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Vignettes in Patient Safety

Volume 2

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



VIGNETTES IN PATIENT SAFETY - VOLUME 2

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

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Edited by Michael S. Firstenberg and Stanislaw P. Stawicki

Contributors

Jesse Clanton, Meghan Clark, Whitney Loggins, Robert Herron, Michael S. S Firstenberg, Stanislaw P. Stawicki, Mamta Swaroop, Andrew Lin, Rebecca Jeanmonod, Donald Jeanmonod, Ben Bird, Maureen Cheung, Logan Mellert, Kyriakos Souliotis, Vasiliki Kapaki, Philip Salen, Ken Norman

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Meet the editors



Editor, Dr. Michael S. Firstenberg is a board-certified thoracic surgeon actively practicing adult cardiac surgery at the Summa Akron City Hospital in Akron, Ohio. He serves as an Associate Professor at Northeast Ohio Medical University. He attended Case Western Reserve University for Medical School, received his general surgery training at University Hospitals in Cleveland, and completed a fellowship in thoracic surgery at the Ohio State University. He also obtained advanced training in heart failure surgical therapies at the Cleveland Clinic.



Co-Editor, Dr. Stanislaw P. Stawicki leads the Department of Research & Innovation and co-directs the Post-Doctoral Research Fellowship and the IRB at St. Luke's University Health Network. A specialist in General Surgery, Surgical Critical Care & Neurocritical Care, he co-authored >490 scholarly publications, including 5 books. He is a member of numerous editorial boards. His areas of expertise include patient safety, academic leadership, mentorship, trauma, critical care, injury prevention, and sonography.

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Preface

This text represents the second volume of *Vignettes in Patient Safety*. The tremendous interest in the first volume motivated us to begin the work on the current tome—a testament to the importance of the topic and the high quality of work published in the inaugural book. The enthusiasm evident through the positive response of our readership clearly demonstrates the growing interest in patient safety across the world. We are proud to play a small part in raising awareness of this critically important—and rapidly developing—area of patient care. As we reflect on the above “positives,” we realize how much more work remains to be done to further reduce and eliminate the “negatives” associated with the still-too-prevalent patient safety events. With the goal of “zero incidence” for many of the so-called never events, there continues to be a significant room for improvement. As the reader will find throughout this second volume of *Vignettes in Patient Safety*, the need to develop, encourage, and support patient safety champions throughout medical and surgical departments, institutions, and health systems is now greater than ever. It is these patient safety champions that will ultimately help transform the current vision for safer care delivery into the “zero defect, zero incidence” healthcare environment of the future, through the universal embrace of a culture of safety.

Similar to the first volume of *Vignettes in Patient Safety*, we again chose to pursue a case-based approach, focusing on practical aspects of identification and remediation of commonly encountered medical errors, including their root causes and preventive strategies. The reasons for this remain grounded in the concept that by providing our readers with realistic, case-based scenarios, we are able to more effectively help the audience in relating the educational material to their daily activities of patient care. Through the use of hypothetical scenarios that are based on “patterns of errors,” each chapter highlights its own set of diverse categories of potential “patient harm” events. At the same time, we are able to more effectively focus the reader’s attention on opportunities for improvement in bedside care delivery, clinical team interactions, and pertinent system-based processes. It is our hope that equipped with this knowledge our audience will be better positioned to continually reduce the ever-present risk of medical error in their daily clinical practice.

Another important component of the case-based approach to patient safety is the demonstration that as healthcare providers (at all levels of our organizations) we do not function in a vacuum of time and/or place. Rather, we operate in an ever-complex continuum of an overall patient experience. The impact of even small “misadventures” or lapses anywhere within the vast healthcare system, while potentially perceived as minor at the time of occurrence, can have a substantial and unpredictable impact on a patient’s outcome during both the current and future care encounter(s). Furthermore, as one reads each of the patient safety vignettes, it becomes increasingly apparent that thousands of patients are at constant risk

of being harmed across healthcare facilities across the world. It is therefore our duty and responsibility to proactively and relentlessly work on decreasing (and eventually eliminating) any iatrogenic risk(s) to our patients.

Encouraging is the fact that significant system-wide efforts are being proposed and gradually implemented to improve the entire patient care experience, with safety increasingly becoming a major cornerstone of such initiatives. Institutional and systemic culture change is ongoing, and although it takes a lot of time and effort to change practices and behaviors that contribute to medical errors, it is now almost universally recognized that patient safety is the foundation around which care delivery systems ought to be built. Parallel to this fundamental tenet is the growing understanding that healthcare-associated adverse events (including corresponding clinical outcomes) are rarely the result of a single provider's actions, but rather represent cumulative and synergistic deficiencies within existing systems and processes. Consequently, the process of assessing and evaluating patient safety events has evolved beyond "placing blame" and is now firmly focused on identifying "how and why" a specific set of events took place. Thus, the overall emphasis has shifted toward proactively and constructively identifying various opportunities for improvement, instituting appropriate remedies, and investing in education and patient safety advocacy.

Better appreciation of the etiology of patient safety events allows us to better understand various processes and failure modes that lead to adverse clinical outcomes. This, in turn, has resulted in the evolution of concepts such as "failure to rescue," the introduction of "root cause analyses," and implementations of organizational improvement programs based on industries that have successfully reduced critical error rates (e.g., air transportation, banking, or nuclear power industry). Broader adoption of such ideas and management tools has not only resulted in a safer care and improved patient experience but also brought significant cost-savings as a by-product. In this context, the focus of *Vignettes in Patient Safety* is to present alongside each case scenario an evidence-based overview of the best practices and remedial interventions that were proven to be effective under specific circumstances. The intended end result is the implementation of positive change across our institutions and health systems.

The editors of *Vignettes in Patient Safety* would like to acknowledge the tremendous efforts of all of the people involved in bringing this work to fruition. We also want to thank our friends and family who supported our efforts, extending into this second volume, for their patience and understanding in response to the many hours of work necessary to complete a project of this magnitude. In addition, we formally acknowledge and express our appreciation to all of the authors that have contributed their valuable work to this second tome of the *Vignettes in Patient Safety*. Their efforts, especially in the context of an open-source publication model in which the authors support the expenses of a publication, clearly reflect their dedication to the primary objectives of this text—and willingness to share and promote this work's noble message. The institutional development of a culture and climate focused on patient safety can be very difficult to achieve and can be frustrating to those who are truly committed to such efforts. Yet, the growing number of healthcare safety champions, whose vision is to continually improve patient outcomes through individual and institutional culture change, continues unimpeded on their quest to achieving better and safer clinics, hospitals, and pharmacies around the world. One form of such championship is the willingness to share experiences and knowledge through authoring scholarly works in the form of articles and chapters. Finally, we must recognize the important role of various departments and institutions in this publication effort, both through their support of faculty time and effort and

through generous contributions to the open-access publication process. It is only through such collaborative undertakings that we will be able to fulfill our shared goal of promoting patient safety efforts worldwide.

As we embark on planning the next volume of *Vignettes in Patient Safety*, we hope that the content of the second tome within this cycle will provide our readers with important and actionable knowledge. We also hope that members of our audience may consider contributing to this and other projects in the area of patient safety. After all, sharing one's knowledge and experiences, with the goal of helping others and making a difference, constitutes the highest form of giving.

Michael S. Firstenberg MD, FACC,

Summa Health System, Cardiothoracic Surgery,
Akron, OH, USA

Stanislaw P. Stawicki MD, MBA, FACS,

St. Luke's University Health Network, Department of Research and Innovation,
Bethlehem, PA, USA

Introductory Chapter: Developing Patient Safety Champions

Julia C. Tolentino, Noel Martins, Joan Sweeney,
Christine Marchionni, Pamela Valenza,
Thomas C. McGinely, Thomas R. Wojda,
Michael S. Firstenberg and Stanislaw P. Stawicki

Additional information is available at the end of the chapter

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1. Introduction

Despite tremendous progress in improving their safety performance, modern healthcare systems still have a long way to go compared to other high-risk, low-error industries such as banking or air transportation. To that end, it has been proposed that adoption of the aviation industry's high-reliability models (HRMs) by healthcare systems may help reduce the occurrence of medical errors. These HRMs are based on in-depth analyses of failure modes and are characterized by their inherent focus on team approaches and the commitment to identifying often complex solutions to existing problems [1]. Within the highly complex environment of modern healthcare, the process of improving patient safety (PS) is certainly a long and arduous journey. This chapter is intended to serve as a framework to the broader discussion of strategies to improve PS outcomes. The overarching themes of this book series revolve around continually institutionalizing and further refining a culture of safety within modern healthcare systems.

The emphasis on both individual and team excellence, backed by well-established, system-based support structures and mechanisms, provides the most optimal substrate for further enhancements in PS [2, 3]. The organizational quest for improving PS revolves around embracing continuous self-improvement, effective change management, realistic goal setting, and rewarding positive individual and team behaviors [4, 5]. Only when all of the above elements are present in "correct proportions" and harmoniously interact to produce synergies can our healthcare systems enter the state of sustainable culture of safety. The goal of the

Vignettes is to expose our readers to a broad range of key PS concepts that will cumulatively provide a foundation for building safe systems and synergies required for continued progress in this critical area.

Important and formidable challenges exist within the broader domain of PS. The development of HRMs in those key areas, summarized in the subsequent sections of this chapter, will help bring about the desired, optimal systemic outcomes. In aggregate, our healthcare systems need to become more effective in proactively addressing preventable harm, with a focus on reducing primary occurrences and minimizing any recurring or subsequent (e.g., secondary) adverse events [6]. Also, despite progress in multiple areas amenable to harnessing the full power of technological advances to the benefit of our patients and their safety, the human factor continues to be the “weakest link” when it comes to sustainable reduction in iatrogenic harm.

2. Why is patient safety important?

While it is easy to advocate for the establishment of a universal framework for improved patient outcomes, practical implementations are not as easy as it might superficially appear. In fact, well-intended initiatives that are designed to help improve PS can often be met with substantial resistance by those who inherently feel that their “...way of doing it is better...,” that “...rules do not apply to them...,” that their “...patients never have such problems...,” or the most concerning of excuses “...institutional leadership does not feel that such activities are worthwhile or justified in terms of the time, resources, changes to existing institutional cultures and structures, and costs” [7–9]. Nevertheless, there are more practical and clearly less altruistic reasons to focus on PS—specifically, the quickly growing number and types of complications that are deemed “avoidable,” “never events,” or “hospital acquired” and are becoming attributable to “actual or perceived lapses” in standards or processes aimed at their prevention. As such, the value-based healthcare paradigm is leading to diminished reimbursement for cases complicated by preventable—or potentially preventable—events.

If there is one overarching theme that has become clear throughout the different clinical scenarios discussed in the *Vignettes in Patient Safety*, it is that adverse patient events have broad-ranging and far-reaching consequences. From physical and emotional harm to the patient, to significant added healthcare expenses, to medico-legal sequelae, and finally to financial penalties imposed by third-party payers, patient safety events are among the most impactful negative occurrences for patients, practitioners, institutions, and health systems [10, 11]. In addition to the abovementioned “direct” effects of PS occurrences, there are numerous “indirect” by-products that are often difficult to appreciate and/or quantify. For example, the increase in publically available patient safety reports both directly and indirectly affects the hospital’s external perceptions and the ability to attract new patients [12]. The overall patient experience and the risk of medical liability litigation also tend to correlate with

institutional commitment to patient safety [13, 14]. Within this complex “value” equation, hospital finances and reputation can also be significantly affected [15].

Increasingly, both government payers and private health insurance companies decline to reimburse healthcare systems and providers for the care involving, or resulting from, such lapses in patient safety (or complications thereof). The financial burden of managing various adverse event-related complications is often substantial—and frequently exceed the numerical costs of managing the initial problem for which the patient was hospitalized. Given the trend toward payer cost-avoidance and value-driven approaches, now more than ever, those additional expenses are being shifted toward hospitals and providers. Along the same lines, there is growing impetus by both the public and third-party payers to provide reimbursement based on outcomes and quality of care, and not necessarily for “work performed.” Furthermore, payers are now looking toward financial models that consider not only the patient outcomes but provider- and institution-specific outcomes as well [16, 17]. Within the value-based healthcare paradigm, unusually high wound infection rates or failures to use (or even document the use) of best-practice therapies such as prophylactic antibiotics, pre-procedural beta-blockers, and appropriate DVT prophylaxis are now becoming publically reported data and potential quality metrics for which insurance payers might withhold or adversely adjust payments [18, 19]. In some situations, failure to use or document “best practices” that are focused on patient safety can even result in institutional financial and nonfinancial penalties [20, 21].

Compensation and incentive models at the level of physician practices and individual physicians are also being linked to outcomes that consider patient safety [22]. In addition, as previously mentioned, in the era of transparency and public reporting of outcome data, patients can now seek out hospitals—and even specific providers—that have the best outcomes across multiple domains of performance, from complications to hospitalization lengths of stay and patient safety event rates [23, 24]. Hence, an obvious reason for such growing interests in PS is that it makes good business sense. Furthermore, public reporting of key clinical metrics and safety indicators has transformative effect on institutions, providers, and patients [25]. Finally, adverse events often result in medical-legal discussions regarding “deviations from the standard of care” or even “malpractice” and can result in considerable financial consequences for all involved stakeholders. In brief, fostering patient safety is the right thing to do!

In addition, as our collective experience in achieving a culture and climate of safety grows, organizations should liberally utilize this growing body of knowledge to create and reinforce a framework for delivering safer care, establishing process improvement plans, and emphasizing “best practices” and evidence-based institutional guidelines [26–28]. The primary goal of the chapters in this volume of *Vignettes in Patient Safety* is to provide a solid conceptual foundation for accomplishing a truly formidable task of providing the highest quality care for our patients while ensuring that treatments take place efficiently and safely. As we concentrate our efforts on some of the pressing challenges and barriers to achieving a culture of safety, we should carefully and humbly follow Bagian et al. [29] in the realization that patient safety is a continuous learning process and that in order to “develop and deploy a patient safety program,” we must first accept that we “can’t fix what [we] don’t know....”

3. Focus on challenges

There are several important reasons why challenges remain in the general area of patient safety. Starting with deeply ingrained institutional cultural patterns that are exceedingly difficult to change [4, 30], the immense number of potential ways and contributing factors that may be associated with unintentional harm is beyond any one person's ability to effectively comprehend or influence, either directly or indirectly [31–33]. Lack of awareness, combined with inadequate education and training, continues to create highly unpredictable “blind spots” within the patient safety paradigm [34, 35]. With increasing emphasis on the importance of the patient as an instrumental factor in the overall healthcare safety equation [2, 36], potential exists for both beneficial and harmful effects of the added complexity of the resultant “safety matrix.” For example, a patient may be able to help identify the correct anatomic site before he or she undergoes an invasive procedure, yet the same patient may communicate incorrect medication dosage for their regularly prescribed antihypertensive.

Among potential “safety blind spots” mentioned above, team communication and the patient “handoff” process are associated with the greatest risk of healthcare associated errors. The “handoff” or handover process (HOP) refers to the formal procedure of transferring the clinical care of a patient from a departing provider to an incoming provider and involves targeted transfer of critical information, oversight responsibility, and decision-making authority [37, 38]. Also called the “transition of care” process, the HOP may involve various time schedules (e.g., shift based, daily, weekly) and provider levels, further increasing the potential for miscommunication and potential error(s). The HOP is also the standard operating procedure in both inpatient and outpatient medical settings, as well as during transitions between those two realms [39–42]. The HOP is highly variable and often dependent upon the provider's level of training, the scope of responsibility, area of specialty, and time constraints associated with daily workload [43–45]. Yet, the HOP is often overlooked as a source of miscommunication that potentiates adverse outcomes [46–48]. Of note, in both 2003 and 2011, the Accreditation Council for Graduate Medical Education (ACGME) mandated a decrease in the number of continuous duty hours for house officers [49]. Training programs have acclimated to shorter shift hours from the more classic long call demands. Therefore, there are many more HOPs to cover the increased number of shifts [48, 50–52]. Although the struggle to balance resident work hours and the continuity of care is likely to persist [51], some have suggested that providing “protected handoff environment,” free of distractions and based on predetermined, standardized communication guidelines and EMR-based solutions, may help reduce HOP-related errors [52, 53]. Given this new reality, the healthcare industry must learn from areas where HRMs are the norm, not the exception [1, 54].

Colvin et al. [37] examined the HOP in the intensive care unit (ICU), where errors or omissions of important history can greatly impact critically ill patients. Given the high acuity of care being provided in the ICU, the overall situational complexity makes the HOP extremely important and closely enmeshed with a broad range of PS considerations. Types of communication

breakdowns identified by Colvin et al., during the HOP included (a) critical content omissions, (b) sharing of inaccurate or conflicting information, (c) the provision of irrelevant or distracting information, (d) failure to discuss anticipated problems or plans, (e) “illegible or unclear” HOPs, and (f) failure to communicate rationale behind overnight decisions [37]. The authors highlight the lack of standardization and education regarding the HOP across the healthcare system. Published in 2005, a survey of the Internal Medicine Sub-Internship Clerkship Directors based on input from 125 US Medical Schools showed that <10% of institutions taught students how to perform HOPs in a formal didactic setting [55]. Given the above factors, and the associated inconsistencies in the HOP across organizations, an urgent action is required to rectify this state of affairs and ensure that both training and implementation of HOP-related skills are standardized.

Other barriers to effective teamwork in the healthcare setting involve psychosocial and organizational structure-related factors encountered in the workplace. Weller et al. [56] reviewed roadblocks to communication in the setting of multidisciplinary caregiver teams. The success of information sharing is a primary predictor for the overall performance of any team in any workplace. It was found that the “hierarchical structure” in medicine may be associated with poorer safety outcomes. Less experienced individuals, such as medical students and junior residents, may lack confidence when reporting patient concerns or diagnostic information, potentially withholding important data “out of concern for being wrong.” This pyramidal organizational style can contribute to increased risk of adverse events across a broad range of settings, from medicine to aviation or banking industries. As noted by Malcolm Gladwell in a well-known example from aviation, disastrous consequences may result when junior pilots fail to challenge misguided decisions of more veteran pilots [56, 57]. Areas of systemic vulnerability are more likely to become exposed (or exaggerated) when quick decisions must be made during high-risk situations or procedures [2, 58]. In an important study of episodes of “escalation of care” on surgical wards, failure at any step of the “escalation” process (e.g., from nurse to junior resident to senior resident to attending/consultant) has the potential to result in increased morbidity and mortality [59]. Healthcare systems in general have relatively little redundancy of resources, and when compared to other “high-risk” fields like aviation and the military, the ability to compensate for any systemic error (e.g., dual tasking, debriefing, “backup behaviors”) is very limited [59].

Additional concerns regarding patient safety pertain to the physical plant and/or the geographical location of the healthcare team in relation to specific “points of care” [60–62]. Many hospitals and other healthcare facilities have expanded or branched to many communities, effectively making geography a barrier to direct communication [63, 64]. Outcomes resulting from the complex interplay between variables related to regionalization of care can become problematic when staffing levels fail to adequately match local institutional needs [65–67]. At times, the ability to effectively schedule and coordinate various teams for rounds, meetings, patient care coordination, case management discussions, family meetings, etc., are limited by the physical separation of facilities and stretching of the same resources across multiple sites. As a result, poorly organized meetings and more random encounters occur, resulting in potentially impaired transfers of vital patient information from provider to provider [56].

Another challenging area that affects patient care and safety is the evolution of the electronic medical record (EMR). Advantages of EMR include improved legibility, completeness of record, direct transmission, security and safety of information transfer, and access to large volumes of information [68]. However, the mere presence of EMR does not guarantee enhanced patient outcomes or safety. The built-in safety features like order sets, drug interactions, electronic verification and timing of results/studies, meaningful use, coding, etc., are only helpful and effective if the provider adopts and accesses the system proficiently. Significant education is required to reduce any potential barriers to proper EMR utilization. Among notable “stumbling blocks” in this domain are typing proficiency, motivation and personal initiative, comfort level with workarounds, and on-the-job practice. Other system challenges include physical space, ergonomics, electricity, wireless connectivity, and interinstitutional integration of data [68]. Thus, both personal and systemic limitations of EMRs have the potential to affect the quality and timeliness of patient care.

4. Human factors: individuals, teams, and institutional culture

Within the area of patient safety, human factors feature prominently as direct or indirect contributors to adverse events [69, 70]. A broad spectrum of variables to be considered here includes behavioral, cognitive, sensory, and other personal modulators of individual performance [70–73]. In their interim assessment of progress achieved following the landmark *To Err Is Human* report, Leape and Berwick point out that although the overall “... efforts are affecting safety at the margin, their overall impact is hard to see in national statistics...” [74]. This was one reason for the implementation of duty hour restrictions for residents in 2011; however, in 2017, the pendulum has swung back toward a more “hybrid on-call model” partly because the restriction on hours which was supposed to help prevent errors related to fatigue perhaps did not account for system errors in hand-offs [75–77].

Increasing awareness of the importance of team and system errors shifted the “safety focus” from individual providers to clinical teams, patient care units, and institutions in general [78, 79]. A recent study nicely demonstrated that great majority of patient safety events related to unintentional surgical item retention involved team or system errors and that isolated human factors were involved in fewer than 10% of instances [3]. The complexity of the overall system-wide consideration is further highlighted by the fact that two or more safety omissions were involved in >52% of cases of retained surgical items in the same study [3]. A less recognized aspect of patient safety, yet perhaps the most dramatic, and one that can have lasting deleterious effects on all stakeholders when it occurs, is self-harm in the general hospital setting. Inpatient suicide is the second most common sentinel event (12% of all sentinel events) according to the Joint Commission on Accreditation of Healthcare Organizations, yet research on this is sparse [80]. As we read each chapter in

the *Vignettes in Patient Safety*, it becomes apparent how important effective teamwork and institutional system design are to ensuring that our healthcare facilities and teams are setup for success [79, 81].

A final obstacle to improving safety in healthcare is the very culture of healthcare itself. In the high-risk environment of medicine, a tendency may emerge for quality review processes to employ “culture of blame” instead of a “just culture” or other, more collaborative models [82–85]. Many healthcare professionals are concerned about corrective and punitive actions related to unintentional errors. This fear of failure can lead to under-reporting of medical errors and therefore diminished ability to prevent future correction/remediation for the individual physician as well as their peers [86, 87]. Learning from mistakes is not a common adage that is comforting to a physician. Fear of error should not be thought of as an individual’s failure but rather a “collective responsibility” for future education and improvement [82].

5. Overcoming challenges: embracing effective solutions and evidence-based interventions

Each new patient safety event represents a setback, and many such setbacks occur each and every day. Despite this, it is our hope that the number of patient safety events will show a downward trajectory as the collective awareness of various mechanisms and risks involved improves. We believe that the ultimate goal of “zero incidence” can, and will, be achieved. After all, each setback is an opportunity to learn, self-reflect, and ultimately improve. The complexity of the healthcare industry, with multiple distinct specialties that deal with diverse patient populations, is far greater than that of most other industries. This may be one of the reasons why HRMs that work so well for the aviation industry are only the beginning of a long and challenging process of healthcare safety improvement. Further, the limited scope of the current efforts to improve patient safety, including lack of a truly comprehensive nationwide monitoring and surveillance system, severely hinders the progress of large-scale efforts in this critically important area [74].

Given the above considerations, as well as the heterogeneity of factors that contribute to patient safety events, our editorial team felt it was critically important to direct the reader to some of the most prominent recent studies in patient safety. Instead of reverting to the traditional collection of “classics,” we opted to limit our search to the past 5 years (2012–2017) and present information that may help refocus and redirect global patient safety efforts. These articles are summarized in **Table 1**. Among the most important topics reviewed here are interventions centered on hospital-acquired infections, surgical checklists, patient handoffs, other human factors/team considerations, and the use of EMR to reduce errors. In addition, an outline of recommendations made by the American Medical Informatics Association (AMIA) is provided in **Table 2** [88].

Author (year)	Title/topic	Study details	Summary/comment
Aiken et al. (2012) [89]	Patient safety, satisfaction, and quality of hospital care: cross-sectional surveys of nurses and patients in 12 countries in Europe and the United States	Cross-sectional survey of >33,600 nurses and >11,300 pts. in Europe as well as >27,500 nurses and >120,000 pts. in the United States	The study involved nursing surveys from 488 hospitals in 12 European countries and 617 hospitals in the United States. Patient surveys were administered in 210 European hospitals and 430 US hospitals. The authors found an association between nursing environment (staffing, teamwork, and managerial support) and patient satisfaction, quality, and safety of care
Arriaga et al. (2013) [90]	Simulation-based trial of surgical checklists	Operating room teams from three institutions participated in a series of surgical-crisis scenarios. Each team managed half using a checklist and half by memory	A total of 17 teams participated in 106 simulations. Only 6% of “steps” were missed when checklist is used versus 23% when teams utilized memory without checklist(s). Study findings suggest that checklist may enhance surgical care protocol compliance during crisis scenarios
Borchard et al. (2012) [91]	A systematic review of the effectiveness, compliance, and critical factors for implementation of surgical safety checklists in surgery	The authors performed a meta-analysis of 22 source manuscripts. The study examined outcomes including checklist effectiveness and compliance	The use of surgical safety checklists reduces the relative risk for both mortality (OR 0.57, 95% CI 0.42–0.76) and complications (OR 0.63, 95% CI 0.58–0.67). Overall “checklist compliance” varied between 12 and 100%, although compliance for “time out” procedures was notably better (70–100%)
Climo et al. (2013) [92]	Effect of daily chlorhexidine bathing on hospital-acquired infection	The authors performed a multi-center, cluster-randomized, non-blinded crossover trial that included 7727 patients in 6 hospitals (ICUs or bone marrow transplantation units) between August 2007 and February 2009. Authors compared chlorhexidine-impregnated washcloths with nonantimicrobial washcloths	The study demonstrated that the rate of multidrug-resistant organism acquisition was 23% lower in the chlorhexidine bathing group. It was also noted that the rate of hospital-acquired bloodstream infections was 28% lower with chlorhexidine versus nonantimicrobial washcloth use
Fan et al. (2016) [93]	Association of safety culture with surgical-site infection outcomes	The authors examined 12 dimensions of safety culture and colon surgical-site infection rates in surgical units of Minnesota community hospitals. Adjustments for surgical volume and ASA classification were made	The study suggest that positive surgical unit safety culture, teamwork, and engaged hospital management significantly correlate with lower colon surgical-site infection rates
Kwan et al. (2013) [94]	Medication reconciliation during transitions of care as a patient safety strategy: a systematic review	The authors conducted a meta-analytic exploration incorporating 18 studies evaluating 20 interventions in the area of medication reconciliation	The authors noted that while medication reconciliation is intended to avoid potentially significant errors during transitions of care, clinically significant discrepancies affect only a few patients. They further point out that although hospital-based medication reconciliation alone does not reduce post-discharge hospital utilization within 30 days, it may do so when combined with other interventions designed specifically to enhance discharge coordination. Finally, the authors emphasize the critical importance of pharmacists in the transitions of care process

Author (year)	Title/topic	Study details	Summary/comment
Lau et al. (2015) [95]	Individualized performance feedback to surgical residents improves appropriate venous thromboembolism prophylaxis prescription and reduces potentially preventable VTE: a prospective cohort study	Prospective cohort study evaluated the effect of performance feedback to general surgery residents regarding safe venous thromboembolism (VTE) prophylaxis prescription practices and compliance in the context of patient outcomes	The authors found that personalized “clinical effectiveness feedback” including data and peer-to-peer coaching improved residence compliance and reduced preventable VTE. Resident performance was assessed at three study periods: (a) baseline, (b) scorecard implementation, and (c) scorecard plus coaching. Both interventions resulted insignificantly improved resident prescription practices, ultimately reducing patient harm
Magill et al. (2014) [96]	Multistate point-prevalence survey of healthcare-associated infections	The authors conducted a 1-day survey of randomly selected inpatients in participating hospitals. Healthcare-associated infections (HCAI) were defined in accordance to the National Healthcare Safety Network criteria. The survey included nearly 11,300 patients in 183 hospitals	The study estimated that HCAI affected 4.0% of surveyed patients (95% CI, 3.7–4.4%). The authors point out that there were approximately 648,000 patients with 721,800 HCAI in the United States acute care hospitals in 2011. Most common types of HCAI, according to the study, included pneumonia (~22%), surgical-site infections (~22%), and gastrointestinal (~17%) infections
De Meester et al. (2013) [97]	SBAR improves nurse-physician communication and reduces unexpected death: a pre- and postintervention study	The study involved the training of 16 hospital ward nurses in the use of SBAR technique to enhance communication with physicians in cases of patient clinical deterioration	Out of more than 37,200 admissions, 207 serious adverse events (SAE) occurred. These events were checked for SBAR-related items, including 425 associated nurse interviews. The study found that the post-intervention use of SBAR during SAE increased markedly, from 4 to 35%. Although the number of unplanned ICU admission increased, the number of unexpected deaths decreased as a result
Middleton et al. (2013) [88]	Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA	Report outlining recommendations from the task force dedicated to addressing errors associated with the use of electronic health records (EHR); AMIA = American Medical Informatics Association	After comprehensively reviewing and analyzing existing literature, in combination with expert-based experiences, the AMIA task force proposes 10 recommendations regarding HER use and human factors, policy, industry, and clinical practice. These recommendations are further outlined in Table 2 of this chapter
Moffatt-Bruce et al. (2014) [98]	Risk factors for retained surgical items: a meta-analysis and proposed risk stratification system	A meta-analytic study of the best available evidence on risk factors for retained surgical items (RSI). Three retrospective, case-control studies were included	The authors found substantial synergies between existing studies, with seven out of ten parameters common to the three source studies becoming significantly associated with RSI risk in the meta-analysis. These factors included operative blood loss >500 mL, incorrect or absent surgical count(s), more than one sub-procedure, more than one surgical team, longer duration of surgery, and the presence of unexpected intraoperative factor(s)
Morello et al. (2013) [99]	Strategies for improving patient safety culture in hospitals: a systematic review	The authors performed a meta-analysis of 21 articles utilizing quantitative measures of patient safety climate in a hospital setting	The effect of patient safety climate strategies, including leadership rounds, educational programs, simulation, and team-based approaches, remains controversial. Further studies are needed to better define the impact of comprehensive programs designed to enhance institutional patient safety culture

Author (year)	Title/topic	Study details	Summary/comment
Randmaa et al. (2014) [100]	SBAR improves communication and safety climate and decreases incident reports due to communication errors in an anesthetic clinic: a prospective intervention study	The article describes the result of an implementation of the SBAR communication tool in anesthesia clinics at two hospitals in Sweden	The introduction of SBAR enhanced staff member perception of communication and safety climate and decreased incident reports related to communication errors (from 31 to 11%)
Richter et al. (2014) [101]	The influence of organizational factors on patient safety: examining successful handoffs in healthcare	Over 515,600 participants from more than 1050 hospitals completed Hospital Survey on Patient Safety Culture Perceptions. Organizational factors that influenced patient safety were assessed, including data from institutional staff and management respondents	The perception of teamwork was the best predictor of perceived successful handoffs among hospital units. Management and staff encouragement of safe practices also strongly correlated with positive outlook on patient handoffs
Sheth et al. (2016) [102]	Changes in efficiency and safety culture after integration of an I-PASS-supported handoff process	Prospective intervention to determine the efficacy of I-PASS (illness severity, patient summary, action list, situation awareness and contingency plans, and synthesis by receiver) handoff process	The implementation of the I-PASS tool improved transfer efficiency, safety culture scores, and satisfaction of providers and families transferring from the cardiovascular ICU to the acute care unit
Starmer et al. (2014) [103]	Changes in medical errors after implementation of a handoff program	The authors conducted a prospective interventional study involving 10,740 patients in 9 hospitals. Study intervention included (a) mnemonic to standardize verbal and written handoffs, (b) handoff and communication training, (c) faculty development and observation program, and (d) sustainability campaign. Active surveillance of error rates was conducted	As a result of the study intervention, the rate of medical errors decreased by 23% and the rate of preventable AEs decreased by 30%. Of note, the authors did not observe any negative effects on work flow
Stawicki et al. (2013, 2014) [3, 104]	(1) Retained surgical items: a problem yet to be solved (2) Natural history of retained surgical items supports the need for team training, early recognition, and prompt retrieval	(1) A retrospective, case-control study of risk factors for retained surgical items (RSI) (2) Post hoc analysis of data from the original RSI study, descriptive in nature	The original study [104] demonstrated that longer duration of surgery, safety variances, and incorrect surgical counts all independently elevated RSI risk. Of note, the study also demonstrated that lack of documentation was associated with RSIs—an indirect validation of patient safety documentation compliance efforts. The post-hoc analysis demonstrated that most RSI events involved team or system errors and that more than 50% of occurrences featured two or more safety omissions—an indirect validation of the “Swiss cheese” model of patient safety

Author (year)	Title/topic	Study details	Summary/comment
Tad-y et al. (2016) [105]	Leveraging a redesigned morbidity and mortality conference that incorporates the clinical and educational missions of improving quality and patient safety	Pilot program of system-based morbidity and mortality (M&M) conference model combining educational and clinical goals of enhancing patient safety	The authors' institutional M&M conferences reviewed 27 AEs over a 2-year period. A total of 63 action items were identified, of which 33 were actively pursued. Resident and faculty feedback to this model was positive, and as a result, more departments decided to adopt the same approach
Treadwell et al. (2014) [106]	Surgical checklists: a systematic review of impacts and implementation	The authors conducted a meta-analytic study of 33 source articles. Types of checklists eligible for analysis included the WHO checklist, the Surgical Patient Safety System (SURPASS) checklist, a wrong-site surgery checklist, and an anesthesia equipment checklist	Surgical checklists, adopted in various settings and specialties throughout the world, have been associated with decreased surgical complications and infections. Successful implementation depends on team communication, support of institutional leadership, and continuous feedback
Weaver et al. (2013) [107]	Promoting a culture of safety as a patient safety strategy: a systematic review	The authors performed a meta-analysis of 33 source studies, focusing data extraction on "... health care workers practicing in inpatient settings..." and "...change in patient safety culture or climate after a targeted intervention"	Team-based approaches, executive and interdisciplinary rounding, and the Comprehensive Unit-Based Safety Program have been found to be effective in improving clinician and staff perceptions of patient safety culture

Studies are listed alphabetically, sorted by the first author's last name.

OR = Odds ratio; 95% CI = 95% confidence interval; SBAR = Situation, Background, Assessment, Recommendation

Table 1. Summary of selected studies on patient safety and related topics, published since 2012.

Area of opportunity	AMIA recommendations
Usability and human factors in health IT	<p>Prioritization of standardized use cases</p> <p>Development of a core set of measures for AEs related to health IT use</p> <p>Research and promotion of best practices for safe and efficient implementation of EHR</p>
Policy related	<p>Standardization and interoperability across HER systems should incorporate "usability" concerns</p> <p>Establishing an AE reporting system for health IT, including voluntary health IT reporting</p> <p>Development and dissemination of educational materials and information regarding the safe and effective use of EHR</p>
Industry related	<p>Development of a common user interface style guide for select (e.g., critical) EHR functionalities</p> <p>The performance of formal "usability" assessments on patient safety-sensitive (e.g., critical) EHR functionalities</p>
Clinical end-user related	<p>Adoption of best practices for EHR system implementation and ongoing management/maintenance</p> <p>Monitoring of how IT systems are being utilized and reporting of IT-related AEs</p>

IT = Information technology; AE = Adverse event

Table 2. Summary of recommendations made by the American Medical Informatics Association (AMIA) regarding patient safety and quality of care related to electronic health record (HER) use [88].

6. Summation and future directions

In the ever-changing healthcare environment, one fundamental principle must remain constant—universal and steadfast commitment to the continued improvements in PS, with corresponding assurances to those who literally entrust their lives to healthcare institutions and systems around the world. Steps to improve PS, as outlined in this chapter and throughout the *Vignettes*, include (a) recognizing current patient safety issues (and patterns); (b) dynamically modifying systems, education, and training related to patient safety; (c) educating healthcare professionals on the significance of PS models and the importance of patient safety culture; and (d) developing collaborations with all stakeholders, including patients, to decrease the incidence of errors and never events [2, 108]. Successful PS paradigms must recognize that humans are fallible and that mistakes in medicine will likely continue to be made, even if our current efforts decrease adverse events by 1–2 orders of magnitude [109]. Whenever identified, “slip-ups” or “near misses” should be promptly identified and addressed with appropriate training, successful communication, and safety checks. Additionally, patient safety systems must foster a culture of safety that emboldens communication, trust, and honesty [110]. This paradigm should include a universal understanding that most sentinel events are not a product of a single individual acting in isolation, but rather of multiple cofactors combining simultaneously and unpredictably to result in a patient safety occurrence.

There is growing evidence that institutions able to ensure appropriate staffing and balanced workloads can positively affect patient safety, lengths of stay, and organizational finances [111–114]. A retrospective observational study in a large tertiary medical center found that nurse staffing below target levels was associated with increased mortality [115]. Another prospective, randomized, controlled study showed that interns were less likely to make serious medical errors when they worked shorter shifts [116]. There is also data to suggest that patient mortality and resident well-being both improved after the American College of Graduate Medical Education (ACGME) reduced resident work hours in 2003 [117].

Communication errors between providers can adversely affect PS during routine care and even more so during emergency care and in code situations. Training and new processes have been put into place to minimize communication errors. It is also hoped that EMRs will decrease some of the communication errors resulting from poor handwriting. Diagnostic errors could be due to a wrong, missed, or delayed diagnosis. Since a missed or delayed diagnosis can lead to significant downstream costs, implications on both patient well-being and financial expenditures can be dramatic [118]. Encouraging providers to improve their metacognition (or “thinking about thinking”) and awareness of overconfidence can be helpful in reducing diagnostic errors [119]. Recently, there has also been an increased emphasis on systemic changes to minimize diagnostic errors, such as computer-based decision support tools. However, these can be associated with some unintended consequences. These tools can be time-consuming, and they can lead to unnecessary downstream testing. There is also a concern they could lead to provider “deskilling” over time [119].

Over the past two decades, the emergence of EHR/EMR led to a significant paradigm change in healthcare. In addition to diagnostic, communication, and other types of medical errors our systems have grown accustomed to addressing, health IT errors have emerged as a category of patient safety events requiring increasing levels of attention [120, 121]. There are a number of different types of health information technology-related errors, including occurrences resulting from equipment malfunction, incorrect usage, lost data, or unavailable equipment (downtime) [122]. In aggregate, these errors or any resulting clinical decisions could lead to significant patient harm. Having redundant hardware in place for essential patient care activities, improving data displays and user interface, and implementing robust training programs and prerelease testing are just some of the many ways we can reduce the number of health information technology-related errors [122].

Important ways to eliminate human error in medicine are safety checklists and standardized handoffs. A systematic review of safety checklists showed that operating room teamwork and communication greatly benefited from the introduction of these simple tools [123]. Checklists were thought to improve outcomes by opening pre-procedure communication, urging dissemination of valuable case-related materials, promoting teamwork and decision-making, highlighting knowledge gaps, and cultivating camaraderie [123]. The Situation, Background, Assessment, Recommendation (SBAR) handoff tool was created to enhance communication (Table 1). Through systemization of communication, healthcare teams have a shared expectation of what information is being exchanged and how it is organized. Implementation of the communication tool in the clinical setting has been shown to enhance the acceptance of patient safety climate, staff members' perception of communication between one another, as well as the number of incident reports associated with communication errors [100].

Finally, it must be acknowledged that our understanding of complex human systems continues to be poor at best. Consequently, our ability to reliably and consistently improve team and individual interactions remains severely limited. For example, the assessment of disruptive behavior(s) and their impact on PS is one of the key areas needing urgent attention and high-quality research [124, 125]. In the area of ineffective communication, significant amount of descriptive information is available, yet research on how to effectively intervene to improve outcomes in this domain continues to be deficient [126–128]. Last, but not least, it is critical for us to better understand the relationship between PS and provider quality of life, emotional intelligence, and mindfulness [129, 130].

7. Conclusion

As we open the second volume of the *Vignettes in Patient Safety*, we hope to provide the reader with a compelling argument for continued need for steadfast patient safety advocacy at all levels of our healthcare organizations. Although scenarios presented in this volume may be different from those presented in the first volume, common threads continue to emerge throughout the *Vignettes*—communication, checklists, teams, standardization, quality improvement, etc. Along those thematic lines, we also compiled a list of some of the most

impactful new (2012–2017, **Table 1**) studies in PS, and although this list is by no means comprehensive, it covers some of the most influential work in this field of scientific and clinical investigation. Your continued patronage and readership are greatly appreciated and will allow us to expand this series of practical and insightful books well into the future.

Author details

Julia C. Tolentino¹, Noel Martins², Joan Sweeney³, Christine Marchionni⁴, Pamela Valenza⁵, Thomas C. McGinely⁵, Thomas R. Wojda⁶, Michael S. Firstenberg⁷ and Stanislaw P. Stawicki^{1,6*}

*Address all correspondence to: stawicki.ace@gmail.com

1 Department of Surgery, St. Luke's University Health Network, Bethlehem, PA, United States

2 Department of Medicine, Division of Gastroenterology, St. Luke's University Health Network, Bethlehem, PA, United States

3 Center for Neurosciences, St. Luke's University Health Network, Bethlehem, PA, United States

4 Department of Psychiatry, St. Luke's University Health Network, Bethlehem, PA, United States

5 Department of Family Medicine – Warren Hospital Campus, St. Luke's University Health Network, Phillipsburg, NJ, United States

6 Department of Research & Innovation, St. Luke's University Health Network, Bethlehem, PA, United States

7 Cardiothoracic Surgery, Summa Health System, Akron, OH, United States

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Effective Handoff Communication

Jesse Clanton, Meghan Clark, Whitney Loggins and
Robert Herron

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Abstract

The patient handoff—the transfer of patient related health information from one caregiver to another—has come under increased scrutiny in recent years. This is due to many factors including high-profile and well documented incidents of medical errors, a subsequent magnified focus on patient safety by the general public, and changes in resident work hours which have had the unintentional consequence of increasing the number of necessary handoffs during a given patient hospitalization. As medical care becomes more specialized and increasingly fragmented, handoffs are necessary in order to maintain consistency of information and plans of care. However, despite this increased focus, errors in transferring medical information are still common. In order to meet standards, many training organizations and medical institutions mandate lengthy handoffs at all levels. While initial studies demonstrated a decrease in medical errors after implementation of a standardized handoff bundle, more recent evidence calls into question those results. Certainly many components are necessary, can improve handoff communications, and reduce errors during a patient sign-out. However, more is not always better, and caregivers should not blindly attempt to transfer information unless there is medical necessity. Achieving a balance between “safe” and “effective” communication is the goal that we are still trying to achieve.

Keywords: handoff, sign-out, physician communication

1. Introduction

The patient handoff—the transfer of patient related health information from one caregiver to another—has come under increased scrutiny in recent years. As medical care becomes more specialized and increasingly fragmented, handoffs are necessary in order to maintain consistency of information and plans of care. High-profile incidents of medical errors, a magnified focus

on patient safety by the general public, and changes in resident work hours have all brought increased attention to patient handoffs. The unintended consequence has been a significant increase in the number and focus of handoffs a patient requires during hospitalization. However, despite this increased focus errors in transferring medical information are still common.

Communication among medical providers is a crucially important aspect to maintaining safe medical care. This becomes even more important as medical care becomes more complex, and more healthcare workers become involved in the care. This chapter evaluates the types and necessary components to effective handoffs, with particular attention placed on the current evidence concerning patient handoff communications and how they affect patient care and medical errors.

1.1. Clinical vignette

A group of residents meet for evening sign-out at the end of a long shift. Two residents arrive who are assigned to the night float service that month to receive the sign-out. The handoffs take place in the resident lounge, where many residents from other services are working and talking. The outgoing residents begin describing all the patients on each list to the night float team, taking time out to tell funny anecdotes about the day. The evening sign-out takes approximately one hour to cover over 100 current inpatients. That evening, Ms. Smith, a 53 year old female who is postop day #4 after a colostomy reversal begins to have shortness of breath and tachycardia, with a SpO₂ of 89%. The night float resident gets paged about the patient, but cannot recall anything special about her or any specific details to differentiate her from the other 100 patients that they recently discussed during sign-out. The resident evaluates the patient and reviews her history and hospital course on the electronic medical record system, noting that she has been doing well postoperatively but has a history of congestive heart failure and takes daily diuretics at home, which has not yet been prescribed as an inpatient. A CXR is ordered and demonstrates pulmonary edema. Lasix is given and the patient improves.

2. Importance of handoffs

Without a doubt, as medical care becomes more specialized, the care of patients consequently becomes more fragmented. Resident work hour restrictions have also contributed to this increased fragmentation. Several studies and organizations, namely the Accreditation Council for Graduate Medical Education (ACGME) and Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), have emphasized the training of residents in effective handoff communications, as well as recommending the implementation of consistent evaluations of the handoff communication systems to ensure the transition of adequate patient care between physicians [1, 2].

In order to understand why effective handoffs are paramount to safe patient care, it is important to appreciate the adverse consequences that result from a lack of adequate communication. Errors in communication between treating providers have been implicated in delayed diagnostic evaluations, medications errors, and more patient complications [3]. Lapses in communication are currently considered the leading cause of unexpected events that lead to

serious physical harm or even death to the patient [4]. This has led the Agency for healthcare research and quality (AHRQ) and the accreditation council for graduate medical education (ACGME) have made the improvement of patient handoffs a priority in order to promote the improvement of patient safety [5, 6]. These agencies recognize the importance of an effective handoff and communication system to prevent errors that may lead to significant patient harm, ultimately resulting in better the care of the patient.

A key factor that has necessitated the increased use of handoff communication systems has been the advent of restrictions to resident physician duty hours. In 2003, the ACGME instituted the 80-hour work week in an attempt to reduce resident fatigue and thus improve patient safety [7]. A survey conducted by Antiel et al. found that as of 2013, most residency program directors agree with the current duty hour restrictions and resident workloads, indicating that the restrictions in resident duty hours are here to stay [8]. These restrictions have constituted one of the main reasons why handoffs have become so important. The unintended consequences have been a “shift work” mentality among residents striving to adhere to duty hour restrictions and more transitions of care that must necessarily occur. The resultant increase in necessary sign-outs and handoffs during a particular patient’s hospitalization has risen as the rules have become ever more stringent. For example, after the implementation of the 16-hour limit, a typical PGY-1 resident participated in excess of 300 handoffs per week [9]. This many handoffs can lead to residents unfamiliar with a patient’s condition, and the patient and family members may even sense a lack of continuity of care. Therefore, more research has been devoted to the creation and effective utilization of handoff systems [6, 7]. The ACGME has recommended not only implementation of a handoff communication system, but also the evaluation and training of residents as part of their residency training as a whole [10]. Thus, the importance of adequate communication between physicians and effective handoffs cannot be underestimated. To avoid miscommunication between treating physicians as they enter or leave their now shortened shifts, detailed handoffs are now the standard when it comes to modern graduate medical education.

The increasing complexity of medicine as a field has led to an increase in specialization, and thus a tendency towards more fragmented care. A hospitalized patient, who would have had a single physician care for them 30 years ago, now may have dozens of physicians, consultants, specialists, residents, and medical students take part in their care. As this becomes more frequent in medical practice, the ability to provide consistent and satisfactory communication between providers will continue to prove paramount. Organizations such as the ACGME and JCAHO continue to place increased emphasis on the improvement on handoff communication and highlight another reason why handoffs are an important part of medical care. This aspect of medical care will continue to be at the forefront of the continued efforts to improve quality of care and patient safety for the foreseeable future.

3. Characteristics of an effective handoff

Prior to the implementation of duty hour limitations, little focus was placed on physician handoff practices. However, since the advent of duty hour restriction in 2003, examination

of transitions of care, resident handoffs, and physician sign-outs have become a topic of much research. Multiple investigations have attempted to determine how this process is optimally conducted and what actually constitutes an effective handoff that successfully improves patient safety. Particular measures in the literature that have been studied include length of hospital admission, delays in care, ordering of unnecessary laboratory tests, and adverse safety events. However, because historically handoff procedures in medicine have not been well studied or standardized, even now there is no true consensus on a standardized approach or universal curriculum for handoffs. Therefore, some studies suggest using handoff models from other industries, especially other high-risk industries such as commercial aviation. In these fields handoff systems are standardized and typically involve aspects that are thought to improve success, such as utilizing specific checklists, face-to-face communication, and meeting in a designated/non-distracting environment [11].

As the topic of handoffs continues to remain in focus, multiple national healthcare organizations have weighed in. The Joint Commission made a “standardized approach to hand-off communications” a National Patient Safety Goal in 2006 [1]. Current ACGME Common Program requirements include transitions of care as a requirement for patient safety [6]. The ACGME’s requirements for handoffs/transitions of care are defined as:

1. Programs must design clinical assignments to minimize the number of transitions in patient care.
2. Sponsoring institutions and programs must ensure and monitor effective, structured hand-over processes to facilitate both continuity of care and patient safety.
3. Programs must ensure that residents are competent in communicating with team members in the hand-over process.
4. The sponsoring institution must ensure the availability of schedules that inform all members of the health care team of attending physicians and residents currently responsible for each patient’s care [10].

In our example vignette, the residents participated in mandatory handoff procedures, but it was likely not optimal. This is just one example, and in reality the current practice of handoffs can vary widely among residency programs across the country. A handoff can be as short as one minute for a whole patient list [12]. The location of the handoff is not always standard and it may be conducted almost anywhere. Content of a given handoff is rarely standardized, and is generally up to the discretion of the physician giving the handoff. All of these inconsistencies in the handoff process may lead to suboptimal care. Improvement of the handoff process requires greater attention to closed loop communication with team members.

Multiple items have been suggested in the literature to improve the handoff process [9]. An effective handoff first requires a tool to make the process simpler and easier, so as not to rely solely on the memory of the physician. A consistent and updated list of patients should be maintained and utilized to assist with sign-outs. This could be a computerized check out tool, whether a Word document, Excel spreadsheet, or linked into the electronic medical record

(EMR). While a written sign-out list is beneficial, it should not be a substitute for verbal communication with team members. The use of electronic communication alone could lead to inadequate handoff and lead to missed information [10]. Effective communication skills such as “read back” should be used to guarantee that information is accurately passed along. This is best accomplished by face-to-face interactions [9]. Many experts recommend a systematic way of proceeding during sign-outs, such as a specific system or mnemonic. It is also vital to allow enough time for a complete check out on each patient. Handoffs should be completed at the beginning and at the end of each shift in order to keep changing teams adequately informed. It has been shown that morning handoffs are often ignored and that one in three events that occur overnight are not reported to the day team [12]. This can lead to adverse outcomes as the oncoming day team is not aware of most current events. It is also recommended that handoffs take place in a quiet, well-lit, designated area that respects patient confidentiality. This place should also include access to computers [9]. Efforts should be taken to minimize distractions and interruptions from phone calls and non-emergent pages during this designated time [12]. The example handoff at the beginning of this chapter lacked many of these suggested best practice items, and subsequently the quality of the handoff suffered and the information passed on to the night float residents during the sign-out was ineffective for the problem that occurred during that shift.

Residents have a significant stake in successfully implementing effective handoffs, not only because of their involvement in patient care, but because they are the ones most often performing said handoffs. Among residents surveyed, the following items were found to be important in improving the handoff process: up-to-date room number, recent cognitive/cardiopulmonary status, problems the patient has already experience and treatment already tried, code status and level of care discussions, and results that were likely to return while covering physician was on-call and what to do, and any psychosocial issues [9]. It is of note that handoffs are conducted most of the time by interns.

Ultimately while organizations such as JCAHO and ACGME recommend training in and evaluation of effective handoff communications, a major obstacle is that it is unclear exactly what “effective handoff communication” entails. There is not currently a proven best practice standard for handoff communication. Several methods have been proposed (SBAR, I-PASS), but do not work in all situations for all levels of medical caregivers. A truly effective handoff would be the most efficient transfer of only the necessary information required to care for the patient. However, it is still unclear exactly what components of a handoff are necessary, and which components are superfluous and do not improve communication or contribute to patient safety.

4. Obstacles to effective handoffs

It is well documented in the literature that issues in handoff communications exist among residents and can lead to adverse events. These issues can be related to communication, the handoff process itself, or even hospital or system-wide problems.

4.1. Communication failures

Communication failures in transition of care are one of the most frequently cited contributing factors to adverse and sentinel events. While they are a frequent cause of errors, unfortunately miscommunications are commonplace during resident handoffs. In a study of pediatric interns, the most important piece of information about a patient was not communicated 60% of the time [13]. Additionally, another 60% of the time post-call and on-call interns did not agree on rationale for items discussed during the handoff [13]. Although the interns did not often agree on necessary items, they still rated handoff quality as high, suggesting that they overestimated the effectiveness of their own handoffs.

Distractions also represent a major obstacle to effective communication. Distraction is documented as the cause of up to half the errors that occur in the aviation industry [14]. Studies have been conducted to define what type of distractions and disruptions plague the handoff process. Anderson et al. found that distractions were common, being present in 48% of handoffs observed, and these distractions were often multiple [14]. It was found that junior residents often had more distractions [14]. Pages and phone calls were the most common offenders being present 38 and 33% of the time. Increased number of distractions led to significantly increased time spent on handoff. Despite these factors, just as the residents above, those surveyed did not feel the distractions negatively impacted their handoff process. Hasan et al. found distractions even more common, at 70% of handoffs, and more numerous averaging five distractions per handoff [15]. Extraneous staff entering/exiting room was found to be the most common distraction in this study.

Distractions may slow the momentum of the handoff, negatively impacting the process. This most commonly happens when opportunities for teaching are taken and when a large number of side conversations are present in the area where the handoff occurs. This emphasizes the importance of handoffs taking place in a quiet area away from other hospital personnel. Many of these distractions were present in the example vignette, as the handoff did not take place in a designated quiet room free of distractions. Many of these distractions can lead to an increased time to complete handoffs, and take away from other clinical or education activities.

An interesting barrier to effective handoffs is resident relationships with each other. The presence of a hierarchy negatively affected the handoff process, while a good relationship between the residents was associated with more positive outcomes [15]. This accentuates the importance of developing a hierarchy-free environment during handoffs. Handoff should be dynamic and a forum to ask questions in an active discussion [16]. This is more easily achieved in a collegial environment of peers.

4.2. Ineffective handoff processes

Many causes of poor handoffs are a result of the handoff process itself. In order for any standardized approach to communication to succeed, it is important that all team members are properly aware of and educated about the process before implementation. However, residents often do not receive any formal training in handoff communications and procedures. Additionally, even if residents are required to participate in formal handoff procedures, there is often a lack of instruction

or guidance in the form of a standardized handoff process. Standardizing the handoff process has been shown to significantly improve feelings of confidence related to the handoff [15].

Other obstacles are often more intrinsic to the residents and day-to-day operations of residency. These obstacles to effective handoff are things such as team members being unavailable at the time of handoff, feeling the EMR is difficult [17]. The most significant problem repeatedly stated however is time constraints [17]. The feeling of time constraint as an obstacle to proper handoffs underscores the importance of designated time and space for handoff communications.

Interns are typically the team members who most often participate in handoffs, creating an inherent problem where the least knowledge and experienced members are responsible for the transfer of important information. Observations are conflicting on whether postgraduate levels affect quality of handoff, however. Inadequate plans from upper levels residents has been suggested as an additional obstacle to effective handoffs. There are some observations that handoff was superior when completed by a PGY-2 or greater, but this has not been validated by additional studies [15].

4.3. System processes and barriers

Creating the necessary culture where handoffs are accepted can be a major hurdle to implementation. Without buy in from senior leadership, administrators, and respected peers, even the most well designed handoff would be doomed to fail. Many institutions continually promote a “culture of safety” in order to point out the rationale and benefits to patients. Including residents into this process can improve success, as they have a natural stake in promoting patient safety. In one resident survey, 59% of residents considered patient safety was compromised due to ineffective/problematic handoff and 12% reported the harm to the patient was major [18].

The 2011 ACGME revisions to duty hour requirements has also had unintended consequences related to handoffs. As interns are the ones most frequently participating in handoffs, the 16 h rule has created so-called “double sign-outs” or receiving sign-out on another service’s patients, followed by signing those patients out to a subsequent shift of cross coverage [17]. As the frequency of double sign-outs or handoffs is common, this has caused interns to have major concerns about treatment plans for these patients or failure to carry out said plans.

The complexity of the obstacles facing patient handoffs is great, but not insurmountable. As ongoing research and standardization of the handoff process continues, improvement is inevitable. Handoffs are a vital part of patient care and need to be in a state of constant evaluation for best practices to minimize adverse outcomes caused by these obstacles.

5. Handoff models

Many models have been developed in an effort to systematically address the common barriers to effective handoff communication. There is still only limited data on the effect of specific models on patient safety and outcomes. Generally, handoffs are composed of verbal and written components.

5.1. Verbal handoff models

5.1.1. SBAR

The most commonly utilized handoff model currently used in healthcare is “SBAR.” SBAR stands for situation, background, awareness, recommendation and refers to four topics that should be addressed for a complete and efficient transfer of information about a patient. It was developed by Dr. Michael Leonard on behalf of Kaiser Permanente in an effort to develop a verbal communication paradigm to aid physicians in cultivating a shared mental model of each patient’s clinical picture and in the spirit of reducing communication errors known to be a root cause of adverse events [19]. The goal of this model was to transcend communication differences between interdisciplinary team members so that all members have the same knowledge of each patient’s clinical situation. It establishes a framework of communication for what information is relayed and how, which is paramount in cultivating teamwork and a culture of patient safety [20].

The physician guidelines for SBAR tool are presented in **Table 1**: [generously provided for redistribution by the Institute for Healthcare Improvement in the spirit of patient safety].

Of the verbal communication models in healthcare, SBAR is one of the oldest and most widely known. SBAR was designed specifically to target communication hurdles that can arise in healthcare settings, such as different training backgrounds, hierarchy, poor working relationships, or differences in communication styles, which makes it broadly applicable in healthcare [19]. Many early studies describing implementation of a verbal communication model and the effects on patient safety outcomes utilized SBAR. In 2004, after a community hospital implemented an institution wide adoption of the SBAR verbal communication tool the rate of adverse events went from 89.9 per 1,000 patient days to 39.96 per 1000 patient days the following year [19]. Since then, several studies have been conducted with similar results [19, 21]. Given that physicians constantly have to communicate with other professionals on the health-care team, and that improved interdisciplinary communication improves patient safety, it

	Definition	Instructions
Situation	The event happening at the present time that has warranted the SBAR communication	Identify self, unit, patient, room number Briefly state the problem, when it happened, and how severe.
Background	Pertinent background information related to the situation	Admitting diagnosis and date of admission Most recent vital signs Pertinent medications, allergies, and lab results (including date and time done and results of previous tests for comparison) Code status
Assessment	The current assessment of the situation	
Recommendation	What is the recommendation or what does he/she want?	Notification that patient has been admitted Patient needs to be seen now Order change

Table 1. Physician guidelines for SBAR tool.

is reasonable to deduce how resident training using the SBAR model is advantageous. Its impact on hierarchies and facilitation of open communication is of particular use in residency where steep hierarchies often exist and have been shown to impede communication. Effective verbal tools, such as SBAR, improve all aspects of clinical communication, not just physician-physician interactions.

Practically speaking, implementation of the SBAR verbal communication strategy for resident handoffs is relatively straightforward and requires minimal time investment. Tews et al. [22] piloted an SBAR training program among first year Emergency Medicine residents during their first year curriculum from 2008 to 2011 in an effort to improve inter-physician communication skills. The residents were individually presented a case developed by faculty and asked to present to an examiner who evaluated their presentation according to a 17-item SBAR checklist adopted from Haig et al. [19]. Following the initial presentation, they had a 1 h didactic session on patient safety and SBAR presentations. After the didactic session they were re-evaluated and given a survey. They found statistically significant improvement in scores post training compared with pre training. After the training session they were given an SBAR pocket card with instructions for reference. A few months later they were given another case to present and were re-evaluated. They found no statistically significant difference in scores from the initial post training evaluation, suggesting good retention of skills acquired from the initial training session. Additionally, the implementation of SBAR was well received by the residents according to surveys. Residents reported their training was effective, had potential to prevent medical errors in communication, and were more comfortable with case presentations. Although this study showed promise in the practicality of integrating SBAR verbal handoff skills into resident curriculum, it should be noted that this was done in the setting of emergency room transitions of care, and thus we cannot necessarily be extrapolated to other settings or specialties.

Although SBAR is a verbal communication model that is broadly applicable across healthcare settings, it does have some limitations, especially in physician-physician handoffs. It is unrealistic and overly simplistic to expect a standardized verbal communication structure to be the most efficient form of communication among all specialties. There is very little research specifically on SBAR applied to physician-physician communication—most studies have been on nurse-nurse or interdisciplinary communication. Physicians communicate with each other differently than they do other members of the healthcare team, which is likely attributed to training, shared fund-of-knowledge, and culture [19]. Given the complexity of information transferred between physicians during handoffs and fundamental differences in communication style, it is intuitive that a handoff tool so broadly applicable in healthcare settings such as SBAR is not particularly well suited for such information transfer. One of the most prominent criticisms of SBAR is its shortcomings in the settings of intensive care units and complex patient [23].

5.1.2. Signout

While SBAR is widely known across healthcare settings, it is not the only available verbal handoff model. In a review done by Riesenberget al. of the handoff mnemonics in literature, SBAR was the most frequently cited at 32 out of 46 total articles [24]. The only two verbal

handoff strategies reviewed by Riesenbergs with any post-implementation data were SBAR and SIGNOUT. Horwitz et al. [25] originally developed the SIGNOUT model in an effort to implement a standardized verbal sign-out curriculum. They prioritized concrete language, sufficient description of clinical picture, anticipatory guidance, and clear plans with rationales for all assigned tasks [25].

5.1.3. Signout mnemonic: (adapted from Horwitz et al. [25])

S—Sick or DNR? (emphasize unstable patients, designate DNR/DNT patients)

Example: “This patient is pretty stable—she is a full code”

I—Identifying data (name, age, gender, diagnosis)

Example: “Ms. Smith is a 68-year-old woman admitted for mesenteric ischemia.”

G—General hospital course

Example: “She came in with sudden onset severe abdominal pain, nausea, and vomiting. Abdominal CT suggested embolic SMA occlusion. Status post SMA embolectomy, postop day 1.”

N—New events of the day

Example: “Lactic acid and WBC counts are trending down. She had low urine output for a few hours this morning, but we increased her fluids to 150 and it has picked back up.”

O—Overall health status/clinical condition

Example: “She is normotensive, 98% on room air, and afebrile.”

U—Upcoming possibilities with plan and rationale

Example: “If her oxygen level decreases overnight, turn off her fluids and give her a 40 mg of Lasix.”

T—Tasks to complete during shift with plan and rationale

Example: “Her wound VAC seal alarm keeps going off, please go change the adhesive dressing. Leave the sponge.”

?—Opportunity for questions and clarification.

The SIGNOUT model was intended to address some of the shortcomings of SBAR, particularly the information required in complex clinical situations and inter-physician communication. Unfortunately, Horwitz et al. [25] did not utilize an evaluation tool to objectively measure the quality of handoffs post-implementation, and their evaluation was based solely on resident surveys. Additionally, there is no data on any patient or safety outcomes after implementation of the SIGNOUT model. Essentially, there is very limited data on the SIGNOUT verbal communication model and its impact on quality of resident handoffs and patient safety. However, SIGNOUT was further elaborated and a source of inspiration for a resident handoff education bundle known as I-PASS, discussed in further sections.

5.2. Written handoff tools

Although limited research has been done on specific verbal handoff models, there have been even fewer studies to elucidate best practices for the written handoff document. Written hand-off documents traditionally contain a list of patients a provider or team is responsible for and corresponding demographics and clinical information. In the era of information technology we have seen a shift from paper-based hand-written handoffs to computer-based handoff tools. It is hopefully apparent that with all the technology at our disposal, manually writing hand-off documentation for each patient is archaic and a poor utilization of time. Computer-based handoff tools are either standalone documents (i.e., word or excel document) or integrated into the hospitals electronic medical records. Vidyarthi et al. [9] were one of the first to set out to make recommendations on resident handoffs, and they proposed that the content of written handoff be divided into five categories based on the mnemonic ANTICIPate (Administrative data, new information, tasks, illness, contingency planning/code status). These items were validated by both expert opinions and subsequent resident evaluations of the tool.

Anticipate checklist (adapted from Vidyarthi et al. [9])

- | | |
|---|--|
| • Administrative data | <ul style="list-style-type: none"> • Patient name, age, gender • MRN, room number • Admission date • Primary team • Family contact information |
| • New information | <ul style="list-style-type: none"> • CC, brief HPI, dx/ddx • Updated list of medications with doses • Allergies • Assessment and plan by system with dates • Current status: mental, cardiopulmonary, vitals. Note stability and patient norm • Recent procedures and significant events |
| • Tasks | <ul style="list-style-type: none"> • Specific tasks that need to be done in that shift • Highlight any results expected to come back and what to do about them |
| • Illness | <ul style="list-style-type: none"> • Illness severity—stable, watcher, unstable |
| • Contingency Planning/code status | <ul style="list-style-type: none"> • Anticipate possible issues and provide detailed plans for what to do when they arise • Brief statement of therapies that were successful and unsuccessful for that patient • Family/psychosocial situation • Code status |
-

According to a review of literature on handoff tools by Abraham et al. [26] in 2012, there has been a shift in increased use of EMR-integrated sign-out tools since 2008. This is likely due to

federal mandates pushing for standardization of electronic health records. The shift towards EMR-integrated written handoff tools is ideal because they are inherently more amenable to standardization initiatives by automatically populating current and accurate patient data from multiple sources in a patient's electronic chart [26].

The Joint Commission requires institutions to standardize patient handoffs and the ACGME requires residency programs to ensure their graduates are proficient in handoff skills, but neither organization provides any guidelines for essential components of the written handoff process [1, 10]. Though studies on standardized written handoff tools have been shown to decrease medical errors, no studies to date have been done on which elements of the written handoff document contribute to this improvement. Rosenbluth et al. [27] compared the written handoff tools of nine different academic institutions and found considerable variability between them. Their panel of experts made recommendations for best practices regarding essential elements of a written handoff document. A list of the essential elements agreed upon by the panel are as follows:

- Patient identifiers (name, MRN, date of birth)
- Hospital service identifiers (attending name, team/service, room number)
- Admission date
- Age
- Weight
- Illness severity
- Patient summary
- Action items
- Situation awareness/contingency plans
- Allergies
- Medications (preferably an auto-populated med list)

The following items the panel categorized as recommended, but not essential:

- Primary language
- Emergency contact
- Primary care provider
- Code status
- Labs
- Access
- Ins/outs
- Vitals

Although there have not been any data driven recommendations on which elements of information are essential for the written handoff document, there is some data to support that the structure of the information in the handoff document matters. Interestingly, the structure of written handoff documents has been shown to influence verbal communication during handoffs [26]. Traditionally, written handoffs have been constructed in a SOAP format—organized by subjective information, objective information, assessment/plan in problem list and associated interventions. Abraham et al. [26] compared the verbal communication patterns of care teams using traditional problem-based formatted written handoff documents with a novel systems-based document, called HAND-IT. It was designed to mirror medical school training by body system and organized by relevance of critical-care workflow—pulmonary, cardiovascular, infectious disease, renal/genitourinary, gastrointestinal/liver/nutrition, neurology, endocrinology, hematology [26]. Each category is organized in a checklist to include physical exam findings, laboratory data, current medications, problem list, and assessment/plan. Additional categories such as patient admission, pending tasks, and contingency plan were developed for information that does not fit neatly into body system categories. They quantitated communication between teams by defining a communication event as the passing of a message through a channel for a particular purpose and rated exchanges based on effectiveness and efficiency. From this, communication events (CE) were categorized as ideal or non-ideal. Ideal CEs contained information that was sufficient and accurate. Exchanges that required additional information were considered non-ideal CEs and represented communication breakdown. They described the following four common types of communication breakdowns:

1. Incomplete information from senders: inability of the outgoing team to provide requested information.
2. Inaccurate and conflicting information: inability of outgoing team to provide correct information.
3. Irrelevant information: inability of outgoing team to provide appropriate information.
4. Incomplete or inaccurate information from team: inability of rest of the team to provide complete and accurate information.

Abraham et al. [26] found that teams using their HAND-IT written handoff document had more ideal CE communication and fewer non-ideal CEs than teams using the traditional SOAP format. Use of the SOAP format was associated with significantly more Type 1 and Type 4 errors. HAND-IT utilization was associated with significantly fewer communication breakdowns regarding diagnostic evaluation, management, or treatment. These findings indicate that teams using HAND-IT had more streamlined communication based on more complete information on their patients and a clearer understanding of their clinical condition.

5.3. I-Pass handoff bundle

The most comprehensive analysis of physician handoffs has been conducted on a combination of guidelines for both verbal and written handoff components, as well as a structured handoff curriculum for residents, called I-PASS [23]. The designers of the I-PASS handoff bundle set

out to combine techniques that optimize verbal and written handoff strategies in addition to a resident curriculum to implement it all. Taking inspiration from SBAR and SIGNOUT verbal strategies and combining with resident input, they developed the mnemonic I-PASS (illness severity, patient summary, action list, situation awareness and contingency plans, and synthesis by receiver), which served as a foundation for their verbal and written handoff strategy. I-PASS has gained popularity due to its focus on risk stratification, promoting early detection of patients most likely to decompensate and prompting providers to come up with contingency plans should the patient condition worsen. Table of I-PASS curriculum can be found in **Table 2**. Starmer and colleagues designed a resident curriculum on effective handoffs based on principles of the Team STEPPS approach to integrating teamwork into practice to improve the quality, safety, and efficiency of healthcare [18, 23]. I-PASS was first implemented in pediatric units at two hospitals, which after promising results was expanded to the pediatric units of nine Boston area hospitals [28, 29].

The authors looked at medical errors, adverse events, assessments of written handoffs, and resident workflow during their evaluation of the efficacy of the handoff model. There was a reduction in medical errors from 33.8 to 18.3 per 100 admissions after implementation on both units combined. Preventable adverse events were reduced from 3.3 to 1.5% after implementation. There were no changes in rates of non-preventable adverse events. Interestingly, 77% of errors and adverse events were related to medications. Although both units had improvement in quality of written handoff documents, the unit utilizing EMR-integrated tool showed significantly less data omissions (reduced omissions in 11 of 14 categories) compared to the unit utilizing the word processing tool (reduced omissions in 2 of 14 categories). There was no significant change in overall time spent at the computer or in time spent editing computerized handoff documents, but the time spent writing on printed copies of handoff documents decreased significantly. The amount of time spent with patients and families increased from 8.3 to 10.6%. The amount of time devoted to verbal handoffs did not change.

2-h communication training session based on TeamSTEPPS
Introduction of I-PASS mnemonic to standardize verbal handoffs
1 h role-playing session to practice skills from workshop
Computer module to allow for independent learning
Restructure verbal handoffs so both oncoming and off-going team members are present
Relocation of handoff to private, quiet space
Introduction of periodic handoff oversight by a chief resident or attending by a minimum of one observed handoff per resident per month to provide resident feedback
Faculty development program
Process-change and culture-change campaign to ensure program adoption and sustainability
EMR-integrated computerized handoff tool created to auto-populate useful and necessary patient information, and also contained free-text fields for: patient summary, to-do list, and contingency planning

Table 2. I-PASS curriculum.

Following the success of the initial I-PASS study, it was expanded to nine institutions [29]. All used standardized I-PASS written handoff tools—seven utilized EMR-integrated, while two utilized word processing. Across all nine institutions, combined medical-error rate decreased from 24.5 to 18.8 per 100 admissions. Preventable adverse events decreased from 4.7 to 3.3 per 100 admissions. Quality of verbal and written handoffs significantly improved at all nine sites, but only six institutions saw statistically significant reductions in error rates. For all combined sites there was no change in time spent with families, creating/editing handoff document, working at the computer, or writing on printed copies of handoff document.

Although the follow-up I-PASS study re-demonstrated improvement in the quality of verbal and written handoff skills without impacting resident workflow or time devoted to handoffs, the magnitude of its impact on medical errors and adverse events was less impressive than the initial study. The I-PASS handoff bundle is designed to be customizable to serve the needs of the unit using it. All subjects of these two studies were inpatient pediatric units at academic medical centers, and despite their similarity, institutions showed marked variability in their in their outcomes, ranging from 45% relative reduction to an 18% relative increase in medical errors. The variability between institutional responses calls into question the reproducibility of the effects of I-PASS on clinical outcomes, the ultimate goal of improved patient handoffs.

Studies conducted at small community pediatric residency programs demonstrated improved resident satisfaction, organization, and quality of handoffs while the time devoted to the hand-off process remained unchanged [30, 31]. Neither study had data on patient outcomes. These studies by Walia, Huth [30], and colleagues demonstrated that the I-PASS handoff bundle is effective at improving the quality of physician handoffs in programs with fewer resources to devote to implementation. Unfortunately, lack of patient outcome data precludes these studies from evaluating clinical significance of the bundle.

5.4. Maybe less is more

In order to meet standards, many training organizations and medical institutions mandate lengthy handoffs at all levels. This is done not only to attempt to reduce medical errors, but also often for bureaucratic compliance. While initial studies demonstrated a decrease in medical errors after implementation of a standardized handoff bundle, more recent evidence calls into question those results.

Another shortcoming on the previously discussed I-PASS studies is they were conducted on inpatient pediatric units and thus give limited information on how useful the bundle would be to other fields. Clarke and colleagues at M.D. Anderson Cancer Center addressed this when they adopted the I-PASS handoff bundle and modified it to accommodate their needs as a surgical oncology service [32]. All residents in the study completed the standard I-PASS handoff bundle training. They used the I-PASS approach to create a standardized electronic handoff tool with a database framework. Information was entered into a centralized secure database from resident responses through a structured data form with point-and-click and drop-down menus to speed entry of patient identifiers, acuity, ongoing issues, on-call tasks, and attending preferences (crystalloid vs. colloid, etc.) [32].

Overlapping responsibilities in the OR present a unique barrier to handoffs in surgical fields. Therefore, patient risk stratification guided the type of verbal handoff conducted for each patient, and only higher acuity patients were verbally handed off. Patients were divided into several categories: “watchers” were patients recommended to have the electronic handoff supplemented by a phone call, while “unstable” patients required a face-to-face handoff. Patients categorized as “stable” were not verbally handed off to the oncoming team. Percent of handoffs completed, accuracy of handoffs, number of documented postoperative checks, time required to create action lists for all patients (surrogate for workflow), mortality, duration of stay, and 30-day readmission rates in the pre- and post-intervention periods were measured. Only 21% of patients during the post-intervention period necessitated a verbal handoff to supplement the electronic handoff based on their illness severity. Overall, handoff compliance increased from 73 to 96%. The time spent preparing electronic handoffs decreased from 15 ± 2 to 5 ± 1 min. Outcome data of the randomly sampled surgical oncology patients (14%) during the study periods showed no statistically significant change in duration of stay (4.8 vs. 4.2 days; $P = 0.19$) or 30 day readmission rate (8.3 vs. 5.9%; $P = 0.43$). The I-PASS handoff bundle with modified electronic handoff tool linked to institutional database resulted in increased compliance, improved workflow, decreased communication errors, with no statistically significant impact on patient outcomes. Although the patient outcomes had positive trends, this study was not sufficiently powered to show changes in outcomes related to enhanced communication [32]. This study demonstrated adoption of I-PASS handoff bundle, with modifications to suit needs of the service can at the very least serve to achieve bureaucratic compliance of standardized handoffs without sacrificing workflow and even achieve improved communication and workflow efficiency.

The premise of standardized handoff recommendations and concomitant resident education made by the Joint Commission and ACGME is to improve patient care by reducing the number of errors due to communication breakdown. The effort to improve communication by standardizing the handoff process, while well intentioned, is proving to have only marginal effects on patient outcomes [29, 32, 33]. A large randomized trial by Clanton and colleagues compared a rigorous formal handoff and a minimalistic approach found no significant differences in patient outcomes [33]. This study differed from most recent handoff studies by virtue of being a randomized controlled trial, whereas previous studies all evaluated outcomes in only a before-and-after model, which can be subject to significant bias. Additionally, this study was conducted by implementing two different interventions: Formal vs. focused handoff methods during the study period. Before implementation all residents received formal training on SBAR verbal handoff mnemonic and participated in simulation to hone skills. The formal handoff protocol called for both written and verbal components, took place in a private, quiet environment, face-to-face in the presence of senior residents. Focused handoffs were minimalistic and informal with focus on high-acuity patients. The setting of these handoffs was left to the discretion of the residents and at times omitted when there were no high-acuity patients to discuss. The written component of handoffs generated from the patient list in the EMR remained the same throughout the study period and was used in both

formal and focused handoffs. Outcome data consisted of mortality, negative events, adverse events, length of stay, and ICU length of stay. Handoffs were evaluated randomly by trained observers during the study period to obtain data on duration, number of tasks assigned, and number of patients handed off. Formal handoffs had a mean of 35.2 ± 11.5 patients and took 20.6 ± 8.2 min with an average number of assigned tasks 5.7 ± 4.9 . Significantly less time was devoted to focused handoffs with a mean duration of 6.7 ± 9.5 min to discuss an average of 6.3 ± 9.9 patients. They found a slightly increased length of stay in the focused handoff group compared to the formal handoff group (5.50 vs. 5.88 days), but no statistically significant difference in mortality, negative events, or adverse events.

6. Recommendations/further research

The recent studies by Clarke et al. [32] and Clanton et al. [33] demonstrated that more communication does not equal better communication or better patient care. They showed that brief, thoughtful communication at the discretion of physicians trained in effective handoffs produced outcomes on par with labor intensive and time consuming handoffs. We speculate that the lack of influence formal handoffs have on patient outcomes is multifactorial. The amount of detail relayed in formal handoffs is far too much for anyone to reasonably retain and apply in a clinical fashion. No formal research has been done on the retention of information in handoffs, which could be an opportunity for future exploration. Furthermore, medical information is rapidly accessible to medical professionals and when intervention requiring application of individual patient information is necessary it is unreasonable to expect that the practitioner is going to act without consulting the chart first, making many details in formal handoffs superfluous [33].

We recommend departments adopt a handoff system that fits their individual needs. We encourage resident involvement and resident input throughout development and implementation of the handoff protocol, especially as the process is evolving, in an effort to create a system that best serves its users. Specific approaches, such as integration with an EMR, as well as utilizing effective communication strategies are recommended for any handoff and should result in fewer errors [9]. However, a trial-and-error approach with continuous self-evaluation is a reasonable strategy to take when making modifications to the process. It is important not to lose sight of the objective in improving communication during transitions of care—improved patient outcomes. If the time-consuming handoff systems improve communication by objective standards but have no meaningful impact on patient outcomes, then the effort is futile. The ultimate goal of the handoff is to reduce medical errors that stem from communication breakdown, and as of yet there is not enough data to support that any method in particular achieves this. Wasting time complying with bureaucratic rules is not in the best interest of your patients. It is clear that more is not always better, and we would caution caregivers to utilize effective strategies, rather than blindly attempt to transfer information without medical necessity. Achieving a balance between “safe” and “effective” communication is the goal that we are still trying to achieve.

Author details

Jesse Clanton*, Meghan Clark, Whitney Loggins and Robert Herron

*Address all correspondence to: jesse.clanton@hsc.wvu.edu

West Virginia University School of Medicine, Charleston Area Medical Center, United States

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The Impact of Fatigue on Medical Error and Clinician Wellness: A Vignette-Based Discussion

Philip Salen and Kenneth Norman

Additional information is available at the end of the chapter

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Abstract

Fatigue-induced medical errors and complications spark concern in patients, clinicians, and policy makers, as documented by the Institute of Medicine report in 1999 that approximately 100,000 Americans die annually secondary to potentially avoidable injurious events. Over the last 2 decades, multiple organizations have advocated for the implementation of labor hour restrictions to redress physician in training fatigue and enhance patient safety. Advocates for duty hour caps in physician training programs cite the potential for improvements in patient safety, whereas adversaries allege that curtailing duty hours compromises medical education and readiness for solo practice. Sleep deprivation impairs multiple aspects of cognition, function, and capacity, including many aspects essential to the practice of medicine, e.g., cognizance, recollection, and dexterity. Resident physicians' traditional extended duty shifts for 24–30 consecutive hours pose significant hazards not only to patients but also to the physicians in training themselves. Burnout among physicians in training occurs commonly and results from work-related stress characterized by emotional prostration, depersonalization manifest as cynicism and detachment toward patients, and diminution of personal esteem. Curtailed shift duration correlates best with improved patient care of the strategies for managing physician fatigue. Adequate supervision of residents and medical students has the potential to improve resident education and further patient safety. Night float shifts improve resident's well-being in terms of acclimating to a consistent nocturnal schedule. Data supporting capping physician work hours demonstrates evidence of amelioration of fatigue, thereby improving physician's quality of life; evidence supporting duty hour restriction for enhancing patient safety, decreasing medical errors, and physician training, including surgical, is mixed and more nuanced.

Keywords: fatigue, burnout, sleep, graduate medical education

1. Clinical vignette demonstrating the impact of physician fatigue

An exhausted resident, on 17 hours of a busy 24-hour trauma shift, has participated in six trauma-alert cases in the last 4 hours. The senior resident signed out 3 hours ago, and he and his attendants have responsibility for the entire trauma service. Notification of an oncoming trauma alert indicates that three critically injured motor vehicular trauma victims will arrive within minutes. The trauma attending, finishing an exploratory laparotomy in the operating room, instructs the trauma resident to manage the first trauma and she will arrive as soon as possible to facilitate the management of the oncoming trauma victims.

As the worn-out resident walks to meet the first trauma, he continues getting paged with issues from the floor as one patient in particular has become increasingly agitated. He reads the page quickly just as the trauma-alert patient, with signs of chest wall trauma, comes through the door. The trauma-alert victim has decreased breath sounds on the right with chest wall crepitus. A cursory completion of the primary and secondary survey identifies no other obvious injuries. As the resident prepares to place a right-sided chest tube thoracostomy, he calls out for the patient to receive vecuronium 10 mg intravenously to sedate the patient. On questioning from the nurse, the resident proceeds to shout for vecuronium 10 mg intravenously for sedation stat. The intimidated nurse proceeds to administer vecuronium 10 mg intravenously. Arriving a minute later, the trauma-attending resident notes the patient's pulsox that has decreased from 95% on oxygen to 50% and that the patient has apneic respirations. The patient subsequently undergoes endotracheal intubation and chest tube thoracostomy without complication. During debriefing afterward, the resident notes that in his fatigued condition, he meant to say valium not vecuronium.

The trauma resident gets another page about the same agitated patient and decides that the patient requires chemical sedation. He orders 5 mg of haloperidol from a workstation computer when he gets an urgent call about a patient in the CT scanner. Feeling weary and defeated, the resident answers yet another page. This nurse on the floor wants to know why haloperidol has been ordered for a calm cooperative 45-year-old female awaiting elective cholecystectomy in the morning? When the resident goes back over his orders, he realized that he ordered the haldol on the wrong patient. With tears threatening, he orders the medication on the correct patient before he goes up to the floor to write some patient care notes.

At the end of his long shift, the resident drives home for dinner and to sleep in his own bed. At a stoplight, he proceeds to fall asleep and his car crashes into the car in front of him causing a multicar pileup.

2. Introduction

Fatigue-induced medical errors and complications spark concern in patients, clinicians, and policy makers, as documented by the Institute of Medicine report in 1999 that approximately 100,000 Americans die annually secondary to potentially avoidable injurious events [1, 2]. The calamitous Exxon Valdez oil spill and its associated public relations uproar demonstrated the

public's focus on fatigue-induced adversity in the workplace [3]. Research demonstrates that progressive exacerbations in sleep deprivation induce slower reaction times and inferior workplace performance in many vocations including medicine [4]. Current physician in training labor hour restrictions developed to address issues raised in the Libby Zion case, a young woman who died as a result of unrecognized serotonin syndrome exacerbated by concurrent medications administered during night shift by on-call resident trainee. This case received press notoriety after Libby Zion's father faulted the inadequacy of resident supervision compounded by excessive work hours worked by physicians in training [5], and ultimately spurred the formation of the Bell Commission, which created and encouraged fatigue-combatting remedies for physicians in training [5, 6].

3. History of extensive duty hours for graduate medical education in the United States

Graduate medical education (GME) exposes medical students and physicians in training to the realities of medical care, including long work hours and a set of professional expectations that often place patients' needs above the practitioner's own [7, 8]. Traditionally, physician training programs in the United States extolled extensive work hours in order to facilitate learning and professional socialization of physicians. Furthermore, until the last two decades, the culture of residents and training programs promulgated a culture of resilience to sleep deprivation and the irrelevance of fatigue [9, 10]. Arduous multi-day shifts extending throughout the night or weekend exacerbated fatigue, the potential for medical errors, and risks to resident physicians, including motor vehicle crashes, occupational injuries, and deleterious effects on well-being [11, 12]. Graduate medical education has lagged behind fatigue management strategies by other industries, such as transportation, aviation, and the military, which have recognized fatigue as an occupational threat [9]. Prior to 2003, no national regulations existed in the United States regarding the frequency, duration, or total number of hours that physician trainees could work [13].

4. Medical commissions advocate for duty hour restrictions

Over the last two decades, multiple organizations have advocated for implementation of labor hour restrictions to redress physician in training fatigue and enhance patient safety [2, 5]. Multiple North American medical commissions have advocated for duty hour circumscriptions including the Bell Commission, which instituted New York State's limit on resident work hours, the Institute of Medicine, the Accreditation Council for Graduate Medical Education (ACGME), and Canada's National Steering Committee on Resident Duty Hours. In 2003 and 2011, the ACGME placed constraints on labor hours by physicians in training mandating a maximum 80-hour work a week, dictating compulsory time off between shifts, and circumscribing on-call periods [14]. In developing the ACGME's 2011 directives, policy makers sought to enhance the safety of patients and to foster learning environments that nurture physicians' professional development by promoting resident respite, wellness, and empathy [7].

5. Critiques of GME duty hour restrictions

The debate over duty hours focuses on contending outcomes: physician-in-training patient management throughout the duration of the patient admission and residents' attainment of cognitive and clinical skills under supervision to prepare for independent practice [7]. To demonstrate the advantages of duty hour caps, research has centered on the relationship between residents' work schedules and adverse events [4, 6]. Despite publication of empirical studies and meta-analyses, the impact of resident duty hour caps on patient care and physician quality of care remains opaque [10]. Meta-analysis of duty hour restriction trials does not demonstrate uniform benefit, some demonstrate no benefit, and others demonstrate unfavorable impact on patient care and resident education [10]. Critics of duty hour restrictions note that multiple transitions of care, utilization of mid-level providers, and abridged clinical exposure impair the quality of physician training and patient care [5]. Advocates for duty hour caps in surgical training programs cite the potential for improvements in patient safety, whereas adversaries allege that curtailing duty hours compromises medical education and readiness for solo practice [2]. Multiple peer-reviewed systematic reviews of the duty hour restriction literature demonstrated mixed benefits and failed to clarify the impact of duty hour restrictions on patient safety, resident education, and resident wellness [10]. The implementation of reliable multi-institutional data documenting the effects of the duty hour limitations on training or patient care represents a limiting factor in evaluating the effect of duty hour restrictions [15].

6. Relationship between physician fatigue and medical error

Sleep deprivation impairs multiple aspects of cognition, function, and capacity, including many aspects essential to the practice of medicine, e.g., cognizance, recollection, and dexterity [13, 16]. Weariness impairs reasoning comparable to alcohol intoxication; specifically, research has demonstrated that mental capacity deteriorates following 17 hours of intense cognition and wakefulness mirroring blood alcohol concentrations of 50 mg/dL [13]. Meta-analysis demonstrates that sleep paucity compromises physicians' clinical acumen and vigilance. Furthermore, progressive exacerbations in sleep disturbance hamper reaction times and hinder surgical residents' operative performance [4]. Residents with insufficient sleep and prolonged duty hours engender depression, which heightens the risk of medical gaffes [17]. The odds of reporting at least one fatigue-related clinically significant medical event increase sevenfold for months during which residents work >5 overnight shifts, in comparison with months without overnight responsibilities. Barger et al. note that fatigue-related medical errors increase fourfold with up to 4 extended shifts per month and eightfold with 5 or more extended shifts in a month [18]. Residents working >5 extended shifts per month reported increased incidence of underperformance during lectures, rounds, and clinical activities when compared to residents working fewer hours [3]. Fatigue after working extended and/or overnight shifts have heightened risk of percutaneous needlestick injuries [19]. Extended shifts exacerbates fatigue-related miscues of the years of training done by the resident physicians, who complied with graduate medical education standards of weekly work hours of 65 hours [18].

7. Initiating duty hour restriction to counter fatigue

In an effort to address issues stemming from potentially unsafe working conditions at US residency programs, the ACGME and the Institute of Medicine have advocated for and implemented progressive work hour restrictions to improve resident training [1, 2]. As US teaching hospitals handle increasing admissions, care for older and/or sicker patients, and discharge patients more rapidly than in the past, residents' workloads have intensified despite work hour restrictions [15]. Attributing physician in training exhaustion only to hours of continuous duty and total duty hours over-simplifies the issue of physician fatigue. Workload, circadian rhythm disruption, tolerance of sleep loss, and work shift intensity also play roles in physician's fatigue [4]. The ACGME and the Institute of Medicine advocate for duty hour restrictions in addition to expanded supervision and sleep enhancement in order to enhance patient safety [10]. Of note, 55% of studies included "quality of life" as an outcome parameter, with 45% of them demonstrating some degree of improvement [2]. Drolet et al. in a national survey of trainees from across all specialties showed that nearly half of all respondents disapprove of 16-hour "call maximums" and only about one in five respondents supported the move to 16-hour in-house call limits. Such restrictions were perceived as deleterious to resident quality of life, education, and supervisory engagement [20].

8. Impact of fatigue on physician's well-being

Resident physicians' traditional extended duty shifts for 24–30 consecutive hours pose significant hazards not only to patients but also to the physicians in training themselves [12, 21]. Residents report more somatic symptoms with a 24-hour shift schedule than with shorter duration shifts [21]. After transitioning from medical school to internship, average nightly sleep decreased by almost an hour, with shorter sleep during internship correlating with escalated risk of depression [17]. Internship initiates a demanding transition from student to physician marked by extended labor hours and sleep loss. Interns have significant risk of depression, which correlates with increased likelihood of self-documented and supervisor noted medical errors [17]. The risk of an internal medicine resident reporting a major medical error increases from 15 to 28% as fatigue, depression, or both increase [1]. Research indicates that resident duty hour restrictions in various medical and surgical residencies resulted in enhanced resident well-being, fatigue, and burnout after the implementation of the 80-hour rule, closely corresponding to the 2003 ACGME mandate [20, 22]. Conversely, teaching faculty reported increased workloads and job dissatisfaction after implementation of work hour restrictions [22].

9. Relationship between fatigue and physician burnout

Numerous reports document that burnout among physicians in training occurs commonly and results from work-related stress characterized by emotional prostration, depersonalization manifest as cynicism and detachment toward patients, and diminution of personal esteem. Burnout corrodes professionalism, contributes to errors in medical practice, features

in substance abuse and relationship difficulties, and can result in physician attrition, depression, and suicidal ideation [19, 23]. Medical students and physician trainees report depression more frequently than similarly matched and aged segments of the US population [19]. To ameliorate burnout and emotional exhaustion, graduate medical education programs have implemented wellness programs and work hour limitations in recent years [23]. Despite work hour caps intended to promote adequate rest for medical trainees, both medical students and physicians in training continue to commonly report fatigue, which suggests that the solution to physician fatigue and burnout requires a multifactorial approach that does not solely focus on duty hour caps [19].

10. Impact of duty hour restrictions on resident education and skill development

Limiting work resident's work hours by using cross-coverage or shift work has impacted on residents' training experiences and job satisfaction, resulted in loss of continuity of patient care, and potentially resulted in hospital adverse events and complications [3]. Inherent to more restrictive resident work hours, frequent shift changes can reduce the trainee's ability to effectively engage in continuity of care education/learning, any associated clinical observations, and the recognition of deviations from an expected recovery course and/or postprocedural morbidity [20]. A 16-hour limit on continuous duty attributed the beneficial outcomes to increased involvement and coverage of first-year residents' work by more senior residents and faculty [11]. Traditionally, medical training has relied on long work hours to help facilitate the proper acquisition of procedural skills and to foster the long-held concept of "patient ownership" [22]. Among the most debated topics in relation to the restriction of duty hours and surgical training were, unexpectedly, continuity of care and trainee operative experience [22]. Many European surgical training programs have limited resident surgical work hours to less than 60 per week while still exposing their residents to acceptable amounts of operating-room experiences to ensure adequate training [22]. Implementation of duty hour restrictions has resulted in an increase in overall operative case volume in multiple high-quality studies, while in comparison, other reports on surgical specialties have documented no change or decrease in surgical caseload volume [2, 22]. Despite evidence to the contrary, surgical faculty reports negative effects with respect to resident training, quality of patient care, and continuity of patient care [22]. Finally, although not a direct clinical outcome metric, duty hour restrictions have not negatively impacted board certification scores [22].

11. Impact of duty hour restrictions on medical error and patient safety

Curtailed shift duration correlates best with improved patient care of the strategies for managing physician fatigue, although the evidence does not demonstrate universal beneficial effect [10]. Enactment of resident work hour constraints has abated provider-induced aftereffects and morbidity-signaling-enhanced patient safety [24]. A recently published study conducted

in the critical care setting found that elimination of extended-duration work shifts, defined as >24 hours, actually reduced the rates of significant medical errors and polysomnographically documented attentional failures [18]. Studies that failed to demonstrate patient care benefits secondary to physician duty hour restrictions, mostly in high-acuity critical care patient neurosurgical and cardiac surgery populations, attribute these outcomes secondary to the increased transfers of care of patient care responsibilities [20]. The increased frequency of patient handovers can fragment care and result in the loss of crucial patient information [20]. Intensive care unit staff reported perceptions that physicians in training know fewer clinical and social details about their patients and make lower quality decisions when working in a shorter schedule [21]. In addition, surgical educators in the future should consider focusing more attention on new technologies and didactic tools (e.g., simulation and web-based learning) to optimize the learning experience in surgery training programs [22].

12. Duty hour restriction alternatives for combating physician fatigue

Devising schedules to reduce resident physician fatigue, enhance education, and boost continuity of care represents a core goal of program directors throughout the United States [15]. In Canada, the National Steering Committee on Resident Duty Hours proposed fatigue-management strategies as a promising alternative to prescriptive “one-size-fits all” restrictions on resident duty hours [9]. Multiple organizations in the US and Canada have advocated for new accreditation standards that would require residency programs to develop, maintain, and enhance fatigue risk management plans [9]. In considering alternative strategies to limiting duty hour restrictions, the impact of fatigue during extended shifts needs consideration within the broader context of patient and work schedule factors such as patient illness severity, patient length of stay, cross-coverage, distribution of rest hours, etc. Efforts to address the negative impact of shortened work hours, particularly the 16-hour limit for first-year residents instituted in 2011, have included night float, providing protected time for sleep during the night shift, improved handoff procedures, and attending teaching interactions during the night shift [10, 11]. Although no schedule system alone can protect against overnight fatigue or burnout, judicious scheduling in combination with abbreviated duty hours can ameliorate the trade-offs between residents’ learning requirements, fatigue, and measures of patient safety [21]. Although often neglected relative to work hours despite being a critical component of the landmark New York regulations, adequate supervision of residents and medical students has the potential to improve resident’s education and further patient safety [3]. Because of the association between adverse events and extended shifts, restrictions on extended shifts, not just weekly duty hours, should be considered when designing residents’ schedules [3, 18]. Fatigue-related injury prevention, including the avoidance of driving while drowsy, should be incorporated into medical school curricula and reinforced during residency and actively supported by graduate medical education leadership and hospital administration. Hospitals should consider providing transportation to trainees who report being too tired for safe driving. Additionally, although consecutive work periods should not exceed 16 hours, hospitals should provide transportation for all resident physicians who, because of unforeseen reasons or emergencies,

work for >24 hours continuously. Under such circumstances, transportation should be readily available and provided to house staff accordingly and should not require self-identification or request [25], except perhaps employee status verification.

13. Impact of night float to achieve duty hour restrictions

Night float involves a clinical staffing system in which dedicated physicians work throughout the night and not during the day covering their fellow physicians' patients [10]. Night float implementation has necessitated more frequent handoffs of clinical duties in teaching hospitals in order to comply with applicable rules governing resident work hours; for example, the "night float" trainee may admit patients during the evening shift and transfer them to another clinical team in the morning [15]. Typically, these night float duty periods last for 12–16 hours in North America [21]. Data supporting efficacy of night shift for ameliorating resident fatigue and improving patient safety demonstrates mixed results. While some evidence substantiates night float shifts improvement in resident's well-being in terms of acclimating to a consistent nocturnal schedule, other data suggest that night float impairs resident's well-being through isolation from other clinical care teams and hospital consultants available during the daytime shifts [10, 11, 13].

14. Strategic protected sleep time during prolonged shifts

Protected sleep time involves residents transferring their clinical duties to other clinical personnel, such as patient admissions, carrying out procedures, and managing patient care issues, for a defined time interval just prior or during their night work shift in order to obtain rejuvenating, uninterrupted sleep [11]. Prior work in nonphysician populations has demonstrated that taking naps improves tasks involving memory and learning [9]. For residents, regardless of their nocturnal work schedule, weariness and torpor most likely manifest at 4 am, consistent with the notion that circadian rhythms of nocturnal laborers and time of day exert more impact on fatigue than duration of shift [21]. Strategic protected sleep time during prolonged nocturnal shifts and educational seminars about enhancing sleep hygiene practices have demonstrated inconsistent impact on physician recuperation [9]. However, data substantiate the benefits of strategic napping prior to nocturnal shifts and at midpoints during nocturnal shifts in terms of attentiveness and cognitive performance [13].

15. Conclusion

Exhaustion, somnolence, lassitude, melancholia, and impaired quality of life correlate independently with an increased risk of medical errors and poor patient outcomes [1]. Support for caps on hours for physicians in training comes from data that indicate beneficial effects of restfulness on vigilance and performance [7]. Data supporting capping physician work hours

demonstrates evidence of amelioration of fatigue, thereby improving physician quality of life; evidence supporting duty hour restriction for enhancing patient safety, decreasing medical errors, and physician training, including surgical, is mixed and more nuanced [2]. Enhancing physician training should proactively address burnout, resident fatigue, and any other forms of distress in an effort to preserve trainee's well-being and patient safety [1]. Future studies are warranted to address the impact of duty hour restrictions on other measures of competency, such as professionalism, humanism, and/or communication skills, and such efforts will certainly benefit medical education. The net effect on patient safety hinges on the balance between exhaustion and continuity of care [21]. Public health stratagems such as improving quality of sleep both out of and in the hospital, examination of individual and environmental factors impacting fatigue, and injury prevention models focusing on adverse events and injuries provide promising frameworks for understanding fatigue-related adverse events in the context of physician training [3].

Author details

Philip Salen* and Kenneth Norman

*Address all correspondence to: philipsalen@gmail.com

St. Luke's University Hospital, St. Luke's Emergency Medicine Residency, Bethlehem, PA, United States

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Overcrowding in the Emergency Department and Patient Safety

Donald Jeanmonod and Rebecca Jeanmonod

Additional information is available at the end of the chapter

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Abstract

Emergency department (ED) overcrowding is a recognized problem worldwide. This chapter reviews the scope of the problem, manifestations, repercussions, and potential solutions to this problem.

Keywords: emergency department overcrowding, emergency department safety, emergency department systems, emergency department patient care, emergency department throughput, emergency department output

1. Case vignette

A 68-year-old man presented to the emergency department (ED) with abdominal pain. The pain was fairly abrupt in onset, constant and severe, with accompanying nausea. He had come in not long after it started, on a busy Monday afternoon during flu season. He sat in a chair in the waiting room while his wife waited 15 min to register him at the line at the window. After 30 min, he underwent triage, during which the nurse noted that the patient appeared more comfortable than he stated he was. He was afebrile with an adequate blood pressure, and had a heart rate of 105. She did not count out a respiratory rate in the interest of time, as she still had eight patients to triage and needed to do repeat vital signs on another 10 who had been waiting for over 2 h. The patient was made an emergency severity index score (ESI) of 3, and put back in the waiting room. After 120 min in the waiting room, the patient was brought back into the ED. He was noted by his ED nurse to have a heart rate of 115 with irregular rhythm. He also took note of a respiratory rate of 26 and a blood pressure of 98/56 mmHg. He called for a physician to evaluate the patient immediately. The physician recognized that the patient had severe abdominal pain in the setting of new atrial fibrillation and was concerned for the possibility of ischemic bowel. She

consulted the general surgery service, ordered lactate, type and screen, complete blood count, blood chemistries, coagulation profile, and a CT scan of the patient's abdomen and pelvis. She additionally ordered a fluid bolus and pain medications.

The nurse was able to get an adequate IV line quickly and implemented the orders, fluid resuscitating the patient and improving his comfort. Unfortunately, a multi-car accident occurred on a nearby highway, resulting in several trauma team activations. Since trauma alert patients are ESI 1, the patient's CT was delayed until after completion of the evaluations of the three trauma patients, which took about 90 min. Additionally, since the same surgical team covers both trauma and general surgery, the patient was not evaluated by a surgeon until after the trauma patients were cleared by the trauma team.

By the time the patient underwent CT scanning, all of his labs had resulted, and it was noted that he had a lactate of 5.6 mmol/L, with elevated white blood cells and evidence of hemoconcentration. His CT demonstrated pneumatosis of his small bowel, and the patient was taken to the operating room for small bowel resection secondary to mesenteric ischemia. He had a prolonged intensive care unit stay, but eventually recovered.

2. Introduction

Emergency department (ED) overcrowding is a recognized problem worldwide [1, 2]. Although isolated and not-so-isolated instances of overcrowding likely have occurred for as long as EDs have been in existence, attention was brought to the problem in the United States (US) in the early 1990s, when both the lay press and the research community began to consider the impact of overcrowded EDs on patient care [3]. Although initially described as a phenomenon that was predominantly occurring in large academic centers, overcrowding has now been shown to occur in both public and private EDs of all sizes and locations [4]. The problem has become widespread and is still growing, leading the Institute of Medicine to release a statement in 2006 regarding the future of US emergency care, describing the emergency system as one in crisis [5].

What is ED overcrowding? Although there is no true consensus definition, the best descriptions take into account both the nature of the problem and its outcomes. Overcrowding is not merely a matter of an ED not having adequate resources for the demand placed upon it by the patients or community, it is a supply/demand imbalance in health care needs that results in undesirable outcomes for patients [6, 7]

3. History of overcrowding

The timing of ED overcrowding becoming a major issue in the US coincided with the closing of hospitals across the country, a decrease in the number of available inpatient hospital beds, and an increase in ED visits [8]. By way of comparison, in 1981, there were 1.36 million staffed hospital beds in 6933 hospitals in the US, while the most recent data from the American Hospital Association show 897,961 beds in 5564 hospitals [9]. Meanwhile, there is

no indication that there are fewer sick patients. Since 1991, ED visits have increased nationally from 89 million per year to 130.4 million, and ED patients account for 40% of hospital admissions [10, 11]. Furthermore, 25% of those admitted patients are considered critically ill [11, 12]. Therefore, EDs are seeing a higher volume of higher acuity patients that consume more resources.

In addition to decreased total number of hospitals and beds, this same time period saw the introduction of the emergency medical treatment and active labor act (EMTALA) in 1986 as well as cuts in Medicare reimbursement in 1999. EMTALA mandates that all hospitals with EDs provide emergency care (including “screening exams”) to all patients who arrive there, but provides no mandates regarding payment for these services from payors. Emergency medical care is therefore a civil right, but one without funding to match the mandate for care, leading to institutions seeking to find the most cost-economical way to provide that care, often with little margin for error so as to avoid waste and improve the bottom line.

The burden of increasing patients in limited beds has been increased by advances in technology. As medical imaging has improved and expanded, ED workups have grown to utilize more advanced imaging, increasing ED length of stay (LOS) for patients [13]. Furthermore, physicians’ medicolegal concerns and fear of lawsuit increase their diagnostic testing as well as impacts their admission decisions, contributing to resource/demand mismatch [14].

Finally, ED overcrowding is impacted by staffing shortages. Although a record number of medical school graduates are entering fields in emergency medicine, the current need for board certified emergency physicians is not projected to be met until 2038 [15]. Furthermore, although nursing is one of the top occupations in terms of projected job growth over the next 5 years, the gap between nursing supply and demand is widening and is reaching critical proportions [16]. In spite of the growing need, thousands of nursing school applicants are turned away every year because of insufficient funding, faculty, and training sites to support them [16].

4. Health care system factors in overcrowding: output, input, and throughput

It is always a failure of understanding to refer to ED overcrowding as an ED issue. Truly, overcrowding is a health care issue, impacted by and affecting every aspect of medical care. Although a full discussion of all the elements involved is beyond the scope of this text, a brief synopsis is warranted.

ED overcrowding occurs when hospitals are full [3, 17, 18]. Full hospitals create a bottleneck to ED output of patients. Although 40% of inpatient admissions pass through the ED, the others are direct admissions, scheduled surgical or procedural admissions, or transfers. When the hospital is at or near capacity, patients who are admitted through the ED are unable to move from the ED to an inpatient bed, resulting in ED holding [19]. ED holding is cited as the number one reason for both ED overcrowding and diversion of ambulances [19]. Hospitals may be operating at or near capacity for a number of reasons. Inpatient beds may be taken because

of seasonal variations (such as flu season). They may fluctuate in predictable ways based on days of the week and operating schedules of surgeons (who often operate earlier in the week to facilitate discharging patients before the weekend). Inpatient bed availability is dependent upon nurse staffing availability, and nursing shortages may limit a hospital's capacity to accommodate patients. Furthermore, beds that are already occupied may stay occupied longer because of inefficiencies of inpatient medical care, delay to consultation, advanced diagnostic testing, or disposition processes that delay discharging or transferring patients from the hospital. For instance, discharge from the hospital may be delayed because of rehabilitation, nursing, or care facilities not having available beds and also operating at capacity.

ED overcrowding also occurs when patients intended for discharge (as well as those for admission) from the ED remain in the ED for longer than necessary. This may occur secondary to delays in contact or input from consulting services, delays to imaging or specialist interpretation of tests, delays to laboratory results, technological failures, or delays in transportation back to a care facility [4–7, 13]. ED throughput processes contribute to overcrowding through inefficient registration and triage processes, laboratory and radiograph turnaround times, clerical and technologist support, inadequate nursing and physician staffing, and delays to decision-making [6, 7, 20].

ED overcrowding is obviously impacted by the number of patients arriving to the ED, or the patient input [6, 20, 21]. Although often cited for the reason for overcrowding, low acuity patients using the ED for their minor injury and primary care needs have not been shown to be a large contributor to the overcrowding process [7]. However, when a given ED becomes overcrowded and diverts ambulances to surrounding EDs, those surrounding EDs often become overcrowded, perpetuating overcrowding in a regional way [20, 21]. Beyond ambulance diversion, patients may increasingly use EDs because they cannot find other ways to access primary or specialist care, whether because there are no appointments available because of physician shortages or because they have been instructed to go to the ED when calling their physicians with their symptoms. ED facilitation (or lack thereof) of close follow-up may result in patients returning to the ED for scheduled rechecks, as well.

5. The impact of overcrowding on patient care

Numerous studies have demonstrated that ED overcrowding is harmful to patient care. In an effort to avoid overextending available resources, some hospitals divert ambulances when they are at capacity (although this is illegal in some states). Although this is done purportedly because the hospital cannot safely accommodate more patients, it is unclear whether this practice is beneficial. In the pre-hospital arena, ambulance diversion results in delay to patient care, and increases ambulance utilization, resulting in fewer available ambulances [22]. In patients with cardiac events, ambulance diversion is associated with increased mortality and decreased revascularization [23, 24]. That said, diversion has not been shown to have an impact on pediatric mortality [25]. Clearly, ambulance diversion as a means to address overcrowding shifts the problem to either pre-hospital providers or other area hospitals, as opposed to solving the problem.

Data for patient harm secondary to ED overcrowding at the ED and hospital level are abundant in numerous patient groups. In patients with acute cerebrovascular accidents, ED overcrowding is associated with delay to CT scanning, and boarding of these patients is associated with increased mortality, complications, and poorer recovery [26, 27]. Overcrowding increases delays to antibiotics in patients with pneumonia as well as febrile neonates [28, 29]. Patients with painful conditions are less likely to receive timely analgesia in an overcrowded ED [30]. Patients with non-ST elevation myocardial infarctions who board in the ED have increased adverse events and less adherence to standard of care therapy, and those admitted with chest pain have higher rates of adverse events [31, 32]. Although ED crowding has not been found to have an impact on resuscitation outcomes or quality in patients suffering out of hospital cardiac arrest, boarding of patients with return of spontaneous circulation is associated with worse outcomes [33, 34]. This relationship holds true for other critically ill patients who are held in the ED for lack of bed space in the intensive care unit [35]. Patients who are seen and discharged from the ED during periods of overcrowding have higher risk of mortality and hospitalization within 7 days as compared to patients who are discharged during non-overcrowded times [36]. Overcrowding is associated with increased number of medication errors [37]. Finally, and not unexpectedly, overcrowding leads to increased length of stay and delay to treatment, even in patients with ESI 2 triage scores [38].

6. Solutions to the problem

Solutions to the problem of ED overcrowding can be seen as broadly falling into one of two arenas: Institutions can focus on efforts to directly decrease crowding and/or mechanisms can be placed to mitigate bad outcomes that are associated with ED crowding. Within the parameters of decreasing overcrowding, the problem is often approached from an input-throughput-output model, with solutions to decrease the number of patients presenting to EDs, decreasing total time spent in the ED, and facilitating either transfer to other locales within the hospital or facilitating outpatient follow-up.

The Agency for Healthcare Research and Quality recommends forming a Patient Flow Team consisting of including a team leader (day-to-day leader), senior hospital leader (e.g., the chief quality officer), individuals with technical expertise related to the strategy, ED physicians and nurses, ED support staff (e.g., clerks, registrars), a research/data analyst, and representatives from inpatient units [39]. Having input from multiple staff with unique insight into the delays specific to their specialty as well as ways that delays may be approached can lead to more effective change. As well, having individuals involved in the clinical arena can improve the team approach to problem solving and implementation of new systems. Prior to initiating solutions, management teams must know their own baseline benchmarks, must identify goals and strategies to decrease crowding in their unique environment, must plan the approach to implementation with estimates of time and costs of implementation, and then must remeasure after implementation to determine how they have approached their benchmark. Introduction of process improvement teams in one health care system resulted in a 72% reduction in the number of ambulance diversion hours [40].

Measures that an ED may track can be individualized, or could follow the CMS measures that are reported nationally to compare ED performance (**Table 1**). With the introduction of electronic health record systems, such measures should become increasingly effortless to obtain and track over time. Implementing “Rapid Cycle Change,” where the Patient Flow Team picks a discrete intervention, implements an improvement initiative through the Plan-Do-Study-Act cycle, and measures the outcome, can quickly determine whether a change should be accepted, reworked, or discarded. The data that are generated need to be rapidly disseminated in a transparent manner to reinforce the values of change or to justify reworking the solutions.

Measure name	CMS effective date
Head CT scan results for acute ischemic stroke or hemorrhagic stroke patients who received head CT scan interpretation within 45 min of arrival	2013
Troponin results for ED acute myocardial infarction (AMI) patients or chest pain patients (with probable cardiac chest pain) received within 60 min of arrival	2013
Median time to pain management for long bone fracture	2013
Patient left before being seen	2013
Door to diagnostic evaluation by a qualified medical professional	2013
Median time from ED arrival to ED departure for discharged ED patients	2013
Median time from ED arrival to ED departure for admitted ED patients	2014
Admit decision time to ED departure time for admitted patients	2014
Additional measures to track	
ED arrival to bed placement	
Disposition to departure	
Hours on diversion	
Time of inpatient bed assignment to bed placement	
Time of day of discharge	
Inpatient bed turnaround time (patient discharge to bed readiness)	

Table 1. Measurements of emergency department crowding.

7. Decreasing patient presentations to the ED

Initiating processes to decrease patient presentations to the ED have limited effectiveness in reducing ED crowding. In a study performed in Ontario hospitals, low acuity patients were found to have a negligible effect on ED length of stay [41]. Although ambulance diversion is frequently employed in the setting of ED crowding, a review of ambulance diversion from 2006 found no papers specifically addressing the effect of ambulance diversion on ED crowding [22]. Computer-generated simulation models have suggested that ambulance diversion

will have little effect on an already overcrowded ED [42]. One such model suggested that for every percentage point increase in the time spent on ambulance diversion, ED waiting room time would decrease by 2 min [43]. Further evidence suggesting that ambulance diversion is not an effective method to decrease ED crowding is provided by the state of Massachusetts, who banned ambulance diversion statewide, and saw a small drop in ED LOS [44].

8. Improving emergency department patient throughput

Improving ED front-end operations has been seen as a potential way to increase ED patient throughput. A review of literature found articles that supported that bedside registration decreases patient waiting time, total ED LOS, and the number of patients who leave without being seen [45]. The authors point out that a number of the studies that they reviewed are fraught with methodological flaws and include only single centers, limiting the conclusions that can be drawn from these studies [45].

As ED wait times increase with overcrowding, utilizing the patient waiting time for processes that would otherwise take a long time becomes important. Groups have proposed initiating evaluations or treatments for standard problems from the waiting room [46]. Initiating lab testing from triage has two potential effects. It can effectively decrease the turnaround time (TAT) for lab tests which has been shown to directly decrease ED length of stay (a 17-min increase in ED LOS per 30 min increase in lab TAT) [47]. Additionally, performing labs from triage could potentially identify patients requiring more immediate attention if there is a way to flag critical values to a responsible provider [48]. A systemic review of triage nurses ordering radiographs has demonstrated nearly a 20-min decrease in patient LOS with implementation of triage nursing orders [49]. Studies have suggested that having an advanced practitioner or a physician in triage may reduce the ED LOS and rates of leaving without being seen [45, 50]. Two randomized trials of physician in triage demonstrated reduced patient LOS by 36 min in one study (12% reduction) [51], and 122 min in the other (35% reduction) [52]. Both of these studies occurred in Canada, however, where delivery care might be different than other settings, thus limiting their generalizability [51, 52]. Two other randomized controlled trials demonstrated no affect of physician in triage on LOS [50].

In cases where there are patients in the ED waiting for providers (long ED bed placement to provider evaluation times), adding providers can decrease patient TATs, effectively decreasing crowding. In a study in a Swiss ED, adding a provider to a busy evening shift decreased the average LOS of discharged patients by 35 min. Similarly, if it is determined that patients are awaiting nursing care in the ED, improving nursing ratios may decrease TATs and ED crowding. Although decreasing nursing to patient ratios has not been proven to improve overcrowding, a study demonstrated that when nursing to patient ratios fell out of California-mandated ratios (1:1 for trauma resuscitation patients, 1:2 for critical patients, and 1:4 for all other ED patients), wait times were 16% longer and total ED care time was 37% longer [53].

Although it would seem intuitive that increasing space in the ED (by adding more beds) would decrease ED LOS, this is not the case. In their computer-generated model, increasing

ED bed numbers increased LOS, while increasing the rate at which patients left the ED to be admitted to the floor decreased total ED LOS [54]. Additionally, a pre-post observational study performed in conjunction with nearly doubling an ED's capacity found that this had no affect on the time of ambulance diversion or left without being seen [55].

Introducing a system with a rapid admission policy whereby stable ED patients are admitted to the hospital without having a prior ED evaluation by the admitting staff and with incomplete diagnostic testing, minimally decreased ED LOS (10 min) but decreased weekly ambulance diversion time by nearly 3 h [56].

9. Facilitating the output from the emergency department

The single factor that has been demonstrated to be the most effective at reducing ED crowding is to reduce ED boarding of admitted patients and facilitate movement of ED patients to inpatient beds [19, 57–61]. Therefore, any attempt to focus on improving ED throughput should focus on attempts to minimize ED boarding and facilitate inpatient admission.

Because ED crowding has been associated with holding in the ED while awaiting inpatient bed assignment, an obvious mitigator would be to increase inpatient beds. A study observing overcrowding over 10 years while Toronto restructured its medical system decreasing acute care bed numbers by 39% demonstrated that overcrowding increased [17]. It has been suggested that when average occupancy rates approach 90%, fluctuations in need for inpatient beds will result in periodic bed shortages [17, 18]. A study of the effect of increasing the number of ICU beds in one hospital from 47 beds to 67 beds demonstrated that they reduced the average numbers of ambulance diversion by 66% and decreased the ED LOS of critically ill patients by 25 min. Likewise, increasing beds outside of the ED with the formation of observation or short stay units has been demonstrated to decrease crowding and decrease ambulance diversion [62]. Another strategy that has been suggested is the boarding of patients in inpatient hallways as opposed to the ED. Although effects on hospital crowding have not been documented, survey studies have demonstrated that patients have a preference for inpatient hallway boarding to ED boarding [63–65].

Inpatient hospital process improvement, such as earlier hospital discharge, has been demonstrated to decrease overcrowding when the hospital nears full capacity. Improving time to hospital discharge by as little as 1 h has been demonstrated to have significant effect on crowding [66]. Toward this end, some have advocated that discharge from inpatient hospital beds should occur before 12 o'clock noon and impact on emergency department crowding should be studied before and after [67]. One health network has found that incentivizing housekeeping staff to more rapid inpatient bed turnover has led to significant decreases in ED waiting times and ambulance diversions [68]. Other systems issues that have been targeted for improving hospital flow include smoothing the elective surgical schedule [69].

Ultimately, there is no single fix that will improve the entire system. Rather, the implementation of multiple solutions (**Table 2**) is required to decrease emergency department crowding.

Improved staffing	<ul style="list-style-type: none"> • Physicians • Nurses • Techs • Registration •
Decreased process turnaround	<ul style="list-style-type: none"> • Triage • Registration • Diagnostic imaging • Laboratory processes • Specialist consultations
Decreased care time	<ul style="list-style-type: none"> • Medication availability • Stocking issues • Time to completion of nursing tasks • Workload balance among staff
Physical space	<ul style="list-style-type: none"> • Hallway beds • Observation units • Flex beds
Standardized resources	<ul style="list-style-type: none"> • Disease pathways
Hospital dynamics	<ul style="list-style-type: none"> • Decreased OR scheduling variability • Early hospital discharge • Automated inpatient bed cycling • Automated nursing report • ED-inpatient bed transport • Hallway boarding • Reverse triage

Table 2. Process improvement opportunities to decrease emergency department crowding.

Careful scrutiny of the institution's existing processes and identification of specific areas of improvement is the first step to managing patient flow issues. Beyond this, hospitals must buy in from both administration, nursing, physician, and ancillary staff, and must also be willing to make resource investments to improve patient flow. Implementation of best practice bundles like the Urgent Mattes Toolkit across health systems has demonstrated great successes but demonstrated no improvements in about a third of hospitals, because it is often difficult for smaller, nonteaching, rural hospitals to invest the resources in staff and infrastructure that are required to make change [70, 71].

10. Mechanisms to mitigate bad outcomes in the setting of overcrowding

ED crowding is a reality in many EDs and is likely to persist at times despite implementation of all reasonable strategies to mitigate crowding. In these situations, it is important for all providers to be aware of the increased likelihood of potential errors and to mindfully employ mechanisms to avoid them. Delivery of quality care in the face of crowding can be challenging, but is not impossible.

The first step in quality care occurs with an adequate and accurate triage to identify those individuals who really cannot wait. The future of medicine may include the use of predictive biomarkers in addition to standard triage to identify patients at the highest risk of mortality [72]. At triage, interventions to initiate care like triage EKGs that are reviewed real time by a physicians, drawing of triage labs based on complaint to identify those with severe disease, and ordering of appropriate radiographs may improve delivery of quality care. Likewise, analgesia for fractures, topical anesthetic for lacerations or anti-pyretics for fever could be protocolized to decrease time to effective therapies.

As EDs become busier, the number of simultaneous tasks that need to be coordinated and tracked by staff increases. This cognitive workload can be lessened by the use of protocols, teamwork training to facilitate inter-provider assistance, and by the use of information technology solutions such as flagging abnormal results or communicating a patient's completed care tasks. Existing safeguard mechanisms to appropriately identify patients by wrist bands prior to medication administration and test and procedure performance need to be strictly adhered to despite the time taken to complete these tasks. As departments become busier, interruptions increase which can lead to decreasing performance, so mechanisms to limit interruptions could be important to decreasing errors [73]. Although research priorities into patient safety have been developed, little literature exists regarding how interventions and specific processes affect safety [74].

Author details

Donald Jeanmonod and Rebecca Jeanmonod*

*Address all correspondence to: rebecca.jeanmonod@yahoo.com

Temple University, Department of Emergency Medicine, St. Luke's University Health Network, Bethlehem, PA, USA

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Disruptive Physicians: How Behavior Can Undermine Patient Safety

Leah Tatebe and Mamta Swaroop

Additional information is available at the end of the chapter

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Abstract

Disruptive physician behavior is a pervasive threat to patient safety and a source of emotional and financial hardship on the health care system. It causes increases in medical errors, staff turnover, and risk of litigation. Behavioral problems can be symptoms of underlying issues that must be addressed, such as substance abuse, psychiatric conditions, or burnout. Reporting of disruptive behavior is low, especially by colleagues. Current methods in place in many health care systems do not adequately recognize warning signs or take appropriate corrective actions to limit the effects of disruptive physicians. Changes must be made at a system level to improve rehabilitation of problem physicians.

Keywords: disruptive physician, patient safety, physician behavior

1. Introduction

Professional physician *competence* is considered “the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served” [1]. When competence breaks down, a physician may become *impaired* if they have “any physical or mental condition that detrimentally affects or is likely to affect, [the] capacity to practice medicine” [2, 3]. At least 30% of all physicians will be impaired at some point in their career, with about 1–2 per 100 physicians per year being affected. Such impairments create a substantial burden on health care systems. In 2015, the Federation of State Medical Boards (FSMB) issued 7942 state medical board disciplinary actions. Over 4000 physicians were disciplined, with 655 placed on probation, 594 licenses suspended, and 267 licenses revoked [4]. Across multiple studies, it appears that only a subset of impaired physicians, about 3–5% overall, will become *disruptive* [5].

2. Clinical vignettes

Attending Vascular Surgeon, Dr. Brown is consulted for a cold leg on an intubated septic patient in the ICU requiring vasopressors. He evaluates the patient and finds a faint Doppler signal. As he is leaving, he brashly complains outside the patient's room to a medical student that the intensivist is a "bumbling idiot who probably couldn't even find his own pulse if he tried. Why am I being asked to waste my time on this? This is why I hate working here. I really should just go to the hospital across town where people aren't so incompetent."

The family in the patient's room overhears his comments and approaches the nurse very concerned if they should ask to have the patient transferred to the other hospital, asking, "If Dr. Brown doesn't trust this place, why should we?"

...

After a long day of rounding, seeing consults, and trying to sift through dispositions, Dr. Smith, the night House Officer, settles in for a brief rest in the call room. Ten minutes after her eyes close, the pager breaks the silence: "Question about medication order for patient in room 5312—Judy RN ext 1234." Cursing under her breath, Dr. Smith stuffs the pager under her pillow and goes back to sleep.

Thirty minutes later, it alarms again: "Second page—Question about patient in 5312—Judy RN ext 1234." Dr. Smith calls back: "What question could you possibly have? Read the orders. I was very clear about what I want."

Judy tries to get her question out, "You ordered ceftriaxone for this patient, but he is allergic to penicillin. Would you like..."

"I would like him to get the drugs I ordered! You want a new order? Nursing communication: Do not call me again!" Dr. Smith hangs up.

Frustrated, Judy goes to her supervisor and is advised: "Dr. Smith gets like that sometimes. It's better not to engage her after 10 pm. Don't give the antibiotic and clarify with a different hospitalist in the morning." Consequently, a patient with a serious infection had a 10-hour delay in the administration of appropriate antibiotics.

...

Interventional Radiologist, Dr. Jones, is performing an embolization for a bleeding ulcer. She calls for the next contrast bolus to be given only to find out there is no more contrast ready to be administered. Angered, she yells at the circulator, Michael: "I drove in here in the middle of the night to save this man's life and now he's going to die because you're not paying attention!" Flustered, Michael initially goes to the wrong cabinet to get more dye. Dr. Jones picks up a bloodied syringe and throws it at the appropriate cabinet. "In there! What the hell? Do I need to do everyone's job around here? It's on you if he dies!"

After having his self-confidence shattered, Michael requests transfer to another department the following morning.

3. What constitutes disruptive behavior?

While Dr. Jones clearly demonstrated unacceptable behavior, Dr. Smith’s could be deemed a difficult night on call, except for the repetitive nature of the behavior. To the casual observer, Dr. Brown’s could be simply expressing frustration; however, the patient’s family saw it in a very different light. When does cathartic venting erode into disruptive behavior?

Disruptive physician behavior is defined as that which “interferes with patient care or could reasonably be expected to interfere with the process of delivering quality care” [3, 5]. The FSMB outlines a number of behavioral sentinel events attributed to disruptive physicians (Table 1). While an event taken in isolation may only raise an eyebrow, a pattern of such behavior undermines a physician’s ability to provide quality patient care.

Behavioral sentinel events
Profane or disruptive language
Demeaning or intimidating behavior
Sexual comments or innuendo
Inappropriate touching, sexual or otherwise
Racial or ethnic jokes
Outbursts of rage or violent behavior
Throwing instruments or charts or other objects
Inappropriately criticizing health care professionals in front of patients or other staff
Boundary violations with staff, patients, surrogates, or key third parties
Comments that undermine a patient’s trust in a physician or hospital
Inappropriate chart notes
Unethical or dishonest behavior
Difficulty working collaboratively with others
Repeated failure to respond to calls
Inappropriate arguments with patients, family, staff, and other physicians
Resistance to recommended corrective action
Poor hygiene, slovenliness

Table 1. Behavioral sentinel events of disruptive physicians from the Federation of State Medical Boards (FSMB) [6].

4. The ripple effect of disruptive behavior

Only over the last 20 years has the true effect of disruptive physician behavior begun to be understood. In 2008, a sentinel event alert was issued by the Joint Commission declaring

that “intimidating and disruptive behaviors can foster medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators and managers to seek new positions in more professional environments” [7]. **Table 2** highlights a number of these effects [8]. Resident physicians are at increased risk of suffering from mood disorders partly because of high levels of workplace stress and exposure to abusive behaviors [3]. A prospective study of pediatric residents showed that depression was associated with six times the number of medication errors. Self-criticism over an error can lead to a deeper depression, thus worsening the issue [9].

Physician disruptive behavior is more commonly focused on nonphysicians, such as nursing staff [10]. Verbal abuse from a doctor was reported by 64% of nurses as occurring at least once every few months [10]. Members of the care team are less likely to approach disruptive physicians to clarify plans of care or speak up if they feel an error is being made. This may deeply compromise the quality of medicine provided [5, 11, 12]. A 2003 survey of over 2000 health care providers showed that 49% of responders changed the way they approached an order that required clarification because of intimidation. Many either asked a colleague for help or avoided calling the intimidating provider all together. Seven percent reported being involved in a medication error event as a result of intimidation [13]. A 2005 study of nurses cited disruptive behavior as contributing the most to decreased job satisfaction [14]. Approximately 20% of nursing turnover was as a result of abusive behaviors [10]. High nursing turnover rates not only put strain on management but also lead to less continuity of care for patients and situations where nurses are unfamiliar with the practice habits of physician’s workflow.

When intimidating or abusive behaviors occur in front of patients, further issues arise. The trust in patient-physician relationship is compromised [15–17], and it has a “corrosive effect on morale” [5]. Not surprisingly, associations have been found between the number of patient complaints filed regarding a doctor and the likelihood of malpractice litigation against said clinician [18]. In the most extreme cases, news agencies pick up stories of inappropriate behaviors, severely tarnishing the reputation of a hospital. All of these reasons contribute to the way disruptive physician behavior can threaten patient safety and undermine quality care.

Consequences of disruptive behavior
Decreased morale and self-esteem among staff
Poor quality of patient care
Increased staff turnover
Incomplete and ineffective communication
Heightened financial risk and litigation
Reduced public image of hospital
Unhealthy and dysfunctional work environment

Table 2. Consequences of disruptive behavior on the healthcare system, from Piper et al. [8].

5. The tip of the iceberg

Everyone is entitled to have a bad day. There are times when frustration builds, and the breaking point is reached; people lash out and say or do things they otherwise would not normally say or do. An adaptive behavior would then be to have insight and attempt to make amends by apologizing and taking responsibility. Maladaptive behavior exists when such events persist and become pathologic. Disruptive behavior should be considered a manifestation of an underlying issue [5]. The most common include substance abuse, stress, burnout, and depression [3].

Approximately 10% of doctors will struggle with substance abuse at some point in their careers [19]. While often sensationalized, substance abuse is associated with only 10% of disruptive behaviors [10]. High functioning substance abusers will often be able to compartmentalize and keep issues outside of work before spilling into the professional realm [5]. Nevertheless, this needs to remain on the radar when addressing a disruptive physician.

It is no secret the medical field is wrought with high-stress environments. A survey of 700 physicians revealed a 31% incidence of excessive anxiety and a 60% incidence of exhaustion and stress [20]. This can lead to burnout a “pathological syndrome in which emotional depletion and maladaptive detachment develop in response to prolonged occupational stress” and is comprised of the constellation of emotional exhaustion, depersonalization, and low sense of personal accomplishment [21]. Burnout is universal across all specialties; physician burn out rates now exceed 50% [22]. The behaviors listed in **Table 1** can be easily tied to indicators of burnout. Disruptive physicians are often less able to cope with these high levels of stress [23].

Mood disorders such as depression and bipolar disorder have the same incidence in physicians as the population at large [3]. Some reports cite even higher rates of depression [24] and suicide [25] in physicians. Risk factors for psychiatric morbidity include being a resident physician, of advanced age, female, and having personality traits such as perfectionism, self-criticism, discipline, idealism, and high degrees of empathy [3]. Emotional lability as exhibited by disruptive physicians can be related to these underlying conditions.

6. Barriers to improvement

Physicians have been long held to a different standard of professional conduct. Often to the highest standard, but also considered untouchable, exempt from the norms because of their place in the hierarchy of medicine [8, 26]. Medical billing is the backbone of health care systems. Hospitals are dependent on the revenue streams created by physicians; this shields physicians such that many otherwise intolerable behaviors have been overlooked. In addition, particularly high-producing service lines subscribe to the “squeaky wheel” phenomenon. Through attempts to placate disruptive yet valuable physicians, inappropriate behaviors can result in changes in allocation of resources [10]. A survey of physician executives revealed that nearly 40% felt that “physicians who generate high amounts of revenue are treated more

leniently when it comes to behavior problems than those who bring in less revenue" [27]. This behavior can further be propagated through the hidden curriculum of attending physicians to residents [28].

Lesser infractions and herald events are often overlooked [5]. Part of the delay is due to the lack of objective evidence to an often subjective problem [8]. Many situations can be spun to favor one side or the other. When there is a hierarchical difference in physician-nursing confrontations, this becomes even more difficult. Despite that over half of physicians are witness to disruptive behavior in colleagues [29], peer reporting rates remain low. Reporting is more common for gambling and substance abuse than for emotional outbursts [30]. Colleagues who witness disruptive behavior may have concerns about being stigmatized themselves if they report the issue, or they may be conflicted over protecting the privacy of the impaired individual. They may fear social, financial, or legal repercussions [3]. This is especially true when the physician in question is a partner or part of the referral base [5]. When disagreements do surface between physicians, tensions escalate with egos preventing either party from backing down. As high-functioning individuals working in stressful environments, physicians are prone to denial and/or to attempt management of the situation on their own, which may lead to further disruptive behaviors [3].

7. Corrective actions

In a system where physicians were all independent practitioners, little oversight existed outside of hospital credentialing committees and state licensing boards. As the landscape of health care transitions physicians into employees of conglomerate medical groups, more managerial roles to address practice-based issues including disruptive behavior are being created. Hospitals have been mandated for some time to have systems in place to maintain credentialing and disciplinary actions, but receive little guidance on how to do so [5].

The Joint Commission actively pushed to remedy this over the last decade [7, 31, 32]. **Table 3** outlines basic recommendations for a framework on how to build policy for managing disruptive behavior. First, there must be a clear understanding of performance standards from not only the standpoint of practicing medicine, but also professionalism [15, 16, 33]. Health care systems are leading the way in developing said standards and are mandating new hires agree to comply otherwise be subject to remediation, disciplinary action, or termination. Being upfront with expectations and holding firm to a zero-tolerance policy for unprofessional behavior is essential to objectifying this difficult issue [11, 34].

Commitment to professionalism must come from all levels of the health care system hierarchy [35, 36]. In 2011, the American College of Physician Executives conducted a survey of members regarding the prevalence, impact, and management of disruptive behaviors. Only 17% of male and 11% of female physician executives strongly agreed that they were "well prepared to deal with disruptive behavior," and 61% of respondents wanted more training in confronting disruptive behavior [37]. The medical field cannot hope to make strides in correcting behavioral issues without providing those asked to intervene with the tools to do so.

Managing disruptive behavior
Making expectations explicit by having a code of conduct supported by appropriate policies
Ensuring robust board support for clinical leaders in implementation
Support and training for those dealing with disruptive and intimidating behaviors
Screening for health and personal issues
Proactive surveillance systems
Dealing consistently and transparently with infringements
Dealing with lower level aberrant behavior early
Having graded set of responses (informal, formal, disciplinary, regulatory) depending on the severity of the incident
Making resources available to help those displaying and those affected by disruptive and intimidating behavior

Table 3. Joint Commission recommendations on managing disruptive behavior [31].

Much debate remains over the appropriate way to screen for health and personal issues among physicians. Letters of reference have been shown to not be a reliable way to identify potential problem physicians [38], likely an effect of selection bias. There was significant interest in utilizing emotional intelligence scores during residency interviews as a predictor for future success; however, studies have shown mixed results [39–41]. Further research into this area is needed.

Proactive preparation and screening alone cannot correct behavioral issues. Minor deviations from appropriate behavior must be recognized and intervened upon to prevent escalation [18, 42]. Anonymity of reporting parties must be assured to reduce the fear of retaliation [43]. However, there also must be a commitment, from all members of the treatment team, to quality patient care. Physicians who are reluctant to report disruptive events should remember that “failure to ensure the quality and safety of the performance of colleagues is a breach of medicine’s fiduciary responsibility to the public” [5]. Health care systems should “promote willingness to confront disruptive coworkers and subordinates in a nonthreatening and beneficent manner” [3]. A formal evaluation process annually to ensure competence and compliance to standards is strongly recommended [5, 31]. Others have suggested using Root Cause Analysis to help tease out when the physician’s frustrations are justified, but perhaps, the resulting behavior is not [44]. However, several court cases have held up hospitals’ right to deny or revoke the credentials of a physician because of disruptive behavior, even if it did not directly cause patient harm [45, 46].

Figure 1 illustrates a graded response to levels of disruptive behavior. Lesser events can be managed internally to guide the physician back to professional standards. Escalation occurs with the severity of the disruption [17]. Several Continuing Medical Education courses have been developed to facilitate remediation of disruptive physicians [42, 47, 48]. This can include communication skills training to improve the physician-nurse working relationship [49]. Others explore comprehensive assessments and “fitness-for-duty” evaluations to determine if remediation has been achieved [50, 51]. Additionally, the stigma of mental health must be

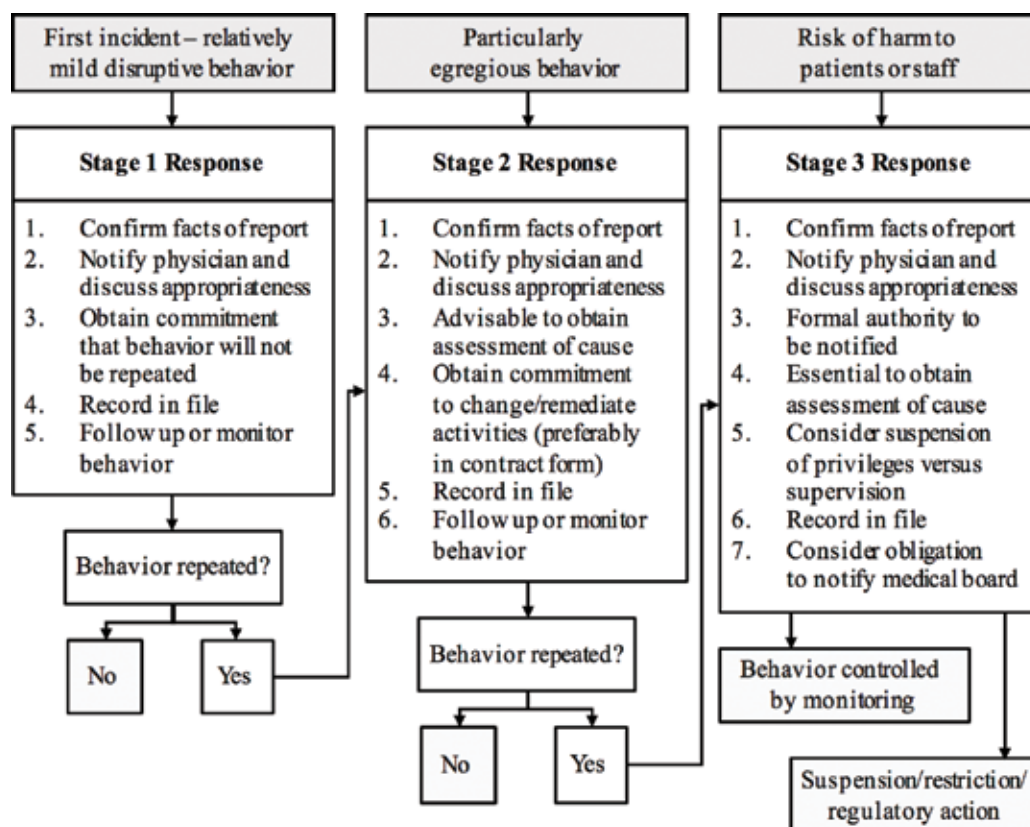


Figure 1. Behavior management flowchart, adapted from College of Physicians and Surgeons of Ontario [53].

eliminated and utilization of supportive resources encouraged, including stress management education, and counseling [3]. In response to a survey demonstrating a limited capacity by state medical boards to act as there is a lack of standards of behavior, the FSMB Essentials published a mandate in 2015 stating disciplinary action may be taken on physicians who exhibit “disruptive behavior and/or interaction with physicians, hospital personnel, patients, family members, or others that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient” [6, 52].

8. Conclusions

Disruptive physicians pose a substantial threat to patient safety that is often unrecognized or unsatisfactorily addressed in hospitals and other health care organizations [5]. It is a universal concern that is pervasive throughout medicine. Early warning signs need to be recognized, and “the most effective surveillance tools for detecting unprofessional behavior are the eyes and ears of patients, visitors, and health care team members” [54]. Attention must be paid

to mitigating risk factors for deviant behavior and breaking down barriers for those seeking assistance. The current reactionary system appears only aware of the most egregious behaviors and should be set aside for a regular monitoring system with set standards of professionalism [5]. Through a comprehensive policy of appropriate expectations, zero-tolerance policy for nonadherence, and utilization of rehabilitation techniques, the negative effects of disruptive physician behavior on patient safety can be corrected.

Author details

Leah Tatebe and Mamta Swaroop*

*Address all correspondence to: mswaroop@nm.org

Feinberg School of Medicine, Northwestern University, Chicago, Illinois, United States

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Interhospital Transfers: Managing Competing Priorities while Ensuring Patient Safety

Joshua Luster, Franz S. Yanagawa, Charles Bendas,
Christine L. Ramirez, James Cipolla and
Stanislaw P. Stawicki

Additional information is available at the end of the chapter

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Abstract

Interhospital patient transfers (IPTs) are highly complex logistical undertakings, involving a multitude of interdependent procedures, critical steps and a degree of unpredictability. Beginning with interfacility communication and patient acceptance agreement, a cascade of numerous handoffs takes place, ultimately culminating in safe arrival of the patient at the receiving facility. Due to the complexity of the IPT process, significant potential for critical errors and adverse patient safety (PS) outcomes exists. To minimize any associated risks, key PS considerations include checklists, handoffs, vehicle/aircraft safety, distance of travel, crew training, team factors, and many other critical components. Detailed knowledge of factors that may influence the risk of errors or adverse events is critical to optimizing both PS and clinical outcomes.

Keywords: interfacility patient transfer, interhospital patient transfer, medical transportation, patient safety, patient transfers, transitions of care

1. Clinical vignette

A young male patient is involved in a head-on motor vehicle collision resulting in heavy vehicle damage with steering wheel deformity. After prolonged extrication, the patient is evaluated by emergency medical services (EMS) personnel, who determine that he is stable for ground transfer and subsequently bring him to a nearby community hospital. Upon further evaluation, the patient is found to have blunt cardiac injury, multiple rib fractures, and bilateral pulmonary contusions. At this point, the treating physician at the community hospital determines that transfer to a higher level of care is required. He promptly contacts a nearby trauma center that has the required expertise to effectively manage this patient's injuries.

A dialog between the community physician and the trauma surgeon from the destination facility is initiated. The receiving trauma surgeon approves the transfer but is in the midst of an acute trauma evaluation and cannot receive a full report on the patient's condition or injuries. The community physician, having received approval for transport, begins the process of moving the patient to the trauma center without any further discussions with the receiving surgeon. Because the patient was hemodynamically stable throughout his evaluation, basic life support (BLS) was determined to be sufficient to transport the patient to the receiving facility, approximately 40 minutes away by ground. The patient is then placed on a BLS ambulance, and the transfer commences. En route, the patient starts to deteriorate with clinical signs of cardiogenic shock, most likely secondary to blunt cardiac injury. Within their scope of practice, BLS personnel attempt to provide care for the patient, but eventually he becomes pulseless, requiring cardiopulmonary resuscitation (CPR). After 10 minutes of CPR, the patient arrives at the trauma center. At this time, the surprised receiving trauma team begins large-scale resuscitative efforts. Because the patient was transported with only a handful of printed pages from the medical record, the receiving team frantically scrambles to accumulate relevant clinical information from the sending hospital. After approximately 20 additional minutes of cardiopulmonary resuscitation, the patient dies. What were the contributing factors to this tragic outcome? How could similar occurrences be prevented in the future?

2. Discussion

Interhospital patient transfer (IPT), a special case within the transitions of care (TOC) domain, is one of the most complicated and high-risk procedures in terms of coordination and patient safety (PS) [1–3]. Interhospital transfer is a type of interfacility transfer (IFT) defined as a transfer following assessment and stabilization at one healthcare facility with movement of the patient to another facility (e.g., clinic to hospital, hospital to inpatient rehabilitation, hospital to long-term care, or hospital to hospital, etc.) [4–6]. In this chapter we will focus primarily on hospital-to-hospital transfers. As in many other areas of PS, communication plays a critical role in ensuring effective and uneventful IPT [3]. Teamwork and attention to detail are important components of each and every IPT, regardless of how simple or “routine” the process may appear to be [7, 8].

The hypothetical case presented in this chapter's clinical vignette describes, and exemplifies, common failure modes encountered in the current system of IPT, with focus on inadequate communication and incomplete understanding of patient condition(s) leading to inappropriate transport-level triage, ultimately resulting in preventable loss of life. The communication between the transferring and accepting physician was deficient, characterized by an unstructured handoff, lack of follow-up, and errors in clinical judgment that led to decreased awareness of risk. Again, the consequence of the above events was the patient's death. More specifically, the lack of planning and incomplete understanding of the circumstances by the community hospital physician, coupled with lack of effective communication from the receiving trauma surgeon, contributed to the request for inadequate resources (both in terms of equipment and trained

personnel) during patient transport. The choice of ground transportation may have been satisfactory for short-distance transfers (e.g., <10–15 miles), but in the case of a projected 40-minute travel time, the choice of air transportation may have been more optimal [9]. Regardless of the modality chosen, the level of crew training (e.g., BLS versus advanced life support or ALS) was equally critical to the current patient's condition.

The capacity for IPTs within our healthcare system will likely grow with the progressive regionalization of care and the associated concentration of specialty medical and surgical expertise at regional referral centers [10–12]. The subsequent discussion will touch upon the many potential interventions that should be considered to reduce the overall risk associated with IPT. The authors will discuss checklist use, handoffs, medication safety, provider-to-provider communication, nursing communication, timely transfer of medical record and imaging information, crew training, team collaboration, critical supplies, as well as safety of the vehicles or aircraft involved in the transfer process.

3. Interfacility patient transfers: basic facts and indications

Each year, >500,000 IPTs take place in the United States [13]. One of the main indications for an IPT is the requirement for additional resources not available at the referring hospital in order to provide an adequate level of patient care and expertise [2, 14, 15]. Specific reasons may include the need for medical subspecialty (e.g., neurosurgery or transplantation) coverage, lack of the required level of nursing care (e.g., intensive care, trauma care, or epilepsy monitoring), or lack of equipment necessary to provide acceptable standard-of-care management (e.g., imaging or interventional capability) [16–20].

For instance, a patient presenting to a small community hospital with signs of an acute myocardial infarction may require an emergent percutaneous coronary intervention which likely will be unavailable at this particular facility [21]. As a result, based on acuity, this patient would then need to be urgently transferred to a tertiary hospital that can provide the required interventional procedure and any subsequent definitive care. While the transfer to such tertiary facility would allow this patient to undergo the optimal therapeutic management, the very presence of a myocardial infarction, even if successfully temporized, may increase the risk of IPT. Hypothetically, the patient's condition could deteriorate, and he or she could develop a cardiac arrhythmia and become unstable en route to the receiving facility, or the much needed intervention could be delayed because of the transfer [22]. In both circumstances, any risk(s) associated with transferring the patient should be carefully considered in the context of potential benefits of percutaneous coronary revascularization [23]. In the end, each IPT must be well justified, with the patient standing to gain from the presence of procedural, technical, or knowledge assets that are unavailable at the original hospital [2, 23]. Accurate assessment of the current patient condition (**Table 1**) is the most important initial step when determining both the need for transfer and the level of care required during IPT.

Patient acuity level	Patient characteristics
Stable, with no risk of deterioration	Routine vital signs, IV line placement, supplemental oxygen administration [level 1]
Stable, with low risk of decline	Level 1 + need for active IV infusion and/or IV medications, pulse oximetry monitoring, personalized care with advanced assessment skills [level 2]
Stable, with moderate risk of decline	Level 2 + EKG/telemetry, cardiac and/or other life-sustaining medications and measures [level 3]
Stable, with high risk of decline	Level 3 + advanced airway or intubation, mechanical ventilatory support/management, vasoactive drips [level 4]
Unstable, with clinical deterioration	Level 4 + unable to achieve sustained hemodynamic stability; actively deteriorating clinical picture; ongoing requirement for invasive monitoring and/or procedures [level 5]

EKG, electrocardiography; IV, intravenous.

Table 1. Patient acuity level definitions.

4. Overview of guidelines for patient transfer

As stated previously, each and every IPT needs to be assessed carefully from the standpoint of potential risks, benefits, and alternatives. Physicians at both the transferring and receiving hospitals must be aware of the patient’s up-to-date clinical status and any specific management requirements [2]. The logistics of medical direction should be determined prior to the initiation of the transfer process [24]. In brief, the responsibility for ongoing care of the patient being transferred rests with the designated “medical director” for the duration of the IPT. This supervising provider may be the transferring physician, the medical director of the transporting service, or the accepting physician. At times, a shared responsibility model that has been agreed upon by all supervising parties can be employed [24].

Given the complexities involved (**Figures 1** and **2**), great care must go into choosing which patients need to be transferred and how they should be transported [2]. Significant amount of customization may be required, with patient safety and hemodynamic stability being among top priorities throughout the entire process. Each patient should be transported under the care of specially trained healthcare professionals, which can include physicians, nurses, advanced life support (ALS)-trained or basic life support (BLS)-trained personnel, respiratory therapists, and others as required, in order to ensure that the transfer is safe and that continuity of care occurs seamlessly both during the IPT and after the arrival at the destination facility [25, 26].

The situation becomes more complicated when various practical aspects of the patient transfer process come into play, both in terms of IPT appropriateness and safety. As stated earlier in this chapter, patients should be transferred only when the facility where they are currently being treated does not have the expertise, equipment, or other accommodations necessary for the patient to receive the appropriate-level care [27–30]. Regardless of the exact scenario, the goal should always be to stabilize the patient prior to transport in an effort to maximize the likelihood of uneventful interfacility transit, timely arrival, and smooth care transition at the receiving institution [18, 31]. During the transfer, constant communication between the medical command and the transporting vehicle/aircraft should be taking place [32], especially given the

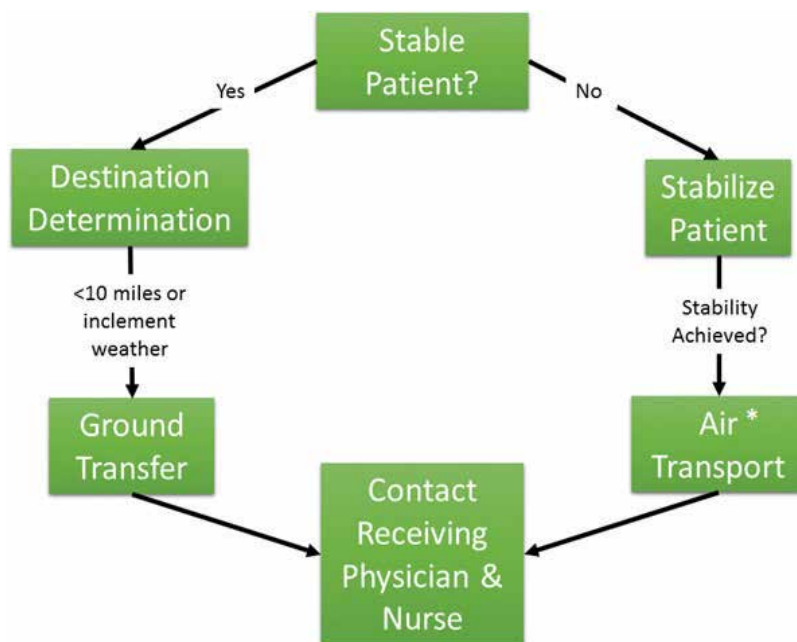


Figure 1. Clinical assessment of the patient in the context of interfacility transfer. The overall process begins with the assessment of patient stability, with subsequent determinations of the transportation modality (ground versus air transport). At all times, communication lines should be open between the referring and receiving facilities; *The ultimate choice of air versus ground transfer should be made after considering patient acuity and weather conditions.

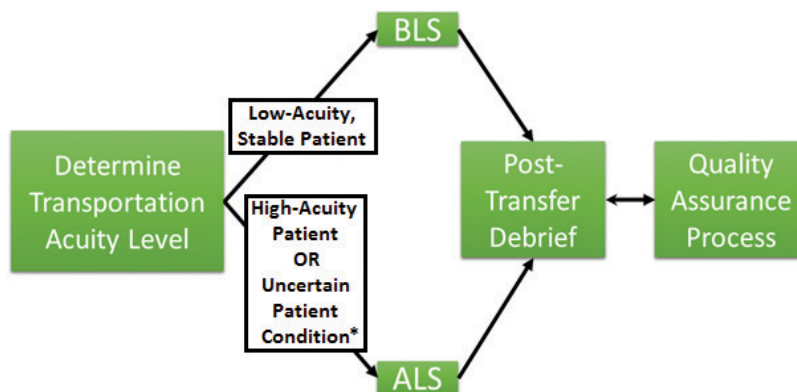


Figure 2. Simplified decision-making algorithm outlining the process of determining whether to use basic (BLS) or advanced (ALS) life support. Post-transfer debriefings and continuous quality assurance are critical to ensuring that safe and effective transfer services continue to operate; *When patient condition is not known, over-triage is preferred to under-triage.

evolving capabilities for continued remote patient monitoring [33]. Consistent with the above principles, if a patient is sufficiently stable to undergo IPT, the sooner the transport process begins, the sooner the necessary (e.g., definitive) interventions can take place. If the patient's baseline status is stable, and the need for transfer is triggered by the requirement for specialty

treatment or the higher level of care, then they can be transported within a reasonable time frame that is convenient for both the transferring and receiving facilities. In such cases, multivariable consideration should include the assessment of need, the overall urgency, current bed capacity at the receiving institution, and the availability of transportation resources.

5. Medical oversight during patient transfer: the role of the medical director

The role of the “medical director” is complex and requires detailed knowledge of IPT-related regulations, which can differ from state to state or region to region. The most important legal framework pertaining to interfacility transfers is the Emergency Medical Treatment and Labor Act (EMTALA) of 1986. It is a federal law whose primary purpose is to ensure that patients with emergency medical conditions are appropriately screened and treated at U.S. Medicare-participating facilities, regardless of a patient’s financial or insurance status and/or their national origin, race, creed, or color [34, 35].

EMTALA automatically applies when an individual presents to a department that is specifically equipped and staffed for the initial evaluation and treatment of outpatients with emergency medical conditions, such as emergency departments. EMTALA also governs how these patients are transferred from one hospital to another and applies specifically to unstable patients. An unstable patient cannot be transferred unless (1) a physician certifies that the medical benefits of transfer outweigh any associated risks or (2) a patient makes a transfer request in writing after being informed of EMTALA and the risks of transfer [34, 35].

EMTALA dictates that the referring physician is the responsible individual for the care of the patient during transfer, although the accepting physician may provide direction/advice [2, 36, 37]. The transferring hospital is obligated to treat and stabilize the patient within its capabilities until the IPT process commences. This mandate serves to minimize interfacility transit risks by optimizing patient condition prior to transfer. The referring facility must also provide copies of medical records, confirm that the receiving institution has space and qualified personnel to treat the condition and has accepted the transfer, and ensure that the IPT can be safely facilitated using qualified personnel and appropriate medical equipment. Conversely, the receiving hospital is obliged under EMTALA to accept an appropriate transfer of a patient who requires specialized care if the hospital has the capacity and corresponding capabilities and facilities to treat the individual. It is critically important for providers to clearly understand the EMTALA framework, not only from the standpoint of patient safety but also from the perspective of level of care and health coverage considerations. All EMTALA violations are considered to be very serious and may lead to substantial penalties, up to and including large civil fines (e.g., for both physicians and hospitals), lawsuits, and potential exclusion from federal and state medical reimbursement programs including Medicare and Medicaid [34, 38].

Consequently, medical direction is of utmost importance throughout the entire IPT process [2]. Logistically, this form of patient oversight can take a number of different forms. Most commonly utilized is the model where the referring physician provides online/on-scene direction.

While a patient is in transport, medical oversight can be maintained by the referring or accepting physician as well as the medical director of the transporting agency or the medical director's specialty care proxy. The latter may require that the medical director consults specialist providers with highly specific area(s) of expertise. Due to the broad range of tasks and responsibilities, the selection process for medical transport program director should ensure that suitable candidates demonstrate sufficient knowledge and skills across numerous domains, as outlined by the National Association of EMS Physicians [39].

In addition to direct oversight of patient transports, the responsibilities of EMS medical director also include activities such as personnel training and education as well as the development of pertinent protocols and procedures. Finally, medical directors are also tasked with reviewing IPT documentation records to determine the appropriateness of care and to verify that sufficient quality of services is being maintained. Regularly scheduled reviews of EMS performance, including quality improvement and compliance oversight, ensure that operations can continue at desired levels of safety and efficiency [40]. Formal education consisting of structured curricula offered at local/regional levels should be encouraged and supported, with the goal of disseminating and reinforcing fundamental knowledge and skills related to the provision of high-quality, safe, and effective emergency medical services. Less formal education often takes place as well, focusing on practical aspects of daily EMS operations, especially at the individual/team level. As outlined elsewhere throughout the *Vignettes in Patient Safety*, it is critical that personnel participating in IPTs are able to report any safety concerns in an anonymous and fair manner, without fear of being judged or punished for doing so.

6. Communication

The first step in the process of IPT is the initiation of proper communication channel(s) between the two institutions involved. The transferring physician should gather clinical information necessary for an orderly handoff and then initiate the transfer request by contacting the hospital department tasked with such procedures. This organizational functionality is often termed "patient transfer center," "patient placement center," or "patient referral center" and will reach out to an analogous department at the receiving institution. The staff at each institution's "transfer center" then contacts key stakeholders (e.g., referring and accepting physician, bedside nurses, etc.) so that the receiving physician is fully aware of the patient's condition and any other information pertinent to the situation in order to determine the appropriateness of the proposed transfer, assess patient suitability for transfer in the context of available clinical data, allocate appropriate level-of-care resources (e.g., ICU bed, operating room), and finalize the decision on transfer modality (e.g., ground versus air transport) [41, 42]. Not only is it necessary for the referring and accepting physicians to be in close contact and discuss the transfer and any potential challenges, but it is also critical for the nurses from the receiving and transferring facilities to communicate details of care pertaining to the patient [43, 44]. This helps facilitate a smooth transition and minimizes any ITP-related disruptions. Lack of communication is a major, preventable source of medical error and is especially prevalent when the care teams are from two different facilities [41, 44]. While distance, distractions,

incongruent treatment goals/plans, uncertainty of timing, and contrasting information sources are all barriers to continuity of care, standardized medical handoffs can help reduce situational and informational confusion, reduce medical errors, and hopefully result in better and safer patient care [2]. Although the authors of this chapter do not advocate for any specific approach to transfer-related communication, the reader is encouraged to consistently employ one of the many previously described systems of handover (Table 2).

In addition, patients should be transferred with readily available medical records, laboratory results, radiologic studies, and any other important documents needed to make optimal treatment decisions [41]. Whenever electronic access to patient record is feasible, the referring facility should enable appropriate viewing rights for authorized provider(s) at the receiving

ISBAR:

- Identity—patient’s identification, including current location, clinical care team, etc.
- Situation—current clinical problem, including signs, symptoms, and stability
- Background—pertinent medical history elements, including hospital length of stay, past medical and surgical history, and medication use (past and current)
- Assessment and action—current diagnosis and clinical impression, followed by specific description of clinical interventions and plan(s)
- Recommendation—communication regarding potential future treatment(s), diagnostic workup, clinical evaluation(s), and any other clinically relevant plan(s)

POET-PC:

- Preparation—exchange of basic information, including staff introductions and the general description of the patient and his/her condition
- Organization—the use of established format for standardized information exchange. Personnel is empowered to ask questions and clarify information
- Environmental awareness—ensuring that required equipment is functioning. Safety checklists are followed to verify and cross-check any environment-related variables that may influence patient condition and/or safety (e.g., intravenous medication administration)
- Transfer of responsibility and accountability—formal communication takes place regarding transfer of clinical responsibilities, including formal change in accountability for direct patient care (and safety)
- Patient and caregiver involvement—active participation of both the patient and his/her caregiver(s) is encouraged, whenever possible and/or applicable

SBAR:

- Situation—how is the patient doing at the time of communication?
- Background—pertinent demographic and clinical information, including patient identification, medical/social history, medications/allergies, and any intervention(s)
- Assessment—brief outline of the patient’s current condition, acute medical problem(s), and prognostic information, with any associated management plan(s)
- Recommendations—discussion of potential future course, including associated diagnostic and therapeutic input/suggestions

SOAP:

- Subjective—recorded patient complaints, symptoms, and other nonobjective data
 - Objective—details including vital signs, clinical signs, physical examination, and other objective data
 - Assessment—summative evaluation of the patient’s overall condition, incorporating pertinent diagnostic, and physical exam findings
 - Plan—specific clinical step(s) based on the most recent assessment, including diagnostic and therapeutic recommendations
-

Table 2. Commonly used standardized systems of handover. Compiled and modified from Aslanidis et al. [78], Chaboyer [79] and Abraham et al. [80]. Queensland Government: Clinical handover at the bedside checklist [81].

facility. Otherwise, all available records should either be copied or printed and sent with the patient to avoid critical information gaps at the receiving institution [2]. If laboratory results or other critical documents are not available when a patient is ready for transfer, then the referring facility must alert the receiving facility of any outstanding documentation and ensure timely and accurate transmission (including direct communication) of required information.

It is critical to emphasize the importance of family communication that should occur in parallel to the interfacility dialog. Not infrequently, this important task becomes lost among the plethora of clinical information exchanged during IPTs. The healthcare team must manage expectations of the family, including the real possibility—despite all safety measures—of patient clinical decompensation during the transfer process. An important component of the dialog involving the patient's loved ones is to establish good rapport and an open conversation between the receiving facility and the family who may not be familiar with the staff and/or capabilities of the destination hospital. It also allows both the transferring and receiving facility to better understand family expectations (e.g., goals of care) and to establish an effective platform for any follow-up inquiries [45]. The additional allocation of time and effort that is devoted to informing the patient's loved ones far outweighs the risk of any associated delays [46].

Finally, providers from each facility should consider discussing the necessity of obtaining additional imaging and/or laboratory tests prior to and while awaiting transfer to another hospital. However, it is important to keep in mind that while these results may help facilitate treatment management at the receiving facility, delaying transfer because of additional diagnostic studies may inadvertently result in increased morbidity and mortality.

7. Determining air versus ground transport

There has been a great deal of research and discussion surrounding the benefits and limitations of utilizing ground emergency medical transport (GEMT) versus helicopter emergency medical services (HEMS) during IPTs [47, 48]. Some studies have suggested that there is little difference between GEMT and HEMS during optimal conditions and that there is no measurable benefit in outcomes such as disability, health status, or healthcare utilization [48–50].

For GEMT, the estimated number of annual dispatches in the United States exceeds 10–20 million, giving a glimpse of the enormity and the complexity of the EMS system [51]. According to the National Highway Traffic Safety Administration (NHTSA), the mean estimated number of motor vehicle crashes involving an ambulance stands at approximately 4,500 per year [52]. For HEMS, it is estimated that more than 400,000 patients are transported each year by aeromedical means [53, 54]. While HEMS accidents have decreased in recent years, there is still an incident rate between 0.56 and 0.73 per 10,000 missions, with fatal accidents occurring at a rate of 0.04–0.23 per 10,000 missions [9, 55]. Factors that may contribute to HEMS flight safety include weather conditions, crew training and experience, technical equipment maintenance, as well as the time of day during the conduct of the mission [9, 56, 57]. For both GEMT and HEMS agencies, it is critical to ensure the safety of patients being transported,

to reduce the risk of injury or death to occupants of the medical transport platform (e.g., ambulance or aircraft), and to avoid any injuries/casualties or losses involving other vehicles, aircraft, people, or property.

In terms of modality selection, ground transport is generally faster when travel distances are less than 10 miles using simultaneous dispatch as the reference point, or the cutoff mark of 45 miles in the setting of nonsimultaneous dispatch [9, 58]. Generally speaking, GEMT vehicles are more readily available than air transport platforms (e.g., helicopter or fixed-wing aircraft). For IPTs involving longer distances (and greater amount of ground travel time), aeromedical transportation may be faster and more effective [49]. Others suggested that air transportation should be considered when the expected duration of ground travel exceeds 30 minutes [59, 60].

When determining which type of transport to utilize and under which circumstances, it is imperative to consider each patient's unique situation, as well as any limitations of the facilities involved. In addition to patient stability, travel distance, and time-based considerations outlined in the previous paragraphs, it is also important to account for weather conditions, time of day, as well as the availability and distance of landing facilities from both the referring and receiving facilities [61, 62]. For example, if a receiving hospital utilizes a local airport as a waypoint for HEMS transfers, the additional transit time from the airport to the destination should be examined and compared to a GEMT alternative that may take the patient "from door to door" in equal or lesser amount of time. Additional factors to be considered should include transport priority/acuity, relative cost, resource availability, and the clinical justification (e.g., the determination of medical necessity of the transport) [63, 64]. If a patient is clinically stable, does not require any time-critical interventions, and is expected to remain stable, the more precious resource of air transport may be unnecessary and should be reserved for scenarios involving greater acuity of illness that better justify more expedient transfer [61, 62, 64].

8. Advanced life support (ALS) versus basic life support (BLS): determining the level of care and patient needs

Ensuring appropriate match between EMT personnel skills, knowledge, and the available equipment and infrastructure is the cornerstone of safe and effective IPT. It should be noted, in accordance with the NHTSA EMS guidelines, that the transferring provider should "err on the side of caution" and secure resources for transport that may ultimately exceed needs while at the same time anticipating a patient's possible deterioration [65].

In addition to ensuring that appropriate safety protocols (including vehicle-related, equipment-related, and provider-related considerations) are in place [25], IPTs demand a unique set of provider skills compared to other types of healthcare settings. The aforementioned guidelines organize patient need levels into three tiers: (a) basic life support (BLS, **Table 3**), (b) advanced life support (ALS, **Table 4**), and (c) critical care transport (CCT, **Table 5**) [66–69]. The Centers for Medicare and Medicaid Services (CMS) defines yet another level of care known as the specialty care transport (SCT), which involves the transfer of a critically ill or injured patient that requires

Basic Life Support (BLS): Knowledge and Skills

- Appropriate radio and communication technology
- Transport equipment, logistics & related technologies
- Patient records & other documentation
- Patient is secured for optimal safety and accessibility
- Medical oversight & physician orders
- Level of care determination prior to transport

Table 3. Basic life support (BLS): minimal transportation requirement which includes equipment, basic medical knowledge base, and personnel skill set that will be necessary to safely transport a patient who is stable.

Advanced Life Support (ALS): Knowledge and Skills

- Basic Life Support skills PLUS:
 - Ventilatory mechanical support / management
 - Ability to administer broad range of medications, with pharmacology education at the level of DOT EMT Paramedical National Standard Curriculum
 - Advanced knowledge of vasoactive and antiarrhythmic drugs
 - Proficiency in circulatory management and support

Table 4. Advances life support (ALS): basic life support PLUS more advanced equipment, greater depth of medical/pharmacy/resuscitation knowledge, and broader technical personnel skill set in order to safely transport a patient who may be stable, but is at risk of clinical deterioration. ECG, electrocardiogram; DOT EMT, Department of Transportation Emergency Medical Technician.

knowledge and skill beyond that of the EMT and paramedic [70]. It is applicable when a patient's condition is such that it requires a provider in a specific specialty area (e.g., critical care nurse, emergency physician, orthopedic surgeon) to safely and adequately transport the patient.

The next and very important question to be answered is when to use ALS versus BLS. As outlined previously, triaging patients to the appropriate level of transport requires accurate matching of provider skills, ambulance crew composition (e.g., paramedics, EMTs, nurses, physicians, and respiratory therapists), equipment availability, and the implementation of pertinent patient care protocols. In addition to the general principles and fundamental considerations, the level of care and crew training must also be in compliance with local and state laws and guidelines [71–74].

The main difference between ALS and BLS transports is the ability to provide care at increasing levels of patient acuity [75]. Therefore, the key triage decision that drives the use of ALS

Critical Care Transport: Knowledge and Skills

- Basic + Advanced Life Support skills PLUS:
 - Advanced ventilatory management
 - Ability to administer complex IV medication regimens, with pharmacology education at the level of DOT EMT Paramedical National Standard Curriculum
 - Advanced use of vasoactive and antiarrhythmic drugs
 - Proficiency in circulatory management and support
 - Familiarity with a variety of critical care procedures, including the use of advanced intravenous and extracorporeal devices

Table 5. Critical care transport (CCT): basic and advances life support PLUS specialized skills in the areas of medical/ pharmacy/resuscitation, including familiarity with advanced critical care devices (e.g., extracorporeal support, various intravenous devices) to safely transport a patient who may be in stable of guarded condition, but may face imminent life-threatening decline. DOT EMT, Department of Transportation Emergency Medical Technician; IV, intravenous.

over BLS is the status of the patient. If the patient is considered to be more acutely ill and might require advanced interventions (e.g., ACLS protocol) during the transfer, then ALS is recommended. If, however, a patient is stable and is expected to remain stable, and the acuity is such that he or she will likely not require additional support while in transit, then BLS would be most appropriate option. No matter the level of training of the transport team, it is recommended that the transferring physician be available to communicate with them (see the previous section on medical command). This serves to ensure that any complications which may arise during the IPT can be identified and addressed immediately, thus optimizing the overall patient safety equation during transport. **Figure 3** demonstrates major possible risks

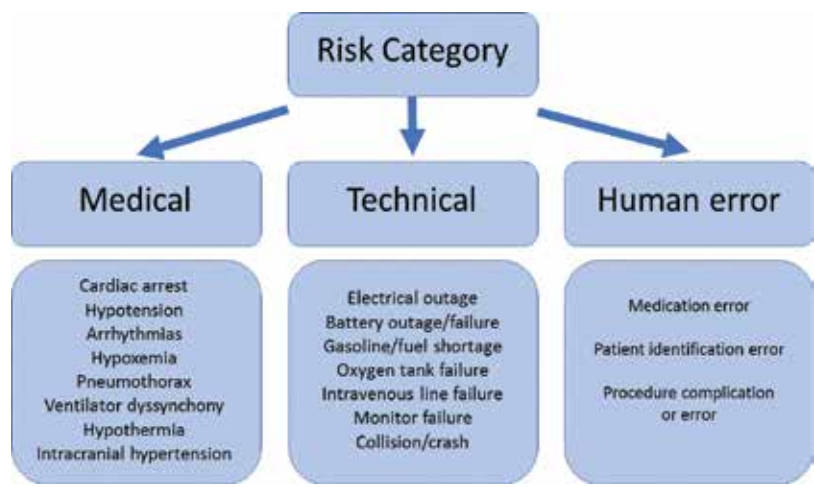


Figure 3. Potential risks associated with interfacility transfers, listed by category.

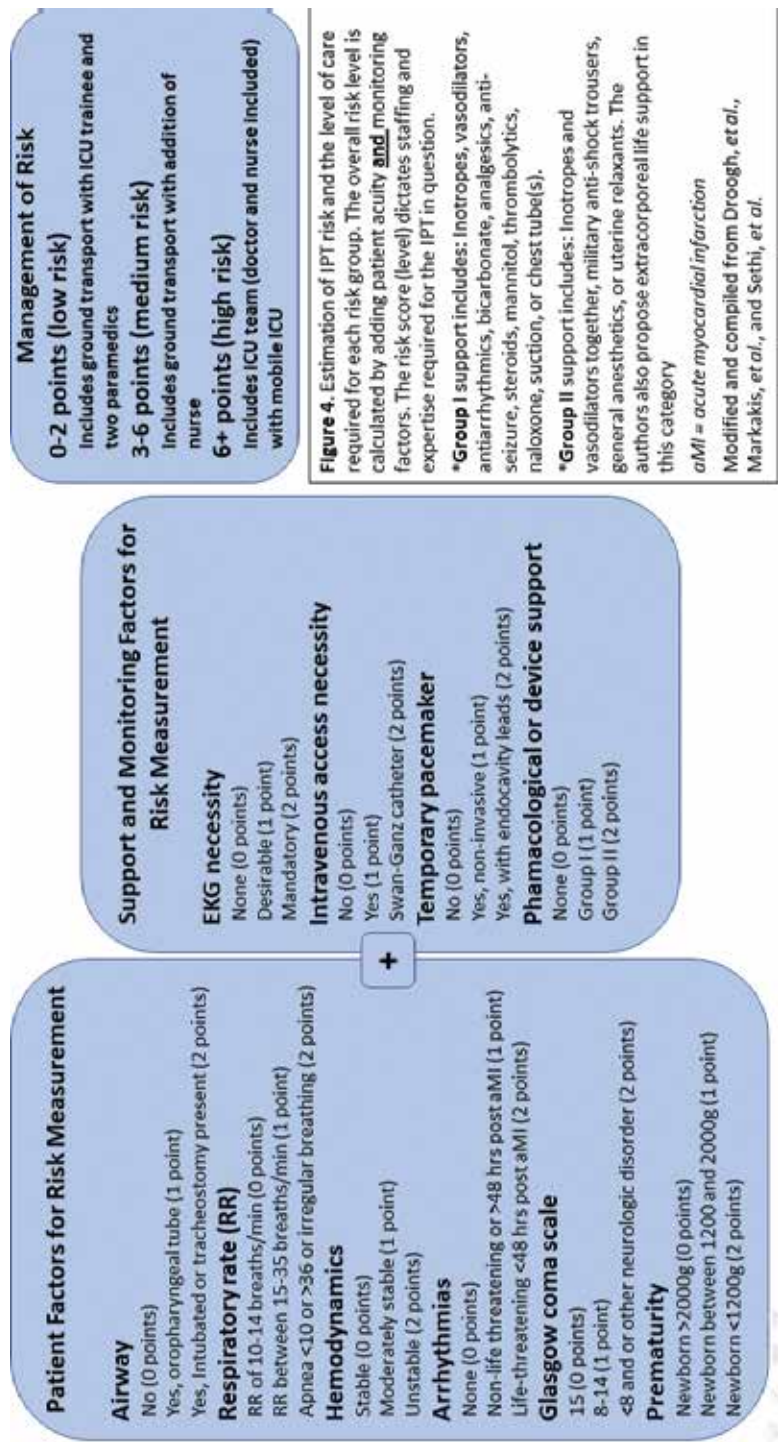


Figure 4. Estimation of IPT risk and the level of care required for the corresponding physiologic acuity. The overall risk level is calculated by adding patient acuity and monitoring intensity as main co-factors. The risk score (level) dictates staffing and expertise required for the IPT in question. *Group I support includes inotropes, vasodilators, antiarrhythmics, bicarbonate, analgesics, antiepileptic agents, steroids, mannitol, thrombolytics, naloxone, suction equipment, or chest tube(s). *Group II support includes inotropes and vasodilators together, military antishock trousers, general anesthetics, or uterine relaxants. The authors also propose extracorporeal life support in this category. Legend: aMI, acute myocardial infarction; EKG, electrocardiogram. Modified and compiled from Droogh et al. [77], Markakis et al. [76], and Sethi and Subramanian [4].

associated with IPTs, and **Figure 4** summarizes the IPT risk assessment process, highlighting the multitude of interdependent factors that may contribute (alone or in various combinations) to the occurrence of adverse events during interfacility patient transport [4, 76, 77].

In certain uncommon cases, a physician may be asked or required to travel with the patient to the receiving facility. Special care must be taken that a physician in this situation be compliant with any and all regulations regarding out-of-hospital privileges, medical command, and liability coverage, as these may all vary from state to state. Although some institutions may routinely use physicians as part of the transport team, most do not. Consequently, care must be taken to avoid any medicolegal pitfalls.

9. Conclusion

Interhospital patient transport (IPT) represents a critical process that involves multiple providers, intersecting communication lines, and large volume of exchanged information. Because of its complexity, IPT is inherently associated with significant risks to the patient being transported, from the potential for clinical deterioration to the possibility of a medication error. The decision to transport the patient is just as important as the determination of the level of care (e.g., ALS, BLS, CCT) during the transfer process. Patients should only be transferred when the clinical benefit(s) outweigh any risk(s), resulting in the patient being able to receive procedural, technical, or cognitive assets that are unavailable at the referring hospital. Appropriate oversight during IPT is critical and is provided through the use of medical command protocols. Lastly, HEMS versus GEMT should be decided carefully based on patient acuity, the distance between facilities, weather conditions, and a number of other important considerations. As with any healthcare endeavor, the most vital considerations during IPT should be the safety and well-being of the patient.

Author details

Joshua Luster¹, Franz S. Yanagawa², Charles Bendas³, Christine L. Ramirez³, James Cipolla³ and Stanislaw P. Stawicki^{3,4*}

*Address all correspondence to: stawicki.ace@gmail.com

1 St. Luke's University Hospital Campus of Temple University School of Medicine, Bethlehem, Pennsylvania, USA

2 Warren Hospital, St. Luke's University Health Network, Phillipsburg, New Jersey, USA

3 St. Luke's Level I Trauma Center, Bethlehem, Pennsylvania, USA

4 Department of Research & Innovation, St. Luke's University Health Network, Bethlehem, Pennsylvania, USA

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Retained Foreign Body

Jonathan F. Bean and Mamta Swaroop

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Abstract

Retained foreign bodies after surgeries or procedures are a rare complication with great consequences. The most commonly retained surgical items are guidewires, surgical sponges, and suture needles. The procedure at highest risk for retained foreign bodies is central venous catheterization. The literature regarding specific risk factors that increase the potential for retained surgical items varies. Evidence suggests that procedures with blood loss over 500 mL, lack of or an incorrect surgical instrument and sponge count, longer procedures, and unexpected intraoperative events all increase the risk of retained surgical items. There is conflicting evidence on the effect that elevated body mass index (BMI) or the emergent nature of a procedure has on retained surgical item risk. Interventions aimed at preventing retained foreign bodies include surgical counts, mandatory imaging after procedures, bar-coding of items used during surgery, and radiofrequency detection systems. These interventions have varying detection rates. Regardless of the safety measures used, none are perfect and a high index of suspicion must be maintained to prevent retained surgical foreign bodies.

Keywords: gossypiboma, retained foreign body

1. Case vignette

A 23-year-old man presented via ambulance to a level 1 trauma center after sustaining multiple gunshot wounds to the chest and abdomen. The patient was in hemorrhagic shock upon presentation to the trauma bay with a heart rate in 140 s and blood pressure of systolic 70 s. The patient had decreased mental status, and he was cool and diaphoretic. On primary survey, he was found to have one gunshot wound to the left thoracoabdominal region and another to the right thoracoabdominal region. Resuscitation efforts were initiated in the emergency department with blood products, and he was emergently brought to the operative theater for exploration. While in the operating room (OR) prior to beginning surgery, the patient underwent



Figure 1. Postoperative chest x-ray demonstrating the radio-opaque markers of the laparotomy pads around the liver. Note the same radio-opaque marker of a laparotomy pad in the left hemithorax.

cardiac arrest from hemorrhagic shock despite resuscitation. A left anterolateral thoracotomy was performed in order to explore the left thoracic cavity and cross-clamp the aorta. Some hemothorax was encountered upon entering the chest. There was no pericardial tamponade. A minor lung laceration secondary to the penetrating injury was encountered during the thoracic exploration. Only after the aorta was cross-clamped and resuscitation continued was return of spontaneous circulation achieved. Exploratory laparotomy was performed, and the patient was found to have a large hemoperitoneum secondary to a shattered spleen and left kidney, and a large liver injury. The patient underwent left nephrectomy and splenectomy, and the liver was packed with laparotomy pads. The aortic cross-clamp was removed, and there was no further surgical hemorrhage. The remainder of the abdomen was explored, and small bowel perforation GIA stapler is resected for damage control to prevent further spillage of succus. By this point in time in the procedure, the patient was cold, acidotic, and coagulopathic due to the major trauma and massive blood loss. Due to the coagulopathy of trauma as well as the need for further massive resuscitation, the decision was made to leave the liver packed with laparotomy pads with a plan for returning to the operating room for repeat abdominal exploration after resuscitation was complete. The abdomen was temporarily closed with a vacuum-assisted abdominal pack dressing. Since there was only minor trauma in the left chest, the pleural space was irrigated and examined for retained surgical instruments and laparotomy pads, two chest tubes were placed, and the thoracotomy was definitively closed. The closing instrument and laparotomy pad counts were not accurate due to the laparotomy pads left in the abdominal

cavity to maintain hemostasis of the liver injury. The patient was taken to the trauma intensive care unit for continued resuscitation, warming, and correction of the coagulopathy. His routine postoperative chest x-ray is shown in **Figure 1**. This was diagnosed with a retained laparotomy pad in the left hemithorax. An extensive discussion and disclosure of this adverse event were performed with the family of the patient. At the time of planned re-exploration of the abdomen, a left video-assisted thoracoscopic surgery was performed to remove the retained laparotomy pad from the thorax and to wash out any retained hemothorax. The patient had a prolonged hospitalization. He underwent multiple subsequent abdominal surgeries for debridement of his abdominal wound. Eventually, he survived to discharge.

2. Overview of retained surgical foreign bodies

Retained surgical foreign bodies are objects typically used in the course of a procedure or surgery that is inadvertently left remaining in the patient after the completion of the procedure. These items range from surgical instruments, to surgical sponges, to needles. Given the increased awareness and promotion of patient safety in medical care, much effort has been devoted to the elimination of retained surgical items in the past several years and several clinical reviews and meta-analyses have been performed to examine this topic.

Of the potential items at risk of unintentionally remaining within a patient after a surgery or procedure, guidewires for central venous catheter placement and surgical sponges are the two most commonly reported items [1–3]. Other items at risk are surgical instruments, suture needles, and any other item utilized during a surgery or procedure [2]. These various items can cause a variety of different responses depending on how long and where these items were misplaced. The duration of time between the index procedure and recognition has been found to correlate with symptomatology [4]. Local and systemic signs and symptoms associated with retained foreign objects can include abdominal pain, abscess formation, nausea and emesis, wound complications, palpable mass, systemic inflammatory response, and ileus. Furthermore, fibrosis, purulence, erosion, and fistulization can occur with long-term retention of foreign objects after surgery [4].

Considering all procedures, the median incidence of retained surgical foreign bodies is estimated to be 1.32 events per 10,000 surgical procedures [1]. The highest risk procedure for a retained foreign body is central venous catheter placement at 3.04 events per 10,000 procedures [5]. This is followed closely by 2.98 events per 10,000 surgeries for cavitory explorations for emergent trauma surgery [6].

Beyond the risk to the patient, the medico-legal risks associated with retained surgical foreign bodies are great. Gawande et al. found in their case control series that each retained foreign body that ended in litigation resulted in \$52,581 on average in costs for compensation and legal defense expenses [7]. In contrast, other studies have found that average defense costs for retained surgical sponges were \$572,079 per case with indemnity payments of \$2,072,319 per case [8]. Certainly, differences between these studies can be accounted for by regional differences in tort reform as well as differences in how these cases are handled by the risk

management and legal defense teams of different institutions (e.g., out-of-court settlements versus trial awards). Regardless of the differences, it is clear that these cases are an immense financial burden on physicians and their medical malpractice insurance. Additionally, there are other stressors that are not accounted for by these studies, namely the emotional stress and time demand that these cases have on those physicians involved. These unquantified costs can take an immense toll on the physicians that cared for their patients and could potentially have other repercussions that alter the care that individual doctors provide as well as a systemic effect in the future as the medical community naturally would respond by shifting to a practice of more defensive medicine.

Studies vary in the specific risk factors for an increased risk of retained surgical foreign bodies. The meta-analysis by Moffatt-Bruce et al. identified: an estimated blood loss >500 mL, incorrect surgical counts, multiple operative procedures, longer procedures, lack of performance of a surgical count, and unexpected intraoperative factors that portend a greater risk for retained surgical foreign bodies [3]. Procedures with increased blood loss could necessitate more use of laparotomy pads and instruments. As this blood loss becomes more critical and acute, the stress level in the OR is worsened and would increase the chance of losing track of sponges and instruments. As the number of operative procedures, length of procedures, and involvement of multiple teams in the care of a patient increase, there is heightened potential for miscommunication among the different teams or error during the safety checks already in place to protect patients from these adverse events.

Studies differ on the risk that emergent procedures and elevated body mass index (BMI) portend toward retained surgical foreign bodies [3, 4, 6, 7, 9–11]. In one example, Gawande et al. found that emergent procedures were of very high risk for retained foreign bodies [7]. Emergent procedures intuitively seem a high risk since these procedures are more likely to not have a properly completed sponge and instrument counts prior to the initiation of the surgery. It was additionally found that for each 1 unit increment of BMI increase, the risk ratio of retained foreign bodies increases significantly by 1.1 [7]. In another study on the risk of retained foreign bodies in emergent surgery, Teixeira et al. identified the need for a damage control operation in trauma (i.e., liver packing and temporary abdominal closure) as a risk factor in their case series [6]. In contrast, Moffatt-Bruce et al. found that elevated BMI and emergent surgery were not risk factors for retained sponges or instruments [3]. Regardless of the evidence, a high index of suspicion for retained surgical foreign bodies is warranted in those patients undergoing an emergent procedure or in patients with increased body mass indices.

A retrospective study by Vannucci et al. examined the risk factors associated with retained guidewires after central line placement by anesthesia providers. Through a small case series, their retrospective analysis revealed that worsening of clinical condition during line placement and complex surgical procedures necessitates multiple line placements as risk factors for retained guidewires [5]. This seems to echo the findings of Moffatt-Bruce et al., concerning surgical procedures and risk factors for retained foreign bodies after surgical procedures.

Several interventions have been attempted to reduce the risk of retained bodies in surgical procedures. These interventions include procedural modifications such as mandatory instrument and sponge counts at the start and completion of procedures. Others have attempted

technology utilization to reduce the human error aspects of retained surgical foreign bodies (e.g., automated counting devices and mandatory imaging for foreign body detection).

Surgical counts remain a mainstay in operating rooms in the United States. The process is simple. All sponge and instruments are counted both before surgery and after surgery, and these numbers should be equal. This is a logical starting point to reduce the risk of retained surgical foreign bodies. Unfortunately, this process has much potential for error built into the process. Cima et al. found in their series that 62% of patients with a retained surgical foreign body had a correct postoperative sponge and instrument count [2]. The limitations of this preventative measure result from the reliance upon the accuracy of both a preoperative and postoperative sponge and instrument count. Naturally, any procedure reliant upon human accuracy and performance will be prone to error as seen in the evidence.

Since the standard surgical sponge and instrument count have much potential for error such as miscounting by staff, improper recording of the counts or additional surgical supplies introduced after the start of the procedure, some have attempted to remove the potential of human error via computer tracking. Greenberg et al. compared a computer-based bar-coded sponge system to standard surgical counting protocols [12]. The bar-coding of surgical sponges significantly improved the error detection rate in surgical counts compared to standard counting protocols. The difficulty of the bar-coding approach is that it is labor intensive to scan every single surgical instrument and sponge and it still relies upon accurate scanning of these items by the OR staff. Furthermore, there is a lack of availability of the bar-coded technology for all surgical instruments which prevents its wide acceptance.

Another approach attempted has been to utilize mandatory intraoperative or postoperative imaging. Intraoperative imaging has been found by Cima et al. to only detect 67% of the retained surgical foreign bodies [2]. This lower than expected detection rate was attributed by the authors of that study to the poor resolution of portable imaging equipment, poor communication of the purpose of the imaging study to radiology, or multiple other objects obscuring the imaging field. They found that the intraoperative imaging was better at detecting larger items compared to small items such as needles. Routine screening imaging has been advocated prior to definitive closure of body cavities after damage control surgery [6]. Furthermore, some have advocated for routine imaging in those patients at high risk of retained foreign bodies [7]. This specific protocol would assist in the identification of retained laparotomy sponges since these have very noticeable radio-opaque indicators within the sponge. Gawande et al. calculated that the number needed to treat for routine postprocedural imaging to prevent one retained foreign body was 300 [7]. With the average cost of legal defense and indemnity payments ranging from \$52,000 up to over \$2 million per case, and the NNT for routine imaging being 300, it has been argued that routine imaging in high-risk patients would be a cost-effective measure to reduce medical malpractice costs [7]. The downside to mandatory postoperative imaging includes increased radiation exposure as well as the reliance upon the need for human interpretation of the imaging study, and this is not perfect.

Radiofrequency detection systems (RFDS) have been used to aid in the detection of retained surgical foreign bodies. These devices come in various configurations, from RF detection wands waived over the patient to mats on the OR table that the patient is positioned upon.

Regardless of differences, they all utilize a radiofrequency signal to detect tagged devices or sponges that remain in vivo. Rupp et al. enrolled 2285 consecutive surgical patients into a prospective study where they utilized RFDS to detect foreign bodies, near-miss events, and to resolve miscounts [13]. They found that the RFDS assisted in the detection of one near-miss event (a Raytec sponge in the surgical drapes) despite a correct surgical count. Furthermore, they found that in the 35 miscounts that were identified, the RFDS aided in the detection of 11 items retrieved from a surgical site or body cavity. These systems seem to be effective in the prevention of retained foreign bodies and have the added benefit of having rapid and reliable feedback to the team on the presence or absence of retained surgical items. The downside to these systems is the initial cost but in a study by Williams et al. that examined the implementation of an RFDS in five healthcare systems. They found that upon the implementation of the RFDS, there was a 77% reduction in the rate of retained foreign bodies [14]. Furthermore, taking into account the cost savings from avoidance of x-rays, the decreased time in the OR, and the avoidance of litigation, the cost-benefit analysis favored the implementation of the RFDS [14].

Future surgical technologies remain to be developed to improve the detection of retained surgical foreign bodies. Some potential avenues of development include the use of near-infrared coatings on surgical instruments to allow their detection. Other potential systems combine aspects of the prior described technologies. For example, the ASSIST system combines the RFDS technology with bar-coding. In an automated way, all sponges and instruments are electronically logged and tracked in a spatial and time manner to prevent retained surgical foreign bodies [15]. This future technology among many others will hopefully improve patient safety through decreasing the rate of retained surgical foreign bodies.

In conclusion, retained surgical foreign bodies are rare events for which all surgeons should have a high index of suspicion. Surgeons should recognize those risk factors that impart a greater risk of retained surgical foreign bodies such as increased blood loss, incorrect surgical counts, multiple procedures, changes in the surgical team, or unanticipated intraoperative events. They should also consider those factors that have been inconsistently found to be potential risk factors of retained foreign bodies such as emergent surgery and increased BMI. Furthermore, surgeons and other staff must recognize the limitations of the surgical count and be wary of a normal count when multiple risk factors exist for retained surgical foreign bodies. Finally, some technology and protocols exist that attempt to decrease this risk in surgical patients and hopefully more will come in the future. These interventions potentially decrease the risk of retained foreign bodies but do not replace the role of the surgeon and other staff in having a high index of suspicion for this to occur, and a desire to prevent these events from occurring in the future.

Author details

Jonathan F. Bean and Mamta Swaroop*

*Address all correspondence to: mswaroop@nm.org

Division of Trauma & Critical Care, Department of Surgery, Northwestern University, USA

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Wrong-Site Procedures: Preventable Never Events that Continue to Happen

Andrew Lin, Brian Wernick, Julia C. Tolentino and
Stanislaw P. Stawicki

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Abstract

A comprehensive discussion of “never events” or preventable and grievously shocking medical errors that may result in serious morbidity and mortality is incomplete without a thorough analysis of wrong-site procedures (WSP). These occurrences are often due to multiple, simultaneous failures in team processes and communication. Despite being relatively rare, wrong-site surgery can be devastating to all parties involved, from patients and families to healthcare workers and hospitals. This chapter provides a general overview of the topic in the context of clinical vignettes discussing specific examples of WSP. The goal of this work is to educate the reader about risk factors and preventive strategies pertinent to WSP, with the hope of propagating the knowledge required to eliminate these “never events.” To that end, the chapter discusses pitfalls in current surgical practice that may contribute to critical safety breakdowns and emphasizes the need for multiple overlapping measures designed to improve patient safety. Furthermore, updated definitions regarding WSP are included in order to better characterize the different types of WSP. Most importantly, this chapter presents evidence-based support for the current strategies to prevent wrong-site events. A summary of selected recent wrong-site occurrences is also provided as a reference for researchers in this important area of patient safety.

Keywords: never events, patient safety, patient safety errors, safety protocols, wrong-site surgery

1. Introduction

The rare but dramatic adverse occurrences as inexcusable and difficult to comprehend as wrong-site procedures (WSP) continue to shed negative light on our medical systems and

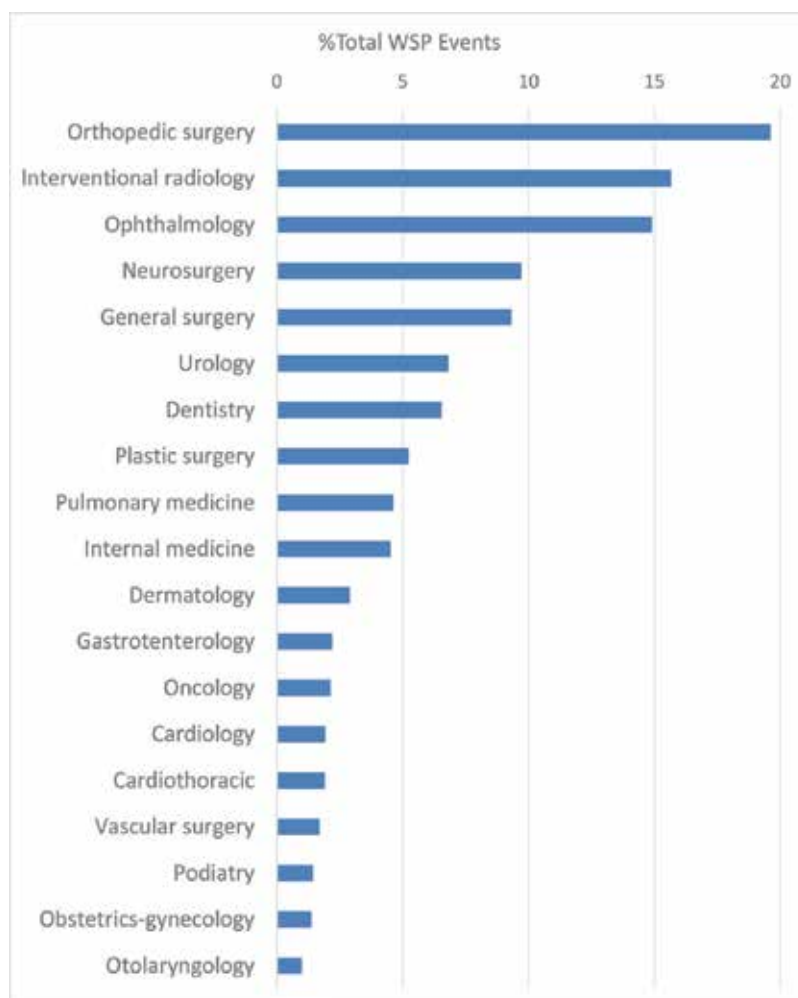


Figure 1. Relative frequency of wrong-site procedures (WSP) listed by specialty. Note that specialties with high percentage of laterality-specific cases (e.g., orthopedics, neurosurgery) report much higher percentage of WSP (data from 2007 to 2011). Data compiled from multiple sources.

bring into the light the fallibility of today's advanced healthcare environment [1, 2]. Dramatic news about the incorrect extremity amputation, spinal fixation above or below the intended level, or wrong rib being removed, intermittently appear on the landscape of headline news and "hard to believe" factoids. Personal, social, healthcare, and medico-legal burdens of WSP are significant, especially when one considers that these never events should never have happened in the first place [2, 3]. Indeed, well-functioning operating and procedural teams should be able to prevent these occurrences [4], especially when patients are actively participating in surgical site verification [5].

Malpractice database data suggest that approximately 1 in 113,000 surgical procedures are complicated by some sort of intervention at a "wrong site" [6]. For a typical hospital, it means

that WSP occur once every 5–10 years [7]. Wrong-site procedures constitute the second most frequent type of sentinel event reported, accounting for nearly 13% of all occurrences [8]. Literature regarding the frequency of WSP varies widely, depending on the reporting specialty and procedure type(s) involved. It is recognized that specialties performing frequent procedures involving various extremity [9], symmetric truncal/cranial/facial locations [2], or level-based surgeries [10] will inherently be more prone to WSP events (**Figure 1**) [6, 11–13]. For example, one study reported that 16% of hand surgeons reported prepping to operate on the wrong site but then noticing the error prior to incision, and >20% of respondents admitting to WSP at least once during their career [9]. Fortunately, major injury attributable to WSP is very rare [6].

Notable initiatives implemented to reduce WSP include the surgical safety checklist [14], the “sign, mark, and radiograph” initiative [15], various measures to empower the patient to participate in the perioperative safety process [5], as well as the Joint Commission’s “Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery” [16]. It has been postulated that current site verification procedures aimed at reducing the incidence of WSP are questionably effective and not supported by scientific evidence [6]. To corroborate the effectiveness of the above measures, it has been shown that interventions such as operating room (OR) briefings have been shown to produce benefits in terms of the perceived risk of WSP [1], and that the surgical safety checklist is not only productive but also non-disruptive—an accusation frequently heard during initial implementation phases of various patient safety initiatives [17]. As previously mentioned, it is undisputable that insufficient communication is among the most commonly identified root causes of patient safety events [18–20], with various verification and safety procedures being only “as good as” the implementation team.

2. Definitions

It is important to utilize uniform language conventions and definitions when discussing WSP. DeVine et al. [8], defined the conceptual framework for WSP that will be utilized in this chapter (**Table 1**). Additional important definitions have been defined in the introductory chapter of this book, and the reader is referred to that resource for further information and guidance. Although this language was originally developed to reflect WSP that occur in spinal surgeries, it is certainly applicable to other types of invasive procedures and specialties. Additionally, the definition of the wrong implant is added to make these terms truly inclusive of all types of procedural settings. **Figure 2** shows the distribution of WSP events broken down according to the definitions provided in **Table 1**, with data derived from Neily et al. [11, 12].

2.1. Clinical Vignette #1

According to a published report [21], a 15-year-old boy with seizure disorder was scheduled for surgery to remove epileptic foci on the right side of his brain. The patient was prepped and draped, but the surgical site was not marked, and no “surgical time-out” was documented.

Term	Definition
Wrong-site procedure	Invasive procedures performed on the incorrect body part or incorrect patient. This is a “catch all” term for wrong level/part, wrong patient, and wrong side surgery
Wrong level/part	Invasive procedure performed at the correct site but at the wrong level or part of the operative field
Wrong procedure	Invasive procedure that unjustifiably differed from the originally planned procedure, performed at the correct site
Wrong patient	Incorrect patient identification leading to a procedure performed on the wrong patient
Wrong side	Invasive procedure that involves operating on the wrong side of the body
Wrong level exposure	Surgical exposure performed on an unintended level, however, does not imply that surgery was performed at the incorrect level
Wrong implant/prosthesis/device	Placement of an implant, prosthesis, or device other than what was intentionally planned for the specific surgical procedure. This does not include intentionally placed implants, prostheses, or devices that are later found to perform optimally or fail

Modified from DeVine et al. [8].

Table 1. The conceptual and definitional framework for wrong-site procedural occurrences.

After removal of brain tissue, the surgical team realized that they were operating on the left side of patient’s brain. They elected to continue with the intended procedure and went on to remove brain tissue from the right side of the patient’s brain.

The neurosurgeon subsequently informed the patient’s parents that he initially operated on the wrong side of the patient’s brain, but switched to the correct side and completed the originally intended procedure. He reassured the parents that no brain tissue had been removed

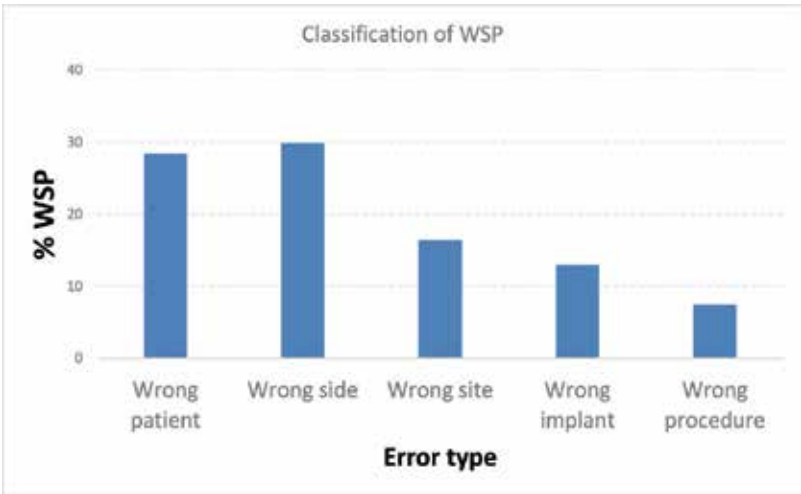


Figure 2. Bar graph showing WSP event frequency grouped by error type. The most common occurrences involve either wrong patient or wrong side.

from the wrong side and that overall “no harm was done.” It was only after approximately 17 months that the parents discovered via magnetic resonance imaging that their child was missing portions of his left amygdala, hippocampus, and had a detectable injury to other regions of left cerebral hemisphere. The parents also claimed that their child had suffered cognitive problems, personality changes, and developed episodes of “blank and void look in his eyes.”

Given the newly revealed information, the parents initiated a legal complaint against the surgeon, the hospital, and their insurance carrier citing medical malpractice. It was also alleged that the hospital administration failed to stop the surgery to the right side of the brain once the surgical team realized they have operated on the incorrect side. A \$20 million award to the parents of the patient was upheld by the state supreme court after a jury verdict in their favor [21].

2.2. Clinical Vignette #2

A 53-year-old patient presented to the hospital with abdominal pain and hematuria. Diagnostic workup included a computed tomography (CT) scan which revealed a mass in the right kidney consistent with renal cell carcinoma (RCC). Despite this finding, all of the hospital medical records erroneously documented a left-sided tumor. The patient was subsequently transferred to another hospital for definitive surgical management. The CT scan from the initial hospital was not available, and the patient did not undergo repeat imaging at the receiving center prior to surgery.

Despite the lack of imaging, the surgeon decided to proceed with the surgery and removed the patient’s left kidney based on the available medical record information. The left kidney was sent to the pathologist who detected no evidence of RCC. It was only after the pathologist called the surgeon the following day and after the surgeon reviewed the imaging that he realized that the incorrect kidney was removed.

The patient was then scheduled for a second surgery to remove the right kidney harboring the RCC. As a consequence, the patient was rendered dialysis-dependent having lost both kidneys, and due to his cancer, he is not eligible for renal transplant. No information regarding legal consequences was available for this case [22], but certainly, the risk of liability is extremely high.

3. Discussion

The two clinical vignettes presented above are both tragic cases of preventable wrong-site surgery occurrences. In addition to causing major harm to the patients involved, these events resulted in significant emotional distress to the patients’ relatives as well as major medico-legal, professional, and reputational consequences to the healthcare providers and institutions involved. In the first case, where the tissue was removed from the wrong side of the patient’s brain, a series of cumulative errors were made even before the surgery began. Available details from the subsequent legal proceedings indicated that during the day of the surgery, local

reporters were invited to take photographs and observe the surgery. This may have created an unacceptable level of distraction [23, 24]. Additionally, standard pre-procedural safety measures were not utilized, such as a pre-operative checklist and marking of the operative site. It has been shown that the presence of formalized OR briefing prior to making the incision increases the operative team's level of awareness (and thus confidence) regarding critical details of the procedure to be performed [1].

The occurrence of "never events" prompts clinicians, administrators, and patients to wonder why these errors continue to happen. **Figure 3** compiles data regarding contributing factors and causes of WSP from three studies reported between 2007 and 2010 [11, 13, 25]. Inadequate communication is the most frequent contributory cause of wrong-site surgery. In over 20% of cases reviewed during root cause analysis sessions, communication error was a major contributing factor in the wrong site, wrong procedure and wrong patient surgery [26]. Potential reasons for disorderly or deficient communication in Case Vignette #1 include the presence of reporters in the OR and the associated atmosphere of distraction. The presence of distractions and "unexpected" factors during the operation, in turn, has been shown to increase the risk of safety errors [27–29]. The latter may be due to lack of team or individual focus, and the subsequently diminished ability to "intercept and detect" errors [30–32].

The tragic cascade of errors in Clinical Vignette #1 was further compounded by the omission of the pre-operative checklist, surgical "time-out," and surgical site marking. This highlights the importance of the existing patient safety framework, mandated by the Joint Commission for continued institutional accreditation, and consisting of three specific measures to be conducted prior to all operations [16, 33]. Despite that, some have questioned the effectiveness of the measures required by the Joint Commission. For example, DeVine et al. noted the lack of data on the efficacy of pre-operative checklists and suggested the addition of intra-operative imaging, specifically for spine surgery, to verify the correct site [8]. However, a multicenter prospective study of the main components of the Joint Commission's recommendations did demonstrate the effectiveness of these simple and easy to implement measures [34].

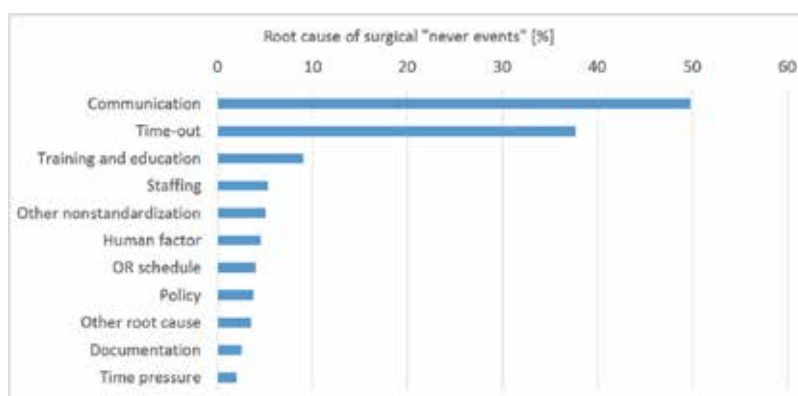


Figure 3. Most common causes of wrong-site procedure (WSP) events. By far, communication and "time-out" related issues predominate among all causes.

Surgical “time-outs” have been validated and studied thoroughly. One study showed that an extended pre-induction surgical “time-out” improved communication within the OR [35]. Marking of the surgical site is particularly important. Clarke et al. noted that the surgeon’s actions in the OR are a major contributing factor to the occurrence WSP [36]. Others have emphasized that structured protocols combining various safety measures, and not their individual subcomponents, are the key to reducing wrong-site events [37] and improving patient safety in general [20, 31].

Appropriate measures, including redundant safety systems, to prevent catastrophic outcomes have been implemented in other high-risk areas including aviation, maritime, and nuclear industries [38]. Modern industrial safety systems emerged with the broader understanding that it is not any individual components or cross-check that by itself reduces the risk of failure, but rather a strategically designed combination thereof [19, 20]. This philosophy aligns itself with the idea that medical errors resulting in adverse outcomes usually stem from a series of individual and systemic failures, all “aligning” within the framework of the so-called Swiss Cheese model [19, 39]. Research on adverse events in the OR suggests that the “Swiss Cheese” theoretical framework can serve as a good foundation for improving not only safety and quality of care but also as an agent for lasting, sustainable institutional culture change [40].

Different “failure modes” exist in regard to WSP. For example, one report describes a scenario where a surgeon marked the correct operative site with a marker, but in the period between the original surgeon marking being made and the subsequent initiation of a surgical “time-out,” the patient created an imprint of the mark on the other leg [41]. This occurrence highlighted the possibility of a new “failure mode” in a system designed to prevent WSP, and despite everyone’s best intentions, the end result was two marked sites, one on each leg [41]. In addition, surgical “time-out” is an effective tool but may fail if it is not appropriately instituted, properly followed, or not taken seriously by the team [42]. Particularly in the office setting, where standardized protocols may not be universally implemented, WSP are a risk during invasive outpatient procedures, such as excision of a suspicious skin lesion. Under such circumstances, it has been proposed that WSP risk may be reduced by photographing and marking the surgical site, introducing “universal protocol,” and examining any specimens of questionable quality before concluding the procedure [43].

Pre-operative verification is another critical component in the overall WSP equation. Again, failure may arise if the verification procedure is performed improperly if there is confusion, or when communication is deficient. Based on >400 reports of WSP, as many as 25% involved scheduling errors as a contributing factor. In addition, the authors stated that “...surgeons verifying procedure with the patient in pre-op holding had the greatest net contribution to the prevention of wrong-site errors” [36]. It has been suggested that the balance between the relative importance of various checklist items and the perception of risk associated with each respective element also plays a role in implementation and overall compliance with various patient safety verification procedures [44].

Various safety procedure compliance issues have been researched over time, both individually and at the health system level. In this domain, the implementation of simple but redundant checks to prevent occurrences of patient safety events has been proposed as an effective

methodology [4]. However, non-compliance despite simplification of these safety checks continues to frustrate the attainment of “zero defect” safety goal [45]. Patient safety advocates continue to argue for more personal accountability at the level of key surgical team members [42]. In addition, it has been shown that non-compliance may be strongly related to the overarching themes in patient safety events—poor communication and ineffective team collaboration [44].

In the Clinical Vignette #1, non-compliance with established safety protocols was the root cause of the failure. However, the situation was made worse by the way the error disclosure was made and further compounded by the family finding out the true magnitude of the surgical mistake at a much later time. This brings us to the final issue in this particular patient scenario—professionalism and communication involving patients and their loved ones. It has long been established that honesty and apologetic stance both decrease, rather than increase, the likelihood of subsequent blame and anger [46–49]. Humble and honest acknowledgment, along with an authentic apology, can also improve the relationship and increase trust between the involved physician and patient or their family [46, 48, 50, 51]. By the time, it was discovered that significant damage occurred as a result of WSP, it was too late for any form of reconciliation outside of the legal system. Such confluence of factors is not unique to this particular case and has occurred in a number of high-profile occurrences including disclosure-related issues [52–54].

Clinical Vignette #1 demonstrates critical safety errors at multiple points in time and on multiple levels during the patient care. Beginning with distracting events prior to surgery and critical communication failures perioperatively, the subsequent series of mishaps involved the lack of adherence to mandatory safety protocols (e.g., the pre-operative checklist, a “time-out” before the surgery, and marking of the surgical site) followed by lax professionalism standards and incomplete disclosure of the magnitude of the error to the patient’s family. In conclusion, this “never event” could have been prevented and any harm avoided or minimized had the OR team adhered to protocols and follow simple, standardized safety procedures.

The second case, outlined in Clinical Vignette #2, involves breakdowns at the systemic level as well as critical judgment errors that highlight the importance of the adherence to established Joint Commission safety measures [55]. Having said that it must be noted that the involved surgeon’s actions and poor judgment may have been difficult to intercept without a more robust system of cross-checks at the institution where the procedure occurred. Although the error occurred at the referring hospital, the “Swiss Cheese” model discussed earlier in the chapter suggests that another omission at the receiving hospital likely “allowed” the error to continue undetected [19]. Communication errors, once again, played an important role here, with critical contributions to the mishap originating with the co-occurrence of incorrect medical documentation and the lack of source imaging data that could be used to “verify or rectify” the laterality of the involved kidney. In terms of human factors, the surgeon exercised extremely poor judgment by proceeding to the operating room without imaging [22].

A series of system errors were described in Clinical Vignette #2. As a consequence, the patient underwent unnecessary surgical procedures, experienced a complete loss of renal function, and was faced with the prospect of being dialysis dependent due to the underlying malignancy precluding him as a kidney transplant recipient. Much like in the first vignette, communication failures again arise as major contributors to WSP occurrence. Critical communication errors

have been reported both in the setting of intra- and inter-hospital transfers, especially in the context of the ever-evolving information systems infrastructure [56–59]. In Clinical Vignette #2, an unacceptable communication breakdown between two hospital facilities was further compounded by either the lack of appropriate verification policies or disregard for existing patient safety procedures. Failure to correctly document the kidney affected by malignancy, combined with the lack of confirmatory imaging greatly increased the risk of error. However, it was ultimately the judgment of the surgical team at the second hospital to forego preoperative and intra-operative imaging. In theory, any OR team member should have been empowered to stop an unsafe process (e.g., much like a flight attendant who is empowered to abort an airline flight departure) [19, 60–62]; however, this apparently did not occur in Clinical Vignette #2.

In a perfect scenario, the patient should not have been transferred without all necessary documentation, including the presence of all pertinent radiography data and results. Upon arrival at the receiving hospital, patient safety and verification procedures should have ensured that all required elements for the safe conduct of a surgical procedure with pre-specified laterality are satisfied. At the minimum, the lack of source imaging should be included as a “hard stop” during the conduct of pre-operative checklist and then during the surgical “time-out” [63, 64]. This applies to a variety of potential clinical scenarios, from the one outlined in Clinical Vignette #2 to extremity procedures performed on multiply injured orthopedic patient, to thoracostomy tube, or orthopedic traction pin placement [65, 66]. Invasive interventions classified as “wrong site,” “wrong patient,” or “wrong procedure” are all considered to be “never events” and require mandatory reporting and root cause analysis [19, 67].

As defined earlier in this book, the term “never event” includes a heterogeneous group of complications that involve unacceptable outcomes are considered preventable and have been deemed intolerable by both the public and the professional standards of the medical community [19, 68]. Just as airline customers should not be concerned about landing in a wrong city or airport, patients should never have to consider or be concerned about the potential risk of their procedure being potentially complicated by wrong site, incorrect patient identity, or wrong operation. As outlined throughout this text, any potential or actual harm to the patient carries the burden of legal liability and regulatory reporting [69]. Because of the cumulative costs associated with medical and surgical errors, government agencies and the medical community continue to devote significant resources to prevent “never events.” Targeted interventions, such as the “surgical safety checklist,” help reduce adverse occurrences applicable to specific circumstances [70], whereas more general interventions help optimize provider performance by reducing factors that lead to undue stress, inefficient team communication, distractions, or fatigue [20, 71, 72].

It is well established that medical errors are associated with more deaths per year than Alzheimer’s disease and illicit drug use combined [73, 74]. In an effort to enhance patient safety in the United States, policies have been implemented to reduce and/or prevent a broad range of “never events,” including wrong site, wrong patient, or wrong procedure occurrences. In 2004, uniform safety checks were put in place by the Joint Commission of Hospital Providers (JCAHO), now known and well recognized as the “universal protocol” (UP) [16, 33]. To help enforce this initiative at the institutional level, failure to adhere to UP jeopardizes the hospital’s accreditation with the organization. The UP consists of three mandatory components:

1. A preoperative verification of the patient, and the procedure to be conducted.
2. Any site to be operated on must be physically marked.
3. A “time-out” must be carried out immediately before any surgical procedure.

Despite the implementation of the universal protocol, cases of wrong-site surgery still surface at alarming rates (**Table 2**). Kwaan et al. [6] reported an incidence rate of 1 in 112,994 for WSP cases between 1985 and 2004, which includes all inpatient OR occurrences. However, an editorial that followed suggested that WSP rate may be as high as 1 in 5000 cases due to the under-reporting of these events [75]. Despite multiple calls to action and corresponding patient safety initiatives, medical errors are still considered among the leading causes of death in the United States on annual basis [76].

Location (year) [reference]	Details of occurrence(s)	Comment
Massachusetts, USA (1992) [77]	A 22-year-old man underwent surgery intended to treat his L4-5 disc herniation demonstrated on MRI. The patient underwent surgery, but his symptoms continued. Approximately 2 years later, he underwent another MRI, which showed that the original operation was carried out at the L3-4 level	The surgeon attempted to explain the error by suggesting that the original plan involved determining the level of intervention at the time of surgery. However, no mentions of such plan were ever made in the medical record or (according to the patient) communicated in such fashion. The case was settled for \$150,000
Florida, USA (1995) [78]	Incorrect leg was amputated following a series of communication and documentation errors	The physician involved was subject to disciplinary action and loss of license. Numerous potential systemic safety issues may have been involved
Rhode Island, USA (2009) [79]	Five separate wrong-site operations were carried out at a facility. Different anatomic locations were involved, including head/neck, mouth, hand/finger, and the brain	Substantial fines were imposed by the Rhode Island State Department of Health. In addition, multiple additional safety checks were mandated, including the presence of OR video cameras for monitoring and oversight purposes. The involvement of multiple anatomic locations, and presumably different surgical teams, strongly suggests a systemic etiology of errors
Romford, UK (2011) [80]	A 5-month pregnant patient underwent surgery for acute appendicitis. During the procedure, her right ovary was removed in error. The patient was then readmitted with continued abdominal pain, suffered a miscarriage, required evacuation of appendiceal abscess, and subsequently died during repeat surgery to remove her appendix	Multiple errors, at multiple organizational levels, were made. The initial pathology result demonstrated that an ovary was removed instead of the appendix. Yet, this information was not read by relevant hospital staff. Based on available data, there were several opportunities to rectify the error, all of which were missed. Medical tribunal review followed
Basildon, UK (2012) [81]	Female patient required a superior segment of her lung removed. Instead, surgeons removed a basilar segment	Error was attributed to incorrect information in medical record. Similar to Clinical Vignette #2, the case involved inter-hospital transfer and a number of systemic factors

Location (year) [reference]	Details of occurrence(s)	Comment
Florida, USA (2013) [82]	Surgical incision was made into a patient's RLE instead of the LLE. The error was discovered intra-operatively and LLE surgery was completed	During disclosure, the error was allegedly presented as "justified mistake". Subsequent review of the facility found multiple patient safety and regulatory issues
Baku, Azerbaijan (2016) [83]	A 87-year-old woman was supposed to undergo LLE amputation for complications of diabetes. Instead, the RLE was amputated	Following the error, the surgeon avoided the family, later providing irrational explanations for the mistake Governmental committee was created to examine this event and improve patient safety in the country
Connecticut, USA (2016) [52]	Patient was undergoing surgery for 8th rib resection. Instead, part of the 7th rib was removed. Patient then required another operation shortly after	The patient alleged that the communication regarding the event was inadequate. Legal action followed as a result. It is likely that several different factors played a role in the event
New Delhi, India (2016) [84]	A 24-year-old man required surgery for RLE injuries. Surgeons erroneously inserted two rods into LLE	After filing unsuccessful complaints with the hospital, the family filed a lawsuit
Hanoi, Vietnam (2016) [85]	Surgical team mistakenly operated on a patient's RLE instead of the LLE	Errors at the team level were identified. The surgeon and the involved surgical team were suspended. The hospital agreed to cover all charges related to care
Massachusetts, USA (2016) [7]	It is alleged that a kidney was removed from the wrong patient	Communication and system errors at multiple points in the preoperative and operative process were involved, leading to patient misidentification and then propagation of the incorrect information

Reports are based on various publically available sources and only publically available information is included. Note the global nature of the problem, with events of similar type taking place around the world.

L3–4/L4–5, lumbar 3rd/4th/5th levels; LLL, left lower extremity; MRI, magnetic resonance imaging; OR, operating room; RLE, right lower extremity.

Table 2. Selected wrong site, wrong side, and wrong patient surgery occurrences.

4. Preventive strategies

Numerous preventive strategies to reduce rates of WSP have been proposed. It has been recommended that the UP be expanded to non-surgical specialties and that "zero-tolerance" philosophy be implemented in the setting of recurrent events [13]. In addition to vigilant adherence to the UP [86], calls have been made to foster open dialogue regarding WSP and other "never events," including frank discussions of each individual occurrence [87]. Others suggest the use of simulation training to achieve universal staff compliance with safety procedures [88, 89]. The addition of a formal pre-operative briefing as an additional "checkpoint" may also play a role [11]. Emphasis on professional behavior during periods of critical transitions (e.g., patient transfers, surgical "time out," and surgical site marking) is an important

factor in preventing communication-related failures [90]. Team-based approaches that encourage both individual engagements and foster collective responsibility are critical to the safe operations of the modern OR [20, 26, 55].

5. Conclusions

WSP are a high-impact, low-frequency “never event” that occurs throughout all procedural specialties. Consequences of WSP are profound, beginning with the psychological and physical harm to the patient. In addition, the affected patient’s loved ones are also highly likely to suffer emotional consequences of having been indirectly exposed to a wrong-site event. Finally, all individuals involved on the healthcare team are deeply affected by the event itself as well as by its aftermath [19]. Finally, WSP occurrences significantly damage the trust between the public and the healthcare system, creating a negative atmosphere that requires tremendous efforts and long periods of time to overcome. From the medico-legal perspective, there is little in the way of legal defense from an event as obvious as WSP. Consequently, physicians leave themselves and their institutions open to malpractice suits when such events occur.

Due to the damaging effects of WSP on all stakeholders involved, significant resources have been dedicated to the elimination of WSP, with the goal of “zero incidence.” Measures implemented to achieve this goal include the UP, which involves a preoperative checklist and “time-out” prior to the start of any invasive procedure. Surgical site marking procedures are also of critical importance and should proactively involve the patient whenever feasible. In the end, every WSP event ultimately involves human teams. Among all the safeguards implemented and studied, the ultimate responsibility will always rest in the hands of the surgical team performing the procedure. No “checklist” or another safeguard can ever perfectly substitute for the astute and observant provider with the mindset of doing their best, ensuring safety, listening carefully, questioning and speaking up when needed, and conducting the operation according to the highest professional standards.

Author details

Andrew Lin¹, Brian Wernick², Julia C. Tolentino² and Stanislaw P. Stawicki^{3*}

*Address all correspondence to: stanislaw.stawicki@sluhn.org

1 Temple University School of Medicine—St. Luke’s University Hospital Campus, Bethlehem, Pennsylvania, USA

2 Department of Surgery, St. Luke’s University Health Network, Bethlehem, Pennsylvania, USA

3 Department of Research & Innovation, St. Luke’s University Health Network, Bethlehem, Pennsylvania, USA

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Exposure Keratopathy in the Intensive Care Unit: Do Not Neglect the Unseen

Benjamin Bird, Stephen Dingley,
Stanislaw P. Stawicki and Thomas R. Wojda

Additional information is available at the end of the chapter

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Abstract

Exposure keratopathy (EK) is a frequently overlooked complication seen in nearly 60% of sedated or intubated intensive care unit (ICU) patients. Signs and symptoms of EK often start as mild subjective complaints of eye pain and irritation, but can progress to vision loss in the most severe cases. For many critically ill patients, the presence of sedation effectively precludes their ability to communicate clinical complaints typically associated with EK. This, combined with the potentially severe sequelae, makes EK a potentially preventable complication and a patient safety issue. Clinical management of EK can be challenging for both providers and patients due to the nature of treatment with eye drops and ointments as well as the burden and expense of associated procedural interventions. Risk factors for EK have been extensively described in the literature, and wider dissemination of this knowledge should facilitate education of physicians and nurses regarding EK prevention. The most common risk factors include lagophthalmos, chemosis, Bell's palsy, and congenital deformities. Additionally, critically ill patients are less likely to be promptly diagnosed due to the focus of staff on life-threatening problems over ocular prophylaxis. However, the potential severity of complications associated with EK mandates that prevention remains a crucial component of the care of at-risk patients. The reader will explore the broad category of adverse medical occurrences included under the umbrella term, "errors of omission" (EOO): an error category that is most likely to culminate in EK. The most critical preventive measure is education of health care providers, although this may not be enough by itself. To this end, universal precautions against EK in combination with education may be used to help combat the relatively high incidence of this easily preventable ocular pathology.

Keywords: exposure keratopathy, ophthalmology, critical care, patient safety

1. Introduction

Intensivists caring for high acuity patients must be able to actively track an impressive number of clinical variables on daily basis. Failure to do so may be associated with significant morbidity and mortality in cases involving omissions or systemic failures [1, 2]. While management priorities of the critically ill patient must emphasize life-threatening problems, other issues with less immediate consequences may go unnoticed. Exposure keratopathy (EK), noted to occur in 37–57% of sedated or intubated ICU patients, is one of those “silent” morbidities [3–6]. Visual impairment or loss of vision due to EK, especially when secondary complications such as corneal infection are present, is a serious problem that can arise if proper precautions are not observed, and has the potential to cause long-term disability [7–9].

The preventability of EK is predicated on the assumption that its occurrence is frequently a result of omission, broadly included under the category of, “errors of omission” or EOO [8, 10]. Closely related to EOO is the associated companion phenomenon of “delay to treatment” (DTT) which results in further propagation of the potentially preventable problem amidst many competing treatment priorities [8, 10–15]. In support of the latter argument, and in an attempt to prevent overall harm, it has been suggested that implementation of relatively simple protocols can help prevent most cases of EK in the ICU. In fact, implementation of evidence-based nursing practices and protocols may be the key to significantly reducing the incidence of exposure keratopathy [9, 16]. In this chapter, we will discuss various prevention strategies, as well as explore the pathophysiology, etiology, and treatment of ophthalmic EK.

2. Patient vignettes

In the following section, the authors will introduce clinical aspects of EK by presenting two patient vignettes that demonstrate the usual genesis and course of EK in the ICU. In addition, a third patient vignette will outline a fairly typical outpatient scenario involving EK. Because the main objective of this chapter is to present patient safety (PS) considerations with a clear focus on prevention, clinical management of EK in each of the three cases will not be discussed in detail.

Clinical Vignette #1. T. W. is a young man in his mid-20s who was involved in a motor vehicle collision, and presented to the local hospital’s emergency department with serious injuries that required multiple surgeries. He has required an extended, 4-month stay in the ICU, a significant portion of which was spent under deep sedation for traumatic brain injury. Upon awakening and recovering his mental status, the patient complained that his eyesight was “extremely blurry” and that he had significant pain and tearing in both eyes. An ophthalmology consult showed that the patient was noted to have >20/400 vision in both eyes, despite having 20/20 vision before the car crash. A dilated fundus exam was performed and revealed no gross abnormalities. A fluorescein stain was then performed on the lens and cornea of both eyes leading to the diagnosis of EK.

Clinical Vignette #2. V. C. is a Caucasian male in his early 50s who underwent an elective blepharoplasty. Because of his anxiety regarding “objects too close to his eyes,” the patient requested general anesthesia. Unfortunately, the patient’s surgery was complicated by a deep

orbital hemorrhage in the left eye requiring a stay in the hospital. Due to multiple hospital-acquired infections and procedures during the ensuing hospitalization, he required escalation of care to multiple weeks spent in the intensive care. During the ICU stay, the patient was noted to have a degree of lagophthalmos in his right eye due to the recent blepharoplasty. He developed deep redness, pain, and severely impaired vision in his right eye. An ophthalmology consultation confirmed that he has EK via fluorescein stain.

Clinical Vignette #3. L. P. is an African American female in her late 70s who presented to the ophthalmology clinic reporting 5 years of bilateral “blurred vision.” She was found to have cataracts and surgical correction was recommended. The patient was noted at the time to have significant proptosis as a result of pre-existing graves’ disease, but no other medical history was deemed contributory at this time. The patient had the cataracts removed during two surgeries scheduled separately over a 6-month period, without any perioperative complications. The day after her second surgery, she returned to her ophthalmologist with the complaint of “foreign body sensation” underneath the bandage over her left eye. Upon uncovering the eye and examining it, the ophthalmologist found that the patient’s eyelid was not fully closed due to proptosis. The patient was noted to have a yellow film over her eye and the diagnosis of EK was made after fluorescein testing and a dilated fundus exam.

3. Summation of clinical vignettes

All three clinical vignettes presented above demonstrate fairly typical presentations of EK. For patient #1 and patient #2, the circumstances leading to the development of keratopathy included an extended stay in an ICU, in which proper ophthalmic preventive care presented significant opportunities for improvement. In the case of patient #3, the simultaneous presence of a post-operative complication and a pre-existing condition predisposed her to EK. In all cases, patients showed similar symptoms, including a change in the color of the eye, the appearance of pain, and the concurrent decrease in visual acuity. In all of the above examples, early detection was critical in terms of avoiding disease progression, instituting prompt treatment, and preventing the loss of vision. The most important question, from the etiologic standpoint, is whether these cases of EK could have been prevented. Did any EOO’s contribute to the genesis of EK in one or more of these occurrences? After discussing the pathophysiology, clinical characteristics, and risk factors associated with EK, the authors will provide an overview of EOO’s in the context of our case vignettes and potential preventability.

4. Exposure keratopathy: pathophysiology, diagnosis, symptoms, and risk factors

Corneal epithelium helps defend the eye from external exposure and related insults [17, 18]. It is composed of avascular, stratified, nonkeratinized epithelium, which is intimately associated with the maintenance of physiologic homeostasis of lachrymation [19–21]. Tears provide lubrication to the surface, oxygen to the cornea, wash away pathogens, and adhere to the eyes via mucins produced by the corneal epithelium [22]. Lysozyme, lactoferrin, tear lipocalin, and

secretory Immunoglobulin A (IgA) help prevent infection [23, 24]. The palpebral conjunctiva moves over the cornea during blinking and dispenses/distributes tears uniformly over the ocular surface, thus inhibiting evaporation [25–27]. Tear evaporation modifies the conjunctival sac milieu, making bacterial growth difficult [28]. Orbicularis oculi contraction and levator palpebrae superioris inhibition protects the cornea from dryness by shutting the eyelid [29–31]. When any of the above components of this highly intricate and interconnected innate eye protection mechanism are interrupted, alone or in combination, whether by disease processes or natural aging mechanisms, the risk of EK increases significantly.

McHugh et al. demonstrated in a study of ICU patients that poor or inadequate eyelid closure was associated with 70% incidence of EK when compared to 29% incidence among patients able to fully close their eyelids [4]. The use of pharmacologic-induced paralysis or heavy sedation may inhibit this important natural mechanism of eye protection [6]. Fluid imbalances, increased vascular permeability, and positive pressure ventilation (PPV) may increase conjunctival edema, leading to difficulties with eye closure [32]. It has also been noted that the use of high flow oxygen through face mask or nebulizer can lead to desiccation damage of the corneal epithelium [33]. To further complicate the issue, it has also been pointed out that ICU-related reductions in rapid eye movement sleep (REM) may elevate the probability of prolonged direct corneal exposure [12]. Additional clinical factors associated with ICU-related EK include, but are not limited to: low Glasgow Coma Scale (GCS < 8), ICU stay duration of >1 week, and the presence of significant metabolic imbalances [13]. **Table 1** provides a more complete appraisal of various associated risk factors.

Exposure keratopathy is primarily a clinical diagnosis. This makes the identification and management of EK especially challenging in the critically ill and neurologically impaired patients. Also, because of the generally more vulnerable status of ICU patients, any care-related omissions that lead to EK reflect potential opportunities for improvement in overall care quality. Therefore, the incidence of EK should be considered as either direct or indirect PS indicator [9, 34]. Optimally, surveillance and prevention efforts aimed at EK should be incorporated into evidence-based nursing practice, where awareness of the problem is coupled with appropriate education that helps facilitate around-the-clock attention to the specific PS issue [9, 35]. It is important to remember that even small amount of lagophthalmos – the inability to close the eyelids completely – has negative effects on the corneal epithelium, yet is easily overlooked [36]. In addition, ointments and eye drops used in an effort to protect the eyes can be harmful in the event of an infection, with the potential for microbial transmission when using the same medication tube or applicator for treating both eyes [36]. Further, if the clinical staff is unaware, left-in-place contact lenses can increase the risk of corneal drying and infection [37].

For non-sedated patients, corneal damage usually results in severe pain due to the presence of rich innervation of this highly sensitive anatomic area, with robust nerve networks located between the epithelial cells of the corneal surface [22]. Unfortunately, in the ICU, symptoms may not be readily communicated by the patient or promptly detected by health-care personnel, leading to delayed detection and treatment of EK. As soon as EK is suspected, the physician should check for any trauma, contour malformation, and other causes of eyelid malposition. Further, the patient's past medical history should be reappraised for

Pre-existing risk factor	Description
Bell's Palsy	A seventh cranial nerve palsy localized to one side of the face affecting the eyelids.
Blepharitis	An inflammatory condition affecting the sweat glands of the eyelids, leading to swelling.
Blepharoplasty	A surgical procedure that corrects either congenital, functional, or esthetic issues related to the eyelids.
Chemosis	A swelling of the outer conjunctival membrane(s) covering the inner eyelid and the eye.
Coloboma	A congenital or traumatic full-thickness defect of the eyelid, often leading to incomplete eye closure.
Ectropion	An outward turn of the eyelid, either upper or lower. Causes include congenital (Treacher-Collins) conditions, acquired (trauma, Bell's palsy) etiologies, and aging-related processes.
Entropion	An inward turning of the eyelid, involving either upper or lower lid. Trauma, aging, and conjunctival scarring are all causes of entropion.
Facemask ventilation	A method of short-term administration of high-flow oxygen, which possibly directs airflow over the eyes.
Floppy eyelid syndrome	Chronic conjunctivitis of the upper eyelid, more prevalent in patients with a history of sleep apnea or snoring.
Graves' disease	An autoimmune disorder of the thyroid, known to cause severe proptosis. In some cases, it can lead to incomplete closure of the eyelids.
Iatrogenic	Pharmaceutical agents leading indirectly to EK. Propofol, benzodiazepines, and other sedative hypnotics in susceptible patients can contribute to the development of EK, particularly among ICU patients with eyelid dysfunction.
Lagophthalmos	Any state or condition of the eyelids leading to incomplete closure. Examples include severe proptosis or paralysis of the eyelids.
Myasthenia gravis	An autoimmune myopathy, which may lead to issues with full closure of the eyelids.
Parkinson's disease	Gradual deterioration of control over the eyelids leads to impaired blinking mechanism.
Sjogren's syndrome	An autoimmune disorder leading to dryness of the mucous membranes throughout the body. Sjogren's syndrome is often associated with other autoimmune disorders such as systemic lupus erythematosus and rheumatoid arthritis.
Symblepharon	Adhesion of the conjunctiva of the eyelid to the conjunctiva of the eyeball itself.

Legend: EK = Exposure keratopathy; ICU = Intensive care unit.

Table 1. Various factors associated with increased risk of exposure keratopathy.

any conditions that may result in malposition or proptosis. In order to aid the diagnosis, a fluorescein stain may be applied to the cornea to highlight any erosion under a black light lamp (**Figure 1**) [5]. Microepithelial defects are pin-point epithelial elevations or slightly depressed erosions in the cornea, whereas macroepithelial defects (e.g., corneal abrasions) are larger confluent zones of epithelial loss [36]. Additionally, a penlight using blue filter after the administration of fluorescein dye may help outline the epithelium and detect corneal abrasions or ulcers at bedside [16].

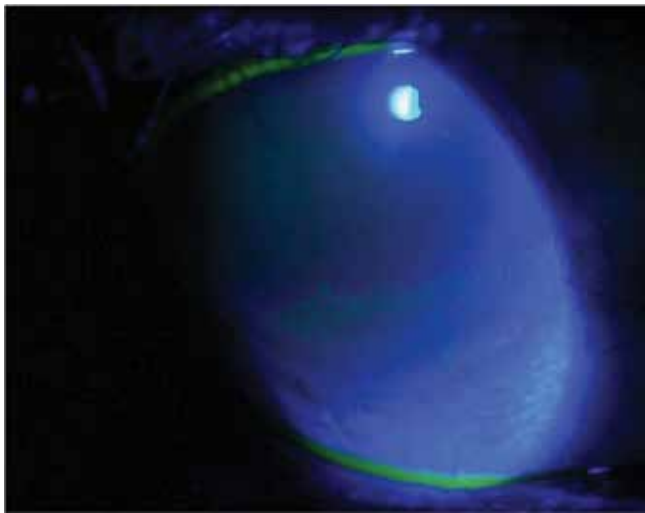


Figure 1. Punctate corneal lesions are seen upon administration of fluorescein dye under a black light lamp.

A comprehensive list of physical signs and clinical symptoms of EK can be found in **Tables 2** and **3**. It is important to note that these signs are not specific to EK and therefore the examining healthcare provider must be well-versed in other disorders which may cause similar signs and/or symptoms. A comprehensive differential diagnosis listing can be found in **Table 4**. Once the patient is alert, EK often resolves spontaneously; however, it may also lead to corneal scarring and vision loss, especially if sufficiently advanced [16, 36, 38]. Consequently, any evidence of EK, especially an opacity or haziness of the cornea, should prompt consultation

Symptoms	Description
Pain	Particularly common in the morning when the patient first awakens, especially if the underlying problem is an issue with the eyelid. It should be noted that in select patient populations presenting to ophthalmology clinics, there might be a lack of pain sensation in the eye due to other underlying or co-morbid condition(s).
Corneal irritation	May present as redness of the eye. Some cases may feature a yellow-green film over the cornea.
Foreign body sensation	Associated with irritation of nerve receptors supplying the cornea. Patients may report the feeling of an “eyelash caught” in the affected eye.
Excess tear production	Epiphora is another commonly reported symptom in EK patients experiencing significant corneal irritation. The discharge from the affected eye is often mucopurulent, particularly if the patient has acquired a superinfection during their hospital stay.
Photophobia	Corneal erosions, such as those seen in EK, can commonly allow too much light to enter the eye, causing the patient to complain of “sunlight hurting their eyes.”
Blurred vision	Corneal abrasions may also contribute to an acute decrease in visual acuity, which may become permanent if the patient’s condition is allowed to progress to corneal scarring. Prompt treatment is critical to healing and to regaining lost vision, thus avoiding significant long-term morbidity.

Table 2. Symptoms of exposure keratopathy.

Signs	Description
Punctate corneal erosion	A result of the cornea of the affected eye experiencing unusual dryness, culminating in epithelial cell loss. This sign can be visualized via fluorescein stain. In EK, these erosions may appear small or coalesce into a single, much larger lesion.
Chemosis	A swelling of the conjunctiva, leading to edema of the eyelids. This sign, along with lagophthalmos, is highly correlated to the development of EK in ICU patients.
Decreased tear meniscus	A normal eye should have a thin tear layer along the margins of the eyelid. Absence of this indicates dry eyes.
Corneal filaments	An appearance of “mucoepithelioid” areas of adherence involving the cornea, related to corneal epithelial dysfunction in the setting of dry eyes due to an increased mucus-to-tear ratio. Lubricating drops may help remove them, or these can be removed during a slit lamp exam.
Corneal ulceration	An open wound that appears on the cornea due to severely dried eyes. This condition carries a serious risk of corneal scarring and thus must be treated promptly.

Legend: EK = Exposure keratopathy; ICU = Intensive care unit.

Table 3. Clinical signs of exposure keratopathy.

Condition	Description
Exposure keratopathy	A result of severe eye dryness over a significant period of time. Signs include pain, redness, blurred vision, and a mucopurulent discharge from the affected eye. Must be treated immediately in order to avoid vision loss.
Corneal abrasion	An injury to the eye resulting in breach of the corneal epithelial layer, but does not progress. Commonly present as a foreign body sensation in the affected eye. Typically heals without intervention, though antibiotics may be given in select cases involving contact lenses.
Vernal keratoconjunctivitis	A dry eye condition that arises in dry climates with a seasonal periodicity. It features the appearance of giant papillae in the upper tarsals. Treatment includes artificial tears and removal of allergens.
Corneal foreign body (FB)	Irritation of the eye resulting from presence of a FB, commonly an eyelash or material related to the patient’s occupational exposure (e.g., dust, metal or wood fragments). Treatment includes removal of the FB under slit lamp exam.
Toxic irritation	Redness of the eye associated with the presence of a toxic irritant. Appears as a bilateral infiltrate, usually associated with contact lenses. A similar form of this condition appears within a day after laser assisted <i>in situ</i> keratomileusis (LASIK) surgery, and resolves without intervention.
Hypersensitivity reaction	Redness of the eyes and mucopurulent discharge usually due to seasonal allergies/hay fever. Can be treated with cool compresses and antihistamines as needed.
Ulcerative keratitis	Thinning of the cornea related to autoimmune disease, such as systemic lupus erythematosus or rheumatoid arthritis. These patients are vulnerable to such complications as superinfection and perforation. Management tends to be medical, although surgery is indicated for patients with impending or current perforation.
Mooren’s ulcer	An idiopathic corneal thinning that may be unilateral or bilateral. It may lead to corneal ulceration. This condition carries important associated risks, including glaucoma, perforation, and blindness, but is a diagnosis of exclusion.
Epithelial keratopathy	Punctate erosive lesions of the cornea that do not progress to EK, given that there are no other predisposing factors.
Band keratopathy	Corneal scarring that leads to a subepithelial opaque calcified plaque over the lens of the eye. These mostly appear in the elderly and have a particular horizontal deposition pattern, along with a chalky appearance. Treatment is typically conservative and requires only observation. However, in severe cases surgery is ~95% effective.

*In all of these cases, cultures yielded from corneal scraping must be negative in order to rule out infectious causes.

Table 4. Differential diagnosis of keratopathies.

with an ophthalmologist [38, 39]. Such expert evaluation is critical to confirming the diagnosis of EK and the initiation of appropriate therapy, as exemplified in this chapter's clinical vignettes.

5. Epidemiology of exposure keratopathy

Although the reported incidence of EK varies, some studies have estimated the rates to be as high as 57% in mechanically ventilated ICU patients who do not receive proper prophylactic eye care [3]. These clinical studies have also shown that up to 75% of patients with EK will show signs of lagophthalmos and chemosis before developing the condition [16]. Following proper precautions has been shown to reduce the risk of developing EK in ICU patients by more than 40% [16].

6. Treatment

Successful treatment of EK begins with a thorough assessment of the patient's eyes, including the corneas and a complete slit-lamp and fundoscopic exam (**Figure 2**). This is essential to ruling out several other conditions, as listed previously in **Table 4**. The conjunctival fornices should also be swabbed and the resulting sample sent out for bacterial culture testing, as microbial superinfection is a major complication that can be associated with this condition.

Effective management of EK necessitates the restoration of proper lubrication of the eye to prevent further damage. Lenart et al. studied 50 patients who each had one eye that

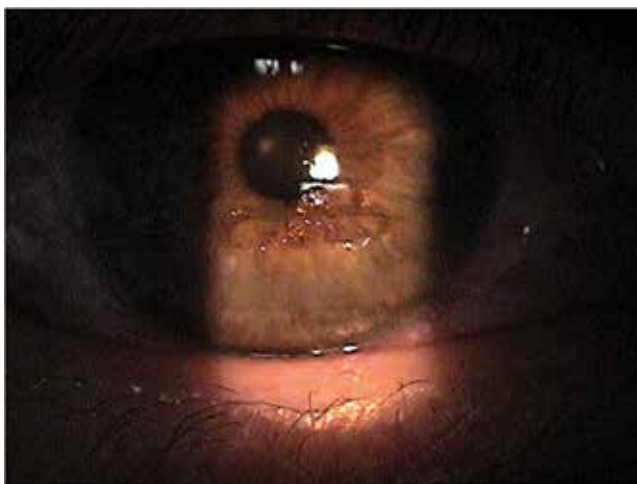


Figure 2. Appearance of punctate corneal lesions characteristic of exposure keratopathy, illuminated via slit lamp exam.

received artificial tear ointment every 4 h, while the other eye was passively closed by nurses when it was found open. The authors found that there were nine abrasions in the passively closed eyes, compared with only two abrasions in the ointment-treated eyes [40]. Ezra et al. [41] compared “eye toilet” using two alternative treatments – Geliperm versus Lacrilube. Twenty-four patients comprised the “eye toilet” group, 13 of which (53%) acquired EK. The group receiving Geliperm was found to have EK in 90% (9 out of 10) cases, while only 2 out of 13 (15%) patients in the Lacrilube group (15%) developed EK. The authors concluded that Lacrilube was more effective at preventing EK than “eye toilet” or Geliperm [41]. Nonetheless, a 2003 survey found that despite the above findings, 75% of British ICUs were using Geliperm [42]. If artificial tears are unavailable, the use of punctal plugs in the lacrimal ducts may be used [3]. Further lubrication with ointment up to four times daily is also recommended [3]. Strict adherence to these steps allows for the eye to re-establish its homeostatic moisture levels and promote healing of the erosions.

The maintenance of “moisture chambers” may protect the cornea when the eye remains open. In a study of 60 critically ill patients with a limited or absent blink reflex, half of participants were assigned to receive “lubricating eye drops” every 2 h while the remaining participants’ eyes were covered with polyethylene film to create a “moisture chamber.” Eight of thirty “lubricating eye drop” patients demonstrated corneal staining with fluorescein, which signified EK, contrasted with only 1 of 30 moisture chamber patients [43]. Koroloff et al. [44] studied 110 ICU patients with reduced or absent blink reflex. Groups either received hypromellose drops and Lacrilube every 2 h or had polyethylene covers on the eyes to create a “moisture chamber.” Eyes in both patient groups were cleaned every 2 h with saline. The study showed that none of the patients developed corneal ulceration in the polyethylene group while four patients experienced ulceration in the hypromellose group [44]. In another report, 146 patients were assigned to receive treatment with either a “moisture chamber” created with swimming goggles and gauze soaked in sterile water (closed chamber), or ocular lubricants with securing tape over the eyes (open chamber). Thirty-nine (32%) eyes of the open chamber group versus ten (8%) of closed chamber eyes acquired EK [39]. Lastly, a meta-analysis comparing “moisture chambers” versus ocular lubricants was conducted, including three randomized trials that cumulatively enrolled nearly 300 patients [16]. Rates of EK were significantly lower when “moisture chambers” were used to protect the eye (7.1%) when compared to lubricating ointment use (21.2%). Despite some heterogeneity between component studies, cumulative results of this meta-analysis (Odds Ratio, 0.208 with 95% Confidence Interval 0.090–0.479) strongly support the use of “moisture chambers” [16].

Finally, if all of the previously outlined management steps fail and the patient’s EK continues to progress, there are surgical options available that have been proven effective. Tarsorrhaphy may be performed, but it may significantly interfere with serial examinations of the affected eye(s) [39]. Consultation with Ophthalmology is strongly recommended. Additional procedures are described in **Table 5**.

Surgical technique	Description
Partial tarsorrhaphy	A surgical procedure in which the eyelid of the affected eye is sewn shut, either laterally or medially. Complete tarsorrhaphy is also used when functional vision is not immediately necessary
Eyelid reconstruction	A surgical procedure used to reconstitute the integrity of the eyelid itself, usually in cases of ectropion/entropion or coloboma.
Gold or platinum weight implant	A gravity-assisted method of eyelid closure accomplished by the implantation of a weight on the upper eyelid. This procedure is most useful against palsy-related causes of eyelid defects.
Orbital decompression	A gravity-assisted method of eyelid closure accomplished by the implantation of a weight on the upper eyelid. This procedure is most useful against palsy-related causes of eyelid defects.
Conjunctival flap	Grafting of the conjunctiva in order to provide pain relief and assist with healing of the cornea.
Sutured amniotic membrane graft	A procedure used for severe refractory EK when other procedures have failed to resolve the problem. This procedure has been shown to have some benefit and assist healing.

Table 5. Surgical procedures to reduce exposure keratopathy.

7. Complications of exposure keratopathy

If the eye is allowed to become too dry, small deficiencies in corneal epithelium may develop and lead to superficial keratopathy. This can be detected on slit lamp examination. As superficial keratopathy worsens, the corneal epithelium becomes more permeable [45, 46]. Of note, superficial keratopathy has been found in as many as 60% of intubated and sedated ICU patients [3, 28]. Moving further along the continuum of acuity, eyelid swelling, conjunctival swelling with hyperemia, and eyelid crusting or discharge are the primary signs of infection in an ICU patient [3, 37, 47, 48]. Slit lamp examination typically shows evidence of the presence of bacterial corneal ulcer while penlight examination reveals ulcerated corneal epithelium with a gray or white infiltrate [16, 49, 50].

One of the most feared complications associated with EK is microbial (or infectious) keratitis, which may lead to perforation, scleritis, endophthalmitis, and even blindness [46, 51–53]. In severe cases of corneal infections refractory to maximal medical therapy, treatment of microbial keratitis may require corneal transplantation [52, 54–56]. Of note, survival rates of grafts performed for this indication tend to be significantly lower than comparable rates for other conditions [56].

Bacterial superinfection is another serious complication that can occur in an ICU patient with EK. Thus, it is prudent to be aware of the clinical characteristics associated with the most common agents of superinfection (**Table 6**) [3, 53, 57, 58]. When left untreated, these infections can progress to complications including perforation, scleritis, endophthalmitis, and loss of vision [16, 57–59]. In terms of other factors associated with the risk of corneal infection, it has been postulated that exposed corneas may also be susceptible to aerosol droplets spread via tracheal suctioning [60–62]. If nurses hover at the head of the bed, direct inoculation may occur if the suction catheter is withdrawn directly over the patient’s eye [62].

Bacteria	Associated sign
<i>Streptococcus</i> spp.	Purulent or crystalline infiltrate that can follow either a fulminant or indolent course. Indolent course is associated with chronic steroid use.
<i>Staphylococcus</i> spp.	Well-defined stromal infiltrate that can progress to an abscess.
<i>Pseudomonas</i> spp.	Rapidly progressive necrotic infiltrate, usually associated with the use of contact lenses.
<i>Moraxella</i> spp.	Indolent inferior corneal infiltrates that occur in the setting of immune deficiency.

Table 6. Clinical characteristics of superinfections seen in the setting of exposure keratopathy, including associated signs, symptoms, and clinical course.

Anecdotally, because right-handed nurses generally remove the suction catheter over the left eye, it has reported that higher bacterial contamination may be seen in the left eye than the right eye [60]. Finally, in cases involving severe infections leading to visual loss, corneal transplantation may be required [60–63].

A further major complication of EK is corneal ulceration (**Figure 3**), which represents a progression of this pathological state [3, 64]. The ulceration is often peripheral and displays corneal thinning that presents upon slit lamp examination [3, 65, 66]. If this occurs, the treating physician should be careful with the administration of steroids, which may exacerbate the ulceration [45, 53, 67, 68]. If the patient's ulceration progresses to the point that a perforation is imminent, then corneal transplantation surgery or amniotic membrane graft may be indicated [45, 69]. Prevention of ulceration is therefore critically important in patients with EK; for prophylaxis, the use of bandage contact lenses and concurrent broad-spectrum antibiotics can help decrease the incidence of this morbidity [49, 53]. Treating providers must remember that the above procedures can be a source of



Figure 3. Corneal ulceration becomes apparent under examination as a saucer-like thinning of the epithelium.

significant stress to the patient, thus highlighting the importance of limiting the overall risk of EK through good clinical practices and the developing and closely following protocols aimed at prevention. This chapter's clinical vignettes touch upon both the short- and long-term sequelae of EK, with emphasis on prevention, early identification, and prompt treatment. The overall complexity of care, especially in high acuity environments such as the ICU where "competing priorities" are the norm, can contribute to a variety of errors of omission (EOO) – a topic discussed in greater detail in the subsequent sections of the chapter.

8. Exposure keratopathy: preventive strategies and patient safety considerations

Although maintenance of a favorable ocular environment may not be critical to saving the patient's life, attention to this important aspect of patient care is both an indirect measure of quality of care provided and an essential component of preventing significant morbidity following extended ICU stays. Despite this, one ICU audit discovered that only about one in four patients received appropriate eye assessment, and only about 55% had the provision of eye care properly documented [51]. What is more, even experienced nurses have difficulty following eye-care guidelines [52], likely due to the above-mentioned large number of competing priorities. Despite these barriers, progress is being made and numerous prophylactic/preventive measures, screening techniques, procedures, and guidelines have been designed, implemented, and reported to help reduce the incidence of EK.

In one study, McHugh et al. [4] set out to determine if specialization enhanced ocular disease detection. Two junior ICU physicians, twice a week, examined lid position and ocular surfaces of all patients continuously sedated for >24 h. An ophthalmologist performed similar examinations with a slit lamp. Cumulatively, 48 examinations were performed on 18 patients. ICU doctors had 77.8% sensitivity and 96.7% specificity in detecting EK, with all "missed" cases having erosions involving <5% of the corneal surface. The authors concluded that using regular eye checks, ICU staff should be able to adequately diagnose EK and facilitate ocular therapy [4].

Suresh et al. [70] created a protocol where patients with closed lids received no treatment, those with exposed conjunctiva received lubricants, and patients with exposed corneas or ventilated patients in the prone position received both lid taping and lubricants. Of 34 patients examined, 11 were excluded (4 because of protocol non-compliance and 7 because of errors in initial assessment of lid position). The 23 patients who were followed demonstrated an 8.7% rate of ocular surface disease, compared to 42% prevalence in historical controls [70].

In another study, authors concentrated on reducing the risk of ocular *Pseudomonas aeruginosa* infection [29]. Their clinical guideline stipulated that unconscious patients should receive eye care every 2 h. Any swelling, conjunctival hyperemia, corneal clouding, and epithelial loss were noted and recorded. Exposed corneas were lubricated every 2 h and patients at risk for corneal exposure had their eyes taped shut. Tracheal suctioning was performed at bedside, with the patient's eyes covered and daily swabs of the eyes obtained. If eye swab cultures grew *P. aeruginosa*, topical gentamicin was started and ophthalmology consultation was requested.

Once implemented in the ICU, conjunctival *Pseudomonas* isolation rates decreased from 0.8 to 0.05% [29]. This particular intervention very nicely highlights the powerful effects of simple, easy-to-follow protocols on both PS and care quality.

A review by Alansari described a nurse driven protocol for eye care in the ICU. For patients with risk factors as previously described, clinical assessments for lid closure were recommended every 8 h [71]. In addition, the following recommendations were made:

- In the presence of incomplete closure, application of Duratears (lubricating eye ointment) every 4 h or polyethylene coverage, depending on the severity of the lack of closure, was recommended.
- Lid cleanliness should be inspected every 4 h, with basic eye hygiene implemented if any issues are identified.
- Eye dryness should be inspected every 4 h and Duratears added as needed.
- Assessment for ocular surface disease should be made every 4 h, and the supervising care provider should be notified with any findings of concern.

It is this and other, similar protocols that are most likely to result in significant and sustainable reduction in the incidence of EK. In the modern PS and care quality paradigm, continuous self-improvement and evidence-based, protocol-driven care are the cornerstones of ensuring optimal clinical results for our patients.

Providers should remember that patient management does not end in the acute care setting. Therefore, during the post-acute phase of treatment, the follow-up examination frequency will depend on each patient's individual case of EK, the length of stay in the ICU or hospital, and the details of any surgical procedures performed. If the lesion(s) on the patient's eye are mild and vision is not threatened, then follow-up eye examinations on a weekly or even monthly basis may be appropriate [3]. If EK has progressed to corneal ulceration, then eye examinations should occur daily, or every 2 days at most [3]. However, even if daily examinations are not needed, proper precautions (i.e., the provision of eyedrops and appropriate ocular ointment) to prevent EK or worsening thereof must be observed.

9. Errors of omission: a focused discussion

Errors of omission (EOOs) can be defined as actions that lead to adverse events that happen because of the healthcare provider (or team) not having done something, whether intentional or not [72]. On the other hand, errors of commission involve performing an action, but not carrying it out correctly. For example, prescribing the incorrect dosage of a medication or carrying out a procedure that is unintentionally different from the one originally intended, may be considered in the latter category of errors.

Figure 4 demonstrates the key differentiation between errors of omission versus those of commission. **Figure 5** shows the taxonomy of errors of omission and commission. In terms of frequency,

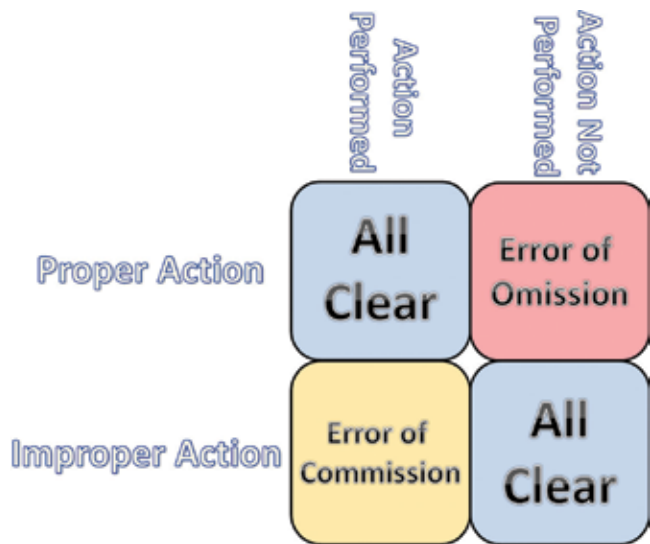


Figure 4. Schematic representation of the interplay between the appropriateness of a specific action, its performance, and the presence and type of error. Errors of omission occur when proper action is not carried out.

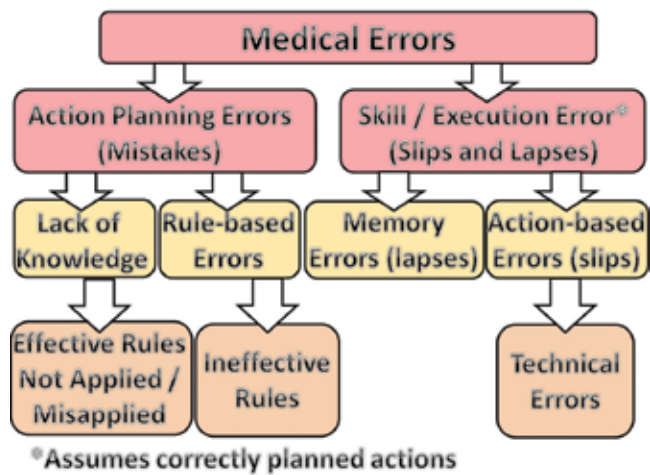


Figure 5. Schematic taxonomy of different types of medical errors (Adapted and compiled from: <http://cecourses.org/preventive-care/preventing-medication-errors/> and <http://www.thebestmedicalcare.com/patient-safety/when-why-and-how-things.html>).

errors of omission tend to be more common than errors of commission (see the “Introductory Chapter” of *Vignettes in Patient Safety, Volume 1*) [72–74]. Factors that contribute to EOOs include deficient or lack of education [75], faulty communication [75, 76], insufficient labor resources [75, 77], and the absence of necessary tools (e.g., checklists, technological support, etc.) [75].

It has been shown that EMR implementation can lead to significant improvements in compliance with protocolized care paradigms and the reduction of EOOs [72]. In addition, omissions associated with documentation of medical history and clinical events may lead to error

propagation and escalation [72], further highlighting the importance of process standardization and protocol compliance. Finally, the importance of education and skills maintenance must be strongly emphasized. In addition to ensuring adequate medical knowledge, practitioners should remain acutely aware regarding the ever-present possibility of an error as well as ways to prevent adverse events [78].

10. Summation and conclusions

Exposure keratopathy is a preventable complication that most often is due to errors of clinical omission. In addition to discussing the etiology, risk factors, management, and complications of EK, this chapter also discusses an important category of medical errors – those of omission. Among strategies to reduce errors of omission, a multi-pronged approach involving clinical education, evidence-based protocols, and hardwired quality improvement seems to be most optimal. In conclusion, with proper education of providers and establishment of protocols, the incidence of EK, and thus the incidence of any associated sequelae, should decrease.

Author details

Benjamin Bird^{1*}, Stephen Dingley², Stanislaw P. Stawicki^{2,3} and Thomas R. Wojda^{3,4}

*Address all correspondence to: tuf80248@temple.edu

1 Lewis Katz School of Medicine at Temple University, Philadelphia, PA, USA

2 Department of Surgery, St. Luke's University Health Network, Bethlehem, PA, USA

3 Department of Research & Innovation, St. Luke's University Health Network, Bethlehem, PA, USA

4 Department of Family Medicine, Warren Hospital Campus - St. Luke's University Health Network, Phillipsburg, NJ, USA

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Bedside Procedure: Retained Central Venous Catheter

Maureen E. Cheung, Logan T. Mellert and
Michael S. Firstenberg

Additional information is available at the end of the chapter

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Abstract

The placement of central venous catheters (CVC) is a common medical procedure and adjunct to current medical therapy. With millions of CVC placed yearly in the United States, complications occur. It is important to be aware of the potential immediate and long term complications associated with this procedure. In this chapter, a representative case of retained CVC guidewire is presented. Provider experience, appropriate patient selection and insertion technique can minimize the risk of immediate complication in most cases. A brief discussion of CVC complications with emphasis on guidewire malfunction is presented along with management and retrieval options.

Keywords: retained guidewire, central venous catheter, catheter complications, bedside procedures, J wire, guidewire fracture, intravascular foreign body

1. Introduction

With more than 5 million central lines placed in the United States every year, complications are anticipated [1–4]. The most common immediate complications of central venous catheterization (CVC) include pneumothorax (incidence of 0.5–1.5%), arterial puncture (0.5–3.7%), and cardiac ectopy (0.9%) [1, 5, 6]. Retained guide wire is a recognized but rare complication during insertion of CVC. The estimated incidence is 0.05–0.1% during CVC insertion [7, 8]. Causes of retention include guide wire looping, entrapment, wedging within catheter and fracture during insertion [9–11]. While retained guide wire is a rare complication, it is entirely preventable except in cases of catastrophic equipment failure and is considered an unacceptable occurrence by physicians.

2. Vignette

A 69 year old female presents with pneumonia and sepsis. She is hypotensive and unresponsive to multiple fluid challenges. The placement of a CVC is necessary for norepinephrine infusion therapy. She has a past medical history of hypertension, diabetes mellitus (type II), and chronic obstructive pulmonary disease. Her past surgical is significant for laparoscopic cholecystectomy and Cesarean section. She denies a history of head/neck surgery or prior central venous instrumentation.

After obtaining consent, a right internal jugular (IJ) CVC is placed using ultrasound guidance. After gaining venous access, the guide wire is threaded. It initially passes easily but resistance is met at approximately 10 cm. An attempt is made to withdraw the guide wire, however significant resistance is met. After multiple attempts to withdraw and advance the guide wire, there is a sudden change in resistance and the guide wire is easily advanced. The remainder of the procedure is completed using the modified Seldinger technique and a triple lumen catheter is placed. All ports easily draw blood and flush with saline (**Figure 1**).

A post procedure chest X-ray is obtained. The tip of the catheter terminates in the mid-superior vena cava (SVC) and a linear hyperdensity within the right atrium is noted. This is approximately 8 cm in length and consistent with retained guide wire. You inspect the procedural guide wire and note that the distal end does not have its characteristic "J" bend.

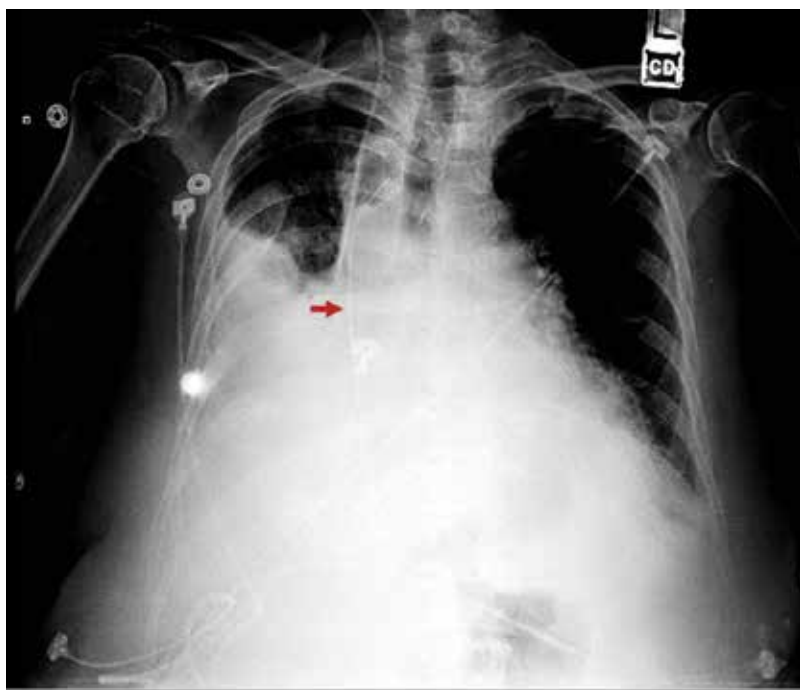


Figure 1. Chest X-ray revealing a retained guide wire (arrow).

3. Discussion

When inserting a CVC, it is essential that the provider is experienced and has been appropriately trained, supervised, and privileged to perform the procedure. If the clinical scenario allows, informed consent should be obtained. An appropriate insertion site should then be selected. The modified Seldinger technique is utilized for catheter placement. If an IJ or subclavian (SC) catheter is inserted, chest X-ray is performed to confirm placement location and ensure no pneumothorax has developed [2, 6, 12–16].

3.1. Indications and catheters

CVC are an important component of medical care. They provide temporary short-term or long-term vascular access and are used for hematologic sampling and monitoring, long-term antibiotic administrations, hemodialysis, and the delivery of caustic therapeutics such as vasopressors, total parenteral nutrition (TPN), and chemotherapy. During insertion and when not in use, these catheters are flushed to maintain patency. Flushes are usually a sterile saline or heparin saline solution which is injected to fill the catheter. If an institution utilizes heparin saline for flushes, care should be exercised to identify patients with contraindications to heparin such as history of hypersensitivity reaction, and heparin-induced thrombocytopenia (HIT) [17–19]. There are many devices available for central venous access but they are generally composed of silicone or polyurethane which allows for relative stiffness at room temperature and a softened state at body temperature [6, 11]. CVC can be broadly categorized into non-tunneled, tunneled, and implantable with ports.

Of these, non-tunneled CVC are the most frequently inserted. They are typically placed at bedside for short-term therapy (1–4 weeks) and in patients with significant physiologic distress [12]. The most frequent entry sites are the internal jugular (IJ), subclavian (SC), and femoral veins. Peripherally inserted central catheters (PICC) are similar to non-tunneled CVC. They are non-tunneled catheters placed at bedside, although generally in a more elective fashion. They are inserted through a peripheral arm or leg vein and advanced until the tip lies in the SVC. They are small-bore catheters that usually enter the system in the brachial, antecubital or long saphenous veins. They have the benefit of comfortable positioning for the patient and have lower reported infection rates than IJ, SC, or femoral catheters. PICCs have a smaller total diameter with only 1–2 lumens and slower maximum infusion rates [20]. Midline catheters are placed in the same entry sites as PICCs but terminate in the axillary vein. While still considered a short-term device, PICC and midline catheters are often maintained longer than a non-tunneled CVC due to their lower infection rates. In the literature, there is emphasis that these should still be considered a short-term catheter and to cautiously maintain them for >4 weeks [20].

Tunneled CVC are placed in a procedure or operating room utilizing fluoroscopy for visualized insertion. These catheters are tunneled through subcutaneous tissue and contain a Dacron cuff which causes fixation. The combination of tunneling and cuffed fixation creates physical barriers to infection, reducing infection rates and allowing for long term use of these

catheters. Implanted ports are also long-term devices placed in the operating room. They consist of a catheter and diaphragm which is accessed via cutaneous puncture. Inserted subcutaneously, ports are typically placed in upper anterior chest wall through an IJ or SC approach [12]. Once inserted, they have no externalized components allowing for the lowest infection rates amongst CVC [21]. For the purposes of this paper, we will briefly review relevant anatomy and insertion technique for non-tunneled IJ, SC, and femoral catheters. PICC and midline catheters are not addressed here as most hospitals have a dedicated team of providers who perform these insertions [22].

3.1.1. IJ catheterization

After selecting an appropriate access site, the care team should don hat and masks. The provider will then wash his/her hands and dress in sterile gown and gloves. The area is prepped and draped in normal sterile fashion with chlorhexidine solution. During the prep, the provider should examine the contents of the sterile central line insertion kit. Each hospital has its own standard CVC kit and it is important to be familiar with the equipment prior to proceeding. The catheter lumens are then flushed with sterile saline or heparin saline and compatibility of the needle, guidewire, and catheter should be confirmed. The contents of the kit should be organized in a fashion that allows for easy transition from one portion of the procedure to the next.

After sterile draping, the desired cannulation site is infiltrated with local anesthetic. If utilizing ultrasound, this should also be sterilely draped at this time. The provider will position themselves at the head of the bed with ultrasound in the nondominant hand. The patient is then placed in Trendelenburg position and the head rotated 30–45° away from the access side to allow access to the neck. Additional rotation of the head to the contralateral side does not aide the provider as it brings the sternocleidomastoid muscle into an anterior position over the IJ and increases the anterior-posterior overlap of the IJ with the carotid artery [2]. Therefore, only as much rotation as is needed to gain access to the neck is utilized.

Next, IJ and carotid artery are inspected sonographically. It is important to be familiar with regional anatomy and anatomic landmarks. For the IJ approach, the landmarks are the sternal and clavicular muscle heads of the sternocleidomastoid, and the clavicle. These borders create a triangle known as Sédillot's triangle. The carotid and IJ are identified slightly superior to the apex of the triangle. IJ is typically anterior/lateral and is easily compressed with ultrasound probe. For patients with difficult to identify IJ or complex anatomy, color doppler mode or duplex mode can be utilized for identification. Once identified, the large-caliber introducer needle is inserted through the skin at the apex of the triangle with approximately a 20–30° angle. While maintaining aspiration, it is advanced under direct visualization into the IJ. This is typically encountered 0.5 cm below the skin with the needle along an axis towards the ipsilateral nipple [2].

Once venous access is obtained, the US is set aside and the syringe is removed, taking care not to disturb the needle. With the J end of the guide-wire directed towards the midline, it is passed through the needle. It should thread smoothly and advance without resistance. If cardiac arrhythmia or ectopy is noted, immediately withdrawal the wire until it ceases. The

needle is then removed, maintaining continuous control of the wire. A stab incision is made at the insertion site. A dilator is then passed over the wire, dilating the subcutaneous tissue. This is removed and the catheter is threaded over the wire. At this point, it is necessary to back feed the wire proximally until control is regained from the distal aspect of the catheter port. Once obtaining control of the wire, the catheter is inserted over the wire into the vessel. The wire is then removed and blood return is confirmed from each port with a following flush. Ultrasound can be utilized to confirm placement within the IJ and examine the lung fields for violation. The catheter is then secured in place and a sterile occlusive dressing is applied. Prior to removal of any equipment, a final sharps count and examination of the guidewire should be performed to ensure complete retrieval of guidewire with J-shaped tip and no sharps were misplaced. An upright chest X-ray is then obtained to confirm placement and verify no pneumo or hemothorax.

3.1.2. SC catheterization

A similar method is utilized for a SC approach [2, 12, 14–16]. A small shoulder roll may be placed between the shoulder blades to allow the shoulders to drop backwards. This maneuver exposes the necessary anatomy and brings the SC ventrally. If the shoulder roll is too large, the vein can collapse between the first rib and clavicle [1, 2]. Anatomic landmarks for SC access are the sternal notch, and the junction of the middle and medial third of the clavicle, near the deltopectoral groove. The provider will position him/herself on the side that is to be accessed. Following shoulder roll placement, the head is rotated slightly away from the side of insertion and the patient is placed into Trendelenburg position. The provider will place the nondominant index finger in the sternal notch and thumb on the clavicle above the deltopectoral groove. If accessing the right SC a right handed provider will turn their hips slightly towards the feet, if accessing the left their hips will be turned slightly towards the head; this allows comfortable positioning throughout the procedure. Local anesthetic is infiltrated and the access needle is inserted approximately 1–2 cm inferior and lateral to the junction of the middle and medial thirds of the clavicle. With continuous aspiration, the needle is directed medially and slightly cephalad in an axis towards the sternal notch and parallel to the floor. The needle may be “walked down” the clavicle if desired and passed beneath the clavicle with gentle downward pressure applied with the nondominant hand and advanced until venous blood is withdrawn. The syringe is then removed and the guidewire introduced with the J end directed caudally. The needle is removed; skin incised, and subcutaneous tract dilated. The catheter is then inserted over the guidewire again taking care to maintain continuous control of the wire throughout. The wire is removed, blood return verified and ports flushed. The catheter is secured and dressed. Post-procedural equipment verification is completed and an upright chest X-ray obtained.

3.1.3. Femoral vein catheterization

In the case of femoral vein catheterization, ultrasound can aid in anatomic visualization, however, the procedure is typically performed with anatomic landmarks only [2, 14]. The femoral triangle is identified with superior border of the inguinal ligament, medial border of the adductor longus muscle and the lateral border of the sartorius muscle. Within the triangle,

the femoral vein is found medial to the common femoral artery, contained within the femoral sheath. It is important to remember that the inguinal ligament runs between the anterior superior iliac spine and the pubic tubercle and does not necessarily correspond to the “groin crease” [1, 2].

The most advantageous patient positioning is with the hip in a neutral or slightly abducted and externally rotated. Unlike the SC or IJ approach, the patient is placed supine or in slight reverse Trendelenburg position. The insertion site is identified by locating the arterial pulsation 1–2 cm below the inguinal ligament within the femoral triangle. The needle insertion site is approximately 1 cm medial to this maximal pulsation and the axis of insertion is cephalad and medially towards the umbilicus at a 45° angle from the skin. The femoral vein is typically encountered 2–4 cm below the skin and is accessed below the level of the inguinal ligament. The modified Seldinger technique is again utilized; post-procedure imaging is not typically indicated [2].

3.1.4. Other considerations

Each insertion site has advantages and disadvantages; appropriate selection is affected by patient and clinical factors. The IJ can be accessed under direct visualization with ultrasound guidance and has a lower pneumothorax and hemothorax rate than the SC approach. However, it can be difficult in certain subsets of patients. Those with limited neck mobility, history of neck surgery, cervical collar, substantial subcutaneous tissue or significant cervical kyphosis can make IJ placement challenging [1, 14]. The SC has lower rates of arterial puncture than femoral or IJ locations and the lowest infection rate of the three. The femoral site has the advantage of no hemothoraces or pneumothoraces. It is a relatively safe and accessible location which is typically distant from other monitoring devices and can be placed without interruption of intubation or cardiopulmonary resuscitation. Femoral catheterization allows for free motion of the upper extremities and neck. Despite this, it has the highest rate of infection, limits ambulation and has the highest risk of associated thrombus formation [2, 15].

For proper positioning of SC and IJ CVC, the distance between insertion site and the SVC-atrial junction is vital to appropriate positioning and the avoidance of inducing arrhythmias. In an American based prospective study, fluoroscopy was utilized to determine this distance. It was found that the distance for right IJ insertion averaged 16 cm, right SC averaged 18.4 cm, left IJ averaged 19.1 cm, and left SC 21.2 cm [23]. A South Korean retrospective review of patients with CVC who underwent chest CT revealed slightly shorter distances. They reported a right IJ of 15 cm, right SC 14 cm, left IJ 18 cm, and left SC 17 cm [24]. These distances should be considered when selecting and inserting a CVC to ensure appropriate placement.

3.2. Complications

There are numerous case reports and case series documenting the potentially devastating complications of CVC. These include bleeding events, arterial puncture, infective sequela, cardiac conduction abnormalities, catheter malposition, thrombotic events, and mechanical device failure [1, 6, 25]. Identified risk factors for complications during CVC insertion are number of unsuccessful needle passes, inexperience of provider, body mass index >30

or <20, hypovolemia, large catheter size (specifically related to vascular complications), and previously failed catheterization attempts [1, 5, 25, 26]. When failed catheterization occurs, complications are reported as high as 28% [5]. Ultrasound assistance reduced immediate complications with the overall incidence decreased from 11.8 to 4–7% [5, 26]. In this section, the complications associated with CVC will be discussed briefly as well as advised action if they are encountered. The associated morbidity and mortality of these adverse events can be reduced with prompt recognition and appropriate action.

3.2.1. *Bleeding events*

Bleeding events include hemorrhage, hematoma, and hemothorax from arterial or venous injury. While uncommon, innominate, aortic, SVC, and right ventricular perforation are reported in the literature [25, 27–30]. In those cases, improper use of the dilator and guide-wire kinking were cited as the cause for injury [5, 25, 27, 28]. More common, is injury from puncture or cannulation of the carotid, subclavian, common femoral, or external iliac artery. The incidence of arterial injury from puncture (≤ 18 G) is reported to be 4.2–9.3% and 0.1–1.0% from cannulation (> 7 Fr.) [25]. The majority of these injuries are identified at the time of occurrence with recognition of blood coloration, pulsatile flow, ultrasound visualization, or pressure measurements. If a needle puncture has occurred, it can typically be addressed with application of pressure. If the artery is cannulated, symptoms are reported in 30% of patients. In this subset, mortality reaches a rate of 20–40% [5]. Arterial catheter removal with direct pressure is associated with major complications in 47% of patients [31]. When removed by a surgical specialist or intervention radiologist under direct visualization with immediate surgical or endovascular intervention a 0% complication rate is reported [31]. This disparity in outcomes prompted the recommendation that if arterial cannulation is suspected, leave the catheter in place and seek immediate surgical consultation [25, 29, 31].

Arterial cannulation can lead to hemorrhage/hematoma, neurologic deficits, pseudoaneurysm, and AV fistula formation. Neurologic deficits are the result of either cerebral vascular ischemia or hematoma with nerve compression [5, 25, 31, 32]. Cerebral vascular ischemia from arterial CVC occurs when the inadvertent cannulation is not recognized and vasopressors are administered [5, 31]. Pseudoaneurysm and AV fistula formation can be an acute or delayed complication of arterial injury and discovery is reported years after catheterization [5]. The estimated incidence of AV fistula formation is 0.2% for IJ and 0.6% for SC catheterization attempts and can lead to symptomatic intracranial hypertension [5, 26]. Pseudoaneurysms are a recognized complication associated with arterial cannulation or rupture of a mediastinal vein during CVC placement [4, 33, 34]. The incidence of this rare complication is not defined in the literature. When a pseudoaneurysm does occur, treatment via endovascular stenting and open repair are described [4, 33]. Pseudoaneurysms can also occur with embolization following fracture of a catheter and in one case report resulted in a 5×4 cm pulmonary artery pseudoaneurysm which required surgical excision via lobectomy [33]. Both of these conditions require intervention. Various methods are described in the literature with coils, thrombin injections, manual compression, stenting, and open surgical approach utilized for repair [5, 26]. Once identified, the management of these complications should be undertaken with the aid of a vascular surgeon.

Localized hematomas with nerve compression of the brachial plexus or the sympathetic trunk (causing Horner syndrome) occurs in 4.7% of all CVC. It is caused by either arterial or venous hemorrhage [5, 26]. Other complications which can arise from hematomas include vocal cord paralysis, phrenic nerve injury, respiratory distress and airway obstruction [5, 26]. Venous hematomas can arise from multiple punctures, venous laceration, and attempted access at an inappropriate site. The utilization of ultrasound or fluoroscopy is advocated for prevention of these complications [1, 6, 25].

Catastrophic hemorrhage is a surgical emergency which requires prompt recognition and action. It occurs in the acute setting from puncture or perforation into regions of large potential space including the thoracic, abdominal, and retroperitoneal cavities [5, 28, 35, 36]. Unlike the mediastinum or neck which has relatively limited space, these cavities can accommodate a large amount of blood without clinical signs until hemodynamic instability is reached. Similar to arterial cannulation, if this occurs or is suspected, the catheter should be left in place and a vascular or cardiothoracic consultation immediately obtained. In this case, the catheter is partially occluding the tract and removal of the catheter blindly can lead to increased hemorrhage and death. If circumstances allow, imaging studies to define the path of the catheter are obtained to aid in planning for its safe removal [5, 25, 36].

3.2.2. *Central line-associated bloodstream infections (CLABSI)*

Infective sequela of CVC has become an area of interest in recent years, particularly as the Centers for Medicare and Medicaid Services (CMS) withdrew reimbursement for the treatment of hospital-acquired infections (HAI) including central line-associated bloodstream infections (CLABSI) [37]. The cause of CLABSI in non-tunneled CVC is attributed mainly to the migration of skin organisms at the insertion site through the cutaneous catheter tract and into the bloodstream with colonization of the external surface of the catheter. This modality of contamination is part of the rationale for tunneled CVC. Both non-tunneled and tunneled CVC contamination can occur via the catheter hub with intraluminal colonization of the catheters. Rarely, CVC can become seeded from other hematogenous infections [20, 38]. The infective organism encountered most frequently is *Staphylococcus* (37%), followed by *Enterococcus* [20, 22, 26, 38, 39]. The overall incidence of CLABSI is reported at 5.3 per 1000 catheter days with a CDC estimated cost per infection of \$16,550 and an attributed mortality of 18% [5, 26].

Higher rates of infection are noted based on entry site, emergent status of insertion, increased number of lumens, and type of CVC. With regards to location, PICC have the lowest infection rates of non-tunneled CVC at 1–2 per 1000 catheter days [20, 26, 38]. These are followed by SC (4 per 1000 catheter days) then IJ (8.6 per 1000 catheter days) and finally the femoral vein (15.3 per 1000 catheter days) [5, 20, 22, 26, 38]. In the case of elective non-tunneled CVC, infection incidence is reported at 1.1–3.35 per 1000 catheter days, significantly lower than the reported overall infection rates [5, 20, 38]. The rate for tunneled CVC is 1.3 per 1000 catheter days and for implanted ports is 0–1 per 1000 catheter days [20, 26].

In recent years, a number of guidelines emerged to aid in the safe insertion and utilization of CVC. These were prompted by the Michigan Keystone project published in 2006 by Pronovost

et al. which demonstrated significant reduction in CLABSI by implementing simple infection-control practices [40]. These measures included maximum sterile barrier precautions, aseptic insertion technique, chlorhexidine skin preparation, transparent dressings, and removal of the catheter as soon as clinically possible [40–42]. It was also determined that the routine exchange of catheters for infection prevention was not necessary and may cause contamination [40, 42]. The increased interest and financial considerations have also led to device innovations for infection reduction. These include alcohol impregnated caps for the covering of hubs, and the development of antimicrobial-impregnated CVC with both internal and external surface impregnation [41, 42].

3.2.3. *Cardiac arrhythmias and ectopy*

Cardiac arrhythmias and ectopy are a recognized phenomenon during the placement of central venous devices and are frequently observed with incidence reaching 75% when the guidewire is advanced 25–32 cm from the IJ entry site [5]. Occurrence rates during insertion of CVC in adult patients are 41% for atrial arrhythmias, and 25% for ventricular ectopy [43]. A slightly lower rate is reported for pediatric patients with a 30% overall incidence of arrhythmias [44]. While complications from these are rarely reported in the literature, malignant/fatal arrhythmias have been described including complete heart block and sudden death. Typically these coincide with preexisting conduction abnormalities. In one such case report, a patient with a left bundle branch block was converted into a complete heart block during guidewire insertion [3]. The suggested mechanism was the superficial location of the right bundle branch making it vulnerable to guidewire trauma [3].

Continuous cardiac monitoring should be utilized throughout CVC placement. If any ectopy or arrhythmia is identified, the guidewire should be withdrawn until it resolves completely. It is imperative that the provider is aware of the guidewire length. Guidewire insertion for the placement of a CVC should never exceed 18 cm and insertion of 14 cm should be adequate for all insertion sites [23, 24]. Late onset of arrhythmia is also reported with an incidence of 0.9% in indwelling tunneled or implanted port CVC [5]. These are typically responsive to removal or replacement of CVC. Another cause of delayed arrhythmia which must be considered is mediastinal or cardiovascular perforation which is the result of catheter malposition [6].

3.2.4. *Catheter malposition and thrombosis*

Catheter malposition occurs in 3.3% of CVC insertions with the highest incidence with right SC entry (9.1%) and least frequently with right IJ (1.4%) [45]. Catheter malposition into the innominate, left internal mammary, azygous, hemiazygos, lateral thoracic, inferior thyroid, intercostal, and thymic veins have occurred [46, 47]. Incorrect position can result in inaccurate hemodynamic monitoring, thrombosis, and arrhythmias [6, 45–47]. While a rare event, perforation is possible. CVC perforation without tamponade occurs at a rate of 0.4–1% with an associated mortality of 12%; the rate of perforation with subsequent tamponade is 0.2% with a mortality of 81–90% [5, 6]. These perforations are attributed to catheter malposition [5, 6]. The exact definition of catheter malposition has evolved over the years but today is accepted as placement within the heart, an angle of incidence (the angle between the CVC tip and the wall of the vein) $>40^\circ$, and placement into vessel other than the SVC or IVC [5].

The ideal catheter position for SC and IJ is with the tip in the SVC just above the right atrial junction. The accepted corresponding surface landmarks are the angle of Louis (the junction between the manubrium and sternum) or the right sternal border of the third intercostal space [1, 12, 15]. These can be used to estimate the appropriate length of catheter for insertion but final positioning should always be confirmed with a chest X-ray or fluoroscopy. The most reliable radiography landmark for placement verification is the CVC tip at the right tracheobronchial angle which ensures it lays ≥ 3 cm above the pericardial reflection [5]. This is accurate even when patient positioning gives the appearance of the CVC within the cardiac silhouette.

CVC thrombotic events are site, catheter, and patient dependent. In the case of non-tunneled CVC, site appears to be the major determining factor with the highest incidence occurring at the femoral site (21.5–29%) and lowest at the SC site (1.9%) [1, 6]. Catheter-related thrombosis in tunneled and indwelling port CVC has a reported incidence of 33–59% with a SVC obstruction rate of 0.1% [5]. Patients with malignancies are at particularly high risk for thrombus formation with an incidence of 41%; 15–30% of these patients will be symptomatic and 11% will experience an associated pulmonary embolism [5]. Anticoagulation and thromboprophylaxis was studied in this subset of patients without evidence of prevention or benefit [5]. Efforts to reduce the thrombogenicity of the catheter materials have been ongoing for >30 years [48–50]. This led to the refinement of materials with recognition that polyethylene catheters have a higher incidence of thrombus while silicone and polyurethane exhibit improved biocompatibility [49, 51]. Newer efforts have investigated the application of an athrombogenic layer, impregnation of catheter with medications including heparin and nitric oxide, as well as improved composition of catheter materials [51–53]. Due to the interaction between the catheter surface and hematogenous components, thrombus formation can occur at any point along the device. Morbidity from thrombus formation includes embolic events (particularly if the thrombus is associated with the tip of the catheter or >3 cm), infected thrombus, SVC occlusion, and ipsilateral edema [6, 54–57]. If a thrombus is identified and is <3 cm, the CVC can be safely removed without evidence of adverse events. However, if >3 cm there is an increased risk of embolic event upon line removal; anticoagulation or thrombolytic therapy is utilized to reduce the thrombus size but surgical removal is sometimes necessary [26]. In the event of thrombus identification, therapy should include symptomatic management, determination of the continued need to catheterization, monitoring for propagation and anticoagulation or thrombolytic therapy if indicated.

3.2.5. *Mechanical failure*

The mechanical failure of equipment is a potential complication of any device. Immediate mechanical failure is generally related to guidewire issues including retention from looping, entrapment, wedging within the catheter and fracture during insertion [9–11]. Cases of wire and catheter entrapment within inferior vena cava (IVC) filters, knotting with existing CVC, and incorporation with cardiac sutures are reported [26]. These have been managed with fluoroscopic endovascular procedures but at times require surgical intervention [11, 26]. When identified, immediate correction is preferred in stable patients. Known complications include catheter fragmentation with distal embolization and access site injury [26, 58]. The available literature on these cases is limited.

During insertion, guidewire fracture risk can be minimized by careful attention to associated resistance. If resistance is encountered, it may be from extraluminal placement, kinking, entrapment, or

intraluminal stenosis [8, 25, 47, 58, 59]. When this occurs, remove the needle and guide wire en bloc (together), inspect immediately to verify complete removal, obtain new equipment and reinstate procedure [12, 15, 16]. In this way, wire fracture and embolization is avoided. If you continue to encounter resistance, an alternative insertion site or fluoroscopic guidance should be considered.

Delayed mechanical failure is more commonly encountered with catheter fracture and embolization occurring in 0.5–3% of indwelling CVC with a morbidity rate of 71% and mortality of 30–38% [5]. Arrhythmia, cardiac arrest, pulmonary embolism with hemoptysis, perforation, and thrombosis are reported. Causes of delayed failure include breakage during catheter removal, entrapment, material properties of the catheter, and long-term mechanical fatigue [60, 61]. Material analysis from fractured catheters has shown an increased fracture risk with silicone catheters compared to polyurethane [60, 61]. Additionally, fatigue is particularly prevalent in SC catheters where mechanical shearing between the clavicle and first rib can occur [2, 5, 62]. This is referred to as pinch-off syndrome and is characterized by functional occlusion with postural changes. It will be reported by patients and staff as an inability to aspirate and difficulty flushing the catheter which is improved when the arm is raised. When pinch-off syndrome occurs, the repeated shear stress on the catheter will eventually cause fracture and embolization [2, 5, 62]. It is estimated that pinch-off syndrome is responsible for 41% of catheter embolic events and should be addressed immediately upon identification [2].

3.3. Foreign body retrieval

Retained intravascular foreign bodies can occur during a variety of procedures. With the rapidly expanding scope of endovascular interventions, this complication will continue to be of clinical significance. In the case of CVC, guidewire retention during insertion is estimated at a rate of 0.03–0.1%, catheter retention during removal is estimated at 1.5%, and the overall incidence of retained foreign body due to CVC is reported between 0.3 and 1.5% [63–65]. Reports of CVC retention and recovery are presented in case reports, case series and retrospective reviews. These often pool the identification and recovery of all intravascular foreign objects. Embolization is common with identification in the venous system (46%), right heart (35%), and pulmonary arterial system (19%). The reported cases occur both immediately following procedures and with indwelling devices. In the case of procedure related retention, delayed identification of the foreign body is reported in 54% of cases, with the longest time to identification reported at 6 weeks [10]. Since post-procedure imaging often fails to demonstrate a retained object, the true incidence may be higher than reported. When an intravascular foreign object is identified, they are symptomatic in 5.6% of cases and an incidental finding on unrelated imaging in 37% of cases [64]. When identified, endovascular retrieval is the preferred method of recovery due to its minimally invasive approach [5, 9–11, 64, 66].

Endovascular retrieval methods have substantially improved since first reported by Thomas et al in 1964 [67]. Approaches for endovascular retrieval include fluoroscopic, CT, ultrasound, and rarely MRI guided retrieval [9]. Retrieval devices include a variety of loop snares, intravascular retrieval forceps, and retrieval baskets [9, 11, 64, 66]. A recovery rate of 86.6–94% is reported [64, 66]. One case series noted that two thirds of the non-retrieved items were related to CVC [64]. Interestingly, the rate of failed retrieval in case reports is 14.4% while only 3.7% in case series, suggesting publication bias is likely prevalent [66]. Proposed relative contraindications

to recovery include small fragment size, difficult to access location, predicted potential for subsequent complication, patient's clinical status, and associated symptoms [64, 66].

Complication rates associated with retained intravascular foreign bodies vary substantially. In the pediatric literature, Chan et al described no complications in a case series of four retained CVC in pediatric patients with a median follow up of 7.5 months (range 1–53 months). Within the international literature, they noted an overall retention rate of 48.6% with no major complications reported [63]. When retention and embolism occurs in the adult literature, the rate of major complication is 71%. Major complications include persistent infection with sepsis, thrombosis, vascular occlusion, and migration into surrounding structures [63, 64, 66, 68–70]. Bacterial contamination is noted in 28% of these patients. Overall mortality associated with all intravascular foreign bodies ranges between 24 and 60% whereas the mortality rate specific to CVC related events is estimated to be much lower at 1.8% [64, 66, 71].

Attempts to identify complication risk factors and implement appropriate preventive measures prompted a recent study of intravenous retained surgical items (ivRSI) spanning 6 years [10]. In this multicenter study, 13 ivRSI were identified. Risk factors associated with ivRSI were unexpected procedural factors and equipment failure. Unexpected procedural factors were defined as blood loss >500 mL, technically difficult procedure, lack of familiarity with equipment, and difficult/emergent setting. Equipment failure included any documented malfunction/breakage of instrument, hardware, wire, or catheter during the procedure. While this study was specific to endovascular procedures, similar risk factors can be anticipated in bedside procedures (**Figure 2**).

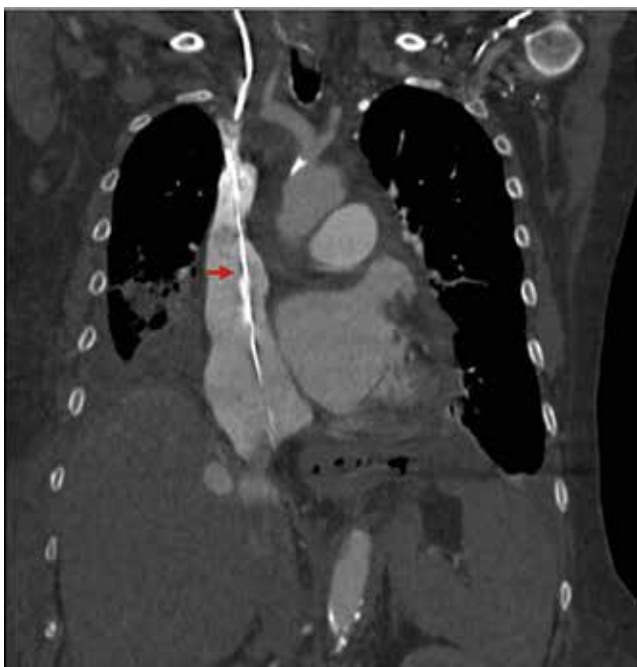


Figure 2. CT-chest revealing a retained guidewire within right atrium (arrow). This was removed under local anesthetic with fluoroscopic guidance via an 8 Fr. right IJ sheath with a 2.5 cm loop snare and guiding catheter.

4. Conclusion

Central venous catheters represent an important clinical adjunct. Their utilization for the delivery of life saving therapies continues to expand. The complications discussed represent the most frequently reported and potentially devastating complications. With more than 15 million central venous catheter days yearly in the US, it is likely that providers will encounter complications [26]. Identified risk factors include number of unsuccessful needle passes, inexperience of provider, body mass index >30 or <20, hypovolemia, large catheter size and previously failed catheterization attempts [1, 5, 25, 26]. As a provider it is necessary to have a basic knowledge of complication management. Prompt action reduces the morbidity and mortality. In the case of a retained guide wire or embolized fragment, immediate retrieval is indicated.

Author details

Maureen E. Cheung^{1*}, Logan T. Mellert¹ and Michael S. Firstenberg²

*Address all correspondence to: cheungme@gmail.com

1 Department of Surgery, Western Reserve Hospital, Cuyahoga Falls, OH, United States

2 Department of Cardiovascular Surgery, Summa Health System, Akron, OH, United States

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Psychometric Properties of the Hospital Survey on Patient Safety Culture (HSOPSC): Findings from Greece

Vasiliki Kapaki and Kyriakos Souliotis

Additional information is available at the end of the chapter

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Abstract

Background: Safety culture has been considered to be as one of the most crucial pre-mises for the further development of patient safety in healthcare.

Objective: To study the psychometric properties of a translated Greek version of Hospital Survey on Patient Safety Culture (G-HSOPSC) of the Agency for Healthcare Research and Quality (AHRQ) in the Greek healthcare settings.

Methods: Factor analysis (FA) was performed to examine the applicability of the factor structure of the original questionnaire to the Greek data. In addition to the previously mentioned, internal consistency with Cronbach's coefficient alpha and construct validity was evaluated.

Results: Ten factors with 37 items were extracted by FA, with acceptable Cronbach's coefficients alpha and good construct validity. The factors jointly explained 62% of the variance in the responses. Five items were removed from the original version of the questionnaire. The composition of the factors was similar to that of the original questionnaire and five items moved to other factors. All the composites consisted of two to eight items.

Conclusions: The G-HSOPSC depicted sound psychometric properties for the evaluation of patient safety culture and therefore it is a reliable tool for use in research.

Keywords: hospital survey on patient safety culture, construct validity, reliability, internal consistency

1. Introduction

Safety culture has been deemed as one of the most significant premises for following improvement of patient safety in healthcare [1]. The term 'culture' is often substituted with 'climate' when questionnaire surveys are utilized to assess an organization's culture. The definition of 'safety culture' derives from the nuclear power industry and has been transferred to the field of the healthcare: 'the safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's safety management' [2]. Safety climate can be faced as the superficial features of the underlying safety culture [3]. It assesses workforce perceptions of procedures and behaviours in their work environment that point out the priority given to safety relative to other organizational goals [4, 5].

Therefore, individual and self-administered questionnaires allow measuring an organization's safety climate [6–9] while for assessing safety culture, other types of assessment (i.e. 'interviews, on-site observations, focus groups') are more suitable [10–12]. These questionnaires are distributed to a group of professionals that operate in the healthcare field having an aim to provide information on aspects of the organizational culture underlying active failures and latent conditions that have to be addressed by patient safety initiatives [13].

Most of the available tools were developed in the United States (US) but some researchers suggest that various US tools cannot be adapted to European context. For this exact reason, after translating a questionnaire into another language and applying it in a different setting, it is of crucial importance to validate it before extending its use to populations differentiating from the specific geographical and healthcare contexts for which it was initially developed. The psychometric techniques are commonly used in order to ensure potential users that tools will be a good predictor of safety events and provide actionable information [9].

2. Clinical vignette

M.G., a 75-year-old woman with stage four chronic kidney disease (CKD), hypertension and gout was admitted for a total knee replacement under the orthopedic team. According to the routine renal biochemistry results and following advice from nephrology group, she was on a low dose of an activated vitamin D analogue. She was also taking a diuretic, an angiotensin receptor blocker, aspirin, sodium bicarbonate and a statin drug. Serum calcium was not verified again during her admission. Even though discharge communication included the recently started medication with the advised dose, no advice was given to the general practitioner about the required rate of monitoring serum calcium and renal function post discharge and the patient was not duly informed of the necessity for this monitoring. At her home, the patient made a slow recovery from her operation and had limited ability to move around. Her son phoned for the surgery and requested a general practitioner to make a visit to his mother 3 weeks after discharge, as she looked very sick, was more and more confused and was not consuming food or water. The general practitioner arranges for the patient to be re-admitted

into the hospital. The last diagnosis was stage 2, acute kidney injury (AKI), second in importance, iatrogenic hypercalcaemia and dehydration.

2.1. Key learning points

- i. Knowledgeable safety culture is when bidirectional communication is open and honest, trust exists for the total levels of the health care structure, and messengers are trained and prized for making better systems. The system is precisely in the handling of employees, reporting of errors is valued, and learning from errors is recognized and valued.
- ii. Communication has an effect on health care transactions among health care staff. To be more precise, it is necessary that the list of a patient's medications that is accumulated at admission be communicated successfully to following providers as the patient is transferred between settings and practitioners extending all the way to discharge.
- iii. Keeping patients properly informed is essential to good medical practice and may bring in a level of protection to the test results management system. Patients and where right their families and caretakers, need to be informed at the point of discharge that follow-up tests are needed, what the system for follow-up tests is, and how to navigate it.

3. Methods

3.1. HSOPSC measurement tool

The self-administered HSOPSC tool was developed by the US Agency for Healthcare Research and Quality (AHRQ). The HSOPSC tool assesses safety climate from the staff perspective and covers 7 unit-level composites (24 items) of safety climate, 3 hospital-level composites (11 items) and 4 outcome variables. **Table 1** depicts the characteristics of the specific measurement tool [14].

HSOPSC was selected as the tool for testing for several reasons: (a) Organizations can use the tool to assess their patient safety culture, track changes over time and evaluate the impact of patient safety interventions [15]. (b) It had been designed for surveying all hospital personnel (clinical/non-clinical) [14]. (c) It was considered one of the few healthcare safety climate instruments for which initial psychometric results had been reported [6, 7]. (d) Benchmark statistics of HSOPSC can be retrieved from the internet [16]. (e) The questionnaire has been translated into 27 different languages and it is currently used in 59 countries [17]. To use the specific tool will allow for future international comparisons.

3.2. Translation process: pre-test

Firstly, permission was obtained from the authors to use HSOPSC. It was translated into Greek language and then translated back into English by two independent researchers to ensure validity of the translation. In the translation process, it was stressed that the same meaning and 'strength' should be reproduced in the translation into the Greek language. In order to test if respondents understood the meaning of all items, HSOPSC was pilot tested in a group of 35 healthcare professionals which was not incorporated to the final sample. The overall Cronbach's alpha of the pre-test was 0.87.

Characteristics	HSOPSC measurement tool
Writers and date of development	Sorra and Nieva, 2004
Country	USA
Objective	To empower hospitals to evaluate their patient safety culture
Number of items	44
Scale	On a 5-point Likert scale
Setting	Hospital
Staff	Health care staff
Dimensions/elements	<ol style="list-style-type: none"> 1. Communication openness 2. Supervisor/manager expectations and actions promoting patient safety 3. No punitive response to error 4. Staffing 5. Hospital management support for patient safety 6. Teamwork within units 7. Teamwork across hospital units 8. Organizational learning—continuous improvement 9. Feedback and communication about error 10. Hospital handoffs and transitions 11. Overall perception of patient safety 12. Frequency of event reporting 13. Overall patient safety grade 14. Number of events reported in the past 12 months
Psychometric evaluation	<ol style="list-style-type: none"> 1. Sufficient psychometric properties 2. Cronbach's alpha range from 0.63 to 0.84 3. Tested on large specimen

Statistical analysis such as item analysis, exploratory factor analysis, confirmatory factor analysis and correlated composites scores across elements were performed to evaluate psychometric properties. It has a solid content validity and has been validated in all levels. FA resulted in 12 factors.

Table 1. Characteristics of the HSOPSC measurement tool.

3.3. Sample

The study was carried out in 12 Greek hospitals over the period from May 2014 to November 2014. The participating hospitals included nine general hospitals, one of them is a teaching hospital, and three specialty hospitals (1 anticancer-oncology hospital, 1 psychiatric hospital and 1 cardiac surgery centre). The HSOPSC was originally designed for application to all hospital professionals [14]. However, the pre-test showed that items dealing with direct patient care could often not be answered by staff not involved directly in patient care (i.e. hospital managers, administrators). Consequently, the survey was returned by 820 participants (response rate = 59.6%), 10 questionnaires in which fewer than half the items were answered were also excluded. Finally, 810 questionnaires were retained for further analysis.

3.4. Statistical analysis

Factor analysis (FA) clarifies the items which are in depth connected and allude in collaboration to a below composite (or factor). Therefore, the items are able to be lessened to the smallest potential number of understandings that as before make the largest potential part of the variance

clear [18]. A FA was carried out (principal component analysis with varimax rotation) for the purpose of proving that the current scales/dimensions may be fairly employed within the Greek context. When proving the number of elements, the Eigen value (Eigen value > 1: Kaiser's criterion) was taken into consideration, in comparison with the range of explained variance, the shape of the screen plot and the future outcome of interpreting the elements. Kaiser's criterion is trustworthy in a specimen of more than 250 respondents and when the average communality adds up to or is larger than, 0.6. The figure of the screen plot supplies dependable knowledge when the sample is larger than 200 respondents [18]. The data fulfil the requirements.

The Kaiser-Meyer-Olkin (KMO) calculation of sampling appropriateness was ascertained. This value is able to fluctuate from 0 to 1. A value near 1 points out that there is just any diffusion in the correlation pattern, empowered trustworthy and unique elements by FA [18]. The KMO score was 0.9, not close to Kaiser's standard of 0.5.

Additionally, the writers confirmed whether the inter-item correlations were adequate, by a test of the correlation matrix. Queries are a member of the common underlying composite, which will be related as they calculate the identical feature of patient safety culture. Objectives that are not related, or correlate with only a few other variables, are not compatible with FA [18]. Bartlett's test of sphericity illustrated that the inter-item correlations were adequate: ($\chi^2 = 12,190$, $df = 861$, $p < 0.001$).

Last but not least, the writers confirmed whether the contrary existed: too much connection between the items. According to an ideal, each feature of patient safety culture exclusively is responsible for the patient safety culture. An important connection between two items signifies that patient safety culture aspects cross each other to a comprehensive range. The amount overlapped in the answer patterns is about 50% when a connection is 0.7 [18]. No connections surpassed the specific boundary score. The pre-analyses depict that the data could be employed for FA.

The construct validity was accomplished by determining scale scores for each factor (after any essential opposite coding) and next measuring Pearson correlation coefficients (r) between the scale scores. The construct validity of each factor is revealed in scale scores that are reasonably connected. Despite this, strong correlations ($r > 0.7$) would point out that factors calculate the identical concept and the above factors may be joined and/or a few objectives could be taken out. Also, connections of the scale scores were measured with the outcome variable 'Patient safety grade'. No connections were measured with the other outcome variable, 'Number of events reported', due to the shortage of variability and distorted type of the specific item (40.1% of the respondents pointed out not to have reported any events during the past 12 months and 35% had reported only one or two events).

Cronbach's alpha was determined to examine the internal consistency of composites. It is expressed as a number between 0 and 1. In case that separate items are considered to calculate the identical concept, the internal consistency (reliability) should be greater than or equivalent to 0.6 [18]. To the reason that the form with questions composed of in a positive and negative way phrased items, the negative ones were made an entry in first reason, due to ensure that a higher score every time signifies a more affirmative reply. Statistical analysis was carried out using the IBM SPSS 21.0 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.).

4. Results

4.1. Sample

Most respondents were nursing staff (45.7%), followed by physicians (25.4%), nurse/unit assistants (17.9%) and physical/occupational/speech therapists (3.8%). These percentages give a reasonable reflection of the real distribution of disciplines at the units (**Table 2**).

Characteristics	Category	N (%)
Hospital type	General hospital	501 (61.9)
	Anticancer-oncology hospital	110 (13.6)
	Psychiatric hospital	132 (16.3)
	Cardiac surgery centre	67 (8.3)
Hospital size (beds)	100–250	642 (79.3)
	400 or more	168 (20.7)
Location of hospital	Central hospitals	9 (75)
	Peripheral hospitals	3 (25)
Work area/unit	Many different hospital units/no specific unit	166 (20.5)
	Medicine (non-surgical)	166 (20.5)
	Surgery	204 (25.2)
	Emergency department	12 (1.5)
	Intensive care unit (any type)	49 (6)
	Laboratory	38 (4.7)
	Psychiatry/mental health	117 (14.4)
	Rehabilitation	11 (1.4)
	Pharmacy	1 (0.1)
	Social services department	19 (2.3)
	Other	27 (3.4)
Staff position	Resident physicians	110 (13.6)
	Specialist physicians	95 (11.8)
	Nurses (university training)	49 (6.1)
	Nurses (technological education institute training)	320 (39.6)
	Nurse assistants	136 (16.8)
	Unit assistants	9 (1.1)
	Physical/occupational/speech therapists	31 (3.8)
	Psychologists	5 (0.6)
	Welfare workers	26 (3.2)
	Pharmacy staff	1 (0.1)
	Other	26 (3.2)

Characteristics	Category	N (%)
Gender	Male	247 (30.5)
	Female	563 (69.5)
Age (years)	Mean	41.35
	Std. deviation	7.9
	Median	41
	Min	18
	Max	65
Education level	University	268 (33.1)
	Technological education institute	386 (47.7)
	Secondary education	156 (19.3)
	Master degree	130 (17)
	PhD	12 (1.6)
Professional experience (years)	Mean	14.97
	Std. deviation	8.71
	Median	15
	Min	0.02
	Max	36
Professional experience in the specific hospital (years)	Mean	12.12
	Std. deviation	8.8
	Median	10
	Min	0.02
	Max	35
Professional experience in the specific unit (years)	Mean	7.74
	Std. deviation	6.84
	Median	6
	Min	0.02
	Max	35
Working hours per week	Mean	44
	Std. deviation	12.88
	Median	40
	Min	4
	Max	120
Interaction with patients	Direct	724 (89.6)
	Indirect	84 (10.4)

Table 2. Respondents—hospital characteristics.

4.2. FA: internal consistency

Ten factors were drawn by FA with 37 items. All the items of 'Hospital handoffs and transitions' (F3r, F5r, F7r, F11r) blended into the factor 'Teamwork across hospital units'. Two of the items of 'Feedback and communication about errors' (C3, C5) from the US version blended into the factor 'Communication openness'. A new factor originated, which comprised four items from the original questionnaire (B3r, B4r, A7r, A10r). The factors of 'Non-punitive response to error', 'Hospital management support for patient safety' and 'Frequency of event reporting' from the American study remained stable to the G-HSOPSC. The overall Cronbach's coefficient alpha for the G-HSOPSC was 0.91. Seven out of 10 factors in the G-HSOPSC had Cronbach's coefficients alpha > 0.70 and three factors had values between 0.60 and 0.70, which indicate fairly good internal consistency of the Greek version of the questionnaire (Table 3).

HSOPSC factor analysis				G-HSOPSC factor analysis		
Composite	Items ^a	Cronbach's α American data	Cronbach's α Greek data	Composite	Items ^a	Cronbach's α
Unit-level						
1. Supervisor/ manager expectations and actions promoting safety	B1, B2, B3r, B4r	0.75	0.70	1. Competent supervisor/manager expectations and actions promoting safety	B1, B2	0.84
2. Organizational learning— continuous improvement	A6, A9, A13	0.76	0.49	2. Organizational learning	A9, A13	0.60
3. Teamwork within units	A1, A3, A4, A11	0.83	0.61	3. Teamwork within units—continuous improvement	A1, A3, A4, A6	0.80
4. Communication openness	C2, C4, C6r	0.72	0.62	4. Feedback and communication openness about errors	C2, C4 C6r, C3 C5	0.77
5. Feedback and communication about errors	C1, C3, C5	0.78	0.74	*	*	*
6. Non-punitive response to error	A8r, A12r, A16r	0.79	0.71	5. Non-punitive response to error	A8r, A12r A16r	0.71
7. Staffing	A2, A5r, A7r, A14r	0.63	0.51	6. Sufficient staffing	A2, A5r A14r	0.60
Hospital-level						
8. Hospital management support for patient safety	F1, F8, F9r	0.83	0.79	7. Hospital management support for patient safety	F1, F8 F9r	0.79

HSOPSC factor analysis				G-HSOPSC factor analysis		
Composite	Items ^a	Cronbach's α American data	Cronbach's α Greek data	Composite	Items ^a	Cronbach's α
9. Teamwork across hospital units	F4, F10, F2r, F6r	0.80	0.82	8. Teamwork across hospital units and handoffs and transitions	F4, F10 F2r, F6r F3r, F5r F7r, F11r	0.88
10. Hospital handoffs and transitions	F3r, F5r, F7r, F11r	0.80	0.78	*	*	*
Outcome variables				*	*	*
11. Overall perceptions for safety	A15, A18, A10r, A17r	0.74	0.68			
12. Frequency of event reporting	D1, D2, D3	0.84	0.82	9. Frequency of event reporting	D1, D2 D3	0.82
				10. Adequate procedures and systems for safety	B3r, B4r A7r, A10r	0.62

^aThe codes in items' column refer to the sections in the questionnaire and the numbers of the questions.

*Some of the items of the American factors 'Feedback and communication about errors', 'Hospital handoffs and transitions' and 'Overall perceptions for safety' assimilated to other factors and other items removed from the questionnaire.

Table 3. Cronbach's alpha and characteristics of the factors after factor analysis.

Five items (A11, A15, A17r, A18, C1) did not have a sufficient factor loading on any of the factors (all loadings < 0.50) and were eliminated. **Table 4** gives the mean scores with standard deviations and factor loadings per item. The factors jointly explained 62% of the variance in the responses (**Table 4**).

4.3. Construct validity: inter-correlations

For each of the 10 factors, scale scores were calculated by obtaining the mean of the item scores within one factor for every respondent. Immediately after, the mono-item outcome variable 'Patient safety grade' has been determined with the connections of the scales. The factors were anticipated to be related in a positive way with the specific outcome measure. Every one of connections with 'Patient safety grade' was important. With the 'Teamwork across hospital units and handoffs & transitions', the most significant correlation of this outcome was measured ($r = 0.49$). Moreover, correlations between the scale scores were calculated. The highest correlation was between 'Hospital management support for patient safety' and 'Teamwork across hospital units and handoffs & transitions' ($r = 0.52$) but no correlation was exceptionally high (**Table 5**).

Item	Factors											
	Mean	SD	1	2	3	4	5	6	7	8	9	10
B1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	3.62	0.95	0.823									
B2. My supervisor/manager seriously considers staff suggestions for improving patient safety	3.67	0.91	0.805									
A9. Mistakes have led to positive changes here	3.12	0.94		0.772								
A13. After we make changes to improve patient safety, we evaluate their effectiveness	3.29	0.91		0.597								
A1. People support one another in this unit	3.52	0.91			0.802							
A3. When a lot of work needs to be done quickly, we work together as a team to get the work done	3.71	0.89			0.711							
A4. In this unit, people treat each other with respect	3.50	0.89			0.778							
A6. We are actively doing things to improve patient safety	3.98	0.75			0.618							
C2. Staff will freely speak up if they see something that may negatively affect patient care	3.78	0.92				0.695						
C3. We are informed about errors that happen in this unit	3.75	0.95				0.645						
C4. Staff feel free to question the decisions or actions of those with more authority	2.77	0.96				0.687						
C5. In this unit, we discuss ways to prevent errors from happening again	3.66	0.89				0.626						
C6r. Staff are afraid to ask questions when something does not seem right (reverse worded)	3.62	0.99				0.604						
A8r. Staff feel as if their mistakes are held against them (reverse worded)	2.35	0.94					0.753					
A12r. When an event is reported, it feels like the person is being written up, not the problem (reverse worded)	2.68	1.00					0.699					

Item	Factors											
	Mean	SD	1	2	3	4	5	6	7	8	9	10
A16r. Staff worry that mistakes they make are kept in their personnel file (reverse worded)	2.66	0.97					0.781					
A2. We have enough staff to handle the workload	2.16	1.03						0.663				
A5r. Staff in this unit work longer hours than is best for patient care (reverse worded)	2.29	1.05						0.732				
A14r. We work in ‘crisis mode,’ trying to do too much, too quickly (reverse worded)	2.27	0.97						0.578				
F1. Hospital management provides a work climate that promotes patient safety	2.82	0.98							0.745			
F8. The actions of hospital management show that the patient safety is a top priority	3.10	1.09							0.753			
F9r. Hospital management seems interested in patient safety only after an adverse event happens (reverse worded)	2.76	1.04							0.752			
F2r. Hospital units do not coordinate well with each other (reverse worded)	2.73	0.93								0.638		
F3r. Things ‘fall between the cracks’ when transferring patients from one unit to another (reverse worded)	2.94	0.97								0.736		
F4. There is good cooperation among hospital units that need to work together	3.33	0.85								0.674		
F5r. Important patient care information is often lost during shift changes (reverse worded)	3.44	1.01								0.598		
F6r. It is often unpleasant to work with staff from other hospital units (reverse worded)	3.13	0.89								0.795		
F7r. Problems often occur in the exchange of information across hospital units (reverse worded)	2.96	0.91								0.804		
F10. Hospital units work well together to provide the best care for patients	3.20	0.88								0.718		
F11r. Shift changes are problematic for patients in this hospital. (reverse worded)	3.48	0.97								0.569		

Item	Factors											
	Mean	SD	1	2	3	4	5	6	7	8	9	10
D1. When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	3.41	1.11									0.788	
D2. When a mistake is made, but has no potential to harm the patient, how often is this reported?	3.05	1.13									0.881	
D3. When a mistake is made that could harm the patient, but does not, how often is this reported?	3.17	1.19									0.808	
A7r. We use more agency/temporary staff than is best for patient care.	3.44	1.02										0.571
A10r. It is just by chance that more serious mistakes do not happen around here.	3.24	1.12										0.505
B3r. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts. (reverse worded)	3.41	1.01										0.596
B4r. My supervisor/manager overlooks patient safety problems that happen over and over. (reverse worded)	3.91	0.94										0.656
A11. When one area in this unit gets really busy, others help out.	2.30	1.11								0.29		
A15. Patient safety is never sacrificed to get more work done.	4.12	0.81								0.41		
A17r. We have patient safety problems in this unit. (reverse worded)	3.24	1.07				0.49						
A18. Our procedures and systems are good at preventing errors from happening.	3.07	0.97								0.46		
C1. We are given feedback about changes put into place based on event reports.	3.06	0.98								0.44		

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.^a

^aRotation converged in seven iterations.

Table 4. Mean scores and factor loadings of the items regarding patient safety culture.

Correlations												
Factor		1	2	3	4	5	6	7	8	9	10	
1. Competent supervisor/manager expectations & actions promoting safety	Mean (SD)	3.62 (0.86)										
	Pearson r	0.36	1	0.36**	0.34**	0.45**	0.11**	0.11**	0.29**	0.27**	0.16**	0.31**
	Sig. (two-tailed)	<0.001		<0.001	<0.001	<0.001	0.002	0.003	<0.001	<0.001	<0.001	<0.001
	N	810	806	796	802	794	792	793	806	784	806	767
2. Organizational learning	Mean (SD)	3.20 (0.76)										
	Pearson r	0.40	0.36**	1	0.30**	0.38**	0.15**	0.18**	0.37**	0.37**	0.17**	0.26**
	Sig. (two-tailed)	<0.001	<0.001		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	N	810	796	800	796	789	785	788	800	780	800	759
3. Teamwork within units—continuous improvement	Mean (SD)	3.66 (0.67)										
	Pearson r	0.34	0.34**	0.30**	1	0.38**	0.16**	0.09**	0.29**	0.39**	0.14**	0.39**
	Sig. (two-tailed)	<0.001	<0.001	<0.001		<0.001	<0.001	0.009	<0.001	<0.001	<0.001	<0.001
	N	810	802	796	806	794	791	794	806	783	806	763
4. Feedback and communication openness about errors	Mean (SD)	3.51 (0.68)										
	Pearson r	0.41	0.45**	0.38**	0.38**	1	0.25**	0.15**	0.25**	0.39**	0.36**	0.33**
	Sig. (two-tailed)	<0.001	<0.001	<0.001	<0.001		<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	N	810	794	789	794	798	784	786	798	777	798	757
5. Non-punitive response to error	Mean (SD)	2.54 (0.77)										
	Pearson r	0.22	0.11**	0.15**	0.16**	0.25**	1	0.38**	0.22**	0.29**	0.13**	0.29**
	Sig. (two-tailed)	<0.001	0.002	<0.001	<0.001	<0.001		<0.001	<0.001	<0.001	<0.001	<0.001
	N	810	792	785	791	784	795	784	795	772	795	755
6. Sufficient staffing	Mean (SD)	2.23 (0.74)										
	Pearson r	0.29	0.11**	0.18**	0.09**	0.15**	0.38**	1	0.30**	0.30**	0.08**	0.21**

Correlations											
Factor	1	2	3	4	5	6	7	8	9	10	
	Patient safety grade										
	Sig. (two-tailed)	<0.001	0.003	<0.001	0.009	<0.001	<0.001	<0.001	<0.001	0.019	<0.001
	N	810	793	788	794	786	784	797	797	775	797
7. Hospital management support for patient safety	Mean (SD)	2.86 (0.87)									
	Pearson r	0.44	0.29**	0.37**	0.29**	0.25**	0.22**	0.30**	1	0.52**	0.11**
	Sig. (two-tailed)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	N	810	806	800	806	798	795	797	810	787	810
8. Teamwork across hospital units and handoffs & transitions	Mean (SD)	3.13 (0.69)									
	Pearson r	0.49	0.27**	0.37**	0.39**	0.39**	0.29**	0.30**	0.52**	1	0.15**
	Sig. (two-tailed)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	N	810	784	780	783	777	772	775	787	787	748
9. Frequency of event reporting	Mean (SD)	3.20 (0.97)									
	Pearson r	0.30	0.16**	0.17**	0.14**	0.36**	0.13**	0.08*	0.11**	0.15**	1
	Sig. (two-tailed)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.019	0.002	<0.001	<0.001
	N	810	806	800	806	798	795	797	810	787	810
10. Adequate procedures and systems for safety	Mean (SD)	3.49 (0.70)									
	Pearson r	0.38	0.31**	0.26**	0.39**	0.33**	0.29**	0.21**	0.31**	0.42**	1
	Sig. (two-tailed)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	N	810	767	759	763	757	755	756	767	748	767

NA: non applicable.

*Correlation is significant at the 0.05 level (two-tailed).

**Correlation is significant at the 0.01 level (two-tailed).

Table 5. Mean factor scores, correlations with patient safety grade and inter-correlations of the 10 composites.

5. Discussion

Cultural and healthcare differences in terms of context between US and Greece set obvious that reproduction of HSOPSC would be meaningful in Greek hospital settings. The available evidence from studies which were conducted in European and non-European countries—such as Norway [19]; Sweden [20]; Slovenia [21]; the West Bank [22]; Iran [23]; Scotland [24]; the United Kingdom [25]; the Netherlands [26]; Norway [15]; Switzerland [26] and Belgium [27]—suggests that the HSOPSC developed based on the original US version should be cautiously adjusted to other healthcare contexts. In Switzerland, for instance [26], the use of agency staff in nursing is currently relatively uncommon. Moreover, the role of hospital management and the way it is organized presents differences between hospital types and national or regional regulations. Consequently, taking into account the relative published studies, the number of composites varied between 8 and 15 and included 27 to 50 items.

This is the first study which was conducted in Greece which reports the structure as well as the psychometric properties of G-HSOPSC in accordance with the guidelines of the AHRQ. Despite the fact that our results are aligned with the original version, some adaptations were demanded so that the Greek context is fitted correctly. A 10-factor model with 37 items performed better than the original one in the sample of the 12 Greek hospitals. The main difference was that the composite 'Teamwork across hospital units' merged with 'Hospital handoffs and transitions' and 'Communication openness' merged with 'Feedback and communication about error' except an item (C1). The studies [21, 28, 29] showed the same confluences. The items B3r and B4r, A7, A10r loaded slightly more on a new composite which was named 'Adequate procedures and systems for safety' instead of 'Supervisor/Manager expectations & actions promoting safety', 'Staffing', 'Overall perceptions for safety', respectively. Last but not least, the item A6 loaded slightly more on 'Teamwork within units' instead of 'Organizational learning—continuous improvement' which renamed the first one as 'Teamwork within units—continuous improvement'.

Finally five items (A11, A15, A17r, A18, C1) of the original questionnaire were removed. Three of them (A11, A15, C1) have been eliminated from the Arabic, Dutch and French version, respectively too [22, 26, 28]. Ten underlying factors offered 62% of the variance of the items. The originally proposed 12 safety culture composites had explained 64.5% of the variance in the US version [14] and 57.1% and 59.8% in the Dutch adaptation and German version, respectively [26, 29].

If the factor structures of the various applications of the HSOPSC in Europe are compared to the original pilot tested US version, most of the composites presented similar patterns in the Cronbach's alpha. The internal consistency of G-HSOPSC ranged between 0.60 and 0.88 with lowest Cronbach's alpha values for 'Organizational learning' and 'Sufficient staffing' (both $\alpha = 0.60$). These findings have also been presented in other studies [25, 26, 29, 30]. As far as the present study is concerned, our belief is that these composites and items should be kept since they signify important aspects of patient safety and as such shape a useful foundation for improvement work.

Correlations among the 10 safety culture composites varied from 0.08 to 0.52 ($p < 0.01$). These correlations are deemed satisfactory and do not indicate problematic associations among dimensions. 'Patient Safety Grade' showed its highest correlations with 'Teamwork across hospital units and handoffs & transitions' ($r = 0.49$). 'Frequency of events reported' has actually only a small interrelationship with the other safety culture sub-dimensions (the highest with 'Feedback and communication openness about error', $r = 0.36$). The above results underline the crucial role of the hospital procedures in developing a cooperative and communication openness environment that cultivates free process of evaluation about the adverse events, sharing data about the errors that take place, discussing the way to prevent adverse events and reporting the identified errors. As data indicate an aftermath of that environment will lead to a frequency of event report and improved patient safety grade [31]. Finally, the highest inter-correlation was between 'Hospital management support for patient safety' and 'Teamwork across hospital units and handoffs & transitions' ($r = 0.52$). Considering that both composites share some attention towards transference of important patient care information, this outcome was not considered as surprising; although these composites share a common meaning, they were not integrated into one concept.

5.1. Strengths and limitations of the study

The main strength of the study is the heterogeneity of the selected healthcare facilities. The sample was opted from different types of hospitals in order to capture a more comprehensive view of perceptions towards patient safety culture because the studies which have been published show that the patient safety culture composites may vary among different types of healthcare settings [32]. On the other hand, the study has some limitations. Firstly, selection bias might have occurred as hospitals were selected on a voluntary basis and as head nurses were responsible for distributing the questionnaires. It is possible that head nurses chose not to include some healthcare professionals. Secondly, the relatively lower internal consistency of some scales (i.e. organizational learning, sufficient staffing) than that of the original AHRQ data consist another cause. Further studies are needed to investigate the possible association between certain composites and their items. Thirdly, the difficulty of achieving high response rates among hospital professionals, which was thought to be the most practical challenge after conducting this study.

6. Conclusion

The G-HSOPSC is suitable for clinical and research purposes and allows clinicians and researchers to make cross-national comparisons. Healthcare managers could benefit from using the G-HSOPSC for benchmarking when improving hospital patient safety culture in general and at the same time to obtain knowledge about specific areas of improvement (i.e. shift-working, staffing and over-occupancy). Examination of patient safety culture differences between staff groups and factors affecting patient safety culture is also a term of need in order to obtain knowledge of areas in order to take action to improve safety.

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Ethical approval

The research complied with every one of the dilemmas concerned with ethics. The privacy and secrecy or anonymity of employees were made certain.

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
FA	Factor Analysis
HSOPSC	Hospital Survey on Patient Safety Culture
G-HSOPSC	Hospital Survey on Patient Safety Culture in Greek version
KMO	Kaiser-Meyer-Olkin
US	United States

Author details

Vasiliki Kapaki^{1*} and Kyriakos Souliotis²

*Address all correspondence to: vkapaki2005@gmail.com

1 Health Policy Institute, Athens, Greece

2 Faculty of Social & Political Sciences, University of Peloponnese, Corinth, Greece

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Over the past two decades, the healthcare community increasingly recognized the importance and the impact of medical errors on patient safety and clinical outcomes. Medical and surgical errors continue to contribute to unnecessary and potentially preventable morbidity and/or mortality, affecting both ambulatory and hospital settings. The spectrum of contributing variables—ranging from minor errors that subsequently escalate to poor communication to lapses in appropriate protocols and processes (just to name a few)—is extensive, and solutions are only recently being described. As such, there is a growing body of research and experiences that can help provide an organized framework—based upon the best practices and evidence-based medical principles—for hospitals and clinics to foster patient safety culture and to develop institutional patient safety champions. Based upon the tremendous interest in the first volume of our Vignettes in Patient Safety series, this second volume follows a similar vignette-based model. Each chapter outlines a realistic case scenario designed to closely approximate experiences and clinical patterns that medical and surgical practitioners can easily relate to. Vignette presentations are then followed by an evidence-based overview of pertinent patient safety literature, relevant clinical evidence, and the formulation of preventive strategies and potential solutions that may be applicable to each corresponding scenario. Throughout the Vignettes in Patient Safety cycle, emphasis is placed on the identification and remediation of team-based and organizational factors associated with patient safety events. The second volume of the Vignettes in Patient Safety begins with an overview of recent high-impact studies in the area of patient safety. Subsequent chapters discuss a broad range of topics, including retained surgical items, wrong site procedures, disruptive healthcare workers, interhospital transfers, risks of emergency department overcrowding, dangers of inadequate handoff communication, and the association between provider fatigue and medical errors.

By outlining some of the current best practices, structured experiences, and evidence-based recommendations, the authors and editors hope to provide our readers with new and significant insights into making healthcare safer for patients around the world.

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