Patient Safety in the Critical Care Environment

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KEYWORDS

• Infection control • Isolation • Hand hygiene • Care-bundles • Medical device safety • Imaging safety • Intensive care

KEY POINTS

- In the United States, more than 5 million patients per year are admitted to the intensive care unit (ICU), composing 30% of the acute care cost or approximately $160 billion per annum nationwide.
- Errors in patient care at some level cause up to 10% of patient fatalities in trauma ICUs in patients with otherwise survivable injuries; estimates are that critically ill patients may suffer up to 1.7 medical errors a day, mostly from medication administration errors.
- It will be of utmost importance to implement quality and safety measures that are already supported by evidence, such as hand hygiene, implementation of evidenced-based care bundles, adequate identification and treatment of health care–acquired infections, and increasing the percentage of patients in ICU settings that are cared for by dedicated intensivists.

INTRODUCTION: CREATING A CULTURE OF SAFETY

In the United States, more than 5 million patients per year are admitted to the intensive care unit (ICU), composing 30% of the acute care cost or approximately $160 billion per annum nationwide.[1] The ICU would intuitively be one of the safest places within the hospital environment; however, the reverse is often true. A recent multinational study found that, on average, 38.8 sentinel events occur per 100 patient ICU days.[2] The genesis for these sentinel events revolves around 2 separate but intertwined factors: the complex interactions between medical/nursing/technician health care professionals and therapeutic intervention per disease entity.[3] The complexity of care within the ICU requires that health care professionals exhibit a transdisciplinary level of competency. This circumstance has lead critical care teams to embrace

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evidence-based guidelines that encourage the use of standardized process measures for managing ICU patient populations. For example, the concept of the *care bundle* (aggregated evidence-based interventional practices) has reduced the risk of central line–associated blood stream infections (CLABSIs), ventilator-associated pneumonia (VAP), deep vein thrombosis, and stress ulcers, which are frequent hospital-acquired conditions.[3,4]

In the past decade, creating a safe patient-care environment has placed a spotlight on preventable medical errors within health care organizations. This emphasis, which encompasses a broad spectrum of care, is focused on improving patient outcomes. This commitment to improving the quality of care and creating a safe patient-care environment does not come without a significant investment in both infrastructure and resources. A recent study demonstrated that the implementation of a hospital-wide culture of safety required a significant fiscal investment, suggesting that hospitals with greater financial and institutional resources are more effective at promoting patient safety through effective infection control interventions.[5,6] A pivotal component of effective quality improvement is leadership, that is, a leader who cannot only implement change but who can also anticipate the need for change.[7] Finally, the relationship between leadership, culture of safety, and outcome cannot be dismissed. In a recent study by Huang and colleagues,[8] a lowered perception of management or lowered institutional commitment to safety was independently associated with an increase in both length of stay (LOS) and mortality. Perceptions of management and a safe patient environment for ICUs in the United States were moderately linked to patient outcomes. The concept of a *safety climate* refers to a tangible perception of a strong and proactive organizational commitment to safety, which exists not just for the benefit of patients but also for the staff. The present article reviews several selective patient-care practices that are vulnerable to errors, placing patients at an increased risk for morbidity and death but amendable to selective interventional practices leading to enhanced patient outcomes.

HEALTH CARE–ASSOCIATED INFECTIONS IN THE ICU: EPIDEMIOLOGY OF A PATIENT SAFETY ISSUE

Health care–associated infections (HAIs) adversely impact approximately 5% of hospitalized patients, leading to increased morbidity and death. HAIs are, in fact, the fifth leading cause of death in acute care hospitals.[9] The total economic burden for all HAIs in the acute care environment approaches $20 billion per year. A large number of these events are associated with temporarily placed biomedical devices, such as endotracheal tubes, indwelling urinary catheter, and central venous access devices. The personal and fiscal morbidity associated with these HAIs is significant; a CLABSI is estimated to increase mortality by 18%, increasing ICU LOS on average by 13 days while adding $10 531 to $56 167 to the total hospital cost.[10–12] The risk for infection is actually greater within the ICU patient population. A multi-institutional study revealed that 19% of ICU patients develop an infection sometime during their ICU stay.[13] The microbial pathogens and the percent occurrence of selective HAIs have been documented by the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (**Table 1**).[14] Many of these infections occurring within the ICU pose a significant safety burden to this high-risk patient population. The implementation of evidence-based interventions directed against specific mechanistic components of selective HAIs offers the best opportunity for reducing risk and creating a safe and effective health care environment.

Table 1
Microbial pathogens associated with HAIs in critical care patients

Pathogen	Overall Percentage (%)	CLABSI (%)	CAUTI (%)	VAP (%)	SSI (%)
CNS	15.3	34.1	2.5	1.3	13.7
Staphylococcus aureus	14.5	9.9	2.2	24.4	30.0
Enterococcus faecalis	3.5	5.5	3.6	0.4	2.8
Enterococcus faecium	5.6	8.2	6.0	0.6	4.9
Candida albicans	6.8	5.9	14.5	2.4	1.6
Candida spp	3.9	5.9	6.5	0.3	0.4
Escherichia coli	9.6	2.7	21.4	4.6	9.6
Pseudomonas aeruginosa	7.9	3.1	10.0	16.3	5.6
Klebsiella Pneumonia	5.8	4.9	7.7	7.5	3.0
Enterobacter spp	4.8	3.9	4.1	8.4	4.2
Acinetobacter baumannii	2.7	2.2	1.2	8.4	0.6
Klebsiella oxytoca	1.1	0.9	0.9	2.2	0.7
Other	15.6	10.5	14.1	23.1	19.4

Abbreviations: CAUTI, catheter-associated urinary tract infection; CNS, coagulase negative staphylococci; SSI, surgical site infection.

Adapted from Hidron AL, Edward JR, Patel J, et al. National Healthcare Safety Network team; participating healthcare network facilities. NHSN annual update: antimicrobial-resistant pathogens associated with healthcare-associated infection: annual summary of data reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006–2007. Infect Control Hosp Epidemiol 2008;29:996–1011.

IMPLEMENTING EVIDENCE-BASED PROCESS MEASURES: PROMOTING EFFECTIVE INFECTION CONTROL INITIATIVES

Care Bundles

The concept of the care bundle has become central to mitigating the risk of HAIs within the ICU environment. The care bundle was developed in an effort to move away from dependency on individual knowledge, motivation, and skills and focusing instead on a systematic approach for delivering structured care. The care bundle is comprised of a series of separate but interrelated elements that flow in a cohesive manner and have evidence-based validation for improving patient outcomes.[15] An interesting observation in the development of an early care bundle to reduce the risk of VAP found that the process as designed did not immediately result in a decreased risk of VAP in a trauma unit. It was only after a process tool was put into place that measured the daily compliance to the bundle that the rate of VAP actually declined in the trauma ICU.[16]

Although evidence-based medicine has been a guiding factor in the development of care bundles in the ICU, it should be recognized that evidence-based practice is a moving target and these interventions must evolve over time. Although stress ulcer prophylaxis was a prominent component of the bundle package in the original Institute for Healthcare Improvement (IHI) VAP bundle, subsequent iterations have omitted this element of the package and are instead substituting subglottic suctioning as new evidence emerges validating efficacy.[17,18] As these processes become standardized in the ICU, compliance rates should be in the 90% to 100% range. A high level of compliance with process measures, such as the ventilator bundle or central line bundle, is documented to improve patient outcomes by reducing morbidity and mortality.[10,15–17] Unfortunately, this has not been the case with all recent process initiatives. A case in point is the Surgical Care Improvement Project (SCIP).[19] High compliance with the SCIP core process measures

has resulted in mixed reviews, with some reports documenting little to no decrease in the rate of surgical site infections (SSI), whereas others have observed an increased SSI in the presence of high compliance.[20] The complexities of surgical interventions, patient morbidities, and variations in surgical technique all challenge the concept of process standardization, especially in postoperative patients who end up in the ICU. However, the convergence of scientific inquiry, public perception, and legislative initiatives has targeted HAIs as a patient safety issue thereby creating the national momentum necessary for improving patient outcomes within a culture of safety.[21]

Hand Hygiene

Although hand washing is considered the cornerstone for disrupting the transmission of health care–associated pathogens, the strength of its scientific efficacy has produced mixed results. There is no argument that the hands of all health care workers become contaminated during the execution of their duties and that this contamination can be transferred to inert surfaces or other patients and/or staff members. Unfortunately, the current educational efforts aimed at improving hand hygiene tend to focus on personal consequences rather than patient consequences, which is a classic disconnect. Failure to practice appropriate hand hygiene creates an endangerment not necessarily to self but to that "next individual who you will be caring for."[22] The number of hand hygiene opportunities (HHOs) can vary greatly from one health care facility to another and are also influenced by the metrics used to document compliance. McArdle and colleagues[23] reported a total of 350 individual HHOs over a 24-hour period in an ICU; however, several HHOs (~190) did not fall within the World Health Organization's (WHO) 5 indications (HHOs) for hand hygiene (**Box 1**).[23,24]

Box 1
WHO 5 moments for hand hygiene

1. Before patient contact
   - When: clean hands before touching patients
   - Why: prevent transmission of organisms from hands to patients
2. Before performing any aseptic tasks
   - When: clean hands immediately after aseptic technique
   - Why: prevent transmission of intrinsic and extrinsic contamination
3. After exposure to blood or body fluids
   - When: after removing gloves, cleans hands immediately after blood and body fluid exposure
   - Why: protect yourself and health care environment from contamination
4. After patient contact
   - When: clean hands after touching patients and/or the immediate patient-care environment before leaving the room
   - Why: protect yourself and health care environment from contamination
5. After contact with patient environment
   - When: clean hands after touching any object or furniture in patients' immediate environment, even if patients were not touched
   - Why: protect yourself and health care environment from contamination

Adapted from World Health Organization. WHO guidelines for hand hygiene in health care. Geneva (Switzerland): World Health Organization; 2006.

Compliance rates measured in selected ICUs following patient contact reported in the literature were reported as 59% (surgical ICU [SICU]), 77% (medical ICU [MICU]), and 88% (neonatal ICU [NICU]), whereas hand hygiene compliance rates following contact with potentially infectious body fluids were reported as 49% (SICU), 76% (MICU), and 74% (NICU).[25] Although these rates are shockingly low, they agree with other published observational studies.[23,26,27]

Some investigators have reported a direct linkage between increased hand hygiene compliance and a reduction in infection.[28,29] Unfortunately, these studies have not been confirmed by recent observations that question the singular role of appropriate hand hygiene as a sentinel interventional strategy for reducing the risk of selective HAIs.[30,31] An interesting observation was recently published by a collaborative group in Australia. They found that multidrug-resistant (methicillin-resistant *Staphylococcus aureus* [MRSA] and vancomycin-resistant enterococci [VRE]) biofilm-forming microorganisms (MDROs) actually persisted on inert surfaces within the ICU following routine terminal cleaning. The investigators hypothesized that the relative humidity within the ICU was sufficient to produce surface condensation, allowing biofilms to develop with the resultant exopolysaccharide matrix-shielding microorganism from the biocidal cleansing activity of disinfectants or desiccation.[32] Mechanistically, these inert contaminated surfaces would be an excellent reservoir for subsequent transmission of MDROs via the hands of contaminated health care workers, supporting the rationale behind moment 5 of the WHO hand hygiene guidelines (see **Box 1**).[24] Finally, hand hygiene compliance is multifactorial and highly variable from unit to unit within a hospital. A recent study conducted among surgical services in 9 different countries found that staff workload was an important determinant of compliance; although educational campaigns had an effective short-term impact, the effect was not long lasting among clinical practitioners.[33] There is no debate that appropriate hand hygiene reduces the transmission of nosocomial pathogens; however, the disconnect between recognition and practice continues to be problematic.

Isolation Practices: Improving Outcome or Restricting Quality of Care?

Patients are placed in isolation as an intervention to prevent the spread of infectious agents among other patients or, in some cases, to protect the health care worker (tuberculosis [TB]). Airborne precautions (suspected patients with TB) require patients to be placed within a negative pressure room and all doors kept closed during the period of isolation. Health care professionals caring for known or suspected patients with TB must wear an N95 respirator mask and be fit tested at least once a year in areas where the burden of TB is considered high.[34] If patients are to be transported outside of the unit, they must wear a surgical mask. Removal from airborne isolation requires the following conditions: (1) patients are receiving effective therapy (TB) and are no longer considered infectious and/or (2) have had 3 consecutive negative sputum smears collected on different days ruling out pulmonary disease. Droplet precautions (influenza, meningococcal disease, and so forth) require that patients be placed in a private room or in cohort isolation. All health care workers are required to wear a surgical mask when working or coming within 3 ft of a patient. Protective eyewear and other personal protective equipment (PPE) may be appropriate depending upon the circumstances. Patients must wear a surgical mask when being transported outside of the unit, and patients must remain in droplet precautions for the duration of illness or following effective antibiotic therapy. Appropriate hand hygiene must be practiced when entering or leaving the patients' room (see **Box 1**).

Contact precautions (ie, MDRO gram-negatives, MRSA, VRE, and *Clostridium difficile*) dictates that patients be placed in private or cohort isolation. All personnel or

visitors must wear gloves when entering the room and remove gloves on leaving the patients' room. Hands must be washed with an antimicrobial soap immediately on removal of the gloves. Gowns are to be worn if it is anticipated that clothing will have substantial contact with patients' blood or body fluids, environmental surfaces, if patients are incontinent, have diarrhea, an ileostomy, colostomy, or excessive wound drainage. Gowns are removed before leaving the patients' environment. Efforts should be made to insure that dedicated patient care equipment (blood pressure cuffs, stethoscopes, and so forth) not be shared with other patients. If not disposable, these items must be thoroughly cleaned and disinfected before used on other patients. Contact precautions cannot be discontinued unless a negative culture is obtained 48 hours after stopping antibiotics. Historically, patients with diarrhea from *C difficile* must be symptom free or have a negative stool toxin assay before discontinuation of contact isolation; however, these patients often shed the organism into the environment for several weeks after resolution of symptoms.[35] This circumstance has resulted in some institutions implementing policies that require patients to remain in isolation until discharged. Following discharge, the patients' room undergoes a thorough terminal cleaning, which includes disposal of all patient items, including privacy drapes, in an effort to reduce the risk of disseminating *C difficile* spores to the next patient occupying that room.

Isolation precautions should be based on current epidemiologic information that identifies transmission patterns of infectious agents within the hospital environment. The current guidelines from the CDC are intended to recognize the importance of body fluids in the transmission of HAIs while addressing adequate precautions for traditional routes of transmission (ie, droplet, airborne, and contact).[36] Isolation policies should always be viewed in an evidence-based-practices context, subject to review and updated as further data are available on acquisition and transmission of infectious agents within the hospital environment. Contact isolation has long been viewed as restrictive to patient care, especially within the ICU, potentially limiting physician and nursing encounters.[37–39] A recent report has suggested that patients in contact isolation were independently associated with lower compliance of selective hospital process-of-care measures for pneumonia and smoking cessation. Any barrier to the vaccination process-of-care measure for *Pneumococcus* and influenza can have a potential adverse clinical impact in this high-risk patient population.[40] Over the past 10 years, selective hospital process-of-care measures have increased significantly, with some evidence correlating compliance with lower mortality.[41,42] Infection control interventions, which include contact isolation, have contributed to decreased morbidity and mortality.[43] So although the implementation of some hospital care processes and infection interventions, such as contact isolation, would seem at times to be in conflict, they are both in essence part of the same culture-of-safety initiative. The intrinsic conflict between these two processes would suggest that further studies are warranted to investigate the unintended consequences that arise when one sentinel intervention practice directly conflicts with another.

MRSA Carriage, Surveillance, and Decolonization

The mean prevalence of nasal carriage of *S aureus* in the United States has been reported to be 32.4%, suggesting that a third of the US population is colonized with *S aureus*. Although asymptomatic colonization with MRSA has been described previously as a risk factor for subsequent MRSA infection, the use of nasal cultures as a screening tool is viewed as a controversial strategy for reducing the risk (incidence) of MRSA acquisition and dissemination within the hospitalized patient population.[44,45] Published studies clearly reveal that an active MRSA surveillance program will

uncover previously occult patients colonized with MRSA, leading to an increase in the rate of contact isolation.[46] In light of numerous reports that point to an increased risk for infection associated with patients colonized with MRSA admitted to the ICU, several investigators have suggested that screening patients for MRSA colonization before ICU admission may be a prudent risk-reduction strategy in those high-risk individuals undergoing invasive medical or surgical procedures.[47,48] The CDC is currently revising the SSI prevention guidelines and, in all likelihood, active MRSA surveillance will be listed as a strong evidence-based practice for preoperative surgical patients. At present, the CDC has no recommendation for MRSA surveillance in either MICUs or SICUs.

Although many acute care facilities have active surveillance programs in the ICU, the question of whether or not to decolonize patients who are MRSA positive remains an open question. A recent study from Singapore where active MRSA surveillance was applied to all ICU admissions over a 12-month period found no significant difference in mean MRSA infection rate when compared with the previous 12-month baseline period.[49] Other recent studies in ICU patients have suggested that coupling active surveillance with topical decolonization (mupirocin or chlorhexidine gluconate) was beneficial in reducing MRSA transmission and selective HAIs.[50–52] It would seem that mupirocin is effective in eradicating nasal carriage and reducing the risk of infection over the short term; however, the longer-term benefits are presently unknown.[53] There is sufficient data to suggest that inappropriate use of mupirocin is associated with the emergence (rapid) of resistance, which is highly problematic because mupirocin is the primary agent for MRSA nares decolonization.[54,55] In addition to using mupirocin for nares decontamination, several evidence-based clinical studies have documented the benefits of daily patient skin cleansing with 2% chlorhexidine gluconate (CHG) on a polyester cloth to reduce the risk of selected HAIs in the critical care patient population.[56–58] An interesting study conducted by Peterson and colleagues[59] at 3 suburban hospitals outside of Chicago found that limiting MRSA surveillance to the critical care population did not achieve a significant reduction in MRSA disease. It was only after the adoption of a universal (hospital-wide) MRSA surveillance program in combination with decolonization did a significant reduction occur. The initial capital expense to establish this program was substantial (approximately $600 000) and the universal screening increased the overall burden of isolation by approximately 20%. However, the eventual fiscal savings associated with preventing MRSA-associated HAIs (50 less infections per year) approached $1 200 000 per year. The evidence-based benefits observed in each of these clinical studies required a uniform standard of practice, which was then applied to all eligible patients.

As the US population ages, so will the ICU patient population; many of these patients will express variable levels of immunosuppression, placing them squarely at risk for HAIs. Several well-designed and executed clinical studies have documented that the incidence of HAIs can be significantly reduced within the critical care environment through focused initiatives that embraced bundled interventional risk-reduction strategies. Although many of these processes have originated from the infection control literature and not the surgical literature, successful implementation of these evidence-based interventions requires the commitment of all members of the critical care team, surgeons, nursing, and ancillary health care professionals.

Imaging Safety and Intrahospital Transportation

Radiologic imaging of patients in the ICU is a universal event; although several studies can be performed at the bedside, transport to another department for routine imaging and image-guided procedures may be required for a large number of patients. Mazza

and colleagues[60] documented a 32.4% complication rate in patients transported out of the ICU for imaging studies, although most of the imaging studies obtained were for follow-up of a previously documented abnormality. Complications included agitation, hypotension, hypoxemia, and hypertension with no patient deaths. Other investigators have documented multiple complications caused by transport for imaging studies and other procedures, including death directly attributed to this practice. One study demonstrated a 75% complication rate (hypotension and hypercarbia) in patients being transported for radiologic studies using a manual ventilation system compared with a 44% rate of the same complications in patients transported with a transport ventilator.[61] Another published series of patients being transported for imaging revealed deaths and severe morbidity related to transport and documented other significant complications, such as a drain being removed after being caught in a doorway.[62] In 1990, Smith and colleagues[63] demonstrated a 60% complication rate for patient transport out of the ICU for elective procedures compared with 40% for patients being transported for emergency procedures. An informative retrospective analysis in 1988 demonstrated a 68% rate of complications directly related to the transport of trauma patients out of the ICU for imaging studies and surprisingly revealed that 76% of all studies obtained had no influence on patient management.[64] Similar results are reported by other investigators.[65] A multidisciplinary transport team can reduce the risks associated with these "road trips."[60,66] The decision to undertake a 'road trip' for necessary diagnostic testing or operative intervention requires an analysis of the risk of transport, such as that reported in the present study. This is a quote from the article, next-to-last paragraph of "Discussion" section. Given the volume of literature documenting a large number of complications related to intrahospital transport of critically ill patients, substantial consideration of the potential for a study to alter patient management should be undertaken before sending patients out of the tightly controlled ICU environment for imaging. Bedside imaging and image-guided procedures provide an alternative to transport for radiologic studies in critically ill patients. Examples include portable chest radiography, lung ultrasound, renal ultrasound, and bedside placement of central venous access catheters and inferior vena cava filters.

The portable chest X ray (pCXR) is a mainstay of critical care. As with any other bedside procedure, pCXR entails some amount of risk for dislodging monitoring devices, endotracheal tubes, and invasive monitoring devices, along with the ergonomic risk to nursing and technical staff that have to reposition the patients. Recently, the utility of performing this study on a daily basis has been called into question. This debate is not new. In 1982, Greenbaum and Marschall[67] evaluated 200 routine morning pCXR studies and found that 54 revealed new or worsening findings when compared with previous films. This was confirmed in a study from the University of Chicago in 1992 whereby new abnormalities were detected in 17.6% of routine studies.[68] A randomized controlled trial from France demonstrated that a restrictive policy for pCXR in the ICU was associated with lower costs and no change in outcomes.[69] These results were replicated in a multicenter trial in 2009.[70] Given the risks associated with the procedure, the exposure of patients and staff to ionizing radiation, and the lack of a proven benefit of daily pCXR, a selective approach to these studies is preferred. Although lung ultrasound is being promulgated currently as an alternative to pCXR in critically ill patients,[71] its relative lack of sensitivity to pneumothorax[72] makes the utility of this technique in the SICU questionable at this time.

The cumulative effect of radiation exposure from routine radiologic studies should not be discounted for either patients or providers. The average effective radiation dose to patients from a single pCXR is 0.02 (mSv), whereas the annual average background radiation exposure to an adult in the United States is 3 mSv.[73] Short-term

exposure to radiation doses between 10 to 50 mSv has been associated with the development of malignancies. A review of the National Dose Registry of Canada revealed that the excess relative risk (ERR) of developing any leukemia except chronic lymphocytic leukemia in health care workers was 2.7 per millisievert of occupational radiation exposure, and the ERR for developing any cancer except leukemia was 2.3 per millisievert. These relative risks were very similar to the relative malignancy risks observed in survivors of atomic bomb blasts.[74] Additionally, as imaging technology has improved, the effective radiation dose from traditionally obtained studies has increased. Katz and colleagues[75] demonstrated an increase in radiation exposure during CT urogram from 6.5mSv with single-detector computed tomography (CT) scan to 8.5 mSv with multi-detector row CT scan. Obviously, critically ill patients undergoing multiple imaging studies are at high risk of rapidly accumulating ionizing radiation doses, with the highest risk likely being to patients suffering from cardiac complications that undergo coronary catheterization. Limiting the exposure of health care workers and patients to unnecessary ionizing radiation is of significant importance.

Device Safety

The use of medical devices for monitoring, whether invasive or noninvasive, is ubiquitous in the ICU setting. Errors in the use of these devices can range from improperly set alarms leading to detrimental outcomes from unrecognized complications[76] to accidental removal of life-sustaining devices, such as endotracheal tubes and intra-aortic balloon pumps.[77] Although the exact incidence of device-related complications is unknown, errors can occur at 1 of 4 interactions (**Table 2**). Currently, at least 500 000 medical devices are available on the market in the United States.[76,78] Devices can range in complexity from a cotton-tipped applicator to a left ventricular support device. In the United States, these devices are classified as types I through III.

1. I: Noninvasive devices
2. II: Most diagnostic and treatment equipment, such as x-ray machines
3. III: Implantable and life-support devices, such as pacemakers and implantable defibrillators

These classifications are specified for each of 16 medical specialties. Clearly, not every provider is going to understand the technical nuances of every available device, and even familiar devices can malfunction and cause patient harm if improperly used. It has been reported that most reported critical incidents in the ICU are device-related and often caused by either inadequate training or faulty equipment.[79]

Few objective data exist regarding the incidence of patient-initiated device removal in the ICU. In a 2007 study of 49 adult ICUs, the overall incidence of removal of any

Table 2
Types and examples of medical device errors

Type of Interaction	Example
Patient-device	Self-extubation
Provider-device	Improperly set IV pump or PCA
Device-device	Interaction between device and plugged-in module (ie, brick for multiple wires and ICU physiologic monitor)
Device-environment	Device not plugged in for use or not charged, device malfunction caused by temperature extremes

Abbreviations: IV, intravenous; PCA, patient-controlled analgesia.

therapeutic device was 22.1 per 1000 patient-days, with most commonly removed devices being nasogastric tubes (28.9%), supplemental oxygen (23.5%), and peripheral intravenous (IV) catheters (20.8%). However, more serious issues were observed, including the accidental removal of external ventricular drains, endotracheal tubes, and surgical drains. Of interest, only 48.9% of patients that removed their own endotracheal tubes had to be reintubated, highlighting the supposition that perhaps these devices that are being removed are being left in place too long in the first place.[77]

The US Food and Drug Administration maintains a medical device safety database referred to as MAUDE (Manufacturer and User Facility Device Experience). A common device used in surgical patients, the patient-controlled analgesia (PCA) pump, was evaluated for all errors reported to the MAUDE database from January 1, 2002 to December 31, 2003.[80] This analysis disclosed that 2009 individual PCA-related events were reported during the data collection period. Of these events, 1590 (79.1%) were device safety-related issues, most often related to switch, motor, battery, display board, or software. Eight events (0.5%) resulted in patient harm, including one incident whereby a battery fell on a patient. A large number of operator errors were likewise identified (131), with the most common error being at the provider-device level with problems programming the pump. Three deaths were reported to directly result from programming errors.

As device criticality increases, so often does the complexity of use. Unfortunately, devices that are more complex and more critical to sustaining life are often used rarely, with a corresponding increase in possibility for errors.[81] In addition, the overall level of congestion of instruments, wires, IV lines, and monitors around ICU patients contributes to the number of errors in their care, with up to 30% of errors considered severe enough to potentially cause harm or death.[82] Clearly, improvement of the ergonomic environment of the ICU, along with improvement of device interfaces at all levels, is critical to the improvement of patient safety in the future and a necessary direction of future research.

ICU Staffing Models and Outcomes

From 1985 to 2000, the number of ICU beds in the United States increased by 26.2%. However, dedicated intensivists provide care to a minority of ICU patients in the United States. In fact, only 10% of ICUs have in-house physician staffing on weekend evenings, which compares poorly with staffing models in other countries.[83] There are currently more than 6000 ICUs in the United States, which provide care to more than 2.4 million patients per year.[84] Given that 1% of the US gross domestic product is spent on intensive care services, defining the optimal physician staffing model to deliver that care is of paramount importance.

Physician staffing models continue to be debated with regard to their roles in enhancing the safety of critically ill patients. Dedicated intensivist staffing in ICUs is thought to improve patient outcomes, but this conclusion remains controversial. A 2006 meta-analysis examined 26 studies of low-intensity (no or elective intensivist consultation) versus high-intensity (mandatory consultation or closed ICU) staffing patterns. This study ultimately included 14 356 patients in the high-intensity group and 13 117 patients in the low-intensity group. In 16 out of 17 studies reviewed, high-intensity staffing was associated with lower mortality (relative risk, 0.71).[85] Unfortunately, the opposite outcome has been observed in a large study of more than 101 000 patients by Levy and colleagues.[86] Their study showed that dedicated staffing by intensivists (95% of patients cared for by an intensivist for their ICU stay) was associated with an increased severity-adjusted mortality compared with low-intensity staffing. This study has been subjected to a significant amount of criticism,[83] but it remains a very large patient sample compared with all other studies.

The Leapfrog group has promulgated a set of guidelines related to critical care, and the Safe Practice Survey (SPS) is used to determine quality of care in the intensive care setting. A recent study examined the SPS related to the care of critically ill trauma patients. The 2006 Nationwide Inpatient Sample database was queried for all patients admitted to the ICU with a primary diagnosis of trauma (*International Classification of Diseases, Ninth Revision, Clinical Modification* codes 800.0–959.9, excluding burns, late effects of trauma, superficial trauma, and foreign bodies). HAIs and mortality were the defined end points because previous studies examining only mortality were criticized for exclusion of HAIs. The SPS score had no effect on mortality or HAIs. High-intensity staffing and low-intensity physician staffing models were not correlated with outcomes, and in fact the only outcome related to use of the SPS was that disclosure of medical errors to patient families was correlated with lower mortality.[87] Although this study has several limitations, including selection bias and the possibility of underreporting of HAIs in administrative databases, their analysis certainly suggests that we are missing opportunities to improve patient safety in the critical care environment.

As has been widely reported and discussed, up to 98 000 patients may die of human error in US hospitals every year.[88] Although the veracity of this number can be debated, the fact that a large number of human errors occur in critical care units cannot be denied. Up to 45.8% of ICU admissions are reported to involve an adverse event, with 17.7% of patients experiencing an adverse event that could be considered serious.[89] The Centers for Medicare and Medicaid Services now do not reimburse hospitals for treatment of certain adverse events, highlighting the necessity of preventing these events before they occur.

ICUs are complex environments with multiple interactions occurring between providers, patients, ancillary staff, and medical devices with increasingly complex interfaces. Errors in medical care can occur during any of these interactions and are divided into several broad categories. A 90-month study of a 13-bed ICU found that in 1127 documented critical incidents, hazards included errors in equipment use (30.0%), clinical practice (22.8%), pharmaceuticals (21.1%), administration (18.9%), and health and safety hazards (7.2%). Errors were reported by nursing and physician staff through an on-line data collection system and compared with regional hospitals. The two most common errors reported were “faulty equipment” (113 critical incidents) and “unfamiliarity or incorrect use of equipment” (72 critical incidents). The investigators determined that most of the incidents were related to a lack of training with specific pieces of equipment and addressed this by introducing a practice educator, which allowed for continuous performance improvement and education in the use of all equipment available in the ICU.[79]

Patient handoffs are another area where potentially serious errors in care can occur. The transfer of care between providers is a phenomenon that occurs on a daily basis in hospital settings and is a very common practice in the ICU. The transfer of patients between house staff (sign out) is extensively encouraged, but few rigorous studies are available to document its efficacy.[90] The transfer of patients from the ICU to the ward can result in a lack of transfer of crucial information. A recent study from the University of Calgary revealed that in 112 patient transfers from ICU care to ward care, 13 medical errors were identified as the result of transfer, with 2 patients being transiently “lost to care.” Challenges to effective transfer of information include different focuses between disparate specialties and different workloads. Only 26% of accepting ward physicians received communication directly from the ICU physician at the time the patients were transferred. Additionally, only 32% of patients received communication from their ICU physicians regarding their transfer and ongoing medical care.[91]

ENHANCING PATIENT SAFETY: RISK REDUCTION, ERROR REPORTING, AND FUTURE DIRECTIONS

Errors in patient care at some level cause up to 10% of patient fatalities in trauma ICUs in patients with otherwise survivable injuries[92]; estimates are that critically ill patients may experience up to 1.7 medical errors a day, mostly from medication administration errors.[93,94] Risk reduction is the holy grail of the performance improvement arena.

Computerized physician order entry (CPOE) is proposed as a solution to medication errors, which are ultimately caused by errors in either communication or judgment. The expanded use of health information technology (HIT) is promulgated by the federal government as a way to improve health care quality and reduce risk. The Leapfrog group and the Institute of Medicine have endorsed the expanded use of HIT, and financial incentives are available to health care institutions that demonstrate its "meaningful use."[94] CPOE has not been clearly demonstrated to reduce medication errors in the ICU, and its initiation can in fact cause significant problems. An often-cited study from Pittsburgh[95] showed an increase in unadjusted mortality in a pediatric ICU after the start of CPOE, with CPOE being independently associated with increased mortality. A subsequent study from Seattle refuted this idea.[96] The available data illustrate a significant learning curve to CPOE; although this technology has the potential to reduce errors, there is currently no proof that this has occurred.

Reporting of errors is another area that can potentially lead to risk reduction and performance improvement by allowing rigorous study of modes of failure. It is widely perceived that critical incidents and errors in ICU care are underreported, and consistent error reporting is recommended by the Institute of Medicine as a key error reduction strategy.[97] Two studies show that paper-based reporting systems enhanced overall error reporting, with one study involving card-based replacement of a previously used Web-site–based program.[97,98] Physicians were more likely to report incidents if they caused harm to patients, and the rate of error reporting improved when switching from a computer-based system to a card-based system.[97] These reports suggest that simplicity in a reporting system increases its use and enhances the volume of data available for analysis regarding patterns of errors.

Improving the quality and safety of ICU care in the United States is a significant challenge for the future. Obtaining lasting improvement in our systems of care is difficult given the reactionary mode physicians tend to enter when dealing with moment-to-moment crises.[99] It will be of utmost importance to implement quality and safety measures that are already supported by evidence, such as hand hygiene, implementation of evidenced-based care bundles, adequate identification and treatment of HAIs, and increasing the percentage of patients in ICU settings that are cared for by dedicated intensivists. Improvement of device safety, especially at the device-provider level, will be critical to reducing the large number of device-related complications that occur on a yearly basis in US ICUs. Prospective collection of adverse events with rigorous analysis will be important to allow systematic errors to be exposed and corrected.

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