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Vignettes in Patient Safety

Volume 1

Edited by Michael S. Firstenberg and Stanislaw P. Stawicki

VIGNETTES IN PATIENT SAFETY - VOLUME 1

Edited by **Michael S. Firstenberg**
and **Stanislaw P. Stawicki**

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Preface

Since the late 1990s, a truly global movement to improve patient safety has evolved into the modern paradigm where safety and quality of care are enmeshed with virtually every aspect of healthcare. This would not be possible without the early pioneers of patient safety, whose vision has evolved into a truly global movement that is helping to improve lives and outcomes of our patients around the world.

This work was conceived because of the continued need for a practical, easy-to-use, and at the same time comprehensive reference in the area of patient safety. The goal of this book cycle is to introduce the reader to key concepts in patient safety while providing clinically relevant context to each case vignette. Although there may be some conceptual overlap between different chapters and volumes of the *Vignettes in Patient Safety*, this is done intentionally to help reinforce the most critical concepts and patient safety processes while also allowing for different authors and teams to present their unique perspectives, experiences, and thoughts on these complex topics.

By embracing the case-based, practical approach to patient safety scenarios, we hope to support the next phase of growth and development of the global healthcare quality and safety movement. Within this paradigm, the intent is to build on the foundations of the past two decades, to incorporate new evidence-based data, and to synthesize new knowledge that will rejuvenate the cycle of continuous healthcare self-improvement and further enmeshment of quality and safety into everyday practice of medicine. Moreover, by presenting cases, the authors can better convey to the readers that while such events are common in healthcare, many occurrences can be prevented using system-based approaches to solutions rather than accepting a defeatist perspective that adverse patient outcomes are inherently unavoidable. In essence, healthcare providers—at all levels—must continue to think beyond the events that occurred during their "shift work" to recognize that they are part of a larger continuum of care and that the fundamental guiding statement should always be "how can we all do better for our patients."

The editors would like to acknowledge the contribution and hard work of all the people who made this work possible. First and foremost, we thank our families and friends, without whom the time and effort required to complete this book cycle would simply not be feasible. Second, we would like to express our gratitude to all chapter contributors. Their effort is greatly appreciated, and we are confident that this work will help improve both safety and quality of care for patients around the world. Finally, we would like to acknowledge the generosity of all the departments and institutions for the support of contributing

authors and teams. Institutional embrace of the open access concept helps facilitate the unrestricted, free availability of scientific knowledge contained in this and many other open access books. As such, we believe the open access paradigm to be the ultimate way of fostering scholarly pursuits and universal sharing of scientific information.

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Chapter 1

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

Stanislaw P. Stawicki and Michael S. Firstenberg

Additional information is available at the end of the chapter

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1. Introduction

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

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

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

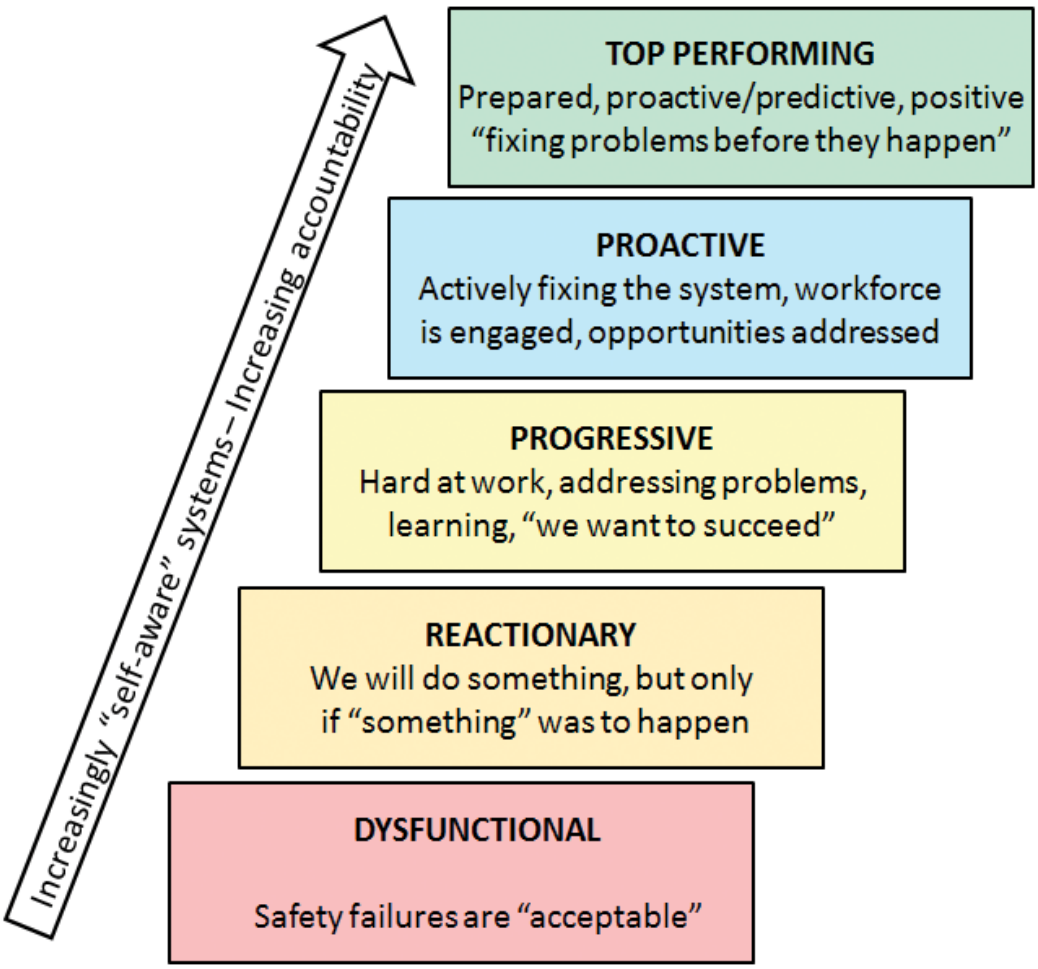

Figure 1. Evolution of patient safety over time. The ultimate goal of all modern healthcare institutions is to create a top-performing, "self-aware", proactive patient safety environment.

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

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

2. Definitions: the roadmap to standardization in patient safety

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

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

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

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

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

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

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

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

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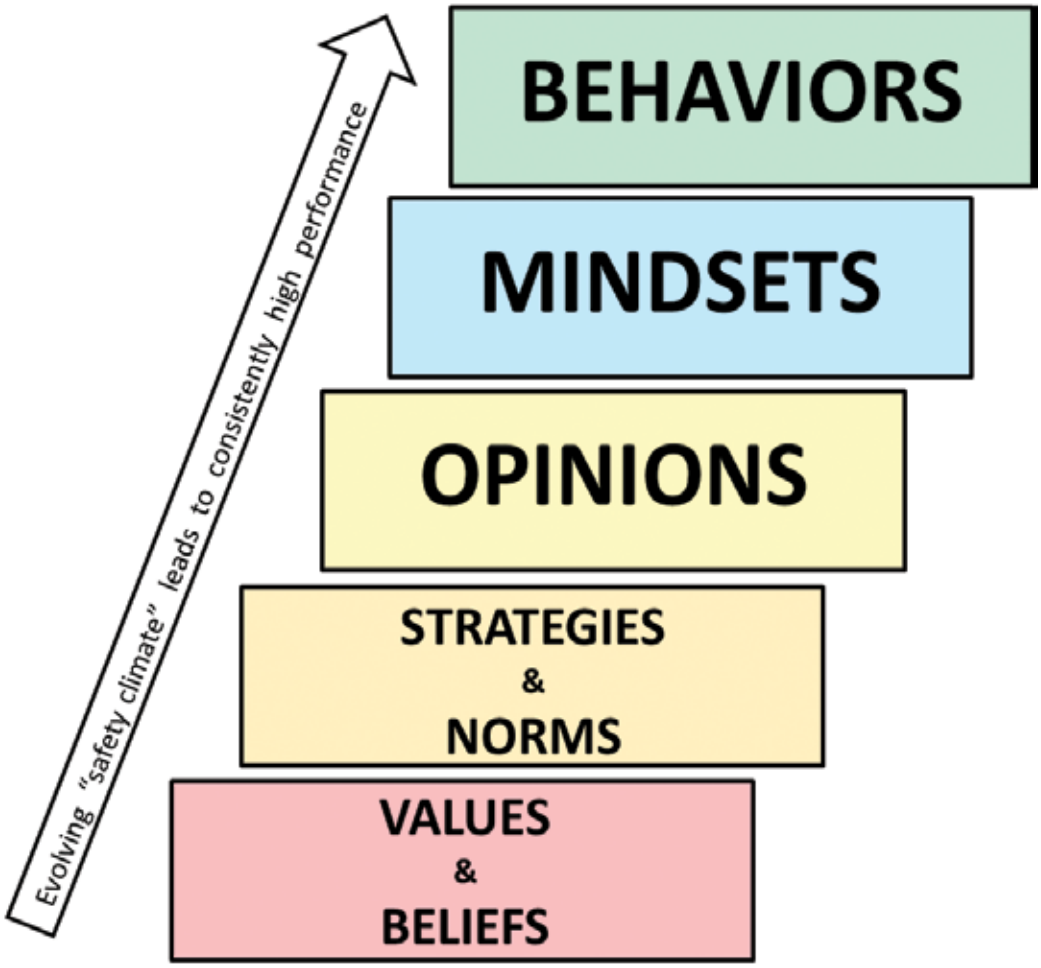

Figure 2. Organizational change starts with values and beliefs, which after being transformed in to norms and strategies lead to the formulation of opinions, mindsets, and finally manifest as a set of organizational behaviors.

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

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

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

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

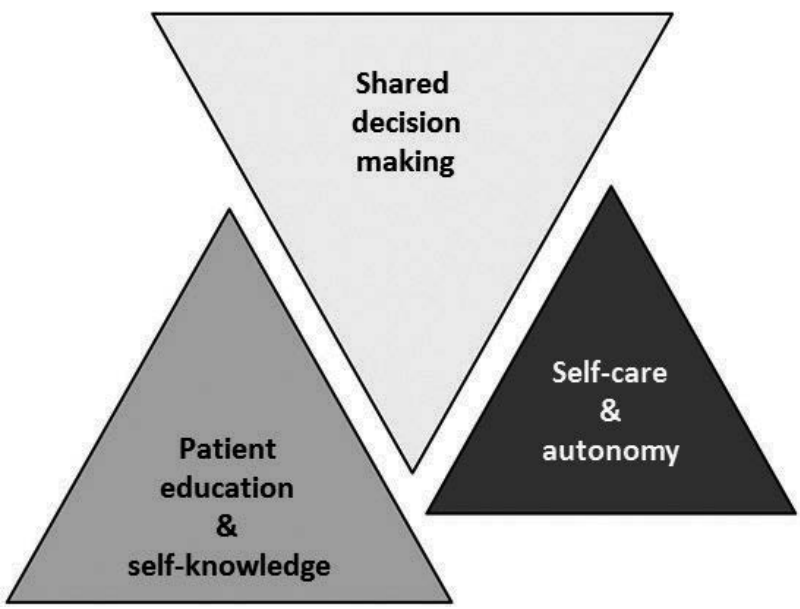

Figure 3. Factors involved in empowering patients to participate in the healthcare safety process. Successful implementation of these concepts requires excellent interpersonal communication skills, appropriate resources, and targeted educational efforts.

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4. Foundations of evidence-based progress

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

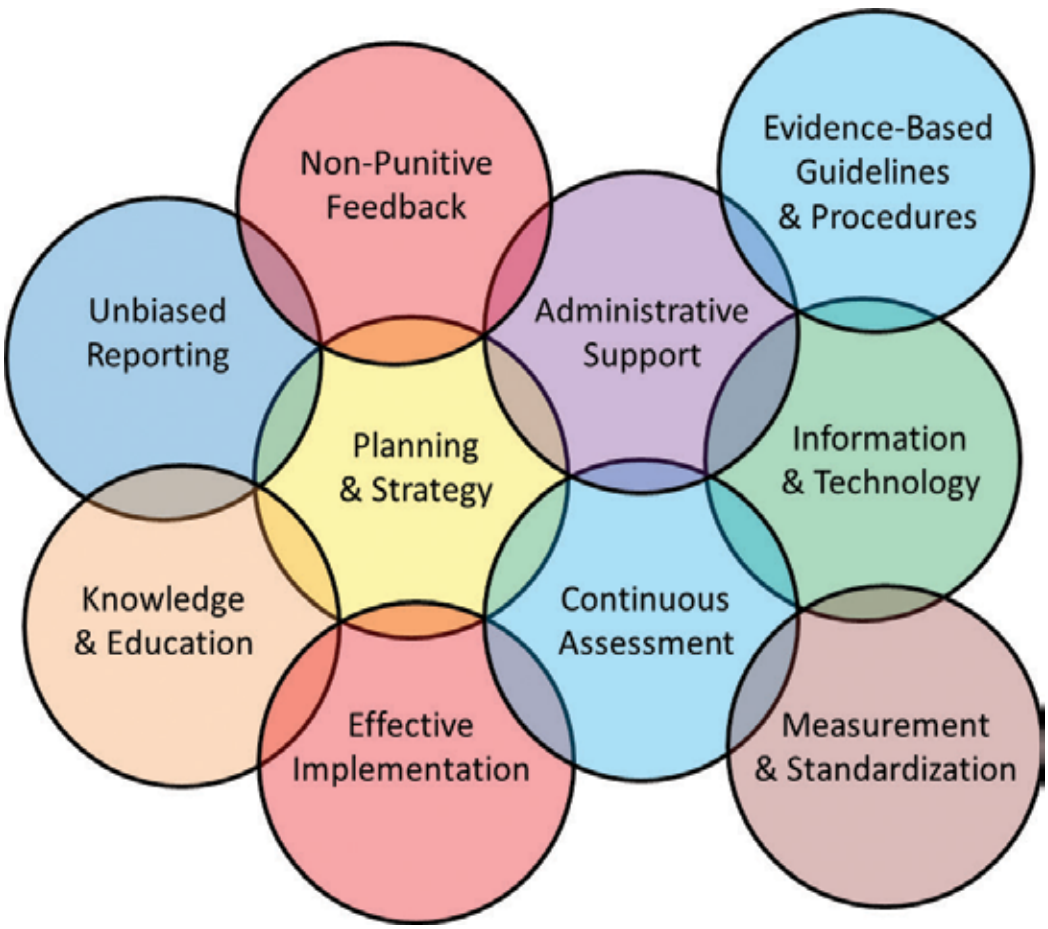

Figure 4. The ever-increasing complexity of the modern healthcare environment requires closely coordinated actions by multiple stakeholders, at various organizational levels.

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

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

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

5. A word of caution

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

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

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

6. Disclaimer

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

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

7. Conclusion

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

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

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Chapter 2

Improving Childbirth and Maternal Care - How to Foster the Use of Good Practices for Patient Safety

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Abstract

Despite the global effort toward improving childbirth and maternity care, there are still complications (hemorrhage, infections, and high blood pressure) that may arise unexpectedly. To end preventable mortality, every woman needs skilled care at birth. The aim of this chapter is to present some solutions implemented by Frontline professionals and healthcare organizations made available through the Italian Observatory on Good Practices for Patient Safety, a national program to improve patient safety by promoting diffusion and active dissemination of evidence-based practices.

Keywords: childbirth, maternal care, patient safety, best practices

1. Vignette

A healthy 30-year-old woman after a straightforward delivery gave birth to a healthy girl. She was discharged from hospital the following day, but within the first week, she felt unwell and had fever. She saw her general practitioner (GP) twice during that week, but he did not notice anything wrong. Later that week, she was admitted to hospital with abdominal pain and septic shock. Her condition worsened rapidly and, despite the excellent inpatient care, she died shortly afterward.

2. Introduction

Despite the fact that maternal mortality rate in Italy is one of the lowest in Europe [1], sepsis remains one of the leading causes of preventable maternal death [2]. The body is vulnerable after pregnancy. Resources are depleted, and whether the birth was natural or surgical, large areas of the body are exposed and vulnerable to infection. To end preventable mortality, every pregnant woman needs skilled care at birth. Furthermore, it is crucial for a safe childbirth that continuity of care is ensured.

To prevent the occurrence of adverse events such as the one described above, the Local Health Authority of Treviso (Italy) has set up a multidisciplinary working group (gynecologists, obstetricians, nurses, anesthesiologists, and neonatologists) that has been mapping the whole path toward childbirth, from pregnancy to delivery, with the aim of ensuring (1) continuity of care before, during, and after childbirth, (2) uniform services are delivered, and (3) appropriate care based on the assessment of pregnancy-related risks regarding the case at hand. Besides the above, an analysis of adverse events and near misses has been carried out and situations that may influence the decision-making of professionals—such as confidence in own skills and lack of or excessive consideration of the patient's perspective—identified. Therefore, the following actions have been carried out:

– Identification of a suitable space for handover, possibly in front of a board so as to ensure that the professionals have all relevant information at the moment of taking charge.

– Definition and adoption of strategies aimed at promoting dialog between professionals in specific situations that are potentially at risk due to human or environment factors.

– Drafting an updated list of procedures already in place within the organization.

Participation of all the professionals involved in childbirth is a key strength of the practice outlined, as it led to the definition of shared procedures and improved the information flow from one step to another.

The importance of safe practices to improve quality not only in maternal care but also in patient care, in general, has been put in the spotlight by the publication of the report by the Institute of Medicine, "To err is human" [3]. The need "to promote safe practices to prevent the most commonly occurring adverse events such as medication-related events, healthcare-associated infections, and complications during or after surgery" has been highlighted by the Council Recommendation on patient safety [4] and, more recently, by the European Parliament Resolution on a safer healthcare in Europe [5].

In Italy, some actions, within a specific national program, have been launched to improve quality and safety in childbirth and maternal care. They are also inspired by what the OECD highlighted in the *Review of Health Care Quality: Italy 2014. Raising Standards* [6]: "a range of quality-related activities have been developed in Italy, with varying depth and scope, and with little co-ordination across these approaches by central agencies." This situation was a result of the organization of the Italian Healthcare System, which is a regional-based system that provides universal coverage free of charge at the point of use. The wide autonomy

granted to the Regions and Autonomous Provinces (R&APs) has led to a huge heterogeneity in the quality and safety of the services provided [6–8]. The need for a nationwide initiative to improve patient safety, coordinated at central level, was translated into an agreement between the Italian government and the R&APs, which entrusted the National Agency for Regional Healthcare Services (Agenas) with the task of monitoring, promoting, and supporting regional and local initiatives on clinical risk and patient safety, with a focus on monitoring and promoting dissemination of good practices for patient safety. Based on this mandate, the National Observatory on Good Practices for Patient Safety was established as a national program to improve patient safety by promoting diffusion and active dissemination of evidence-based practices.

3. The Observatory on good practices for patient safety—aim and implementation

The general aim of the Observatory is to ensure that the care every patient receives is as safe as the state-of-the-art of knowledge allows by stimulating local governments, healthcare organizations, and professionals to implement evidence-based safe practices. Its activities are based on the belief that top-down and bottom-up actions are complementary in order to achieve continuous quality and safety improvement in healthcare [7–10]. Drawing on this belief, multiple stakeholders have been involved in the Observatory's scope definition, design, and implementation (Ministry of Health, R&APs, Agenas, healthcare organizations, and professionals).

The Observatory's scope was defined on the basis of a restricted survey among the leading experts in quality and safety at international level in order to define what a good practice is. The result of the survey was the following definition of good practices for patient safety: evidence-based interventions, sustainable over time and potentially transferable, that have been implemented at regional/local level and proved to be effective in improving patient safety.

The Observatory's activities are implemented through a cyclic model shaped on the PDSA cycle, whose main steps are [7] (**Figure 1**):

The Observatory model of intervention is based on five main phases that are sequential from a logical and temporal point of view: after defining/updating and sharing models and tools, good practices are identified and collected in a web database; they are evaluated, classified, and subjected to dissemination actions while priorities are set for the next cycle. These phases are annually covered in a spiral process tending to continuous improvement.

1. *Defining and sharing the models and tools among all stakeholders*

As mentioned, the Observatory has been designed and implemented based on the input of multiple stakeholders. Furthermore, stakeholders are periodically asked to provide feedback on the tools used to collect and share patient safety practices so as to revise them accordingly.

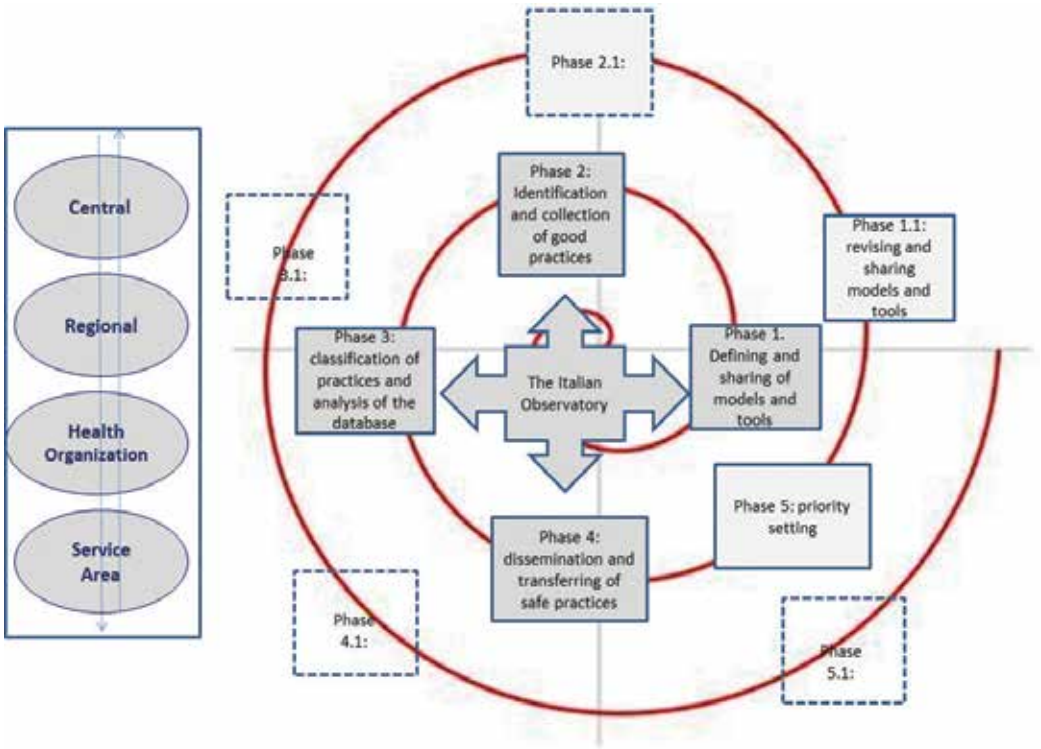

Figure 1. The Observatory model of intervention.

2. *Identification and collection of patient safety practices*

The tool used to collect patient safety practices is the Call for Good Practices, issued annually to invite regional health authorities to coordinate the collection of patient safety activities carried out at regional/local level.

Every year a focus on a specific safety-related problem is defined, so as to align the patient safety activities carried out at national level with the international ones. Therefore, over the years, the Call has been paying special attention to practices related to the following topics: surgical site infections, medication reconciliation, and hand hygiene. The focus of the 2016 edition of the Call has been defined based on the proposals made by the regional representatives who have been participating in the periodic survey aimed at collecting their feedback on the usability of the tools of the Observatory and on possible improvements to be implemented. As a result, childbirth and maternal care have been identified as an area where more needs to be done to ensure good quality care is delivered throughout childbirth and major complications are prevented.

Participation in the Call is fully web based and articulated in a three-level system: healthcare organizations/professionals (reporting); regional representatives—experts in patient safety appointed by the Regional Health Authorities (approval/validation); Agenas (collection/classification).

The Observatory developed and shared with the R&APs a standard form for reporting the practices consistent with Standard for Quality Improvement Reporting Excellence (SQUIRE—www.squire-statement.org) guidelines [11] and supported by a computer-based tool to help professionals calculate the implementation costs. In 2014, a revision was made to the reporting form to allow transfer of the practices at European level. Agenas, in fact, has been participating in and supporting the activities of the PaSQ Joint Action (co-funded and supported by the European Commission under the Public Health Programme, Agreement Number 20112101), whose main objective was to improve patient safety and quality of care through sharing information and experiences and implementing good practices. To do so, a form to collect patient safety practices (PSPs) has been developed and tested at European level [7]. It has then been translated into Italian and made available to healthcare organizations and professionals to report their PSPs to the Observatory.

The Call takes about 5 months, from mid-May to mid-October. The practices submitted, once validated by the regional representatives, feed an Internet archive (http://buonepratiche.agenas.it/practices.aspx) publicly available and searchable by some—simple—search criteria (e.g., year, classification, and adverse event the practice aims to reduce).

3. *Classification of practices*

The practices submitted to the Observatory have been classified into three main categories until 2014:

– **Good practices:** Experiences fully implemented which include a detailed evaluation of results (either by quantitative or qualitative analyses).

– **Potential good practices:** Ongoing/not fully implemented experiences, with incomplete report of results.

– **Initiatives:** Interventions not yet implemented or with very limited documentation about efficacy.

– From 2014 onwards, the Observatory applies the classification model developed at European level (PaSQ Joint Action) [7]:

– **Safe practice:** A practice that was implemented and the before and after measurement has documented that it enhanced one or more aspects of patient safety. The before and after evaluation could be qualitative as well as quantitative.

– **Potentially safe practice:** A practice that was implemented and a before measure was established. However, no after measure is reported.

– **Not proven effective practice:** A practice that was implemented, but the before and after measure did not show improvements.

– **Not implemented practice:** A practice that was not implemented yet. This could be the case, e.g., if the practice is under development or it is just an idea.

– **Not evaluated practice:** A practice that was implemented, but before measure was not established.

4. *Exploitation, dissemination, and promotion of transfer of safe practices—priority settings of next call*

The Observatory approach was aimed at setting up actions for gradual transition from passive spread of safe practices to active and planned adoption in a sustainable way [6, 7, 9, 12, 13]. Therefore, further to web diffusion and traditional dissemination tools (presentations in national and international conferences, brochures, and scientific papers), some specific tools have been tested to disseminate and promote the transfer of safe practices. As a part of an increasingly widespread dissemination of good practices, a model for inter-regional transfer of safe practices has been tested. The model is based on the exchange of experiences and knowledge between three groups of Regions (Northern, Central, and Southern) that are contiguous from the geographical and cultural point of view and their models for clinical risk management have similar organizational features [7]. The tool consists of a standard workshop format that is reproducible and adaptable to different contexts. The strengths of this tool, as declared by professionals, health organizations, and regions involved, lie in the fact that it enables an open and direct discussion between organizations sharing similar problems and allows a more widespread dissemination of the safe practices.

A peer review program for promoting transfer of safe practices at inter-regional level has been developed and tested. For the first test, the peer review program has been focused on good practice for safe surgery (to answer to specific needs expressed by professionals and to keep the Observatory aligned with the international indications). In collaboration with the Association of Italian Hospital Surgeons (ACOI), the Italian Society of Anesthesia Analgesia and Intensive Care (SIAARTI), and the Association of Operating Room Nurses (AICO), the specific model of intervention and procedures have been developed and tested at the Day Surgery Unit of the Niguarda Ca' Granda Hospital in Milan. The program is still ongoing in the Lombardy Region.

4. Results

The main result of the activities described in this chapter is a publicly available database of patient safety improvement interventions including 2628 experiences (**Figure 2**).

Year	Number of practices reported to the Observatory
2008	361
2009	356
2010	282
2011	300
2012	310
2013	230
2014	299
2015	233
2016	257

Figure 2. Number of practices reported to the Observatory per year.

An average of 300 practices per year has been submitted to the Observatory. The number ranged from a maximum of 358 in 2008 to a minimum of 230 in 2013. Since 2014, the trend is in the direction of a recovery.

This year's focus is on experiences aimed at improving quality of maternal care that resulted in submission of the 43 practices some of which are briefly outlined in the box (titles are provided for all of them); they represent evidence-based, implemented real solutions to the problem presented in the beginning of this chapter.

The application of the National Recommendations for the healthcare safety: a questionnaire for the internal monitoring in the Clinical Units of the University Hospital of Parma [14]

Parma Hospital—Emilia Romagna Region

Aiming to improve: (1) Analyze the applicability, relevance, and effective implementation of each National Recommendation within all the clinical units of the University Hospital of Parma. (2) Assess whether the training events for the dissemination of all National Recommendations have had repercussions in the clinical care practice. (3) Check whether the tools provided for the spreading of the specific contents of the National Recommendations are actually considered useful by the chiefs of clinical units. (4) Identify suggestions for improvement in order to increase the safety culture in the University Hospital.

Description of PSP: (1) The Clinical Governance Structure of the University Hospital of Parma has promoted an internal survey, in all clinical units, for monitoring the application of National Recommendations for the Clinical Risk Management. The monitoring has included: (1) The creation of the questionnaire, developed by the professionals of the Clinical Governance Structure in collaboration with the Nursing Directorate (time required 3 months). The questionnaire, prepared in a pdf mode, had "forms" fillable directly online by the managers of all clinical units. The compilation of "filter" questions has allowed managers to bypass entire sections of the questionnaire if they have evaluated one or more Recommendations as "not applicable" in their clinical units. The questionnaire has allowed to automate the insertion phase of data. (2) Sending the online questionnaire by email to all clinical units' chiefs/coordinators evaluated as eligible to the survey. The questionnaire has been accompanied by an introductory note that has explained the survey's objectives and the methodology used. All clinical units have been represented by one or more questionnaires compiled by their representatives (chief of clinical unit or coordinator). (3) Results' processing (time required 3 months). (4) Dissemination of the final report to the chiefs/coordinators through the Intranet site and use of the results for the 3-year program of safety management (time required 3 months).

Methods used for evaluating results: Process indicators—Coordinators participated in 75% of cases, whereas chiefs of clinical unit doctors responded in the remaining 25% of cases. About 81% of clinical units that were eligible for detection has joined the survey (N = 59). The departments that have joined more to the survey were the General and Specialist Surgery Department and the Geriatric Department. Outcome indicators: The National Recommendations that have been highlighted as more applicable in the clinical units are (1) the 9th, regarding the malfunctioning of electromedical devices: 100 of clinical units, (2) the 13th about the falls prevention: 89.8% of clinical units, (3) the 8th for the prevention of violence against healthcare workers: 88.1% of clinical units, and (4) the 17th, regarding the drugs reconciliation 86.4% of clinical units. The more a recommendation has contents that concern all clinical units, much less was found to be homogeneous in its effective dissemination/application in the teaching hospital. In fact, the recommendations, whose contents are general and applicable for 60–100% of clinical units of the teaching hospital, were found to have a non homogeneous application: in fact, except for the two recommendations on the safety of drugs use (the 7th and the 12th), applied in 100% of the clinical units, all the other remaining recommendations have achieved the levels of application inferior to 8.5%. Instead, the National Recommendations whose content was "specific" or limited to specific clinical areas (e.g., the prevention of maternal or neonatal death) have obtained 100% of application in the few clinical units concerned.—An average of 8% of clinical units has evaluated "scarce" the utility of the training events and of the tools made available by the Clinical Governance Structure, in particular for the 9th and 4th Recommendations (regarding "the malfunctioning of electromedical devices" and "the prevention of patient's suicide," respectively), also by considering them highly relevant.—37.5% of the structures in which the Recommendation n.10 is considered has highly relevant, has evaluated the specific tools made available by the Clinical Governance structure as not useful in which the Recommendation 10 (focused on "Prevention of bisphosphonates-induced osteonecrosis") is considered highly relevant, also has evaluated as not useful the specific tools and training events made available by the Clinical Governance Structure to improving safety. These recommendations will, therefore, be the subject of specific projects within the three-year planning (Plan on the Safety of Care Program 2016–2018) in the Parma Teaching Hospital. An average of 8.7 suggestions/proposals for the improvement of the local application of each among the 17 National Recommendations has been obtained.

Newborn Emergency Transport Service (NETS): the experience in the Province of Reggio Emilia [15]

Local Health Authority of Reggio Emilia—Emilia Romagna Region

Nursing skills video-tutorial (infant/child 0–3) [16]

University Hospital of Trieste—Friuli Venezia Giulia Region

Aiming to improve: *Keywords*: maternal and child nursing skills, simulations, safe care, and effective communication. The training of nursing staff in maternal and childcare must take place in the safest possible manner. The simulation provides a solution for safe learning, offering to those who practice two major advantages: on the one hand, the "permission to make mistakes" and, on the other, the opportunity to learn through clinical experience. Building on the experience of the laboratory, 2nd year CDL Nursing 2012–2013 AA will be implementing further simulations for learning in a safe environment with the aim of improving the clinical learning of nursing students within maternal and childcare. To test the possible improvement of the practice, it will compare the performance of students of 2012–2013 AA with those of 2016–2017 AA (CDL Nursing—Department of Medical, Surgical and Health Sciences-University of Trieste).

Description of PSP: Simulation Design Scale (Student Version)

Methods used for evaluating results: Simulation Design Scale (Student Version) and compare the performance of students of 2012–2013 AA with those of 2016–2017 AA (CDL Nursing—Department of Medical, Surgical and Health Sciences, University of Trieste)

"Dry cord care" in the treatment of the neonatal cord stump [17–19]

University Hospital of Udine—Friuli Venezia Giulia Region

HFMEA applied to >24 weeks pregnant patients' pathway [20]

University Hospital of Udine—Friuli Venezia Giulia Region

Aiming to improve: To ensure safer care, we decided to apply HFMEA to our 24th week pregnant patients' pathway. Our analysis started from patient acceptance and ended in temporary observation (before hospitalization).

Description of PSP: First of all, the multiprofessional team was assembled. The team analyzed the entire pathway, describing 6 main phases, 28 activities, and 45 potential failure modes (PFM). For each PFM, the professionals assigned a numerical value, risk priority number (RPN) to identify activities at risk, in accordance with literature. To establish the priority of interventions, we decided to put in place corrective actions for PFM with RPN numerical values > the third quartile.

Methods used for evaluating results: We assigned new RPN scores for PFM > the cut-off and analyzed the improvements through Wilcoxon test: we obtained a statistically significant decrease of the RPN values ($p = 0.0009$).

Continuing education on prevention and treatment of postpartum hemorrhage [21]

IRCCS S. Raffaele—Milano—Lombardy Region

Aiming to improve: The first official Italian guidelines on postpartum hemorrhage (PPH) prevention and treatment were published in November 2016. Our clinical practice has, therefore, been updated, and its compliance to these national guidelines verified. The department's internal guidelines, albeit updated earlier this year, have also been integrated with the newest indications regarding the use and dosage of uterotonic medications. We aim to keep training our obstetric staff and younger physicians, in particular, to face PPH with effectiveness and celerity. We recently introduced the ROTEM analysis for patients undergoing severe blood loss, as this proved to be fundamental in order to guide the utilization of blood product transfusion.

Description of PSP: Thanks to the experience gained during a practical course using a mannequin (Noelle®), we decided to focus on patients who most rapidly reach 1500 ml of blood loss. We trained on positioning intrauterine hemostatic balloons and most specifically on uterine sparing compressive surgical techniques, as our primary objective is the conservation of young patients' subsequent fertility. To improve our further education, we organized audits in order to discuss clinical scenarios that included PPH complications.

Methods used for evaluating results: We have always divulged monthly statistical analyses of PPH cases to our clinical staff in order to raise awareness and stimulate the individual's revision of the adverse event. We also re-examined each single severe PPH case with the obstetric staff, on call at the time, to identify and discuss inconsistencies in different clinicians' approach to the matter. Great effort is implied in supporting the patient and her relatives after PPH. In fact, some patients risk PTSD after such a complication, and we offer an appropriate psychological—behavioral aid to prevent this disorder. Among our PPH patients, none presented this problematic.

Intensive management of pregnant women with HELLP syndrome [22]

ASREM—Molise Region

Good practices in obstetrics: the value of Audit in healthcare [23]

Local Health Authority of Asti—Piedmont Region

Aiming to improve: *Postpartum hemorrhage is a major cause of mortality and maternal morbidity: it occurs at a rate varying* between 5 and 22% of total deliveries and implies a mortality rate of 1:1000 in developing countries and of 3–5:100,000 in industrialized countries. A total of 60–70% of deaths by postpartum hemorrhage is due to nonoptimal treatment. Hence, the need to apply the strategy of an "Active Management" of the third stage able to reduce the incidence of 40–50% hemorrhage. We worked according to the principles of clinical risk management, analyzing and activating adequate proceedings to restrict adverse events.

Description of PSP: The verification on the data collected allowed to confirm the goodness of our practice of active management of the third stage by oxytocin prophylactic administration to all patients. The frequency of postpartum hemorrhage in our ward seems to be comparable to that of other Centres of Excellence in Italy. In all cases of more serious hemorrhage (>1000 ml), the treatment was rapid and an integrated multiprofessional and multidisciplinary approach that allowed us to quickly identify the cause and provide suitable therapeutic measures.

Methods used for evaluating results: examination of medical records

Prevention and management of postpartum hemorrhage in Obstetrics and Gynecology [24]

Local Health Authority of Prato—Tuscany Region

Aiming to improve: Postpartum hemorrhage is one of the most frequent causes of maternal death. More than half of the cases occur within 24 hours of delivery. Good practice calls for actions and tools for better prevention and management of this event. Practice realized in collaboration with Italian Association of Hospital Gynecologists.

Description of PSP: As a part of the project for patient safety, the Regional Center for Clinical Risk Management of Tuscany has launched a campaign on the prevention and management of postpartum hemorrhage. In order to provide a guide to individual health structures for the implementation of interventions that might lead to better prevention and management of this event, it has developed a guidance document "Best Practices for prevention and management of postpartum hemorrhage" (Chapter 2.2 Best Practices for patient Safety in Obstetrics and Gynecology, published in No. 1 of Notebooks of laboratories for patient safety). Based on the indications suggested by the Regional Good Practice LHA 4 of Prato has (1) implemented the dissemination of the document to address GRC Regional Centre to all relevant staff; (2) provided a procedure for the adoption of formalized good practice; and (3) applied the regional indications for the prevention and management of postpartum, according to the responsibilities identified, and in particular: the prevention of post-partum hemorrhage through the active management of postpartum; the timely diagnosis of postpartum hemorrhage (procedure for the estimation of blood loss), the search for the cause of bleeding, and the immediate availability of tools and materials (Kit hemorrhage); coordinated multidisciplinary management of cases of postpartum hemorrhage through the implementation of an operating instruction for the management of hemorrhagic shock; sharing with anesthetists and the blood centers operation instruction for the management of hemorrhagic shock; the planning and execution of training events on laparotomy techniques in postpartum hemorrhage; the implementation of the default grid for the documentation of cases of postpartum hemorrhage; programming an audit of any postpartum hemorrhage.

Methods used for evaluating results: The implementation is evaluated through clinical Audit and periodical internal checks on the correct application of the good practice. INDICATORS—Presence of a procedure for the formal adoption of good practice; certificates on periodic training of the surgical team; presence of a board/grid for the documentation of cases of postpartum hemorrhage; presence of alert reports about systemic analysis of cases reported with postpartum hemorrhage; availability of postpartum hemorrhage kit in the delivery room; and presence of the poster "postpartum hemorrhage" in the delivery room.

Pregnancy and delivery of a cardiopathic fetus [25]

Gabriele Monasterio Foundation Hospital—Tuscany Region

Aiming to improve: The finding of a heart defect in the fetus has significant implications for pregnancy management, delivery planning, and diagnosis of abnormalities in other organs. Fetal echocardiography can help detect fetal heart abnormalities before birth, allowing for faster medical or surgical intervention once the baby is born if needed. This improves the chance of survival after delivery for babies with serious heart defects. Some heart defects will not require immediate intervention, and the baby can be followed at the delivery hospital and as an outpatient after discharge. Other defects are more serious and require pediatric cardiac surgical services immediately after delivery. In some cases, the condition may be severe enough for the pediatric cardiologist to recommend delivery at a pediatric heart center so that an intervention can be performed within minutes of life. In all cases, these issues should be discussed and planned for during the fetal echocardiography visits. Keyword: baby childbirth birth path cardiopathy.

Knowing about a potential heart problem prior to delivery also gives a family a chance to learn more about the problem which can help themselves prepare psychologically for dealing with the extra challenges they may face following birth, such as surgery or other interventions the child may require. A coordinated fetal team that includes pediatric cardiologists, genetics counselors, obstetricians, perinatologists, neonatologists, nurses, and other subspecialists should work closely.

Description of PSP: A clinical pathway was designed in Fondazione Toscana "G. Monasterio" together with Nassau Hospital for precocious diagnosis of fetal congenital heart disease and for the rest of pregnancy and delivery management. Fetal heart abnormalities are detected before birth, allowing for faster medical or surgical intervention once the baby is born in order to improve chance of survival. After in-womb diagnosis, several meetings before delivery with parents, midwife, psychologist, pediatric cardiologist, and neonatologist are planned. Delivery is planned and performed in a special, dedicated area of Pediatric Cardiology/Cardiac Surgery Department, where the presence of specifically trained obstetricians, neonatologists, midwives, and anesthesiologists together with highly trained nurses is guaranteed all over 24 hours. After birth, the baby is transferred to a dedicated Newborn Intensive Care Unit for the first interventions, where she is evaluated also by a pediatric cardiologist and a pediatric cardiac surgeon.

Methods used for evaluating results: Nonquantitative methods are now in use

Prevention and management of shoulder dystocia in Obstetrics and Gynecology [26]

Local Health Authority of Prato—Tuscany Region

Aiming to improve: Shoulder dystocia is a complication associated with childbirth for which the shoulders of the fetus do not come out spontaneously after the escape of the head and require additional obstetric maneuvers. The good practice developed at regional level provides a series of actions and instruments, consistent with international guidelines, aimed at better prevention and management of this event. Made in collaboration with Italian Association of Hospital Gynecologists.

Description of PSP: As a part of the campaign for patient safety, the Regional Center for Clinical Risk Management (RCCRM) of Tuscany has launched a campaign on the prevention and management of shoulder dystocia. In order to provide a guide to individual health agencies for the implementation of interventions that might lead to better prevention and management of this event, the RCCRM has developed a guidance document "Best Practices for the prevention and management of shoulder dystocia" (Chapter 2.1 of the best practices for patient safety in Obstetrics and Gynecology, published in No. 1 of the Notebooks of laboratories for patient safety). Based on the indications suggested by the Regional Good Practice, the Trust of Prato: implemented the dissemination of the document to address GRC Regional Centre to all relevant staff; set up a general procedure for the adoption of formalized good practice; ensured the prevention, when possible, through proper identification of risk factors for antepartum and intrapartum both at the time of taking over of the woman in labor (shared procedures and protocols for the management of all phases of childbirth); ensured adequate treatment of cases by carrying out the maneuvers required by good practice and coordinate the multidisciplinary management of cases; ensured the competence of healthcare professionals (knowledge, skills, and interpersonal skills) through training and simulation; made available the presence of a poster in all venues of labor and of childbirth aid to remember the maneuvers to be carried out; implemented a default grid for the documentation of cases of shoulder dystocia; and ensured the conduct of an audit on all cases of dystocia.

Methods used for evaluating results: The actual implementation of the provisions of good practice is periodically checked: presence of a company procedure for the formal adoption of good practice; presence of the partogram in the medical record; presence of the poster in all rooms of labor and childbirth; presence of analysis of detected cases of shoulder dystocia, with relative alert report; and presence of certificates of training with simulation.

Activation of labor analgesia in first-level structure within 24 hours [27]

Local Health Authority of Mirano—Veneto Region

Aiming to improve: Modern anesthesiology allows women to control pain during labor and delivery through epidural analgesia, a safe and effective technique that ensures the possibility of a spontaneous delivery and at the same time the complete participation of the woman during the birth of her baby. In Italy, this kind of analgesia is not yet a widespread technique, even if it is provided by the most recent Essential Levels of Care. The reasons for this lack in popularity are many: (1) cultural barriers among both professionals and patients, who are often not well informed on the procedure; (2) organizational problems such as the lack of well-trained professionals and the lack of an on-call anesthetist during the 24 hours; and (3) an increasing request of analgesia during labor as a result of safer anesthesiological and pharmacological techniques used. For all these reasons, professionals working in obstetrics and gynecology and resuscitation units of Dolo and Mirano hospitals in the latest years have made a great effort to ensure analgesia during labor to all women who deliver there 24/7 (and not only 12 hours/day as provided by the current Essential Levels of Care). In this way, every woman who desires analgesia during labor can have access to it, if the clinical situation allows it, independently of the

time of the request. Specific objectives: to ensure every pregnant woman, the possibility to have analgesia during labor 24/7, by the continuous presence of an on-call anesthetist; to reduce intrapartum complications, thanks to a specialized assistance; to reduce the number of complications after the birth, thanks to a dedicated and specialist level of assistance; to reduce the number of cesarean sections; and to increase professionals' and patients' knowledge and awareness about pain in labor.

Description of PSP: (1) Information about analgesia during labor is given during childbirth classes and obstetric visits, focusing on the technique, the risks, and the benefits for the mother and the baby and on how to access to the service, giving the pregnant women the specific forms to fill. (2) The anesthesiological visit is offered after 35 weeks of pregnancy, and it is necessary for the clinical evaluation of the pregnant woman and to explain her the technique. (3) The woman is invited to fill in the specific forms for epidural analgesia and to sign the informed consent for the procedure. (4) The working shifts guarantee there is an on-call anesthetist 24/7. (5) Daily briefing and multidisciplinary meetings are fundamental to discuss about organizational problems on the analgesia service and solve them. (6) The data on the anesthesiological chart are important for a quantitative analysis of the service. (7) It is important to evaluate the pain before and after the analgesia, using visual analog scale of pain (VAS) and to collect opinions of the patients about the assistance offered. These two parameters allow doing a qualitative analysis of the service.

Methods used for evaluating results: Evaluation of the results based on the detection of pain before and after analgesia with validated method visual analog scale of pain (VAS). Bromage scale to assess the motor blockade of the lower limbs. APGAR index of newborn.

ST analysis of fetal ECG reduce cesarean section rate for fetal distress [28]

Nursing Home Abano Terme—Veneto Region

Decreasing AUR (antibiotic use rate) in infants = 35 weeks in community-based neonatal intensive care unit (NICU) [29]

Local Health Authority of Vicenza—Veneto Region

Clinical birth pathways: new uncertainties and "error traps" in the risk assessment [30]

Local Health Authority of Treviso

Early identification and treatment of sepsis in pregnancy [31]

Hospital of Feltre

Aiming to improve: Sepsis protocol describes clinical and instrumental methods to early identify the risk of sepsis in pregnant women. The aim is to prevent the onset of sepsis and its complications.

Description of PSP: Healthcare Practitioners evaluate pregnant woman on her symptoms/signs, her risk factors to develop sepsis, and on the Quick-sepsis-related organ failure assessment (SOFA). If there is only a single symptom/sign positive, and all other parameters are negative, woman is monitored for 6–12 hours with re-evaluating of all parameters at least one time every 3 hours, carrying out specific blood chemical tests indicated in the protocol. If the parameters are positive (one or more symptoms and/or one or more risk factors and/or the Quick-SOFA is positive), woman is monitored for 12–24 hours with re-evaluating of all parameters at least one time on every 2 hours, carrying out specific blood chemical tests indicated in the protocol, including a blood gas analysis viewed by anesthetist. The gynecologist explains to the patient and her family the risk of possible sepsis diagnosis. If parameters go down, healthcare practitioners activate a series of countermeasures including the pregnant woman transfer to the intensive care.

Methods used for evaluating results: To evaluate the results, it will use patient's clinical documents; in Italy, a specific information called "flusso SDO (Hospital Discharge Abstract)" is used to search for sepsis diagnosis in pregnant women and verify the sepsis protocol application.

Implementation of Safe Operating Rooms project by applying a surgical safety checklist tailored to the specific needs of cesarean delivery and evaluation of the impact on patient safety [32]

University Hospital of Modena—Emilia Romagna Region

Assisted Maternal Fetal Transport [33]

Local Health Authority of Piacenza—Emilia Romagna Region

Improving the management of shoulder dystocia by updating the knowledge of operators and the participation of pregnant women: health education project [34]

Local Health Authority ROMA E—Lazio Region

Protocol for assisting and surveilling newborns [35]

Local Health Authority ROMA B—Lazio Region

Presence of partner during childbirth [36]

Local Health Authority ROMA B—Lazio Region

Diagnostic-therapeutic pathways (DTPs) improve the affective-relational dimension between mother and baby through contact experiences [37]

Local Health Authority ROMA E—Lazio Region

Baby Friendly Community Initiative UNICEF Family Planners Centre EX ASL Roma B [38]

Local Health Authority ROMA B—Lazio Region

Development of integrated network for mother and child patient safety [39]

ASST Mantova—Lombardy Region

Strategies for reducing the number of cesarean sections as an indicator of quality of care in the delivery room [40]

ASST Valle Olona—Lombardy Region

Safe Delivery Room [41]

Local Health Authority of Bolzano—Autonomous Province of Bolzano

Childbirth checklist [42]

Local Health Authority CN1—Piedmont Region

Standardized procedures for the safety and appropriateness of neonatal emergency transport (STEN) and maternal-fetal assisted transport (STAM) in Piedmont Region [43]

Local Health Authority CN2

Procedure for assisting newborn with hypoxic-ischemic encephalopathy possible candidate for hypodermic treatment [44]

Local Health Authority BAT—Puglia Region

The childbirth from prenatal access to discharge from hospital [45]

Nursing Home Triolo Zancla—Sicily Region

Description of emergencies activities—gynecological-obstetric emergency [46]

Provincial Health Authority of Catania—Sicily Region

Implementation of good practices in relevant clinical obstetrics and gynecology through specific documentation integrated inside the obstetric assistance folder care [47]

Local Health Authority of Lucca—Tuscany Region

Prevention and management of shoulder dystocia [48]

University Hospital of Pisa—Tuscany Region

Prevention and management of postpartum hemorrhage [49]

University Hospital of Pisa—Tuscany Region

The checklist applied to the path medically assisted procreation [50]

Local Health Authority Versilia—Tuscany Region

Procedure for neonatal resuscitation [51]

Local Health Authority Rovigo—Veneto Region

The path leading to childbirth [52]

Local Health Authority of Thiene—Veneto Region

The autonomy of midwife in the management of labor and physiological delivery [53]

Local Health Authority of Mirano—Veneto Region

Safe childbirth [54]

Local Health Authority of Legnago—Veneto Region

Implementation of obstetrician triage at the clinic in midwifery acceptance [55]

Hospital of Padova

Assistance procedure in the postpartum hemorrhage [56]

Local Health Authority of Rovigo

Procedure for prevention of maternal death or serious illness related to labor and/or childbirth [57]

Local Health Authority of Rovigo

Guidelines for the management of sepsis in pregnancy and childbirth [58]

Local Health Authority of Rovigo

Box 1. Patient safety practices aimed at improving quality of maternal care. Titles and abstracts are taken from the Observatory on Good Practice for Patient Safety (http://buonepratiche.agenas.it/).

Below, we also report some of the results achieved by the Observatory by applying the logical model [59–61]. To do this, we performed a temporal analysis (2008–2014) of aggregated data collected through the annual calls for good practices. Over the years, the number of patient safety practices (PSPs) submitted to the Observatory ranged from a maximum of 361 in 2008 to a minimum of 230 in 2013 [7], while the absolute number of Health Providers who reported at least one good practice has had a fairly more stable trend. In particular, we can see an increase in the number of health providers participating in the Call from 2008 to 2010, and then a decrease from 2010 to 2014. The joint observation of this decrease and the number of good practices shows opposite patterns (an increase in the number of good practices from 2013 to 2014). This means that in 2014, a lower number of providers have been actually producing a higher number of good practices (**Figure 3**).

Even though the number of professionals reporting patient safety practices has been decreasing over time, there is an increase in the number of experiences reported from 2013 to 2014. This means that a lower number of providers have been actually producing a higher number of good practices.

Since the practices reported could be at a different stage of development, we also looked at them according to their level of implementation and evaluation of results (**Figure 4**), as derived from the classification in *good practice*, *potential good practice*, and *initiative*. At a decreasing total number of practices reported in 2013 corresponds a more balanced proportion of fully implemented good practices with respect to potential good practices (40% each). This suggests that the quality of the experiences reported has improved over time.

It is interesting to look at the distribution of the practices according to the adverse events they focus on (the experiences reported to the Observatory have to specify one or more adverse events they aim to prevent/reduce). Adverse events have been selected among the most prevalent in literature and in the Italian context [62].

Table 1 shows the list of adverse events and the total number of good practices related to them over the whole period of 2008–2014.

In general, the number of practices that related to prevention of the main surgical adverse events is very high (665). It is followed by the number of practices aimed at avoiding hospital

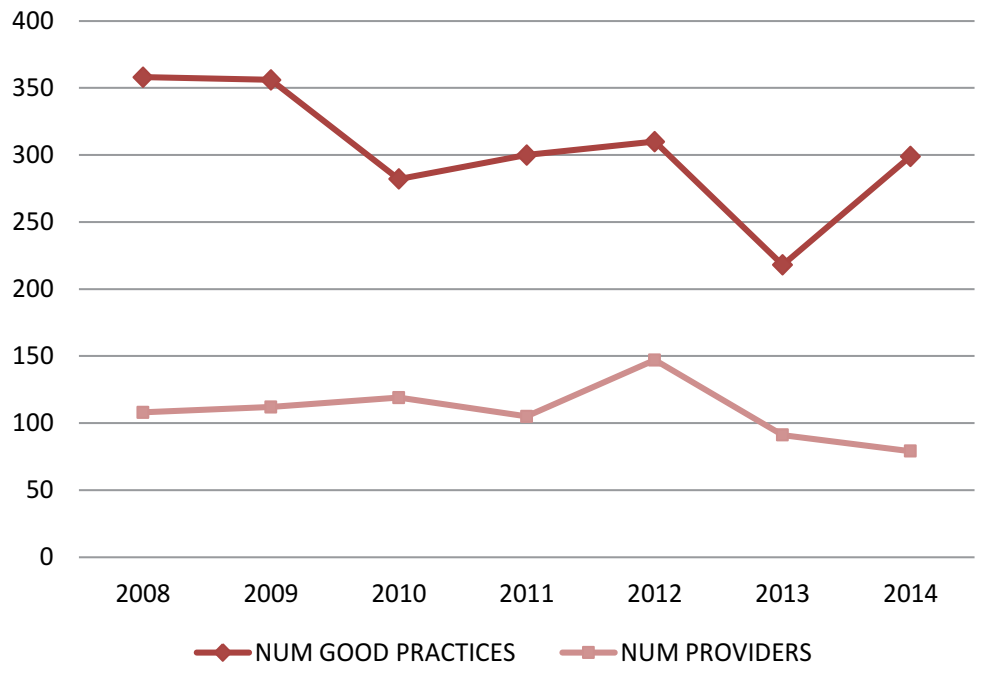

Figure 3. Number of patient safety practices and healthcare providers in the Italian Observatory 2008–2014.

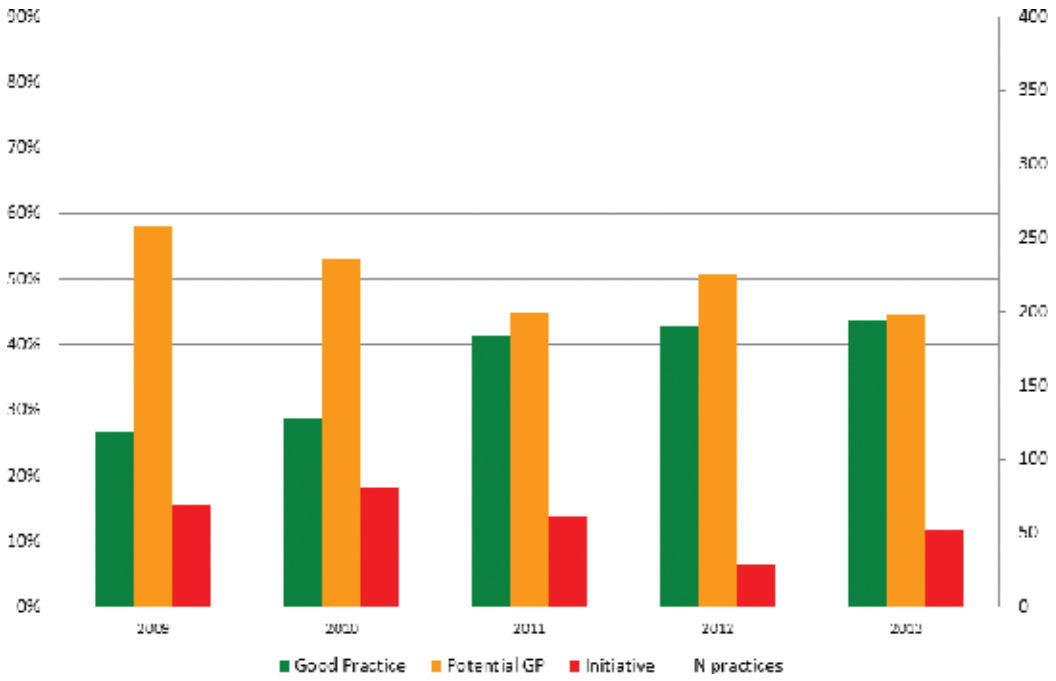

Figure 4. Absolute number of patient safety practices (right axis) and percentage of practices per level of implementation (left axis) per year 2008–2014: Analysis of temporal trend in the level of implementation of patient safety practices.

COD	Adverse events	No. of practices
1	Other clinical adverse events	430
2	Procedure on wrong patient/wrong side or body part or wrong procedure	310
3	Hospital-acquired infections	298
4	Death, coma or disability due to medication errors	296
5	Retention of material in surgical site	181
6	Death or severe adverse event unexpected after surgical intervention	174
7	Patient's fall	166
8	Adverse events related to inadequate hand hygiene	144
9	Transfusion reaction due to AB0 incompatibility	136
10	Deep venous thrombosis	128
11	Pressure ulcers	98
12	Adverse events due to malfunctioning of transportation system	90
13	Death/permanent disability in healthy newborn (weight>2.500 gr)	72
14	Violence against healthcare workers	68
15	Maternal death or severe illness associated with labor and/or delivery	65
16	Prevention of adverse events related to incorrect attribution of triage code	65
17	Suicide or attempted suicide in hospitalized patients	60
18	Violence against patients	48

Table 1. No. of practices per adverse event they are aiming to prevent/reduce.

infections (298) and those related to prevention of errors in pharmacological therapy (296). Many experiences are also aimed at avoiding patient's fall (166), reported to be the most frequent event occurring in the last 7 years in Italy [62].

The evidence of the Observatory's success in supporting and promoting regional monitoring of patient safety practices is in the participation rate in the calls: 100% (21/21) of Regions and Autonomous Provinces have been participating in the call for good practices and developed their own regional model for verification and evaluation of good practices for patient safety. However, participation rates were markedly differentiated among the regions.

Figure 5 highlights the high variability in geographical participation, with Tuscany and Lombardy regions covering together almost 50% of the overall number of practices submitted. As the practices are submitted to the Observatory using a standard form where authors are required to describe the methods they used to evaluate the results achieved using qualitative measures and quantitative indicators, the capacity of the Observatory to spread the culture of self-assessment is proved by the number of the collected practices.

By developing and testing a peer review program, the Observatory also contributed to spreading the culture of external evaluation of quality and safety, as confirmed by professionals in the feedback survey recently carried out by Agenas.

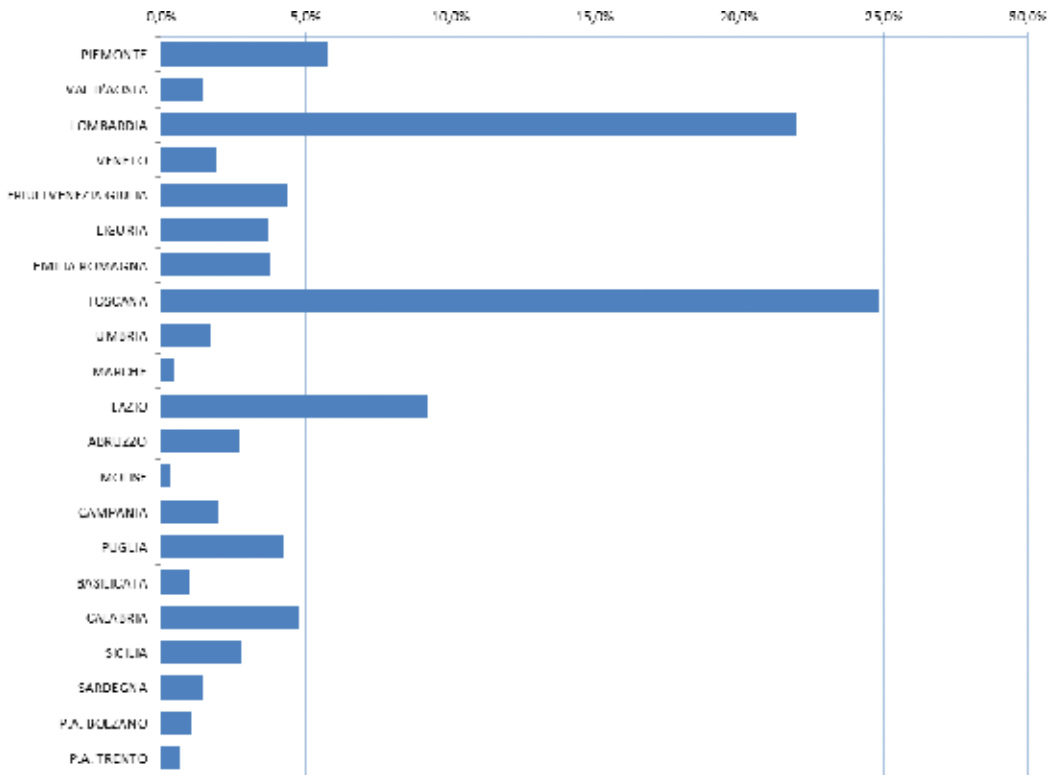

Figure 5. Percentage of patient safety practices per regions/Autonomous Province in 2008–2014: there is high variability in geographical participation, with Tuscany and Lombardy covering together almost 50% of the overall number of practices submitted.

Hundred percent of the practices submitted to the Observatory and published in the web portal includes an abstract, whose aim is to communicate to nonprofessionals in a comprehensible way the intervention informing citizens about the resources used and the results achieved in order to establish transparency and accountability.

Data collected by the Observatory clearly depict its effectiveness as a tool for promotion, dissemination, and application in the Italian context of state-of-the-art of safe practices. The Observatory has also proved to be an effective tool for reducing heterogeneity in patient safety activities among the Italian regions.

5. Conclusion

The adoption of a bottom-up approach within a national improvement program has greatly contributed in Italy to spreading knowledge and experience to improve patient safety in the healthcare system. Both the patient and the GP from the vignette would have benefited from the knowledge-sharing platform provided by the Observatory. As pregnancy is fraught with potential for worry and confusion, the patient would have benefited from the experience of the professionals dealing with quality and safety issues in their everyday life. However,

consultation of the Observatory's database would have provided the GP with the chance of exchanging views with colleagues on the best way for a rapid identification of sepsis.

The Italian experience shows that key success factors of a national patient safety improvement program are a strong government mandate, solid scientific foundation and reference theories, inclusion of stakeholders, and continuous attention to the needs of those (professionals and health organizations) who are in charge of implementing the good practices for patient safety.

In the review carried out by the OECD on the quality of healthcare in Italy [6], the Italian Observatory was described as a "key action to improve patient safety" and as an "example to emulate."

The Observatory has proved to be an effective strategy to overcome some of the main barriers to implementing evidence-based safe practices [63] at an individual level:

- Lack of understanding of the organization or the structure of electronic databases, lack of search skills, lack of library/database: the Observatory database is searchable by simple search criteria and is dedicated exclusively to evidence-based safe practices.
- Lack of knowledge about evidence-based safe practice: the Observatory is a free source of knowledge that is continuously updated by professionals themselves and at organization/institution level.
- Organizational budget for acquisition of information resources.
- Organizational budget for training in resource use: a survey recently carried out by Agenas confirmed that the Observatory free database is usable, used, and useful for professionals.

The debate about method for evaluating healthcare quality improvement and patient safety national programs is still very open [64, 65], whereas outcome evaluation is very complex (case—control studies and randomized control trials are not applicable); the process evaluation we used to assess the results of the Observatory is considered an important tool for describing the intervention and for explaining its success or lack of effect and to enable other people to replicate the intervention with the appropriate adaptations [66].

We applied the logical model that is commonly used in evaluating public health intervention as it grants transparency, accountability, and collaboration with stakeholders [67]. This model well fits for planning, managing, and evaluating quality and patient safety improvement programs [68] as it allows to evaluate, in a transparent and accountable way, whether the objectives for which the intervention had been planned have been achieved. From this perspective, the results achieved by the Observatory on Good Practices for Patient Safety—after 9 years of working—are very encouraging, allowing us to consider it an important lever with which to improve patient safety.

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Chapter 3

Transitions of Care: Complications and Solutions

Philip Salen

Additional information is available at the end of the chapter

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Abstract

The delivery of medical care relies on effective, succinct, and ongoing communication between healthcare providers, called handoffs. Handoffs involve the transfer of professional responsibility and accountability for aspects of care for patients to another clinician or clinical team on a temporary or permanent basis. Handoffs have the potential for deleterious clinical impact if inadequately done. Only recently has data become available that demonstrate improvements in handoffs reduce the rate of subsequent clinical care error. This clinical vignette and subsequent discussion focuses on physician, particularly the resident physician in training, transfer of care: handoff complications, barriers to effective handoffs, regulatory agencies' input on handoff improvement, standardization of the handoff process, assessment of the quality of handoff, handoff error avoidance, and improving the quality of handoff.

Keywords: physician fatigue, resident duty hour restrictions, night float, physician burn out, resident education

1. Clinical vignette

An 84-year-old female presented to the emergency department (ED) for evaluation of left hip pain after a fall at her locked dementia unit. The patient could not ambulate and had a bruise over her left hip. Radiograph demonstrated a left hip fracture and orthopedic consultation was requested for evaluation of a hip fracture by the ED resident. The on-call orthopedic resident after discussion with the orthopedic attending recommended placement of a single compression hip screw for treatment of the hip fracture and requested the internal medicine hospitalist service admit the patient for medical management of the patient's dementia and diabetes prior to operative repair of the hip. The internal medicine hospitalist service admitted

the patient for preoperative clearance prior to repair of her hip fracture. When approached by the orthopedic surgery resident the next day for signed consent for operative hip repair, the patient signed consent for operative repair of her hip. On arrival in the preoperative area during surgical time out, the patient confirmed that the right hip would be operatively repaired. After operative repair of the right hip, the patient returned to the hospitalist service with a request for initiation of enoxaparin anticoagulation to prevent deep venous thrombosis. Postoperative X-ray demonstrated single compression hip screw in the right hip with a persistent left hip subcapsular fracture. Three days after the operation, the patient developed acute hypoxia, CT angiogram of the chest documented pulmonary embolism; the on-call hospitalist noted there had been no initiation of prophylactic enoxaparin postoperatively. On return to the floor prior to the initiation of anticoagulation for pulmonary embolism, the patient became severely dyspneic and hypoxic followed by pulseless electrical activity cardiac arrest; resuscitation efforts failed to return spontaneous circulation and the patient expired.

Allegation: The ED, orthopedic, hospitalist physicians, and staff were implicated in the wrong side operative repair of the left hip fracture and in the failure to initiate anticoagulation prophylaxis. The orthopedic and hospitalist physicians were implicated in the failure to initiate anticoagulation prophylaxis for deep venous thrombosis. At trial, attestation from the hospitalist and orthopedic physicians alleged that ED consultation for the right hip had been ordered.

Disposition: Pretrial mediation prior to the court case resulted in a large monetary settlement on behalf of the plaintiff's heirs.

2. Introduction

Healthcare organizations and providers struggle with the process of communicating crucial patient information from one caregiver to the next, or from one team of caregivers to another [1]. The delivery of medical care relies on effective, succinct, and ongoing communication between healthcare providers, called handoffs [2]. These clinical handoffs, also known as sign outs, shift reports, or handovers, take place throughout the healthcare system between multiple providers with various clinical responsibilities. Patient handoffs are complex, multifaceted events that occur at the beginning or end of clinical shifts [3]. Handoffs involve the transfer of professional responsibility and accountability for some or all aspects of care for the patient or groups of patients to another clinician or clinical team on a temporary or permanent basis [4]. Handoffs have the potential for deleterious clinical impact if inadequately done. Only recently has data become available that demonstrate improvements in handoffs reduce the rate of subsequent clinical care error [5].

This clinical vignette and subsequent discussion focuses on physician, particularly the resident physician in training, transfer of care: handoff complications, barriers to effective handoffs, regulatory agencies input on handoff improvement, standardization of the handoff process, assessment of the quality of handoff, handoff error avoidance, and improving the quality of handoff.

3. Transitions of care: handoff definition

The Joint Commission (TJC) defines handoff as: a means to provide accurate information about a patient's care, treatment, and services; current physical condition; and any recent or anticipated changes in clinical course. Accurate information communicated during handoff must be accurate in order to meet safety goals [6]. The goal of quality handover of care is to ensure continuity of care and high-quality, safe care decision making in a specific physical and cultural environment. More than merely the passive transfer of information, optimum handoffs necessitate the efficient communication of information among participants [3]. Expansion of duty hour restrictions for resident physician trainees in North America have increased handoff frequency, augmented the potential for ineffectual handoff-induced complications, and stimulated the need for new interventions to improve handover quality [7]. The shift from the traditional model of continuous inpatient medicine to a team-based model has further focused attention on patient handoffs [3]. Interunit handoffs, such as the transition from the ED to the inpatient setting, have special challenges, such as changes in personnel, provider specialty, and hospital location [8]. Over the last decade, considerable attention has been given on interventions to optimize the handoff process by enhancing patient safety in order to improve outcomes; adaptation of some enhancements were gleaned from industries such as nuclear power and space aviation in which transition errors also result in serious consequences [9, 10].

4. Insufficient handoffs induce complications

The Institute of Medicine attributes a substantial proportion of preventable adverse events to communication errors during handover [11]. The Agency for Healthcare Research and Quality identifies handoff communication miscues as implicated in surgical errors [12] and as a consequential cause of malpractice claims. TJC has correlated ineffective care transitions to higher rates of readmission [4]. Communication and handoff snafus are among the root causes of nearly two-thirds of potentially significant, preventable adverse clinical outcomes in hospitals [13, 14].

The consequences of substandard handoffs include: delays in therapy, inappropriate treatment, adverse events, care task omissions, increased hospital length of stay, avoidable readmissions, increased costs, and inefficiency from reevaluation [15]. Omissions of clinically important on-call issues by fatigued on-call residents when transferring care to the daytime team at the end of shifts are major contributors to miscommunications and can result in care implementation delays and adverse events [16]. Insufficient handoff communication result in incomplete, inaccurate, and omitted data and effectuate informational ambiguities between the departing and oncoming providers. Examples of information loss during handoffs are failure to communicate: drug allergy, critical comorbidity, relevant history, or current treatments. Distortion of patient history can result in: wrong medication dose, wrong surgical site, or incorrect diagnosis [10]. Cognitive load of handoff exceeding working memory capacity of the departing or oncoming physicians can further exacerbate information loss or distortion [9].

Omitted and undocumented issues introduce risk for delays in expeditious follow-up of clinically relevant overnight issues. Research by Devlin et al. demonstrated that only 14% of clinically important issues from the overnight clinical shifts had an accompanying progress note from the on-call trainee in the patient's medical record [16]. Discontinuity of care secondary to ineffectual handoffs has been correlated with longer hospital stays and increased costs [3]. The morning handover process is highly variable and unreliable and often occurs in a chaotic clinical care environment. On-call trainees fail to hand over numerous clinically important issues to the daytime team and frequently do not document their assessments and responses to the on-call issue in the medical records. These omissions have the potential to cause unnecessary delays and may result in a lack of follow-up for important patient issues [16].

5. Barriers to effective handoffs

Communication miscues and omissions, the most frequently numerated barrier to effective patient transition of care [17], correspond with the lack of consensus about the elements of effective handoff [2]. Substantial variability exists across, and sometimes within, institutions regarding preferred formats and processes for verbal and written handoffs. Research of residency training programs nationally indicate that handoff standardization has not been aggressively implemented and evaluated among residency training programs or implemented with variable compliance [2, 18].

Clinical staff often utilize handoffs as an avenue for socialization, education, and emotional support to facilitate integration and staff cohesion; while these activities have merit, they divert attention from effective patient communication [8]. Resident physicians participating in patient handoffs may not interact regularly with each other, may be located in different parts of the healthcare systems, may have different skill and experience levels, or may come from different clinical backgrounds [3]. Adherence to hierarchical norms between junior and senior residents or attendings can further exacerbate relational communication barriers reflecting differences across levels of training or between clinician types in the willingness to engage in interactive questioning strategies to assertively challenge erroneous assumptions and actions during a handover with peers [7, 17]. Entrenchment of handoff routines in departmental or hospital mores may require transformational change of an institution's culture in order to improve them [19].

6. Regulatory agencies' input to enhance handoff

In 2010, TJC incorporated the patient handoff into its health facility accreditation standards and has encouraged improving and standardizing transitions of care as a national safety goal via implementation of a standardized approach to handoff communications, including an opportunity to ask and respond to questions [3, 20]. TJC's National Patient Safety Goals document contains specific guidelines for the handoff process, many drawn from other high-risk

industries: interactive communications, "read-back" and "repeat-back" practices, verifying up-to-date and accurate information, limited interruptions, a process for verification, and an opportunity to review any relevant historical data. The Accreditation Council for Graduate Medical Education (ACGME) recently mandated that residency programs provide formal educational programs about patient care transitions and that faculty monitor ensure adequate handoff skills through direct observation [3, 19, 21]. TJC, the ACGME, and the Society of Hospital Medicine jointly encourage compliance with a structured format for verbally communicating information utilizing an ordered acronym mnemonic, SBAR: (1) Situation, (2) Background, (3) Assessment, and (4) Recommendation [7].

7. Standardization of patient handoff

House staff judge that strategies for handoff standardization most valuably improve quality of handoff and resident physician satisfaction with transition of care [16]. Most emergency medicine (EM) residency directors agree that standardized handoffs have the potential to reduce errors during transition of care, yet the majority of EM residency programs do not have a policy or a procedure regarding handoffs [17]. Didactic and interactive sessions teach key principles, and communication techniques of verbal and written handoffs utilizing mnemonics and checklists have shown to benefit in improving quality and standardization of handoff communications [19]. The SBAR mnemonic benefits handoff communication because of its simplicity, it provides a consistent framework for handoff scenarios, it can be utilized by different care providers, and it emphasizes on the clinician's assessment and response [16, 22]. Checklists have been effective in several different clinical settings in terms of decreasing medical errors and morbidity; utilization of checklists have the potential to improve the transfer of care process as well [23, 22]. Just as documentation in the electronic medical record about clinically important issues while on-call facilitates communication, a structured, written clinical summary, such as a checklist, by the outgoing clinical team presented to the oncoming team facilitates understanding of critical issues regarding patient care during transition of care in a standardized way.

Starmer et al. objectively demonstrated improved outcomes via an educational intervention utilizing a structured resident handoff bundle to standardize inpatient handovers in care thereby decreasing medical error in multiple institutions [13]. The bundle included three major elements: team training by using focused TeamSTEPPS communication strategies, implementation of a standardized template for the written or printed computerized handoff document, and introduction of several evidence-based verbal handoff processes, specifically I-PASS, an acronym mnemonic [10]. TeamSTEPPS, a teamwork system developed jointly by the Department of Defense and the Agency for Healthcare Research and Quality, works to improve institutional collaboration and communication relating to patient safety [20]. Starmer et al. instituted an I-PASS mnemonic to provide a consistent, structured format for communicating handoff information: I—Illness severity, P—Patient summary, A—Action list, S—Situation awareness and contingency planning, S—Synthesis by receiver [10].

8. Assessing quality and competency of handoffs

The ACGME requires that residency programs assess the competency of trainees in handoff communication. Detecting discrepancies between levels of quality of handoff communication requires training and is made more complicated by the existence of few standardized methods for assessing the competency of sign-out communication [3, 10, 24]. Horwitz et al. developed an evaluation tool for direct observation of house staff and hospitalists during sign out that generates quantifiable data of handoff assessment and performs consistently across different institutions and among both trainees and attendings [24]. Horwitz et al. utilized peers to conduct handoff assessments, reasoning that peers familiarity with the handoff issues would recognize miscues that external evaluators might miss [24]. Starmer et al., as part of their standardized sign-out bundle, developed direct observation assessment tools for assessment of quality of the departing and oncoming clinicians' adherence to the components of their handoff protocol and verbal engagement with one another [19].

9. Simulation improves handoff experience

Simulation activities provide residents opportunities to practice handoff skills prior to clinical practice. Patient care simulation enhances skill acquisition and behavioral modification through practice and reflection. The incorporation of illustrative videos and role-play simulations into the handoff education curriculum can simulate both ideal and less-than-ideal handoff behaviors. Learners rotate the roles of giving, receiving, observing, and evaluating patient handoff [19]. Research has demonstrated that the most efficacious elements of patient handoff simulation include use of trigger videos reviewing particularly challenging handoff scenarios. The opportunity to practice giving and receiving handoffs utilizing new skills during simulation exercises enhances handoff performance in the clinical arena [19].

10. Increasing awareness of handoff culture

Communicating a vision of improved handoffs through institutionalizing an intervention to improve handoffs enhances awareness of this patient safety intervention. Understanding the complex social structures in which residents and attending physicians work, as well as the unwritten rules that govern the handoff of patient responsibilities, must be accounted for because interdisciplinary trust enables negotiating shared care plans and mitigates conflict to encourage a safer transition of patient care [8]. Training programs should introduce new or expand existing handover curricula to raise awareness about the distinct entity of transitions of care and to improve the communication process during this period [16]. Starmer et al. created a Campaign Subcommittee, which was charged with "branding" I-PASS, their acronym for their handoff improvement intervention, to support the communication, implementation,

and sustainability of their handoff curriculum. Recognizing the importance of local agents of change, Starmer et al. conducted focus groups with residents and other stakeholders from seven different institutions to develop "advertising" strategies to encourage adherence to their handoff protocol [19]. To remind clinicians about key handoff concepts, they created point-of-care references, including pocket reference cards and computer monitor frames with handoff mnemonic details. Recruiting teams of faculty champions, respected faculty members actively involved in patient care and resident education, encouraged rapid and early adoption of the handoff curriculum [19].

11. Active communication enhances handoffs

Active communication strategies by the oncoming clinician improve patient safety by detecting erroneous assessments and actions, thereby confronting diagnostic momentum and fixation bias [7]. Face-to-face group handoff, an active communication strategy, enriches the quality of handoffs more than a reliance on written or electronic notes [16]. Face-to-face verbal communication with interactive questioning and updates from oncoming and departing clinicians facilitate these discussions [25]. A vibrant, encouraging communications culture, characterized by openness to and willingness of clinicians, regardless of the level of training, to speak up, to ask questions, and to provide feedback, enhances quality of transfer of information and inculcates a culture of safety among both departing and oncoming clinical teams [4]. The oncoming clinician summarizing the handoff dialogue and restating key actions as part of a standardized handoff bundle has demonstrated benefit in patient outcomes [10]. These clinical team meetings during transition of care promote meaningful dialogue and engender an opportunity to identify and correct errors in real time [3]. Minimizing distractions, limiting interruptions such as nonurgent pages (e.g., ask nursing and allied health staff to defer nonurgent pages), and providing a dedicated space for handover will further supplement end-of-shift patient management discussions [16].

12. Culture of collaboration and professionalism to improve handoffs

Medical professionalism includes a commitment to collaboration to quality clinical decision making, prudent medical error surveillance, and the voluntary reporting of adverse events [3]. Proactive discussion of pitfalls during shift change can impact potential for medical miscues by the oncoming providers during shift changes. A collaborative culture facilitates handoff of responsibility between the departing and oncoming providers by requests for assistance, by voicing clinical concerns, and by clarifying issues through bidirectional conversations. This process creates a shared mental model of the patient's clinical conditional and plan of care [4]. Oncoming clinicians foster the assumption of clinical responsibility by personally reassessing the patient and informing the patient of his or her evaluation with updated results during walking rounds at the conclusion of patient handover [23].

13. Summary

Effective transitions of care facilitate teams of multiple clinicians to deliver secure and effective care without compromising the continuity of care [26]. At a minimum, departing clinicians should provide patient identification, diagnostic summary, the patient's current condition and trajectory, a plan of care, a prioritized to-do list, and a plan for anticipated events. The oncoming clinicians should be able to understand likely contingencies and changes in the patient's condition [3]. To ensure regulatory compliance and improve patient security, educating residents and medical students to effectively perform patient handoffs offers synergistic benefits, including patient safety, continuity of care, and professionalism through teamwork [3]. Best practices ensure communication of essential information including: structured face-to-face and written sign-out, interactive questioning, and checklists in distraction free settings [9]. A culture of professionalism can mitigate errors and procedural violations that arise primarily from aberrant mental processes such as forgetfulness, inattention, low motivation, carelessness, or negligence [8]. A shared common language utilizing a standardized regimen protocol for patient transitions of care communications across all provider types and practice settings will promote a culture of patient safety and enhance patient outcomes [22].

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Chapter 4

Dangers of Polypharmacy

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Abstract

Although the definition of polypharmacy has evolved over time, it has been and remains to be an issue in healthcare. With the prevalence of polypharmacy increasing, those in the health care field must remain vigilant of the adverse effects of medications and work to coordinate care and maintain appropriate prescribing practices. Here we present a clinical vignette that describes an encounter of a patient on multiple medications and the individual, provider, and systems-level issues that may have contributed to an adverse event resulting in a hospital stay. We will discuss the definition of polypharmacy, review the prevalence and economic implications of drug prescription practices, and examine the consequences and complications of polypharmacy in a number of different patient populations. We will discuss a number of scenarios involving polypharmacy that lead to medication errors, decreased quality of life, and patient harm, and then review evidence-based methods of interventions aimed at reducing the prevalence of polypharmacy and its associated complications.

Keywords: polypharmacy, risk factors, root causes, complications, interventions

1. Introduction

Although the definition of polypharmacy has evolved over time, it has been and remains to be an issue in healthcare. With the prevalence of polypharmacy increasing, those in the health care field must remain vigilant of the adverse effects of medications and work to coordinate care and maintain appropriate prescribing practices. Here we present a clinical vignette that describes an encounter of a patient on multiple medications and the individual,

provider, and systems-level issues that may have contributed to an adverse event resulting in a hospital stay. We will discuss the definition of polypharmacy, review the prevalence and economic implications of drug prescription practices, and examine the consequences and complications of polypharmacy in a number of different patient populations. We will discuss a number of scenarios involving polypharmacy that lead to medication errors, decreased quality of life, and patient harm, and then review evidence-based methods of interventions aimed at reducing the prevalence of polypharmacy and its associated complications.

2. Patient vignette

An 89-year old male presents to his primary care provider for follow-up after a recent hospitalization for a non-displaced hip fracture after a fall at home. He has poorly controlled hypertension, gastroesophageal reflux disease, hyperlipidemia, depression, prediabetes, arthritis, cataracts, and a remote history of heart disease with stents placed years ago. He reports two new medications were started in the hospital but he does not know why they were prescribed. The hospital did not fax over any records and the patient did not bring his discharge information summary to his appointment. At this time, he does not report any side effects of the new medicines but he would like to discuss getting treatment for ongoing fatigue, insomnia, and worsening joint pain. He reports seeing his cardiologist a couple months ago, who changed the dose of one of his blood pressure medicines but the patient is not sure which medicine was changed or the milligrams of the new dose. When asked to fill out a release of information to send to the cardiologist, the patient replies his cardiologist retired not long after his last appointment and the patient needs a referral to see a new cardiologist. In addition to a cardiologist, the patient also follows with a gastroenterologist, psychologist, psychiatrist, and ophthalmologist. None of the providers utilize the same electronic medical record system. On review of the list of medications the primary care provider has on file, the patient only recognizes eight out of sixteen medicines. In addition, his primary care provider personally prescribes only six of the medications on the list. When asked about compliance, the patient is adamant he always takes his medications as prescribed, but states his wife, who is currently at home, helps him take his medicines because he has some difficulty reading the labels and remembering to take them at the appropriate times.

3. Defining polypharmacy

Polypharmacy first appeared in the medical literature more than a century and a half ago [1]. Polypharmacy has multiple meanings without a clear consensus in the scientific community of a strict definition. This is most apparent in the wide range of research into the subject and how such datacan be applied differently to various definitions of the term [2]. Defining polypharmacy can be further complicated by patients taking over-the-counter

medications and vitamins that are often not reported and as clinicians, it is not improbable to be treating patients with multiple conditions requiring multiple medications for optimal control. However, most clinicians would agree that polypharmacy is defined as the concomitant use of five to nine medications and hyperpolypharmacy, or excessive polypharmacy, is defined as the use of ten or more medications [3–5].

4. Drug prescription practices

Across all persons aged 20 or older, the prevalence of polypharmacy increased from an estimated 8.2% in 1999–2000 to 15% in 2011–2012 [6]. If the use of non-prescription medications is included, the prevalence of polypharmacy in the adult population increases to 29% [7]. The National Center for Health Statistics estimated that in 2014, approximately 2.8 billion prescription medications were ordered in the ambulatory office setting, of which the most frequently prescribed medications were analgesics, antihypertensives, and antidepressants [8]. Meanwhile, in the hospital outpatient departments, 329.2 million medications were prescribed with the most commonly ordered agents being analgesics, antidiabetics and antihyperlipidemics [8]. Overall, prescription drug use increased in many of the most common drug classes used by Americans including antihypertensives, antihyperlipidemics, antidepressants, antidiabetic agents, prescription analgesics, prescription proton-pump inhibitors, anticonvulsants, bronchodialators, and muscle relaxants [6]. Outpatient pediatric (aged ≤ 18) polypharmacy is also substantial with a prevalence rate of 10%, occurring more often in the setting of a complex chronic condition [9].

Individuals greater than 65 years old are the biggest consumers of medications; however, evidence shows that greater than 50% of elderly patients are taking at least one medication that is not medically necessary [10]. Nearly 40% of elderly adults take more than five prescription medications and almost 20% take more than 10 [6, 11]. Additionally, approximately half of the elderly population takes at least one over-the-counter drug and approximately half of the elderly population takes at least one nutritional supplement in combination with prescription medications [6, 11]. Polypharmacy declines in patients older than 85 years of age secondary to poor drug tolerance with age and increasing deprescribing practices as medical providers fear serious adverse drug reactions that may be more common in the very elderly [12].

5. Economic implications

In 2014, the United States (US) was estimated to have spent $3 trillion on total national health care expenditures, of which 9.8% ($294 million) was spent on prescription drugs [8]. Approximately, $77.7 billion was spent on total expenditures on Medicare Part D program in 2014, and an estimated $165.1 billion will be utilized by 2022 [13].This number will continue to increase as the estimated number of Americans >65 years of age by 2050 is projected to be 88.5 million, more than double that of 2010 (40.2 million) [14]. The US Center for Medicare and

Medicaid Services (CMS) states that polypharmacy has been estimated to cost US health plans over $50 billion annually [8, 15, 16]. With respect to medication discrepancies and patient adherence, if patients took all appropriate medications exactly as prescribed, it is estimated it would save 13% ($290 billion) of total US health care expenditures due to avoidable medical costs [17].

An estimated $16.4 billion and $4.2 billion are spent on inpatient and outpatient preventable medication errors, respectively [18].Adverse drug events (ADEs) occur commonly in hospital settings, which in turn increase the likelihood of morbidity, length of stay (LOS), and the cost of care. A multicenter retrospective cohort study conducted in six community hospitals significantly showed that ADEs are associated with an increased adjusted average hospitalization cost of $6910 and increased length of stay of 5 days [19]. The severity of ADEs are associated with further increased costs and length of stay ($9768 in patients and LOS 7.79 days with significant ADEs versus $15,033 in patients and LOS 10.56 days with life-threatening ADEs) [19]. Research evaluating the effect of computerized provider order entry (CPOE) in the outpatient setting has shown the potential to result in fewer medication errors and ADEs by 1.5 million and 14,500, respectively, with the potential to save $18 million dollars [20]. In the hospital setting, the implementation of CPOE is associated with an estimated 50% reduction of ADEs and medication errors [21].

6. Root causes of polypharmacy

The prevalence of polypharmacy is multifactorial with risk factors spanning from the individual/patient level (increasing longevity, coexistence of chronic medical conditions, availability of over-the-counter drugs, use of more than one pharmacy) to the physician level (medical guidelines, prescribing practices) to systems-level issues (multiple prescribing providers, electronic medical records, transitions of care) [22]. See **Figure 1** for a comprehensive list of the factors associated with polypharmacy [23, 24]. Medical practitioners rely on clinical guidelines to guide their medical practice and clinical decisions to provide the best care to patients. Available clinical guidelines are usually devised with focus on a single disease and often overlook the possibility of comorbidities and the consumption of other medications by the patient [1].Adherence to clinical guidelines for multiple concomitant chronic conditions may inadvertently lead to adverse outcomes for patients due to complications from multiple medications for multiple medical conditions [25]. In the post-acute transition of care setting, patients can often see their medication list expand or see changes in dosages due to their recent debilitation and hospitalization [3].There are often multiple clinicians, sometimes in the form of multidisciplinary teams, making medical decisions. Lack of communication between treatment teams and disruption in communication during transitions of care from the inpatient setting to the outpatient setting and vice-versa can precipitate polypharmacy [23]. If we look at our patient in the clinical vignette, there exists several risk factors for polypharmacy: elderly age, multiple chronic conditions, decreased ability to function, multiple providers, poor physician-patient communication, poor physician-physician communication, multiple prescribers, and disjointed electronic medical records.

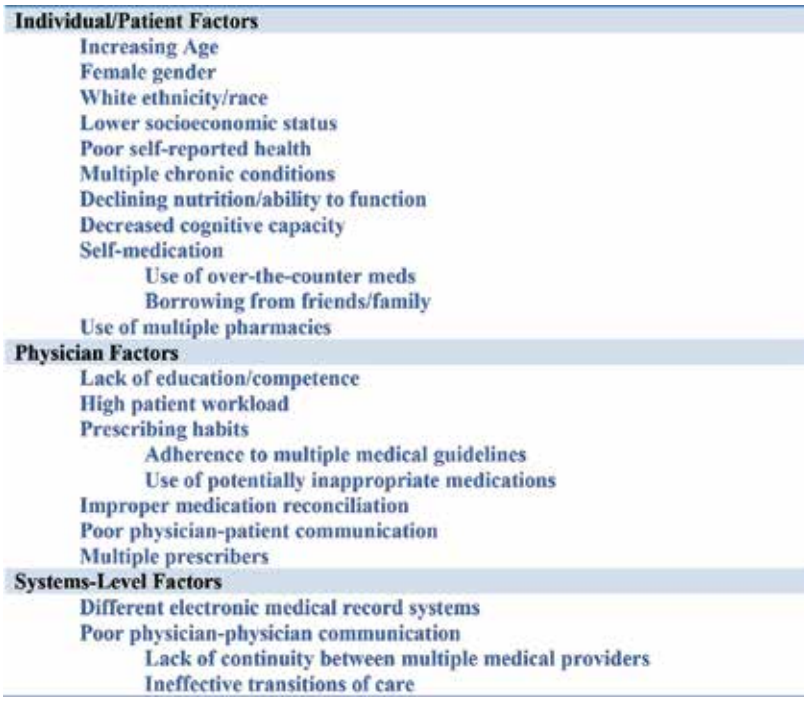

Figure 1. Factors associated with polypharmacy.

7. Polypharmacy complications and consequences

The more drugs an individual takes, the more likely he or she will suffer a complication or adverse outcome [4]. Polypharmacy is associated with increases in many adverse outcomes including adverse drug reactions, drug to drug interactions, drug to disease interactions, non-adherence, falls, cognitive impairment, hospital admission and mortality [4, 12, 26].

Adverse drug reactions (ADRs) are defined as undesired or noxious effects of standard drug treatment doses which include amplified drug effects, side effects, interactions with other drugs and interactions with other nutrients or diseases [11]. ADRs are a common cause of hospital admissions and emergency department visits [27, 28]. Many factors contribute to adverse drug reactions including unnecessary drug use, inappropriate drug choice, therapeutic duplication, inappropriate dosing regimen, physician-patient communication, and long-term medication use without periodic review [26, 29].

In the hospital setting, polypharmacy is a strong predictor of adverse drug reactions in both adults and pediatrics [30]. Not only are hospitalized adults at risk of adverse events from potentially inappropriate medications or drug-drug interactions, patients with polypharmacy are at higher risk due to medication discrepancies that may result from unintended discrepancies in actual regimen versus recorded regimen during transitions from outpatient to inpatient and vice-versa, changes to medication regimens while in the hospital, and poor

communication of medication changes to both patient and next provider of care [31]. Large numbers of hospitalized pediatric patients are exposed to polypharmacy with increased risk associated with longer lengths of stay and presence of complex chronic conditions [32, 33]. Polypharmacy increases potential drug–drug interactions in pediatrics, often due to off-label prescribing of drugs, lack of therapeutic profiles for less common medications, and weight-based medication errors [34].

Medical record discrepancies in the outpatient setting occur in about 75% of cases, with a strong positive correlation with polypharmacy, with rates escalating as high as 95% [17]. Discrepancies may include active prescriptions that the patient did not include on their medication record or patient-reported medications that were not documented in the electronic health record. Adverse events due to medical record discrepancy occur not only from failure to perform reconciliation, but failure to ensure and promote patient adherence to the regimen as intended by the provider [17].

Medication errors cause at least one death every day and injure 1.3 million people annually in the United States [35]. Several factors contribute to medication errors secondary to polypharmacy. Errors can easily occur when patients are seeing multiple specialty providers for comorbid conditions. Nearly 40% of all medication errors and 50% of adverse drug events are a result from errors in prescribing such as overdosing of medications, underdosing of medications, allergies, improper dose, improper drug, and duplication of therapy [36]. Lack of communication and coordination between treating providers increases the likelihood of prescribing medications which may result in adverse drug reactions, side effects or worse. Failing to review patient records and reconcile medications at regular visits by all providers poses greater risk for the occurrence of errors [37]. Omission of performing adequate medication reconciliation, including asking about over-the-counter medications, herbals, vitamins, and nutritional supplements, and patients' failure to disclose other medication use may contribute to the occurrence of a preventable harmful drug-drug interaction [38]. To ensure accurate medication reconciliation, patients should be asked to bring all medications to each provider visit [39].

Transitions of care pose a danger of medication errors and include a change in setting, practitioner, type of service and move from one level of care to another [40]. Ineffective processes during transitions of care can result in adverse events and higher hospital readmission rates and costs [41]. During transitions of care, patient education regarding complicated regimens, lack of accountability of the clinical entity to provide coordination across settings, and lack of effective communication between providers are most often the root causes [42, 43].

Patient adherence to polypharmacy regimens presents another juncture at which errors may arise. Adherence is defined as the extent to which an individual's behavior, including taking medicine, following a certain type of diet, or lifestyle modifications, corresponds with recommendations from a healthcare provider as agreed upon by the patient [44]. Nonadherence is defined as the improper intake of medication [44]. The complexity of a medicine regimen is inversely related to medication adherence with increasingly complex regimens (increased frequency of dose, decreased patient education) associated with lower rates of adherence [45]. Issues of adherence include patients who do not fill their prescriptions, decide to stop taking

medications, or fail to take one or more medications as prescribed [40]. These issues occur for a variety of reasons including financial hardship, symptom improvement, and unreported side effects.

Accidental inappropriate drug use may result from erroneous or repeat doses from poor eyesight or forgetfulness [46]. In addition, patients may not be able to accurately read and understand the labels on medications prescribed. With more than 33,000 trademarked medications, errors have commonly been linked to drugs with similar sounding names. Adding to the drug name confusion, are problems with similar packaging and labeling, incomplete knowledge, illegible handwriting, prescriptions which are orally communicated and a significant number of new products continually being introduced into the marketplace [47].

8. Special considerations in different patient populations

The following sections briefly touch on unique considerations when addressing polypharmacy in different patient populations and certain medical conditions.

8.1. Elderly/end of life

Older adults with comorbidities are often excluded from drug trials, therefore, the use of drugs in older populations to a large extent can be considered experimental [48].The use of multiple clinical guidelines that do not account for multiple comorbid conditions, along with the knowledge of altered pharmacodynamics due to the physiological changes in older adults, can become dangerous to the elderly patient. Certain classes of drugs have been associated with cognitive impairment and falls, with elderly patients being more susceptible than others. Polypharmacy in elderly patients has been shown to be a predictor of frequent hospitalizations, nursing home placement, death, hypoglycemia, fracture, impaired mobility, pneumonia, and malnutrition [22]. As the elderly age, they are at increased risk of complications from polypharmacy including the inability to effectively metabolize and excrete multiple medications due to changes in liver and kidney function [22]. To confound this further, age-related change in pharmacodynamics resulting from changes in drug receptor affinity alters the concentrations of drugs that are effective and toxic [49]. Additionally, increasing use and number of medications seems to have a negative impact on nutrient intake and nutritional status overall in the elderly not only from drug-nutrient interactions, but also from compounded side effects such as nausea, decreased appetite, dry mouth and metallic taste which ultimately decrease food intake [46].

In elderly patients at the end of life, pain is a common symptom [50]. Patients undergoing palliative treatment are especially vulnerable to unwanted adverse effects of medications secondary to their altered metabolism, organ dysfunction, and high likelihood of polypharmacy with ensuing drug-drug and drug-host interactions [51]. In one study, potential drug-drug interactions (DDIs) were detected in 61% of inpatient hospice patients [52]. Polypharmacy was the major predictor for DDIs and the most commonly implicated drugs in therapeutically potential DDIs were antipsychotics, antiemetics, antidepressants, insulin, glucocorticoids,

cardiovascular drugs and NSAIDs [52]. In elderly patients, the remaining life expectancy of the patient should be considered when prescribing medication, as benefits of certain medications may not be valid or may not outweigh risks in a patient with a lower life expectancy. As patients age, it may be important to consider de-prescribing to optimize the patient's total health and reduce unnecessary polypharmacy [48].

8.2. HIV population

With the evolution and advancement of antiretroviral therapies worldwide, HIV is now being considered a chronic disease. Life expectancy for HIV patients has been shown in recent years to closely approximate that of non-infected HIV persons [53]. The HIV population is also aging. Statistics show over 10% of HIV positive persons globally are over the age of 50, with projected data estimating this to increase by an additional 20% in the next 15 years [54]. In the United States alone, it is estimated that more than half of persons living with HIV are ≥50 years old [55]. In 2010, the prevalence of polypharmacy in persons living with HIV was estimated to be 35%, surpassing that of persons not living with HIV [55]. HIV patients have been noted to have greater cardiovascular, renal, neurologic, oncologic and osteoporotic disease despite having decreased viral loads or increased CD4 counts [56]. Presence of age-associated comorbidities increases the risk of polypharmacy in HIV patients, with higher rates of prescriptions for gastrointestinal, neurologic, respiratory, analgesic, or anti-infective drugs than the general population [57]. Antiretroviral therapy has a high risk for DDIs and toxicity, and optimizing management to address this risks and decrease pill burden can be difficult [54]. In older HIV patients, 77% are at risk of potential DDIs due to polypharmacy, with the highest risk in patients with concomitant cardiovascular drug use [58].

8.3. Kidney disease and liver disease

There is a high incidence of polypharmacy in patients with chronic kidney disease (CKD) [59]. Significant medication-related problems, including drug-drug interactions, high incidence of adverse drug reactions (ADRs) and low adherence have been noted [60]. Complex medication regimens may be necessary in CKD to treat related comorbid conditions, however patients are at high risk of DDIs, especially due to changes in pharmacokinetic and pharmacodynamic parameters associated with decreased kidney function, and therefore require constant adjustment of medication doses accordingly [61]. Complicated medication regimens and concerns about side effects were frequently cited as a cause of low or non-adherence in patients with CKD [62]. Additionally, use of certain contraindicated over-the-counter or herbal remedies may put the patient at increased risk of adverse drug events and interactions due to interference with CKD medications [63].

Liver pathology is of special importance especially when treatment of disease includes polypharmacy. Multiple drug regimens have shown to cause development of various forms of hepatotoxic reactions, and many patients with cirrhosis often have complicated medication regimens and are at higher risk for complications from polypharmacy [64]. Frequent reassessment of the patient's baseline renal and hepatic function, medication properties, doses administered and length of therapy are helpful in achieving reduction in DDIs and ADRs [65].

8.4. Mental illness

Prescribing patterns in the adult outpatient psychiatric setting show the median number of prescriptions prescribed per visit have doubled, largely with increased psychotropic polypharmacy (defined as ≥2 psychiatric medications in the same patient) with antidepressant and antipsychotic prescriptions in adults aged 45–64 [66]. Additionally, this number may be an underrepresentation in patients who see multiple providers [66]. Psychotropic polypharmacy is also increasingly seen in the outpatient pediatric population with prevalence estimates ranging from 13 to 35% [67–69]. In this population of patients, both psychotrophic and non-psychotrophic drugs contribute to polypharmacy and brings with it, the associated complications. Low adherence, noncompliance, ADRs, and DDIs contribute to the detrimental effects of multiple drug therapy. In this cohort, polypharmacy increases the risk of potentially inappropriate medication (PIMs) administration, and prolonged polypharmacy can have significant cognitive-impairing effects [70].

8.5. Intellectual and developmental disabilities

Patients with intellectual disabilities are reported to have more than twice as many health problems as the general population and a higher rate of comorbid somatic or mental health disorders [71]. There is a considerably wide range of prevalence of polypharmacy noted in the literature for this population [72, 73]. Similarly to other patient populations, the larger the number of comorbidities, the more likely there is to be polypharmacy and all its associated complications. Specific to this patient population, living in a residential facility and increasing severity of intellectual disability increases risk of exposure to polypharmacy [71]. Affective disorders, psychoses, and anxiety are the three leading co-morbid mental health disorders among adults with intellectual disabilities [74]. However, it may be difficult to make a distinction between the disorders based on behavioral patterns or traditional diagnoses which may contribute to overuse or underuse of medications [74].

8.6. Chronic pain

Chronic pain has been estimated to affect 116 million adults and costs $560–$635 billion annually in the US [75]. There is a multimodal approach utilized for chronic pain that includes nonpharmacological and pharmacological interventions. Previous studies have reported that patients diagnosed with chronic lower back pain or osteoarthritis, and who were prescribed an analgesic such as an opioid, have overall higher health care costs [76, 77]. When looking at more recent literature, the increased financial impact of chronic non-cancer patients continues to persist [78]. Costs for chronic non-cancer pain patients are increased both in older and younger patients, likely secondary to complications from increased drug-drug exposure (DDE) and increased prescription costs related to polypharmacy, respectively [79]. In patients on chronic opioids, the risk of DDE increases with each additional medication a patient is prescribed, with a rate greater than 60% in patients taking four or more prescription medications compared to 14% in patients taking no other prescription medications [80]. Therefore, addressing polypharmacy in chronic pain patients may be an important component in reducing both total medical costs and the risk of drug-drug interactions.

9. Interventions to reduce polypharmacy

There is a growing body of research regarding the development of evidence-based interventions to reduce polypharmacy, inappropriate prescribing, and patient nonadherence. While many of the published tools and interventions have focused on the elderly population, the evidence-based studies encompass numerous themes involving various strategies. The themes include interventions to:

- Address appropriate versus inappropriate prescribing
- Strengthen patient education and patient-physician communication
- Promote better medication reconciliation
- Ameliorate high-risk error areas such as transitions of care
- Enhance physician to physician communication and interprofessional collaboration
- Reduce nonintentional nonadherence by patients.

9.1. Appropriate versus inappropriate prescribing patterns by physicians

A concept that has been discussed in the literature when addressing reducing complications of polypharmacy deals not just with the number of medications, but also with the appropriateness of the treatment regimen. Several guidelines have been established evaluating clinical necessity of medications, irrespective of the number of medications. The theory behind addressing the appropriateness of prescribing and not just the absolute number of medications is that patients with multiple comorbidities may, in fact, necessitate a number of medications, thus being clinically appropriate polypharmacy. Additionally, patients may experience adverse drug events on fewer medications, however they may not get identified through current screening protocols based strictly on number of prescriptions [81].

There are a number of evidence-based studies advocating the use of computerized alerts to decrease potentially inappropriate medications. Using an automated clinical decision support system in an electronic medical record system to prompt physicians to update patient problem lists during inpatient computerized physician order entry can result in increased updated problem list accuracy at a rate of about 95% [82]. That being said, recent studies report between 69 and 91% of medication alerts were overridden by physicians as the alerts were considered irrelevant by the prescribing physicians [52]. Electronic medical record-based interventions have also achieved a significant reduction in the number of medications initiated during the intervention period [83]. Medical decision-making tools and checklists have also been utilized to reduce potentially inappropriate prescribing. Checklists used by physicians to support therapeutic reasoning of the physicians in order to improve the quality of drug prescriptions have resulted in a 22% reduction in the risk of ≥1 of potentially inappropriate medication being prescribed at discharge [84].

There are also a number of published studies advocating the use of review of patient medications to decrease polypharmacy and potentially inappropriate prescribing [85, 86]. Increased

patient-physician medication reviews have utilized physician notifications about high-risk patients, "medication management" reports listing information regarding patient prescriptions, and clinical practice guidelines for preventing and managing inappropriate prescribing resulting in about half of all physicians making at least one change in the patients' medication regimens [87]. These guidelines encouraged "brown bag" medication reviews of medications, including non-prescription medications, during patient office visits. As a result, 20% of patients recorded discontinuation of medication, 29% reported a change in medication and 17% reported taking medication that their physician was unaware of [87]. While numerous studies have demonstrated successful interventions in deprescribing potentially inappropriate medications, there is a paucity of data causally linking generalized deprescribing to clinically significant improvements in hospital admissions, mortality, and patients' overall quality of life [88, 89]. However, targeted patient-specific interventions may have a role in reducing mortality [89]. In elderly patients undergoing a deprescribing protocol, there was a successful reduction in the number of regular medicines taken by elderly patients in residential care settings with no significant adverse effects on survival or other clinical outcomes [90].

Collaborative interdisciplinary teams have been used to improve the quality of care given to patients. The concept of Comprehensive Geriatric Assessment (CGA) is a multipronged approach to provide integrated care of elderly patients through the use of interdisciplinary teams. These teams assess medical, psychosocial and functional capabilities of elderly patients and often include physicians, social workers, nurses and other healthcare providers [91]. CGA uses protocols to assess functional, cognitive, affective, and nutritional status as well as caregiver and social support. CGA also assesses for geriatric problems such as incontinence and falls, and pays particular attention to medication management with a goal of decreasing adverse drug events [91, 92]. Utilizing multidisciplinary teams have been shown to reduce serious adverse drug events by 35% when compared to those in usual care [86].

Many researchers have also looked at the use of validated tools (e.g., Beers criteria, Medication Appropriateness Index [MAI], Screening Tool of Older Persons Prescriptions [STOPP], Screening Tool to Alert Doctors to Right Treatment [START]) to identify elderly patients at risk for high-risk prescribing practices. In older patients with a potentially preventable medication-related hospital admission, the use of STOPP/START 2008 criteria resulted in a 34.1% decrease in potentially inappropriate medications and a 57.7% decrease in potential prescribing omissions [93]. The Beers criteria, based on a consensus panel of experts, has been used for many years in United States as a guide to assist health care practitioners in determining whether or not certain medications may be unsafe for use in the elderly [26]. Altering or adjusting clinical targets may also have a benefit in discerning appropriate versus inappropriate medication prescribing. It appears that setting strict clinical targets in some populations may have adverse outcomes. In the famous Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, there was an increased risk of hypoglycemia, adverse events and death in those with tight glycemic control [94]. By liberalizing our clinical targets, we may decrease medication use and improve clinical outcomes with regards to certain medications and certain groups of patients.

9.2. Strengthen patient education and patient-physician communication

In the vignette above, the patient was not educated appropriately regarding the new medications he was prescribed nor did he appear to have a good understanding of his overall medication regimen. While health care professionals are most frequently viewed as integral to smooth transitions of care, patients and caregivers, and their understanding of treatment needs and readiness to actively participate, are essential to the process. Patient education and understanding of their conditions, necessary treatments, and the importance of follow through with recommendations are key in helping to promote a more seamless flow of movement during transitions of care. Implementing patient education is a potential intervention for reducing the rates of polypharmacy [88]. Educational packets or patient information leaflets, specifically designed and targeted according to patient literacy can improve outcomes and effectively manage polypharmacy [95]. Educational materials can be in various forms including but certainly not limited to videos, individual or group teaching sessions and teach back techniques [96].

The EMPOWER [Eliminating Medications Through Patient Ownership of End Results] study that evaluated a benzodiazepine therapy cessation program found that after 6 months, patients aged 65-95 had a 27% discontinuance of their use of benzodiazepines in comparison to 5% in the control group [97, 98].Through the EMPOWER study, it was demonstrated that consumer education is directly related to effectively eliciting shared decision-making around the overuse of medication. The patient-centered process aims to reinforce known enablers and address barriers to medication cessation. This increases the shared responsibility in decision-making with healthcare providers [99]. Therefore, direct patient education can effectively stimulate shared decision-making around overuse of medications that increase the risk of harmful effects.

9.3. Promote better medication reconciliation

Medication errors and other adverse events during care transitions led the Joint Commission to identify medication reconciliation as a National Patient Safety Goal in 2005 [37]. In 2014, the requirement to inform patients regarding the importance of maintaining updated medication information was added to existing safety goals [100]. The use of interventions to improve medication reconciliation has had direct and positive effects on clinical outcomes. Improvement in electronic medication reconciliation has also been shown to reduce the incidence of medication discrepancies during transitions of care in hospitals, especially regarding medication omissions but also including other areas such as medication error dosing [101]. Some of these interventions have used pharmacists while others have relied on the electronic medical record interventions or other healthcare providers. Hazra and colleagues showed a threefold decrease in the prevalence of antipsychotic polypharmacy after a pharmacist-led intervention provided education to prescribers [102]. Milos and colleagues performed a randomized controlled clinical trial in nursing home patients ≥75 years of age where medication reviews by clinical pharmacists based on nurse-initiated symptom assessments provided feedback to physicians [103]. Two months after the medication reviews, the number of patients in the intervention group with at least one potentially inappropriate medication and

the number of patients using 10 or more medications had decreased [103]. Mekonnen and colleagues performed a meta-analysis of pharmacist-led medication reconciliation programs on clinical outcomes at hospital transitions involving 19 studies, including 11 randomized controlled trials [104]. A total of more than 15,000 patients were included in the data. The results revealed that pharmacist-led interventions were effective strategies to reduce medication discrepancies with a greater impact on admission and discharge transitions as compared to other hospital transitions of care [104]. Additionally, patients should also be encouraged to carry a list of their medications with them for emergencies and visits to all providers [100].

9.4. Ameliorate high-risk error areas such as transitions of care

"The root cause of adverse events associated with transitions of care is poor transfer of information between providers" [105]. Multiple studies demonstrate that improving communication to enhance coordinated care during transitions can result in more cost-efficient care, reduced rate of errors and near misses, and improved patient satisfaction [106–108]. Communication of essential patient medical information among treating providers within and between health care settings is paramount to ensuring safe and comprehensive transitions of care. Several components have been identified which are felt to be key in reducing adverse events as patients move from one level or setting of care to another. As electronic health records have become the primary tool for documenting and storing patient information, they can facilitate the timely sharing of information required for continuity of care [109]. The primary mode of communication with the highest rates of direct transfer of patient information from one provider to another occurs via telephonic communication, with successful communication occurring approximately 70% of the time [110]. Additional interventions, which have been implemented to improve patient care during transitions of care, include patient education, the scheduling of outpatient visits prior to discharge and telephone follow-up. Further, scheduling follow-up appointments with a primary care physician in a timely manner and, when available, home visits, all serve to help provide a greater structure for a more seamless transition [100].

The role of pharmacists has become a greater focus of attention as part of the care team and as a component of the discharge or transition of care for patients. Evidence exists which supports the benefits of involving pharmacists in the process of medication reconciliation at various point of transitions including admission, transfer from the ICU, and upon and following hospital discharge [111–113]. Pharmacists play a significant role in education for both patients and their caregivers. They are uniquely qualified to clearly explain why specific medications have been recommended, and why these medications are the most appropriate for each patient. While it is clear other health professionals can provide such information, pharmacists more likely possess the greatest insight as to the reason for specific medications targeted to a patient's condition [114].

There are currently several emerging models of care designed to address various interventions and resources to help ensure safe transitions for patients and caregivers. The focus of these efforts is to enhance patient safety, improve communication and reduce hospital readmissions. Two notable models include The Care Transitions Intervention and The Transitional Care Model [115, 116].

9.5. Enhance physician to physician communication and interprofessional collaboration

In order to overcome obstacles to reduce polypharmacy, it is imperative to communicate with patients and healthcare providers to understand what their perceptions of those obstacles are and how to work together to overcome them. Palaygi and colleagues performed a qualitative study in long-term care facilities involving focus groups to address perceptions of medication use and deprescribing [117]. Deprescribing was defined as withdrawal of inappropriate medications with the goal of reducing polypharmacy. The focus groups included physicians, pharmacists, nurses, patients, and relatives. All participants acknowledged the burden of too many medications, yet displayed passive tendencies toward reduction. The primary care physician was the central trusted figure in medication initiation and alteration. The primary care physicians complained of systems barriers including poor medical record uniformity, time constraints, challenges with staff and pharmacy collaboration, and the effects of multiple prescribing specialists as obstacles to deprescribing [117]. Skinner conducted an extensive literature review looking for polypharmacy protocol for primary care. Mnemonics, algorithms, clinical practice guidelines, and clinical strategies for addressing polypharmacy were noted, as well as the use of screening instruments for assessing potentially inappropriate medication prescribing [118]. However, there appears to be no standard protocol to address polypharmacy [118]. From these two publications, many problems were identified. However, the importance of communication, particularly physician to physician communication, as well as the need for a standardized polypharmacy protocol, particularly involving deprescribing, seemed to represent the most challenging obstacles in overcoming barriers to successful polypharmacy reduction. Farrell and colleagues have set out to develop guidelines for deprescribing [119].

Additional studies also point out the need for better interprofessional collaboration and communication among other problems. The main concerns and perceptions by general practitioners of factors involved in contributing to polypharmacy include difficulty in keeping exact medication intake lists, challenges in overcoming patients' strong beliefs in their medications and in self-medicating, the involvement of multiple prescribers, the lack of regular medication reviews and revisions, and the pressures placed upon physicians in using medications based upon evidence-based protocols [120]. Lavan and colleagues published a review article about reducing prescribing errors in elderly patients and noted that published data support a few interventions including prescriber education in pharmacotherapy, application of STOPP/START criteria to reduce potentially inappropriate prescribing, electronic prescribing, and a close liaison between pharmacists and physicians to perform structured medication reviews and reconciliations [121].

9.6. Reduce nonintentional nonadherence by patients

75% of Americans have difficulty taking their medication as prescribed with the cost of nonadherence ranging from $100 billion to $300 billion every year [122]. Intentional nonadherence refers to the patient making a certain amount of decision-making in their care often based on their trust in their medical provider and knowing the effects of their medications [44]. The patient's adherence improves when patients feel well informed about their illness and the importance of necessary treatment [44]. In patients over 65 years of age, the most significant predictors for non-intentional non-adherence are forgetfulness and carelessness [123].

Others factors that may impact adherence include medication beliefs, increasing numbers of chronic diseases leading to complicated regimens, and sociodemographic factors such as high costs, co-payments, and lack of understanding [122, 124]. The utilization of cue-based interventions (i.e., phone reminders or alarms) may be helpful for forgetfulness but less likely to reduce non-adherence due to passive inconsistent behaviors [123, 125]. Health literacy interventions can improve patients' education regarding their medications and therefore potentially improve the patients' role in their management of medications. The importance of assessing patient literacy and readiness to be an active member of the health care team is the responsibility of the health care system. A health literacy pilot study found that 40% of patients had a low health literacy, which is defined as below 9th grade reading level [126]. After just 3 months of one patient literacy intervention, patients' self-reported adherence had improved [126].

10. Conclusion

Polypharmacy is a multifactorial, complex issue. There are a number of targeted interventions that focus on addressing a variety of determinants with varying levels of evidentiary support. Optimizing prescribing, reducing potentially inappropriate medications, and minimizing risk is a common theme across all interventions, however implementation must be highly individualized for each patient.

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Chapter 5

Wrong Patient, Wrong Drug: An Unfortunate Confluence of Events

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Abstract

Older adults, aged 65 years or older, represent 14.9% of U.S. population, and are projected to increase to 22% by 2050. It is estimated that almost half of hospitalized patients are older adults and is expected to increase as the population ages. Hospitalized older adults are most vulnerable to adverse events because of aging-related conditions, physiological changes, and multiple comorbidities as well as fragmented care. The primary goal of health care providers is to improve patient safety and decrease adverse events. This chapter will use a complex clinical scenario with numerous potential overlapping risks to address the many active and latent factors that lead to patient safety-related adverse events. Factors involved, as well as preventive strategies, will be discussed in detail.

Keywords: patient safety, medication dosing, elderly, delirium prevention, falls, restraints, culture of safety, clinical informatics, same or similar name, handoffs, disclosing error

1. Introduction

Patient safety events are unfortunately a common occurrence in healthcare systems across the United States [1, 2]. Medication errors, hospital acquired infections, wrong site surgery, and other types of errors contribute to increased morbidity and mortality in hospitalized patients [3, 4]. The question, of course, is how do such errors occur and how can they be prevented? James Reason's 1990 book, "Human Error" created a conceptual framework, commonly known

as the Swiss Cheese Model to understand how such errors take place [5]. While not specifically aimed at healthcare, it instead seeks to explore how failures could occur in any system where holes in each defensive layer can lead to a potential for error. The availability of multiple defensive layers provide protection against a major hazardous event, but eventually, the holes line up and the system fails [5]. Some of the holes are related to active or proximal causes of failure–these are directly linked to how the patient, in the case of healthcare systems, is cared for. Other holes are due to latent causes that are hidden problems involving the entire health system. By dissecting a patient safety event into its active and latent causes, one can take a root-cause analysis approach to understanding, and ultimately preventing error [3]. In this chapter, we will investigate some of the active and latent causes that could have led to an error in the unfortunate clinical scenario outlined below.

2. Clinical vignette

The following is a hypothetical case used to illustrate several key patient safety issues: Mr. Timothy Pearse is an 85-year-old male admitted to the hospital for progressive symptoms of shortness of breath for the past 3 days. He has a past medical history of paroxysmal atrial fibrillation, coronary artery disease, systolic congestive heart failure, osteoarthritis of bilateral knees, and benign prostate hypertrophy. He has had three admissions in the past year for congestive heart failure exacerbations. His home medications include carvedilol, aspirin, furosemide, metolazone, atorvastatin, naproxen, and tamsulosin. Today, he is notably dyspneic and is experiencing oxygen desaturations to 87% on room air. His lung examination reveals bilateral crackles and he is in rapid atrial fibrillation with a rate of 144. He is given intravenous diuretics for his heart failure and beta-blockers for his atrial fibrillation and is admitted to the internal medicine service overnight.

The same night Mr. Thomas Pierce is admitted to the same internal medicine service with fever, confusion, and lethargy. Mr. Pierce is 87-years-old and has a history of Alzheimer's dementia, hypercholesterolemia, hypothyroidism, and neurogenic bladder from a prior back injury. He uses a chronic foley catheter. His initial workup is significant for sepsis secondary to pyelonephritis with acute delirium. He is started on empiric antibiotics and admitted to the hospital overnight.

Both patients are examined during rounds by the residents and attending physician at the bedside. Mr. Pearse had improvement in his atrial fibrillation and symptoms of heart failure but required further diuresis. Unfortunately, he developed acute renal failure from the combination of diuretics and naproxen. The decision was made to cautiously stop diuretics, stop naproxen, and to start intravenous heparin for his atrial fibrillation. The team next reviewed Mr. Pierce who was a few rooms down. Mr. Pierce received an "as needed" dose of lorazepam overnight for agitation and unfortunately experienced an unwitnessed fall in early morning hours, in addition to inadvertently pulling on his foley. This morning he was examined at the bedside where he was in soft hand restraints, with no improvement in his symptoms. His foley catheter had notable blood in the bag. His urine culture results were still pending, but

his fevers had not abated. The decision was made to avoid any further benzodiazepines and request a urology consultation for the hematuria. Antibiotics were not changed at this time, pending culture results which were expected to return within a few hours.

The team finished rounds on their patients and the residents dispersed to complete tasks and follow up on orders. One of the residents who was covering both Mr. Pearse and Mr. Pierce, had a clinic that afternoon and signed out to his co-resident prior to leaving the hospital for the day. While the covering resident was inputting the order for Mr. Pearse's heparin, he received a call from the nurse regarding culture results for Mr. Pierce. Mr. Pierce's urine culture revealed a resistant gram-negative bacterium. The resident discussed the finding with the infectious disease consultant who recommends a change in antibiotic including a dose of gentamycin for synergy. He also placed the orders and informed his attending of the changes.

A few hours later, the resident receives a phone call from the consulting urologist who is confused as to why heparin was ordered for a patient with active hematuria. Horrified, the resident realized that heparin had been ordered incorrectly for Mr. Pierce and gentamycin ordered incorrectly for Mr. Pearse. The resident immediately contacted nurses caring for both patients and is able to prevent the heparin from being started, but unfortunately, the gentamycin had already been administered. The resident and the attending return to Mr. Pearse's bedside to reassess him and then speak to him and his family about the medication error. Unfortunately, his renal failure worsens and his hospital stay becomes prolonged.

3. Active causes

As previously mentioned, causes of patient safety events can be understood easily when categorized by active vs. latent causes. The case above has several active causes that contributed to medical errors and ultimately to a patient safety adverse event. In the following section, we will explore the importance of appropriate medication dosing in the elderly, prevention and management of delirium in the elderly, fall prevention, and use of restraints in the hospital setting.

3.1. Appropriate medication dosing in the elderly

In the elderly, changes in pharmacodynamics and pharmacokinetics result in prolonged effects of medications, making them more prone to toxicity. For most medications, absorption is slower and peak serum concentrations may be lower and delayed [6–8]. On the other hand, metabolic clearance of drugs by the liver may be decreased due to reduced blood flow, size or mass, and changes in intrinsic pathways or reactions [6–8].

The kidneys play a vital role, as they excrete many drugs. With aging, there is a decrease in renal blood flow, kidney size, number of functioning nephrons, tubular secretion and estimated glomerular filtration rate (EGFR) [3–7]. In addition, due to decreased lean body mass, serum creatinine may stay in normal range, masking changes in creatinine clearance and renal function [3–8]. Estimating Creatinine clearance (CrCl) is often complicated in the

elderly due to such fluctuations, for example, the Cockroft–Gault calculation estimates EGFR based on weight, age, serum creatinine levels and gender; it requires, however, a stable serum creatinine level for accurate results [9]. This calculation may underestimate CrCl in those without significant age-related renal decline and may overestimate CrCl in those with renal mass reduction beyond normal aging [8].

Given the above, medication dosing in the elderly can be quite complicated! When prescribing medications in the elderly, the aim is to achieve a balance between over and under-prescribing. Some steps are outlined in **Table 1**.

It is important to note that the elderly are more prone to adverse drug effects and reactions including acute kidney injury, hypotension, delirium, and falls. Aging and illnesses which impair kidney function can lead to drug accumulation and toxicity. Additional risk factors include a CrCl less than 50 ml/min, multiple chronic medical comorbidities and polypharmacy [6–8]. It is important to decide on appropriate medication administration routes, medication forms and suitable times of administration to ensure effectiveness and compliance while minimizing adverse events. An additional tool is the American Geriatric Society's Beers Criteria, which identifies many common medications that cause adverse drug events in older adults and are meant to assist clinical judgment in prescribing medications for this population [10].

In summary, when prescribing in the elderly, it is essential to perform a complete medication review which should include all prescribed and over the counter drugs. Medications should be started at low doses and titrated upwards slowly. Therapeutic endpoints should be clearly defined and reviewed periodically. Close follow-up in this especially vulnerable population is essential.

3.2. Management of delirium in the elderly

Delirium is often multifactorial in origin and is caused by a sum of predisposing factors including advanced age, medical comorbidities, functional impairment and dementia; and precipitating factors which include acute medical problems, bed rest and the use of restraints [11]. Delirium is associated with substantial morbidity and mortality in older people and prevention is the best management. The Hospital Elder Life Program (HELP) is an innovative tool that uses tested delirium prevention strategies to improve the overall quality of hospital

1. Consider non-pharmacological methods for managing the condition in question if possible.
2. Review the benefits vs. risks associated with the medication. Is it truly appropriate?
3. Avoid starting more than one medication at any given time.
4. Consider using a single medication to address multiple conditions if possible.
5. Consider drug-drug interactions (including consideration of over the counter medications) and drug elimination (half-life and clearance) profiles of the medications prior to prescribing.
6. Periodically review medications and discontinue inappropriate medications as soon as possible.

Table 1. Recommendations for prescribing medications in the elderly [6, 8].

care in elderly patients [12]. This can be achieved by addressing predisposing factors such as using frequent reorientation, noise reduction, adequate hydration and early mobilization [11, 12]. In addition, identifying and treating reversible contributors such as pain, constipation, and drug withdrawal can assist in preventing the development of delirium. When delirium is present, early recognition and early non-pharmacological intervention along with patient and family support are very important [11, 12].

Pharmacological interventions can also be used in the treatment and management of acute delirium. Haloperidol has the highest clinical evidence amongst pharmacological agents for use in agitated delirium refractory to non-pharmacologic measures [13–15]. Using the lowest effective dose of this high potency antipsychotic is recommended, and as this medication may cause multiple adverse effects (including QT prolongation, torsades de pointes, withdrawal dyskinesias, etc), patients started on this medication should be closely monitored [13–15]. Other pharmacological agents that have been studied in the management of in-hospital delirium include Gabapentin, second-generation antipsychotics such as Risperidone, Olanzapine, as well as other medications like Cholinesterase Inhibitors, Statins, Corticosteroids, Tryptophan, and Melatonin; however, current data for such pharmacological treatment remains controversial [13]. It is important to remember that certain medications can also result in adverse events. High-potency antipsychotics are contraindicated in Parkinson's disease and Lewy body dementia [14]. Benzodiazepines, such as lorazepam, are not recommended as first-line agents in the treatment of delirium because they often exacerbate mental status changes and can cause over-sedation [13].

In summary, acute delirium in the hospital setting should be managed using a combination of non-pharmacological and pharmacological methods. Had the patient in the case scenario outlined above been approached with the mindset of delirium prevention, some of the patient safety-related adverse events might have been avoided.

3.3. Fall prevention in the elderly

Among older adults, the incidence of in-hospital falls ranges from 6 to 15.9 per 1000 patient days, and a single fall could lead to an approximate increase of $4000 per hospitalization [16, 17]. As such, all providers should conduct a careful history and physical examination aimed at identifying those at increased fall risk in order to reduce in-hospital fall events. Historical clues include a history of previous falls at home, use of an assistive device and any underlying visual or hearing impairment [18, 19]. During the initial examination, a patient's gait, balance, strength, cognition, and mood should also be assessed [18, 19]. Once at-risk patients are identified, several interventions can be started to reduce fall risk including: (1) encourage early mobility, (2) avoid use of restraints, (3) minimize use of medications that contribute to falls, (4) use assistive devices like walkers or canes as indicated, (5) address sensory impairments like vision difficulties with patients home equipment, and (6) provide early inpatient physical therapy [20, 21].

Supplementation with Vitamin D3 has also been shown to be effective in fall reduction in nursing facilities [22]. Multifactorial interventions, increasing patients' awareness of their fall risk through bedside teaching, and careful medication review by clinical pharmacists may also decrease the occurrence of falls; however, continued research is needed in this area [20, 21].

3.4. Use of restraints in the hospital setting

The use of restraints in the elderly is sometimes necessary, such as when the patient poses a threat to themselves, to staff members, or to other caregivers and family. The goal of restraint use is to limit a patient's movement, and should only be used after other methods to calm or redirect the patient have failed. Specific instances were restraints may be necessary include violent behaviors (hitting, biting, scratching, etc) as well as non-violent behaviors (pulling on lines or tubes, interfering with medical care resulting in self-injury, etc). Types of restraints can range from physical (such as waist belts, wrist restraints, mittens or side-rails) to the use of chemical restraints (such as medications like lorazepam or haloperidol) to sedate the individual [23].

The use of restraints in the hospital, however, could potentially lead to adverse events including falls, injury, and even at times death. As such, the use of restraints in the hospital setting is controlled by the specific state and federal regulations, such as those described by the Joint Commission, in addition to individual hospital guidelines [23]. The Joint Commission outlines several items related to restraint use in hospitals, including (1) when restraints are clinically justified, (2) how a physician is to order restraint use, (3) how to safely implement restraint use to a patient's plan of care, (4) how to evaluate/care for the patient properly while under restraints, and (5) how to report death and injury as a result of restraint use [23].

In the clinical case outlined above, while soft restraints might have initially felt to be appropriate to manage an unsafe situation, its use was involved in a chain of patient safety events including a fall, traumatic pulling off a foley catheter and resulting hematuria, and worsening of delirium symptoms.

4. Latent causes

After having reviewed a few specific active causes related to patient safety in this clinical scenario, let us investigate further the latent causes or systemic factors that may have contributed to patient safety events for the hypothetical patients in this case.

4.1. Culture of safety

The broadest category for systemic or latent causes of adverse events in a health system is the 'culture of safety' practiced by the individuals within it. A 'culture of safety' can be described as all of the characteristics, attitudes, behaviors and perceptions of individual health care professionals who consciously play an active role in promoting the patient's health and safety [24, 25]. Given the high-cost burden that anyone adverse event can have, most healthcare systems have now adopted various strategies to improve teamwork and embrace a philosophy where the best patient outcomes become a shared goal. High-Reliability Organizations aim for an ultimate goal of no errors and has been promoted by the Agency for Healthcare Research and Quality as an aim all healthcare systems should strive for [4, 25].

A few methods through which a culture of safety can be achieved within the healthcare setting include safe transitions and handovers between team members, efficient and accurate use of

health information technology, and training in a blame free error reporting and error disclosure [24–27]. Improving team dynamics can reduce error by allowing teammates to coordinate their care, improve efficiency, and reduce stress and fatigue. Given that each team member brings different skills to the care of the patient, creating an environment where all team members share responsibility allows each to safely question and escalate issues that could potentially impact patient safety without fear of backlash [24]. In addition, safety huddles and multidisciplinary team based rounding enables all members of the team to provide input into the plan of care and identify potential obstacles and errors earlier on during the course of a patient's stay [24–27].

In our case above, several team members correctly identified patient safety events and brought it to relevant provider's attention to be addressed, and all quickly responded to reduce the severity of the error. In addition, while the resident in the case appeared horrified at the magnitude of the error, the calm and team-oriented approach taken by the attending physician serves as an example of a positive culture of safety. Key components of a culture of safety are outlined in **Figure 1**.

4.2. Using clinical informatics to reduce error

Due to the impact that medication errors have on healthcare outcomes, the use of clinical informatics to prevent such errors has emerged in recent years and can potentially result in significant costs savings [28]. Medication management and clinical decision support systems can reduce errors in prescribing, transcribing, dispensing, and administration of medications [29]. For example, an electronic medical record system that utilizes computerized physician order entry may allow for automatic checking of drug interactions and allergy contraindications, or even appropriate dosing based on renal function [30]. Alert functions can be utilized by the physician or provider to reduce medication dosing errors as well. It is estimated that such systems could reduce errors by greater than 50% [30]. Similarly, drug dispensing systems

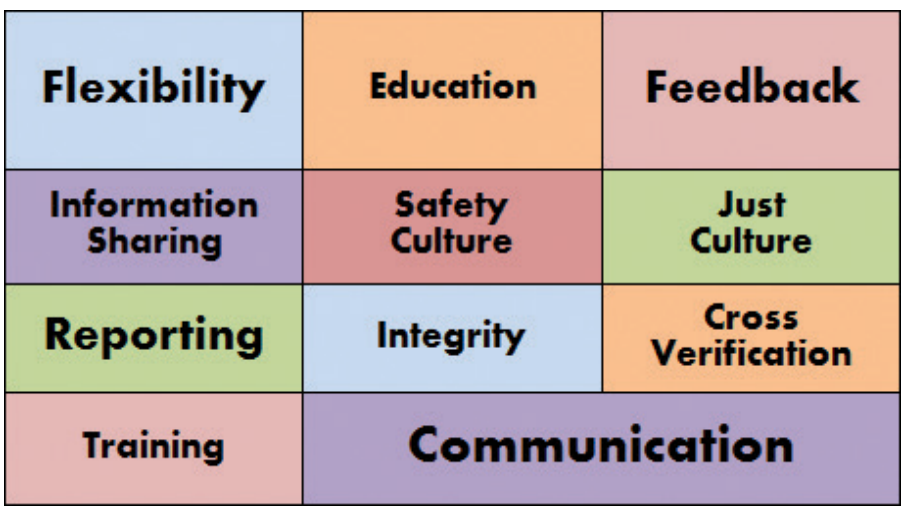

Figure 1. Schematic representation of key components of a culture of safety.

using automated cabinets, bar coding, packaging, etc, can also significantly reduce errors in medication dispensing and ultimately, administration of medications to the patient [31].

While the use of information technology to reduce medication error is quite promising, it is not without its own limitations. The ability of the software to detect error is a function of the underlying man-made program, which is also susceptible to error. For example, poor system design can increase provider workload, leading to inefficiency and alert fatigue, and can ultimately contribute to other types of downstream medical errors [32]. Multitasking can lead to medication errors, as in the case described, as physicians may jump through charts while ordering medications and inadvertently enter orders into the wrong patient's chart. As such, it is critical that providers continue to stay vigilant to mistakes even when using information technology. One simple tool utilized by High-Reliability Organizations is the STAR (Stop, Think, Act and Review) acronym which can be utilized in multiple settings to reduce errors in settings where patient safety (such as when medications are being ordered) is vital [4, 25]. This simple acronym should remind providers to take a conscious effort to focus on the task at hand to ensure that the correct order is assigned to the right patient [4].

4.3. Same or similar sounding names

A common patient safety risk occurs when hospitalized patients have the same or similar sounding names, which causes confusion in identifying and treating the intended patient. Patient identification errors can occur at any point throughout the course of a patient's hospitalization from meal delivery to procedures and interventions. However, there is an incredible potential for harm and even death, when patient misidentification occurs. It is, however, difficult to determine the true incidence of patient misidentification due to underreporting [33–35]. One study, for example, did identify that over 70% of transfusion errors in New York State occurred as a result of patient misidentification [36]. Likewise, the UK Patient Safety Agency identified 236 errors within 2 years which were related to missing or incorrect patient name bands [37]. Although correct patient identification may seem intuitive, there are several steps that hospital systems should take to prevent identification errors, as outlined in **Table 2**:

1. Identify charts of patients with same or similar sounding names with the name in bold or italics [33]
2. Use two or more separate identifiers (Name, Date of Birth, Medical Record Number, etc) to identify a patient prior to any intervention or care delivery [33, 37, 38]
3. Utilize a barcode system for drug dispensation and for patient identification [35, 37, 39]
4. Patient identity wristbands could also include a picture of the patient to provide an additional level of protection [35, 37, 39]
5. Patient identity should be verified by all providers at the time of charting, order entry, and medication administration [40]
6. Use alerts in the electronic medical record that require the provider to acknowledge and verify that they are in the correct chart if a similarly named patient is also admitted to the hospital [40]
7. Empower patients to become actively involved in the self-identification process prior to any intervention, particularly when a similarly named patient is on the same floor

Table 2. Methods to reduce patient identification errors.

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In this clinical scenario, there are several latent causes of patient safety adverse events due to similar sounding names. The patients were both admitted to the same team and were placed on the same hospital floor just a few rooms apart. In addition, as the resident was attempting to multitask, he very easily placed orders on the wrong patient which ultimately led to the medication administration error. Had some of the steps outlined above been in place, the potential for error due to the similarity in names might have been reduced.

4.4. Safe handoffs

Handoffs are the transfer of information during transitions in care and can occur at multiple points during the course of a patient's hospital stay. The handoff is a complex mechanism of communication between care providers and includes transferring of critical information, records and responsibility, all of which impacts patient safety [41]. Ineffective or fumbled handoffs can lead to critical patient safety related events including wrong site procedures, medication administration errors, and even death [41]. As a result, an effective handoff is largely dependent on the interpersonal communication skills of the caregivers involved.

The Joint Commission introduced a national patient safety goal on handoffs to reduce communication-related errors [42]. This patient safety goal requires health care organizations to implement a standardized approach to all handoff communications by emphasizing the transfer of critical patient information [40]. One common approach is the use of sign-out sheets for communication and is often utilized by physicians. The SBAR (Situation, Background, Assessment, and Recommendation) model is being used to bridge the gap between the different communication styles of nurses and physicians to enhance handoff communication [43]. In addition, the use of electronic medical records may be utilized to improve the handoff process by eliminating difficulties with data access or illegible documentation [43].

In the clinical case above, safe handoff between the resident team members is a critical component of ensuring patient's safety. A safe handoff might have included a reminder about similar sounding names, relevant cautions about medication dosing based on age, renal function or allergies, as well as a succinct yet thorough description of the patients' history and plan of care.

4.5. Disclosing error

Medical errors occur; of this, there can be no doubt. A common dilemma for physicians is how–or if–to disclose the error to patients or families. The central ethical tension in this dilemma hinges on the interplay between the four Western biomedical ethical tenets. The unavoidable pragmatic conflict is the legal or financial risks the provider may incur either by openly identifying an error, or knowingly choosing not to disclose one.

Professional societies generally agree that patients have a right to know about their care, including errors that may or may not be directly related to adverse outcomes [44, 45]. These may be good ethical standards, but we believe that no guideline can substitute for a provider's personal sense of ethics. Furthermore, the application of any guideline should be refined by the cross-cultural interactions between a provider, a patient, and family.

In any therapeutic interaction (keeping in mind that all interactions are potentially cross-cultural!), an important first step is identifying how information of any nature should be disclosed. For example, a traditional Latino family may seek multiple familial inputs before making an important medical decision for an elder. In certain Chinese families, the eldest son may hold cultural power; and family members will defer decisions to that son. Identifying dynamics ahead of time is best practice.

Lastly, when encountering a disclosure dilemma, the use of 'therapeutic privilege' should be exercised with caution. According to the ACP Ethics Manual, therapeutic privilege is "is the withholding of relevant health information from the patient if disclosure is believed to be medically contraindicated" [44]. Ultimately, it will be for the provider to decide 1) what information about an error may be medically indicated to disclose, and 2) how that information may be shared therapeutically with the decisional apparatus in the most culturally appropriate way.

5. Summary and conclusion

These two cases highlight multiple patient safety issues, errors and causes for concern–particularly in the relative ease with which such errors occur. While each case on its own presents a patient safety event, the co-mingling of these patients created additional stress points opening the system up to failure. In both cases, a simple error caused or potentially caused significant patient harm and prolongation of the hospital stay. Name similarity, service proximity, and multi-tasking all contributed to the preventable errors. We have discussed the multiple active causes contributing to error as well as contributing conditions such as medication use and dosing in an elderly patient.

Creating a safe space for all team members to be able to pose safety related questions in a blame-free environment and encouraging the disclosure of error whenever it occurs, along with the creation of layers of defense mechanisms (such as the use of computer based technology; simple pictures on wristbands and color coded alerts on handoff/sign-out materials) will all help to foster a true culture of safety within the Healthcare system. Additionally, the cultivation of an Anticipation, Prevention, and Treatment approach to each patient's plan of care, that includes patient safety and the prevention of errors, will move us toward improved care and improved patient satisfaction with the care delivered.

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Chapter 6

Inadequate Decontamination Procedures: Sepsis Following Uneventful Endoscopy

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Additional information is available at the end of the chapter

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Abstract

Exogenous infection following endoscopy remains rare, however, recent attention in the media and the rise of antibacterial resistant strains of bacteria have emphasized the importance of proper sterilization techniques involved in the reprocessing of endoscopes and accessory devices. This chapter serves as comprehensive review into the epidemiology of exogenous infections as well as basic reprocessing techniques and guidelines for all medical professionals that treat patients that would benefit from endoscopy.

Keywords: endoscopy, reprocessing, exogenous infection, sterilization

1. Clinical vignette

A 51 year old Caucasian female, with a past medical history of hypertension, was admitted to the hospital with the diagnosis of gallstone pancreatitis. At the time of admission, the patient had an elevated lipase at 14,528, an abdominal ultrasound demonstrating gallstones with a common bile duct measuring 7 mm without choledocholithiasis. In addition, she was noted to have an elevated total bilirubin, without leukocytosis or fever. Patient was admitted with gastroenterology consultation.

The next hospital day, the patient underwent endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and sludge removal. Post procedure her pain was improved and she was tolerating a clear liquid diet. Forty-eight hours after the procedure, the patient was noted to have a temperature of 101.8°F, and a leukocytosis of 15,600 per mcL. Two blood cultures drawn at the time of fever resulted in carbapenem-resistant Enterobacteriaceae (CRE). Infectious disease consultation was obtained and the patient was treated with tigecycline plus gentamicin.

Within two weeks another patient at the same facility was diagnosed with CRE bacteremia following ERCP, prompting investigation into the technique involved in endoscopy sterilization.

2. Introduction

Although the overall risk of exogenous infection from endoscopy and flexible bronchoscopy remains rare, increased concern and awareness has recently been stimulated by outbreaks reported in the literature and newspapers. In 2015, the United States Food and Drug Administration (FDA) released a safety communication about duodenoscopes, after an outbreak of carbapenem-resistant Enterobacteriaceae (CRE) infections were diagnosed following procedural intervention with duodenoscopes. The communication outlined the close monitoring the association between reprocessed endoscopes and multidrug-resistant bacterial infections caused by CRE, such as *Klebsiella* species and *Escherichia coli* [1]. Subsequently, the increased awareness as well as the emergence of "super-bugs" and anti-bacterial resistant strains of bacteria has emphasized the importance of proper sterilization techniques involved in the reprocessing of endoscopes and accessory devices.

2.1. Epidemiology

Infection following endoscopy can be divided into three broad categories: exogenous infection, endogenous infection, and infection transmitted between patient and endoscopy personnel or vice versa [2]. Exogenous infection involves the spread of bacteria via contaminated equipment between one patient and another. Endogenous infection is not due to contaminated equipment, but rather, the translocation of bacteria from the gastrointestinal tract as a result of the endoscopic procedure. An example of an endogenous infection would be a patient that develops bacteremia secondary to traumatic tissue injury during the endoscopy. Lastly, infection may be transmitted from the patient to the endoscopy personnel and vice versa if proper technique and personal protective equipment are not utilized.

The benefit of endoscopy when compared to the risks has been clearly demonstrated throughout literature [3]. Despite the large number of GI endoscopic procedures performed, estimated at over 24 million procedures in 2004 in the United States alone, instances of infectious complications remain rare [4, 5]. Infectious complications are estimated at frequency of 1 in 1.8 million procedures [6]. The majority of infections following endoscopy are endogenous infections, with exogenous infections occurring even less frequently [7].

2.2. Equipment

Endoscopies are performed in a variety of facilities throughout the United States, including the hospital, ambulatory surgical center as well as physician offices. The term endoscope is a broad term encompassing any instrument used to visualize a hollow viscus. Endoscopes can be used to perform a variety of procedures including bronchoscopy, esophagogastroduodenoscopy, sigmoidoscopy, and colonoscopy as well as a variety of others. The equipment of the endoscope is similar, although slight variations exist to facilitate the performance of one procedure over another.

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The majority of modern day endoscopes are video-endoscopes. These, although technically similar to the original fiber-endoscopes, which utilized fiber optical viewing bundles, conversely utilize a charged couple device (CCD) "chip" and electronics at the tip of the scope to generate an image that can be viewed upon a screen [8]. This advancement in technology has allowed for changes in instrument design, and limited the need for the endoscopist to place their eye close to the instrument. This has obvious hygienic advantages and minimizes the risk of infection transmitted between patient and endoscopy personnel.

Endoscopes are divided into several sections. In general, the scope has a light source, a "universal cord" which is plugged into the light source and the video processor, a the head of the instrument which contains a variety of switches and valves that control many scope functions and positions, and the "insertion tube" which includes the objective lens and the light guide lens. It is just behind the objective lens that the charge-coupled device (CCD) is located. An understanding of the basic equipment as well as the portion of the scopes which may be removed is important to ensure the adequate cleaning and reprocessing of the endoscope (**Figure 1**).

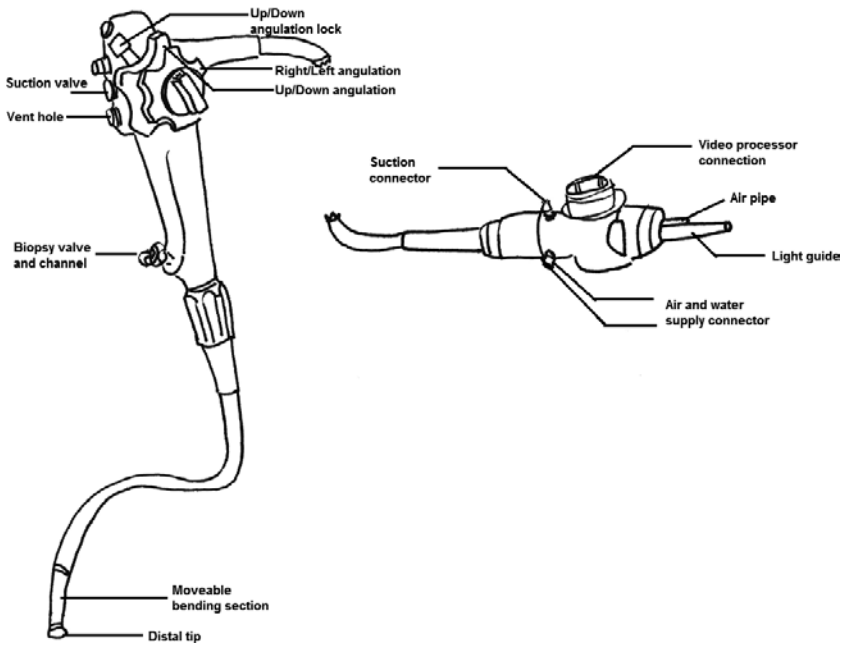

Figure 1. Structure of flexible endoscope.

3. Terminology: critical, semi-critical, noncritical, cleaning, disinfection, and sterilization

A variety of terms exist to describe the different processes and levels of sterilization involved in reprocessing endoscopes. An understanding of these terms is imperative. In general, there are three levels of disinfection of medical equipment. These include sterilization, high-level

disinfection and low-level disinfection, and are based upon the whether the equipment is labeled as critical, semi-critical, or noncritical [2, 9, 10]. A definition of each team, an example and the associated level of sterilization is displayed in **Table 1**.

The classification and terminology involved in the associated level of sterilization and disinfection is based on the ability to eliminate microbial life. Sterilization refers to the process of complete elimination of all microbial life. Conversely, high-level disinfection destroys all vegetative bacteria, mycobacteria, fungi, enveloped and nonenveloped viruses. High-level disinfection, however, does not necessarily eliminate bacterial spores. Low-level disinfection kills most vegetative bacteria, some fungi, and enveloped viruses (e.g., HIV, and hepatitis B, C) but does not kill mycobacteria or bacterial spores [11]. Cleaning is often the first step in removing the microbial burden from a device. It refers to the physical removal of debris.

3.1. Established protocols

All endoscopy units and facilities should have strict procedural guidelines that exist to ensure the correct reprocessing of equipment. Unit personnel should be proficient with the guidelines and methods unique to that institution and procedural monitoring should also be in place to ensure the method is being carried out effectively. Adherence to guidelines is a critical component of reducing infection.

3.2. Pre-cleaning

Following an endoscopy, biomaterial and microorganisms are present on the endoscope. The first step in endoscope reprocessing is an attempt to eliminate as much of the biomaterial as possible. Begin by wiping the insertion tube from the control section to the distal tube with a moist cloth or sponge. Then, all channels and working sites must be cleaned and flushed with detergent/and or water as recommended by the manufacture. This includes channels that are not used, due to the distal end being exposed to material and fluid. We recommend removing the material immediately after the procedure to minimize the risk of the material becoming dry, adherent and hard on the scope. If a delay of over an hour occurs between the endoscopy and pre-cleaning the scope should be soaked within the manufacture recommended detergent [12].

	Definition	Example	Associated level of sterilization and disinfection
Critical	A device that *penetrates* mucus membranes, blood vessels or body cavities	• Biopsy forceps • Sphincterotomes • Snares	Sterilization
Semi-critical	A device that comes in *contact, but does not penetrate* mucus membranes	• Endoscopes • Dilators	High-level disinfection
Noncritical	Objects that *do not come into contact* with patients	• Endoscopy control cart	Low-level disinfection

Table 1. Terminology of endoscope reprocessing.

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3.3. Leakage test

Prior to immersing an endoscope in any fluid, a leakage test should be completed to ensure that the device is air and fluid tight. This is important in the maintenance of the equipment as well as infection control. Begin by ensuring that the water resistant cap is properly attached then, remove the suction valve, air-water channel, cleaning channel, biopsy valve and auxiliary water tube if present. The scope should then be emerged in clean water, with the leakage test device on. Any evidence of continuous bubbles coming from the scope or while moving the control dials indicates a leak and should not be immersed in detergent and reprocessed. The endoscope should be repaired at this point. If no leaks are observed the scope may be removed the water and reprocessed [13].

3.4. Mechanical cleaning

Mechanical cleaning is a multistep process that utilizes equipment such as tubes, brushes and additional flushing devices to reduce bioburden and reduce the risk of cross contamination [14]. Effective cleaning will remove more than 99.9% of the bioburden from the endoscope [15]. For specific details regarding endoscope mechanical cleaning protocols please see the manufacturing guidelines for cleaning. In general, a basin of detergent solution should be prepared. It is important to ensure that this detergent is freshly prepared at the specific concentration and temperature recommended. Never re-use a solution. The endoscope should be completely immersed within the solution and using a soft sponge or brush to clean the endoscope all working channels, valves and portions of the endoscope should be cleaned. Ensure that any brush that is utilized to facilitate the cleaning process is not damaged. Replace any damaged brush.

3.5. Alcohol flushing

The use of flushing the endoscope channel with alcohol promotes drying and inhibits the growth of water born microorganisms. Utilizing 70% Ethyl or Isopropyl alcohol, immerse the injection tube within the beaker of solution. Then flush the solution through the air/water channel as well as the suction port. Complete this step by flushing copious amounts of air through each port with air from a syringe [13].

3.6. Endoscope storage

Once the endoscope has been reprocessed and it is dry, it should be stored vertically, in a well ventilated cabinet. The scope should be labeled or sealed with a date of when it was reprocessed. Ensure that all valves have been removed prior to storage. Angulation locks should also be placed in the "free" position. The distal tip should hang freely, and as straight as possible avoiding contact with other instruments.

The interval of storage between reprocessing and use has been an area of debate and investigation. According to the "American Society of Gastrointestinal Endoscopy Multi-society guideline for reprocessing flexible gastrointestinal endoscopes" it remains an issue requiring

further studies [10]. Data suggests that intervals of 7 to 14 days have negligible contamination and is typically related to skin organisms rather than pathogenic bacterial growth [16–18]. The data for maximal duration of re-use is currently undetermined.

3.7. Precautionary measures and occupational exposure

All personnel involved in handling of endoscopy equipment that has been used is in danger of transmission of bacterial infections to themselves. Personal protective equipment should be worn at all times while handling soiled equipment for reprocessing. This includes gowns, gloves and eye protection [10]. Occupational Safety and Health Administration (OSHA), and manufacture guidelines should be observed while handling any specific detergents, with an importance placed on diluting detergents per protocol. The proper disposal of all products that is not reprocessed is also recommended to decrease the risk of infection among personnel.

3.8. Exogenous infection after endoscopy

With more than 19 million gastrointestinal endoscopies and bronchoscopies performed each year within the United States [19], the overall risk of exogenous infections, or infections involving the spread of bacteria from one patient to another, remain relatively low. However, the importance of proper reprocessing remains fundamental in reducing the transmission risk, particularly in the time of bacterial resistance and the emersion of "superbugs." The variability of endoscopy cleanliness and reprocessing protocols has been shown to be significant. In a study published in 2013 approximately 15% of hospitals within the United States failed to achieve an acceptable level of cleanliness [20]. The specific type or endoscopy impacted the results with a higher level of duodenoscopes being unacceptable than other gastrointestinal endoscopes [20]. The suspected rationale for the inadequate reprocessing of endoscopies has been outlined in a study published in 2003, **Figure 2** [21]. A systemic review of published literature between 1966

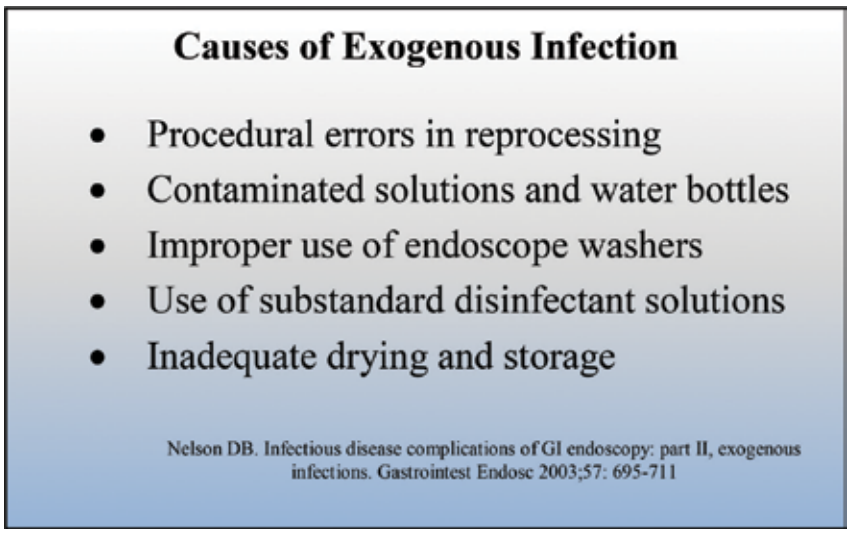

Figure 2. Causes of exogenous infection.

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and 2005 revealed only 70 outbreaks of infection reported within 64 articles [22]. This number may underestimate the amount of infections, due to under-reporting. The recognition of exogenous infection risk and adequate reprocessing techniques is imperative to all personnel and staff involved in endoscopy. Proper reprocessing could reduce the number of infections.

4. Key points

- The three main types of infection following endoscopy include exogenous infections, endogenous infections and infection spread between patient and medical personnel.
- Sterilization, high-level disinfection and low-level disinfection are distinct terms used to clarify the level of sterilization based on the ability to eliminate microbial life. Sterilization refers to the process of complete elimination of all microbial life for critical pieces of equipment.
- All personnel should understand the decontamination and reprocessing protocols within their institution. Protocols should be based off specific equipment protocols by the manufacturer.
- The main steps of endoscope reprocessing include; pre-cleaning, performing leak test, mechanical cleaning, alcohol flushing and proper storage.
- Exogenous infections, though rare, have increased clinical significance given the rise of antibiotic strains of bacteria. All efforts should be made to prevent the exogenous infections from endoscopes.

5. Conclusions

Increased concern and awareness of infections after endoscopies has gained much attention in the literature in recent times. The rise of superbugs and transmission of potentially lethal microbes has led to an increased awareness of the necessity for proper reprocessing of all endoscopes. An understanding of the specific equipment, protocols within each institution and each manufacture guidelines is essential. Also as important, is the implementation of system of periodic and random review of policies and methods, to ensure that all protocols are being followed as intended. In the future, automated endoscope reprocessors, AERs, which are beginning to emerge from a variety of manufacturers have been proposed to enhance the efficiency, consistency and reliability of endoscope reprocessing and may reduce the potential human error associated reprocessing [23].

Acknowledgements

This chapter is meant to provide education in the form of a comprehensive review and act as a guideline all medical professionals that treat patients that would benefit from endoscopy. This guideline should not be mistaken for a legal standard of care. Clinical judgment should be considered in all circumstances, and may vary based on endoscopist and facility.

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Chapter 7

Unnecessary Complications: The Forgotten Indwelling Urinary Catheter

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Additional information is available at the end of the chapter

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Abstract

Complications of indwelling urinary catheters (IUCs) are common, with the infectious one accounting for 40% of all reported healthcare-associated infections. Myths and rituals exist among healthcare professionals in the application of the urinary catheter, and the catheter is often forgotten after the placement, resulting in a potentially significant impact on patient outcomes and healthcare cost. The implementation of institutional protocols through a bundled approach can significantly reduce forgotten IUCs and dramatically improve patient safety.

Keywords: urinary tract infection, indwelling urinary catheter, bacteremia, sepsis, risk factors

1. Introduction

Indwelling urinary catheters (IUC) are among the oldest of medical devices that continue to be used in therapy today. The earliest known documentation of transurethral catheterization is found in an Egyptian papyrus dating to 1500 BC. The report describes catheterization performed primarily to treat male urinary retention utilizing a variety of materials, including bronze tubes, reeds, straws and curled palm leaves [1]. Over the ensuing centuries, the catheterization process underwent several modifications, including the use of various manufacture materials, contours and fixation methods. Eventually, Dr. Frederic Foley developed a self-retaining, balloon-based latex catheter in 1929 while seeking a treatment of post-prostatectomy hemorrhage. With the invention and broad commercial production of the Foley catheter, the accepted indications for catheterization rapidly expanded to include post-surgical care

and both short- and long-term treatment of urinary retention and incontinence from a variety of etiologies. IUCs quickly became an indispensable part of modern medicine, aiding the care and evaluation of critically ill patients while improving patient hygiene.

As the indications for and use of IUCs expanded during the twentieth century, so did the incidence and impact of complications of catheterization. In the 1980s, catheter-associated urinary tract infections (CAUTI) were identified as the most common nosocomial infection with estimates suggesting that CAUTIs comprised up to 40% of hospital-based infections [2]. With the advance of medical knowledge and technology, the incidence of CAUTIs has not significantly decreased [3].

The prevention and treatment of CAUTIs and bacteremia have become a favorite topic for clinical study, especially in the current era of exponentially increasing healthcare costs. Researchers have explored antibiotic impregnated catheters, various metal alloys and alternative drainage systems and nursing protocols to address the issue [4]. Through this scientific inquiry, one conclusion remains constant—the most reliable way to prevent complications is to limit the incidence and duration of the use of IUCs [5]. Over the last 20 years, concerted international efforts have been made to address both of these aims, yet the prevalence of IUCs that have been forgotten or remain past the limits of their original indication remains far too high. In this chapter, we discuss the complications of IUCs with special attention paid to IUCs that have been forgotten and strategies to address this substantial performance improvement and patient safety issue.

2. Clinical vignette

An elderly female is admitted to the surgical service for recurrent adhesive small bowel obstruction, due to open right hemicolectomy 15 years ago, and dehydration. Her past medical history is significant for COPD and congestive heart failure. Upon this current admission, she receives a nasogastric tube for decompression and an IUC for monitoring fluid resuscitation status. On her second day of hospitalization, the patient proceeds to the operating room for laparoscopic lysis of adhesions.

On postoperative day 2, the patient starts passing flatus, and the decision is made to remove her nasogastric tube. During morning rounds, the team notes that her respirations are labored and a chest X-ray reveals pulmonary vascular congestion. The decision is made to treat her with diuretics. The removal of the IUC is proposed, and the resident decides to keep it in place until after the diuretics take effect. The following morning the nurse notices that the team has again ordered furosemide for the patient. Remembering that the IUC remained in place the prior day due to diuretic use, the nurse sees no reason to remind the team that the IUC needs to be addressed. Two days later, a new nurse takes over care of the patient. During her initial assessment, she notes the IUC and mentions taking it out to the patient. The patient remembers that she has had bladder spasms previously. Her physical therapy was slow and painful yesterday, and she worries that she will not be able to get to the bathroom in time. As she becomes more anxious worrying about soiling herself and sitting in her own urine, the nurse takes pity on the elderly patient and decides not to mention it again.

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On postoperative day 7 (IUC day 10), while awaiting rehabilitation placement, the patient develops a fever and lower abdominal discomfort with worsening respiratory status and tachycardia, requiring transfer to the intensive care unit and IV antibiotics. The IUC remains in place for strict monitoring of urinary output. Blood and urine cultures grow *Escherichia coli*. The diagnoses of CAUTI and catheter-associated bacteremia are made, and the IUC is replaced. The patient improves on antibiotics and is discharged to a rehabilitation unit 5 days later.

3. Complications of urinary catheterization

3.1. Mechanical complications

While infectious complications of urinary catheterization, like those experienced by our patient above, have received the most research focus and media attention, clinicians cannot discount the potential noninfectious complications, as documented in **Table 1**. While the relative rates of the various mechanical complications of IUCs are unknown, obstruction, retained IUC due to balloon port obstruction and hematuria are frequently described [1, 6]. There have even been reports of life-threatening hemorrhage following traumatic catheter removal [7].

The original Foley catheter developed by Bard in the 1930s was made of latex. Due to its many beneficial mechanical properties, latex remained the only material of significance used in the

Complications
Mechanical
Obstruction with/without hydronephrosis
Hematuria
Retained catheter due to obstruction of balloon port
Retained balloon fragments
Bladder calculi
Pseudopolyp formation
Urethral or bladder neck stricture
Bladder trauma/rupture
Increased risk of bladder carcinoma
Infectious
Bacterial colonization/bacteriuria
CAUTI
Bacteremia
Epididymitis

Table 1. Complications associated with IUCs [1, 6, 7].

production of urinary catheters through most of the twentieth century. In the 1980s, increased rates of urethral strictures were attributed to the cytotoxic properties of latex [1]. Prolonged latex catheter use leads to chronic urethritis and fibrosis. This problem was addressed through the development of silicone-coated latex and silicone-based catheters that are frequently used today when long-term catheter requirement is suspected. Today, prolonged length of catheterization is known to be a significant risk factor for the development of bladder neck and urethral strictures, calculi and even squamous cell carcinoma of the bladder [6].

3.2. Bacterial colonization and bacteriuria

Asymptomatic bacteriuria, defined as isolation of $\geq 10^5$ colony forming units/mL in an asymptomatic patient, is extremely common among hospitalized patients with nearly half of all catheterized patients demonstrating bacteriuria after 5 days of IUC use and an incidence of bacteriuria onset of 3–8% per day of catheterization [5, 8]. Most clinical studies related to IUCs have been directed at decreasing the rates of bacterial colonization of IUCs. Studies have involved the use of antibiotic-coated and silver- and noble alloy-treated catheters. While some studies have showed decreases in bacteriuria and CAUTI rates in the short term, none of the studies were able to demonstrate durable benefits past 10 days of catheterization [4, 9–11].

Bacteriuria develops in catheterized patients due to the disruption of the of the natural defenses inherent to the urinary system. In the absence of a continuous drainage IUC, the regular distention and emptying of the bladder flush out any bacteria that migrate into the urethra or bladder. With a catheter in place, bacteria can migrate unobstructed from the urethral meatus to the bladder. Bacteria adhere to both the extra- and intraluminal surface of the IUC and secrete bacterial glycocalyces that form an extracellular matrix. This biofilm, thickest on the internal surface of the catheter, protects the colonized bacteria from antibiotic and mechanical eradication. As the biofilm becomes encrusted with struvite and apatite crystals, further complications, such as urethritis and increased retention of small amounts of urine around the catheter balloon, lead to increased bacterial growth and secondary infection [2, 12]

Prospective studies have demonstrated an increase in antibiotic-resistant organisms with antibiotic treatment of asymptomatic bacteriuria [13]. Given this evidence coupled with the cost of routine urinary cultures, the Infectious Diseases Society of America (IDSA guidelines) recommends against screening for and treating asymptomatic catheter-associated bacteriuria [5].

3.3. Catheter-associated urinary tract infection (CAUTI)

Among the adverse events attributed to IUC use, CAUTI is the most common. Reported rates of CAUTIs vary greatly between countries and among studies within a given country and time period [14]. Much of this variability was attributed to the lack of a universal consensus definition of CAUTIs. Several studies failed to differentiate between asymptomatic bacteriuria and symptomatic infection attributed to IUCs. Other reports of CAUTI prevalence were confounded by the presence of concurrent infections.

For the purposes of this chapter, we use the IDSA guidelines definition of CAUTI: the presence of $\geq 10^3$ colony forming units (CFU)/mL of ≥ 1 bacterial species in a single urinary culture in a patient

with concurrent signs or symptoms suggesting a UTI with no alternate source of infection identified. The patient must also have an IUC in place at that time or removed within the prior 48 h [5].

The signs and symptoms of a urinary tract infection in the catheterized patient are significantly different from that of the non-catheterized patient. Clinicians should look for suprapubic pain or tenderness, vague pelvic discomfort (as seen in the patient in the vignette), costovertebral tenderness and acute onset of hematuria. These findings, however, have poor sensitivity in the diagnosis of CAUTIs. Additionally, patients are often critically ill and intubated or sedated, or suffer from neurologic conditions that require long-term catheterization. Patients' underlying conditions can often impede their ability to appropriately communicate subjective symptoms and place them at high-risk for infection from multiple sources in addition to the urinary tract, representing a diagnostic conundrum. Subsequently, CAUTIs are often a diagnosis of exclusion [14].

When clinical findings suggest that a patient has developed CAUTI, it is important to obtain a urine sample prior to initiating appropriate antimicrobial therapy [15]. If an IUC has been in place for longer than 2 weeks, the presence of a mature biofilm can confound urinary culture results. To accurately identify bacteria responsible for urinary infection, the IUC should be replaced using standard sterile protocols prior to obtaining a sample for culture [5].

3.4. Catheter-associated bacteremia

While much less common than CAUTIs, catheter-associated bacteremia is an undeniable problem with greater than 50% of bacteremic episodes in long-term care facilities attributable to IUCs [14]. On the other hand, while the noninfectious complications of IUCs confer a burden on the patient and the medical system, they also increase the risk of infectious sequelae. The disruption of the urothelial lining associated with urethral trauma, stricture formation, bladder stone formation, retained balloon fragments and urethritis, along with the interventions required to treat them (e.g., urethral dilatation, cystoscopy and stone or balloon fragment retrieval) provides a potential route for bacterial access to the bloodstream from colonized IUCs.

Studies have shown that bacteremia associated with a urinary pathogen occurs in fewer than 5% of patients with documented catheter-associated bacteriuria but is associated with a 12–30% mortality rate [14, 16]. Unfortunately, it is difficult to predict which patients are at the greatest risk for developing bacteremia. Studies attempting to identify patients at the greatest risk for catheter-associated bacteremia have been performed with mixed results as presented in **Table 2**. As illustrated in the vignette, patients with bacteriuria do no reliably demonstrate signs and symptoms of CAUTI prior to progressing to bacteremia and sepsis. Furthermore, mortality among patients with bacteremia is not associated with symptomatic CAUTI versus asymptomatic bacteriuria [17].

To identify patients at increased risk of developing catheter-associated bacteremia, Conway et al. [18] performed a matched case-control study to identify independent predictors for development of bacteremia among patients admitted to an acute care hospital with documented nosocomial catheter-associated bacteriuria during the associated admission. Unlike previous studies, they looked at the risk of bacteremia when IUCs were continued after bacteriuria was demonstrated. Continued IUC use after demonstration of bacteriuria was associated with an

Study group	Time frame	Predictors identified	Odds ratio (95% CI)	*P* value*
Conway et al.	2006–2012	Male sex	2.76 (1.80–4.21)	<0.001
		Catheter in place bacteriuria	2.75 (1.65–4.56)	<0.001
		Urinary Tract Procedure	2.70 (1.09–6.74)	0.03
		Recent immunosuppressant use	1.68 (1.06–2.66)	0.03
		Diabetes mellitus	0.70 (0.42–1.18)	
Greene et al.	2000–2008	Neutropenia	10.99 (5.78–20.88)	<0.001
		Insulin administration	4.82 (2.52–9.21)	<0.001
		Underlying renal disease	2.96 (1.98–4.41)	<0.001
		Urinary Tract Procedure	2.49 (1.31–4.73)	
		Liver disease	2.34 (1.35–4.06)	0.003
		Male sex	2.18 (1.52–3.12)	<0.001
		Recent immunosuppressant use	1.53 (1.04–2.25)	
		Antibiotic use	0.66 (0.44–0.97)	
Saint et al.	1984–1999	Recent immunosuppressant use	8.13 (1.02–64.83)	
		Malignancy	1.94 (1.06–3.55)	
		Male sex	1.88 (1.62–2.18)	
		Smoking (last 5 years)	1.26 (1.01–1.57)	
		Antibiotic use	0.76 (0.68–0.85)	

*Where available and $P \leq 0.05$.

Table 2. Table Predictors for catheter-associated bacteremia [18–20].

increased risk of bacteremia with an odds ratio of 2.75. Male sex, younger age, recent immunosuppressant use and urinary tract procedure were also associated with increased risk of bacteremia [18].

Not only do IUCs increase the risk of bacteremia, but they are also associated with an increased disease severity. A 2017 study by Melzer and Welch [21] used multivariate logistic regression to demonstrate that bacteremia secondary to CAUTI is significantly more likely than bacteremia from other hospital-acquired sources to result in severe sepsis, as defined by a Pitt bacteremia score ≥ 2 (OR 3.94). Conversely, bacteremia secondary to a urinary source without an associated IUC was much less likely to result in severe sepsis, with an odds ratio of 1.27 [21].

While rare, bacteremia from an IUC has been clearly documented and is associated with increased severity of illness. The risk of catheter-associated bacteremia increases with the length of catheterization and specifically with continued catheterization after the diagnosis of bacteriuria has been established, suggesting a possible benefit to routine urine cultures in critically ill patients requiring long-term catheterization to identify patients that may ben-

efit from an IUC holiday and intermittent catheterization [18]. The current IDSA guidelines published in 2010 recommend against routine screening for asymptomatic bacteriuria. This suggestion is based on the grounds that treatment of asymptomatic bacteriuria with a short course of antimicrobials and catheter replacement did not prevent the subsequent incidence of urosepsis or repeat bacteriuria [21]. Recent research developments suggested that these recommendations warrant further study.

4. The forgotten IUC

Performance improvement and patient safety studies relating to CAUTIs have identified two major areas for improvement to prevent potential complications: eliminating inappropriate use of IUCs and promoting the prompt removal of appropriately placed IUCs when no longer indicated. Today, the list of accepted indications for IUC placement is short and specific [5, 14]:

- Urinary tract obstruction and urinary retention
- Hourly urine output measurements in acutely ill
- Urinary incontinence in select patients:
  - Terminally ill
  - To facilitate healing of advanced open pressure ulcers or skin grafts.
- Patients requiring prolonged immobilization (e.g., severe pelvic fracture).
- Perioperative period for gynecologic, urologic and prolonged procedures requiring general anesthesia.

Unfortunately, as in the case of our patient at the beginning of this chapter, evidence suggests that IUCs are frequently used for reasons outside these accepted indications within the acute hospital setting. The Keystone Bladder Bundle Program designed to implement protocols to decrease inappropriate IUC use within Michigan hospitals found that only 44.3% of catheters were placed for appropriate indications prior to protocol implementation [22]. Current strategies to decrease the incidence of CAUTIs include ongoing efforts to develop and standardize protocols that encourage practitioners to carefully and critically consider the indications for catheterization prior to submitting the placement order.

Determining the reasons for inappropriately prolonged IUC use is a more complicated undertaking. Krein et al. [23] used a survey-based study design to explore the reasons for prolonged IUC use. They found that two of the major barriers to adequate implementation of a comprehensive CAUTI prevention protocol were poor healthcare staff engagement and patient or family request for IUC placement or continuance. Common reasons for prolonged catheterization use can be found in **Table 3**.

Among the nursing staff, Krein et al. [23] found that IUCs and the associated UTIs were perceived as common, benign and inevitable. They also revealed some nursing myths relating to

IUCs and their effect on patient care. Some nursing staff noted that IUCs were needed to keep the nursing workload manageable, stating that some patients required help with toileting on a more than hourly basis, detracting from the time allotted to perform other important and time-sensitive patient care tasks. Others reported that monitoring urine output and helping patients to get rest were much easier with an IUC in place. Staff also noted that the presence of an IUC could help prevent other "never events" and promote patient safety, referring to unsteady patients who attempt to get out of bed alone to go to the bathroom and risk patient falls [23]. These findings are supported by a study performed in 2010 in which registered nurses in Minnesota were surveyed regarding IUC practices [24]. RNs regularly reported, incorrectly, that inability to stand to void and new or increased diuresis were "sometimes" indications for urinary catheterization, and only 38% of the nurses surveyed reported having received continuing education related to IUCs.

On the other hand, poor physician involvement in infection prevention protocols was also identified as a significant roadblock to CAUTI prevention strategies [23]. Many protocols require physicians to document daily the ongoing indication for IUC use, sometimes by means of a checkbox in the electronic medical record. While these protocols have been demonstrated to decrease the number of inappropriate catheter days, they are subject to the human element. The unengaged, overworked or distracted physician can skip past these checkpoints without giving the matter critical thought. In a Japanese study, the most commonly cited reason for inappropriate IUC use was "convenience of care" [25]. The inadequately engaged or undereducated young resident physician is at risk of being susceptible to pressure from nursing staff to continue IUCs beyond the limits of the initial indication to aid in convenience.

Patients themselves are another source of inappropriate IUC use. In Krein et al.'s study, clinicians reported that patients demanded catheter placement or refused removal for a variety

Nursing factors
Lack of education regarding risks/invasiveness of Foley
Poor understanding of indications
Increased workload of urinary care
Prioritization of patient safety issues
Physician factors
Consider UTI prevention low priority
Poor hand offs between providers or services
Physician negligence/distraction
Patient factors
Postoperative pain control
Family concern for hygiene

Table 3. Causes of inappropriately long urinary catheterization [23–25].

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of reasons [23]. Usually, the patients had incontinence or postsurgical pain that limited their mobility. With the increasing importance placed on patient satisfaction as a determinant of reimbursements, some clinicians are hesitant to ignore patient demands or spend significant amounts of time reasoning with or educating them.

Accurate data about the rates of inappropriately prolonged IUC use are not currently available. Partly, the problem at hand is often caused by a lack of recognition of the problem (forgotten IUCs) but also due to poor adherence to established CAUTI prevention programs and data reporting [3, 26]. It is also hard to compare unnecessary catheter-days between different patient populations, such as critical care, surgical or medical patients because these groups have inherently different rates of appropriately indicated IUC use [3]. Success of programs designed to decrease inappropriate IUC use was usually measured by the change in total catheter days because it was often difficult to determine the point at which the IUC's indication expires and it becomes forgotten.

5. Remembering the forgotten IUC (quality improvement)

In 2008, the Centers for Medicare and Medicaid Services in the United States announced a list of healthcare-acquired conditions that would no longer be eligible for reimbursement, including CAUTIs, as part of their Healthcare-Acquired Conditions (HAC) Initiative. With the introduction of this concept of "never events," the onus was placed on individual institutions to bear the cost of managing these conditions [27]. With CAUTIs estimated the financial impact of 27 million US dollars in 2009 in the United States alone [28], this policy provides a significant financial incentive for facilities to develop and support practices to limit the incidence of CAUTIs.

Several different methods to decrease the duration of urinary catheterization in the acute care hospital setting have been studied. Some of these included nurse-driven approaches such as automatic stop orders, nurse-driven protocols to remove IUCs that failed to meet specific checklist criteria and nurse-driven physician reminders [29]. Other programs were physician focused with IUC renewals as a required daily order or documentation of continued indication as a required part of the daily patient note [30, 31]. Most of the studies revealed a statistically significant decrease in both catheter-days and incidence of CAUTIs with the implementation of any protocol to increase awareness of the need to remove IUCs. The remaining studies revealed a decrease in CAUTIs that was not statistically significant [27, 30]. While the implementation of a CAUTI-prevention program clearly decreases catheter days and CAUTI rates, no single daily intervention has been shown to be superior. A nationwide survey in 2009 found that, among the several identified IUC removal and CAUTI-prevention techniques, none was used in greater than 50% of nonfederal United States hospitals [32]. Some practitioners support the use of external collection devices as an alternative to IUC use. An expert panel in 2016, however, concluded that there is inefficient literature at this time regarding efficacy and cost-effectiveness to make an educated recommendation, and further clinical studies are warranted [33].

Bundle protocols utilizing a multidimensional approach including education, patient care protocols, surveillance and local reporting of compliance and outcomes are generally accepted to

be the most effective way of minimizing CAUTIs. In Michigan, the Keystone Bladder Bundle Initiative was created in 2007 [22]. The Bundle used the concept of Engage, Educate, Execute and Evaluate and the Johns Hopkins University collaborative model to create a team at each hospital to spearhead and maintain the program [34]. A nationwide survey of 470 hospitals revealed that CAUTI incidence decreased by 25% in Michigan hospitals and by 6% in non-Michigan hospitals during the same period [29]. A big component of the success of this initiative was due to the appointment of "champions" that were responsible for addressing individual questions and encouraging continued engagement in the reduction of catheter use [23].

Often the reasons for prolonged urinary catheterization are related to lack of education at multiple levels (see **Table 2**). Education efforts need to focus on both the nursing and physician staff. Nurses are often the driving force in the decision to place or maintain IUCs, especially because physicians are frequently unaware which of their patients have IUCs [31]. Providing the nursing staff with education in techniques, such as scheduled toileting care, to limit the burden of incontinence management can help to change attitudes [23]. The nursing staff also serve as an invaluable resource to patients and their families. Properly educated and convinced nursing staff can help shoulder the burden of educating patients and families about the risks of and appropriate indications for IUCs. Physician education is no less valuable. A prospective study revealed that implementation of an education plan to increase physician awareness of inappropriate catheterization resulted in statistically significant decreases in IUC duration, CAUTI incidence and hospital length of stay [35]. A 2016 study showed that a brief education program provided to both nursing and physicians regarding proper IUC indications resulted in a significant decrease in the proportion of inpatient days with IUC in place [36].

According to a large-scale retrospective review of the rates of CAUTIs in the ICUs of 1166 US hospitals from National Database of Nursing Quality Indicators database from 2008 through 2010, there was a 10% decrease in the rate of change of CAUTIs after the implementation of Medicare's Healthcare-Acquired Conditions Initiative [37]. This was largely attributed to multifaceted prevention programs employing IUC removal protocols. Despite the strength of the evidence supporting the use of written and bundle protocols to fight the CAUTI epidemic, a study published in 2012 found that only 42% of ICUs had developed written policies to decrease urinary catheter days [29]. Bundled prevention programs rely heavily on continuing education and providing individual and group level feedback. Programs that require this level of institutional involvement can only be successful in an environment that supports the efforts from the top of the administration with the allocation of resources to support and reward education efforts.

6. Conclusion

IUC-related complications remain unchanged over last several decades. Several indwelling urinary catheter-related complications can be attributed to the forgotten indwelling urinary catheters, as seen in our clinical vignette patient. In a world with increasing prevalence of antimicrobial resistance, appropriate prevention of these complications is vital. IUCs should not be undertaken lightly. Before placing an IUC, clinicians must carefully weigh the indications and consider whether an alternative would be more appropriate. Fortunately, there remains

significant room for improvement in the initiative to eliminate forgotten IUCs and subsequently decrease the IUC-related complications. Healthcare professionals, physicians and nurses alike, should take it upon themselves to become champions of a CAUTI prevention program through development and effective use of evidenced-based, innovative, streamlined clinical bundle protocols to shorten patients' hospital stays and decrease healthcare costs.

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Chapter 8

Pressure Injury in the ICU: Major Reconstructive Surgery Required

Ashley Jordan

Additional information is available at the end of the chapter

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Abstract

Pressure injury (PI) has replaced the former nomenclature pressure ulcer, a change initiated by the National Pressure Ulcer Advisory Panel (NPUAP) however, substitutes such as pressure ulcers, decubitus ulcers, and bedsores will continue to be used by many. Increased knowledge and awareness of PIs has lead to a decline in their overall prevalence. A review of the most common risk factors, including two risk factor assessment tools, the Braden scale and the Cubbin & Jackson are presented. Diagnosing PIs must be a methodical, meticulous process in order to accurately document and monitor their progression and improvement. In 2016 the NPUAP revised the definitions as well as the stages of PIs incorporating the etiology and anatomical features present or absent in each stage of injury. Treatment strategies such as managing co-morbidities, nutrition optimization, and pain management are important aspects to consider in treating PIs in addition to thorough wound care cleansing and debridement. Highlighted are the various effective debridement options such as surgical sharp, mechanical, autolytic, enzymatic and larval debridement. Wound dressing alternatives, their advantages, disadvantages, indications and contraindications are all are mentioned. Concluding the chapter are pressure injury rates of healing, prognosis and surgical indications.

Keywords: pressure injury, pressure ulcers, decubitus ulcers, bedsores, ulcer prevention, ulcer treatment

1. Case introduction

Cynthia is a 70-year-old retired African-American patient with a past medical history significant for anemia and lung cancer—now 10 years in remission. She initially presented to the hospital complaining fatigue and severe cough that she "just couldn't get rid of." She was

subsequently found to have severe pneumonia requiring intravenous antibiotics. She was transferred to the medical intensive care unit (ICU) due to hypoxia and rapid decompensation on the floor; before she knew it 2 weeks had gone by since her admission. She noticed increasing amounts of lower back pain, presumably from sitting in bed all day. While her family and nurses encouraged her to get out of bed and walk she refused, stating that she was just "too weak to walk." One day while repositioning Cynthia in order to change the bed sheets; her nurse noted a new dime sized, red mark right above her gluteal cleft. She knew that she was supposed to document all wounds but she did not think this small, little mark "counted" as it was pretty minor. The nurse finished her shift and did not think much about the lesion. As the days progressed the dime sized lesion became the size of a nickel, then a quarter and soon the wound was as large as your hand. The patient complained of very severe pain in that region. The once red tissue was now grayish-black and it occasionally it produced a yellow-green exudate. The nurses did their best to pad her sacral region with various dressings however she was so thin and malnourished that you could literally see the vertebrae along her spine; subsequently the tissue continued to break down. Eventually, Cynthia's pressure injury was so deep that a small piece of bone started to protrude from the wound base. The medical ICU team tried various modalities to simulate wound healing, once they had exhausted all options for pressure wound injuries, they felt it was necessary to ask the plastic surgery team to evaluate her. Due to the depth and size of the sacral lesion, the plastic surgeons determined that Cynthia was going to require an operation — more specifically a multistep, rotational flap procedure. The patient and her family cuold not believe the news. How could this have happened? Could this outcome have been prevented?

2. Introduction—what is a pressure injury?

Pressure injury has replaced the former nomenclature pressure ulcer, a recent change initiated by the National Pressure Ulcer Advisory Panel (NPUAP). The change in terminology derives inception from past histopathological work, which indicates that small changes in pressure-related injuries start in the tissue prior to the changes being visible on physical examination [1–3].

A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device [6]. An ulcer is defined as a break in skin or mucous membrane with loss of surface tissue, disintegration and necrosis of epithelial tissue, and often, purulent exudate [5]. Thus, a pressure injury can be present without an ulcer however an ulcer cannot be present without a prior injury [6]. While the new terminology, pressure injury is the more technically correct term; many have argued that the name change does nothing to add clarity, improve accuracy or correct patient outcomes [7, 8]. Regardless of the advisory panels' endorsed term substitutes such as pressure ulcers, decubitus ulcers, and bedsores will continue to be used by many.

Pressure injuries can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear can be affected by microclimate, nutrition, perfusion, co-morbidities as well as the condition of the soft tissue [4]. The foul odors associated

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with many chronic, nonhealing wounds may impair patient's quality of life, lead them toward isolation and can reduce their contact with family, significant others and care givers [9].

3. Patient demographics, incidence and prevalence

Pressure injuries most commonly affect the elderly ages 65–70 years old, those with limited mobility, including hospitalized patients, nursing home occupants, those with neurologic impairment and people with severe illnesses [10]. General facility demographic trends indicate that mean patient age acquiring pressure injuries has decreased, scores for the Braden Scale, a PI risk factor assessment tool have remained constant, and patient weight has increased in most care settings [11].

Increased knowledge and awareness of pressure injuries has lead to a decline in their overall prevalence (OP). A large sample sized study with data collection spanning from 2006 to 2015 showed that the OP of pressure injuries in all facilities declined from 13.5% (2006) to 9.3% (2015) [11]. The annual prevalence of pressure ulcers among patients 65 years and older in general medicine practice has varied from 0.31 to 0.7% [12]. An Australian study found that excluding Stage 1 ulcers, overall hospital-acquired pressure injury prevalence from 2012 to 2014 was 11% for intensive care patients and 3% for non-intensive care patients [13]. Intensive care patients were found to be 3.8 times more likely (RR 2.7–5.4, 95% CI) than non-intensive care patients to develop a pressure injury while in the hospital [13]. Prevalence varies according to the patient's residence or surrounding environment. Facility-acquired prevalence (FAP) declined from 6.2% (2006) to a range of 3.1–3.4% (2013–2015). Acute care OP was 13.3% in 2006 and declined to a range of 8.8–9.3% (2012–2015). Long-term acute care (LTAC) had the highest OP at 32.9% in 2006; it declined to 28.8% in 2015 [11].

The sacrum/coccyx is the most common site of hospital-acquired pressure injury in all patients (intensive care patients 22%; non-intensive care patients 35%) [13]. Stage 2 hospital-acquired pressure injury (HAPI) prevalence is the most common stage reported, 53% for intensive care patients compared to 63% for non-intensive care patients [13]. Mucosal tissue lines the tongue, gastrointestinal (GI) tract, nasal passages, urinary tract and vaginal canal. This type of tissue is vulnerable to pressure from medical devices, such as oxygen tubing, endotracheal tubes, orogastric and nasogastric tubes and urinary catheters. Mucosal pressure injuries have been found to be significantly higher in intensive care patients (22%) than in non-intensive care patients (2%) [13].

Incidence is a commonly reported measure; however it is computed by counting the number of patients with newly acquired pressure ulcers and dividing that number by the number of patients examined for pressure ulcers over a given period of time. Smaller facilities can appear to have a higher percentage of patients with ulcers because there are fewer patients in the denominator. For example, five patients with ulcers in a 100 patient facitlity equals a 5% incidence. The same number of patients with ulcers (5) in a 500 patient facility is only a 1% incidence. Incidence density is the best quality measure of pressure ulcer prevention programs, according to the NPUAP [14]. Pressure ulcer incidence density is a computation based on the number of in-patients who develop a new pressure ulcer(s) divided by 1000

patient days. Using the larger denominator of patient days allows fair comparisons between institutions of all sizes and stabilizes results. Many state reporting systems and hospital-acquired conditions (e.g., CAUTI) currently use incidence density [14].

4. Risk factors

There are a multitude of risk factors that can contribute to PIs. Literature has stated that the elderly, aged >60 years old are the most prone to the development of pressure injuries, due to changes in aging skin such as decreased skin elasticity, insufficient skin hydration, decreased sensitivity, and factors that are associated with chronic comorbid conditions [15, 16]. Conditions that interfere with peripheral circulation and tissue perfusion have also been linked to PIs, such as congestive heart failure (CHF), diabetes mellitus and smoking [16].

Limited mobility is considered a fundamental component of PI formation. A reduction in movement can be related to a spinal cord injury, progressive neurological disorders, stroke, pain, and fractures among other etiologies. Pressure from any hard surface (e.g. bed, wheelchair or stretcher), friction from a patient's inability to move well in bed and shear from involuntary muscle movements are also a major contributors toward pressure injuries. Moisture from bowel or bladder incontinence, excessive perspiration and wound drainage have also been found to be correlated with pressure injuries. Poor nutrition resulting in reduced body mass due to wasting or cachexia typically results in less subcutaneous fat. Less protection over areas of bony prominence can lead to increased risk of pressure injuries, thus optimizing patients' nutritional status is essential for skin protection as well as wound healing.

5. Risk factor assessment tools

The Braden Scale is one of the most common pressure injury risk scales used in the United States. It is valid and effective for assessing the risk of developing pressure ulcers [17]. The Braden and Cubbin & Jackson are valid scales for measuring the pressure injury risk in patients admitted to intensive care units (ICUs) [18]. The health status of ICU patients vastly differs from general hospital patients. ICU patients are more likely to have several comorbid conditions, be hemodynamically unstable, receive vasoactive medications, be ventilator- dependent and are often sedated [19]. Literature states that for every mmHg decrease in diastolic blood pressure, the odds of a deep tissue injury increases by approximately 7.5% (1/0.93 = 1.075) [20]. Some literature has shown that of the two ICU risk assessment tools, the Cubbin & Jackson scale is the most effective in predicting risk of decubitus ulcers in patients admitted in ICU with sensitivity of 99.3% and specificity of 55.5% [17]. The Cubbin and Jackson scale has been used for the ICU population with great results [19].

5.1. Braden scale for predicting pressure sore risk: used on general hospital and ICU patients

The Braden Scale is the most widely used pressure ulcer risk assessment system in the world [21]. It is a clinically validated tool that was developed to help all health professionals, especially

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nurses, assess and reliably score a patient's risk of developing a pressure injury [22]. It consists of six categories: sensory perception, moisture, activity, mobility, nutrition, and friction/shear. Each category is rated on a scale of 1–4, excluding the 'friction and shear' category, which is rated on a 1–3 scale. The total score can range from 6 to 23. The scale is an inverse scoring system thus a lower score indicates a higher risk of developing an injury and vice versa. A score of 23 means there is no risk for developing a pressure ulcer while a score of six points represents the most severe risk for developing a pressure ulcer [22] (**Table 1**).

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name _____ Evaluator's Name_____ Date of Assessment

SENSORY PERCEPTION ability to respond meaningfully to pressure-related discomfort	**1. Completely Limited** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation. OR limited ability to feel pain over most of body	**2. Very Limited** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. Slightly Limited** Responds to verbal commands, but cannot always communicate discomfort or the need to be turned. OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. No Impairment** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort..				
MOISTURE degree to which skin is exposed to moisture	**1. Constantly Moist** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Very Moist** Skin is often, but not always moist. Linen must be changed at least once a shift.	**3. Occasionally Moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely Moist** Skin is usually dry, linen only requires changing at routine intervals.				
ACTIVITY degree of physical activity	**1. Bedfast** Confined to bed.	**2. Chairfast** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. Walks Occasionally** Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair	**4. Walks Frequently** Walks outside room at least twice a day and inside room at least once every two hours during waking hours				
MOBILITY ability to change and control body position	**1. Completely Immobile** Does not make even slight changes in body or extremity position without assistance	**2. Very Limited** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly Limited** Makes frequent though slight changes in body or extremity position independently.	**4. No Limitation** Makes major and frequent changes in position without assistance.				
NUTRITION usual food intake pattern	**1. Very Poor** Never eats a complete meal. Rarely eats more than ⅓ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days.	**2. Probably Inadequate** Rarely eats a complete meal and generally eats only about ¼ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding	**3. Adequate** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	**4. Excellent** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
FRICTION & SHEAR	**1. Problem** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction	**2. Potential Problem** Moves feebly or requires minimun assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. No Apparent Problem** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.					
					Total Score			

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Risk Scale: Low risk: 23-19; Mild risk: 18-15; Moderate risk: 14-13; High risk: 12-10; severe risk: 9-6.

Table 1. Braden Scale [22].

5.2. The Cubbin & Jackson scale for predicting pressure sore risk in ICU patients

The Cubbin & Jackson scale was specifically designed in 1991 for intensive care patients and is a modification of another assessment scale, the Norton scale. The scale consists of 10 items: age, weight, general skin condition, mental condition, mobility, hemodynamics, respiration, nutrition, incontinence, and hygiene. Each item has a 4-point scale; thus, a maximum of 40 points total. This is another inverse scale in that the lower the point total is, the higher the likelihood of pressure ulcer development is [23] **Table 2**.

Categories of scale	Score	Operational definition
Age (yr)		
<40	4	
40–54	3	Age at the time of admission to the ICU
55–69	2	
>70	1	
Weight		
Average weight	4	
Obese	3	BMI on the medical record at the time of admission to the ICU
Cachectic	2	
Any of above and edema	1	Edema on the assessment form
General skin condition		
Intact	4	No pressure ulcer, no sore or sore none on the nursing record
Red skin	3	Redness on the nursing record
Grazed/excoriated skin	2	Abrasion, or bullae on the nursing record
Necrosis/exuding	1	Necrosis on the nursing record
Mental condition		
Awake and alert	4	
Agitated/restless/confused	3	Consciousness on the assessment form at the time of admission to the ICU
Apathetic/sedated but responsive	2	
Coma/unresponsive	1	
Mobility		
Fully ambulant	4	Not applicable
Walks with slight help	3	Not applicable
Very limited/chairbound	2	3 or 4 on position change score of Braden scale
Immobile/bedrest	1	1 or 2 on position change score of Braden scale
Hemodynamics		
Stable without inotropic support	4	MBP ≥ 65 mmHg without inotropic support

Categories of scale	Score	Operational definition
Stable with inotropic support	3	MBP ≥ 65 mmHg with inotropic support
Unstable with inotropic support	2	55 mmHg < MBP < 65 mmHg with inotropic support
Critical with inotropic support	1	MBP ≤ 55 mmHg with inotropic support
Respiration		
Spontaneous	4	
CPAP/T-piece	3	Airway and oxygen supply on the assessment form at the time of admission to the ICU
Mechanical ventilation	2	
Breathless at rest/on exertion	1	
Nutrition		
Full diet, fluids	4	Prescription of regular diets or soft diets
Light diet/oral fluids/enteral feeding	3	Prescription of enteral nutrition, or full liquid diets without regular or soft diets
Parenteral feeding	2	Prescription of TPN only without diets or enteral nutrition
Clear intravenous fluid only	1	No prescription of TPN, enteral nutrition or diets
Incontinence[a]		
None/anuric/catheterized	4	None/anuric/catheterized on clinical assessment form
Urine	3	Not applicable
Feces	2	More than two bowel movements per day
Urine, feces	1	Not applicable
Hygiene		
Competent in maintaining own hygiene	4	Not applicable
Maintaining own hygiene with slight help	3	4 on position change score of Braden scale
Requiring much assistance	2	3 on position change score of Braden scale
Fully dependent	1	1 or 2 on position change score of Braden scale

Table 2. Cubbin & Jackson Scale [23]. Used with Permission.

6. Diagnosing pressure injuries

Diagnosing pressure injuries must be a methodical and meticulous process in order to accurately document and monitor progression as well as improvement. Keen documentation of the physical examination including pictures should be established. Initially, a complete head to toe physical exam should be performed to assess the patient and identify all of his/her wounds and lesions. Look for signs of systemic infection including, fever, chills, fatigue, diaphoresis, hypotension and tachycardia.

6.1. Skin assessment

When diagnosing a pressure injury, it is essential to confirm the presence of pressure and/or shear as a causative factor [6]. In order to perform an accurate visual assessment, pressure injury staging should take place only after the wound bed has been cleansed [6]. Have the patient in a neutral position when assessing the wound and use a consistent method when measuring the length, width and depth of the lesion. Note and document the number, location and size of the lesion(s) at each assessment, ideally with picture documentaiton. Look for accompanying edema, erythema, blanching response, warmth, tenderness, induration, exudate, purulence, odor, sinus tracts, necrosis, eschar formation, tunneling, undermining, wound margins, and possible exposed or palpable bone. Since the NPUAP pressure injury staging system is based on the extent of tissue damage, an understanding of anatomy is essential when evaluating the type of tissue present in the wound [4, 24] (**Figure 1**).

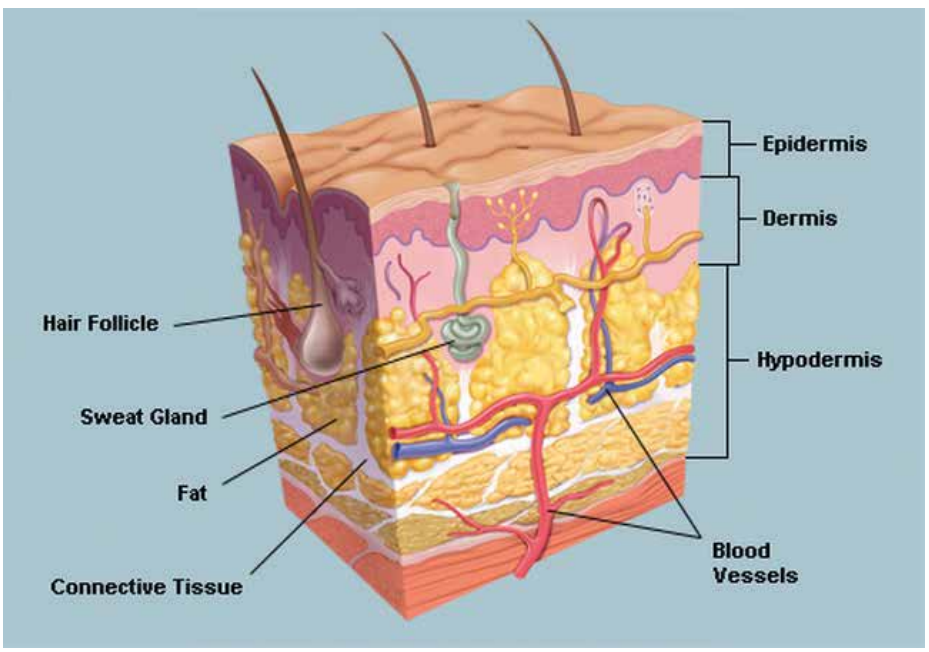

Figure 1. Skin Anatomy. [24] Used with permission. 2014 WebMD, LLC. All rights reserved.

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6.2. Assess for blanching

Finger pressure method: press on erythema for 3 seconds remove finger, then assess for blanching

Transparent disc method: apply pressure equally on all areas of erythema with a transparent disc; access for blanching during the application

Of note, assessing for blanching in patients with dark skin may be challenging; in this patient population focus on skin temperature, skin tenderness, tissue consistency and pain levels. It is wise to rule out neuropathy in all patients by testing the skin's sensation at the level of the lesion. Do this by performing the Semmes-Weinstein monofilament exam. Once a thorough physical exam has been performed and documented, one can make the clinical diagnosis and stage the lesion [25].

7. Staging pressure injuries

Attempts to classify pressure injuries date back to the 1975 staging system developed by J.D. Shea [26]. Since then, other staging systems have been proposed from the International Association of Enterostomal Therapy (now the Wound, Ostomy and Continence Nurses Society), [27] as well as the National Pressure Ulcer Advisory Panel (NPUAP). The NPUAP's initial 1989 pressure injury staging system was based on the International Association of Enterostomal Therapy's system. The NPUAP made revisions by incorporating deep tissue injury and also collaborated with the European Pressure Ulcer Advisory Panel to publish guidelines with category/stage differentiation [28]. NPUAP's staging system has been widely adopted internationally [6].

Most recently in 2016, the NPUAP revised the definition as well as stages of pressure injury. The revision was undertaken to incorporate the current understanding of the etiology of pressure injuries, as well as to clarify the anatomical features present or absent in each stage of injury [6]. Each definition now describes the extent of tissue loss present and the anatomical features that may or may not be present in the stage of injury [6]. The nomenclature and staging changes have caused some uproar. Opponents stress concern that the existing staging system continues to perpetuate the fallacy that pressure induced skin damage presents as a top (epidermis) down (bone) sequence of evolution in severity, that can be accurately classified by simple visual assessment of the skin layers, which is not entirely true [8]. Other changes made by the NPUAP such as denoting the stages using Arabic numerals rather than Roman numerals have caused less of an issue.

Pressure injury staging is important as it has become the basis for treatment, comparison of outcomes, and, if applicable, reimbursement [6]. Regardless of the stage assigned by visual examination, the examiner must take into account all of the available information and incorporate their interdisciplinary clinical expertise into defining the pressure injury etiology and development; he/she should then classifying the lesion [6] (**Figures 2** and **3**).

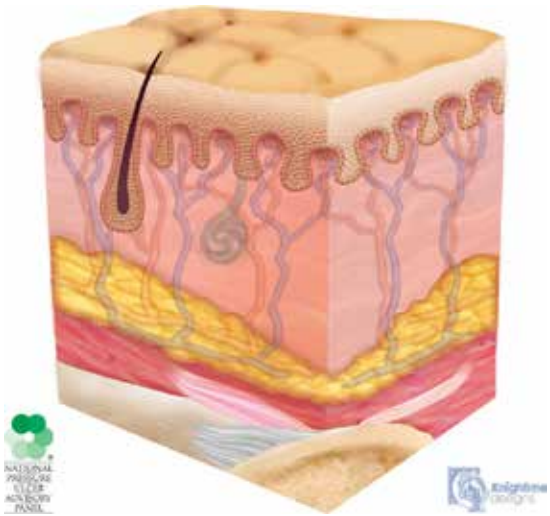

Figure 2. Heathy skin lightly pigemented. Illustrations for figure is used with permission from Ref. [4].

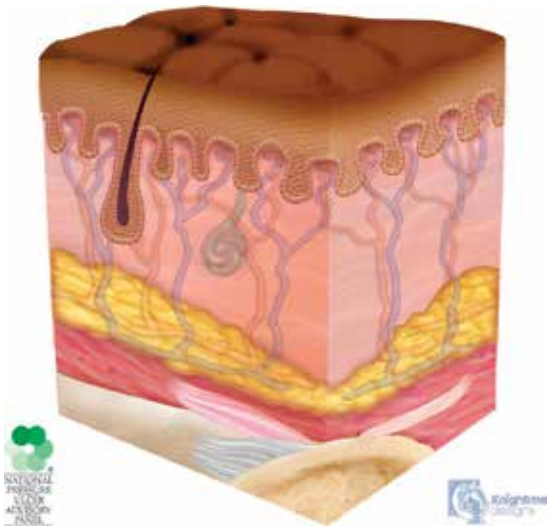

Figure 3. Heathy skin darkly pigemented. Illustrations for figure is used with permission from Ref. [4].

7.1. Newly defined stages of pressure injury as defined by the National Pressure Ulcer Advisory Panel (NPUAP)

7.1.1. Stage 1 pressure injury

Intact skin with a localized area of non-blanchable erythema. The presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes [6].

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Beware: Nonblanchable erythema may appear differently in darkly pigmented skin. Also, color changes do not include purple or maroon discoloration; these colors may indicate deep tissue pressure injury (DTPI) (**Figures 4** and **5**).

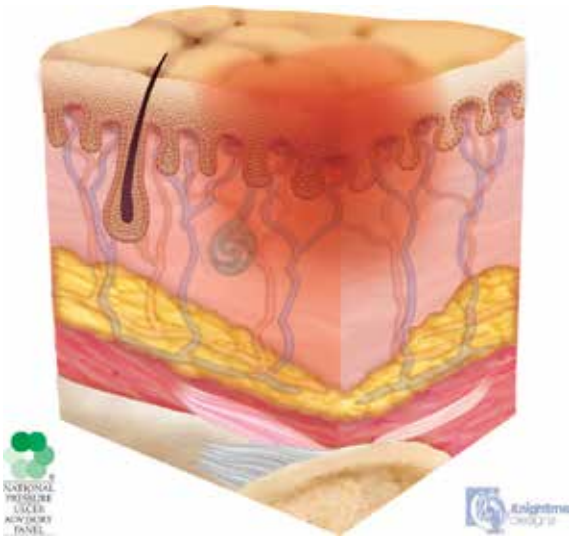

Figure 4. Stage 1 pressure injury lightly pigmented. Illustrations for figure is used with permission from Ref. [4].

Figure 5. Stage 1 pressure injury darkly pigmented. Illustrations for figure is used with permission from Ref. [4].

7.1.2. Stage 2 pressure injury

Partial-thickness skin loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may present as an intact or ruptured serum-filled blister. Fat is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel [4] (**Figure 6**).

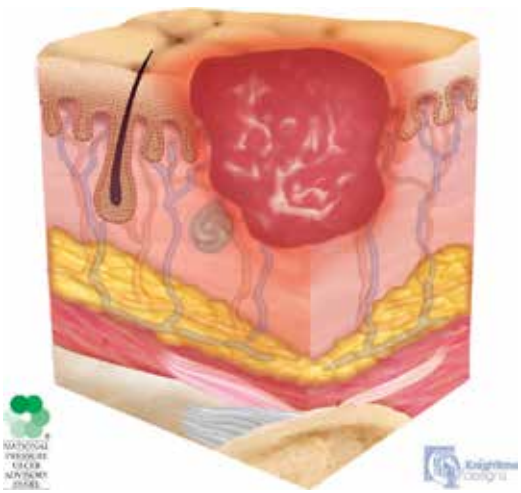

Figure 6. Stage 2 pressure injury. Illustrations for figure is used with permission from Ref. [4].

The revised definition of a Stage 2 pressure injury seeks to clarify the difference between moisture-associated skin damage and injury caused by pressure and/or shear [6]. Stage 2 injuries should not be used to describe moisture associated skin damage (MASD), incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI), or traumatic wounds such as skin tears, burns or abrasions [4].

7.1.3. Stage 3 pressure injury

Full-thickness loss of skin, in which fat is visible within the ulcer; granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss then it should be classified as an unstageable pressure injury [4] (**Figures 7** and **8**).

7.1.4. Stage 4 pressure injury

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone within the ulcer. Like in Stage 3 wounds, slough and/or eschar

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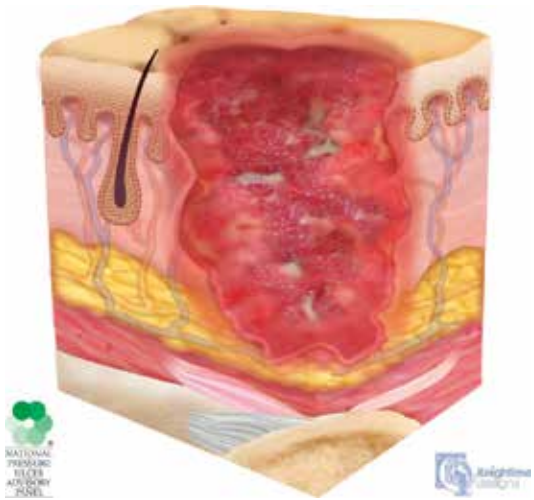

Figure 7. Stage 3 pressure injury. Illustrations for figure is used with permission from Ref. [4].

Figure 8. Stage 3 pressure injury with epibole. Illustrations for figure is used with permission from Ref. [4].

may be visible as well as epibole (rolled edges). Undermining and/or tunneling often occur in Stage 4 wounds. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss then it should be classified as an unstageable pressure injury [4] (**Figure 9**).

7.1.5. Unstageable pressure injury

Full-thickness skin and tissue loss in which the extent of the tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. Once the slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar is often dry,

adherent, and intact without erythema or it is commonly on the heel or on an ischemic limb and should not be softened or removed [4] (**Figures 10** and **11**).

7.1.6. Deep tissue pressure injury (DTPI)

Intact or non-intact skin with a localized area of persistent non-blanchable deep red, maroon, purple discoloration or an epidermal separation revealing a dark wound bed or a blood filled blister. Discoloration may appear differently in darkly pigmented skin. Pain and temperature changes often precede the skin color changes. This injury results from intense and/or

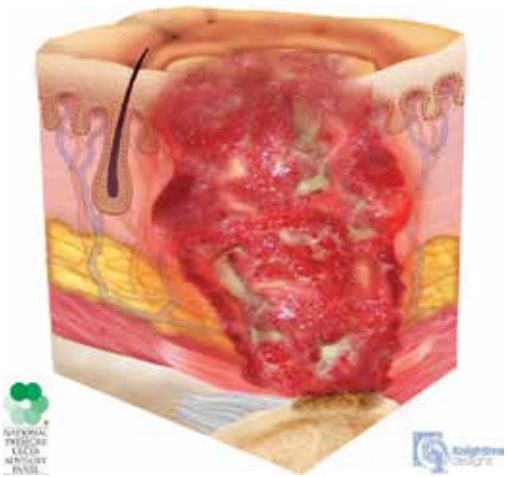

Figure 9. Stage 4 pressure injury. Illustrations for figure is used with permission from Ref. [4].

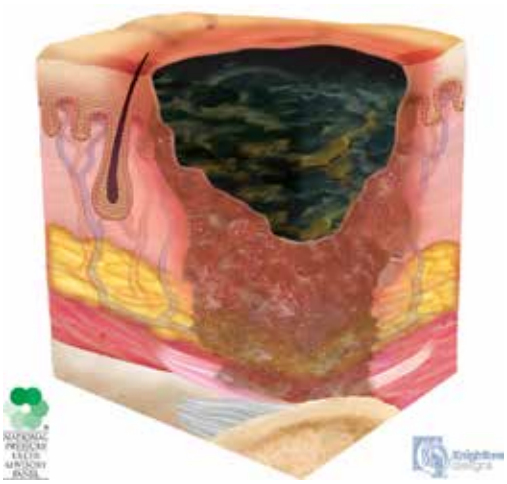

Figure 10. Unstageable pressure injury—Dark Eschar. Illustrations for figure is used with permission from Ref. [4].

prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If there is necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures visible, this indicates a full thickness pressure injury—Unstageable, Stage 3 or Stage 4. Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions [4] (**Figure 12**).

Figure 11. Unstageable pressure injury—Slough and Eschar. Illustrations for figure is used with permission from Ref. [4].

Figure 12. Deep tissue pressure injury. Illustrations for figure is used with permission from Ref. [4].

7.1.7. Additional terms of importance as defined by the NPUAP

7.1.7.1. Medical device related pressure injury

Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system [4].

7.1.7.2. Mucosal membrane pressure injury

Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue, these injuries cannot be staged [4].

7.1.7.3. Important points

The deterioration of a pressure injury does not predictably follow a linear evolution from Stage 1 to Stage 4 [6]. In addition, only pressure injuries should be staged with the NPUAP Pressure Injury Staging System. Many non-pressure-related ulcers and wounds are subject to unique staging or classification systems based upon the wound type for example: diabetic foot ulcers (Wagner Classification System), venous leg ulcers (Clinical Etiology Anatomy Pathophysiology), skin tears (International Skin Tear Advisory Panel), adhesive or tape injuries (medical adhesive related skin injury categories (MARSI)), and burn classification (total body surface area). It is essential that the intended staging or classification system be used for each type of injury to ensure appropriate treatment [6].

8. Treatment of pressure injuries

Managing and treating pressure injuries is only effective when a multidisiplinary team approach is utilized in the management of these patients. One must incorporate teams across several specialties and address the patient's issues as a whole in order for him/her to heal quickly and successfully. Below, we will briefly address some aspects in patient care to be mindful of when constructing treatment strategies; addressing these topics early in the management process will aid you in achieving positive outcomes.

8.1. Manage co-morbidities

Patients may have many comorbidities in addition to their pressure injury all of which need to be addressed and managed appropriately; for example stabilize glycemic control in diabetics and assess peripheral artery disease with a screening ABI ankle-brachial index (ABI) in vascular patients. An in depth discussion of the management of comorbid conditions will not be included in this chapter but be mindful to review all of the patient's comorbid conditions and assess whether or not there are correlations to wound care that need to be addressed.

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8.2. Optimize nutritional status

Poor nutritional status can be a contributing risk factor toward the formation of a pressure injury and can also contribute toward nonhealing. No matter what stage of pressure injury your patient is diagnosed with, if the patient's nutritional status is not optimized he/she will have a delayed healing evolution or even worse—never heal due to lack of energy. Serologic markers such as hemoglobin, serum albumin, prealbumin, transferrin and total lymphocyte count may be beneficial in assessing a patient's nutritional status. You should also use a valid and reliable nutritional screening tool to determine the patient's nutritional risk.

One should determine the patient's daily caloric requirements to ensure they are obtaining enough fuel to support all of the patient's energy expenditures, known as the total energy expenditure (TEE) [29]. During illness, injury, or times of stress, the body may become hypermetabolic. Typically a patient with a wound requires additional calories to offset the hypermetabolic response triggered by the wound [29].

1) A simple way to calculate an estimate of caloric needs is by using a standard number of kcals/kg of body weight per day. Typical standards are listed below:

a. Daily Total Energy Expenditure Estimation

Normal Maintenance: 25–28 kcal/kg
Mild-Moderate stress/illness, injury or malnutrition: 30–35 kcal/kg
Severe major stress, critical illness or injury: 35–40 kcal/kg [25, 29].

Guidelines from the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) state that approximately 30–35 kcals/kg/day are required for most patients with Stage 2 wounds or pressure injuries in risk of malnutrition. Increase to 35–40 kcal/kg/day if the patient is underweight or is losing weight; these estimates will likely achieve the desirable positive nitrogen balance [25, 29, 30].

2) A more precise formula to determine caloric requirements is to use the three-component equation:

Caloric Requirements = Harris Benedict Equation × Injury Factor × Activity Factor [29]

a. Daily Basal Energy Expenditure Estimate (aka Harris Benedict Equation)

Males: 66.5 + (13.7 × Wt. in kg) + (5.0 × Ht. in cm) − (6.8 × age in Yrs.)

Females: 655 + (9.6 × Wt in kg) + (1.8 × Ht in cm) − (4.7 × age in Yrs.) [29]

b. Injury Factor (IF)

IFs are variable and subjectively based according to the practitioner's judgment. Use the numbers below as a guide:

Normal, minor Surgery, burn post graft = 1.0–1.2

Long Bone Fracture = 1.2

COPD, Malnourished = 1.3

Severe Head Injury = 1.4

Cancer = 1.0–1.5

<50% Burns = 1.5

Ventilator = 1.6

Major Surgery, Multiple Traumas, 0–20% Burns Pre Grafting = 1.2–1.6

Acute Sepsis = 1.2–1.7

Severe infection = 1.4–1.8

20–40% Burn Pre Grafting 1.5–2.0

50% Burn = 2.0 [29, 31]

c. Activity Factor (AF)

1.2—Confined to bed

1.3—Out of bed

1.5—Normal, healthy activity [29, 31]

8.3. High protein diet

Provide a high protein diet (1.25–1.5 g/kg/day) to maintain a positive nitrogen balance for adults assessed to be at risk or with an existing pressure injury. A high protein diet in combination with arginine and micronutrient supplements is ideal. Arginine enriched mixed nutritional supplements have been shown to improve mean pressure ulcer healing time [32]. Literature has also shown that an arginine, zinc and antioxidant enriched nutritional formula increased the rate of healing in malnourished adults, [33] yet zinc supplementation alone appeared ineffective and was associated with adverse effects [34]. Thus, possibly it's the combination of both arginine and zinc that improves wound healing. Nutritional shakes in addition to vitamin and mineral supplements are strongly advised. If patients are unable to tolerate oral intake consider enteral or parenteral nutritional substitutions.

8.4. Pain management

While some pressure injuries lead to insensate tissue others injuries can be extremely painful. Pain management strategies should be addressed especially prior to any cleansing or debridement. An in depth discussion of pain management options will not be included in this chapter. However, the application of topical opioids such as benzydamine 3% or diamorphine gel (not available in the US) as well as topical anesthetics such as lidocaine-prilocaine should be considered [25].

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9. Wound care: cleansing

Clean all pressure injuries at each dressing change to help facilitate removal of debris and bacteria. Water or normal saline are appropriate to use as cleansers and irrigation agents for most pressure ulcers. For compromised patients, wounds, or wound healing environments consider aseptic techniques. If there is debris, infection or high bacterial colonization, consider using a cleanser with surfactants and/or antimicrobials. Apply your choice of cleansing solution with ample pressure to clean the wound of debris without damaging the tissue, which may be friable. For each dressing change, a new, unopened container of cleansing solution should be used. Used irrigation solution should be appropriately discarded [25].

10. Debridement

If you are concerned about whether or not a wound needs to be debrided, a surgery consult should be placed. Surgeons have been exposed to a wide variety of wounds and are experts on assessing whether or not tissue debridement is indicated. All necrotic and nonviable tissue needs to be removed so that new granulation tissue may form; this includes the wound bed and edges. Maintenance debridement should occur frequently until all devitalized tissue is removed and the wound is covered with granulation tissue. There are no surgical indications to debride stable, hard, dry eschar in ischemic limbs because there is inadequate perfusion and it will not revitalize [25].

10.1. Infection

One should always have a high index of suspicion for infection in pressure injuries especially if there is necrotic tissue present or if the wound is deep or large in size. Anatomic location also plays a large role in infection control particularly when the area is prone to exposure of contaminants (e.g., near the anus). Ulcers with signs of infection are in need of urgent surgical debridement—emergent surgical debridement if necrotizing fasciitis is suspected. Some signs of necrotizing fasciitis include rapidly spreading erythema, tenderness out of proportion to the physical attributes of the wound and crepitus. Beware of foreign bodies within wounds; they are commonly a nidus for infection. Patients at high risk of infection include those with diabetes mellitus, malnutrition, autoimmune diseases and immunosuppression [25].

If there are clinical signs of spreading infection, such as extension of erythema beyond the wound, induration, purulence, increase in erythema, warmth or pain, obtain a quantitative culture via tissue biopsy or less preferably quantitate swab technique. An initial trial of antibiotics it is reasonable to administer. If you are dealing with a nonhealing pressure injury, needle aspiration or an ulcer biopsy for culture should be performed to determine bio-burden/microbial load. In the absence of clinical signs of infection, the quantity of the organisms or microbial load is believed to be the best indicator of wound infection. Superficial wound cultures are not generally recommended due to the fact that all lesions are colonized with bacteria

and superficial swab cultures are unreliable. The gold standard for determining microbial load is a quantitative culture of viable biopsied wound tissue [25].

The ulcer bed should be debrided if a biofilm is suspected. Be suspicious of biofilm formation if the wound has been present for >4 weeks, if healing still appears delayed after 2 weeks of attention and treatment, or if there is no response to antibiotics. Confirmation of a biofilm can be obtained once biopsy culture shows ≥ 10^5 colony forming units (CFU)/gram tissue. Beta hemolytic streptococci is a common culprit [25].

11. Debridement options

The most common debridement options include: surgical sharp, mechanical, autolytic, enzymatic and larval. The method of debridement chosen depends upon the condition of the wound, the health status of the patient as well as the capabilities and confidence of the healthcare provider. More than one debridement method may be deemed appropriate for a given pressure injury and multiple modalities can be combined as well.

11.1. Surgical-sharp debridement

This type of debridement involves the use of instruments such as scissors, scalpels and forceps to remove necrotic, nonviable tissue from the wound [35]. Surgical debridement can be performed so that it extends into healthy tissue or conservative-sharp debridement can be performed which does not extend into or excise healthy tissue. Surgical debridement is an appropriate debridement option when a large amount of necrotic tissue needs to be removed from the wound bed. Surgical sharp debridement is indicated for extensive necrosis, advancing cellulitis, crepitus, fluctuance and/or when sepsis is related to the pressure injury. Perform urgent surgical debridement for ulcers with erythema, tenderness, edema, purulence, fluctuance, crepitus and malodor suggesting an infection around the injury. Most of the presentations listed above require operating room equipment, however, moderate surgical debridement may be performed by a competent medical professional at the bedside using a sterile scalpel or scissors. Extensive debridement should be executed in the operating room [25].

11.2. Mechanical debridement

Mechanical debridement physically removes nonviable, necrotic tissue with techniques such as wet-to-dry dressings, dry gauze and hydro-surgery such as wound irrigation and whirlpool techniques [35]. The wet-to-dry dressing system is one of the oldest forms of wound debridement. This method typically consists of applying moist to wet dressings to the wound, which are manually removed later once the dressings have dried. This causes non-selective debridement of necrotic tissue, eschar and slough; unfortunately sometimes viable, newly formed tissue is damaged and/or removed as well. This form of debridement can also be very painful to the patient if the dressings are very dry and hardened.

Pulsed lavage as well as high- or low-pressure streams can be quite effective in removing loose necrotic tissue from the wound bed. A common practice after surgical wound debridement is pulsed lavage treatment for wound irrigation. Wound vacuum cleaning is thought to improve the healing of pressure injuries [36]. Ulcer irrigation pressures range from 4 to 15 psi of pressure; this range typically yields successful debridement yet does not cause trauma to the wound bed. Irrigation pressures below 4 psi may not be effective to cleanse the wound and pressures greater than 15 psi may cause trauma and drive the bacteria into the tissue [35]. Some pulsation devices allow copious amount of irrigation, which can be infused with antibiotics. These medical devices are certainly used in the operating room and portable versions are now available for bedside use in the appropriate setting. Normal saline "flushes" through a 60 cc Toomey syringe is another technique that works well to aid with debridement and a copious amount of irrigation is possible with this technique.

Whirlpools may be used initially to loosen and remove debris, bacteria, exudates, and necrotic tissue however prolonged use and periods of wetness may macerate the tissue or may be associated with bacterial contamination. NPUAP guidelines advise against whirlpool use for routine use in treating pressure ulcers due to the potential for contamination and the emergence of newer hydrotherapies [25]. In addition, individuals with dependent lower extremity edema or peripheral vascular disease, [37] immunocompromised individuals, those who are mechanically ventilated and lethargic, and incontinent individuals should never be immersed in water [25, 38].

11.3. Autolytic debridement

Autolytic debridement uses the body's own endogenous enzymes and moisture to break down tough eschar and slough. This form of debridement is accomplished by moist interactive dressings, which allow the patient's natural wound fluid and endogenous enzymes to be kept in constant contact with the wound. The self produced fluid and endogenous enzymes soften and liquefy slough and promote granulation tissue formation [35]. The dressings used can be occlusive or semi-occlusive and consist of various materials such transparent films hydrogels and hydrocolloids. These dressings will be discussed more detail in the Wound Dressings section. Endogenous enzymes do not damage healthy skin however the wound will need to be cleaned after autolytic debridement in order to remove the necrotic debris. The time to break down dead and devitalized tissue can be slow and is quite variable. If tissue autolysis is not apparent in 1–2 weeks, another debridement method should be used [35]. Autolytic debridement is not recommended for infected wounds or very deep wounds that require packing [35, 38].

11.4. Enzymatic debridement

Enzymatic debridement is achieved by topical application of exogenous enzymes to the wound surface to remove necrotic tissue [35]. The chemical agents are useful for debriding wounds with a large amount of necrosis and/or eschar. While enzymatic debridement effectively breaks down nonviable tissue, it also may damage nearby healthy tissue as well. In addition, these agents must be prescribed and a small tube can be quite costly. Enzymatic

debridement is thought to be faster than autolytic debridement however it may cause increased wound pain and /or an uncomfortable burning sensation to the patient. Enzymatic debridement is most useful in patients who cannot tolerate sharp debridement and should not be used if an infection is present. Preparations available in the US include collagenase and papain/urea with or without chlorophyll [38].

11.5. Larval therapy/Medicinal maggot therapy

Maggot debridement therapy is the intentional application of live, "medical grade" fly larvae to wounds. Medicinal maggots have been sited to perform major actions such as debridement, disinfection, stimulation of wound healing as well as biofilm inhibition and eradication [39]. Larval debridement is unique in that maggots selectively only engulf necrotic tissue—no healthy tissue is affected. This method is gaining in popularity due to its low cost, incredible effectiveness and expedited time for successful debridement. Some patients however find the method somewhat painful and their perception of maggots may stand in the way of using this highly effective method of debridement [38].

12. Topical agents

12.1. Topical antiseptics

When it comes to topical agents for pressure injuries the options are vast. Indications for specific topical agents can vary as the pressure stage progresses or the wound starts to heal. Antiseptic agents commonly used in wounds include: iodine (povidone, iodine or slow release cadexomer iodine), silver (silver sulfadiazine), polyhexanide and betaine (PHMB), chlorhexidine, sodium hypochlorite and acetic acid [25]. Topical antiseptics should be used for pressure ulcers that are not expected to heal, are critically colonized or topically infected. They should be used in conjunction with maintenance debridement. In managing biofilms, consider topical antiseptics to control bacterial bio-burden in wounds with delayed healing [25].

Be aware that some skin cleaners or antiseptics may destroy granulation tissue [10]. Avoid hydrogen peroxide as it is toxic to tissues even at low concentrations [40, 41]and should not be used as a preferred topical antiseptic. Its use should be completely avoided in cavity wounds due to the risk of surgical emphysema and gas embolus [28, 41–43].

Iodine products should be avoided in patients with impaired renal failure, history of thyroid disorders or known iodine sensitivity [44, 45]. There is a risk of acidosis when acetic acid is used for extended periods over large wound surface areas [46]. Silver may have toxic properties, especially to keratinocytes and fibroblasts; the extent of the toxicities however, is not fully described. Topical silver products should not be used on individuals with silver sensitivities, and silver sulfadiazine products are not recommended for people with sulfur sensitivities [47]. It is however appropriate to consider using silver sulfadiazine in heavily contaminated or infected pressure ulcers until definitive debridement is accomplished. Sodium hypochlorite

(Dakin's solution) is cytotoxic at all concentrations and should be used with caution, at concentrations no greater than 0.025%, for short periods only when no other appropriate option is available [25, 48–50].

12.2. Other agents of interest

New, less commonly used agents' effectiveness appear promising. Atorvastatin powder mixed with petroleum jelly and beeswax forms an ointment, which has been used as a topical agent resulting in a reduction in the size of Stage 1 and 2 pressure ulcers [51]. Recombinant human platelet-derived growth factor (rPDGF) has been shown to accelerate the healing of pressure ulcers [52]. Topical phenytoin may be more effective than DuoDERM dressing, saline dressings and topical antibiotics for treating pressure ulcers [53].

13. Antimicrobials: systemic & topical

13.1. Systemic

Consider a systemic antibiotic only if clinical signs of systemic infection are present or there is a positive blood culture, cellulitis, fasciitis, osteomyelitis, systemic inflammatory response syndrome (SIRS) or sepsis. If systemic antibiotics are given, empiric antibiotics should cover methicillin-resistant *Staphylococcus aureus*, *anaerobes*, *enterococci* and Gram-negatives such as *Pseudomonas*, *Proteus* and *Providencia* species [25].

13.2. Topical

There is insufficient evidence to support whether topical antimicrobials improve wound healing or reduce infection in patients with ≥Stage II pressure ulcers. Generally topical antibiotics are not recommended and should be limited or avoided if possible. Use is indicated in specific situations where the topical antibiotics' benefits outweigh the risks of antibiotic side effects and resistance. Consider topical Metronidazole for control of odor due to anaerobic bacteria and protozoal infections [25].

13.3. Osteomyelitis & abscesses

Osteomyelitis can be a detrimental finding in any patient thus rapid identification and treatment is necessary. If osteomyelitis is suspected in a patient's wound bed, obtain blood cultures and sensitivities, leukocyte count, erythrocyte sedimentation rate and a C-reactive protein level. Imaging should also be obtained. A plain X-ray is the initial imaging study of choice. Once osteomyelitis is confirmed, a CT scan is useful for needle guided biopsies, identifying necrotic bone and soft tissue extension. The gold standard test of choice for detection of early osteomyelitis and associated soft tissue disease is an MRI with gadolinium [25].

Cultures at the time of presentation or first debridement may not be useful. Swabbing cultures from draining wounds and sinus tracts may not be reliable for predicting organisms

that will be isolated from infected bone, but might be helpful for infection control measures. Obtaining cultures of bone biopsies after an initial debridement is performed can be helpful in guiding therapy. Both aerobic and anaerobic cultures should be sent for culture; if within a few days there is no growth then fungal and mycobacterial cultures should be processed. Drain all local abscesses [25].

14. Types of wound dressings

There are many factors to consider in choosing a wound dressing such as the ulcer size, depth and location, the ability to keep the wound bed moist, the need to address bacterial bio-burden, the nature and volume of wound exudate, the condition of the tissue in the ulcer bed, the condition of periulcer skin, the presence of tunneling and/or undermining as well as the goals of the individual with the pressure injury [25]. Ideally, one should choose a dressing that maintains a moist wound environment and controls exudate without desiccating the ulcer bed all while promoting wound healing. A moist wound environment physiologically favors migration and matrix formation while accelerating healing of wounds by promoting autolytic debridement [35]. It is also thought that moist wound healing reduces wound pain [35]. Keeping the wound environment clean may be a constant challenge especially when the ulcers are in unfavorable, not easily accessible locations however, any contaminated environment will make wound healing extremely difficult.

14.1. Hydrocolloid dressings

Hydrocolloid Dressings are a wafer-type dressing that contains hydro-active particles which, when in contact with wound exudate, forms a fluid/gel environment over the wound bed. Both occlusive and semi-occlusive dressings have been shown to provide and maintain a moist, hypoxic wound environment, provide protection and insulation to a healing wound and facilitate autolytic debridement [54, 55].

Hydrocolloid dressings can be self-adhering with a surface that repels water, bacteria and other outside contaminants. Various specific types of hydrocolloid dressings are on the market in sheet, paste, gel, and powder form. They may differ in size, shape, exudate absorption and intended use [55, 56]. Hydrocolloid Dressings are indicated for light to moderate exuding wounds, typically Stage 2 and shallow Stage 3 pressure injuries. They should be used in areas where they will not roll or melt. Filler dressings beneath hydrocolloid dressings can be used in deep ulcers in order to fill in the dead space. They can often be left on a wound for several days and can be used as a primary or secondary dressing [25, 57].

Contraindications to hydrocolloid dressing use include infected wounds, wounds with heavy exudate, deep cavities, sinus tracts (unless used as a secondary dressing over the packing), burns and grafts.

Examples: DuoDERM, Tegaderm Thin, Reliamed border sacral, Reliamed beveled, Flexicol bordered, Medihoney sheet (hydrocolloid with honey), Medihoney tube [57] (**Figure 13**).

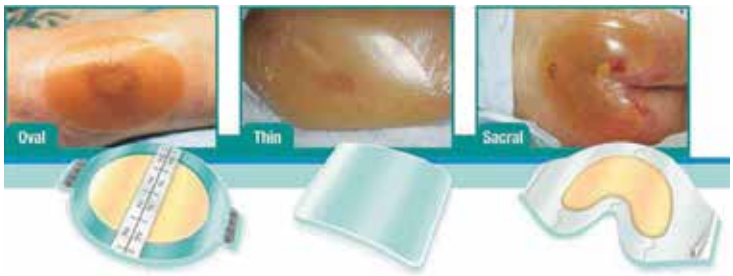

Figure 13. Hydrocolloid dressings.

14.2. Transparent film dressings

Transparent film dressings are semipermeable membranes, generally polyurethane, which are self-adhering, thin and waterproof. They allow gaseous exchange between the wound bed and the environment, but water, bacteria and other contaminants cannot penetrate the dressing. These dressings have a wide variety of uses because they are available in multiple shapes and sizes to conform to many different wounds. The transparency of the dressing allows for wound visualization, assessment of its healing progress and any drainage [25, 57]. Transparent film dressings are indicated for partial thickness wounds, Stage 2 ulcers and dry, necrotic wounds requiring debridement but should not be used in moderate to heavy exuding ulcers. These dressings help to maintain a moist wound surface and facilitate autolytic debridement. They should be avoided in immunocompromised individuals. They can be used as a secondary dressing with alginates or other wound fillers that will likely remain in the ulcer bed for 3 days or more however should not be used over enzymatic debriding agents, gels, or ointments [25, 57].

Contraindications to transparent film dressing use include heavy exudating wounds, deep cavities, sinus tracts, undermining (unless used as a secondary dressing) and wounds with friable skin in the periwound area.

Examples: 3 M Tegaderm, Mefilm [56] (**Figure 14**).

14.3. Hydrogel dressings

Hydrogel dressings vary in composition but most are water or glycerin based, depending on the manufacturer and have a gel consistency. The non-occlusive dressing comes in sheets, beads, impregnated in gauze and in gel form. These dressings are indicated for shallow, minimally exuding pressure ulcers that are not clinically infected and are granulating. They may also be used on painful, dry wounds needing additional moisture such as burns and grafts because they will add additional moisture. These dressings work to provide moisture to a wound site while eliminating or preventing infection however their use is somewhat limited to dry and low exuding wounds because they can cause maceration to surrounding tissues when high volumes of the wound exudate is present [55, 58]. Hydrogel dressings work well on pressure injuries that have contours and/or on body areas that are at risk for wound

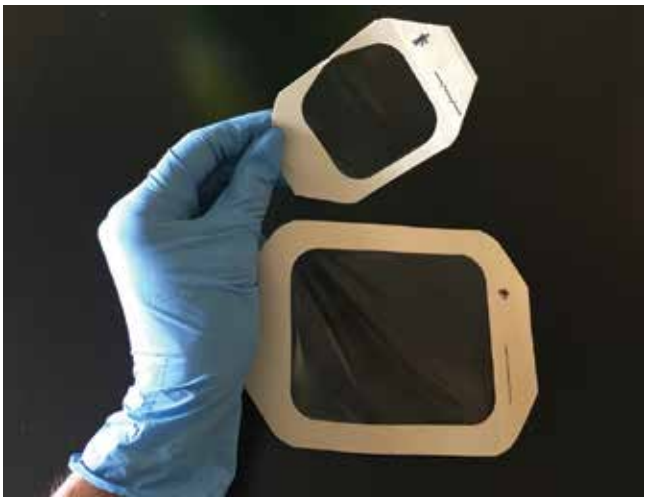

Figure 14. Transparent film dressings.

dressing migration. The sheet form of hydrogel can be used for hastier healing of cosmetic procedures and/or scar reduction. These dressings typically have to be changed daily but are biocompatible with other dressings [57].

There are no specific contraindications to hydrogel dressings, however there is a risk that when hydrogel dressings are used on exuding ischemic ulcers a resultant shift from dry to wet gangrene within the wound can take place [55, 59]. Also, because of the moist nature of these dressings, care must be taken to observe the wound edges and protect the skin from maceration.

Examples: Skintegrity, SpanGel, Normlgel [57].

Of note, Hydrogel dressings are also available with additives such as silver for antimicrobial benefits. However, Hydrogel Silver dressings should not be used in conjunction with Tegaderm Matrix as the deactivation of both dressings will result [25, 57].

14.4. Alginate dressings

Alginate dressings are hydrophilic, non-woven fiber dressings that are derived from brown seaweed [55]. When the dressing contacts a wound's exudate it forms a gel mass in the wound. Alginate comes in a sheet or rope form and is absorbent. The dressing will absorb excess exudate while maintaining a moist wound environment. It facilitates autolytic debridement of loose, necrotic tissue and is indicated for partial thickness and full thickness wounds having moderate to heavy exudate. It is effective in filling cavities, tracts and undermining. A secondary dressing should be used to cover the alginate dressing. Irrigation will aid in its removal from the wound bed. Consider lengthening the interval between wound dressing changes or changing the type of wound dressing if the alginate dressing is still dry at the scheduled time for a dressing change. Alginate dressings are contraindicated in dry wounds [25, 57].

Examples: Maxorb, Algicel, Melgisorb, Reliamed, Sorbion Sachet S [57].

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Of note, this dressing also comes in a silver added form for antimicrobial benefits. The silver form is not to be used with hydrogels and should not be used with products that create an ionic exchange in the wound site. Alginate dressings cannot be used with enzymatic products. (ex Santyl Collagenase)

Examples: Maxorb Extra AG, Silverlon CA, Algicel AG, Reliamed AG-CMC (hydrofiber) [57] (**Figure 15**).

Figure 15. Sheet & strip alginate wound dressings.

14.5. Gauze dressings/"Wet-to-Dry Gauze"

The NPUAP's guidelines recommends avoiding use of gauze dressings for open pressure ulcers that have been cleansed and debrided because they are labor-intensive, cause pain when removed if dry, and can lead to desiccation of viable tissue. The association also advocates against the use of wet-to-dry gauze dressings. Gauze dressing is an economical means of debridement that can be effective when preformed often and appropriately. While the initial cost of moist gauze is less expensive than more advanced wound care products, the notion that moist gauze is more cost effective than all other wound care options may not be entirely true. When determining cost efficacy, one must look at all factors involved in the wound healing process. In addition to the product cost, one must take into account health care provider time, patient care goals and resources, ease of use and healing rate [35]. Once all of these aspects are accurately accounted for, gauze may not be the most economical wound care supply. When other forms of moisture retentive dressings are not available, continually applying moist gauze is preferable to dry gauze. Dry gauze dressings should only be used as the cover dressing to reduce evaporation when the tissue interface layer is moist. Consider using impregnated forms of gauze to prevent evaporation of moisture from continuously moist gauze dressings [25, 57].

Example: Kerlix [57].

14.6. Recommended gauze application technique

If gauze is to be applied as your wound dressing it is recommended that loosely woven gauze be used to treat highly exuding ulcers so that a high volume of the exudate may be absorbed.

Tightly woven gauze should be used for minimally exuding ulcers. Loosely fill ulcers with large tissue defects and dead space with salinemoistened gauze when other form of moisture retentive dressings are not available; this technique is preferred over tightly packing the wound which can lead to excessive pressure on the ulcer bed. Change gauze packing often enough to manage the exudate. It is preferable to use a single gauze strip or roll to fill deep ulcers rather than using multiple gauze dressings; as this will reduce the risk of retained gauze in the ulcer bed, which can serve as a nidus for infection [25].

14.7. Collagen matrix dressings

A collagen matrix dressing is a naturally derived scaffold dressing. Scaffolds facilitate infiltration of cells such as fibroblasts and keratinocytes through pores of a controllable size while maintaining optimal healing conditions [55]. Ideally, a dermal scaffold mimics the tissue's natural extracellular matrix, allowing bioactive molecules to be incorporated while also being biocompatible [55]. Collagen matrix dressings are used for nonhealing Stage 3 and 4 pressure wounds. These dressings come in pads, gels or particles and promote the deposit of newly formed collagen into the wound bed. They can be used on any type of wound with minimal, moderate or heavy drainage. Some specific brands require the wound to be free of necrotic tissue but not all. The collagen provides a moist healing environment and promotes tissue granulation and epithelialization. Some brands reduce destructive elements within wound fluid to trigger healing while allowing the patient's growth factors to effectively heal the wound. No specific contraindications exist however, collagen may enable the transmission of infectious agents and thus it requires vigorous disinfection protocols [55, 57].

Examples: Pads—Prisma, Promogran (collagen with silver), BioPad, Fibracol Plus (alginate/collagen combination); Gel—Stimulen Gel; Powder—Stimulen [57].

14.8. Silicone dressings

Silicone dressings can be considered as a wound contact layer to promote atraumatic dressing changes or as the contact layer within a dressing, for example, Mepilex, a polyurethane foam membrane is coated with a soft silicone layer [55, 60]. Consider silicone dressings to prevent periwound tissue injury when the surrounding tissue is fragile or friable. Silicone can be used on a range of acute and chronic wounds as it is incorporated in many different bandaging strategies [55, 57].

Examples: Mepitel, Mepliex Ag [57].

14.9. Foam dressings

Polyurethane foam dressings have an absorbent wound contact surface and typically also a moisture-repellant outer surface, which is non-occlusive. Polyurethane foam dressings are easy to use and customize as they can be cut to shape and come in a range of absorbencies [55]. Foam's ability to absorb exudate is dependent upon the thickness and density of the dressing. Foam dressings are designed to maintain a moist wound environment but absorb excess exudate thereby preventing maceration of the surrounding healthy tissue. Foam also

has thermal insulation and protection properties. Removal of the foam often facilitates the removal of slough. Foam may be used as a primary or secondary dressing and is available in self-adhering or non-adherent forms although some may have adhesive border. Foam dressings are indicated for partial and full thickness wounds with moderate to heavy exudate. They also can be used to cover wounds containing packing material. Contraindications to its use are wounds with dry eschar as well as wounds with minimal to no exudate [25, 57].

Examples: Mepilex (with Safetac technology), Mepilex Border (water resistant with Safetac technology), Tegaderm foam, Polymem, Polymem Dot (with silver) [57].

15. Special dressings

15.1. Silver-impregnated dressings

One can consider using silver-impregnated dressings for pressure ulcers that are clinically infected, heavily colonized or at high risk of infection. Prolonged use of silver-impregnated dressings should be avoided and silver dressings should be discontinued once the wound infection is controlled. As mentioned earlier, silver may have toxic properties but it is unknown to what extent [25].

15.2. Honey impregnated dressings

Use of medical-grade honey as well honey impregnated dressings has been used in heavily contaminated or infected pressure ulcers. Honey impregnated dressings have been used on Stage 2 and 3 pressure ulcers until definitive debridement is accomplished. Before applying a honey dressing, ensure the individual is not allergic to honey. Individuals who have bee or bee stings allergies are usually able to use properly irradiated honey products [25].

15.3. Cadexomer iodine dressings

Consider using cadexomer iodine dressings in moderate to highly exuding pressure ulcers. Iodine products should be avoided in individuals with impaired renal failure, history of thyroid disorders or known iodine sensitivity [44, 45]. Iodine dressings are not recommended for individuals taking lithium or for pregnant or breast-feeding women. The risk of systemic absorption increases when iodine products are used on larger, deeper wounds or for prolonged periods of time. Iodine toxicity has been reported in a few case studies, especially in those individuals with large wounds, in whom dressings were changed often [25].

16. Biologic dressings

16.1. Recombinant platelet-derived growth factor

Consider using platelet-derived growth factors for treatment of Stage 3 and 4 pressure ulcers that have delayed healing. (Refer to topical agents section for more information) [25].

16.2. Other growth factors

Due to insufficient evidence to support or refute the use of growth factors (other than recombinant platelet-derived growth factor) in the treatment of pressure ulcers, they are not recommended for routine use at this time by the NPUAP guidelines [25].

17. Biophysical agents

A number of biophysical agents have been studied in the management of pressure ulcers. All provide some form of biophysical energy with the goal of promoting healing. Common forms of biophysical agents include energy from the electromagnetic spectrum (e.g., electrical stimulation, electromagnetic fields, pulsed radio frequency energy and phototherapy), acoustic energy (high and low frequency ultrasound) and mechanical energy (e.g., heric energy [hyperbaric and topical oxygen]) [25]. Many of the above mentioned biophysical agents are uncommon and are out of the chapter's scope of coverage. Only commonly used biophysical agents will be addressed.

17.1. Mechanical energy—negative pressure wound therapy (NWPT)

Consider negative pressure wound therapy (NWPT) as an early adjuvant for the treatment of deep, Stage 3 and 4 pressure ulcers. NWPT is not recommended in inadequately debrided, necrotic or malignant wounds; where vital organs are exposed; in wounds with no exudate, or in individuals with untreated coagulopathy, osteomyelitis or local or systemic clinical infection. Cautious use by an experienced health professional is recommended for individuals on anticoagulant therapy; in actively bleeding wounds; or when the wound is in close proximity to major blood vessels [25, 61]. Debride the pressure ulcer of necrotic tissue prior to the use of NPWT. Follow a safe regimen in applying and removing the NPWT system and evaluate the pressure ulcer with each dressing change. The optimal dressing change interval has not been well established, and should be based on characteristics of the individual and the wound. If pain is anticipated or reported consider tactics such as placing a nonadherent interface dressing on the wound bed, underneath the foam, lowering the level of pressure, changing the type of pressure (continuous or intermittent), and/or using a moist gauze filler instead of foam [25].

17.2. Kinetic energy—hydrotherapy—pulsatile lavage with/without suction

Refer to Debridement section 11 for more information

17.3. Kinetic energy—hydrotherapy—whirlpool

Refer to Debridement section 11 for more information

17.4. Atmospheric energy—oxygen

Hyperbaric oxygen therapy (HBOT) and topical oxygen therapy can both be used in the treatment of chronic wounds. Due to an insufficient amount of evidence to support or refute the

use of HBOT as well as topical oxygen therapy in the treatment of pressure ulcers, these forms of oxygen therapy are not recommended for routine use according to the NPUAP guidelines at this time [25].

18. Physical treatment tactics

18.1. Repositioning & offloading techniques

Repositioning & offloading techniques as well as early mobilization are extremely important in the prevention and treatment of pressure ulcers. Repositioning so that pressure is relieved or redistributed will reduce the duration and magnitude of pressure over vulnerable areas of the body. All individuals at risk of or with existing pressure ulcers, should be repositioned often unless contraindicated; this will contribute to comfort, hygiene, dignity, and functional ability. Inspect the skin for changes and any new or developing transformations at every position. Frequent assessment will allow for early identification of signs of pressure damage such as non-blanchable erythema [25].

If skin changes occur or the individual is not responding as expected to the repositioning regime then the frequency, method and technique of repositioning should be reassessed. Controlling the patients positioning contributes to maintenance of capillary circulation [62]. One should avoid positioning the patient on bony prominences with existing non-blanchable erythema as the pressure and/or shearing forces sustained will further occlude the blood supply to the skin, worsen the damage and result in more severe pressure ulceration [25].

Safe manual handling techniques should be utilized to ensure the safety of both the patient and the health professional. Use simple, manual handling aids such as lift sheets to help reduce friction and shear. Lift—do not drag the patient when repositioning. Do not leave moving equipment under the patient after use, unless the equipment is specifically designed for that purpose. Avoid positioning patients directly onto medical devices, such as tubes, drainage systems or other foreign objects. Patients should not be left on a bedpan longer than necessary [25].

18.2. Repositioning frequency

The frequency of repositioning will vary from patient to patient. Pay close attention and consider the patient's tissue tolerance, level of activity and mobility, general medical condition, overall treatment objectives, skin condition, and comfort when determining a patient's frequency of off loading. While medical professionals primarily aid in repositioning, the patient and his/her family should be educated and taught pressure-relieving maneuvers to do themselves throughout the day [25].

18.3. Repositioning individuals in bed

Position patients in the 30–40° tilted side-lying position (alternating, right side, back, left side) or the prone position if tolerable. Encourage patients who can reposition themselves to sleep

in a 30–40° side-lying position. It is best to place the hip joint in the neutral position when the legs are in contact with the bed in order to distribute the pressure over the greater trochanter in the 30–40° laterally inclined positions. The 40° laterally inclined positioned has been shown to have lower average sacral peak pressure index (PPI) than the 30° (15 mmHg versus 20 mmHg) and should be strived for in patients with sacral pressure ulcers [63] (**Figures 16** and **17**).

Individuals should be positioned and supported to prevent sliding down in bed. If sitting in bed is necessary; avoid head-of-bed elevation or a slouched position that places pressure and shear on the sacrum and coccyx. Avoid lying postures that increase pressure, such as the 90° side-lying position, or the semi- recumbent position. Limit the head-of-bed elevation to 30° for an individual on bed rest unless it is contraindicated by medical condition or feeding and digestive considerations. Elevating the head of the bed may be medically necessary to facilitate breathing and/or prevent aspiration and ventilator associated pneumonia; in these cases the semi-Fowler's position is preferred [25, 64].

18.4. Prone

Use a pressure redistribution surface to off load pressure points on the face and body while in the prone position. At each rotation, assess other body areas (e.g., breasts, knees, toes, penis, clavicles, iliac crest, pubic symphysis) that may be at risk of bearing excessive pressure [25].

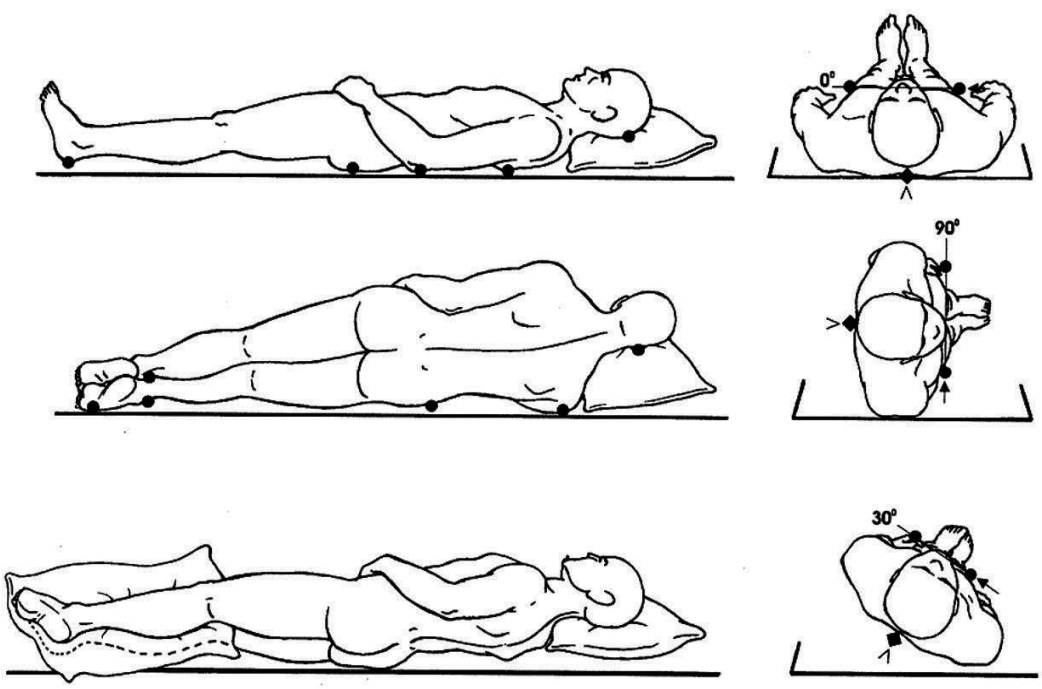

Figure 16. 30°–40° side-lying position.

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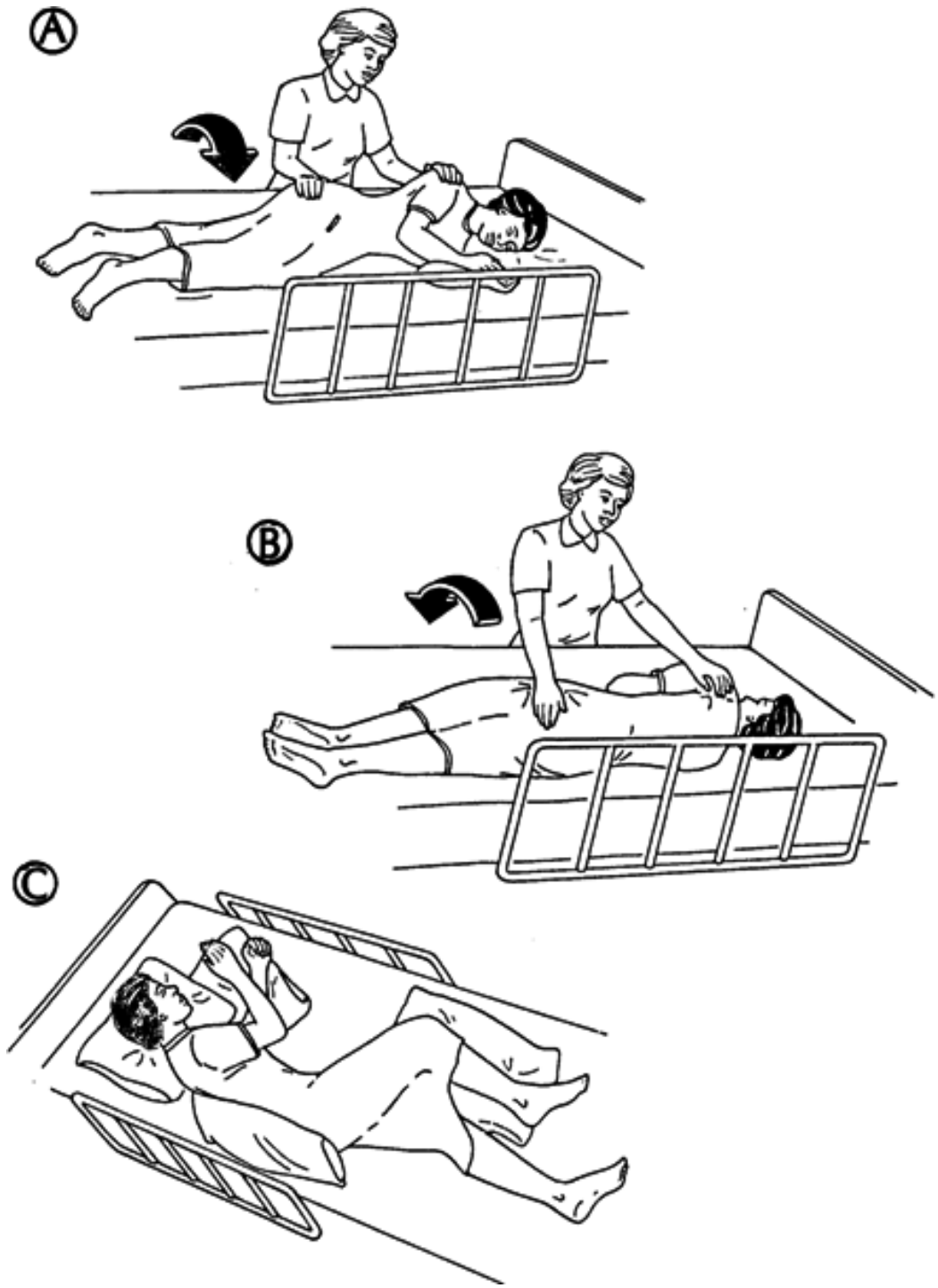

Figure 17. Turning and repositioning.

18.5. Repositioning seated individuals

Select a seated posture with an appropriate seat-to- floor height for the individual to avoid shear and friction. The seat should minimize pressure and shear exerted on the skin and soft tissues. Provide adequate seat tilt to prevent sliding forward in the wheelchair or chair, and adjust the footrests and armrests to maintain proper posture and pressure redistribution. Ensure that the feet are properly supported either directly on the floor, on a footstool, or on footrests when sitting upright in a chair or wheelchair. If the individual's feet cannot be positioned directly on the ground, footrest height should be adjusted so as to slightly tilt the pelvis forward by positioning the thighs slightly lower than horizontally. Limit the time an individual spends seated in a chair without pressure relief. One should limit sitting to ≤3 times a day and for ≤1 h each sitting period [25].

18.6. Recommendations for individuals with existing pressure ulcers

One should not be positioned directly on a pressure ulcer or on area(s) of suspected deep tissue injury with intact skin because pressure reduces perfusion to the injured tissue. Continued pressure on an existing pressure ulcer will delay healing and may cause additional deterioration. If repositioning cannot relieve pressure over the area, select an appropriate support surface and continue to turn and reposition the patient. Inspect the skin for additional damage each time the individual is turned or repositioned. Do not turn the individual onto a body surface that is damaged or still reddened from a previous episode of pressure loading, especially if the area of redness does not blanch. Ongoing assessment of the skin is necessary in order to detect additional skin damage.

19. Relieving devices/support surfaces for pressure injury prevention

Regular positioning is not possible for some individuals because of their medical condition, body habitus, etc. thus alternative prevention strategies such as providing a high-specification mattress or bed may need to be considered. Relieving devices or support surfaces play a major role in reducing compression on dependent tissue & preventing additional breakdown. Certain devices such as mattresses, integrated bed systems, mattress replacements, overlays, seat cushions, and seat cushion overlays have the ability to redistribute pressure for more effective tissue management and can serve other therapeutic functions as well [25].

19.1. General recommendations for mattress and bed support surfaces

Select a support surface that meets the individual's needs. Consider the individual's need for pressure redistribution based on the level of immobility and inactivity, the need for microclimate control, shear reduction, the size and weight of the individual, the risk for development of new pressure ulcers, and the number, severity, and location of existing pressure ulcer(s) [25].

Choose a support surface that is compatible with the care setting. Consider the weight of the bed, the structure of the building, the width of doors, the availability of uninterrupted electrical power,

and a safe location for the pump/motor, including its ventilation. Proper selection and operation of support surfaces is the key to preventing complications. Repositioning is still required for pressure relief and comfort when a support surface is used but typically not as often [25].

19.2. Mattress and bed support surfaces

Pressure redistributing support surfaces are designed to either increase the body surface area that comes in contact with the support surface in order to reduce interface pressure or to sequentially alter the parts of the body that bear load, thus reducing the duration of loading at any given anatomical site. These support surfaces are especially helpful when frequent manual repositioning is not possible such as in morbidly obese patients. Describing the specifications of various mattresses and support surfaces is beyond the scope of this chapter however in general, one should use a high-specification reactive foam mattress rather than a non-high specification reactive foam mattress for all individuals assessed as being at risk for pressure ulcer development [25].

When pressure ulcers deteriorate or fail to heal, the clinician should consider replacing the existing support surface with one that will provide a properly matched support surface environment in terms of pressure, shear, and microclimate for the individual. Changing the support surface is only one of several strategies to consider. More frequent repositioning, preventive interventions and local wound care should also be intensified as needed. For all practical purposes, evolving deep tissue injury should be provided the same level of pressure redistribution as a Stage 3 or 4 pressure ulcer. Off loading and pressure redistribution may allow reperfusion of ischemic and injured tissue, limiting the extent of infarcted or dead tissue. Once the ulcer has fully evolved, the need for a support surface can be re-evaluated [25].

19.3. General recommendations on seating support surfaces

Individualize the selection of a seating support surface for posture and pressure redistribution with consideration to body size and configuration; the effects of posture and deformity on pressure distribution; mobility and lifestyle needs. Select a stretchable/breathable cushion cover that fits loosely on the top surface of the cushion and is capable of conforming to the patient's body contours. A tight, non-stretch cover will adversely affect cushion performance. Assess the cushion and cover for heat dissipation. Select a cushion and cover that permit air exchange to minimize temperature and moisture at the buttock interface. Provide complete and accurate training on use and maintenance of seating support surfaces, including wheelchairs and cushion devices delivered to the individual. If the patient already has an existing pressure injury, select a cushion that effectively redistributes the pressure away from the pressure ulcer [25].

20. Rates of healing, prognosis & surgery

Pressure injuries are difficult to resolve. After 6 months of appropriate treatment the rates of healing are >70% for Stage 2 ulcers, 50% for Stage 3 ulcers and 30% for Stage 4 ulcers [10]. In general, healing time increases with ulcer size. Therefore, it is extremely important to identify

and start treating pressure injuries as soon as they are discovered to avoid problems and complications as time progresses. Overall median time to heal an ulcer has been cited as 46 days, 33 median days to heal small ≤ 1 cm^2 ulcers, 53 days to heal medium, >1 to ≤4 cm^2 ulcers and 73 days for large ulcers >4 cm^2 [65].

The majority of pressure ulcer patients are frail and malnourished; some are too unstable to even be brought to the operating room, thus surgical intervention is only indicated for wounds refractory to less aggressive care or for use when rapid closure is indicated. Surgery is typically saved as a last effort measure once all other non-surgical options in wound management have been exhausted. Surgical procedures can be divided into those that prepare the patient for successful healing, and those that provide definitive closure [35]. Surgical intervention is the final invasive choice because unfortunately, for many large, nonhealing pressure injuries; a reconstructive flap procedure is indicated. Most of the reconstructive flap procedures are long, procedures are long, may have to be performed in several stages and have a high rate of morbidity. The overall complication rate after surgical intervention of pressure injures has been cited as almost 60%. Wound dehiscence is the most common complication seen in >30% of patients and pressure ulcer recurrence rate is slightly <30% [66]. The mortality rate in patients with a pressure ulcer has been found to be significantly higher than in patients without a pressure ulcer (9.1% versus 1.8%, OR = 5.08, CI: 5.03–5.1, P < 0.001) [67]. The importance of early identification cannot be stressed enough. All personnel involved in patient care should seek to minimize the risks of pressure ulcer injuries and address tissue breakdown early on so that ulcer formation can be prevented all together.

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Chapter 9

Wrong Blood Type: Transfusion Reaction

Holly Ringhauser and James Cipolla

Additional information is available at the end of the chapter

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Abstract

Blood products are frequently required in an inpatient setting for a number of serious conditions. It is of the utmost importance that providers are aware of the potential for adverse reactions and human error when ordering or administering these products. Patients who require blood products should have a signed informed consent form and a type and screen performed prior to transfusion. The patient's identity should be confirmed using two patient identifiers. There are two major categories for blood transfusion reactions, immune-mediated and nonimmune-mediated. Common manifestations of a transfusion reaction are nonspecific and may be attributed to a patient's other medical problems, so the index of suspicion must be high in order to identify and treat these reactions.

Keywords: blood transfusion, adverse reaction(s), hemolysis, immune-mediated, safety

1. Introduction

A 28-year-old female is brought in by emergency medical services (EMS) following a motor vehicle collision in which she was the restrained driver. Her initial vital signs include a heart rate of 100 BPM, blood pressure of 90/68 mmHg, respiratory rate of 18/min, pulse ox of 96% on room air, and an oral temperature of 98°F. She complains of abdominal pain, especially in the left upper quadrant. Chest and pelvic X-rays are negative for acute traumatic injuries, and her FAST exam is positive. The patient's blood pressure drops to 76/50 mmHg and she is found to have a point-of-care hemoglobin of 5.8 g/dL. A massive transfusion protocol is started and she is given 2U packed red blood (PRBCs) and 1U of platelets. She is rushed to the operating room, and while she is being prepped for an exploratory laparotomy, she is found to have a temperature of 101.8°F and has dark urine draining from her Foley catheter. The operating room nurse is concerned about an acute transfusion reaction, and the blood transfusion is immediately stopped.

Whole blood, platelets, or plasma are collected from volunteer donors after a careful prescreening process. The prescreening process identifies volunteers with high-risk behavior, who use or have used certain medications, or who have recently traveled to areas affected by endemic diseases which may affect donated blood products. Following donation, these products are then screened by the blood bank for a battery of infectious diseases, undergo typing, and are stored until needed for patient use. Whole blood is separated into components, making it easy to transfuse only what a patient requires rather than whole blood. Packed red blood cells (PRBCs), platelets, fresh frozen plasma (FFP), and cryoprecipitate are the main blood components available in the USA, as well as individual clotting factors for specific disorders (for example, hemophilia A and B). In massive transfusion protocols, PRBCs, platelets, and FFP are given in a 1:1:1 ratio known as balanced resuscitation, which is close to giving the patient whole blood. There are many factors to take into consideration before deciding to transfuse a patient, which are outside the scope of this chapter.

Patients who require blood products should have a signed informed consent form and a type and screen performed prior to transfusion, whenever possible. If the patient is unstable and requires emergent uncrossmatched blood, a type and screen should still be sent for subsequent transfusions. A type and screen will indicate the patient's blood type (ABO and Rh status), whereas a type and cross tests a particular blood product against the patient's blood to confirm that they are compatible. If the patient has a previous type and screen on file with the blood bank, it should be the same ABO and Rh type as the current sample; otherwise, the suspicion for a mislabeled blood specimen should be high.

The patient's identity should be confirmed using two patient identifiers. Appropriate identifiers include the patient's name, date of birth, hospital identification number, or medical record number. Room number should never be used to identify a patient. Prior to administering blood products, two providers (usually RNs) should confirm the quantity and type of product, the ABO and Rh type, and the serial number of the product. Many centers have instituted a checklist to ensure compliance with each of these steps.

There are four major blood groups, A, B, AB, and O. These indicate the types of antigens present on the surface of the RBCs. A patient's immune system produces antibodies to the ABO antigens that are not present (**Table 1**) [1].

A second major surface antigen is the Rhesus factor or Rh factor. Administration of Rh+ blood to a patient who is Rh− typically causes little to no adverse reactions in a healthy adult. However, in women of childbearing age, it is a concern because the fetus and mother can

	A	**B**	**AB**	**O**
Antigens present	A antigen	B antigen	A and B antigens	None
Antibodies present	Anti-B	Anti-A	None	Anti-A and Anti-B
Blood products they can receive	A, O	B, O	AB, A, O Universal recipient	O Universal donor

Table 1. ABO blood types.

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have a different Rh status. If an Rh− mother is pregnant with an Rh+ fetus and is exposed to their blood (i.e., trauma, gynecologic procedures, etc.), she will develop anti-Rh antibodies that can cross the placenta. This will likely not affect the current pregnancy, but subsequent pregnancies with Rh+ fetuses are at risk for developing complications such as jaundice or hydrops fetalis [2]. This process can be prevented by administering rho(d) immune globulin to the mother when there is a concern or high risk for feto-maternal hemorrhage, even in small quantities.

There are two major categories for blood transfusion reactions: immune-mediated and non-immune-mediated. Immune-mediated reactions include all cellular and humoral responses to blood products, while nonimmune-mediated reactions include volume overload, electrolyte abnormalities, and hypothermia, among others [3]. Common manifestations of a transfusion reaction are nonspecific and may be attributed to patient's other medical problems. Signs and symptoms include fever, chills, back or flank pain, or changes in vital signs (specifically, blood pressure and heart rate).

An acute hemolytic reaction is an immune-mediated event, which typically occurs within the first 24 hours of a transfusion [4, 5]. It is due to ABO incompatibility and is most commonly due to human error. Antigen-antibody complexes form between donor and patient blood, leading to complement fixation and catastrophic intravascular hemolysis, which in turn can lead to shock, renal failure, and potentially death [6].

Delayed hemolytic reactions can occur days or even weeks after a blood transfusion and are caused by previously formed antibodies in the patient, which react with antigens on the surface of the donor cells [4, 5]. These are not ABO incompatibility reactions but are instead caused by minor antigen incompatibility. These reactions are difficult to diagnose due to their nonspecific symptoms and delayed onset after a transfusion. They are more common in patients who have undergone multiple transfusions in the past.

Febrile nonhemolytic reactions are also immune-mediated but do not result in the destruction of RBCs. These reactions are defined as an elevation in patient temperature of 1°C or more either during or following a transfusion, which is not explained by the patient's other medical issues [6]. A transfusion should be immediately stopped once there is a concern for a febrile reaction, and the remaining blood products and IV tubing should be returned to the blood bank to rule out acute hemolysis or bacterial contamination. If these tests are negative, a febrile nonhemolytic reaction can be diagnosed. These reactions can be caused by inflammatory cytokines or pyrogens in donor products or by preformed patient cytokines/pyrogens. A majority of patients who are diagnosed with this type of reaction will not have subsequent reactions in the future; however, if a second reaction does occur, the patient should then only be given leukocyte-reduced products and may benefit from receiving antipyretics prior to transfusion [6].

Posttransfusion purpura is an immune-mediated reaction to blood products which results in severe thrombocytopenia. This is a rare disorder caused by alloantibodies against a platelet antigen and is characterized as a precipitous drop in platelets approximately 1 week after blood product administration. Signs and symptoms include purpura, gastrointestinal (GI) bleeding, gross hematuria, or excessive wound bleeding. Treatment includes administration of corticosteroids and IV immunoglobulin or plasmapheresis.

There are two immune-mediated allergic processes associated with transfusion reactions, which are urticarial and anaphylactic reactions. Urticarial reactions are immunoglobulin E (IgE)-mediated and consist of GI distress (nausea and vomiting, abdominal cramping, and diarrhea) and mild upper respiratory symptoms such as rhinorrhea. Treatment consists primarily of antihistamines. Anaphylactic reactions are IgA mediated and begin within seconds to minutes of the start of transfusion. These reactions include a sudden-onset cough, bronchospasm/laryngospasm, angioedema, severe hypotension, shock, or death. These reactions occur primarily in patients with selective IgA deficiency but can also occur in patients with antibodies to other donor plasma proteins. Treatment includes immediately stopping the transfusion, securing the airway (including intubation, if needed), and giving epinephrine, corticosteroids, and antihistamines [6].

Transfusion-associated acute lung injury (TRALI) is an immune-mediated transfusion reaction, which manifests as an inflammatory lung injury within the first 6 hours of transfusion. It is due to donor granulocyte-induced acute respiratory distress syndrome (ARDS). The chest X-ray findings are the same as in other causes of ARDS, namely, diffuse bilateral pulmonary infiltrates, and the treatment is the same (lung protective ventilation strategies and supportive care). TRALI is the leading cause of death due to blood transfusion reactions but is still relatively low around 10% [6].

Graft-versus-host disease can be seen in severely immunocompromised patients who receive blood products. It is an immune-mediated transfusion reaction caused by donor T lymphocytes, which attack patient human leukocyte antigen (HLA) antigens. Signs and symptoms include rash, elevated liver function test (LFTs), diarrhea, and bone marrow suppression and typically develop a week or more after transfusion. Treatment consists of supportive care, and prevention can be accomplished by giving irradiated PRBC or platelet transfusions to at-risk patients [8]. FFP and cryoprecipitate do not have to be irradiated; however, as this is a lymphocyte-mediated reaction and these products do not contain lymphocytes.

In addition to immune-mediated transfusion reactions, there are a number of nonimmune transfusion reactions which can occur, including transfusion-associated circulatory overload (TACO), nonimmune hemolysis, hypothermia, electrolyte abnormalities, and infectious diseases.

Transfusion-associated circulatory overload (TACO) is a nonimmune mediated transfusion reaction which is often confused with TRALI. Similar to TRALI, it also presents with respiratory distress following transfusion, but unlike TRALI, it is a type of acute cardiogenic pulmonary edema [7]. Several clinical features can separate this from TRALI such as elevated brain natriuretic peptide (BNP) and central venous pressure (CVP) and it is generally improved with diuresis. Patients with a history of heart failure, kidney insufficiency or failure, poor nutrition (leading to decreased intravascular oncotic pressure due to low albumin), and patients at extremes of age (pediatric and elderly patients) are at an increased risk of TACO [9]. Treatment consists of supportive care and diuresis, and prevention includes slower rates of infusion or infusing blood products in aliquots rather than whole units.

Nonimmune hemolytic transfusion reactions are due to red cell destruction by transfusing PRBCs at the same time as hypertonic or hypotonic IV fluids or medications, by thermal damage

from warmers or freezers or mechanical damage from cardiopulmonary bypass pumps, extracorporeal membranous oxygenation pumps, or continuous renal replacement therapy [9].

Other considerations regarding adverse blood transfusion reactions include hypothermia, electrolyte abnormalities, and infectious diseases. Trauma patients or patients who are already hypothermic prior to transfusion should ideally receive blood via a warmer. Patients with renal disease or preexisting electrolyte abnormalities should be closely monitored for signs of hyperkalemia or hypocalcemia, including cardiac monitoring during and after transfusion. Although rare, bacterial, or viral contamination of blood products can occur. Proper collection, storage, and administration of blood products are keys in limiting bacterial contamination. All blood products undergo vigorous screening for viral diseases including hepatitis B and C, cytomegalovirus (CMV) and human T-cell lymphotropic virus type 1 (HTLV-1) prior to administration. The overall incidence of blood-borne pathogen transmission during transfusion is low [9].

Once an adverse reaction has been identified, the following actions should be performed:

a. Immediate cessation of blood administration.

b. Transfer blood product(s) and tubing back to the blood bank for analysis. Attach new IV tubing that has been primed with saline.

c. Recheck the patient's identity via their hospital assigned ID number, patient wristband, etc. as well as all blood products.

d. Notify the blood bank immediately. In some hospitals, it may also be necessary to directly notify the pathologist on call as they will be evaluating the patient's posttransfusion blood work.

e. Transfusion reaction orders include repeat type and screen, Coombs' testing (direct antiglobulin), and plasma and urinalysis (in some cases, to check for hemolysis). Other tests that may be considered include a complete blood count, peripheral blood smear, bilirubin, serum haptoglobin, and lactate dehydrogenase (LDH), all of which can indicate hemolysis.

f. Specific therapies geared toward each type of transfusion reaction (diuretics, antihistamines, etc.).

g. Inform the patient of the error. Being honest with patients regarding medical errors is of the utmost importance and should be done promptly.

The patient was found to be blood type O-positive, but an error in the blood bank caused a unit of A-negative blood to be incorporated into the trauma blood container. She was aggressively resuscitated with IV crystalloid to maintain a urine output of at least 100 mL/hr and was found to have a grade IV splenic laceration. She had an emergent splenectomy performed and was subsequently given three additional units of O-positive blood. Postoperatively, she was found to have elevated blood urea nitrogen (BUN) and creatinine (indicating acute kidney injury), elevated indirect bilirubin, elevated serum LDH, and hemoglobinuria (indicating acute hemolysis), and persistent anemia (likely a combination of acute blood loss and

hemolysis). She required intubation and supportive care for 6 days postoperatively and was started on a course of plasmapheresis to remove any A antigen- anti-A antibody complexes that may still have been circulating in her blood stream. Additionally, she required several weeks of renal replacement therapy until her renal function recovered. She was ultimately discharged from the hospital with no long-term sequelae.

2. Analysis of errors

a. The initial type and screen for the patient was waived prior to the first unit being administered because of her hemodynamic instability. In unstable patients with acute blood loss, it is appropriate to give O-negative blood (to women of childbearing age) or O-positive blood (to all other patients).

b. Blood bank crossmatching was also waived prior to administration of the first unit of blood given the patient's mechanism of injury (major trauma) and hemodynamic instability. In most major trauma centers, a cooler of "trauma blood" arrives in the trauma bay for all of the highest level activation trauma patients. This cooler contains uncrossmatched packed red blood cells. This is also the case in massive transfusion protocols. The utmost level of care must be taken by blood bank staff to ensure that only O-negative or positive blood goes into uncrossmatched containers to avoid an ABO incompatibility reaction.

c. The provider who is administering the blood transfusion must check the patient's hospital-issued wristband and identification number against the information listed on each blood product prior to administration. Many hospitals also require a second provider to verify this information to avoid errors.

d. The patient should be reassessed and vital signs documented 15 minutes into a transfusion to ensure that they are not becoming febrile, hemodynamically unstable, or have complaints of itching, flank pain, chills, or other signs and symptoms concerning for a blood transfusion reaction.

e. If a transfusion reaction is suspected, the blood products should be stopped immediately and appropriate actions should be taken to identify and treat the reaction.

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Chapter 10

Patient Self-Harm in the Emergency Department: An Evidence-Based Approach

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Abstract

Violence, deliberate self harm, and suicide in emergency departments and hospitals is likely to remain a significant problem for health care systems well into the future. Understanding how to confront, intervene, and manage episodes of patient deliberate self harm is extremely important, and can be life-saving. Here, through a clinical vignette, and a discussion of deliberate self harm we will highlight the importance of the direct observation of such patients, containment procedures (seclusion and physical restraints), and the use of pharmacological adjuncts. We hope that this concise, practically-oriented review will provide our readers with foundational understanding of the topic, including the most important theoretical and clinical considerations.

Keywords: emergency department, evidence-based approach, patient safety, psychiatric emergency, self-harm

1. Introduction

Violence in the hospital is not a new phenomenon, with health care and social service institutions being disproportionately affected by this serious problem [1, 2]. Also of major concern, every 16.6 min one American dies by suicide, amounting to over 30,000 suicides per year [3]. The prevalence of deliberate self-harm (DSH) in the hospitalized patient population is especially troubling, with one study reporting that DSH may be occurring in nearly 9% of hospital shifts on acute psychiatric wards [4]. Non-fatal DSH has also been called "parasuicide"—a term we will not be using in this chapter for the sake of uniformity and consistency [5].

Fortunately, the vast majority of self-harm events are classified as minor [4]. **Figure 1** shows various factors that may, alone or in combination, result in violent behavior and DSH in the health care setting.

DSH is defined as the intentional act of self-directed injury, irrespective of motivation. Important distinction is drawn between intentional self-directed injury without suicidal intent and an act of attempted suicide [6]. It is important to recognize that hospitalized patient population differs from individuals who engage in DSH across other settings, both in terms of impulsivity and the degree of violence involved during self-harm attempts [7–10]. It has also been noted that certain forms of DSH tend to result in patterns of escalation over time, up to and including suicidal acts [7–12]. The resultant long- and short-term burden is significant, with approximately 20–25% of individuals treated for DSH reporting previous self-inflicted injury [13], and a similar percentage of patients presenting with repeated DSH within 1 year [14]. Among adult patients who seek emergent treatment for self-inflicted injury, about half require admission for behavioral health evaluation and treatment [15, 16]. Despite the grave consequences, there are few standardized ways to reliably determine individual risk of DSH. Furthermore, the assessment of patients who present to the emergency department (ED) with

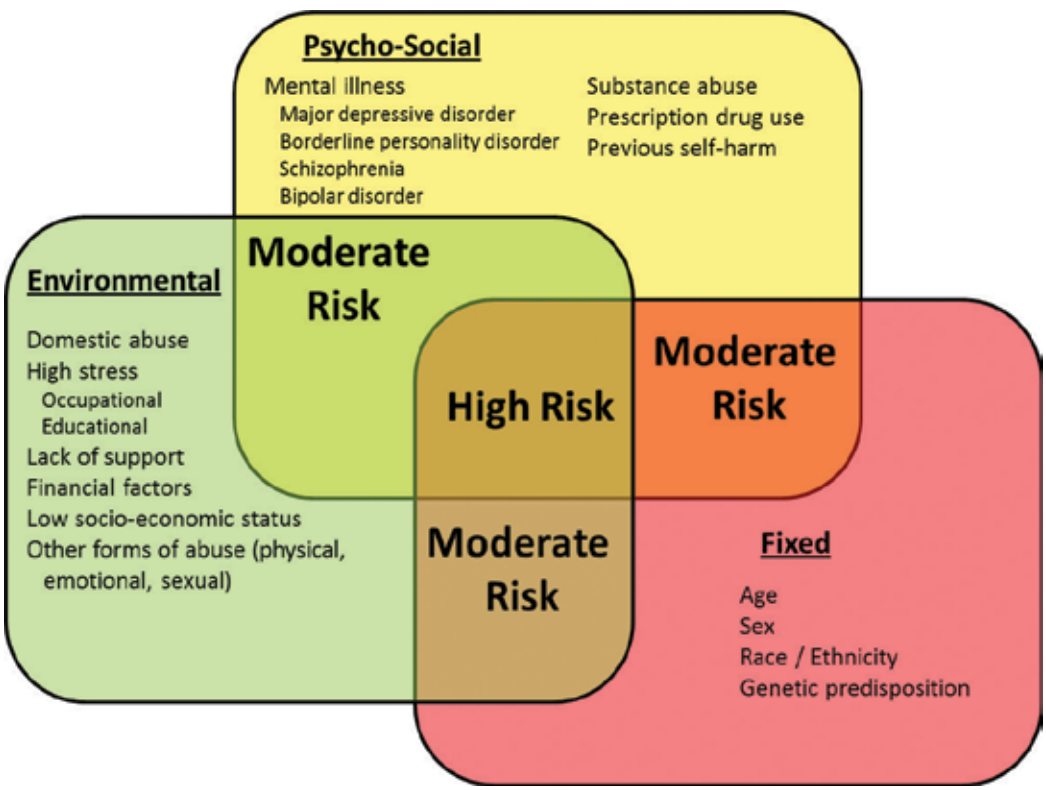

Figure 1. Factors that may contribute to violence and self-harm in the health care setting.

obvious DSH tends to be fragmented and incomplete, with currently employed triage methods in need of significant improvement [17]. This *status quo* is not acceptable, as statistics have shown that a single episode of DSH is associated with 6-fold increase in future suicide risk [15, 18]. The type of DSH, as well as the patient's response to treatment also influence the risk and patterns of subsequent DSH [9, 19]. Finally, the authors believe that the topics of DSH and violent patient behavior are interrelated, and that it is difficult to speak of one without mentioning or discussing the other.

Detailed behavioral health assessment following DSH episodes should commence as soon as the patient is deemed medically stable [20]. There should be an evaluation to determine the presence of any comorbid psychiatric disorders (e.g., depression, substance abuse, personality disorders) [21, 22]. This is critically important because certain psychiatric diagnoses are associated with significant lifetime risk of DSH [23–25]. Specific factors that strongly correlate with risk of future suicide include serious acts of DSH and the associated degree of potential lethality of the self-harming act [26, 27]. The list of proposed risk factors for DSH include young age, male sex, the presence of depression and psychosis, substance misuse, medical comorbidity, impulsivity, aggression, and/or loneliness [22, 28]. There is also evidence suggesting the involvement of specific neurotransmitter imbalances in the overall genesis of DSH [29]. While some factors contributory to DSH may be more readily modifiable (e.g., the availability of effective management of underlying psychiatric condition), some others may be difficult or impossible to influence (e.g., substance abuse, demographic factors). The following case describes a sequence of events secondary to a woman's Emergency Department (ED) admission for an acute psychotic depressive episode. Despite specific precautions being implemented during her ED stay, the patient succeeded in inflicting significant DSH.

2. Clinical vignette

A 35-year-old Caucasian female presented to her primary care physician (PCP) on several occasions within the previous 6 months, complaining of increasing fatigue, loss of interest in daily activities, lack of energy, and "feelings of worthlessness". Her husband prompted her to seek treatment after a recent violent episode in which she threatened to harm herself. Following an initial evaluation, the patient revealed that she had contemplated suicide on several occasions and was threatening to ingest a bottle of "sleeping pills" when she returned home later that day. The patient's PCP called emergency medical services for urgent transport to the nearest ED for further evaluation and possible admission. Her husband was notified of the transfer.

Upon arrival, the patient was found to be irritable and aggressive towards hospital staff. She refused to provide a thorough history. Initial vital signs showed hypertension (160/90 mmHg). A toxicology screening was ordered to rule out substance abuse, and was later reported to be negative. The patient was placed in an isolation room due to her increasing agitation and violent behavior. A dedicated chaperone was placed in her room.

Once onsite, the husband was able to provide a thorough past medical history, revealing episodes of postpartum depression after the birth of their first and second child with symptoms mirroring her current presentation. These post-partum depressive episodes occurred 5 and 8 years prior to the current presentation, respectively. He also explained that the patient's mother has been battling major depressive disorder for several years after the death of her husband. The patient's PCP had previously prescribed Fluoxetine for each depressive episode resulting in complete symptom resolution within 6 months. She is currently not taking any medications, with the exception of a daily multivitamin. The husband reports no other illnesses. Past hospitalizations include the births of her three children during which there were no complications.

The patient's current ED clinical course was complicated when she became increasingly agitated and began hitting her head against the padded wall of the isolation room. Her husband's attempts at intervention were unsuccessful. Meanwhile, the chaperone alerted the nearest nursing station and the patient was sedated with 2.0 mg haloperidol intravenously. While under sedation, the patient was restrained using a four-point restraint system. Of note, the initial ECG showed no abnormalities, and telemetry monitoring was implemented during the initial 24 h following haloperidol administration. A physical examination of the patient following this episode of self-harm revealed a large cephalohematoma at the site of the self-inflicted traumatic injury. A cranial computed tomogram (CT) was obtained, revealing a small right subdural hematoma.

As the effects of the sedative abated, the patient became acutely agitated again and attempted to free herself from the previously placed restraints. During the struggle, the patient suddenly cried out in pain and cradled her right arm within the limits of the restraints. The chaperone immediately notified the nursing station of the patient's pain. Upon further examination by the ER resident, there appeared to be a deformity of the right shoulder. Radiographic work-up revealed an anterior dislocation of the patient's right shoulder. During the struggle, the patient also managed to chip her left central maxillary incisor. Her injuries were immediately treated by the Trauma service, including shoulder relocation. Plans were also made for dental reconstruction after patient stabilization.

During the subsequent 24 h, the patient's mental condition improved significantly. She was started on Fluoxetine and did not require any additional active therapy. Within 2 days of admission, the patient was transitioned to routine hospital care, with discharge to home 3 days later. Her post-injury clinic visit at 2 weeks showed uneventful recovery, and she continued to follow-up with her psychiatrist on monthly basis for the first 3 months, then quarterly for the remainder of the initial post-discharge year. After that, her care was transitioned to the PCP and she was continued on long-term maintenance Fluoxetine therapy.

3. Discussion

Self-harm is defined as the intentional act of an individual to cause self-directed injury or poisoning irrespective of motivation. The World Health Organization (WHO) further qualifies

this definition as an "act with a nonfatal outcome, in which an individual deliberately initiates a non-habitual behavior that, without intervention from others, will cause self-harm… and which is aimed at realizing changes which the subject desired via the actual or expected physical consequences" [6]. The mode of injury can include cutting, stabbing, burning, skin carving, ingestion, and self-medicating, with more severe episodes of DSH resulting in serious secondary manifestations, such as traumatic brain injuries, infections, skeletal fractures, and even unintended death [30, 31]. In this chapter's clinical vignette, the patient sustained significant injuries secondary to violent, self-destructive pattern of behavior. While establishing intent is an essential determinant for differentiating non-suicidal self-injury from a suicide attempt, understanding which populations are at greatest risk for DSH is crucial for properly allocating treatment resources and establishing appropriate patient management [31, 32]. The importance of objective and constructive approach by healthcare providers toward patients who present with DSH must be emphasized [33, 34].

The prevalence of DSH in the United States among adults (regardless of gender or pre-existing mental illness) is estimated to be between 1 and 4%, and this figure is projected to increase [35]. Previous episode of DSH continues to be the primary predictive factor for future DSH, although other parameters must be considered when determining the risk for each individual patient [6]. More specifically, it has been reported that up to 40% of psychiatric patients, independent of illness severity or disorder classification, have reported an episode of DSH [35]. Borderline personality disorder (BPD), marked by patterned instability of moods, behavior, and functioning, is one such condition, with as many as 75% of these patients engaging in self-injury [35]. In addition, it has been estimated that over 40% of patients engaging in DSH also meet the criteria for major depressive disorder (MDD) [35]. Our clinical vignette demonstrates this point well, with the patient having a documented history of depression. Furthermore, more than 75% of patients with substance abuse disorders are estimated to engage in DSH [36]. In the acute setting, a thorough understanding of a patient's history of psychosis will be instrumental in preventing severe self-injury as well as DSH occurrences.

The need for prompt and effective management of DSH in the healthcare setting stems from the pattern of escalation and the high-risk of mortality among hospitalized patients [12, 37]. Of concern, suicide and DSH are among the leading causes of death in the United States, and their incidence is projected to increase over the next 2 decades [38]. The associated long- and short-term burden is also substantial, with approximately 1 in 4 individuals who are admitted for DSH reporting a previous self-inflicted injury [13]. Among adult patients who seek emergent treatment for self-inflicted injury, approximately half are admitted for further evaluation and treatment [15, 16]. Despite hospital admission, this patient population continues to be at high-risk for subsequent episodes of DSH and suicide attempts following discharge. Nearly 20% of patients who were admitted for DSH-related injury will be evaluated within a year for a repeated self-inflicted injury [14]. Although EDs are usually well equipped to manage acute presentations of patient self-harm, significant risk exists for discharge into the community without a mental health assessment [15, 16]. Furthermore, of those patients who were discharged directly, little more than half seek treatment in an outpatient facility within 30-days of their self-inflicted injury [15, 16]. Because previous DSH is among the strongest predictors of future DSH, inadequate clinical management and/or

follow-up is likely to result in substantial financial and human burden for the community. The best way to improve the *status quo* and prevent repeated DSH events (including hospital readmissions) to proactively reform the medical delivery system. Greater availability of mental health specialists in our EDs, combined with protocols to better transition patients to outpatient treatment can help bridge the gap between acute and long-term management. However, without standardized protocols and procedures, even the best designed infrastructure will be unable to meet the enormous need that currently exists in this clinical arena.

4. Management of patients who engage in self-harm

The primary objective in the clinical management of a patient who engages in DSH in the acute setting is to prevent further injury to self and others. In addition to cognitive strategies and direct patient supervision, methods typically employed include both physical restraints and pharmacological agents. Caution must be exercised in the use of all of the above interventions in this population due to the complexity of the patient's mental state and the degree of clinical unpredictability. General management pathway for patients who pose acute risk of self-harm is shown in **Figure 2A–C**.

Figure 2. General management pathway for patients who pose acute risk of deliberate self-harm; [Part A] Patient risk stratification; [Part B] Management algorithms based on overall risk / acuity; [Part C] Interventional considerations based on suspected / established etiology.

5. Direct observation

The use of patient observation assistants (PtOA) or the so-called "sitters" has been utilized to facilitate safer patient environment [39]. Despite the widespread use of PtOAs, there are no clearly defined industry standards regarding key metrics of safety, quality, and effectiveness of this practice [39, 40]. Neither is there firmly established evidence that special observation using PtOAs is efficacious [41]. Nonetheless, the continued need for PtOAs is highlighted by the fact that the other mainstay approaches to preventing DSH—physical restraints and pharmacological interventions—both carry significant rate of complications and a non-trivial risk of mortality [42, 43]. Consequently, the use of PtOAs is considered an important component of the multi-pronged approach consisting of close monitoring and prevention of recurrent self-harm. Of importance, there is evidence to suggest that intermittent observation may be associated with reduced self-harm when compared to constant special observation [4].

6. Seclusion

Seclusion in management of severe agitation and/or violence first started in the mid-nineteenth century as an alternative option to mechanical restraint [44, 45]. In brief, seclusion represents involuntary confinement of the patient alone in a room (or another designated area) where the patient is physically prevented from leaving. In 2001 the UK Central Council for Nursing, Midwifery and Health Visiting determined there were no studies of value in using restraints and seclusion in mentally ill patients and could not recommend their effectiveness or use [46]. The fact is that since 2000 the use of what are termed "containment procedures," i.e., seclusion and restraints, in US psychiatric hospitals has been trending downward [47]. Over the past 10 years best practices have been instituted to limit use of containment procedures in the US to assist mental health professionals in their clinical practices [48, 49]. Additionally, the National Association of State Mental Health Program Directors (NASMHPD) had released its six core strategies for reducing seclusion and restraint use to assist in the development of safe and effective mental health programs [50]. Nonetheless, there have been some reports that show a correlation between reduced use of seclusion and restraints and an increase in patient related violence [51, 52]. However, recent work demonstrated that the implementation of better sound leadership practices, the use of accurate clinical data, developing and training a good workforce, evidence based policies and procedures, along with the use of specialized response teams, behavioral therapy, and the discontinuation of nursing "as needed" orders for restraint and seclusion use resulted in better patient outcomes and more favorable behavioral patterns [44, 53]. When the above mentioned educational, clinical, and administrative best practices are combined with sensory modulation there can be marked reductions in disturbances and a dramatic drop in the use of seclusion [54]. It is critical to ensure both safety and dignity of the patient when using restraints or seclusion.

7. Physical restraints

Approximately 50% of intensive care unit patients [55], 20% of patients on neurology-neurosurgery wards [56], and 25% of individuals admitted to mental health facilities experience at least one type of "control intervention" during acute hospitalization [57]. One method of such "control intervention" is the use of physical restraints (PhyR), defined as any device, material or equipment attached to or near a person's body, which is intended to prevent a person's free body movement to a position of choice and/or a person's normal and unrestricted access to their body [58]. The use of PhyR is relatively common, with some authors suggesting that it is overused [43, 59]. As a consequence, there are numerous initiatives to reduce the reliance on PhyR, especially among the most vulnerable patient populations [60–62]. As mentioned in this chapter's clinical vignette, restraints may not eliminate the risk of DSH. Therefore, the choice to use PhyR continues to be controversial and should only be entertained as a last resort option when there exists a real possibility of serious physical injury to self or others [63–65]. There is therefore a need for caution and balanced judgment on part of the treatment team, beginning with a well-informed understanding of potential complications and safety procedures designed to prevent adverse outcomes [63–65].

Published guidelines provide a framework for the use of PhyR in a variety of settings [66, 67]. The initial criteria for instituting PhyR should be based on a thorough evaluation of a patient's mental status. An individual at risk for DSH, who is cognitively aware of this risk of harm to themselves, is less likely to become violent while in restraints and can therefore be placed in a soft restraint apparatus [56]. However, in the event that a patient becomes increasingly violent when actively restrained, there is an increased risk of limb injury due to a tendency for the device to tighten [68]. Moreover, patients who are restrained and sustain secondary trauma are prone to more serious injuries because part(s) of their body is/are physically tied, which may render normal protective, instinctive responses ineffective. Other complications of soft restraints include abrasions, contusions, immobility, and dislodgement of various devices (e.g., intravenous lines, feeding tubes) [68–71]. In some cases, leather restraints can be utilized if the patient becomes increasingly combative; however, appropriate precautions are critical when using leather PhyR because device removal can be challenging in emergent situations [70].

The specific placement of restraints and number of application points are important in ensuring the balance between satisfactory outcomes and minimizing complications [56, 58, 72]. If the patient poses a low risk of violence, a two-point restraint system can be utilized safely [70, 73]. Four-point restraints should be reserved for combative and violent patients in the acute setting to maximally prevent uncontrolled movements [70]. Again, applicable guidelines should be followed to reduce restraint-related complications (e.g., self-injury, overturning of the stretcher) while ensuring adequate immobilization of the patient [70, 74]. Belt and jacket restraints can serve as adjunct to extremity restraints, but mandate special precautions, such as the concurrent use of full side rails [75, 76].

Consideration must also be given to the immobilized patient's positioning, including appropriate contingency plans if complications occur. If restrained while prone, patients may be in danger of suffocation. Consequently, if this position is utilized, the patient must

General considerations
Detailed documentation of all restraint-related clinical decisions and procedures should be made in the medical record
Duration of restraint use should be firmly justified and continue for the least amount of time applicable
In all instances of mechanical restraint use, an individualized clinical management plan should be established and followed
Information regarding the restraint procedure should be given to the patient
Mechanical restraints should be utilized in "last resort" capacity when all other interventions have failed
Periodic re-evaluation, as frequent as every 30 min, should be performed to determine the need for continuation of restraints
Restraints should always be utilized under the supervision of a qualified physician/practitioner
Restraints should be placed and removed in team setting by sufficient number of staff members to prevent patient harm
The use of restraints for discipline or staff convenience is forbidden an illegal
Vital signs should be monitored at all times during mechanical restraint period
Specific indications for mechanical restraints
Facilitation of diagnosis through behavioral control under conditions requiring minimal or no medication use
Facilitation of the development of a therapeutic alliance with the patient
Mitigation of staff fears/anxiety
Physical containment
Protection of the patient, other patients, staff, and/or property
Provision of a respite for regaining control
Reduction of overall stimuli
Repression/control of aggression

Table 1. Important considerations for placement and maintenance of mechanical restraints.

be provided with adequate space for free chest expansion and his or her respiratory and airway status must be closely monitored [77, 78]. If restrained while supine, patients are at risk for aspiration [79]. Thus, the patient's head should be positioned at 30° with the ability to rotate freely in order to avoid this complication [70, 79]. Moreover, optimal configuration of 4-point restraints calls for one arm being directed up toward the patient's head and the other arm down toward the patient's hip. Aside from these positional considerations, additional precautions must be instituted regarding prolonged immobilization due to the risk of pressure ulcers, focal neurovascular compression, and deep vein thrombosis [70, 80].

In addition to various potential physical complications inherent in the use of restraints, patients may experience significant emotional trauma from the ordeal, such as feelings of powerlessness, humiliation, and/or the sensation of terror seen with PhyR [81]. Common manifestations of restraint-related psychological trauma include "flashbacks" to the emotional ordeal (e.g., retraumatization), hopelessness and helplessness (e.g., "broken spirit"),

negative general psychological impact, and perceptions of unethical healthcare practices [82, 83]. All of the above factors must be considered when implementing PhyR, although they should not prevent the use of restraints if clinically justified and necessary [84, 85].

Due to the potential for severe complications and even mortality associated with PhyR use, the Joint Commission established protocols pertaining to the usage of restraints in the healthcare setting [86]. Restraints need to be justified, well documented, and monitored at all times to help minimize the risk of iatrogenic injury [87]. Current guidelines recommend the restraint use for children ages < 9 years be limited to 1 h; 2 h for adolescents ages 9–17 years; and 4 h for adults before mandatory clinical re-evaluation [70, 88]. These precautions are necessary to minimize both the physical and psychological complications of PhyR use [89, 90]. Details regarding indications and maintenance of mechanical restraints are provided in **Table 1**.

8. Pharmacological "restraints"

The high complication risk of PhyR has led to the increased use of pharmacological agents, as either monotherapy or polytherapy, in the management of high risk patients at risk for DSH. In fact, the prevalence of chemical restraints in certain settings exceeds 33% [91]. At times, pharmacological approaches are used in conjunction with PhyR [92]. Some of the most common pharmacological agents used in psychiatric emergencies include haloperidol, droperidol, lorazepine, olanzapine, and midazolam [93–95]. Due to the ethical considerations of PhyR, these pharmacological agents are often first line therapy in a patient who is at acute risk for self-harm. Multi-modality, high intensity, or combined therapy is often employed when a patient becomes acutely violent or combative, thus posing as an immediate danger to both themselves and others [95, 96].

Haloperidol is a butyrophenone antipsychotic agent with onset of action within 30–60 min of administration and clinical effect lasting up to 24 h [97]. Haloperidol is commonly used in the setting of psychosis and self-harming behaviors because of its minimal drug interactions with non-psychiatric medications, which is essential due to the challenge of obtaining a medical history from acutely agitated patients. In a study of ED patients with agitated, threatening, or violent behaviors, haloperidol resulted in significant clinical improvement within 30 min of administration in 83% of patients [98]. Furthermore, due to the lack of interactions and relatively favorable safety profile, this medication is used as first-line therapy for patients at risk for DSH [99, 100]. Caution is nonetheless necessary due to some rare, yet potentially serious adverse events associated with haloperidol use. The most prominent side effect includes extrapyramidal syndrome and dystonia, which can occur in up to 20% of patients [97]. Haloperidol can also increase the QTc interval, cause torsade de pointes, and even sudden death. Consequently, patients should optimally undergo an ECG prior to haloperidol administration [101].

Another agent, droperidol, may be considered when immediate sedation is required [102]. Droperidol has a rapid onset of 15–30 min, making it more suitable for acute situations

[103]. It has been reported that droperidol can be given intramuscularly at a dosage up to 10 mg to have the same efficacy as other sedatives [103]. Of note, a prior history of cardiac disease is a contraindication due to a black box FDA warning for fatal cardiac arrhythmias when intravenous doses exceed 2.5 mg [104]. This warning carries a strong recommendation to precede the use of droperidol with an ECG to screen for any cardiac abnormalities. Other side effects include the risk of developing dystonia or akathisia [105]. These symptoms can be ameliorated through the co-administration of histamine (H1) antagonists such as Diphenhydramine or Promethazine [106]. Importantly, precautions should be taken when using droperidol (and other similar agents) as adjunctive therapy to mechanical restraints due to potentially elevated risk of suffocation or positional asphyxia [107].

There is a paucity of research on acute manifestations of DSH in patients under the influence of cocaine. The existing literature recommends the use of lorazepam as the primary agent of choice for physiological alterations secondary to cocaine use [108]. This medication can also be used as first-line therapy for patients experiencing withdrawal from alcohol or recreational stimulants, as it has been shown to be more effective than neuroleptic drugs, such as haloperidol [109]. However, due to its CNS depressive effects and long-duration, Lorazepam should not be used if a patient appears intoxicated or if he/she has ingested other sedatives [104]. Further precautions should be taken in patients of childbearing age as this medication is a class D agent in the setting of pregnancy [70].

Olanzapine, a second generation thienobenzodiazepine antipsychotic, may also be considered in cases of acute psychosis with associated DSH [110]. This medication, which antagonizes dopamine and serotonin, is equally as effective as lorazepam and haloperidol in the acute setting [70]. However, a thorough history is necessary before using this drug as it can lead to hypotension when combined with anti-muscarinic medications [70]. Currently, there is limited understanding of the use of this medication in patients presenting with acute psychosis, as well as substance abuse [111, 112].

Midazolam (a benzodiazepine) is indicated for situations where short duration of action is desired [113, 114]. Midazolam has similar efficacy to lorazepam or haloperidol and may therefore be beneficial in patients who do not require long term management and whose risk of DSH may be related to substance abuse and acute intoxication [109]. Furthermore, due to its short action, its systemic effects on the patient quickly wear off, allowing subsequent evaluations, discharge from the ED, and transition to outpatient setting in a more timely fashion [70].

Other agents have been described in the management of acute behavioral disturbances, including DSH, but the limited scope of this chapter does not permit a more in-depth discussion [103, 104, 114–119]. In all similar cases, the goal is to medically stabilize the patient and then prevent recurrent episodes of self-harm [115]. It is important to note that while our discussion describes largely a local pattern of practice, a number of effective professional guidelines have been published in this general area. Consequently, the reader is referred to those guidance documents for further information regarding the

overall diagnostic framework and the associated implementation of both physical and pharmacological restraints [120–123].

9. Management and prevention of deliberate self-harm: key points

Emergency management of acutely violent patients, especially those involved in DSH, can be challenging [124]. Similar to many other medical conditions, prevention of DSH should be given the highest priority. This includes prevention of both initial and recurrent episodes of DSH [125, 126], especially since repeated self-harm is associated with long-term, cumulative risk of death [127]. Many patients who inflict self-harm can be treated quickly and effectively, without the need for clinical escalation. The initial approach to escalation usually involves close direct observation [39–41] and the provision of an injury-proof, secluded environment [128, 129]. However, individuals who continue to exhibit behaviors that constitute danger to self or others may require the implementation of physical or pharmacological restraints, i.e., containment procedures [70, 72, 117]. Because of the significant risk for potentially serious complications associated with the use of restraints, special care and attention is required in such situations [129–131]. Additionally, we highlighted progressive views regarding containment procedures and how they can be implemented effectively, while at the same time referencing their drawbacks. Once the patient has stabilized clinically, a combination of psychosocial and pharmacological approaches is utilized to prevent repetitive self-harming behaviors [125, 132]. Multidisciplinary teams including primary care practitioners, community and behavioral health experts provide the best framework for long-term recovery [133, 134].

10. Conclusions

DSH will continue to be a challenging problem that confronts health care providers in the ED (and other areas of the hospital). The approach to such patients must be multidisciplinary and occur in an evidence-based environment. Practitioners must be aware of their hospital protocols used to address patients who present with DSH. Detailed behavioral health assessment following DSH episodes should be completed as soon as the patient is medically stable. Specifically, an inventory of comorbid psychiatric disorders that put a patient at risk for DSH, especially suicide, must be catalogued as well as a determination of the presence of associated risk factors that may contribute to an escalation of illness severity. The practitioner must also become well versed in the use of direct observation, containment procedures (seclusion and physical restraints), and pharmacological restraints, as well as an appreciation as to the direction of new clinical evidence regarding care and the promulgation of new legislation. Clinical approaches and legal perspectives in this field will continue to evolve.

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It is clearly recognized that medical errors represent a significant source of preventable healthcare-related morbidity and mortality. Furthermore, evidence shows that such complications are often the result of a series of smaller errors, missed opportunities, poor communication, breakdowns in established guidelines or protocols, or system-based deficiencies. While such events often start with the misadventures of an individual, it is how such events are managed that can determine outcomes and hopefully prevent future adverse events. The goal of Vignettes in Patient Safety is to illustrate and discuss, in a clinically relevant format, examples in which evidence-based approaches to patient care, using established methodologies to develop highly functional multidisciplinary teams, can help foster an institutional culture of patient safety and high-quality care delivery.

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