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***“Because of the wide variation in ED procedures and variable risks associated with each procedure, steps to ensure procedural safety should be unique to each procedure.”***

***—Procedural Safety in Emergency Care: A Conceptual Model and Recommendations (p. 516)***



## Addressing Procedural Safety in Emergency Care

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## Procedural Safety in Emergency Care: A Conceptual Model and Recommendations

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Procedures are commonly performed in the provision of emergency medical care. According to the National Hospital Ambulatory Medical Care Survey (NHAMCS), there were 117 million emergency department (ED) visits in the United States in 2007.<sup>1</sup> One or more medical procedures occurred in 46% (53 million) of those visits, with the most common procedure being the administration of intravenous (IV) fluids (31 million visits). Other common ED procedures included splinting or wrapping (7 million visits), laceration repairs (5.1 million visits), wound debridement (2 million visits), incision and drainage (1.2 million visits), foreign-body removal (450,000 visits), and endotracheal intubation (269,000 visits). A sizeable category of “other” was documented in about 10 million visits, which included such procedures as lumbar puncture, central venous line placement, joint reduction, and tube thoracostomy.<sup>1</sup>

ED procedures differ from those performed in other parts of the hospital, such as the operating room (OR). ED procedures are usually performed in awake, otherwise alert, patients with obvious external pathology, such as an abscess. OR procedures are more frequently performed in unconscious patients, often without obvious external pathology. OR procedures carry an inherent risk, with an estimated overall mortality rate of 0.8% and a major morbidity rate ranging from 3% to 17%.<sup>2,3</sup> By contrast, although not directly measured, the risk of morbidity from ED procedures is likely considerably lower than that from OR procedures because most ED procedures are minor. However, like OR procedures, there is tremendous variation in the risk of complications for each procedure. The specific risks are dependent on many factors, including the inherent procedural risks, patient factors, the immediacy of the procedure, environmental conditions, the skill level and training of the provider performing the procedure, and the organizational context.<sup>4</sup> Patient factors such as physiology of the patient’s illness, age, comorbid conditions, and anatomic factors such as body habitus can add to the pro-

cedural risks. The work environment (for example, the physical layout of the ED, crowding, design of tools, goal conflicts, staffing levels, culture of safety) can also affect the risk of procedures.<sup>5</sup> A special issue in emergency care is that certain procedures (such as cricothyrotomy or transvenous pacing) are high risk and require specialized training and practice but are infrequently performed, so there is little opportunity to gain experience or maintain proficiency. Because of the wide variation in ED procedures and variable risks associated with each procedure, steps to ensure procedural safety should be unique to each procedure.

The literature on ED procedural safety is still in its early stages, and much of the foundational work has yet to be conducted. Despite the absence of definitive evidence, Quality Improvement and Patient Safety Organizations have issued policies that must be followed when procedures are performed in the hospital (including the ED).<sup>6</sup>

The Joint Commission, the oldest and largest standards-setting and accrediting body in health care in the United States, has outlined a quality process that has providers follow the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery™ for invasive procedures performed in hospitals.<sup>7,8</sup>

In this article, we explore safety issues related to procedures that are commonly performed in EDs. We first explore concepts in safety in industries outside of health care and then present a brief history of procedural safety in US hospitals, focusing specifically on aspects that are applicable to the ED, such as the definitions of serious reportable events, the Universal Protocol, and the World Health Organization (WHO) Surgical Safety Checklist.<sup>9</sup> We propose a general conceptual model for procedural safety in the ED and categorize common ED procedures in the context of their respective hazards and potential interventions to help mitigate risk. We also provide recommendations for how

to address the risks and safety hazards associated with ED procedures. Finally, we suggest areas for future study in the context of the known benefits of standardization of procedural safety.

Because of the absence of definitive data demonstrating the benefit of many of the recommendations, this article is not intended to be an evidence-based guide to procedural safety in the ED. Rather, we provide it as a starting point for clinicians, researchers, hospital administrators, and policy makers who have an interest in determining what safety interventions may or may not work well when considering the unit-specific safety needs of an ED. This work was undertaken on a voluntary basis by 12 (of the 15 authors) of the 370 members of the American College of Emergency Physicians (ACEP) Quality Improvement and Patient Safety Section (QIPS) who responded to an e-mail invitation. It was funded by an ACEP Section Grant. ACEP (<http://www.acep.org/>) is the largest specialty society in emergency medicine, representing more than 27,000 emergency physicians in the United States and around the world.

### **Safety in Industries Outside Health Care**

The health care industry has much to learn from other industries, which, through decades of experience, have developed methods to become more reliable, improve their production, eliminate waste, and improve safety records. Since the early 1900s, businesses have been concerned with improving their processes to avoid defects (for example, adverse events) that represent cost and quality issues. Deming trained top management on how to improve design, production, and distribution, always aiming to avoid defects.<sup>10</sup> Building on the principles and teachings of Deming, corporations have developed their own versions of quality management. One example is the Toyota Production System, also known as Lean manufacturing, which empowers frontline staff to solve production inefficiencies.<sup>11</sup> The Toyota process is designed to reduce waste, inconsistency, and overcapacity and to create a smoothly functioning system in which each step adds value. High-reliability organizations in the aviation and nuclear power industries have also learned how to become the safest organizations in our society. Much as in medicine, errors in aviation and nuclear power can have grave consequences. The aviation industry, following several high-profile crashes in the 1970s, prompted the development of Crew Resource Management (CRM) to improve communication and teamwork.<sup>12</sup> CRM tools, which include preflight briefings and checklists, have dramatically reduced error rates.<sup>13,14</sup> One of the key elements is a nonpunitive safety reporting system, which is administered by the National Transportation Safety Board (NTSB).<sup>15</sup> Similarly, the nuclear power industry has adopted sys-

tems to prevent adverse events following several high-profile near misses and safety events in the 1970s.<sup>16,17</sup>

### **Procedural Safety in Health Care**

Applying the safety framework from other industries, researchers have identified unique issues and characteristics of safety in health care. Observing high-risk handoffs at mission control of the National Aeronautics and Space Administration (NASA) has yielded important observations about improving the safety of high-risk health care handoffs.<sup>18</sup> In observation of handoffs in emergency care, several important attributes that are unique to the ED have emerged, such as the type of process; the primary content; structural issues (for example, the participants); and dynamic issues, such as the position of a given case in the process of a handoff (for example, early or late in the process).<sup>19</sup> Observational work in health care has been vital to inform interventions; however, the industry has been slower than other high-risk industries in adopting standard safety processes. Some specialties, such as anesthesia, were early adopters of safety principles and have been successful in reducing complication rates, while other specialties have not yet embraced the safety movement in the same way. The aforementioned WHO Surgical Safety Checklist and The Joint Commission's Universal Protocol, as well as the American Society of Anesthesiologists' Standards of Basic Intraoperative Monitoring, are key examples of guidelines developed to help direct continued safety improvement.

### **WHO SURGICAL SAFETY CHECKLIST**

In 2007 WHO started an international campaign aimed at improving safety in surgical settings. The working groups identified four areas—safe surgical teams, safe anesthesia, prevention of surgical site infection, and measurement of surgical services. The WHO safe surgical guidelines were published in 2008 and 2009 and supported 10 basic, essential safety objectives for every surgical case (Table 1, page 518).<sup>9</sup> These elements were compiled into the WHO Surgical Safety Checklist. The checklist involves three basic steps: (1) a sign-in before the induction of anesthesia, (2) a time-out before skin incision, and (3) a sign-out before the patient leaves the OR. During these three time periods, teams stop and focus on the safety check. When possible, it is suggested that the patient should participate in this process. The theory behind this systematic approach is that standardization may increase the likelihood of catching problems when conducting a complex task that involves a team of individuals.

Other checklists, some of which are similar to the WHO Surgical Safety Checklist, have been proposed as one of the central ways to improve patient safety in the OR and other set-

**Table 1. World Health Organization Safe Surgical Objectives**

1. The team will operate on the correct patient at the correct site.
2. The team will use methods known to prevent harm from anesthetic administration, while protecting the patient from pain.
3. The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
4. The team will recognize and effectively prepare for risk of high blood loss.
5. The team will avoid inducing an allergic or adverse drug reaction known to be a significant risk to the patient.
6. The team will consistently use methods known to minimize the risk of surgical site infection.
7. The team will prevent inadvertent retention of sponges or instruments in surgical wounds.
8. The team will secure and accurately identify all surgical specimens.
9. The team will effectively communicate and exchange critical patient information for the safe conduct of the operation.
10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results.

**Source:** World Health Organization, World Alliance for Patient Safety. The Second Global Patient Safety Challenge: Safe Surgery Saves Lives. 2008. [http://www.who.int/patientsafety/safesurgery/knowledge\\_base/SSSL\\_Brochure\\_finalJun08.pdf](http://www.who.int/patientsafety/safesurgery/knowledge_base/SSSL_Brochure_finalJun08.pdf). Used with permission.

tings.<sup>20–23</sup> Surgical checklists have been demonstrated to reduce morbidity and mortality across a variety of settings. In a worldwide study after the implementation of the WHO checklist, the complication rate was reduced from 11.0% to 7.0%, the surgical site infection rate from 6.2% to 3.4%, and the in-hospital death rate from 1.5% to 0.8%.<sup>24</sup> Improvements associated with the use of checklists have been replicated in other studies.<sup>25,26</sup> However, despite the dramatic reductions in complications, these observational studies have demonstrated low rates of compliance or missing checklist steps, raising questions about the exact mechanism of improving safety. One possibility is that the checklist steps could directly improve safety. Alternatively, the process of implementing the checklist could improve the communication, or aspects of safety climate such as speaking up about uncertainties.

### THE UNIVERSAL PROTOCOL

The Universal Protocol became effective on July 1, 2004, for hospitals (including EDs), ambulatory care, and office-based surgical facilities accredited by The Joint Commission.<sup>8,27</sup> The Universal Protocol consists of three principal components: (1) conducting a preprocedure verification process, (2) marking the

procedure site, and (3) performing a time-out before the procedure. Time-outs have been associated with improved reporting of equipment problems and lower rates of wrong-site surgical procedures.<sup>28,29</sup> Performance of OR briefings (similar to time-outs but focused on broader checklists) have been associated with a 50% improvement in the confirmation of patient allergies and availability of blood products.<sup>30,31</sup>

The Universal Protocol is designed to reduce the likelihood of three specific patient safety complications related to OR procedures: (1) wrong site—when the procedure is performed on the wrong body part or wrong side; (2) wrong procedure—when the wrong procedure is performed; and (3) wrong person—when the procedure is performed on the wrong person. The Joint Commission has identified several factors that can lead to an increased risk of wrong-side/wrong-site, wrong-procedure, and wrong-patient events (WSPEs),<sup>32</sup> including (1) more than one surgeon involved in a case, (2) multiple procedures conducted on the same patient, (3) unusual time pressures, and (4) unusual patient characteristics such as physical deformity or massive obesity.<sup>33</sup> WSPEs are serious reportable events. According to the National Quality Forum, a serious reportable event “must be unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting’s safety systems, or important for public credibility or public accountability.”<sup>34(p. 2)</sup>

Of more than 27,000 adverse events reported in a prospective study of self-reported errors in Colorado in the “era of the Universal Protocol” (2002–2008), only 25 were wrong-patient procedures, and 107 were wrong-site procedures. Significant harm occurred in 20% of wrong-patient and 35% of wrong-site procedures, respectively, and many of the wrong-site errors involved nonsurgical specialties (most commonly internal medicine).<sup>32</sup> None of the 25 reported wrong-patient procedures were performed by emergency physicians; by comparison, emergency physicians reported 2 of the 107 wrong-site procedures.

Revisions to the Universal Protocol announced in 2009 included the broadening of its applicability from “all invasive procedures that put patients at more than minimal risk, regardless of the location within an organization” to “all surgical and nonsurgical invasive procedures.”<sup>35(p. 3)</sup> In a survey conducted in 2010 by The Joint Commission, 88% of the more than 2,100 respondents agreed or strongly agreed that their organizations were able to implement the revised 2010 Universal Protocol.<sup>36</sup> When stratified by location, the Universal Protocol was thought to be beneficial by 94% of OR respondents, 93% of ambulatory surgery respondents, and 90% of respondents in hospital units where invasive procedures were performed. Benefits were less commonly perceived in ambulatory clinics (80%) and physician



offices (73%).

*An Emergency Exception to the Universal Protocol?* Our group believes that there should be an emergency exception to the Universal Protocol for time-sensitive conditions where immediacy is the key and the failure to act swiftly may result in imminent death or loss of limb. In a 2002 policy statement regarding elements of the Universal Protocol, the American College of Surgeons supported this concept in reference to OR procedures, stating that as organizations “develop guidelines to ensure correct patient, correct site, and correct procedure surgery . . . in the event of a life- or limb-threatening situation, not all of these steps may be followed.”<sup>37</sup>

In the ED, procedures such as an emergency intubation for a patient in severe respiratory distress, needle decompression of a tension pneumothorax, limb-threatening trauma with ischemia that requires immediate reduction and splinting, or defibrillation for cardiac arrest clearly fall under the emergency exception. In situations involving an emergency exception, WSPEs should be less likely because of the presence of clinically obvious pathology; however, they are still possible in some cases (for example, a wrong-side chest tube). However, a brief pause may be helpful before performing the procedure to ensure that specifically salient features of the case are agreed on, such as the laterality in the case of a chest tube, or needle decompression for a tension pneumothorax. However, it is important that the immediate performance of a life- or limb-saving procedure not be delayed by time-consuming safety checklists.

Although certain emergent procedures should be exempt from the Universal Protocol, other potential safety issues may still come into play. Pertinent safety issues can be addressed in preparation for performing emergent procedures. This may include the availability of the correct equipment that has been checked before the “emergency” (for example, to resolve a difficult airway cart), ensuring the competency of the provider conducting the procedure, and use of techniques to prevent infections. Confirmation of endotracheal tube placement at patient arrival to the ED or immediately after ED intubation is an example of a postprocedure check that has been recommended by the ACEP.<sup>38</sup> A similar practice is recommended following central line placement, when confirmation of line position and assessment for complications are conducted before use of the line.

#### THE STANDARDS OF BASIC INTRAOPERATIVE MONITORING

In the United States, the field of anesthesia was the first to make significant improvements in safety, beginning in the late 1980s and 1990s with the introduction of the Standards for

Basic Intraoperative Monitoring.<sup>39,40</sup> In the 1970s the risk of a healthy patient dying from anesthesia was 1 in 5,000.<sup>41</sup> Although this number has dropped to 1 in 200,000 in developed countries, largely because of the standardization of anesthesia monitoring practices, anesthesia-related mortality still occurs in 1 in 300 to 3,000 operations outside developed countries, where similar safety practices have not been adopted or important technologies are not available.<sup>42</sup>

#### OTHER SYSTEMATIC INTERVENTIONS

Other hospital-based interventions have focused on enhancing teamwork in the OR by undertaking an aviation-style human factors approach. Human factors is the discipline surrounding the human-machine interface, including psychological, physical, social, and safety issues. One study reported significant increases in the use of time-outs and debriefings in surgical teams after the implementation of human factors training at three sites.<sup>43</sup> However, the success of the program was primarily determined by local acceptance by leadership. Another study, which involved interviews of 16 surgical team members, showed that several factors contributed to nonuse of time-outs in a real-life setting.<sup>44</sup> Haphazard implementation of time-outs, lack of proper education of surgeons about the benefits of time-outs, a hierarchical team structure, “tribal” affiliations between team members, and clashing clinical priorities all made it difficult to incorporate time-outs into practice.<sup>44</sup>

It should also be mentioned that there can be some downsides to patient safety mandates. For example, when they increase the time required to complete a procedure and are not seen as important to providers, this can lead to workarounds, avoidance, and gaming. Most concerning, ill-considered approaches to patient safety can lead to cynicism about the entire process.

#### A Conceptual Model of ED Patient Safety

Most of the emergency care literature on procedural safety is in the form of case reports, case series, or basic comparisons of complication rates between specific types of procedures. Several randomized trials have recently been conducted comparing safety among various methods of performing procedural sedation, with specific examination of the types of medications and monitoring used.<sup>45-47</sup> In addition, comparative trials using central venous catheters and point-of-care ultrasound to insert peripheral IVs and other procedures have demonstrated improved procedural success and lower complication rates.<sup>48</sup> Team training has also been used successfully to improve the quality of team behaviors in the ED, as well as to reduce medical errors.<sup>49</sup>

WHO has recommended that safety objectives be adapted

for condition-specific and local environments. Tailored changes have been effective in improving compliance with specific time-out procedures in the OR by making interventions “leaner” and enhancing the perceived salience for the individuals conducting the time-out.<sup>50</sup> Eliminating steps seen as wasteful is vital so that providers perceive the maximum possible value for the additional burden of activities related to pre- or postprocedural care. This same approach is appropriate for ED procedures, for which their respective risk profiles vary greatly.

In the WHO list of objectives for safe surgical procedures (Table 1), several elements are directly applicable to procedures in the ED, while others are not. Certain safety objectives are also more or less applicable to certain procedures. For example, Objective 1 (correct patient, correct site) is broadly applicable to all ED procedures, while somewhat more applicable (that is, the error risk is higher) in patients without obvious pathology or in patients who are either sedated or have an altered mental status because of their primary medical condition. Objectives 2, 3, and 5 address the use of known methods to protect the patient from anesthetic harm, ensure pain relief, prepare for life-threatening loss of airway function, and avoid drug reactions. These objectives are directly applicable to ED procedures involving procedural sedation and underscore the importance of procedure-specific clinical protocols and checklists aimed at common high-risk events to ensure safety. In addition, Objective 6 (minimizing surgical site infection) is applicable to ED procedures that result in breaking the skin surface, such as laceration repair, central venous catheterization, chest tube, incision and drainage, as is Objective 8 (specimens). Objective 4 (preparing for high blood loss, except in the case of severe trauma) and Objective 7 (preventing retention of surgical foreign bodies) have less broad applicability to most ED procedures. Surgical foreign bodies are rare considerations in ED procedures but may sometimes apply in cases such as Seldinger-technique line insertion, thoracotomy, diagnostic peritoneal lavage, or other less commonly performed invasive procedures. Objective 9 (teamwork) is critically important in many ED procedures that involve multiple team members, often from different services, working together for the first time, such as the use of procedural sedation to reduce a fracture. Finally, Objective 10 (data collection) is also important in high-risk ED procedures for benchmarking and quality improvement purposes.

To better frame how procedural safety in the ED may be improved, following the general conceptual model of the WHO checklist, we have listed a series of approaches to improving ED safety. These approaches are divided into clinical and environmental interventions (Table 2, page 521), and training-related

interventions (Table 3, page 521). Although we believe that it is important to mention both types of interventions, we focus herein on clinical and environmental interventions because training interventions go beyond the scope of this article. Many of these interventions are not independent or discrete entities but are rather heterogeneous groupings with considerable overlap. Conceptually, some of the interventions are practice tools (clinical protocols, checklists, Universal Protocol), several are training processes (team training, simulation), several others are facility components (operational environment, technological tools), while others are administrative processes (quality assurance measurement).

Another important step is to define the hazards of ED procedures. Although hazards enter into any ED procedure, certain ED procedures have more objective risk than others. Procedure-specific hazards include WSPEs, medication allergies or interactions, and equipment or environmental hazards. The risk of WSPEs in the ED is related to the procedure type and patient status. A WSPE has virtually no chance of occurring in otherwise stable, awake patients with obvious pathology (such as an abscess or a laceration). However, when patients are sedated, have an altered level of consciousness secondary to their primary medical condition, have no pathology that is visibly obvious, or simply have a poor understanding of their care, there is a higher risk of WSPEs occurring in the ED. For the procedures that involve medications, issues such as allergic reactions or other complications may occur if medications are used without asking about specific allergies or without consideration of interactions with other medications the patient is taking. Equipment hazards may occur if the equipment available for the procedure is defective or unavailable, such as a poorly functioning light bulb on a laryngoscope.<sup>51</sup>

Environmental hazards may occur in a crowded ED where insufficient staff is available to safely conduct a complex procedure or when there are competing demands on time, unexpected arrivals and interruptions, and acute changes in patient status that must be immediately addressed.<sup>52</sup> Finally, health care-associated infections are a risk of many ED procedures, whether they break the skin (for example, central venous catheter placement) or do not (bladder catheter placement), and other risks may come into play such as bleeding or damage to specific structures.

In view of these procedure-specific risks, we present a conceptual model of ED procedural safety (Figure 1, page 522). As depicted in the model, when analyzing procedure-specific hazards, four questions assist with determining level of risk (high, medium, low) of the procedure:

Table 2. Clinical and Environmental Interventions to Enhance Procedural Safety\*

Element	Description	Clinical and Administrative Examples
Optimizing Operational Environment	Workspace and conditions that best support optimal outcomes for procedure being performed	<ul style="list-style-type: none"> <li>■ Culture to minimize interruptions and facilitate communication</li> </ul>
Clinical Protocols	Algorithmic approach for implementation of accepted best practices	<ul style="list-style-type: none"> <li>■ Difficult-airway and intubation protocols</li> <li>■ Procedural sedation protocols</li> <li>■ Other procedural protocols (for example, for central lines)</li> </ul>
Checklist	Method for ensuring that essential components, processes, and subprocesses are in place and being performed	<p>Administrative</p> <ul style="list-style-type: none"> <li>■ Checklist for ensuring that essential equipment is stocked and available</li> </ul> <p>Clinical</p> <ul style="list-style-type: none"> <li>■ Central line sterile protocol checklist</li> <li>■ Pre- and postintubation checklist</li> </ul>
Universal Protocol	Methodologies for ensuring correct patient, procedure, and site for surgical procedure	<ul style="list-style-type: none"> <li>■ Time-out preformed before chest tube for nontension pneumothorax (excluding tension pneumothorax)</li> <li>■ Time-out for central line placement (excluding STAT lines)</li> </ul>
Quality Assurance	Routine use of tools and processes to evaluate the function of the facility, the teams, and individuals in regard to procedural performance and safety. Direct observation or videotaping and evaluation	<ul style="list-style-type: none"> <li>■ Process for regular “sampling,” chart audits, patient follow-up to assess procedure outcome and issues</li> </ul>
Technology Tools (or “Technological adjuncts”)	Devices and technology that may assist in improved safety	<ul style="list-style-type: none"> <li>■ Fiberoptic or video tools for intubation</li> <li>■ End-tidal CO<sub>2</sub> and pulse oximetry monitors for procedural sedation and post intubation</li> <li>■ Ultrasound for central line insertion guidance</li> </ul>

\* CO<sub>2</sub>, carbon dioxide.

Table 3. Training- and Skills-Related Interventions to Enhance Emergency Department (ED) Procedural Safety

Element	Description	Clinical and Administrative Examples
Individual Training and Clinical Competency Assurance	Processes for ensuring that necessary skills are present for clinician performing the procedure. Emphasis on the individual as the functional unit.	<ul style="list-style-type: none"> <li>■ Formal procedure training (for example, residency)</li> <li>■ Employment credentialing</li> </ul>
Team Training	Process for improving teamwork and communication skills. Emphasis on the group as the functional unit.	<ul style="list-style-type: none"> <li>■ TeamSTEPPS training</li> <li>■ Crew Resource Management (CRM)</li> </ul>
Simulation	Method for ongoing clinical “practice” and skills development. Can be high or low fidelity and focus on groups or individuals.	<ul style="list-style-type: none"> <li>■ Clinician using manikin, cadaver, or supervised clinical encounter to obtain and/or retain requisite skill and experience to perform a procedure (for example, videolaryngoscope training on manikin)</li> <li>■ Team practice and simulation for specific clinical procedures such as rapid-sequence intubation, procedural sedation.</li> </ul>

1. What is the inherent risk of complications from the procedure?
2. What is the likelihood that complications will result in a poor outcome?

3. What patient factors may augment these risks?
4. What care factors may augment these risks?

On the basis of the risk level of the procedure, certain procedure-specific interventions should be employed to mitigate these

Conceptual Model of Emergency Department Procedural Safety

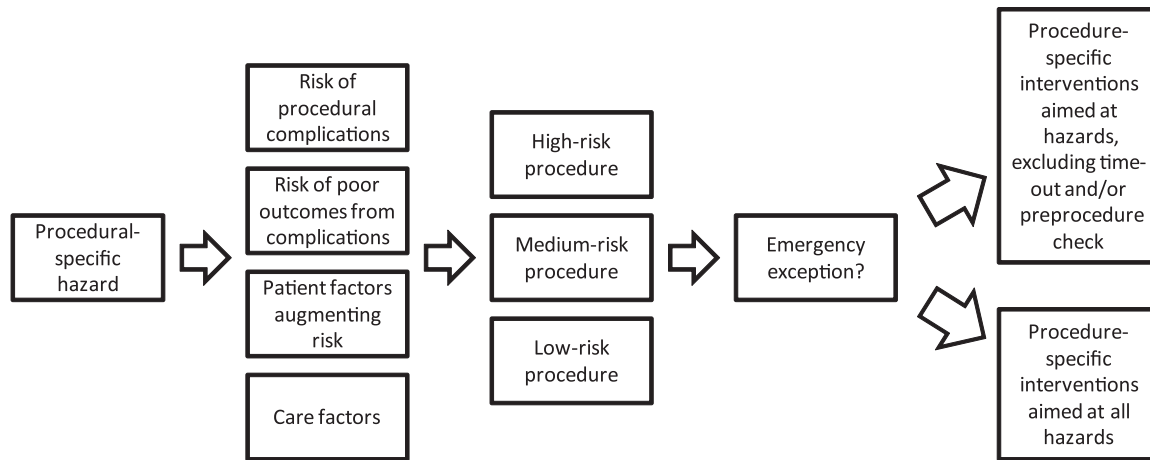


Figure 1. When analyzing procedure-specific hazards, four questions assist with determining level of risk (high, medium, low) of the procedure.

risks. The model takes into consideration the proposed emergency exception and excludes interventions such as preprocedure checklists and time-outs for procedures that must be conducted immediately to prevent loss of life or limb. The ultimate goal is to tailor procedure-specific interventions directly to reduce procedure-specific hazards in the context of whether the procedure is performed on an emergency or a routine basis. It is important to emphasize that the following list of interventions is based on expert consensus rather than evidence. It should be seen as a starting point for defining procedural safety in the ED, and not as a validated guideline. In addition, it should be recognized that specifying individual interventions for separate procedures may increase complexity or confusion. Our group decided to individualize recommendations for specific procedures because of the heterogeneity of procedures within each risk group. We had considered a simpler approach whereby recommended interventions would be organized by risk of procedure, which may be possible after further testing. In addition, studying the impact of these recommendations on patient safety outcomes and how they are accepted in practice is necessary before widespread use.

**Common ED Procedures and Recommendations for Patient Safety Interventions**

From May through September 2010, we used a multiple-round, unstructured, expert consensus process to assign a general risk level (high, medium, or low) to common ED procedures. We also generated a series of general categories of interventions that are designed to reduce the likelihood of one or more hazards re-

lated to ED procedures (Table 4, page 523; also available in color in online article). It is important to note that the scope of emergency medical practice is so broad that not every procedure could be listed. Our intent was to list the most commonly encountered procedures and, for each procedure, to assess an associated general risk level and suggest an optimal safety recommendation. For example, we categorized tube thoracostomy as a high-risk procedure because of the risks of wrong patient and wrong site (patients may be anesthetized during the procedure, and there may be an absence of obvious pathology where the procedure is performed) and because of potential equipment issues (for example, the correct size of chest tube might not be immediately available—it may be too large or too small; the procedure trays might be incompletely stocked; or additional instruments, such as a specific scalpel that may be helpful, might not be available). For interventions, we recommend that tube thoracostomy be eligible for the “emergency exception,” whereby the Universal Protocol could be deferred in cases of immediate life-threatening emergencies, such as a tension pneumothorax; however, a brief pause in this case would be appropriate. In semi-elective cases, we recommend a time-out, as well as a pre- and postprocedure check. A preprocedure check may involve ensuring that all the needed staff and supplies are available for the procedure and that full-barrier precautions and infection control procedures have been done. A postprocedure check may involve detailed steps needed to ensure that the tube is in the right place, that no complications are missed, and that the tube is properly attached to the appropriate drainage unit. An equipment check can be differentiated from a preprocedure check because an equipment check is “offline,” whereas a preprocedure check is



Table 4. Emergency Department Procedures, Risks, Safety Hazards, and Recommendations\*

Emergency Department Procedure	General Risk Level of Procedure	Specific Safety Hazard†				Recommendations				
		Wrong Patient	Wrong Site	Medication Allergies/ Interactions	Equipment Issues (Inadequate/ Malfunctioning)	Emergency Procedure	Time-Out‡	Preprocedure Check	Equipment Check (by Type of Procedure)	Postprocedure Check
Procedural Sedation	High	X		X	X		X	X	X	X
Rapid Sequence and Tracheal Intubation	High			X	X	X	(X)§	X	X	X
Cricothyrotomy	High				X	X		X	X	X
Tube Thoracostomy	High	X	X		X	X	(X)	X	X	X
Thoracocentesis	High	X	X		X		(X)	X	X	X
Thoracotomy	High				X	X		X	X	X
Cardioversion	High			X	X	X	(X)	X	X	X
Pericardiocentesis	High				X	X		X	X	X
Pacing:										
Transvenous	High				X	X	(X)	X	X	X
Transthoracic	High				X	X	(X)	X	X	X
Vaginal Delivery	High				X	X			X	X
Central IV Access	Medium	X			X		X	X	X	X
Arterial Line	Medium	X			X		X	X	X	X
Aspiration of Peri-tonsillar Abscess	Medium		X		X		X		X	
G-tube Replacement	Medium				X					X
IV Placement:										
Peripheral	Low	X								
External Jugular	Low	X								
Access Indwelling Port	Low									
Access AV Fistula	Low									
Anesthesia Blocks:										
Local	Low	X		X						
Regional	Low	X	X	X			X			
Suture Laceration	Low				X				X	
I&D Abscess	Low				X			X	X	
Fracture Reduction	Low									X
Joint Reduction	Low									X
Arthrocentesis	Low		X				X			
Splint Placement	Low		X						X	X
Removal of Foreign Body:										
Skin/Subcutaneous	Low									X
Ear/Nose/Mouth	Low				X				X	X
Eye	Low				X				X	X
Lumbar Puncture	Low	X			X		X		X	X
Foley Catheter	Low	X								X
Nasogastric Tube	Low	X								X
Nasopharyngoscopy	Low				X				X	
Epistaxis Control	Low				X	X			X	
Hernia Reduction	Low									

\* IV, intravenous; G-tube, gastrointestinal tube; AV, arteriovenous; I&D, incision and drainage.

† Safety hazard implies specific safety hazards and risks, not general medical and surgical complications from the procedure.

‡ Time-out involves preprocedure verification of patient, procedure, and site.

§ Parentheses indicate a semi-elective procedure.

**Table 5. Recommendations Regarding the Inclusion of Elements of the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ in Specific Emergency Department (ED) Procedures**

<ol style="list-style-type: none"> <li>1. One-size-fits-all interventions such as the Universal Protocol should not be applied to all invasive ED procedures because the risk profile of ED procedures is materially different from operating room procedures. Interventions should be developed and tested in the ED environment before mandated adoption.</li> <li>2. Patient and procedural verification should be universal when possible.</li> <li>3. In cases in which the procedure involves externally visible pathology, a time-out should not be required.</li> <li>4. The emergency exception is appropriate in certain situations and procedures in which there is an imminent risk to life or limb. For</li> </ol>	<p>these procedures, certain interventions may be eliminated before the procedure, such as time-outs and preprocedure checklists. However, a brief pause before the procedure in specific cases may be indicated (such as laterality before an emergency chest tube), and postprocedure interventions should be applied after the immediate emergency is resolved.</p> <ol style="list-style-type: none"> <li>5. High-risk and medium-risk procedures should be the major focus of ED-based quality improvement interventions.</li> <li>6. Workplace factors (for example, the design of tasks and tools, the physical and social environments) that affect patient safety for all ED procedures should be identified and addressed.</li> </ol>
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“online” and should be performed immediately before a procedure. An equipment check is a regular check to ensure that supplies are readily available if an emergency tube thoracostomy needs to be done.

One example of a low-risk procedure is a simple incision and drainage (I&D) of an abscess. In this case, we believe that the major risk is equipment-related; that is, not having the appropriate supplies for the procedure. To mitigate this risk, we recommend a preprocedure check, which could consist of a short list of steps taken right before the I&D to ensure that the needed equipment—such as the I&D tray and packing material—is ready, that the patient is not allergic to the chosen injectable anesthetic, and that the lighting is adequate. As with the tube thoracostomy, offline checks can be done to ensure that all equipment is readily available for I&D. We list procedural sedation as a separate entity because it may be used either as the main intervention (for example, to sedate a child requiring an imaging study) or to facilitate another procedure.

We recommend that, whenever possible, ED procedures have a minimum required set of safety efforts that represent standard hospital procedures, including use of two patient identifiers—which is not burdensome and is virtually always needed—and appropriate infection control practices. Beyond this, the recommendations for each procedure are based on the mechanisms that may mitigate patient safety hazards and optimize care. The suggestions are general and can be adapted to each individual ED, with standardization within an ED. Many of the equipment checks, such as completing a checklist for airway kits at the beginning of a shift, can be done routinely at regular intervals but should not be necessary and are not recommended just before an emergent procedure. We believe that pre- and postprocedure checklists should be decided on in advance and then implemented routinely to reduce errors. Some procedures, such as pro-

cedural sedation in conjunction with a more complicated procedure, may require more extensive safety procedures, including a time-out, while minor procedures with an obvious site or unilaterality, such as a laceration, should require only standard medical care. We do not provide specific recommendations about training competency in this work, a complex topic that deserves discussion beyond our scope.

We also present several recommendations regarding the inclusion of elements of the Universal Protocol in specific ED procedures (Table 5, above).

### Future Directions

There are several future directions for our conceptual model and recommendations concerning procedural safety in emergency care. First, validation of the recommendations across multiple EDs should be pursued, likely in the form of an ED-based before-after trial or a randomized trial. A major limitation of our work is the assignment of risk to procedures on the basis of consensus of experts in emergency medicine, in the absence of available data. Understanding the risk profiles of common ED procedures and the impact of the recommended interventions on procedural safety will be vital in future research. Procedural competency in the ED, which might include assessment at the residency, board certification, and continuing medical education levels, should also be explored. Another area in need of more attention is the role of communication and feedback loops in procedural safety, which may be particularly helpful regarding high-risk procedures, on which staff may not work together regularly. Finally, creating ways to document interventions steps without creating undue burden on ED staff will be important in ensuring acceptance and adoption of the recommendations. ■

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Table 4. Emergency Department Procedures, Risks, Safety Hazards, and Recommendations (color version)

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EOE



Table 4. Emergency Department Procedures, Risks, Safety Hazards, and Recommendations\*

Emergency Department Procedure	General Risk Level of Procedure	Specific Safety Hazard <sup>†</sup>				Recommendations				
		Wrong Patient	Wrong Site	Medication Allergies/ Interactions	Equipment Issues (Inadequate/ Malfunctioning)	Emergency Procedure	Time-Out <sup>‡</sup>	Preprocedure Check	Equipment Check (by Type of Procedure)	Postprocedure Check
Procedural Sedation	High	X		X	X		X	X	X	X
Rapid Sequence and Tracheal Intubation	High			X	X	X	(X) <sup>§</sup>	X	X	X
Cricothyrotomy	High				X	X		X	X	X
Tube Thoracostomy	High	X	X		X	X	(X)	X	X	X
Thoracocentesis	High	X	X		X		(X)	X	X	X
Thoracotomy	High				X	X		X	X	X
Cardioversion	High			X	X	X	(X)	X	X	X
Pericardiocentesis	High				X	X		X	X	X
Pacing:										
Transvenous	High				X	X	(X)	X	X	X
Transthoracic	High				X	X	(X)	X	X	X
Vaginal Delivery	High				X	X			X	X
Central IV Access	Medium	X			X		X	X	X	X
Arterial Line	Medium	X			X		X	X	X	X
Aspiration of Peri-tonsillar Abscess	Medium		X		X		X		X	
G-tube Replacement	Medium				X					X
IV Placement:										
Peripheral	Low	X								
External Jugular	Low	X								
Access Indwelling Port	Low									
Access AV Fistula	Low									
Anesthesia Blocks:										
Local	Low	X		X						
Regional	Low	X	X	X			X			
Suture Laceration	Low				X				X	
I&D Abscess	Low				X			X	X	
Fracture Reduction	Low									X
Joint Reduction	Low									X
Arthrocentesis	Low		X				X			
Splint Placement	Low		X						X	X
Removal of Foreign Body:										
Skin/Subcutaneous	Low									X
Ear/Nose/Mouth	Low				X				X	X
Eye	Low				X				X	X
Lumbar Puncture	Low	X			X		X		X	X
Foley Catheter	Low	X								X
Nasogastric Tube	Low	X								X
Nasopharyngoscopy	Low				X				X	
Epistaxis Control	Low				X	X			X	
Hernia Reduction	Low									

\* IV, intravenous; G-tube, gastrointestinal tube; AV, arteriovenous; I&D, incision and drainage.

<sup>†</sup> Safety hazard implies specific safety hazards and risks, not general medical and surgical complications from the procedure.

<sup>‡</sup> Time-out involves preprocedure verification of patient, procedure, and site.

<sup>§</sup> Parentheses indicate a semi-elective procedure.