank staff member to verify whether the data on the handheld scanner matches the data on the labels and forms. If they do, the blood product is issued (**Figure 1**).

The SHOT hemovigilance scheme noted that up to 70% of transfusion errors are related to ABO-incompatible transfusion at the clinical bedside, with the majority of these errors attributed to a failure to properly identify the intended transfusion recipient [11, 17]. These sentinel events are unlikely to be caused by a single error in the transfusion process. Instead, a series of errors occurring together allow the opportunity for a sentinel event to occur [18]. Over the past decade, research has suggested moving toward an automated and computerized transfusion process, with the goal of decreasing human-related error [1, 9].

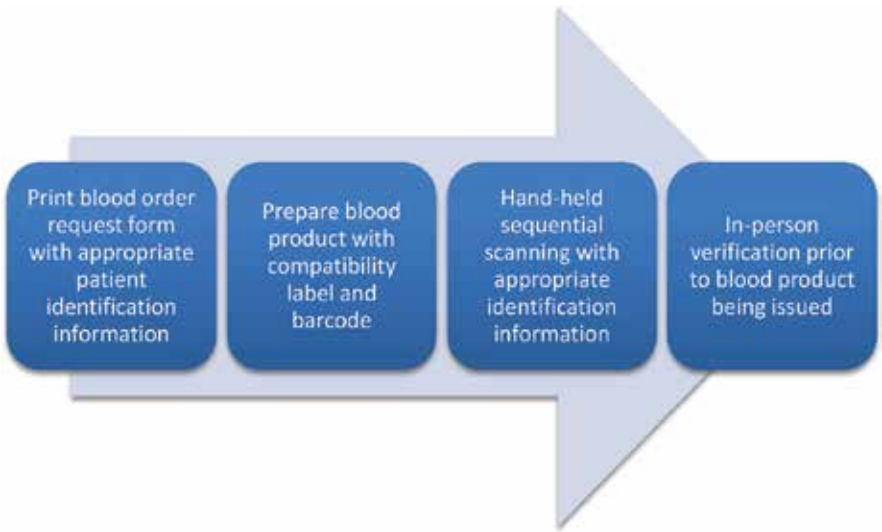

Figure 1. Serious hazards of transfusion (SHOT) best practice flowchart.

Implementation of a software-driven bar code tracking system in place of the conventional "nurse to nurse" double check system for the administration of blood products has been identified as a key strategy for improving transfusion safety [9]. The bar code on blood components identifies blood group, blood type, unit of blood, product number, and the date of collection [9, 10]. Several companies offer a bar code electronic identification system (EIS) which may be portable or built into the electronic medical system [11]. A portable handheld scan and print electronic device can be used to verify and document patient identity. Such a device is utilized at our institution [11]. The common components of the pre-transfusion check list to be scanned include the patient name, medical record number, and blood group [11]. If the bar codes between the patient wristband and blood products match, then the handheld device indicates as such [11]. The bar code EIS is linked to a network host computer that can store, search, and send transfusion data [11]. Multiple studies have indicated that the electronic bar code system is effective in reducing human error related to transfusion procedures as it acts as another barrier for error in the transfusion process [10]. In a time-sensitive event such as a massive transfusion protocol, safety checks including barcoding EIS may be omitted. This may reintroduce transfusion-related human error, such as incorrect blood product administration to the recipient.

Current research is exploring the use of smartphone or tablet devices in transfusion medicine with the aim of achieving enhanced integrity of the transfusion process [10]. In addition, systems utilizing radiofrequency identification (RFID) are being analyzed as a new way of integrating technology into blood transfusion best practice. However, high costs for an institution can be a barrier [10, 11]. RFID is a more user-friendly technology and can be applied to improve visual and bar code electronic identification systems [11, 16]. Radiofrequency transponder microchips have been utilized on patient wristbands, blood sample tube labels, and

blood product containers [1, 16]. The microchips are scanned by a handheld portable device and uploaded to a program with the operator alerted to a misstep and the program pausing until the error is corrected [16]. RFID can be used to further standardize and monitor blood collection, preparation, and transfusion in order to reduce transfusion-related human error and improve patient safety [16].

4. The operational aspects of EBT

The operational aspects of EBT present many challenges that can be overcome by planning and employing best practices. These challenges include describing how to recognize, initiate, and alert others to an EBT. A hospital system must also decide on what kind of blood products to store and how to prioritize select products when they are in high demand. In addition, determining where to store blood products and deciding how to transport them to the bedside require careful planning, especially when faced with multiple concurrent patients requiring EBTs. Personnel should also be trained on how to resuscitate patients while waiting for the arrival of blood products.

The first step in any EBT starts with the attending provider recognizing the need to transfuse. Common indications for EBT include an elevated Assessment of Blood Consumption (ABC) score, the presence of visible rapid blood loss such as that seen in postpartum hemorrhage, or the observation of even moderate blood loss in the setting of comorbidities such as low cardiopulmonary reserve. This list is not exhaustive. The ABC score is calculated by assigning a score of one to each parameter present: penetrating injury, positive focused assessment sonography for trauma (FAST), systolic blood pressure of 90 mm Hg or less, and an elevated heart rate of at least 120 beats per minute (**Table 1**). An ABC score of 2 or higher is 75% sensitive and 86% specific for predicting the need for massive transfusion (MT) [19].

After recognizing the need for transfusion, the second step in an EBT is to alert the blood bank. Our institution offers two levels of response to an EBT: emergency blood release (EBR) and an elevated response level of "code crimson" (CC). Either is initiated by a medical provider dialing a simple hotline—"5555" at our institution—that is answered immediately by the emergency operator. Notification of an EBR arrives in the blood bank via an alphanumeric

Criteria		
Penetrating Mechanism	No 0	Yes + 1
ED Systolic BP ≤ 90 mmHg	No 0	Yes + 1
ED HR ≥ 120	No 0	Yes + 1
Positive Ultrasound FAST Exam	No 0	Yes + 1

ED, emergency department; BP, blood pressure; HR, heart rate; FAST, focused assessment with sonography in trauma.

Table 1. Assessment of blood consumption score.

pager alert. By contrast, a CC is initiated by an overhead announcement broadcast throughout the hospital, alerting support personnel from anesthesia, surgery, trauma, intensive care, and emergency medicine to move toward assisting resuscitation of the patient. Either level of response can be initiated by pre-hospital professionals such as paramedics, transporting a hemorrhaging trauma patient.

Selecting which blood products to offer is an important decision made well before an alert is initiated. While regional blood bank centers can effectively offer continuous availability and supply of blood products to local hospitals—even at times of disaster [20]—there may be occasions when the hospital runs low on specific products, such as platelets or Rhesus negative blood. With only a small minority of the US population exhibiting an O negative blood group, the finite supply of O negative blood may dwindle in the face of ongoing massive transfusion. Switching to O positive blood reserves a minimal supply of emergency O negative blood for obstetric patients or other women of reproductive age who may need blood before depleted stocks can be replenished. This forethought helps prevent alloimmunization-associated problems in future pregnancies [21]. Aside from O negative blood, another scarce blood product is platelets. Though they can be used for up to 5 days after collection, the effective life of a pack of platelets is just 1–2 days by the time the collection is processed, tested, packaged, and transported from the regional blood bank to the hospital. Hospital blood banks can now take advantage of the Platelet PGD test (Verax Biomedical, Marlborough, MA) approved by the FDA in 2015 to extend the life of platelets by an additional 2 days, dramatically reducing the waste and expense of these products.

Once an EBT is initiated, the next consideration at some institutions is to determine which blood bank will respond. Close proximity to blood products is desirable, though not universally feasible. Many hospitals in America feature several hundred beds [22] that are spread across medical, surgical, obstetric, operative, intensive care, emergency, and trauma areas. A large campus with many buildings may have satellite blood stores. Attempts to minimize time and distance to blood products via the setup of decentralized blood refrigeration units add cost, complexity, and forgoes the expertise offered by specialized blood banking personnel during the early stages of an emergency transfusion.

After the appropriate blood bank has been alerted, the transport of emergency blood products to the patient requires a transport protocol. At our institution's centralized blood bank, an EBR utilizes a pneumatic tubing system (PTS) to move a maximum of two units of ice-packed erythrocytes, whereas a CC uses a human transporter—a "runner"—with a cooler. The cooler contains six units of iced erythrocytes, four units of thawed fresh-frozen plasma, and a single unit of platelets. Subsequent coolers are prepared regularly until the CC is terminated. The number of runners and their speed is the limiting factor in bringing blood to the patient, not the rate of cooler preparation. A PTS is faster than a runner [23], moving at up to 25 feet per second, often taking a route that is more direct than what is achievable by hallways and stairwells. PTS performance can be further enhanced with priority signaling or the use of dedicated tubing channels to patient areas that frequently require EBT, such as the emergency department.

Though advantageous in some ways, the PTS also has disadvantages. The dimensions and weight capacity of PTS containers can be limiting, with six containers needed to carry the cargo of a single cooler. Though rare, leaking blood product packaging can seep into the container.

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If the seal of a poorly maintained container is compromised, the leak can enter into the system tubing. Cleanup of a contaminated PTS system is a non-trivial task. Another limitation of PTS containers is that they arrive only in the vicinity of the patient and still require a runner for final transport to the bedside. A final concern with a PTS is that once a container enters the tubing system, the acceleration and speed of the system exerts at least some hemolytic effect [23].

In concurrent emergency transport of blood products for two or more patients, separate pneumatic tube containers or separate runners must be used to carry blood products for each patient. Runners should be instructed to avoid exchanges along their route to the patient. The requirement of a unique runner for each patient can be challenging to meet during off-peak times when staffing levels are reduced.

During the interval between recognition for the need of EBT and the arrival of blood products, medical personnel should work to prepare the patient for transfusion. The airway needs to be assessed and protected. Vital signs should be measured. If possible, an attempt should be made to correct the underlying etiology of the hemorrhage. Tourniquets should be applied to the bleeding wounds of trauma patients, packing should be used to tamponade bleeding surgical patients, and uterotonic agents should be administered in cases of postpartum hemorrhage. A blood sample should be collected to facilitate a type and cross-match, though providers should expect at least a 45-min wait time for the screen to be completed. Large bore needles should be inserted to establish intravenous access. A baseline set of hemoglobin, platelets, electrolytes including calcium, a calculated anion gap, creatinine, lactate, prothrombin time, partial thromboplastin time, and fibrinogen level should be drawn [21]. The patient should be warmed to help stop the development of a coagulopathy. Depending on the clinical situation, volume resuscitation using intravenous fluid boluses may be judiciously used. The infusion of a crystalloid may dilute the remaining platelets and coagulation factors as well as cause hypothermia.

The next step in an EBT lies in the administration of emergency blood products from the responding blood bank. Two different patient identifiers, such as hospital identification number and patient name, should be used by medical personnel to confirm the patient identiy [24].

While many different transfusion protocols exist, warmed erythrocytes, fresh-frozen plasma, and platelets are commonly transfused at a 1:1:1 ratio. Some centers have added 6–10 units of cryoprecipitate to their MBT practice to aid repletion of low fibrinogen levels [25]. However, there is a lack of high-quality randomized trials to show improved outcomes with the use of cryoprecipitate to raise fibrinogen levels [26]. The FDA's approval of the human fibrinogen concentrate drug RiaSTAP (CSL Behring, King of Prussia, PA) has been investigated in the off-label setting of MTP [27]. A second similar drug—Fibryna (Octapharma, Lachen, Switzerland)—was approved by the FDA in 2017. Further clinical trials are needed to establish whether human fibrinogen concentrates improve outcomes in severe hemorrhage featuring hypofibrinogenemia.

Irrespective of the products transfused, the rate of infusion is a prime concern. Rapid infusers such as the RI-2 (Belmont Instruments, Billerica, MA) inductively warm and infuse blood at selectable rates of up to 1000 mL/min. This speed can surpass the loss in a postpartum hemorrhage patient, in whom at term blood perfuses the placental site at a rate of 500–700 mL per minute [25].

In addition to the use of fibrinogen-rich medications or cryoprecipitate, anti-fibrinolytics also play a role in EBT. Tranexamic acid can safely reduce the risk of death in both trauma and obstetric-related hemorrhage [28, 29]. The drug must be administered within 3 h of bleeding onset. It is associated with a minimal adverse event rate [28].

Different solutions exist for bleeding while anticoagulated on warfarin. The prothrombin complex concentrate drug Kcentra (CSL Behring, King of Prussia, PA) can reverse coagulation factor deficiency induced by a vitamin K antagonist faster than fresh-frozen plasma [30].

Determining when to stop transfusing can also be challenging. An i-Stat device (Abbott Point of Care Inc., Princeton, NJ, USA) should be avoided if possible [31]. Evaluating the response to transfusion can be achieved via a serum hemoglobin value 15 min after transfusion. Other reassuring laboratory values include a platelet count greater than 50,000/μL, an international normalized ratio (INR) of less than 1.5, or a fibrinogen level greater than 100 mg/dL. Ultimately, the normalization of the patient's hemodynamic status in conjunction with visible signs of hemostasis should signal the medical provider to terminate the code crimson. Alternatively, the recognition of the futility of resuscitation should also be viewed as a terminal end point. Upon termination of the blood transfusion, unused blood products should be returned to the blood bank for refrigeration and storage. The blood products transported by runners or the PTS are continuously monitored thermally to ensure the integrity of returned, unused products.

5. Benefits of emergency blood transfusion protocols

EBT protocols facilitate the efficient ordering and transport of blood products for patients with moderate to severe hemorrhage. These protocols also ensure that an ongoing supply of blood products arrives at the patient's bedside until hemostatic control is achieved. Many hospitals have established an MTP. In obstetrics, 95% of hospitals with a postpartum hemorrhage protocol possess an MTP [32]. An MTP is traditionally defined as more than 10 units of pRBCs in 24 h or more than four units of pRBCs in 1 h.

An MTP can be used to manage severe maternal hemorrhage and improve patient safety. In their study, Shields et al. showed a faster resolution of maternal bleeding, the use of fewer blood products, and a 60% decline in the rate of DIC with the use of MTP [33]. In addition, the establishment of an MTP protocol led to both physicians and nursing staff reporting improved clinical knowledge and comfort level with responding to significant bleeding events.

Health-care providers have varying experience levels in dealing with EBT and MBT. The relatively low frequency with which MBT is encountered limits the accumulation of experience with severe hemorrhage. This suggests that standardized interventions are critical in order to achieve an optimal outcome. One way to gain experience and familiarity with standardized EBT protocols is through simulation.

6. Benefits of simulation

Simulation is used to train and familiarize providers with how to respond to emergency situations. By using team approaches to problem solving and utilizing root cause analysis, patient

outcomes can be continuously improved [34]. Such methods are highlighted in the *Joint Commission Sentinel Alert* publication that recommends the adoption of protocols to address, for example, morbidity and mortality associated with maternal hemorrhage [35].

There are many advantages to developing high-fidelity simulations. They include establishing a safe environment for patients and trainees, the opportunity for multidisciplinary team training, and the rehearsal of specific behavioral skills. In addition, simulations allow the difficulty levels of scenarios to escalate, providing multiple exposures to complex clinical scenarios. Simulators also allow the testing and learning of new technologies without exposing the patients to learning-associated risk [36]. High-fidelity simulators also allow individuals to train on demand rather than waiting for an uncommon or very specific situation to occur. Simulations allow for pause, discussion, feedback, and reflection in response to certain circumstances, as well as the opportunity to identify and correct recurrent mistakes in an expedited manner [37].

7. Error tracking systems

Though uncommon, transfusion-associated adverse events can occur in the emergency setting. In response, programs have been established that track these events. The goals of these programs are to ultimately improve patient safety by minimizing the morbidity and mortality of transfusion procedures. The programs also serve to identify emerging complications, including errors and near misses, as well as pathogens associated with blood transfusion. One such surveillance protocol is the National Healthcare Safety Network Biovigilance Component Hemovigilance (NHSN HV) module [38]. This module can be used by any US health-care facility where blood components and products are transfused. Participation requires a comprehensive surveillance of patients and blood components throughout the transfusion process, from product receipt until patient administration. In addition, the reporting of all adverse transfusion reactions and associated incidents that occur for patients transfused at the studied facility is required. By participating in the module, health-care facilities can use data entered into the National Healthcare Safety Network to monitor adverse reactions and events. This allows for better identification of areas requiring intervention and to modify prevention strategies that reflect the specific needs of a particular health-care facility.

8. St. Luke's University Health Network: blood transfusion information

Like other tertiary-care centers, our hospital system has implemented an MTP designated as "code crimson" to facilitate the rapid availability of blood products when persistent hemodynamic instability occurs in a patient, among other indications. In line with our institution's initiative for continuous quality improvement, departmental risk assessments and safety management plans have been enacted. This program requires managers of departments with unique risks to assess their department's risk profile and submit a summary of safety guidelines to the safety and security manager of their campus. This call for ongoing quality improvement allows for brainstorming sessions with physicians and staff to identify risk and to determine the methods, equipment, policies, and training that can be used to manage and mitigate such risks.

9. Conclusion

Emergency blood transfusion remains a clinical challenge, occasionally marked by improper transfusion of incompatible blood that leads to severe patient morbidity and mortality. Through this hypothetical case scenario, we have highlighted the risks of improper transfusion and discussed improvements in patient safety during emergency transfusion, including developing best practice models, integrating new technologies, as well as improvements in operational aspects via simulation and error tracking systems. By further investing in protocols and systems that enhance safeguards in transfusion medicine, we can continue to strive toward the elimination of transfusion errors and their sequelae. Ongoing research, continuous intensive analysis, and quality improvement initiatives are needed for further advancement of transfusion safety.

Conflict of interest

The authors report no conflict of interest.

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Chapter 9

Patient Safety Issues in Pathology: From Mislabeled Specimens to Interpretation Errors

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Additional information is available at the end of the chapter

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Abstract

Catastrophic breaches in patient safety often involve point-of-care settings such as the operating theater or intensive care unit, quite frequently without due consideration given to the elements leading up to such errors. Among such occurrences, wrong site procedures (WSPs) and diagnostic discrepancies continue to result in significant morbidity and mortality among patients. Addressing adverse events is difficult for all stakeholders involved. Furthermore, clinician familiarity with the workflow specific to particular disciplines or procedures may be poor, amplifying communication lapses that precede patient safety occurrences. The patient care paradigm has become increasingly multidisciplinary, and it is important to discuss, improve, and be more cognizant of measures required to achieve "zero defect" performance. Despite the rarity of "never events," their consequences may damage patient and community trust, provider morale, and institutional reputation. This chapter aims to assess current preventive measures and risks in the context of errors involving surgical pathology in the setting of the operating theater utilizing the framework of clinical vignettes. The discussion below will further center on the practical and interpretative errors that occur in the pathological workflow, and the potential for compounding of such errors in the operating theater. Definitions concerning WSP and diagnostic discrepancies will be outlined to characterize potential outcomes of communication errors.

Keywords: never events, patient safety, patient safety errors, safety protocols, pathology, laboratory medicine, diagnostic uncertainty

1. Introduction

The seminal 1999 Institute of Medicine report was significant for U.S. health care, citing that approximately 100,000 annual deaths resulted from medical errors [1]. This report motivated a

cultural shift into the research of various topics including medical errors and their prevention. More specifically, health care initiatives concerning public reporting of outcomes, provider and institutional reimbursement, and methods to improve existing systems, combined with individual accountability, were introduced. Beyond public and private agency investment, government involvement was also increased with the Agency for Health Care Research and Quality providing funds for identification of best practices, in addition to patient safety indicators and standardizing metrics. Despite the above measures, contemporary analyses suggest that medical errors may actually result in over 400,000 deaths per year [2], with the U.S. Department of Health and Human Services Offices of the Inspector General reporting 180,000 deaths resulting from medical errors among Medicare beneficiaries in 2008 [3], and an annual cost exceeding $17 billion [4].

Medical errors continue to illuminate the fragility and complexity of the medical system. Within this context, it is critical to point out that most of these errors are potentially preventable [2]. For example, it has been estimated that roughly 1 in 113,000 surgical procedures involve an incorrect operative intervention [5]. Subsequent analyses performed by the Joint Commission further revealed that communication errors (70%), procedural noncompliance (64%), and leadership (46%) were significant contributors to such events. However, other commonly cited antecedents to sentinel events include team competency, availability of information, organizational culture, failure to mark or clearly mark the operative site, inadequate medical record review, and of paramount importance, deficient continuum of care [6]. It is important to recognize the systemic and procedural breakdowns that often preclude post-diagnostic procedures that may not be operative in nature but may be catastrophic for the patients if improperly conducted (or erroneously delivered and/or interpreted).

There are two broad categories of occurrences in terms of potentially introducing serious medical errors into the arena of laboratory medicine:

- **Practical errors**, which involve the production of patient samples into therapeutically relevant data, and
- **Interpretative errors**, which concern the processing of these diagnostic data into a report for use in the subsequent step(s) along the patient's care continuum.

At the same time, reporting of errors that occur across the various sub-specialties of laboratory medicine often proves difficult. For example, validated studies have demonstrated increased propensity toward error through the inherent systematic complexity (e.g., due simply to the increasing number of process-related steps) [7]. Surgical pathology is particularly vulnerable to breaches in patient safety, in part due to the wide variability in tissue types, anatomic nuances, biologic sampling, inconsistency and human involvement in diagnostic interpretation, as well as time constraints (and pressures) [8]. The Quality Practices Committee and College of American Pathologists (CAP) designed validated guidelines and metrics in laboratory quality, with data collection and peer review initiatives such as Q-PROBES (a peer-comparison quality assurance service offered by the College of American Pathologists that was created in 1989), in order to establish patient safety benchmarks [9]. However, despite increased awareness, the necessity of improving pre-existing pathology paradigms has only been considered recently [10]. Additionally, an expert panel from The CAP, as well as the Pathology and Laboratory Quality Center, in association with the Association of Directors of

Anatomic and Surgical Pathology, drafted several *recommendations* aimed at avoiding interpretative errors, ultimately designating case review as an effective deterrence to error [11].

2. Definitions

In order to familiarize other surgical subspecialties with potential procedural weaknesses within the pathology workflow, a conceptual framework of practical and interpretative errors derived from Meier [12] is outlined (**Table 1**). A brief overview of the taxonomic

Classification	Definitions
Practical errors (in stepwise order)	Patient identification
	Selection of tissue specimens
	Labeling and specimen transport
	Specimen accession
	Receiving sampling specimens
	Fixing, embedding, cutting section
	Mounting, staining, and labeling slides
	Delivery of slides to pathologist(s)
	Examination, collation, and interpretation of slides
	Consideration of ancillary tests, Other information
	Composition of report for subsequent review
	Reception and interpretation of report
Interpretive errors	Errors of commission—wrong or incorrect diagnoses, false positives (i.e., overcalls)
	Errors of omission–mixed diagnoses, false negatives (i.e., undercalls)
Case reports	Amendments—changes that are not pure additions of information
	Addenda—changes that purely add information
	Specimen defects—Specimens that are lost, of inadequate sampling size and/or volume, absent or discrepancy measurements, inadequately representative sampling, absent/inappropriate ancillary testing
	Misinterpretation: **i.** Overcalls **ii.** Undercalls **iii.** Confusion/conflation which results in not altering primary (positive/negative or benign/malignant) or secondary (grade, stage, margin, etc.) characteristics
	Report defects—do not directly influence diagnostic information but often diminish redundancy in information, presented as: **i.** Absent or incorrect non-diagnostic information (e.g., concerning practitioners, procedure, billing) **ii.** Dictation/transcription errors—typographical errors **iii.** Aberrations in electronic formatting (i.e., "computer glitches")

Table 1. A taxonomic framework for discussing errors in pathology; derived from Meier [12].

structure of altered case reports will be provided, which constitutes one way of identifying error in pathology. **Figure 1** highlights significant sources of error in both of these processes [13, 14]. It is of paramount importance for providers to understand the limitations of research in the current literature regarding the preponderance/magnitude of potential and actual error that exists in pathology (as well as the common failure modes in such settings) (**Figure 2**).

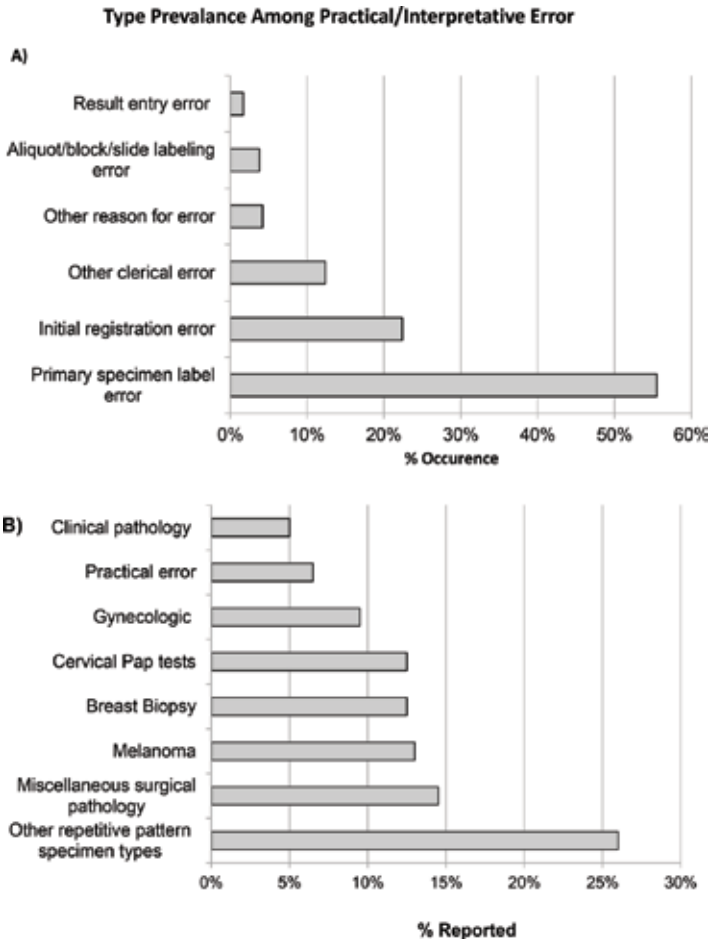

Figure 1. Relative frequency of errors occurring during practical/systemic and interpretive/diagnostic processes. (**A**) Reasons for clinical lab error prior to delivery of sample for interpretation. These errors are not differentiated between pre- and post-verification [13]. (**B**) Data for cases of medical negligence resulting in practice considered below the standard of care. Clinical pathology refers to laboratory error, practical error refers to system errors, miscellaneous surgical pathology errors refer to claims which show no pattern in specimen diagnostic criteria and are considered random, and other repetitive pattern errors include sarcomas, lymphoma, lung, gastric, fine need aspirates, prostate, bladder, and nongynecologic cytology errors; 57% of claims are from practical errors, melanoma, breast, Papanicolaou, and gynecologic samples [13, 14].

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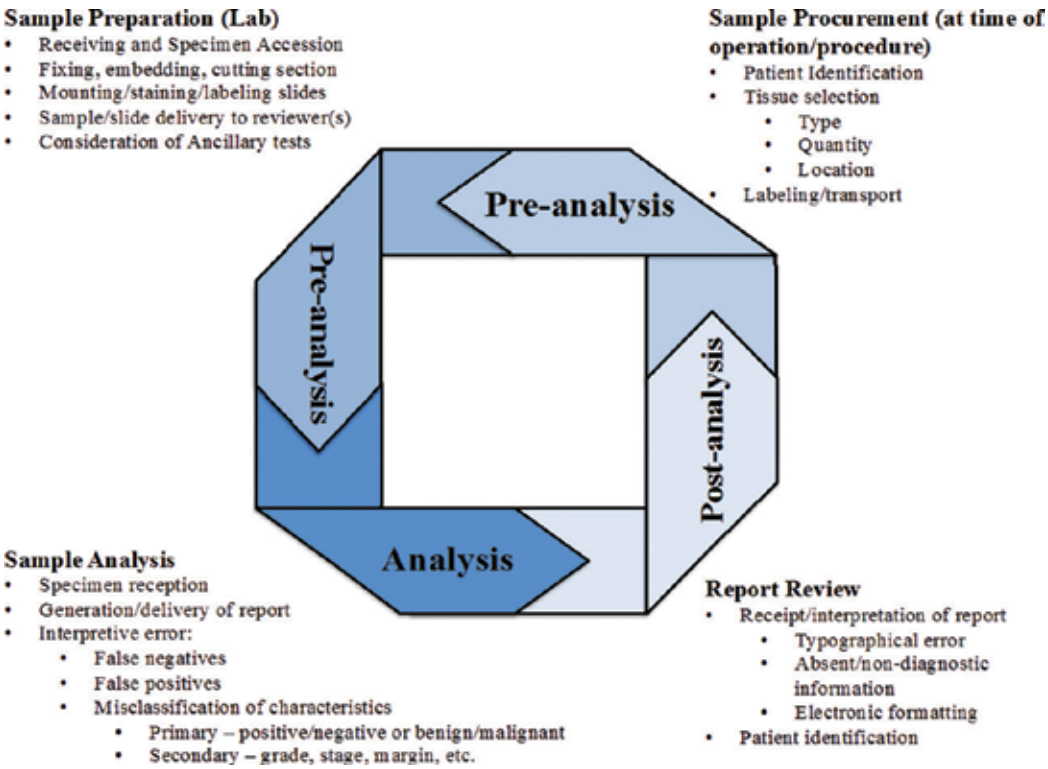

Figure 2. Brief overview of common errors in the pathology workflow; derived from Zarbo et al. [15].

3. Clinical vignette #1

Shahar et al. [16] described a 47-year-old man who presented to the emergency room after reports of progressive right lower extremity weakness. Relevant history included 40-pack-year of tobacco abuse as well as upper-limb dysmetria. Magnetic resonance imaging (MRI) revealed distinct ring-enhancing lesions in the left frontal lobe of the brain, which were biopsied and reported as metastatic small cell lung carcinoma. The patient received radiation treatment for increasing right lower extremity weakness, headache, and blurred vision.

The patient demonstrated worsening lethargy and headache prompting a brain computed tomography (CT) that showed an enlarging mass with midline shift. Histopathological examination suggested glioblastoma with no evidence of metastatic carcinoma. Despite suspicion of a possible rare "collision tumor" (a tumor specimen from a single patient in which pathology reports do not coincide), DNA sequencing of the two biopsies was performed to determine if the tumor was monoclonal. Several genotypic and microsatellite analyses revealed that the samples did not originate from the same patient.

In this particular case, the patient and clinicians were fortunate enough to identify the sampling error early in treatment, which allowed for an appropriate adjustment of the treatment (for the correct diagnosis of glioblastoma).

4. Clinical vignette #2

A 26-year-old man reported intermittent blood in his stool for more than 1 year [17]. The patient appeared well nourished and in no distress. Rectal exam demonstrated scarring from previous anal fissures. Stool examination was negative for occult blood, although laboratory testing did suggest a low mean corpuscular volume and total serum iron. During outpatient colonoscopy, a large ulcerated circumferential lesion was identified in the right colon, which was biopsied and submitted to pathology.

The pathology report had indicated "histologically normal colonic mucosa with prominent submucosal lymphoid aggregates, no malignancy identified" [17]. The lesion had a high probability of neoplastic potential, suggesting a possible false-negative biopsy due to inadequate sampling. A surgery consult was ordered as well as an abdominal CT and barium enema. The CT reaffirmed a mass in the area of the cecum, but did not confirm whether the mass was inflammatory or neoplastic; the barium enema highlighted a mass consistent with malignancy. Following the resection of right colon and terminal ileum, pathology identified a moderately differentiated infiltrative cecal carcinoma with negative margins and metastatic carcinoids in 2 out of 24 pericolonic lymph nodes. The patient did well, although treatment was not initiated until 5 weeks after the procedure.

5. Discussion

The two clinical vignettes highlighted both the ease with which an error can occur, as well as the ability of a well-functioning system of cross-checks to detect errors [17–19]. The above-mentioned cases provide a framework for an in-depth discussion of common pitfalls than can occur within pathology operations, as well as the interpretative errors that may influence both therapy and prognosis. However, it is important to note that despite comprising a relatively small fraction of health care-related errors, adverse errors in both anatomic and clinical pathology continue to occur with unacceptable consequences, including mortality [14, 20]. Such errors have the potential to consume patient and provider time, increasing costs, while diminishing trust in the health care system. Experts in the field of pathology are only beginning to understand the implications of the 1999 IOM report on their specialty, with particular emphasis on a need for collaboration with other specialties, including surgery [10].

5.1. Clinical vignette #1: discussion of "lessons learned"

Case vignette #1 (CV1) includes several key points that highlight the problem of "latent errors," both during the pre- and post-analytical phases. The crux of this case is that

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somewhere during the process of securing specimen(s) for the initial biopsy sample and review, an error occurred resulting in patient-specimen mismatch. Labeling error is not a phenomenon unique to pathology, but can occur in any process leading up to a report generation for therapy or prognosis. Labeling errors may occur when specimens are labeled with incorrect patient name/identification, or accession number, but may also be related to the sample's origin (e.g., lower versus upper extremity); time (e.g., two procedures by two different surgical teams); or location (e.g., endoscopy suite versus operating room). The possibility of labeling errors also exists within the analytical framework whether in regard to the pathologist(s) or in the context of report retrieval/delivery [21, 22]. About 0.25% of cases are subject to a labeling error during the pre-analytical phase, with a majority of errors (73%) being associated with patient name [21]. Implementation of safety measures such as open communication with the patient and formalized checklists incorporated in transfer of information/specimens from the operating room to the laboratory and vice versa have shown significant efficacy in reducing labeling errors (as in aviation) [23]. Root cause analysis performed in CV1 ultimately determined that the error occurred during the initial specimen processing stage due to a clerical mistake [16].

Due to the potential for substantial downstream impact of erroneous labeling and thus the generation of incorrect pathology/laboratory reports, these events warrant an expanded discussion (**Figure 1**). It has been reported that specimen labeling errors tend to be evenly distributed among the processes of accessioning, gross pathology processing, and tissue cutting, with some additional errors being identified in subsequent steps of processing [24]. Approximately 1.3% of these errors affect patient care [24]. The many "moving parts" within the pathology/specimen processing workflow may be subject to significant risk of errors and "near misses" [25]. The emergence of adverse or "never events" in patient care typically involves multiple breakdowns in both systemic and individual processes (the phenomenon known as the "Swiss cheese model") [17, 26, 27]. Failure to recognize errors in multiple successive steps of specimen preparation and interpretation can result in significant errors and resultant patient harm, as demonstrated in CV1. A proactive and critical review of processes may aid in reducing the incidence of such events [28].

The inherent complexity of multi-step processes is implicated in the genesis of pathology errors. Lack of adequate coordination and/or communication is often cited in this context. Lapses in communication are among the most common sources of medical error, with over 20% of cases identifying communication errors as directly contributing to wrong site, wrong procedure, and wrong patient surgical procedures [29], and there are numerous calls for improvements in this area throughout all specialties [8, 17–19, 30]. CV1 highlights a breakdown in communication, and the importance of cross checks and verifications used for initial error rectification. Every critical communication carries a risk of error, but at the same time, it presents an opportunity for detection of error. For example, preoperative checklists and surgical "time-outs" have been shown to make operative care safer [31, 32]. A similar framework for preventing "never events" may also be effective in reducing pathology labeling errors [33]. Moreover, the initial errors that may have occurred during initial specimen processing in CV1 may have been compounded by other errors, including potential oversight issues from downstream employees who were under time constraints/heavy workloads thereby failing to

institute proper quality and verification procedures. There was also a degree of confusion following the second biopsy, generating unnecessary work and consuming additional resources. Finally, appropriate disclosure of errors should be provided to the patient in order to help foster mutual trust and understanding [10].

Despite the relative commonality of labeling errors, research on their prevalence and consequences is sparse [10]. To elucidate the nature of error in specimen/patient labeling, large Q-PROBES studies have been conducted, with one study noting an error rate of 6% involving specimen identification and accession defects, with specimen misidentification constituting nearly 10% of the errors [34, 35]. Issues involving labeling have been classified as follows:

- **Class 1**—Typographical errors that do not result in clinical consequences.
- **Class 2**—Errors which are unlikely to result in clinical consequences.
- **Class 3**—Errors which may be detrimental to patient care.

One study in particular documented a 0.09% rate of Class 3 errors among 8231 specimens [36]. This underscores the need for better preventative measures, with the aviation industry as one of the prime examples of error reduction [37]. Moreover, current studies underestimate the true error frequency, as many are undetected [35].

Both gross and histological laboratories need to continue to strive for error correction in regard to sample/patient labeling. With the former, specimen containers may be paired with cassettes that involve incorrect case numbers (e.g., incorrect patient specimen) or incorrect part identification (e.g., incorrect anatomic site), while the latter tends to involve pairing cassettes with erroneous slides (e.g., incorrect patient and/or site) or incorrectly applying a digital/paper label to a pencil-labeled slide. To highlight this problem, one 18-month review of errors in the laboratory setting noted a 0.25% class 3 mislabeling rate [36]. Of note, stratification of error based on specimen type/procedure may prove useful in patient safety optimization.

While CV1 does not delve into specific root cause(s) of error, it serves as an excellent platform for further discussion. One study noted a 0.25% error rate was recorded across 29,479 cases, with a significant proportion of errors (69%) occurring in the gross specimen processing room [36]. Most errors were associated with incorrect patient (73%) or specimen site (24%); and further demonstrated that a significant proportion of labeling errors (88%) were made by laboratory assistants [36]. However, these near misses were largely recognized in subsequent steps by histology technologists or surgical pathologists signing out casework. Improved training programs, as well as initiatives to improve error reduction, may involve optimizing work load and alleviating time constraints [10].

A smaller, but still significant proportion of labeling errors occur in histology laboratories (25%). Errors in the histology laboratory tend to be limited largely to two event types [38]:

- Block specimens that were matched with pre-labeled (penciled) slides (63%).
- Placement of the incorrect pre-printed label on pencil-labeled slides (37%).

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Some institutions have developed alternative methods including placing labels opposite to pencil labels on glass slides to reduce such errors [38]. Samples that were often small and relatively uniform in appearance were associated with higher rates of labeling error (e.g., renal and skin biopsies). In addition, processing difficult and similar samples in batches may also carry a higher risk of error [21]. For high-throughput laboratories, incorporation of inking practices to patient biopsies as a means of secondary identification has reduced errors without affecting sample integrity during subsequent steps. However, such methods have also resulted in a 20% increase in grossing time [39]. Large-scale reviews of labeling errors also suggest that laboratories with built-in quality assurance protocols have statistically significant reductions in identification errors [40].

Beyond any process-related lapses concerning patient/specimen identification, the complexity of the clinical picture surrounding the sample is often cited as a potential source of error for the interpreting pathologist(s) [8]. Access to complete information regarding the clinical picture, including clinical discussions prior to analysis or during intraoperative consultation, can better equip pathologist(s) to assess and relay accurate information. Advances in computer and information technology (i.e., electronic medical record) have yielded anecdotal improvements [8], but efficacy in this regard is not compelling.

Specimen integrity verification and standardization of variables during clinical analysis is of key importance. Specimen defects are typically classified as errors that may include inadequate sample size/volume, inappropriate representativeness, or failure to invoke ancillary testing, all of which may result in misdiagnoses [15]. For example, the variability in discerning and recognizing clinical landmarks within resected tissue specimens may depend on the type of tissue marking dye used [41]. Currently, sample criteria standardization (e.g., tissue, blood, plasma, molecular, etc.) and general laboratory workflow continue to be areas of opportunity for improvement [42, 43]. Contribution of specimen defects toward errors in patient safety is small, but important. Furthermore, the relationship between false-negative (and false-positive) diagnoses and the associated medico-legal implications needs to be addressed [14].

For errors that manage to "evade" redundant safety measures, there are two significant considerations relevant to patient safety. The first aspect is the completeness of report and the second regards the presence of any critical values [8]. The pathology report remains a mainstay and foundation for communication between the pathologists and clinicians involved in patient care, whether it concerns diagnosis, treatment, or prognosis. Studies of physician satisfaction with pathology reports highlight the importance of timeliness of reporting, emphasis on significant results, and general communication of relevant details [44, 45]. While there is currently no universal methodology regarding composing pathology reports, the four following tenets have been identified as useful in improving communication between physicians [46]:

- ***Use headlines to emphasize key elements***—Highlighting the main diagnosis apart from additional case details. These tend to predominate amongst "patient-centered" reports as opposed to "specimen-centered" reports.
- ***Maintain layout continuity***—Providing a redundant layout for reports so health care professionals within an institution may become familiarized with interpretation of the report.

- ***Optimize information density***—Grouping information within a report into familiar units for optimal reader retention
- ***Reduce clutter***—Exclusion of nonessential information, or grouping of additional, yet insignificant details into report addenda so that it does not detract/confuse the reader.

Advancements in information technology and the electronic medical record have allowed prompt delivery of reports, incorporated synoptic checklists, improved physician satisfaction, and increased completeness of reporting by 28.4% [47–49]. The field of oncology provides a strong example of standardized report elements designated by the Commission on Cancer of the American College of Surgeons [50, 51]. However, information technology improvements in report composition and delivery are not without flaws [52]. Reports to physicians/surgeons must incorporate clear and concise information whether it is at the time of specimen collection or in relaying diagnostic and therapeutic information. Face-to-face is still the preferred modality for communication [31], primarily because flaws in communication continue to prevail as serious barriers to patient safety [10].

There remain several areas of concern regarding sample handling and final reporting as it relates to clinical communication. Sample labeling and transport continue to persist as major sources of error and are compounded by subsequent failure to adhere to standard protocols, whether it involves secondary review or quality verification. One method of cross-checking and verification involves the inclusion of molecular testing prior to acting on pathology reports; however, this has been hindered by both time constraints and costs [22, 53]. In CV1 diagnostic reporting yielded highly unlikely results, which through high clinical suspicion led to further confirmatory testing. Despite ultimately receiving the correct treatment, the patient had to commit to additional time, molecular testing, and potential exposure to iatrogenic harm.

5.2. Clinical vignette #2: opportunities for improvement

Let us turn our attention to the topic of interpretive error, which is generally more localized within the overall pathology laboratory workflow. Interpretative contributions to error tend to be more insidious and have proven difficult to research, and classify [10]. Clinical vignette #2 (CV2) outlines the challenge and the importance of interpretive errors in patient management. While root cause analysis of this vignette determined that the error in question most likely involved sampling issues rather than lack of interpretive prowess, this case nonetheless prompts discussion of how providers may classify, discuss, and develop methods to reduce any associated potential harm to patients [54]. The consequences of interpretative error are legitimate causes of concern and continue to be a source of confusion (and harm) to patients [14, 20].

Case review predominates as the fundamental preventative modality for interpretive error and continues to be utilized as the primary source for research into such errors [55, 56]. In the case review discussion, it is important to first address the various applications of review, whether it is pre- (i.e., prospective) or post-sign out (i.e., retrospective), internal, external, focused, or unfocused examination. Internal reviews are often performed within a single

Specimen Type/Diagnostic Modality	N	%
General report review		
Random review	1523	2.2
Organ-specific malignancies		
Lymphomas	1291	6–7
Urological	213	10
Gastrointestinal and liver	194	12.4
Breast	610	16–20
Pediatric neoplasms	705	25.1
Soft tissue carcinomas	34	47
Historically difficult diagnoses		
Liver transplant biopsies	30	43
Thyroid aspirates	50, 113	52, 34
Vulvular dysplasia	60	23
Gestational trophoblastic disease	1851	26
Cytological:histological comparison		
Bronchoscopy biopsies	231	2.3
Cervical specimens	5159	6
Female genital tract tumors	279	6.8
Fine-needle aspiration, non-cervical specimens	898	9–12
Bladder cancer biopsies	508	41
Fine-needle aspiration, breast lesions	90	46
Cytological:cytological comparison		
Cervical specimens	13,745	45
Histological:histological comparison		
Skin biopsies	589, 478	6.5, 35
Pigmented skin lesions	392	14
Primary versus review diagnoses	354	56
Taxonomic variability (Gleason grading)		
Prostate biopsy	278	42

Discrepancy rates in interpretative outcomes of specimen types as well as varying diagnostic modalities including cytologic:histologic comparison, cytologic:cytologic, histologic:histologic, taxonomic grading (e.g., Gleason grading of prostate biopsies). Adapted from Meier, FA [12].

Table 2. Discrepancies in pathologic interpretation.

practice, allowing the opportunity for discussion of difficult diagnostic scenarios prior to clinical action while also offering the ability to develop diagnostic thresholds and taxonomies relevant to the disease process. A large study (n = 18,032 cases) regarding pre-sign out diagnostic reports indicated that at least one additional pathologist reviewed each case for ~78% of cases, thereby adding a layer of safety [57]. Despite the benefits of an internal review, it often becomes impractical because of costs and time, especially in small practices [12]. External reviews reduce diagnostic uncertainty [58], but are plagued by similar issues, especially for large practices. For this reason, conferences, which utilize a panel of experts and non-experts of various clinical backgrounds, minimize the need for external review.

Expert review for various disease processes allows for reviewers within a practice to define diagnostic thresholds and criteria of which general pathologists may not be privy. Furthermore, skillful and trained reviewers can provide specialized reports and quickly parse through highly relevant information. Such expertise is routinely utilized in oncological settings [59]. Expert reviewers help create a robust system within a practice that provides a "knowledge trickle down" effect in the practice. Nonetheless, expert review may skew agendas when reviewers encourage criteria set forth by one dominant pathologist (e.g., senior or most experienced partner) [60].

On a related note, research comparing diagnostic discrepancies between random case reviews and focused review of certain difficult diagnoses has shown that the latter intuitively tends to produce higher rates of interpretative divergence (2.7% and 13.2% discrepancy rates, respectively) [61, 62]. Perhaps what is most interesting is that cases subjected to focused reviews (3.2%) generated a 10-fold increase in the likelihood of serious error/threat to patient safety as compared to random review (0.36%). Points of focused review include specimens such as premalignant breast lesions, melanocytic skin lesions, as well as taxonomic classification including Gleason grading of prostate biopsies, etc. [63–68].

Much research has been conducted to assess discrepancy rates in pathology practice, placing attention on some of the more arduous specimen types and clinical scenarios. **Table 2** outlines some of this research to display the spectrum of challenges in stratifying specimen interpretation [12]. Of significance is the general reported discrepancy rate of 2.2%. While there is variability in discrepancy rates, some diagnostic circumstances tend to result in higher discrepancy rates (when assessing case reports). Historically troublesome specimens involve organ systems that tend to encompass "linked" diagnoses (e.g., soft tissue carcinomas). Furthermore, comparison of different diagnostic modalities suggests that certain specimens are more difficult in terms of reaching consensus between the use of cytology and histology or within the same processing mechanism (e.g., histological comparison of dermatopathological specimens).

Case reviews are needed for assessing/stratifying interpretative errors in pathology, but can be flawed. Nakhleh et al. indicated that while only 8% of casework falls under case review, a typical practice expends significant time and costs in such case review [57]. Considering discrepancy rates, an argument can be made for shifting toward focused reviews. With significant variance in interpretative aptitude and experience, complete prevention of diagnostic error will be difficult. Nonetheless, pathologists should continue to work toward

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standardizing/stratifying diagnostic criteria, taxonomy, and improving ancillary tests to achieve diagnostic precision. The following five *recommendations* have been made to help reduce interpretive error [69]. Anatomic pathologists should consider:

1. Developing procedures for the review of selected cases to detect disagreements and interpretive errors.
2. Performing case reviews in a timely manner to avoid impact on patient care.
3. Documenting case review procedures relevant to their practice setting.
4. Continuously monitoring and documenting the results of case reviews.
5. Taking steps to improve agreement if case reviews show poor agreement within a specific case type.

There are three mandates within the patient safety framework for institutional accreditation designed by the Joint Commission, which include the use of pre-operative checklists, surgical time-outs, and surgical site marking [31]. These mandates provided by the Joint Commission have improved communication within teams in the operating room [70], including potential identification of discrepant results and/or potential errors. While some studies have suggested that surgical teams are the most significant determinants of patient safety in the operative setting [71], others have focused on structuring preventative protocols and safety measures as the apex of patient safety [26, 72]. While these mandates have undergone significant structural changes to maximize patient safety, adherence and noncompliance continue to negatively impact patients [73]. Increased personal accountability to reduce noncompliance is needed [74], as is the development of a diagnostic, clinical and legal environment that increases accountability, communication, and prevents adverse events [10].

CV2 presents a challenging dilemma by introducing a number of subtle "diagnostic clues" that may evade even the most experienced diagnostician or may be missed due to sampling error [14, 20]. Prolonged or extensive case reviews may prove costly for a practice and impractical for clinical situations that require both timeliness and accuracy to avoid potentially dangerous management delays. Consideration of the entire clinical picture beyond pathology testing is mandatory for the interpreting pathologist. Conversely, clinicians such as surgeons must also consider the overall "clinical picture" while reviewing the pathology report and intervening as appropriate. Lastly, this vignette poses the question as to "if, when and how" pathologists should be involved in disclosing error to patients. Research suggests that pathologists are seldom involved in error disclosure, and a significant proportion has never been involved in such processes [75]. Moreover, focused research often cites pathologists as not having the training and experience to be part of such discussions and that pathologists tend to be somewhat apprehensive regarding having discussions with clinical colleagues who may not fully grasp the intricacies of laboratory work [76]. Pathologists must make a concerted effort to not only help prevent patient harm, but also openly discuss it, especially with medical colleagues involved in the case [10].

6. Conclusion

While patient safety events, including the so-called "never events" can occur within the realm of pathology practice, the research and implications involving pathology remain limited and in early stages [10]. Errors that result in missed diagnoses, wrong site procedures, or false-positive interpretations continue to cause profound physical injury and psychological trauma for the patients, and deeply affect involved providers, teams, and institutions. Consequently, pathologists must engage in a concerted effort to build and embrace mechanisms for high reliability specimen and data processing, verification and cross checks involving diagnostic interpretations, efficient event reporting, outstanding communication, and excellent coordination involving both internal and external interactions. This, in turn, will lead to better and safer pathology systems of the future.

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Chapter 10

Avoiding Fire in the Operating Suite: An Intersection of Prevention and Common Sense

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Additional information is available at the end of the chapter

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Abstract

The operating room (OR) is a complex environment that involves large teams and multiple competing priorities, dynamically interacting throughout the entire course of a surgical procedure. The simultaneous presence of flammable substances, volatile gases, and the frequent use of electrical current results in a potentially dangerous combination. Operating room fire (ORF) is a rare but potentially devastating occurrence. To prevent this "never event", it is critical for institutions to establish and follow proper fire safety protocols. Adherence to proven prevention strategies and awareness of associated risk factors will help reduce the incidence of this dreaded safety event. When ORF does occur despite strict adherence to established safety protocols, the entire OR team should know the steps required to contain and extinguish the fire as well as essential measures to minimize or avoid thermal injury. If injury does occur, it is important to recognize and treat it promptly. Appropriate and honest disclosure to all injured persons and their families should be made without delay. As with all serious patient safety events, regulatory reporting and root cause determinations must take place in accordance with applicable laws and regulations. The goal of patient safety champions at each institution should be the attainment of zero incidence of ORF.

Keywords: operating room fire, patient safety, prevention, surgical fire, surgical safety, intraoperative fire, operating room, patient safety, prevention

1. Introduction

Although rare, ORFs continue to occur despite staff education and preventive efforts [1, 2]. The scope of patient harm spans an entire spectrum, from aborted surgery to fatal injuries [3].

Although all ORFs should be potentially preventable, their rarity combined with relatively more focus on other OR complications contribute to knowledge gaps and inconsistent approaches to stop these "never events" [4, 5]. Institutions must overcome common misunderstandings about risk factors associated with ORFs including the misconceptions that fires are largely nonpreventable, staff is appropriately trained in fire safety and aware of critical actions required in an ignition event, and fires do not happen at institutions with well-developed cultures of safety [2].

The abovementioned fallacies must be actively countered at all levels of the establishment from the executive suite to the equipment maintenance staff. Continuous education, including didactic sessions, web-based self-assessment activities, multimedia materials, and readiness drills, form the foundation of organizational excellence that is based on the combination of high performing teams, well-designed safety protocols, and zero tolerance for complacency [6, 7]. When implementing and disseminating information about operating room fire safety, all stakeholders must be actively engaged, including nursing staff, surgical technologists, anesthesia professionals and surgeons. As with other forms of patient safety events, effective communication is essential in both prevention and management of ORFs [8]. It is also important to note that the healthcare environment is inherently more prone to fires than other nonindustrial workplace environments, primarily due to the coexisting use of flammable materials and surgical energy sources [8]. As such, other locations within hospitals may be at elevated risk of procedure-related fires, including the emergency department, labor and delivery, and endoscopy suites [9]. In this chapter, we present two realistic clinical vignettes describing ORFs. Detailed discussion of risk factors, preventive strategies, fire preparedness, and post-event management then follows.

2. Clinical vignette #1

Mr. "A" is a 65-year-old male admitted to a local Ambulatory Surgery Center for a minor surgical procedure. He has cervical lymphadenopathy and is scheduled for excisional biopsy of a palpably enlarged right-sided cervical lymph node. After all preoperative medical and safety checks are completed, Mr. "A" is escorted into the OR and positioned supine. General anesthesia is induced after an uneventful endotracheal intubation. The surgical resident assisting with the procedure preps the patient's neck, shoulder and chest using alcohol-containing chlorhexidine solution. Soon after, the surgical site is draped with sterile surgical cotton drapes. An incision is made over the enlarged lymph node, and subcutaneous tissue is exposed. Electrocautery is then introduced into the field for hemostasis and surgical dissection around the enlarged lymph node. Immediately following electrode activation, a flame ignites and rapidly spreads over the surgical field prepped with chlorhexidine. The surgeon in charge immediately removes the drapes, the electrocautery is switched off, the fire is extinguished within seconds, and the lymph node biopsy procedure is aborted. The patient suffers from first degree burns over his neck and chest. His recovery is complete, although he requires another trip to the OR for completion of his lymph node biopsy.

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3. Clinical vignette #2

Mrs. "W" is a 75-year-old female, admitted to the intensive care unit (ICU) for severe pneumonia. She subsequently developed respiratory failure and was unable to successfully wean from mechanical ventilatory support. Consequently, she was scheduled for a tracheostomy due to anticipated prolonged need for mechanical ventilation. On the morning of surgery, the patient was transferred directly from the ICU to the OR, with required preoperative safety checks performed at her bedside in the ICU. After the anesthesiologist administered total intravenous anesthesia, the surgical intern prepped and draped the patient's neck in the usual sterile fashion. The surgeon proceeded to perform a transverse incision above the suprasternal notch and dissected down to the trachea using a combination of sharp (scissors) and blunt techniques. The trachea was subsequently exposed and, with appropriate anesthesia (lowering of inspired oxygen concentration) and surgical team (abstinence from electrocautery) precautions, incised sharply. Without consulting the attending surgeon, the surgical intern suddenly noticed significant amount of bleeding in the area of the retracted strap muscles and proceeded to use coagulating diathermy to secure hemostasis. Immediately following the use of diathermy, a loud noise was heard and a large flame burst from the tracheal stoma. Ventilation was immediately stopped, the anesthesia circuit was disconnected from the tracheal tube, and the fire rapidly extinguished using normal saline administered through the endotracheal tube. Without delay, the surgeon gained access into the trachea with a tracheostomy cannula and once the positioning of the tracheostomy device was confirmed, the endotracheal tube was removed. The endotracheal tube was notably burned, with carbonized plastic material visible in the distal portion. The patient suffered superficial thickness burns around the stoma site. Fiberoptic bronchoscopy demonstrated minimal burn injury around the tracheostomy site and the proximal airway. Fortunately, the patient recovered without other major complications and was discharged from the hospital to rehabilitation facility after successful tracheostomy decannulation 2 weeks later.

4. Risk factors for fire in the operating room

Key risk factors for ORF should be well known to all OR team members, should be included as standard parts of staff educational curriculum, and should be readily identified whenever present (alone or in combination) [10, 11]. According to Apfelbaum *et al*., prevention of ORFs begins with minimizing patient exposure to the presence, alone or in combination, of "oxidizer-enriched atmosphere," potential ignition source(s)/surgical energy device(s), flammable liquids (e.g., alcohol-based surgical prep), and other potentially flammable materials (e.g., paper or plastic drapes) [12]. Mandych and his group reported an intraoperative fire that occurred during tracheostomy placement for a patient who had an unresectable lingual carcinoma [13]. When attempting to recreate the circumstances of the fire under laboratory conditions, they found that electrocautery did not ignite any towels, sponges, or other materials without the presence of oxygen. The authors concluded that an "ignition source," a "combustible agent," and oxygen were necessary for a fire to occur. Interestingly, they also cited the organic gases which emanated from the necrotic tumor to be a potential source of combustible

Risk factors for operating room fires
Ignition sources
• Electrosurgical and electrocautery units
• Electrical hemostatic devices
• Lasers
• Fiberoptic light sources and cables
• Defibrillators
• Flexible endoscopes
• Sparks from surgical drills
Fuel sources
• Flammable prepping agents including tinctures (chlorhexidine, thiomersal, iodophor)
• Drapes, towels, surgical sponges, dressings
• Gowns, hoods, masks
• Mattresses, pillows, blankets
• Patient hair (face, scalp, body)
Oxygen sources
• Oxygen (O_2)
• Nitrous Oxide
Risks are grouped by their primary category of "ignition source," "fuel source," and "oxygen source."

Table 1. Listing of major risk factors for operating room fire.

material [13]. Ladas and colleagues have also cited the potential for colonic gas explosion, though arguably this is a very rare scenario and preventive measures seem limited. In their review, they found 11 cases of colonic gas explosion during surgery and nine cases during colonoscopy. Looking back to the 1980s when mannitol was used as the most common bowel prep agent, colonic aspiration evaluation revealed a high concentration of hydrogen in the colon secondary to the mannitol's fermentation by *E. coli*. Though mannitol has largely gone by the wayside, there are still polyethylene glycol solutions with sorbitol, which, if the sorbitol is malabsorbed, can result in formation of combustible gases due to the same fermentation process [14]. Not only is this the case, but sorbitol is present in one's daily diet and malabsorption of sorbitol has been found in up to 60% of normal, healthy patients [15].

A rather thorough set of experiments were performed by Barker and Polson after a 73-year-old man's case of bilateral burr holes for evacuation of subdural hematomas ended up in an OR fire. Having experienced this, the group decided to embark on laboratory simulations using a nonflammable plastic manikin and concluded the following: (1) even without oxygen, paper drapes could be ignited by the electrocautery knife, but that fire was slow-burning and self-resolving; (2) when 5-min drying time was implemented, or if no alcohol based solution

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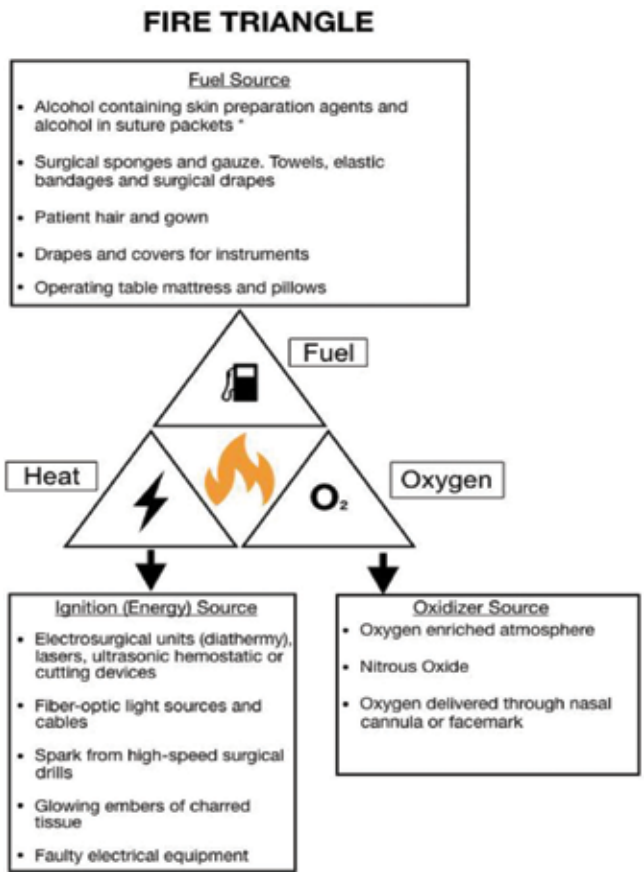

Figure 1. Components of the "fire triangle" that interact to create conditions ultimately responsible for various degrees of risk for operating room fire.

was used, there was no resultant fire; (3) in the absence of closed spaces where oxygen or vapor from the prep solution could gather, there was no fire. In this context, the authors found that the concentrations of oxygen under drapes could be as high as 50% [16].

Overview of major risk factors for ORF, grouped according to specific risk contribution, is provided in **Table 1** and **Figure 1**. Additionally, when considering and conducting the assessment, consideration of the delivery method of oxygen is a critical component. The use of a laryngeal mask airway or an endotracheal tube reduces the risk of fire by decreasing the oxygen concentration under the drapes and in the patient's upper airway [17].

From procedure-based standpoint, operations can be categorized as "general risk" or "high-risk" for ORF [12, 18]. For "general risk" procedures, such as abdominal hernia repairs, any flammable skin-prepping solutions should not be allowed to pool and must be dry before the placement of surgical drapes [19]. Assurance of the same is required before using any surgical energy devices (e.g., electrocautery or laser) [19, 20]. In addition, surgical drapes should be applied in a manner that prevents oxygen from flowing into the surgical site or pooling near

the operative field [12, 21]. Finally, surgical gauzes and sponges should be moistened when used in proximity to any potential source of ignition [22].

Examples of "high-risk" procedures include tracheostomy creation (e.g., direct exposure of surgical field to highly concentrated oxygen) or maxillofacial/head and neck surgery (e.g., close proximity between the endotracheal airway and surgical energy source) [23–25]. For such "high-risk" procedures, where proximity exists between an oxidizer and an ignition source, special caution is required by the entire OR team, including close communication and coordination between the surgeon and the anesthesiologist, as well as the use of operating field suctioning to scavenge any excess oxygen [12]. This is demonstrated well in our Clinical Vignette #2, where both the surgeon and the anesthesiologist took immediate and appropriate course of action. In addition to avoiding/limiting the use of nitrous oxide, the concentration of oxygen being delivered to the patient should be minimized, preferably based on close monitoring of patient oxygenation (e.g., pulse oximetry, and if possible tracking of inspired/expired/delivered oxygen concentration) [12].

The use of surgical laser equipment in a high-risk area (e.g., head and neck, trachea) should be done in the presence of laser "resistant" tracheal tubes, intended specifically for a given procedure and type of laser [12, 26, 27]. For any operative work requiring surgical energy application within the airway, reduction in oxygen or nitrous oxide concentration is thought to be safe for anywhere between 1 and 5 min at a time [12]. The same applies to procedures involving immediate proximity of the oxidizer and surgical energy source in the setting of nasal cannula or face mask [12]. Surgical suction should be utilized to scavenge oxygen or nitrous oxide from the oropharynx during cases involving this anatomic area [26].

5. Operating room fire: true magnitude of the problem

According to the Emergency Care Research Institute (ECRI), approximately 200–240 surgical fires occur each year in the United States [28]. Other sources provide a much wider range of occurrences, ranging between 100 and 2260 annually [2, 24, 29, 30]. Generally speaking, the incidence of ORF appears to be similar to that of wrong-site surgery or retained surgical items [28], some of the most prominent categories of surgical "never events" [31–33]. As outlined in previous sections, the simultaneous presence of key components required for the ignition of a fire is the single biggest risk determinant (**Table 1** & **Figure 1**). Therefore, it is not surprising that surgical fires involve electrosurgical equipment in approximately 67–90% of all cases, and that supplemental oxygen administration was nearly universally present [2, 34]. Of importance, the operative environment is defined as being "oxygen-enriched" when the oxygen concentration is greater than 21% [17]. Most commonly and not surprisingly, given the previously outlined risk factors, ORFs result in burns to the head, face, neck, and upper chest [22]. Thankfully not all ORFs involve patients, operating room staff, or result in significant injury [2].

6. The fire triangle: focus on education and knowledge

As discussed earlier in the chapter, the initiation (and propagation) of ORF is dependent on the simultaneous presence of an ignition source (e.g., surgical energy device), fuel (e.g., paper drapes, alcohol-based skin prep), and an oxidizer (e.g., oxygen, nitrous oxide) [22]. **Figure 1** lists

common types of items and categories within the "fire triangle" paradigm. Although beyond the scope of the current discussion, it is also important to mention that non-anesthetic causes of ORFs have been reported, including flammable gastrointestinal gases (mentioned earlier in the chapter) [35, 36] and surgical lights [37].

The final component is an oxidizer [38]. Although most people realize that oxygen greatly enhances the rate of combustion, many do not know that nitrous oxide supports combustion in roughly similar manner. Oxidizers reduce the fuel ignition temperature, thus elevating the risk of a fire and its continued propagation [39].

7. Fire containment: strategies and procedures

In an event of a fire, healthcare facilities commonly employ the "rescue-alarm-confine-extinguish" or RACE protocol [40, 41]. All team members, regardless of assigned function or seniority, should be aware of the location of pertinent emergency equipment, including the "fire alarm" trigger, fire extinguisher, and phone/extension to be used for notification [42]. Within the OR environment, additional considerations may need to be taken into account, depending on specific circumstances, such as whether the fire involves the patient. Scenarios involving the patient (both cutaneous and within the airway) and those without patient involvement will now be discussed.

If the fire directly involves the patient, the initial steps should involve extinguishing the flames and removing any burning material from the patient [2, 43]. Simultaneously, other team members should be tasked with initiating the established "fire response" protocol, including alarm notification, personnel evacuation, removal of flammable materials from the vicinity of the fire, as well as using fire extinguisher to contain and put out the fire [44, 45]. Alarm notification should clearly indicate the precise location of the fire and any critical information regarding the circumstances of the occurrence [42, 45]. Due to the risk of thermal injury, timing of actions and team coordination are critical. The administration of exogenous gases (oxygen and nitrous oxide) should be discontinued immediately. Once fire control is achieved, care for the patient should resume, with specific management based on the degree of danger from smoke in the area.

If the fire is not able to be immediately contained, then evacuation from the room, notification using established facility infrastructure (e.g., facility alarms, the emergency operator, and the OR operational leadership), and immediate notification of the fire department should take place. The surgeon typically recognizes the fire first and thus is involved in extinguishing and removing the fire, primarily by dousing the area with saline. Equipment immediately available in the event of an ORF includes ample supply of sterile saline or water; a "carbon dioxide" or a "water mist" fire extinguisher; replacement tracheal tubes, guides, and facemasks; rigid laryngoscope equipment; sponge and drape sets ready for rapid re-deployment; replacement ventilator circuits, tubes, and lines [2]. Because many drapes are waterproof, it is important for saline to cover all burning areas. If saline is not available, moist surgical towels draped across the operator's forearms may be used to smother the flames, with a sweeping motion away from the patient's airway. Of note, patting a fire may cause the flames to worsen [46].

During tracheostomy placement and other tracheal procedures, the fire may directly involve the patient's airway [47]. Although rare, this type of event can be fatal [48]. Due to its anatomic location, fire in the tracheobronchial tree is approached differently compared to other

circumstances. As soon as the airway fire is recognized, the administration of all gases by anesthesia must be stopped and the tracheal tube removed (to prevent plastic melting within the airway and the oropharynx) [2, 48]. Any items at risk of ignition should also be immediately removed, followed by the administration of saline or water into the airway [2]. After the fire is extinguished, the patient can be reintubated and ventilated, provided that no smoldering materials remain [2, 48]. Concentration of administered oxygen can be increased after the risk of re-ignition is no longer present. It is important for OR teams to remember that a tracheostomy procedural setup should include a readily available source of saline, preferably in a large syringe suitable for direct and immediate intra-tracheal administration.

One important, and thankfully exceedingly rare consideration is the secondary ignition of the operating room team's gowns, gloves, possibly resulting in thermal injuries among operating team members [49]. Electrical injury causing harm to hospital staff has also been described [50]. Although generally underreported, these and other similar scenarios may put at risk both the patient and his or her caretakers, especially when the fire is intense, when an explosion occurs, or when heavy smoke causes inhalation injury [49, 51, 52]. Also of importance is the need for the OR staff to be aware of the potential for patient thermal injuries from improperly placed electrocautery grounding pads [53].

In fires that occur in the operating suite or its immediate proximity, not involving the patient, the source is usually related to faulty electrical equipment or wires [2, 53]. In case of such occurrence, the initial step is to turn off (if possible, of course) and then safely unplug the affected equipment and remove it physically to reduce any potential future threat of fire [53]. However, if this is not feasible, the device may need to be extinguished in its stationary location [2].

Fire extinguishers using carbon dioxide should be readily available, easily accessible, and regularly checked for operational readiness [25]. Consequently, extinguishers must be clearly identified by an appropriate sign, and each employee should be familiar with operational characteristics of these life-saving tools. It has also been recommended that extinguishers should be located near pull stations, stairwells, and fire exits [2]. All fire extinguishers used in the OR are of the *ABC* variety, meaning that they are effective across all major fire types (A, ordinary combustibles; B, flammable liquids; C, electricity) [41]. The dry chemical fire retardant used is ammonium phosphate and is mildly corrosive in moist environments. If the patient becomes the fuel source, a CO_2 extinguisher (effective on electrical fires and flammable liquids) would be preferable because of its lack of ammonium phosphate and thus less potential for contamination and tissue damage. Proper extinguisher use can be described using the PASS (pull pin, aim, squeeze, and sweep) acronym [54].

Strategically located, centrally monitored fire, smoke, and heat sensors must be present and fully functional at each healthcare facility, including all procedure/operating rooms [55]. Additionally, fire alarm pull stations should be located near evacuation stairwells and other predesignated locations. When any fire is present, both visual (strobe lights) and audible alarms should activate [2]. The hospital fire response plan should immediately go into effect, notifying designated fire response team about where to respond. The response team includes but is not limited to security and facility management personnel. Determinations regarding resource mobilization and whether to initiate additional evacuation procedures should also be made.

In addition to the primary location of the ORF, the alarms should also sound on the floor above and below the fire. Although this may seem obvious in larger hospitals, where fire alarm notifications are usually announced throughout the entire building, some smaller facilities may require specific modifications to ensure this important safety feature. In the case of hospital fire alarm activation, the on-site safety team must determine whether an evacuation is necessary [2, 56]. This is especially important when one considers the risks associated with moving patients who are critically ill or actively undergoing surgery. Thus, in the event of an actual fire, personnel would be notified of detailed plan(s) to have the fire contained and controlled to facilitate safe and orderly evacuation of the involved building or structure [57–60]. Operating room personnel should conduct an assessment of specific patient needs such as monitoring equipment, ventilator availability and appropriate transport platform to safely perform evacuation procedures. Central to the ability to quickly and safely evacuate large number of patients and personnel is the need for specialized infrastructure, including critical components such as "fire-safe" elevators [56].

Gas shut-off valves are used to stop the flow of anesthetic gases into the ORs and are designed for easy access. The front of these gas supply consoles should be clear of medical equipment and clutter at all times [61]. The gas shut-off procedure should be managed using preexisting plans and/or protocols, again emphasizing staff education and periodic team drills. All pertinent equipment should be clearly labeled, including the relationship between valve position and its functional state [61, 62]. As with other emergencies that may involve limited visibility and/or lack of power, emergency lighting, battery-operated safety equipment, and any smoke management devices should be available and operational [63–65].

8. Consequences of fire in the OR: thermal injury

It has been noted that approximately two-thirds of surgical fires occur on the patient while approximately one-third occur in a cavitary location (e.g., airway) [17]. In terms of decreasing frequency of anatomic locations, approximately 40–45% ORFs involve the head, neck, and upper chest; about 25% involve other "external" body areas; and finally about 20% occur in the airway, with the remainder occurring in other "cavitary" locations [17].

In addition to traditional electrocautery equipment, various forms of devices utilizing different types of nonionizing radiant energy have been introduced into medical applications, including ultraviolet, visible light, microwaves, and radio-frequency waves [66, 67]. Starting with overall exposure and risk reduction, providers must be aware of the potential dangers—as well as the full spectrum of possible injury—associated with these devices [66, 68]. Prompt recognition and timely management of injuries from both direct thermal exposure and other forms of "surgical energy" misapplication cannot be overstressed. This includes immediate attention to any injuries sustained by the patient and/or staff [29, 69, 70]. Thermal burns are associated with coagulation necrosis of the involved tissues, with the degree of severity depending on the temperature and the duration of the exposure. The initial tissue response primarily results from the direct transfer of energy in the localized area of injury, resulting in protein denaturation and coagulation [68, 71–73].

In case of cutaneous burn, skin is an effective thermal barrier, causing most of the immediate damage to be confined to epidermis and dermis. At the same time, various humoral mediators (cytokines, prostaglandins, oxygen free radicals, histamine, complement) are released that may result in vasoactive response, increased capillary permeability, and the appearance of local as well as distal tissue edema. Beyond the general pathophysiology of the burn wound, additional factors contributing to the overall physiologic response include resuscitation fluid administration, effects of various therapeutic agents, impaired host defense leading to elevated risk of infection, endocrine system changes, and the associated hypermetabolic state that affects metabolism across a broad range of tissues (e.g., muscle, liver, kidneys, gastrointestinal tract) [73].

If airway or intracavitary fire is present, the abovementioned considerations may become amplified, potentially worsening the clinical prognosis [35, 74, 75]. Injuries involving the airway may become life threatening if not promptly and properly managed [48]. More specifically, what may appear to be a minor injury can result in severe tissue edema that severely restricts or obstructs an airway over the course of a few hours [74, 76, 77]. Long-term follow-up is required in cases of severe airway injury [78].

9. Medico-legal, reputational, and regulatory implications of ORF

Additional consequences of ORFs, above and beyond direct patient harm, include serious medico-legal repercussions, financial costs, and severe reputational damage to both involved providers and their institutions [79, 80]. Moreover, such events inculcate mistrust toward the healthcare system among the public [80]. Although the majority of patients who sustain medical injury do not file lawsuits, the medical system is riddled with an abundance of frivolous claims, the cost of which is not trivial [81–84]. It has also been noted that lack of provider awareness, combined with inadequate levels of communication, may result in elevated malpractice risk [85]. The development of appropriate internal reporting mechanisms and educational programs may help mitigate the overall legal risk associated with adverse events, including ORFs [85, 86]. Factors known to prevent litigation by patients who suffered complications include excellent surgeon-patient relationship, full and honest disclosure, and effective communication between patients, providers, and teams [87, 88].

Consequences of unusual or elevated incidence of ORFs can be significant, up to and including mandatory closure of operative suites at an institution [2]. Consequently, thorough assessment of risks, institutional protocols, and employee competency in this critical area is mandatory [2]. Regular (e.g., quarterly) fire drills may help reinforce the knowledge of essential patient safety protocols and serve to refresh key information among the OR staff [89].

10. Checklists, communication, education, safety protocols, and teamwork

It has been noted that in the presence of all three components necessary for intraoperative fire ignition, the risk of ORF may be further elevated by poor team communication and coordination [90]. From patient safety perspective, virtually all surgical fires should be preventable. Standardized

OR safety checklist aimed at reducing the risk of ORF, either alone or in combination with other existing checklists, has been proposed as one potential solution to the problem [91–93]. Another area where iatrogenic fires can occur, yet the issue appears to be relatively neglected despite some procedural similarities to the OR, is the clinical setting of the emergency department [94].

One important focus of existing guidelines (with some exceptions) is that the traditional practice of using highly concentrated oxygen should be discontinued during head, face, neck, and upper chest surgery [28, 46]. The recommended practice is to use medical air whenever possible in such cases, and if the patient's condition warrants supplemental oxygen, additional precautions should be taken to protect the surgical field from oxygen "contamination" [2]. The exception to this rule would be a case in which a patient must remain responsive but requires supplemental oxygen while undergoing a procedure involving the head, face, neck, or upper chest. Under such circumstances, the lowest concentration of oxygen should be employed (e.g., 30%), and if concentrations exceed 30% prior to using any surgical energy source, one should stop oxygen and deliver medical air at 5–10 L/min for at least 1 min to dissipate any trapped oxygen [95, 96]. As previously outlined, tracheal incision should only be performed using "cold" devices such as scalpels or scissors. Finally, communication among the team members is essential, including universal patient safety education and utilization of patient safety checklists [97].

Because ORF requires the simultaneous presence of an oxidizer, an ignition source, and a fuel, the key to prevention is intentionally minimizing (or eliminating, if applicable) one or more of these components so combustion is not possible [98]. Thus, the overall framework for ORF prevention must incorporate specific steps to identify risk level for each surgical case, ensure proper use of surgical energy devices, safe and appropriate use of supplemental oxygen, excellent communication and coordination, as well as meticulous attention to detail when using any potentially flammable materials to prep and/or drape the surgical field [99]. The assessment of fire risk potential should take place during the universal surgical time-out for every single patient and for each individual procedure [99, 100]. The fire risk is calculated/estimated by considering all possible risk factors associated with a particular surgical procedure [101, 102]. The resulting "risk score" (with "1" representing "low risk," "2" representing "intermediate risk," and "3" representing "high risk") should then be communicated to the surgical team during the "time out" or "pre-op briefing" [102].

In the OR, each healthcare worker takes the "ownership" of a part of the fire triangle. For example, alcohol-based skin preparations have become more common as a source of fuel since the Centers for Disease Control and Prevention identified them as the preferred skin disinfection method. Thus, the team member who applies the prep (e.g., circulating nurse) must work closely with the surgeon who controls the surgical energy device, and these stakeholders must ensure that the potentially flammable prep agent is completely dry, without any identifiable pooling, before proceeding with the use of electrocautery [99].

One never knows who will be present when the fire occurs; thus, the role of each team member may change in any given scenario. A simplified guideline for all three broad types of ORF (e.g., involvement of airway, cutaneous/non-airway, and environment) is presented in **Figure 2**. High degree of flexibility on the part of all team members is required, and this can only be accomplished in the presence of meticulous preparation, optimized use of resources, readiness drills, simulation, and other forms of team practice [103, 104]. For

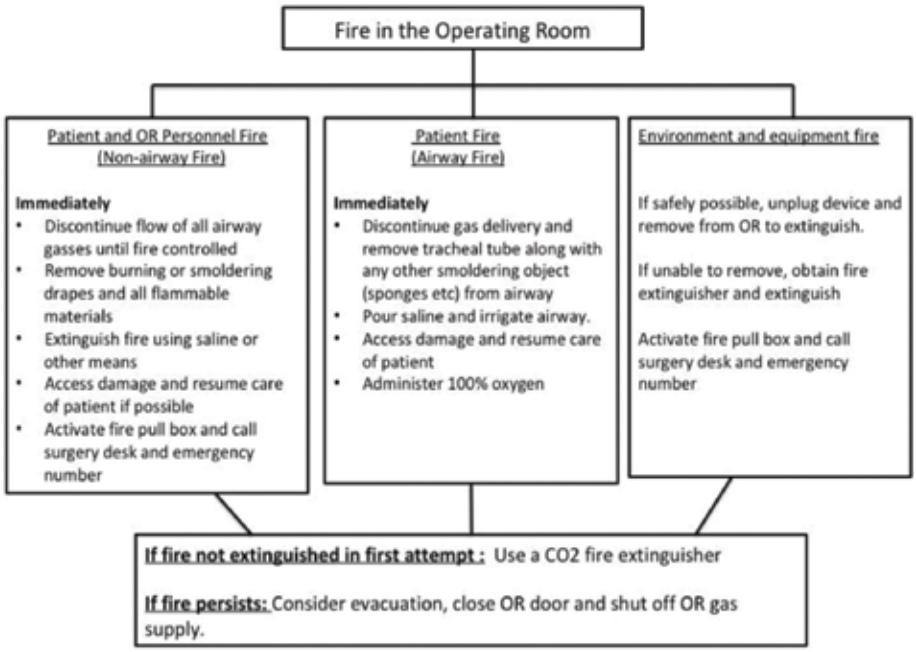

Figure 2. Schematic summary of guidelines for optimal approach to operating room fire. Note: Both carbon dioxide and "water mist" extinguishers can be utilized. Legend: CO_2 = carbon dioxide; OR = operating room.

example, the American Society of Anesthesiologists (ASA) strongly recommends fire safety simulation as a team preparedness tool [12, 89]. It is important that such simulations are as realistic as possible, and that "lessons learned" are discussed during a post-simulation debrief in a constructive, team-oriented fashion, and disseminated afterwards to all stakeholders. Sharing of experiences between different institutions and teams is also very valuable. Helpful information regarding ORF prevention and management is available on the Internet, including the Association of periOperative Registered Nurses (AORN), Anesthesia Patient Safety Foundation (APSF), ASA, and Emergency Care Research Institute (ECRI) websites [105–107]. Finally, in an event of a major unforeseen event in the OR, a crisis checklist has been proposed to help streamline decision-making and team processes required during an orderly response [108].

11. The importance of honest disclosure and risk management

Although uncommon, adverse events and clinical errors do occur, and physicians have an ethical and professional responsibility to honestly disclose such occurrences to patients [109]. Open discussion regarding unfavorable events is an indispensible component of effective clinical risk management in health-care. Failure to do so undermines the public's confidence in the medical profession and has the potential to create legal liability [110]. Moreover, patients need to be informed about medical errors so that additional harm can be avoided, and well-informed decisions about their care can be made [111].

Honest disclosure can be challenging for practitioners as it may be difficult to recognize errors openly before both patients and colleagues [112, 113]. In addition, physicians' fear of litigation can also pose as a major barrier to frank disclosure [114]. However, when handled appropriately, immediate and genuine disclosure of errors frequently leads to improved patient rapport and fewer malpractice claims [115, 116]. Practitioners are encouraged to follow hospital-specific guidelines for the disclosure of errors, patient safety events, and other risk management issues [117–119]. Disclosure needs to take place in an appropriate setting and at the right time, when the patient and/or their family is/are able to understand and sufficiently process the information provided. The surgeon should always take the lead and approach the patient/family with empathy and concern [120]. Behavior that translates into acts of evasiveness or lack of understanding inculcates mistrust and anger in the patient, which may ultimately lead to a legal action against the physician and/or the hospital [121]. Manner and tone are extremely important aspects of disclosure and often more impactful than the actual content of the discussion. A simple "I am sorry" is often appreciated by the patients and results in a stronger patient-physician relationship. In addition, it is important for the physician to articulate clearly what has been done to overcome consequences of the error and to reassure the patient and their family that every effort has been taken to prevent similar events from happening in the future [122].

Open physician-to-patient and physician-to-physician communication is a fundamental aspect of effective clinical risk management and cannot be overemphasized [110]. As outlined throughout the ***Vignettes in Patient Safety*** book cycle, every health-care organization should encourage the internal development of patient safety champions and strictly enforce policies and procedures that prevent occurrence of adverse events [32]. At the same time, when these incidents do occur, all team members (physicians and non-physicians) should be trained to report them without fearing backlash or facing undue blame [32, 33, 123].

12. Conclusions

Although rare, ORFs occur more often than most people realize. Fire safety in the OR is every team member's responsibility, with attention to established safety protocols and focus on prevention constituting the overarching priorities of intraoperative patient care. All stakeholders should be well aware of the "fire triangle" concept, and how the combination of an "ignition source," "fuel source," and "oxygen source" can create a potentially dangerous environment. When ORFs do occur, optimal outcomes depend on immediate recognition, appropriate response, and a coordinated team effort. The focus on team education/training and fire preparedness (through regular exercises and simulations), along with a comprehensive fire safety program, constitute an integral part of preventing adverse occurrences. Patients entrust health-care provider teams with their lives. With this trust comes the expectation that all team members have excellent knowledge (and control) of risk factors potentially responsible for ORF occurrences. In order to further improve our collective understanding of ORFs, including quantitative risk-factor determination, future efforts should include the development of a national registry that will help facilitate prospective tracking of all ORF occurrences, including their relationship to known risk factors and documented risk-reduction strategies. Only when working together can we effectively achieve the "zero incidence" of major patient safety "never events."

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Over the past decade it has been increasingly recognized that medical errors constitute an important determinant of patient safety, quality of care, and clinical outcomes. Such errors are both directly and indirectly responsible for unnecessary and potentially preventable morbidity and/or mortality across our healthcare institutions. The spectrum of contributing variables or "root causes"—ranging from minor errors that escalate, poor teamwork and/or communication, and lapses in appropriate protocols and processes (just to name a few)—is both extensive and heterogeneous. Moreover, effective solutions are few, and many have only recently been described. As our healthcare systems mature and their focus on patient safety solidifies, a growing body of research and experiences emerges to help provide an organized framework for continuous process improvement. Such a paradigm—based on best practices and evidence-based medical principles—sets the stage for hardwiring "the right things to do" into our institutional patient care matrix.

Based on the tremendous interest in the first two volumes of *The Vignettes in Patient Safety* series, this third volume follows a similar model of case-based learning. Our goal is to share clinically relevant, practical knowledge that approximates experiences that busy practicing clinicians can relate to. Then, by using evidence-based approaches to present contemporary literature and potential contributing factors and solutions to various commonly encountered clinical patient safety scenarios, we hope to give our readers the tools to help prevent similar occurrences in the future. In outlining some of the best practices and structured experiences, and highlighting the scope of the problem, the authors and editors can hopefully lend some insights into how we can make healthcare experiences for our patients safer.

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