Critical Care Administration

A Comprehensive Clinical Guide

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Dedicated to our families who have been able to cope with our time constraints and frustrations, always supporting us, making everything worthwhile. With love.

Foreword

"He's standing right behind me, isn't he …?"

Eight pairs of eyes had shifted up from the green scrub-clad fellow facing them, fists on her hips, back to the "boss" who had silently entered her ICU. She had just finished the "Beginning of the rotation" speech that ended with "Attention to detail is the difference between life and death."

Eight heads solemnly nodded, and I knew I was a witness to greatness. No dad could be more proud, and, as I knew then and have seen since, she has eclipsed those who have taught her and found her place among the true leaders and founders of our world, the world of critical care.

I have been blessed and honored to have met, learned from, worked with, and occasionally cared for the giants of our world. Hal Weil, Roger Bone, Eric Rackow, Dennis Greenbaum, Bill Kaye, and Vlad Kvetan were personal friends and mentors who lived rather than practiced critical care and radiated rather than taught. We who were so honored to learn from them also knew their mantra was simple but immense "Attention to detail …."

The baton has passed from those gods to the authors of these chapters and others whose names we recognize. They have written of setting goals, of budgets and planning, of humanized care, and of research. Some of these concepts would make Dr. Weil's eyes twinkle with delight for he, like others, was never satisfied with "how it is." Attention to detail; live the life that is critical care; radiate the lesson through the ether to your eager protégés. If you do it so well as those gods above or the authors on these pages, perhaps you too will be able to see the face of one that you know will soon surpass you in all ways. For as that green scrub-clad Brown Critical Care Fellow turned around to address her "boss," me, I saw the next giant of critical care standing before me: Gloria Rodríguez-Vega.

Livingston, NJ, USA
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Paul C. Yodice, MD, FCCM, FCCP

Preface

During critical care training, fellows and residents spend many hours understanding the complexity of the disease and the myriad of diagnostic tests and treatments required by a critically ill patient. Countless sessions, both clinical and theoretical, cover differential diagnosis, complicated organ interactions, and the always changing world of evidence. However, there is a minimal formal training on the administrative aspects of the practice. Once exposed to the "outside world," the intensivist confronts a different reality, a more complex one, filled with not only clinical demands but also the requirements for leadership and administrative roles. Whether in an academic center, a private practice, or a government-based facility, intensivists are usually viewed as leaders and oftentimes tasked with positions in important committees within their system. It is then when the intensivist is challenged with the labyrinth of organizational aspects involved in ICU administration.

The critical care environment is full of interactions. The elements of the ICU microcosm include different physicians of many specialties; other healthcare professionals; several departments such as pharmacy, radiology, and social work; as well as patients and families, with moving boundaries extending outside the ICU walls. Modern critical care medicine requires standardization, implementation of protocols based on best evidence, humanization, and personalization of the delivery of care. Critical care physicians must guarantee that their patients are consistently managed with the state-of-the-art performance, the best evidence available, with personalized attention and with care delivered in a humanized manner with full attention to the patient's dignity and rights. Mastering these skills becomes everyday more challenging in the increasingly demanding healthcare environment we live nowadays.

Intensivists are in-hospital-based physicians present physically in the institution, oftentimes 24 hours a day. The shortage of intensivists demands many times overworked schedules. That, together with the stress produced by the nature of the job as well as the significant burden created by the different guidelines, protocols, and regulations, creates dissatisfaction and plays an important role in burnout for critical care physicians. Intensivists are required to make complicated and precise decisions in a timely manner and under major stress, leading to physical and

psychological fatigue. Perhaps moved by the natural skills and qualities of the intensivist, administrators invite them and expect from them to participate and many times lead committees and teams in the institutions. Intensivists are everyday more and more involved in dimensions of operations beyond the clinical and technical duties.

Critical care, as opposed to other lines of service, rarely results in financial revenue for the institution, although it might significantly impact costs and savings. Critical care is also subject to continuous pressure from many services, some requesting ownership over critical care units aimed to offer specialized care for their more complicated patients but creating fragmentation of services. At the same time, critical care physicians feel themselves continuously scrutinized being the subjects of financial, clinical, and social analysis.

All these factors determine the extreme importance for the intensivists to acquire administrative and operational knowledge and skills in order to confront the different challenges that modern critical care comprises. That is challenged by the scant information and educational resources available, a problem carried from our training.

This book does not intend to replace those aspects of the training that we, the editors, believe should be fully included during fellowship and even medical school. The book *Critical Care Administration: A Comprehensive Clinical Guide* is intended to help the critical care clinician to navigate through some of those challenges present in the complex world of the administration of a critical care unit.

During the preparation of this book, we tried to cover topics using a global perspective, avoiding regional variances. However, we used the US prevalent ICU model for some of the aspects such as billing and coding. The book navigates through aspects of the administration from the interaction among critical care professionals (physicians and non-physician providers, attendings, and residents) to the financial facets of the day-to-day operations, including the use of precise documentation to obtain the credit for the work developed. The book reviews the different models of care, protocols, and guidelines, as well as the levels of institutional involvement. We did not forget to leave space to discuss the increasing role of modern technologies including tele-ICU and aspects of digital transformation and data analytics. We allocate special attention to the humanization of care and the development of the right environment aimed to fulfill the needs of patients and families. We also explore elements leading to burn-out syndrome for professionals and measures aimed to create the right environment for the accomplishment of professional satisfaction and retention strategies. We discuss some of the uncomfortable situations that the professional encounters such as medical errors and their disclosure.

Finally, we, the editors, share with the authors the utmost wish of positioning this book as a reference, as the basis for the foundation of vertical critical care in the continuum of care, having the patient as the center of care, from the community to post-acute care in the rehabilitation center or home.

Through the understanding of all the administrative aspects, we believe critical care physicians are better prepared to accept the challenges of modern delivery of care. Critical care is not a place; it is a service, universally delivered and managed.

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We would also like to thank our mentors, Janice Zimmerman, Mark J. Hauser, and Paul Yodice, who had the vision to train us, to share their knowledge with us, and to become not only our colleagues but also our friends in the life of the critical care physician.

Finally, many thanks to our patients, the ultimate motive of our existence, to whom we must express our eternal gratitude. They trust us with their life and impulse our learning and actions and make us always keep the utmost attention to details.

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Chapter 1
Critical Care Services: Scope of Practice

Janice Zimmerman and Mukhtar Al-Saadi

Introduction

Critical care services utilize specialized staff and teams to provide care, therapeutic interventions, and advanced monitoring to critically ill patients with life-threatening conditions or injuries and complex multi-organ dysfunction using protocols and principles to reverse pathophysiologic processes [1]. The standard goals of critical care services are improving quality of clinical care and decreasing morbidity and mortality of critically ill patients [2]. Critical care services should be patient-centered, directed by critical care physicians, collaborative, and multidisciplinary following protocols and guidelines to provide a high quality of care around the clock to critically ill patients [3, 4].

Critical care may be delivered within the intensive care unit (ICU) or in other areas of the hospital outside of the ICU. Although the ICU is a unique part of the hospital that is structured in a defined geographic area, its activities often involve other areas such as emergency departments, postanesthesia care units, general floors, and follow-up clinics [5]. The demand for an ICU bed often exceeds capacity, and plans should be developed to provide critical care expertise wherever it may be needed in the hospital.

In this chapter, we review types of ICU organizational models and critical care services outside the ICU. We also discuss clinical rounds in the ICU including the definition and composition, as well as structure and organization.

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ICU Organizational Models

A variety of models of ICU organization currently exist to manage critically ill patients: the open model, closed model, intensivist co-management model, high-intensity staffing model, low-intensity staffing model, and other mixed or transitional models [6–16]. These models vary by availability of an intensivist or ICU team and the level of involvement of the intensivist or ICU team in the care of the patients. The wide variation in organizational models in the ICU is mostly due to local practices, available resources, and economic factors of the hospital or institution [17].

Definitions

The Open Model An ICU in which patients are admitted under the care of a physician other than an intensivist. Any physician can admit patients to the ICU in this model. The admitting physician usually has competing responsibilities outside of the ICU such as outpatient clinics or operating rooms. Intensivists may play a primary role in the management of some patients, but only at the discretion of the admitting physician. Critical care consultation in this model is optional [7, 9, 15, 18].

The Intensivist Co-management Model (Transitional Model) This is an open ICU model in which all patients receive mandatory consultation from an intensivist. The physician of record remains the admitting physician with intensivists collaborating in the management of all ICU patients [15, 19–21].

The Closed Model An ICU in which patients are evaluated and approved for ICU admission by the intensivist or ICU team. Once the patient is admitted to the ICU, the intensivist becomes the physician of record and all other physicians are consultants. The intensivists have ICU admission and discharge privileges for all ICU patients and take the role and responsibilities of the primary admitting physician. In this model, the intensivist and ICU team are dedicated to providing care to ICU patients on a full-time basis with no other competing clinical responsibilities [8, 15].

The organization of ICUs has also been described on the basis of intensivist staffing and the amount of time spent by intensivists in providing care to ICU patients.

High-Intensity Staffing Model Includes both closed models and open models with mandatory consultation to critical care physicians for all patients admitted to the ICU [16]. In general, high-intensity staffing involves availability of intensivists throughout the day. The level of the intensivist involvement in open models with mandatory ICU consultation is still unclear with roles not comprehensively described.

Low-Intensity Staffing Model Any model other than closed or mandatory ICU consultation model (the intensivist co-management model) [16]. This may include no intensivist, elective intensivist consultation to care for specific ICU patients, or

Table 1.1 ICU organizational staffing models and the level of intensivist involvement

	Open	Closed	Mixed/ transitional
ICU admission/discharge decision	Any physician	Intensivist	Both
Primary attending physician	Nonintensivist	Intensivist	Either
Responsibility for management	Attending physician	Intensivist/ICU team	Variable
Intensivist involvement	Elective	Mandatory	Variable
Order writing	Any physician	Intensivist/ICU team	Either
Attending commitments	Multiple areas (OR, clinic, floor patients)	ICU only	Variable
Line of authority for management	Confusing	Clear	Not clear
Difficulty of implementing protocols	Higher	Lower	Variable

variable intensivist involvement such as rounding on certain patients. Intensivist availability is less than in high-intensity staffing models.

Mixed ICU Models Models that may share features of some or all of the aforementioned models. The above models may overlap to a considerable extent. Thus, some ICUs may have limited involvement of ICU physicians in patient care such as daily rounds by an intensivist or intensivist directorship with no specific organizational model [18, 21–23].

Closed ICU organizational models are more common in larger academic centers that have trainees present in the ICU [15]. Open ICU organizational models are more common in the United States [15, 24], and only 26% of ICUs have high-intensity staffing [25], while closed ICU models are more common in other countries [26–29]. Excluding closed ICU models, there are a number of knowledge gaps in accurately defining ICU organizational models relevant to staffing by ICU physicians. These include, but are not limited to, the exact roles of ICU physicians, the extent of intensivist involvement, and the duration of involvement throughout the day. Table 1.1 summarizes three ICU organizational models with the degree of ICU physician involvement.

Clinical Outcomes Associated with Different ICU Organizational Models

Many studies have tried to assess outcomes of ICU patients linked to various ICU organizational models. The ICU can be considered an organized complex adaptive system (CAS) which provides care to seriously ill patients [30, 31]. In such systems, many elements, including groups or teams, interact, change, and adapt with each

other for specific goals. It is difficult to evaluate and determine if better outcomes are solely related to intensivist involvement as it would require standardization and control of all variables that may influence clinical outcomes including ICU design, structure, size, type of cases, and the composition and functions of multidisciplinary teams [15].

Young et al. reviewed nine studies to evaluate the effect of a closed ICU model on patient mortality in the United States [32]. Relative reductions in mortality rates associated with the closed ICUs ranged from 15% to 60%, and the study concluded that even with modest reductions in mortality rates, lives can be saved given the large number of ICU patients. Pronovost et al. conducted a systematic review and meta-analysis which examined 27 observational and randomized controlled trials of different ICU organizational strategies from 1965 through 2001 [16]. ICUs were categorized into low-intensity staffing and high-intensity staffing models. In the high-intensity staffing model, the critical care physician consultation was mandatory. The high-intensity staffing model was associated with lower ICU and hospital mortality and shorter ICU and hospital length of stay. The improved outcomes linked to high-intensity staffing could be explained by the implementation of evidence-based care and standardized protocols provided by the ICU physicians and the multidisciplinary team [33]. Levy et al. conducted a cross-sectional study from the project IMPACT database, a US database originally developed by the Society of Critical Care Medicine [34]. The study included 101,832 patients in 123 ICUs throughout 100 hospitals from 2000 to 2004. Surprisingly, hospital mortality was higher when ICU physicians were involved in patient care. In this study, there was a concern of residual confounders for illness severity and selection biases that were not adequately assessed or recognized. Treggiari et al. examined the association of closed versus open organizational models with patient mortality from acute lung injury across 24 adult ICUs in the Seattle area [35]. The results showed that patients with acute lung injury cared for in a closed ICU had lower mortality (adjusted odds ratio, 0.68; 95% confidence interval, 0.53, 0.89; $P = 0.004$).

Outcomes Related to 24/7 and Night Coverage by ICU Physicians

The intensity of staffing of ICUs by critical care physicians may also have an impact on patient outcomes. As a high-intensity staffing model showed positive results related to patient outcomes, Gajic et al. evaluated the benefits of continuous presence of a critical care specialist in the ICU of a teaching hospital [36]. The 2-year prospective cohort study compared the quality of care and patient, family, and provider satisfaction before and after changing the staffing model from an on-demand to continuous 24-hour critical care specialist presence in the ICU. The results showed that a 24-hour on-site ICU specialist was associated with improved processes of care, staff satisfaction, decreased ICU complication rate, and hospital

length of stay. There was no effect on hospital or ICU mortality. The potential advantages of 24-hour in-house ICU physicians are enhancement in efficiency and quality of care and improvement in staff, trainee, patient, and family satisfaction. In contrast, potential but significant disadvantages may include physician burnout and higher costs [37, 38]. In a cross-sectional survey, Diaz-Guzman et al. surveyed 374 critical care training programs in United States academic medical centers [39]. A total of 138 responses from program directors and 380 responses from critical care fellows in training were received. The responses showed that 24/7 coverage was associated with better patient outcomes and trainee education, but concerns about trainees' autonomy were expressed using this model. A large retrospective cohort study was conducted by Wallace et al. in 49 ICUs of 25 hospitals to evaluate a 24-hour intensivist staffing strategy and associated quality of care [40]. Their results found that the presence of a critical care physician at night decreases mortality in low-intensity staffed ICUs but not in high-intensity daytime staffing models. Kerlin et al. conducted a 1-year randomized trial in an academic medical ICU to assess the effects of nighttime staffing with in-hospital intensivists (intervention) as compared with nighttime coverage by daytime intensivists who were available for consultation by telephone (control) [41]. A total of 1598 patients were included. Nighttime in-hospital intensivist staffing did not improve patient outcomes (ICU length of stay, in-hospital length of stay, ICU and in-hospital mortality, discharge disposition, and rates of readmission to the ICU). A meta-analysis and systematic review of 52 studies conducted by Wilcox et al. to evaluate staffing patterns in the ICU demonstrated that high-intensity staffing was associated with reduced ICU and hospital mortality [42]. Within high-intensity staffing models, 24-hour in-hospital intensivist coverage did not reduce hospital or ICU mortality. The benefit of high-intensity staffing was concentrated in surgical (risk ratio, 0.84; 95% CI, 0.44–1.6) and combined medical-surgical (risk ratio, 0.76; 95% CI, 0.66–0.83) ICUs, as compared to medical (risk ratio, 1.1; 95% CI, 0.83–1.5) ICUs. The effect on hospital mortality varied across different decades. In 2017, a systematic review and meta-analysis by the American Thoracic Society on the effect of nighttime intensivist staffing on mortality and length of stay among ICU patients suggested that nighttime intensivist staffing is not associated with reduced ICU patient mortality and recommended the evaluation of alternative staffing models [43].

The current evidence suggests that the high-intensity staffing model during the day improved patient outcomes in the ICU while benefits of 24-hour in-hospital intensivist coverage were mainly evident for low-intensity staffing models. The main obstacle to achieve these objectives is the existing and anticipated shortage of ICU physicians in some areas of the world [44] given the recommended ICU bed to intensivist ratio of less than 15:1 for optimal delivery of quality critical care services [45]. Strategies to meet these challenges may include regionalization of services, telemedicine (see Chap. 8), the use of nonphysician critical care-trained healthcare providers such as nurse practitioners and physician assistants, and a co-management model with noncritical care-trained physicians such as hospitalists (see Chap. 7).

General and Specialized ICUs

Two types of ICUs can be recognized: general ICU and specialty ICU. General ICUs provide care for a variety of patients and diagnoses. These ICUs, also called medical-surgical ICUs, are commonly found in smaller and community-based hospitals. Specialty ICUs provide diagnoses-specific care for an identified population of critically ill patients. These ICUs include cardiac and cardiothoracic ICUs, medical ICUs, surgical ICUs, and neurological ICUs. They are more commonly found in larger hospitals and teaching institutions [25]. The proposed advantages of specialty ICUs are convenient and efficient utilization of resources such as experienced providers including nurses and physicians to deliver care to patients with specific disease processes, conditions, and interventions, decrease treatment variability, provide focused education for trainees, and improve patient outcomes.

There is limited evidence to support the development of specialty ICUs. Lott et al. conducted a retrospective cohort study to examine patients admitted to 124 ICUs in the United States [46]. The authors analyzed data of 84,182 patients admitted to specialty and general ICUs with an admitting diagnosis or procedure of acute coronary syndrome, ischemic stroke, intracranial hemorrhage, pneumonia, abdominal surgery, or coronary-artery bypass graft surgery. No significant differences were found in risk-adjusted mortality between general and specialty ICUs for all conditions other than pneumonia. There was no consistent effect of specialization on length of stay for all patients or for ICU survivors. The study also revealed that admitting patients with a nonideal diagnosis (a diagnosis commonly not cared for by the specialty ICU) to a specialty ICU (boarding) was associated with increased risk-adjusted mortality.

The effect of a specialty ICU on patient outcomes related to a specific diagnosis has shown some positive outcomes. Mirski et al. conducted a retrospective review of patients with a primary diagnosis of intracerebral hemorrhage treated in medical or surgical ICUs and those treated in a neurosurgical ICU in the same institution [47]. Mortality and disposition at discharge in patients with intracerebral hemorrhage were significantly improved ($P < 0.05$) in patients treated in a neurosurgical ICU compared with those treated in a general ICU. The patients treated in the neurosurgical ICU had shorter hospital stays ($P < 0.01$) and lower total costs of care ($P < 0.01$). Diringer and colleagues conducted a prospective study analyzing data collected by project IMPACT over 3 years from 42 participating ICUs (including one neurological ICU) across the United States [48]. Patients with acute intracranial hemorrhage admitted to a neurological ICU had reduced mortality compared to a general ICU. Duane et al. conducted a retrospective review of registry data of 1146 trauma patients treated in a surgical trauma ICU compared to 1475 patients treated in a nonspecialized ICU [49]. Penetrating trauma and care in a nonspecialized ICU were predictors of mortality. A specialty ICU for cardiac patients has also been proposed based on specialized monitoring, interventions, and devices needed for the management of patients with advanced heart failure and cardiogenic shock.

A factor that may limit the role and effectiveness of specialty ICUs in treating critically ill patients is the need for multi-organ support in conditions such as sepsis, acute respiratory failure, acute heart failure, and acute renal failure. Another factor could be related to the concept of organized care provided by experienced ICU providers (intensivists, nursing staff, respiratory therapists, dietitians, and others) who adopt a multidisciplinary approach of care and use strict protocols and guidelines. Nevertheless, ICU specialization may offer efficient use of resources, treatment of specific conditions by an experienced provider, enhancement of trainee education pertinent to a particular group of diseases and clinical conditions, higher family satisfaction, and reduction of the cost of care.

Critical Care Services Outside the ICU

The goal of critical care services is to deliver specialized care to critically ill patients. A comprehensive approach to critical care services should consider the provision of these services to all critically ill patients in the hospital irrespective of their physical location. This may include emergency departments, hospital units, intermediate care units, and postoperative units. Thus, the term "intensive care system without walls" has evolved to describe delivery of critical care and ICU expertise outside the walls of the ICU to any critically ill patient in the hospital [50].

Rapid response systems represent the main approach to deliver necessary critical care services in every part of the hospital outside the walls of traditional ICUs. Different terms may be used to identify these teams such as rapid response teams, medical emergency teams, and critical care outreach teams. They usually share the concepts of an afferent limb that represents the activating team and an efferent limb that represents the response team. The afferent limb can be activated by anyone in the hospital and at any time. The response team is a specialized team that consists of critical care-trained providers led by an intensivist, advanced critical care provider, or nurse that respond to patients with deteriorating clinical conditions in the hospital. The main functions are identification of at-risk patients and resuscitation, stabilization, and safe transfer to an ICU if indicated for critically ill patients [51]. The advantage of rapid response teams is the availability of experienced critical care providers that can respond immediately to seriously ill patients. Both experience and time to response at bedside may result in safe and effective management of critically ill patients and improve outcomes [52]. Other advantage of rapid response teams may also include minimizing the inappropriate utilization of ICUs by providing adequate care to prevent admission to the ICU and following up with patients after ICU discharge to prevent readmission [21]. Rapid response systems use a set of criteria to identify patients who are at risk [51, 53]. The utilization of appropriate criteria can be effective in decreasing admissions to the ICU for patients who are at low risk [54, 55] or for patients who have minimal or no chance of survival or recovery [56].

The effectiveness of rapid response systems in reducing hospital mortality, non-ICU cardiopulmonary arrest, and ICU admissions has been evaluated in a number of studies. Priestley et al. conducted a pragmatic randomized trial that found critical care outreach teams reduced mortality in general hospital wards compared to wards with usual care [57]. Hillman et al. conducted a trial randomizing 23 Australian hospitals to usual care compared with the presence of medical emergency teams [58]. No difference in the incidence of cardiac arrest, unplanned ICU admissions, or unexpected death occurred between the two groups. A systematic review and meta-analysis by Chan et al. included 18 studies to evaluate the effect of rapid response teams [59]. The results showed that implementation of a rapid response team in adult populations was associated with a 33.8% reduction in rates of cardiopulmonary arrest outside the ICU (relative risk [RR], 0.66; 95% confidence interval [CI], 0.54–0.80) but was not associated with lower hospital mortality rates (RR, 0.96; 95% CI, 0.84–1.09). The implementation of a rapid response team in children was associated with a 37.7% reduction in rates of cardiopulmonary arrest outside the ICU (RR, 0.62; 95% CI, 0.46–0.84) and a 21.4% reduction in hospital mortality rates (RR, 0.79; 95% CI, 0.63–0.98). A systematic review by Winters et al. showed that rapid response systems were associated with reduced rates of cardiorespiratory arrest outside the ICU and reduced mortality [60]. In a recent systematic review and meta-analysis of 29 studies, Maharaj et al. found that the implementation of a rapid response team was associated with a decrease in hospital mortality in both the adult (RR 0.87, 95% CI 0.81–0.95, $p < 0.001$) and pediatric (RR 0.82, 95% CI 0.76–0.89) in-patient populations [61]. The rapid response system team was also associated with a reduction in cardiopulmonary arrests in adults (RR 0.65, 95% CI 0.61–0.70, $p < 0.001$) and pediatric (RR 0.64, 95% CI 0.55–0.74) patients. Similarly, a systematic review by Solomon et al. found that the implementation of a rapid response or medical emergency team was associated with a reduction in hospital mortality (relative risk [RR], 0.88; 95% confidence interval [CI], 0.83–0.93) and a reduction in the number of non-ICU cardiac arrests (RR, 0.62; 95% CI, 0.55–0.69) [62].

The weight of the available evidence suggests that rapid response systems are associated with a decrease in hospital morality and non-ICU cardiopulmonary arrest [59–62]. Rapid response teams were also associated with a decrease in unnecessary ICU admissions, length of hospital stay, and adverse outcomes such as respiratory failure, sepsis, stroke, and acute renal failure requiring renal replacement therapy [55, 63, 64]. The scope of critical care services has been expanding beyond the walls of the ICU. Critical care services and expertise may include the management of non-ICU patients who are at risk or whose clinical condition is deteriorating to prevent serious adverse events such as cardiopulmonary arrest or even death. Other roles of the critical care experienced teams may also include consultation about the appropriate level of care for individual patients within the hospital or for patients transferred from an outside hospital; ongoing treatment for patients while waiting for ICU bed availability; conducting or assisting in resuscitation of patients with cardiopulmonary arrest; performance of procedures such as central venous access, arterial line insertion, or endotracheal intubation; and discussing goals of care and end-of-life decision-making. The composition and responsibilities of a rapid

response or medical emergency team should be carefully planned and continuously evaluated to ensure goals for patient care and anticipated outcomes are achieved.

Summary

ICU organizational models are variable throughout the world. High-intensity staffing and closed ICU organizational models result in favorable outcomes including lower hospital mortality related to the use of evidence-based care and protocols and a multidisciplinary approach. The benefit of nighttime coverage by intensivists is mainly evident in low-intensity staffing models. The main obstacle to the high-intensity staffing model is availability of intensivists.

ICU Rounds

Clinical rounds in the ICU represent a planned activity where healthcare providers in the critical care setting review and discuss clinical information and develop and establish treatment plans for ICU patients using a multidisciplinary approach. Thus, they are called multidisciplinary or interdisciplinary rounds. Multidisciplinary rounds are usually defined as scheduled assemblies that are regularly conducted by healthcare providers from different specialties, clinical fields, or disciplines who are involved in the care of the same patients or the same clinical management unit in the hospital or institution [65]. Clinical rounds vary in type, structure, composition, time, and functions. Despite these variable elements, the main focus should remain patient-centered to provide high quality of care. In this section, we refer to clinical rounds in the ICU as multidisciplinary rounds, clinical rounds, or ICU rounds.

The Composition of the Multidisciplinary Team

The characteristics of the multidisciplinary team (such as size, the training and experience of the physicians and other healthcare providers, or the exact members comprising the team) may differ depending on the ICU organizational model for the hospital (academic vs community hospital), type of ICU (general vs specialty), or level of care (level 1 vs tertiary ICU). The multidisciplinary team includes an ICU physician or a primary physician (depending on the ICU organizational model), the bedside nurse, and at least one other healthcare provider such as a pharmacist or respiratory therapist. It is unclear what the optimal size of the multidisciplinary team is or specific characteristics of the multidisciplinary members that are associated with improved outcomes.

The 2015 guidelines from the Society of Critical Care Medicine recommend a devoted multidisciplinary ICU team led by an ICU physician (intensivist) to deliver effective care to critically ill patients [66]. The multidisciplinary clinical rounds in the ICU focus on collaborative team-based care. The multidisciplinary team may include, but is not limited to, physicians, advanced practice providers (nurse practitioners or physicians assistants), nursing staff, pharmacists, physical therapists, occupational therapists, respiratory therapists, case managers or social workers, palliative care clinicians, other healthcare providers, and patient and family members. In academic centers, multidisciplinary rounds include trainees rotating in the ICU. While some members of the rounding team may be present every day, other members may join rounds several times a week. During clinical rounds, the ICU multidisciplinary team addresses clinical information, various aspects of the clinical condition, and the overall plan of care for patients on daily basis [15, 33, 67]. This allows adequate exchange of information through direct and organized communication. Interaction among the multidisciplinary team members is shown to foster communication, coordination of care, and leadership qualities in the ICU that are significantly associated with deceased length of stay, improved family and staff satisfaction, and lower rates of preventable adverse events [68–71].

In addition to critical care physicians, other healthcare providers from different disciplines with complementary clinical skills and expertise are also essential for successful ICU rounds. The nursing staff role is extremely important as the bedside nurse spends the majority of working time caring for the patient; thus, she/he can provide valuable knowledge about the patient's medical condition and family dynamics and play a pivotal role in the management of critically ill patients [15, 72]. The role of the ICU pharmacists in assisting with pharmacotherapy, dosing, related potential adverse events, and overall management plan is crucial. Pharmacist participation in ICU rounds is associated with a significant reduction in the total number of preventable adverse drug events [69]. Studies have also shown improvements in infection control management, anticoagulation therapy, and sedation and analgesia utilization in ICUs with critical care pharmacists [73]. Advanced practice providers (APPs) may also assist in the treatment of ICU patients. The outcomes related to involvement of APPs in ICUs were at least equivalent to that provided by resident physicians [74]. The role of respiratory therapists in the ICU is paramount given the high percentage of patients requiring invasive or noninvasive mechanical ventilation [75, 76]. Nutrition assessment and recommendations from specialized dietitians have important value in caring for seriously ill patients [77]. Palliation and end-of-life care for ICU patients with different cultural backgrounds and beliefs is critical. Palliative care service participation in ICU rounds and throughout the ICU stay provides comprehensive care to patients and their families [78]. Involvement of a bioethics team can function as an additional key resource in cases with ethical dilemmas and end-of-life care [79]. The role of social workers and case managers is evident in ICU rounds to determine the appropriate disposition for patients ready for discharge from the ICU, facilitate communication between healthcare providers and patients and their families, and provide resources to patients and families [80, 81]. Family participation in ICU rounds to discuss the plan and goals of care, improve

collaboration, inform decision-making, and communicate wishes and concerns is important. The American College of Critical Care Medicine's guidelines describing evidence-based best practices for patient and family-centered care in the ICU recommend family participation in ICU rounds to improve bidirectional communication [82]. Other members of the ICU multidisciplinary team such as physical therapy and occupational therapy have effective roles for ICU patients to achieve mobility and engage in regular daily activities [83, 84].

Overall, it is apparent that all members of the multidisciplinary team can provide a critical and collaborative role during ICU rounds. This includes, but is not limited to, discussion, planning, and executions of the treatment strategy for ICU patients. Multidisciplinary rounds represent a key mechanism for communication and coordination of care among various specialties in the ICU [65].

The Structure and Organization of ICU Rounds

Clinical rounds in the ICU may vary from an informal and unstructured format led by a physician to a more structured and formal multidisciplinary rounds among the critical care team. Structured multidisciplinary rounds have been shown to have a positive impact on collaboration and teamwork for physicians and nurses [71, 85, 86]. One of the major components of high-quality critical care includes multidisciplinary rounds. Multidisciplinary rounds reduce the ICU length of stay [87] and mortality of critically ill patients [88].

In a large population-based retrospective cohort study, Kim et al. examined the effect of multidisciplinary daily rounds on 30-day mortality in 112 hospitals that included 107,324 patients [88]. The lowest odds of death were in ICUs with a high-intensity physician staffing model and multidisciplinary care teams (OR, 0.78; 95% CI, 0.68–0.89 [$P < 0.001$]), followed by ICUs with a low-intensity physician staffing model and multidisciplinary care teams (OR, 0.88; 95% CI, 0.79–0.97 [$P = 0.01$]), as compared with hospitals with a low-intensity physician staffing model but without multidisciplinary care teams. The results also emphasized the role of evidence-based treatment adopted by the multidisciplinary team in which protocols and guidelines were used to standardize care and the value of effective communication and collaboration among the multidisciplinary team members. In ICUs with a low-intensity staffing model, multidisciplinary rounds may still improve patient outcomes with significant mortality reductions achieved with a team-based approach. These findings provide an alternative solution to hospitals when there is a shortage of ICU specialists. The study also confirmed previous results that demonstrated the role of high-intensity staffing models in decreasing mortality.

Lane et al. conducted a systematic review to examine the evidence for facilitators and barriers to clinical rounds in the ICU [89]. The authors reviewed 43 articles that were mainly performed in academic adult medical ICUs in the United States. There was considerable variation in the structure and process of the clinical rounds with a duration of 5–15 minutes per patient. The review showed that 75% of ICU rounds

Table 1.2 Facilitators and barriers practices for ICU rounds

Facilitators	Barriers
Open collaborative discussion environment	Interruptions
Reduce nonessential time-wasting activities	Increased rounding time
Access to patient data	Nonstandardized structure
Discussion and documentation of goals	Allied healthcare provider perceptions of not being valued by medical doctors
Standardized rounds structure and process	Electronic health record use
Checklist use	Poor information retrieval and documentation
Pharmacist participating on rounds	Hierarchical healthcare provider structure
Multidisciplinary rounds	
Greater healthcare provider autonomy	
Explicit healthcare provider roles	
Visibility of healthcare provider	

Adapted from Lane et al. [89]

were performed daily, 84% by a multidisciplinary team, and 56% at bedside. The process mainly included reviewing a patient's medical history, course in the ICU, acute clinical status, and making a plan of care. The authors recognized 13 facilitators and 9 barriers for practices during ICU rounds as shown in Table 1.2.

The study concluded that rounds conducted using a standardized structure and best practices checklist by multidisciplinary team members with explicitly defined roles and a goal-oriented approach had the strongest impact. The main barriers during ICU rounds included long rounding time and interruptions during rounds [89]. In another study, interruptions and resource utilization were identified as the main barriers to task completion during ICU rounds [90]. Key recommendations to improve ICU rounds include structure and process modifications. The structure modifications include standardization of location, time, and composition of the ICU multidisciplinary team. A multidisciplinary ICU team, comprised of (at a minimum) an ICU physician, nurse, and pharmacist, promotes both effectiveness and safety of clinical rounds. An explicit definition of each healthcare provider's role in discussions aids in increasing patient-centeredness and facilitates more effective discussions [89]. Conflicting evidence exists about the location of ICU rounds with most studies in the review conducting ICU rounds at the bedside to increase the multidisciplinary team collaboration and patient-centeredness of the discussions. One study described longer rounding times and lesser communication at the bedside compared with discussions held in a conference room [91]. Conference room rounds yielded a reduction in interruptions and timeliness efficiency of ICU rounds and improved the quality of communication among the multidisciplinary team members.

The process modifications to ICU rounds may include building a goal-oriented discussion centered on patient care goals. Discussing and documenting goals in patient records improves effectiveness of communication among providers [67]. An open and collaborative environment facilitates increased healthcare provider participation, improved patient outcomes, and reduced costs to the healthcare system

[92]. There is an association between provider understanding of the daily treatment plan and goals of care with provider satisfaction, perception of quality communication, and adherence to practice guidelines. Justice et al. implemented a standardized rounding process, including documentation of patient daily goals at bedside or utilization of daily goals checklists, which showed improved understanding of daily goals by all ICU team members and improved family satisfaction in addition to improvement in goal-directed care [93].

There is evidence for implementing structured (including the use of a checklist) multidisciplinary ICU rounds, in a standard location, at a standard time, with explicit roles defined for each participating healthcare provider. Weaker evidence is available for identifying the ideal location for discussions or the value of open discussion environments [89]. Table 1.3 depicts evidence-based recommendations to improve ICU rounds as recommended by Lane et al.

In a cross-sectional survey of 111 Canadian adult medical and surgical ICUs, Holodinsky et al. examined ICU rounding practices and potential solutions for improvement [94]. The results showed that a variety of rounding practices existed with the majority reporting a multidisciplinary approach (81% of ICUs) in which 98% of ICU physicians, 94% of bedside nurses, 89% of respiratory therapists, and 85% of pharmacists regularly attended the ICU rounds. The study confirmed the positive role of collaboration and communication among the multidisciplinary team members and standardization of structure and process of ICU rounds including

Table 1.3 Practices to improve ICU rounds

Best practice	Strength of recommendation
Implement multidisciplinary rounds (including at least a physician, nurse, and pharmacist)	Strong – definitely do it
Standardize location, time, and team composition	Strong – definitely do it
Define explicit roles for each healthcare provider participating on rounds	Strong – definitely do it
Develop and implement a structured tool (best practices checklist)	Strong – definitely do it
Reduce nonessential time-wasting activities	Strong – definitely do it
Minimize unnecessary interruptions	Strong – definitely do it
Focus discussions on development of daily goals and document all discussed goals in the health record	Strong – definitely do it
Conduct discussions at bedside to promote patient-centeredness	Weak – probably do it
Conduct discussions in a conference room to promote efficiency and communication	Weak – probably do it
Establish an open collaborative discussion environment	Weak – probably do it
Ensure clear visibility between all healthcare providers	Weak – probably do it
Empower healthcare providers to promote a team-based approach to discussions	Weak – probably do it
Produce a visual presentation of patient information	No specific recommendation

Adapted from Lane et al. [89]

optimal location and identifying team members' roles and the negative role of interruptions during ICU rounds. The survey also found that 80% of rounding time was spent on patient care activities and 20% on teaching. Opportunities for teaching and learning for team members were reported as positive during ICU rounds. Teaching can be included in ICU rounds when it does not adversely affect patient care but rather enhances it. The ideal balance between patient care and teaching activities during ICU rounds is unknown and may depend on certain situations related to the urgency of the patient's clinical conditions.

In academic hospitals, the multidisciplinary ICU team often consists of trainees from multiple specialties with different levels of training and experience. Challenges for education are attributed to a combination of factors such as patients with life-threatening and unpredictable clinical conditions, variability in trainees' experience and their primary specialties, limitations in trainees' duty hours, competing responsibilities of ICU physicians, and factors related to achieving patient safety and optimal quality of care [95, 96]. In a survey study by Giri et al. exploring the objectives of multidisciplinary rounds in the ICU, 72% of the multidisciplinary team members identified developing a plan of care as the main purpose of rounds, while only 11% of the multidisciplinary team reported education as an important element of rounds (the least reported goal) [90]. ICU multidisciplinary rounds, if used effectively, can simultaneously improve the quality of care and enhance trainees' education [97].

Centofanti et al. conducted a mixed-method study using a qualitative and quantitative approach to evaluate the role of daily checklists during ICU rounds [98]. The results showed that the daily goals checklist improved communication among multidisciplinary providers and enhanced patient care by creating a structured, systematic, and comprehensive approach and fostered education of residents as it offered multipurpose teaching opportunities for ICU trainees.

Cao et al. performed a prospective unblinded, nonrandomized parallel study to evaluate the effects of patient-centered structured multidisciplinary bedside ICU rounds on rounding efficiency, provider satisfaction, and patient and family satisfaction [99]. Data were compared between 367 patient-centered structured multidisciplinary bedside ICU rounds and 298 nonstructured rounds. The results showed that family presence was significantly more likely in the structured multidisciplinary bedside ICU rounds. Total rounding and interruption times were significantly shorter in patient-centered structured ICU rounds with improved communication of the plan of care among team members. A significant increase in teaching occurred during patient-centered structured multidisciplinary bedside ICU rounds. The authors concluded that patient-centered structured multidisciplinary bedside ICU rounds increased ICU rounds efficiency, providers' satisfaction, and teaching.

Other components of high-quality critical care are effective team dynamics. Effective team dynamics rely on strong team leadership, effective communication among providers, and team structure [15, 100]. Attributes which defined positive team dynamics include safe work environments in which questions and concerns are addressed, errors are reported, and team members' skills and attributes are recognized to promote a team-oriented approach to patient care [101].

Summary

Multidisciplinary rounds in the ICU represent a key activity to achieve effective communication among critical care providers and collaboratively exchange clinical information, develop care plans, and make clinical decisions for critically ill patients. This process is optimally performed during a scheduled discussion among the multidisciplinary team members on a daily basis. Multidisciplinary clinical rounds in the ICU are associated with positive outcomes related to patients and healthcare providers.

A standardized and systematic approach to conduct multidisciplinary rounds in the ICU with explicit goals and defined roles is highly recommended. The rounds should be efficient, professional, interactive, and educational to provide value for patients, their families, and the multidisciplinary ICU team members. Since ICU rounds are a key tool for communication among providers, failures during this process may have a profound impact on the quality and safety of patient care.

Conclusion

The ICU functions as a complex adaptive system. In such an organizational system, improvement in performance and outcomes depends on improving the structures and processes of the system. The ICU organizational model is one component of this system. Factors that affect the organizational system of the ICU have been associated with improved outcomes including the model of ICU staffing (high-intensity staffing model being associated with positive outcomes), the process and quality of care delivered to critically ill patients such as a dedicated ICU physician-led multidisciplinary critical care team that provides collaborative high quality of care, and multidisciplinary patient and family-centered ICU rounds. Effective communication is especially important in complex healthcare settings such as the ICU. ICU multidisciplinary rounds are a key mechanism by which healthcare providers communicate and make patient care decisions collaboratively.

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Chapter 2
Planning and Budgeting

Ahmed Taha and Gloria Rodríguez-Vega

Introduction

Critical care planning and budgeting can be a daunting experience. The origin of health economics as a distinct discipline is often credited to Kenneth Arrow, who in 1963 outlined conceptual differences from general economics. He discussed the principle of Pareto optimal (Vilfredo Pareto (1848–1923)), which describes the state of optimal cost and benefit for a system. Conversely, when conditions are not Pareto optimal, it means that resources can be redistributed with marginal gains for some and without any personal losses. Market forces alone do not result in Pareto-optimal health conditions. The medical care industry exemplifies this tendency to intervene when it is out of balance [1]. More recently, the principle of Pareto optimal has been challenged as not modeling a desirable equilibrium in healthcare, but it is nonetheless conceptually useful for thinking about resource allocation [1].

Critical care medicine is one of the most expensive fields of medicine for patients, hospitals, and society. In 2005, the US critical care cost was $81.7 billion, accounting for 4.1% of national health expenditures and 1% of the gross domestic product. Critical care services are also expanding, with an increasing number of hospital beds allocated to intensive care, increasing number of patient-days spent in intensive care units (ICUs), and increasing occupancy rates. The growing costs and increasing use of resources have focused our attention on cost-effectiveness studies as a method for evaluating resource allocation, weighing the value of new interventions, while trying not to sacrifice quality of care and patient outcomes. Based on the current environment, it becomes evident the increasing importance of budget and planning for intensive care services [2, 3].

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Controlling ICU costs requires excellent interdisciplinary communication and optimization of resources while keeping patient outcomes [4].

Budget and planning are necessary activities that an intensive care team should undertake. Moreover, to be successful, the team must have a clear vision of the short-, mid-, and long-term plans for the ICU while continuously monitoring actual costs. It should determine the future direction of the unit through clear objectives, design, and planning strategies to achieve its goals. This step is important to help the physician-manager focus on outputs. That means that ICU activity should be directed to attain predefined objectives (or outputs). Decision-makers should develop priorities and make ultimate decisions on allocating available resources by measuring progress based on results according to the pre-established plan [4]. Outputs could refer to efficient patient care, leadership in teaching, and creating a "world-class" program in health services research.

A successful leader understands that adaptive change is critical to the success of the ICU team in order to achieve the required targets. Such changes can be continuously applied to the current plan to optimize the goals as a part of the dynamic nature of intensive care practice [4].

There are two types of planning according to the time frames: The first is the strategic plan, usually a 5-year plan, where long-term goals and objectives should be addressed. The second is the budget plan, which runs for short-term, usually developed on an annual basis to support the short-term goals [5].

Strategic Planning

Strategic planning is both externally and internally focused. Outcomes of strategic planning include the development of a vision, a mission statement, objectives, and policies and procedures. Strategic planning involves three steps, which are undertaken in sequence: a strategic assessment, formulating objectives, and making strategic choices.

A Strategic Assessment

A strategic assessment involves gathering information from several sources, compiling and evaluating this information, and making plans for the future. Also referred to as "an environmental analysis," this first step forces the manager to analyze and understand trends, both internal and external to the ICU. This analysis should also include elements that could adversely impact the ICU's future, for example, changes in reimbursement, variable staffing needs, and the introduction of new technologies. As a result of this environmental analysis, the ICU director could identify future opportunities. For example, changes in research funding opportunities through industry might cause the team to consider a strategy that emphasizes in the

recruitment of new staff with expertise in clinical trials, or the introduction of new technologies that require unique skill sets from the clinicians using these technologies might determine the need for time and resources for training of those professionals [5].

Formulating Objectives

After identifying strengths, weaknesses, opportunities, and threats, the ICU team should be able to create a mission and vision statement, followed by clear goals and objectives. These goals and objectives need to be specific, measurable, achievable, relevant, and timely to enable the team manager to prioritize the criteria for decision-making and work plans directed toward endpoints. Proper formulation of objectives gives ICU colleagues and co-workers a sense of direction that can create stability, which is particularly important to face the current economic climate [5].

Making Strategic Choices

The planning process in this step should be able to identify strategies that will lead to achieving the unit's objectives. Such plans require commitment of resources and identification of opportunities, determining the need for additional support to and from other departments, and place the goal in enhancing patient satisfaction, minimizing the time to access the service, and offering services or skills that can save further service consultations.

Budgeting

Budgeting is the numerical expression of planning, and it is a fundamental part of managing intensive care to optimize resource use in the short-, medium-, and long-term. Short-term budgeting focuses on planning operations, whereas medium- and long-term budgeting should have a strategic perspective. Budgeting estimates the needed resources mostly based on historical data and professional opinion [6].

The Budgeting Context for Intensive Care

Intensive care is regarded as a tremendous resource consumer with increasing demand for all aspects (personnel, treatment, equipment). A simplistic view sees the intensive care unit as a service that is difficult to deliver and requires significant

resources. Service-level agreements (SLAs) have moved healthcare purchasing from an agenda dominated by the detail of activity and finance to one where service standards are at the fore. Most SLAs or contracts do not separate critical care from other specialties; critical care is funded mostly as an overhead to these specialties' costs. This important conceptual point mirrors the way many non-intensivists view the service. Prospective payment system for hospitals, which is a form of reimbursement process, may not cover the cost of the intensive care component. Regardless of the funding system used to cover the cost, accurate and actual information is necessary to estimate the required resources to cover the cost or at least what can be done within the available resources [7, 8].

Characteristics of Intensive Care Budgeting

Salaries, pensions, and allowances paid to the staff make up most of the ICU's budget (up to 90% of direct costs). Drugs and materials are 10% or less of the total costs. As a result of this, cost containment must focus mainly on process control and optimal allocation of personnel. Cost containment dictates a culture of shared responsibility and mutual trust and requires transparency. Proper planning can enhance patient flow without compromising the quality of care and patient safety [9].

Unique services such as laboratory services, administration, radiology, housekeeping, and maintenance are considered indirect cost and exhaust about 40% of total costs. Multiple cost assignment methods exist including using time as a proxy or assigning cost items directly to the patient. Each has an element of cross-subsidization. Indirect costs can be managed in different ways, like allowing other production services to carry the risk or share the risks with the requesting units or creating an internal billing of service known as the internal market. Cost containment is possible without compromising outcome; strategies to enhance interdisciplinary collaboration and optimized resource allocation can include cross-subsidization which may reduce the effective cost of low-volume or expensive therapies by assigning part of these costs to the price of high-volume less expensive interventions [10].

Types of Budgets

Revenue

Revenue budget can be generated from patient care (through patients billing and governmental funding), education, and research. In a for-profit system, the price includes the profit; in governmental funded systems, the price can be distorted due to political policies, account policies, and cross-subsidization within the hospital.

As a rule, there is no fixed relation between the cost of service and the price charged for the service [9].

Operating Expenses

Operating expenses can include the direct cost of day-to-day operations (staffing, medications, interventions) and indirect costs by services provided by other departments. To determine the direct cost per patient, we can utilize the case mix index (CMI).

Case Mix Index (CMI)

Is a relative value assigned to a diagnosis-related group of patients in a medical care environment? The CMI value is used in determining the allocation of resources to treat the patients in a particular group. Resource use group patients are classified into groups having the same condition (based on main and secondary diagnosis, procedures, age), complexity (comorbidity), and needs. These groups are known as diagnosis-related groups (DRG), or resource utilization groups (RUG). Each DRG has a relative average value assigned to it that indicates the amount of resources required to treat patients in the group, as compared to all the other diagnosis-related groups within the system. The relative average value assigned to each group is its CMI.

The CMI value of a hospital can be used to adjust the average cost per patient (or per day) for a given hospital relative to the adjusted average cost for other hospitals by dividing the average cost per patient (or day) by the hospital's calculated CMI. The adjusted average cost per patient would reflect the charges reported for the types of cases treated in that year. If a hospital has a CMI greater than 1.00, their adjusted cost per patient or per day will be lower, and conversely if a hospital has a CMI less than 1.00, their adjusted cost will be higher. The CMI of a hospital reflects the diversity, the clinical complexity, and the use of resources for specific populations.

Intensive Care Costing Methodology and Efficiency

Several attempts have been made to measure the resources used in intensive care. However, as noted in a review by Gyldmark [10], comparisons between studies are difficult, as different studies have included different elements of resource use. In 1999, a London Audit Commission compiled a report, "Critical to Success," which revealed significant variations in intensive care practice and subsequently costs [11]. Resource data collected in a standardized manner is an essential component of modern practice. Approximately 50–60% of the total costs are direct costs. The majority

of these are related to personnel expense. Some costs are fixed and independent of activity level (e.g., cost of space), while others vary according to the volume and content of care. Staff costs are often considered as fixed costs; however, if staffing is adapted to the volume of patients, then some of the staff costs become variable [7].

Healthcare costs can be calculated by two methods: "top-down" and "bottom-up." According to the top-down method, the use of resources and costs are calculated retrospectively after a specific time, usually one financial year. The bottom-up approach means prospective data collection by resource use, and after a particular time, the cost is allocated to each individual resource use. The bottom-up approach is more time- consuming; however, it is more accurate than the top-down approach.

Several ways of grouping healthcare costs have been described. One is to separate direct costs (patient related) and indirect costs (unrelated to direct patient care). Direct costs comprise, for example, the cost of drugs, consumables, and radiology. Indirect costs include the personnel costs, heating, and admission costs. These are permanent costs and apply to intensive care units even if there are no patients on the unit. Another mode of cost reporting is the "cost block analysis." In this method, the cost is separated into six groups: (i) capital equipment, (ii) estate, (iii) nonclinical support, (iv) clinical support, (v) consumables, and (vi) personnel costs. Each group can be further divided into subgroups, which makes possible to perform a very detailed cost analysis. The first three groups comprise unrelated patient costs (indirect costs) [7] (Fig. 2.1).

Often, total intensive care costs are derived from the hospital budget and apportioned by the number of patients to produce an average cost per patient. While this

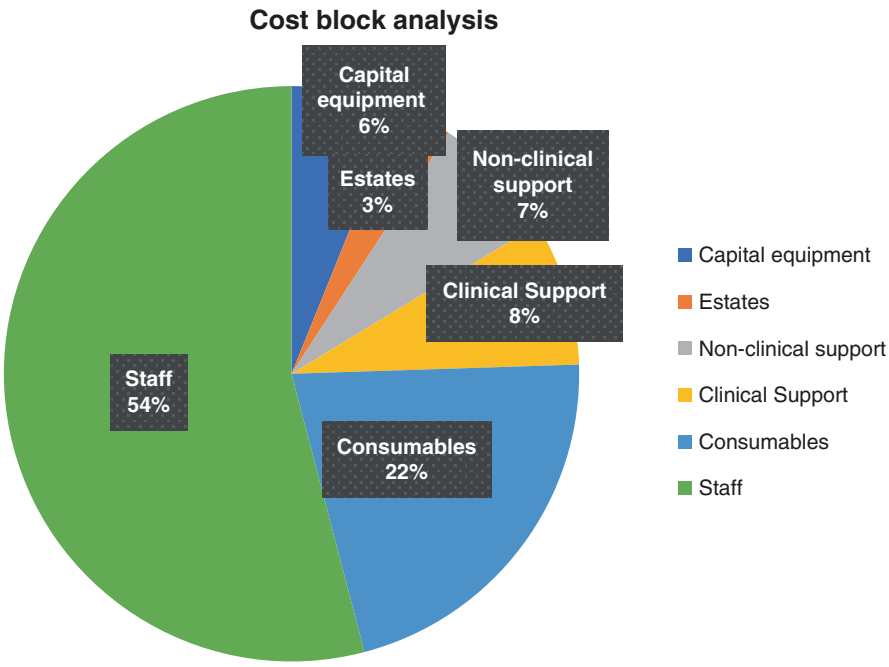

Fig. 2.1 Cost blocks, their elements, and proportion of costs [12]

approach avoids laborious costing of each patient, it is not capable of comparing the costs of individual patients or groups of patients as it assumes an equal amount of resource consumption per patient daily. The bottom-up approach necessitates the accurate, prospective measurement of resources at a unit level that is ascribed to individual patients [7, 11]. For example, delivering a medication would be costed by measuring the numbers of syringes used, the drug itself, and the amount of nursing time required to prepare and deliver the drug. Against these values, unit costs are assigned. While this approach facilitates the costing of individual patients and groups of patients, it is laborious, complicated, and expensive to operate. As a result, various hybrid-costing methodologies have been used in intensive care [10, 11].

Accurate and unbiased cross-country cost comparisons, even including alternative treatments, in which the costs and consequences of the treatments vary, are yet to be achieved. The ideal methodology would have the following characteristics: universally applicable; easily attained; accurate; stable over time; able to compare costs and resources, not charges; and capable to reflect purchasing power [13].

Defining patients according to a dependency measure attempts to overcome the assumption that resources are distributed evenly between patients in the "top-down" approach. A period of "bottom-up" calculation may be used to define the costs of the high-dependency patient assuming remaining costs are distributed among the intensive care patients [10, 11, 14].

There are two types of efficiency in health economics. The first is allocative efficiency, ensuring that the value derived from a service outweighs the costs of its production. The higher the value relative to cost, the more allocatively efficient the service becomes. The second type of efficiency is technical efficiency, which is concerned with maximizing the outcomes available with a given level of resources. The more outcomes that can be produced for a given budget, the more technically efficient is the service [15].

Allocative efficiency, for example, is concerned with determining what should be the budgetary allocation for critical care (budget setting) and which groups of patients should have access to critical care (case selection). Technical efficiency considers how a given budget can be used best to maximize delivery or how to minimize the cost of a service. Clinical governance and quality improvement projects in critical care mostly focus on the technical efficiency of service provision through performance improvement and cost containment at a local or regional level. Critical care admission practices could affect both local allocative efficiency and technical efficiency. It is possible for a service to be technically efficient while being allocatively inefficient [15].

Population Mix/Payers Mix

ICUs are occupied by different patient populations and vary according to national or regional demographics, hospital size and location, and healthcare-related delivery of care. Some systems primarily provide care in mixed medical-surgical ICUs, while other systems may favor specialized care units, such as cardiac, neurological, or trauma ICUs [16].

The inclusion or exclusion of certain types of patients from individual units, as well as varied beliefs regarding the appropriateness of intensive care for certain groups, such as patients with metastatic cancer, vegetative states, or the very elderly, may impact the targeted patient population within an individual ICU. In this regard, intensive care medicine is unique from other medical specialties in that there is no specific target organ system or pathology.

Consensus committees in many medical fields have found that standardization improves data collection and ensures comparability of patient data, such as in oncology and hematology [17–19]. Within the field of critical care, standardization of basic definitions may allow for more accurate comparisons. For example, the ability to conclude trends in mortality for patients with acute respiratory distress syndrome (ARDS) was facilitated by the adoption of a standard definition in 1993 [20]. The study determined that mortality had not changed, and this steady mortality across many studies was evident only after the adoption of the standardized definition [21]. The specialty of critical care medicine would benefit from the adoption of additional international definitions, particularly regarding the definition of an ICU bed and critical illness, to facilitate clear discussion and aid in appropriate comparisons across regions and countries.

Understanding the Need for Intensive Care Beds

With so much heterogeneity, what can be gained by examining intensive care across countries? Even accounting for possible discrepancies due to differences in definitions, ICU bed availability varies substantially worldwide, ranging from less than 1 to greater than 30 ICU beds per 100,000 people [22–29]. Despite this enormous variation, there is no consensus on the ideal number of ICU beds to serve a population [30]. Information on the relative impact of fewer or more ICU beds is essential information that can be gleaned by examining different systems. A comparison of medical admissions to ICUs in the USA and UK highlights the impact of different choices regarding bed availability on access to intensive care. For example, the comparison of data demonstrates that having more beds, such as in the USA, allowed for more patients to be transferred directly from the emergency room, rather than receiving care on a general ward first [31]. Further data from the UK, with very few ICU beds, suggested that their provision of intensive care was too low [32]. This was supported by a number of studies, demonstrating that many denials of ICU admission based on bed availability [33], as well as premature discharge from ICU [in a scarce ICU system] [34] associated with significant mortality, whereas reduced mortality was trended when more ICU beds were built throughout the country [32] (Fig. 2.2).

However, we must be cognizant of the fact that many factors may drive the applicable provision of, and therefore need for, intensive care. First, there are distinct differences in patient populations. Data comparing middle-aged Americans with a similar population in the UK demonstrated a higher burden of chronic illnesses among the American cohort—double the rate of diabetes and a third higher rate of

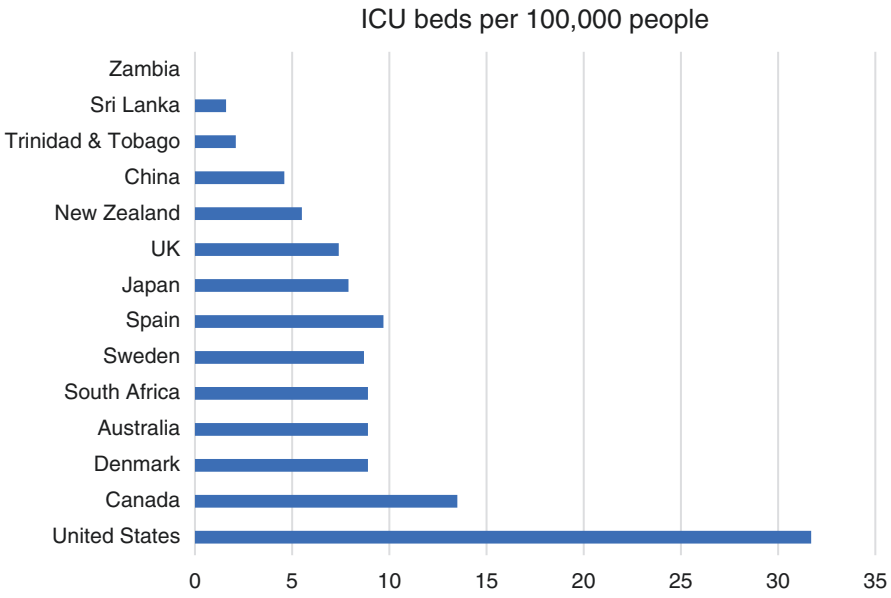

Fig. 2.2 Estimates are pooled from multiple sources and involve different definitions of ICU beds, and different years of data include all public and private expenditures, not limited to critical care [22–29]

hypertension [35]. Such comparisons are essential to understanding the relative healthcare needs of populations. Frequency of interventions and surgical procedures may also impact the need for intensive care. For example, patients who receive a liver transplant will require a stay in an ICU. This need for intensive care is, therefore, driven not solely by disease but also by management choices [36]. An older study comparing admissions to intensive care in Alberta (Canada) and western Massachusetts (USA) found that ICU days per million population were two to three times higher in western Massachusetts, primarily due to a higher ICU bed incidence (i.e., percent of hospitalized patients treated in the ICU) [37].

Outcomes with Intensive Care

Despite the a priori idea that ICU care improves patient outcomes, studies empirically supporting this idea are ethically challenging to design. Therefore, comparisons across systems and cultures where different choices are made regarding "appropriate" use of intensive care are helpful. Data from multiple countries with relatively limited number of ICU beds suggest that ICU bed availability can affect patient mortality. The critical difference in these studies is that they examine not just the patients who received intensive care but also those who were deteriorating in

some way and did not receive the higher level of care, thus avoiding selection bias. For example, Robert et al. studied 1762 French patients referred for ICU admission and found mortality was higher in patients who refused admission secondary to bed shortage (33.3% vs. 27.2%, $p = 0.06$ at 60 days) [38]. The study also found a significantly higher mortality rate in those patients admitted to ICU after subsequent referral compared to patients who had been admitted directly. In an observational study of patients admitted to ICU versus general ward (in the setting of bed scarcity), mortality was lower in those for whom early intensive care was available [39], which was confirmed in a follow-up study across the European Union [40]. Other studies have not demonstrated a direct correlation between ICU bed availability and mortality but have shown that bed scarcity contributes to a decreased likelihood of ICU admission and alterations in care choices, such as increasing the likelihood of the decision to withhold or withdraw care [41]. It is notable that these studies were carried out mostly in countries with relatively low provision of intensive care (and not in the USA, where pockets of under-provision of intensive care occur but where overall provision is very high in comparison with most of the world) [28].

Decreasing the Cost of Care

Healthcare expenditure accounts for a large percentage of the gross domestic product (GDP) in most countries, and critical care expenditures alone now account for almost 1% of the US GDP [12]. Population studies suggest that critical care demand is growing almost exponentially as the population ages [42]. This is especially true in developed countries that can provide organ transplants, cardiovascular surgery, and chemotherapy for cancer. These interventions increase both lifespan and morbidity, further increasing the need for critical care [24]. Despite these trends, there is limited research on ways to decrease the costs of critical care.

Increasing per capita healthcare expenditure is associated with increased delivery of critical care, demonstrating that the economics of critical care resources and delivery are at least partially shaped at the national level [28]. In order to begin to decrease costs, delivery of critical care must minimize both fixed and variable costs. The fixed costs of critical care include staff salaries and equipment (e.g., beds). Variable costs include treatments, provision of studies, and invasive equipment (e.g., ventilators, catheters). Many questions can only be addressed by looking beyond small regions to gain information from models other than what is currently in place in a given location. Like any business, a for-profit hospital cannot survive unless costs are lower than charges. The payer is usually the commercial insurance industry whose primary responsibility is to their shareholders. In this model, the intensive care manager focuses his/her efforts on maximizing the unit's revenue and minimizing its costs.

In a not-for-profit organization, revenue that exceeds costs is reinvested to support growth and development. Not-for-profit hospitals receive operating funds from two sources—consumers and philanthropy. In this situation, the intensive care

manager needs to ensure that costs are lower than revenue income (which is approved by the hospital's senior management team during the annual budget building process) [12].

In hospitals funded by the government, the intensive care manager needs to ensure providing care is accomplished within a predefined budget. In some government-funded systems, maintaining efficiency leads to reinvestment for growth and development. Some organizations limit access to intensive care by limiting the number of funded beds (implicit rationing) with a fixed budget for a financial year irrespective of demand changes. Others have increased intensive care capacity on the back of activity-based funding systems where additional capacity provides additional income to increase intensive care budgets [12].

Each service within the hospital may be a "cost center" or a "profit (revenue) center." Cost centers typically produce services that are not directly charged to third-party payers, e.g., housekeeping. Some clinical services, e.g., radiology and laboratory, can be regarded as cost centers. The profit centers (e.g., surgical departments) have their costs attributed in charges to third-party payers directly, and their charges also include the costs of the cost centers. Critical care can function either as a cost center, trading internally, or a profit center charging third-party payers directly, or as a mix of the two. In the latter case, some are charged directly, e.g., patients admitted primarily for critical care and discharged directly to other institutions [12, 43].

Return on Investment

There are two basic approaches in return on investment (ROI) in intensive care, namely, increasing the revenue of the operation or reducing the cost per production item. The application of these approaches in intensive care is different when compared to other industries.

There are several ways to increase the revenue from the operation into which the investment was made. This could be done either by expanding the market, taking a market share from competitors, or improving the quality of the product offered.

The fundamental approach is to reduce the cost per service item which could be achieved by a reduction of resource consumption, by an increase in the number of procedures done with the same resource, and finally by a decrease in complications for the delivered service item. This last approach could be the most applicable in intensive care since it is a complex and expensive resource-consuming environment that could potentially generate an increased length of stay, therefore requiring further procedures and compensation for malpractice claims. Thus, a small reduction in the complication rate may have a significant effect on the cost-effectiveness of intensive care financial operation. Improvements in the quality of care will typically lead to better profitability [44, 45].

In terms of intensive care cost, reduction and cost-effectiveness can be addressed without changing operational medical processes. This can be achieved by decreasing

the costs of drugs or ancillary devices. This approach carries only limited risk. However, it typically yields only limited benefits, and the effect may not be sustainable over more extended periods. However, productive investment can be used to change the entire process of care. Some examples include electronic physician order entry systems, clinical pathways, clinical decision support systems, evidence-based practice guidelines, and telemedicine. These processes may reduce complications and medical errors or help to sort out additional services [46–48]. However, they lead to complicated changes in the processes of healthcare delivery and require the commitment of all healthcare professionals involved. Therefore, the actual ROI in these cases is difficult to anticipate, although many clinical studies have shown that they can have the most significant impact on cost-effectiveness [49–52]. In other words, changing the process of care carries considerable risk but may also lead to a significant ROI that may be sustainable over time.

In addition, it needs to be determined whether the reduction in staff workload can also translate into immediate cost savings. It may not always be possible to close beds or lay off staff after the changes have been implemented.

Practical steps of an ROI analysis from the perspective of an intensive care point of view can be summarized in Fig. 2.3.

Analysis of the cost structure, handling both variable and fixed costs, should be identified and measured. This may be impossible in many institutions, because the necessary cost accounting methodologies may not be in place. Ideally, activity-based costing does not only provide a detailed cost structure of the entire process of care but may help in improving cost-effectiveness [53].

It is essential to check whether the anticipated changes will happen. Many of the anticipated changes depend on the commitment of the healthcare professionals affected by the changes. If the expectations toward the changes are unrealistic, or changes do not materialize due to lack of commitment, the complete ROI analysis may fall apart. This is the reason why any project involving changes in processes of

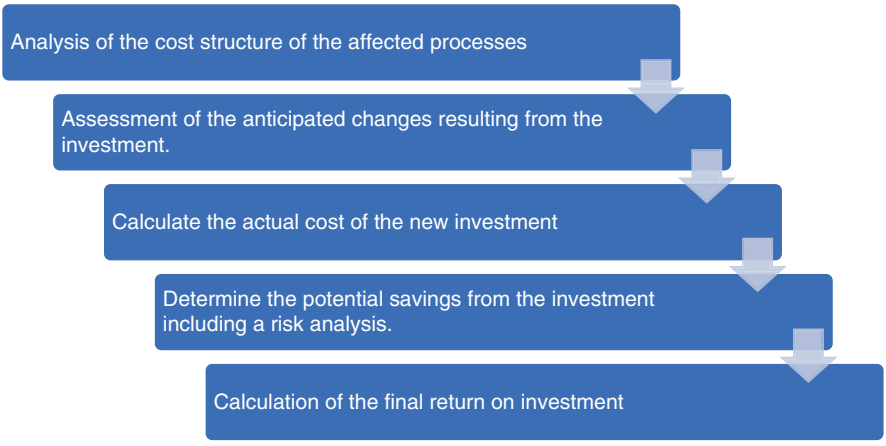

Fig. 2.3 Intensive care perspective of practical steps of an ROI analysis [53]

care should have clinical champions, respected and well-accepted leaders that would carry forward the implementation of the changes.

Calculating the return on investment is the final step of our analysis. If the first four steps lead to precise results, then this final phase is relatively easy. At this step, we must calculate the sum of all direct and indirect savings and subtract all investment costs and running costs over a defined time. This is also the last opportunity to check again for uncertainties and errors in the previous analyses, especially for hidden cost. The result of our calculations will be the return on investment. Specific methodology of probabilistic modeling can be used in ROI analyses in healthcare [54].

Tele-ICU as a Key Element of Achieving ROI

The introduction of the tele-ICU, or Tele-Critical Care, has proven to be efficient in intensive care units (ICUs) nationwide, beginning with saving lives, decreasing infection rates, reducing the length of stay (LOS), and decreasing ventilator duration. Kumar et al. (2013) examined patients who received care at an ICU with eICU technology and reported that these patients were:

- 26% more likely to survive the ICU.
- 20% earlier discharged from the ICU.
- 16% survive hospitalization and are being discharged.
- 15% faster discharged from the hospital [55].

Tele-ICU delivers significant operational benefits, such as improved protocol compliance and reduced care costs. This benefit remotely provides patient data and adds analytical data that is often more extensive than those available within the hospital; the data analysis enabled through the tele-ICU technology provides the basis for ongoing clinical and operational process improvement [56].

The ROI of a tele-ICU program has consistently ranged from 3:1 to 6:1 across a range of implementations. Several areas of attention are critical to achieving the desired goals. Successful tele-ICU programs are dependent on expert staffing, clear process development, and close collaboration between the hospital and tele-ICU partner [55].

The remote clinician can deal with staff, as well as observe patient's physical characteristics while integrating the team and the patients and their families enabling a range of routine hospital workflows [55].

The remote care team has access to patient information avoiding reliance on a single geographic talent pool. This has been reportedly translated into a reduction in mortality rates, in-hospital infection, and shorter length of stay [55].

Another example of the potential for significant improvement in operational and clinical outcomes arises when tele-intensivists assist on weaning from mechanical ventilation. Tele-ICU teams can work with bedside staff and respiratory therapists to extubate the patients, eliminating additional ventilation days [55].

Tele-ICU implementation resulted in increased ability to attract and treat higher acuity patients, better ICU bed utilization, and improvements in case mix index (CMI). Tele-ICU in the era of simultaneously addressing the shortage of intensivists and reducing ICU costs deserves, without any question, a special seat on the administrative budget tools [55].

Cost-Effectiveness Analysis

Cost-effectiveness analysis is the current dominant methodology for healthcare cost and outcome evaluation. One metric from a cost-effectiveness analysis is the incremental cost-effectiveness ratio—the ratio of the net change in costs to the net change in effects associated with two different programs or therapies. The denominator represents the gain in health (e.g., life years gained, number of additional survivors, cases of disease averted), while the numerator reflects the marginal cost in dollars. As the units are different for the numerator and denominator, the expression will take the form of cost per unit of benefit (e.g., dollars per life years gained, dollars per additional survivor, dollars per cases of disease averted). Alternatively, the ratio of cost to outcome can be reported for individual therapy, rather than in comparison to another therapy (this is known only as of the cost-effectiveness ratio).

After calculating the incremental cost-effectiveness ratio, it remains an entirely separate and subjective decision whether that therapy or program is deemed cost-effective. That determination is based on a spending threshold—the amount that society is willing to pay overall for a given outcome. For many years, this threshold was held as $50,000, derived from an argument made in the early 1980s–1990s that renal dialysis is cost-effective, renal dialysis costs $50,000 per quality-adjusted life year saved, and, therefore, $50,000 is cost-effective. Some experts challenge this threshold, but there is a consensus that a level somewhere between $50,000 and $100,000 per year of life gained is acceptable in the USA today. Therefore, a new therapy with an incremental cost-effectiveness ratio of $82,000 per year of life gained would be viewed as cost-effective [1, 3].

To create these ratios, a typical cost-effectiveness analysis requires collecting a significant amount of information on costs and effects for both standard care and the new intervention, often from varying sources. Assimilating this information may be difficult, requiring a decision analysis model to show critical clinical decisions and outcomes. These models are represented by trees, where each branch has a probability of occurrence and a cost. At its simplest, the tree will contain only branches for treatment allocation (e.g., inhaled nitric oxide or standard therapy) and outcome (e.g., alive or dead). To calibrate the tree, we need to know the probability of living or dying, based on each therapy, and the average cost of care for survivors and non-survivors in the two treatment arms.

We could expand this model to include other elements that affect morbidity and cost, such as extracorporeal membrane oxygenation (ECMO) use or sequelae other than death. The new therapy, while expensive alone, may offset its own expense

with a reduced need for other supportive care and may, therefore, be comparatively more cost-effective than standard therapy. This stands in contrast to the cost-benefit analysis, where downstream effects are not accounted for. As additional elements are incorporated in the decision analysis model, new branches must be added to the tree. For each branch, we must know a patient's likelihood of entering the arm and the average costs. Indeed, this is how inhaled nitric oxide for neonates with respiratory failure was shown to be a dominant strategy—through a substantial reduction in the need for the even more expensive ECMO therapy and reduced incidence of patient-centered outcomes such as chronic lung disease [57].

Cost-utility analysis is a case of a cost-effectiveness analysis where the effects are converted into standard units of utility. Typically, this approach involves adjusting the number of years of survival for the "quality" of that survival. A person living for one year with a quality-of-life score of 80% would be "awarded" 0.8 years of quality-adjusted survival. The advantage of this approach is that it allows comparison of different interventions for different diseases through a standard metric (e.g., inhaled nitric oxide can be directly compared to a hepatitis B vaccination program for newborns, via quality-adjusted life years) [57, 58].

Training for Staff, Fellows, and Residents

The dynamic nature of the ICU carries many challenges in planning and budgeting training for fellows and residents. One of the most concerning challenges is when the number of learners exceeds the capacity of the trainers and training sites. Although this may be perceived as a challenge confined to academic health science centers, it affects every hospital and critical care site because critical care staffs predictably have a high turnover. There is a need, even with the most experienced professional joining a new hospital or ICU, to ensure that the new hire knows the scope of practice, is familiar with the local emergency procedures, and achieves minimal competency with the electronic medical record. All of this takes professional time, and it is rarely (if ever) accounted for in the budget. The administrator is therefore required to verify training assignments while ensuring that patient care needs are met. This invariably requires prioritization of needs, balancing most requests, and declining requests when they would cause hardship to the unit or danger to the patients.

The challenge can emerge in several forms, most often surfacing after an adverse outcome or a complaint about professional behavior. Often, the root of the problem can be traced to the failure to transition from a "parallel play" to a "team effort" mindset. The challenge, then, is to create educational experiences that catalyze the transition. One approach involves shared educational experiences, such as setting requirements that all staff must train toward specific certificates (e.g., Fundamental Critical Care Support, Advanced Cardiac Life Support). Another approach involves simulation of common emergencies at a simulation center or within the ICU. Another approach involves multi-professional educational conferences, including morbidity and mortality [59].

Continuing education is required of all professions and professionals who practice in the ICU to maintain licensure and credentialing. Although this requirement might seem a challenge for the professional more than the administrator, failure to plan for continuing education incurs in substantial cost. Some requirements are intramural, such as completion of annual infection prevention education. Staff members who fail to complete the intramural education are summarily suspended. Other requirements are extramural, including a set number of hours of continuing education to maintain licensure. In the absence of planning to meet the licensing requirements, there is typically a hurried effort to gain credits. There may even be a temporary lapse of privileges (and the need for expensive replacement staff) while necessary continuing education credits are acquired. Such problems are best prevented by planned intramural continuing education appropriate to many of the critical care professions complemented by planned attendance at regional and national professional meetings [60].

As noted above, administrative costs consist of the costs of program staff to coordinate recruitment, orientation, schedules, curriculum administration, and documentation of evaluations, as well as recruitment costs, costs of educational materials, and rental of office space. These costs can be readily identified in the departmental budget and are determined by local circumstances.

Fellowship Training Requirements

The Residency Review Committee of the University of Pittsburgh School of Medicine, mandates that fellowship-training programs provide 0.2 faculty full-time equivalent (FTE) for each 1.5 fellow FTE within the hospital plus a program director at 20% effort to administer the fellowship (rules state one faculty member at 10 hours per week for each 1.5 fellow trainee) [59]. In addition, each fellowship director spends 20 hours per week on the program. For example, a fellowship program with 6 fellow-FTEs at the hospital would require 0.8 FTE of time of a faculty member in the subspecialty of the fellowship as well as an additional 0.2 FTE to provide for the program director, which must devote at least 20 hours per week total to the program [59].

The regulations governing fellowships stipulate that fellowship directors have a certain degree of experience beyond their initial training, particularly 5 years prior experience as a fellowship faculty member. Because fellowship directors perform a high proportion of the teaching, it is reasonable to assume that the faculty FTE necessary to teach the fellows will be made up of individuals who have at least the level of experience in the subspecialty that the fellowship directors have. On this basis, the FTE necessary for training will need to be reimbursed to the department using an income level at the median level for the subspecialty of the fellowship, using either national or local guidelines for academic physicians. The cost for this faculty time includes salary, fringe benefits, and overheads [60, 61].

Interprofessional Education (IPE) Approach

Critical care education represents an amalgam of learners from various medical and surgical training specialties as well as nursing, pharmacy, respiratory therapy, and other professional disciplines. The educational program must break down traditional training "silos" and seek to create a shared identity among trainees as part of the critical care team. This integrated approach helps create a versatile workforce in critical care where trainees acquire the strengths and employ the best practices of a wide range of professional backgrounds. It is essential that the multidisciplinary nature of critical care be reflected in both clinical and didactic aspects of the critical care education program.

Integration of educational programs centers on the establishment of a culture of interprofessional training. Learners trained using an interprofessional education (IPE) approach are more likely to become collaborative and respectful team members who work toward improving patient outcomes [59]. Trainees should share clinical rotations and didactic training. The clinical environment must support the notion that the different training backgrounds of critical care team members are equally vital to patient care and that differences in expertise should be considered a teaching opportunity. Didactic experiences may be integrated by selecting high yield topics from education consensus statements and program requirements and then leveraging online learning management systems to deliver didactic material in a learner-controlled manner. Subsequent pairing of online content delivery with interactive in-class team experiences such as high-fidelity simulation may help learners to better retain and consolidate critical care knowledge while reinforcing the IPE culture [59].

There are multiple threats to the internal and external validation of cost-effectiveness research in the education of healthcare professionals. There are multiple models, based on current health economics theory and existing cost-effectiveness studies that can guide educators, administrators, and decision-makers in choosing and prioritizing training strategies. Providing evidence of cost-effectiveness in future experimental medical education trials may bridge the gap between best practice and actual practice.

Administrators are thereby enabled to prioritize training interventions based on cost-effectiveness evidence rather than effectiveness evidence alone. However, this requires cost estimates to be reported in future effectiveness studies.

Professional Development Program

Professional development represents a long-term process of academic maturation that is essential to sustaining a pool of local expertise that supports each mission of the critical care organization. In addition, there is a need to produce leaders with the political and administrative skill sets required to lead the organization into the

future. Critical care professional development programs must help faculty and trainees identify and pursue a desired career pathway, find robust mentorship, and acquire an understanding of a broad range of professional skills that will enhance their leadership abilities [62].

Many critical care trainees perceive the support to help them achieve their career goals as inadequate. Organizations must develop a structured way of helping its members cultivate a career pathway. Academic medical centers have developed tracks for faculty advancement and promotion, and this strategy may also work for training programs. Additionally, a robust mentorship program using an interprofessional pool of mentors is needed. Such mentorship has been shown to enhance professional success and improve overall career satisfaction [63].

An additional important aspect of professional development is helping members to establish basic leadership and professional skills and a broad-based fund of knowledge of the other academic missions of the critical care organization, including teaching, business, work/life balance, and scholarly writing skills that critical care team members require [60, 61]. A recent study featuring a seminar-style curriculum established topics needed for broad-based professional development and suggested that this type of curriculum may help develop professional skills that are durable over time [61].

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Chapter 3
Setting the Goals

Mary Jane Reed and A. Joseph Layon

Introduction

It is not news to anyone working in healthcare that medicine today – everything from the model of care delivery to financing – is in turmoil. While we in the USA have the most costly healthcare system in the world, increasing costs of healthcare are an obstacle to access to medical care not only in the USA but also in the rest of the world. In the USA, we have not been able to solve problems as universal access or standardization of care. There is no easy fix for all these problems, but we healthcare workers must collaborate with political leaders to find solutions. This is critical because – despite the advent of the Affordable Care Act – a large portion of our population remains unable to properly access healthcare and, further, nationally we have some of the worst outcome metrics in the industrialized world.

The task at hand – which we undertake with joy – is to lay out how, in the extant quasi-healthcare system, intensivists might function to provide high-quality, safe, and efficient care to those who present themselves to us. Below we outline both the medical staff and the institutional requirements to make this happen.

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Medical Staff Needs

How do we determine the best way to organize critical care medicine (CCM) services? Specialty units? Open versus closed versus hybrid units? Staffed by "all-comer" intensivists or specialty specific clinicians? How are the shifts managed? Do we work in shifts at all? How are nights covered? What is the "optimal" – or safe – patient load for a CCM team? How are the finances handled? Let us attempt to tackle all of these questions.

The ICU: What Type of Unit and Who Staffs It?

Are specialty units of any significance? There is a small literature on this issue. It appears that, in general, medical-surgical units are as good as split specialty units with a couple of exceptions. While, for example, there are many branch points in the development of medicine as we know it, with a new specialty branching or budding from an older one, there are not always data suggesting that this alteration in structure is beneficial to our patients. However, in the context of our ICUs, there are both quality and operational-efficiency rational to alter this structure that has stood for many years.

As regards neurocritical and trauma critical care differentiation, data suggest strongly that differentiated units and subspecialist intensivists improve outcomes as compared to treatment in a general ICU [1, 2]. Markandaya and colleagues [1] reviewed a relatively robust literature suggesting the care provided in a neurocritical care unit (NCCU) resulted in improved outcome and decreased mortality in selected disorders – as compared to a general ICU – as well as decreased length of stay and complications, and an increased proportion of patients discharged home or to a rehabilitation center [3–7].

Mirsky et al. [3], in a before-after design looking at a single disorder, nontraumatic intracranial hemorrhage, ICD-9431, found that patients cared for in the NCCU by neurointensivists had decreased mortality (36% versus 19%, $p < 0.05$) and improved outcome – defined as discharge to home or a rehabilitation facility – 48% versus 69% ($p < 0.05$). It appeared that more invasive and aggressive neurointerventions impacted this improved outcome. Costs and length of stay, compared to a national database (not the before-after groups that made up the main components of the study), were statistically significantly lower in the NCCU patients – LOS decreased by 24% to 45% and costs by 11% to 29%. Finally, in this study, there were significantly fewer consultations for patients cared for in the NCCU than for patients cared for with the same ICD-9 diagnosis in the MICU or SICU (SICU 3.4 ± 0.7; MICU 2.8 ± 1.1; NCCU 0.4 ± 0.5, $p < 0.05$).

Diringer and Edwards [4], in a study looking at outcomes of intracranial hemorrhage patients cared for in general ICUs versus NCCUs, found similar results, with

the odds ratio for the risk of hospital mortality being 3.43 when care for these patients occurred in a general ICU.

Studies from the mid-1990s [5, 6] suggested that the implementation of a stroke program – akin to the clustering of neurocritical care resources – led to a decrease in length of stay, morbidity, and hospital charges. The presence of a neurointensivist-led team in the NCCU also led to a decrease in morbidity, mortality, and length of stay.

Varelas et al. [7] – in a somewhat flawed before-after study in which the baseline demographics showed significant differences – noted that the addition of a neurointensivist significantly decreased early (first 3 days) mortality, NCCU and hospital length of stay, and total hospital mortality for those patients who stayed in the NCCU for less than or equal to 3 days.

Similarly, Suarez et al. [8] found a statistically significant decrease of 30% in mortality and 14% to 18% in length of stay (NCCU and hospital, respectively) with the introduction of a neurocritical care team that coordinated all care.

A prospective UK series [9] involving evaluation of outcomes in patients having suffered traumatic brain injury (TBI) found that patients cared for in a NCCU – as opposed to a combined neurocritical/general critical care unit – had similar mortality and improved quality of life with somewhat increased costs. When patients were evaluated based upon early transfer to a neuroscience center versus no – or late – transfer, early transfer was associated with lower mortality (OR 0.52) and higher quality of life for survivors, although at a expense of an excess £15,000 compared to late or no transfer.

Is the improvement in outcome noted in the NCCU a result of the unit and its nurses; or is it the team; or is the combination? In a retrospective study of 400 patients in a before-and-after model, Bershad et al. [10] noted that the addition of a neurointensivist-led team resulted in improvements in outcome of patients suffering from acute ischemic stroke. LOS in the NCCU was significantly reduced (2.9 ± 2.0 versus 3.7 ± 2.9 days, $p < 0.01$), as happened with hospital LOS (7.5 ± 4.7 versus 9.9 ± 7.6 days, $p < 0.01$). The proportion of home discharges was increased in the neurointensivist-led team (47% versus 36%, $p < 0.05$). There was, however, no difference in either in-hospital (13.3% versus 15.3%) or 1 year (43% versus 47%) death rates. Specialized nursing skills may also have an impact on improved outcomes in the NCCU.

Specialty trauma units also appear to be important for improving outcomes in trauma patients. Bukur and colleagues [2] retrospectively studied 3833 trauma patients over a 5-year period in two state-verified level I trauma centers in South Florida. One of the trauma centers had a dedicated trauma ICU, and the second had a mixed medical-surgical ICU; ICU team structure was similar between the two centers. The primary end points of investigation included in-hospital mortality, complications that occurred in the ICU, and failure to rescue (FTR), defined as death after a major in-hospital complication. Post-injury complications analyzed included acute respiratory failure, pneumonia, acute renal failure, deep vein thrombosis, and pulmonary embolism and were defined in accordance to the National

Trauma Data Bank Data Standard Dictionary. The secondary study outcomes included hospital LOS, ICU LOS, and ventilator-free days. Analysis of the results showed that trauma patients cared for in a dedicated trauma ICU had lower incidence of post-injury complications (17.0% versus 27.5%, $p < 0.001$), FTR (1.8% versus 3.7%, $p < 0.001$), and in-hospital mortality (2.9% versus 5.4%, $p < 0.001$). The incidence of specific post-injury complications – post-injury acute respiratory failure (19.0% versus 11.0%, $p < 0.001$), pneumonia (5.9% versus 4.0%, $p = 0.003$), and acute renal failure (7.8% versus 2.2%, $p < 0.001$) – were all less likely to occur after admission to the dedicated trauma ICU.

The initiation of differentiated – medical, surgical, neuroscience, and trauma – ICUs leads to outcomes that are significantly better than undifferentiated ICUs. While this effect is primarily seen in the NCCU, it is also noted in the trauma population [2]; in the medical and surgical ICUs, the IPS standard appears to be of primary significance. To summarize, data on the intensive physician staffing (IPS) model, with one exception [11],[1] suggests that the IPS model leads to improved outcomes and decreased costs. The one database analysis [11] attempting to refute these findings could not explain the significantly higher hospital to hospital transfer rate in general ICUs as compared to specialty ICUs noted in their data nor determine whether intensivists were involved in the care of critically ill patients. Lott and colleagues [12], in a retrospective cohort study, could find no mortality improvement in specialty versus non-specialty specific units; other outcomes were not evaluated. Risk-adjusted mortality was higher in what the investigators termed *nonideal specialty units*. They challenged the above assumptions that specialty units will improve care.

Staffing (Continued) and Organization

In an integrated healthcare delivery system, while preventive and primary care services retain central importance, CCM services are a critical component in multiple contexts, certainly regarding the delivered quality of care and resource utilization. In the best-integrated system, prevention will fail, motor vehicular crashes, and penetrating injuries will occur, and neurologic injuries will manifest. In these cases, the ability of the CCM service to provide high-quality, patient- and family-centered, reproducible care is significant. If quality and patient centeredness are to be more than declarative statements, the manner in which such services are organized and delivered deserves comment.

Firstly, given the tendency in our health system to reward silo-based behavior, there must be real support by institutional administration for integrated CCM services. While we have begun this journey, it is clear that our histories and biases have

[1] Retrospective analysis of the SCCMs Project IMPACT national database. This had significant limitations, perhaps the most significant on being that it was not always possible to determine whether patients had been cared for by intensivists or not (Reference # 12, page 808).

not been overcome. In many institutions, CCM is still viewed as an ancillary service, belonging to – depending upon the audience – medicine, surgery, or anesthesiology. This flies in the face of all evidence and is a recipe for mediocrity. Critical care medicine is a multidisciplinary specialty in its own right and needs be treated as such if there is a desire for excellence.

Secondly, while, as much as possible, decisions must be data- and consensus-driven, and transparent, decisions must be made. All involved in CCM meetings – whether system-wide for multihospital systems or local for smaller institutions – will have the opportunity to take part in the meetings and decisions; however, nonparticipation is unacceptable as it jeopardizes the development of consensus, impedes progress, and prevents execution.[2] While, given the heavy investment in information technology at most institutions, one might think that communication and involvement are the least worrisome issues we face, the extent of nonparticipation suggests that this is an incorrect assumption.

Thirdly, an item that should exist in any CCM standards is that, in the ICUs, care is provided by intensivists and orders are written only by intensivists, as suggested by the Leapfrog Group. In the *open model* of ICU care, a physician may admit a patient to the unit and provide all the care themselves; if they desire, they may place a consult for an intensivist or any other specialist, but this is not required. The *closed model* of ICU care results in all admitted patients being cleared through the ICU physician and transferred to the intensivist service. Many of our ICUs are not closed as regards admissions/discharges or order writing, even though there is movement toward this goal. A hybrid model – the *collaborative care model* – ensures that the patient's admitting service remains a key member of the care team and is welcome on rounds and in all other forums, yet care and orders are provided by the CCM team. This is the model most closely approximating ideal in our mind.

Fourthly, everything related to critical care medicine – administrative, clinical, education, and discovery – should be housed in critical care medicine, whether CCM is a department, a service line, an institute, or any other administrative construct. CCM leadership must be held accountable for quality and financial metrics; but responsibility without authority is a recipe for failure and frustration. The CCM leadership – with authority and responsibility – will have no problem being held accountable for the development/management of the units, clinical care, educational and research programs, and development of the junior faculty.

What "flavor" of intensivists should be sought? We have trained and recruited intensivists whose primary specialties were internal medicine, anesthesiology,

[2] For example, over an approximate 8- to 12-month period, the Department of Critical Care Medicine developed Service Line Standards. These were distributed and discussed over 3 months at our system-wide CCM meetings. In January 2014, they were formally approved by our multicampus and multi- and interdisciplinary committee and sent to MLC for approval. Those not taking part in the multi-month process when they were asked for input cannot be allowed to holdup the process of implementation. ICU standards were ultimately put into effect but were, indeed, held up for almost 12 months by individuals who had not taken part. This health system leadership issue was poorly handled in our institution.

emergency medicine, surgery, neurological surgery, neurology, maternal and fetal medicine, and even family medicine. Training and working with colleagues from each of these specialties has shown us that there is very little that differentiates a well-trained intensivist; we would hire for our institutions' colleagues with any of these backgrounds. What a diverse group of intensivists *does*, on the other hand, is to provide a slightly different set of assumptions when considering a particular problem. Thus, we have felt – and continue to do so – that a multidisciplinary CCM team is a stronger team.

How, you might ask, can such a multiheaded hydra be organized and led? We think it is relatively simple. Intensivists are intensivists; if the leader is a respected colleague, it matters very little whether that individual is an anesthesiologist, a surgeon, a neurosurgeon, or an EM physician. As our friend and colleague Mitch Fink, of the University of Pittsburgh Medical Center, once said: Salaries are the salaries of intensivists. A neurosurgeon functioning as an intensivist is paid as an intensivist, not a neurosurgeon. The finances work.

We have shared faculty, too. So, the neurosurgeon may spend 50% of her time doing clinical neurosurgery, and the other 50% working in the neuroICU with us. As long as departmental leadership views this as a plus, it works. The authors have been fortunate to work in institutions that, until recently, felt this way.

A few words on the chain of command are in order. Firstly, in a multidisciplinary CCM group, we work very hard to place our intensivists where they want to be; a trauma intensivist is usually a bit unhappy in the medical ICU. Since we do try to meet the expectations of our colleagues, we find that, when there is a staffing problem, they will step forward to fill the breech. Secondly, the institution, if it is to invest in a CCM service, needs to have a return on that investment. Working as hard as we can, we may be lucky to break even on our billings. More importantly for the institution, financially and in terms of outcomes, our focus is on the quality and safety of our patient care. For example, somewhere between 30% and 50% of spending in health is waste [13, 14]. This includes misdiagnoses, nonuse of evidence-based care, administration of care not indicated, hospital-acquired conditions, and so forth. Our ability to prevent this waste, improving quality and safety while decreasing length of stay and morbidity and, perhaps, mortality proves our worth to the institution.

Outreach Services

It is recognized by the Centers for Medicare and Medicaid Services and insurers that the provision of critical care services is not limited to the walls of the ICU. Although this has implications for billing, our point is not finance. Rather, our experience has been that a CCM outreach service (CCMOS) may decrease complication on the medical-surgical floors. While the utility of such a service – in our case a daytime CCM ICU service providing consultation to any adult medical or surgical service with patient concerns, as well as responding to nursing concerns in cases

falling short of the need for a rapid response and a night CCMOS staffed by intensivists – will be variable depending upon the strength of the house staff and nursing staff as well as the presence of senior physicians in house at night, we have found this service extremely useful. The central function and main area of responsibility of the nighttime (1900–0700) CCMOS is the adult medical-surgical floors; duties are as follows:

1. Respond to all cardiac arrests and appropriate rapid responses on the adult floors (our daytime consult team provides this service as well).
2. Respond to nursing, advanced practitioner, and resident requests for assistance.
3. Respond to emergency department sepsis alerts and other requests for critical care assistance (our daytime consult team provides this service as well).
4. Triage patients into and out of intermediate care and intensive care units.
5. Function as a patient advocate as needed.
6. As possible and as time allows, provide assistance when requested to the night CCM advanced practitioners, residents, and fellows.

The metrics followed for our CCMOS are:

1. Numbers of rapid response called.
2. Numbers of cardiac arrests called.
3. Transfers to higher or lower levels of care.
4. Numbers of episodes of failure to rescue.
5. Finally, we will follow the percentage completion of our evidence-based guidelines for sepsis alerts in ED.

In addition to the CCMOS, we developed two other innovative services. First was a Reading Program [15] to awake ICU or lightly sedated patients, the thought being that sensory deprivation and social isolation are delirium risk factors [16]. While most delirium prevention strategies focus on pharmacology, mobilization, and improvement of sleep-wake cycling [17], we hypothesized a program of reading on a daily basis would decrease delirium days.

Readers were comprised of high school and college student-volunteers and were oriented to the program. Each student read between 60 and 90 minutes twice weekly to patients selected by the ICU charge RN. Reading material included newspaper, religious material, or novels, depending upon the patient' wishes; at times, patients requested conversation.

This was a service and not a formal study, so we only looked for the presence of a possible "signal," a decrease in CAM-ICU designated delirium days; patients served as their own controls with 48–72-hour period before the reading was initiated being the control period and the 48–72-hour period after the reading the study period. CAM-ICU was measured three times daily by the bedside ICU RN.

Evaluation of our initial data – made up of 33 ICU patients read to, of whom 12 were diagnosed with delirium using CAM-ICU methodology – showed that total delirium days and delirium days per patient before and after the reading intervention were, respectively, 27 versus 10 and 1.04 versus 0.38 ($p < 0.05$). This very small, preliminary report – nonrandomized, controlled, and hypothesis-generating – suggests

that this relatively simple and very low-cost intervention may help with treatment and perhaps prevention of delirium. Delirium impacts readmission in an adverse manner; any cost-effective method to decrease delirium should be considered. A randomized, controlled, multicenter study needs be carried out to determine if these limited data can be generalized [15].

The second innovative program was a post-ICU clinic ([18], PICUC). We became one of 10 initial institutions worldwide involved in the Society of Critical Care Medicine's Project Thrive. The PICUC, a multidisciplinary team focused.

on problems noted in 25% to 30% of ICU survivors, is a relatively uncommon care process for which limited data exist. While the limited literature primarily focuses on pulmonary function, quality of life, and neuropsychiatric outcomes, a relationship exists between hospital readmission and increased morbidity and mortality. We hypothesized that an interprofessional PICUC would reduce hospital readmission rate. Our prospective pilot was carried out between December 2016 and March 2017. Patients with an ICU admission diagnosis of severe sepsis or acute respiratory failure with 1 or more days of mechanical ventilation or those with more than 4 days of ICU delirium were invited by a case manager before hospital discharge for PICUC enrollment. The enrolled patients were called within 48 hours of hospital discharge, visited at home by a lay community health associate, and seen in clinic within 2 weeks and then scheduled for appointments at 1 and 3 months. Clinic visits included evaluation by teams consisting of a registered nurse, case manager, intensivist, and neuropsychologist. Eighty-two patients met inclusion criteria, 20 (24.4%) were seen in PICUC; of the remaining patients, 1 (1.2%) died, 37 (45.1%) declined or cancelled their appointment, 11 (13.4%) went to hospice, 10 (12.2%) were unable [due to continued intubation [5], suicide attempts [2], and non-verbal [3]], and 3 (3.7%) did not respond. The study group included those patients who were seen in PICUC ($n = 20$), while the control group encompassed those who declined to be seen or cancelled their appointment ($n = 37$). Sixty-day readmission rates were significantly lower in the study group versus control group (5.00% versus 48.7%, $p < 0.05$).

Both the PICUC and the Reader Program are examples of outreach services that enhance the "value" of a CCM program to the institution while, we think, significantly improving patient care. One might argue, reasonably, that palliative care and, perhaps, a home care program to prevent readmission could be managed out of the CCM department/service line/institute.

Institutional Needs

The institutional needs are not so different from medical staff needs. They, generally speaking, want a group of committed and invested clinicians willing to "take ownership" of the ICUs and, often, the intermediate care units if they exist. Leadership may well ask the intensivist group for input as to whether a two-level (floor and ICU) versus three-level (floor, intermediate care, and ICU) system is optimal. They

will want input – eventually if not immediately – as to whether an open versus closed staff ICU (and even intermediate care) model is optimal. Assistance will be requested with quality initiatives: root cause analyses, failure to rescue studies, education of nursing and allied staff, development and management of evidence-based protocols, and so forth. The most enlightened leadership – difficult to find but they exist – want partners to promote excellence. If the reader is fortunate enough to be in an institution where this is the style of leadership, you will find the pathway to quality and safety a smooth walkway. Unfortunately, as a wise woman once informed one of us (AJL): "Everyone wants to want to change/improve, but change is difficult."

Hopefully, your leadership has figured this out. But if not, you may expect turf, financial, and quality/safety battles, for it is too easy for leadership, especially those trained as businesspeople, to "see" only the institutional spreadsheet.

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Chapter 4
Administration Support

Asad Latif, Ho Geol Ryu, and Todd Dorman

Introduction

The birth of modern intensive care units, meaning those staffed with physicians in addition to nurses, took place in 1958 at Baltimore City Hospital, now known as the Johns Hopkins Bayview Medical Center, to be able to closely monitor patients who were not doing well [1]. From a historical perspective, the initial intensive care unit (ICU) model started as an open-unit model as they were primarily high-intensity nursing units. With progress in physician staffing in the ICU, and the development of critical care as a specialty, there has been a transition from an open-unit model toward a closed-unit model. A landmark systematic review of physician staffing patterns and clinical outcomes by Pronovost et al. showed the association between high-intensity physician staffing and reduced ICU and hospital length of stay and lower ICU and hospital mortality [2]. Since then, the discussion regarding the best framework for an ICU structure has become more nuanced, shifting to the intensity of physician staffing and the duration of coverage by intensivists.

A significant amount of resource investment across personnel, technology, and infrastructure, is required to develop and maintain a modern ICU. Given the complexities of caring for critically ill patients, the wide variability of their quantity, type, and timing, managing the resource requirements of an ICU can also be extremely challenging. Administrative support plays a critical role in helping ensure

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an adequate harmonization between resource, structure, process, and function that is required to ensure the successful running and outcomes of an ICU.

Resource optimization is a critical administrative supportive function for the success of an ICU. Probably even more so than the rest of healthcare, the type and amount of staff is critical to the success of an ICU, both in terms of function and patient outcomes. Human resources, especially intensivists, are key and have been shown to impact ICU patient outcomes [2], and will be discussed in this chapter. The impact of other types of providers has been studied in less detail, with the effect of nursing care on ICU patient outcomes being the second most studied. Much of that has been focused on the quality of nurse staffing and appropriate nurse-to-patient ratios [3, 4]. Existing evidence supports that having a ratio of one nurse caring for more than two patients, particularly at night, is associated with more complications such as infections and increased resource utilization [5, 6]. In certain specialized populations, like the neonatal ICU, even stricter nurse-to-patient ratios of 1:1 might be required to minimize mortality outcomes [7]. Of course, there are nuances in the types of patients who might benefit from higher nurse-to-patient ratios. For example, the British Association for Perinatal Medicine and America Academy of Pediatrics recommend different nurse-to-patient ratios ranging from 1:1 to 1:4 depending on predefined levels of care based on patient acuity [8, 9]. Furthermore, a higher nurse-to-patient ratio was found to be associated with improved technical efficiency of nurses in the ICU as well [10]. Participation of nonphysician medical providers and critical care pharmacists are some of the other human resources that based on existent evidence play significant roles in patient care [11, 12].

ICU Models of Care

Functional Considerations

There can be significant variation in how an ICU attempts to meet standards like the Leapfrog ICU physician staffing (IPS) [13]. This is usually dependent on administrative decisions based on organizational priorities and resources. Understanding the reality of the local environment and using a common nomenclature to help define it becomes crucial for this purpose.

An open ICU implies that daily decisions concerning patients located in the ICU, including admission and discharge, are made by the primary physician or service responsible for that patient. In an open model, the ICU is merely a physical space with equipment and trained personnel, like nurses, required to take care of a critically ill patient. Full-time intensivists are typically not available or may only be involved in patient care when requested by the primary physician. In contrast, a closed ICU implies that an intensivist is responsible for all aspects of care for patients located in the ICU, from day-to-day management to admission and

discharge decisions for the patient. However, most contemporary ICUs are organized to perform in a much more complex fashion to fit their needs and circumstances, making the historical open versus closed classification unable to adequately represent the minutiae of what is often actually happening in an ICU. For example, a particular unit may be "open" in terms of admission and discharge allowing any staff physician with admitting privileges to send a patient to the ICU, but "closed" for patient care (orders, procedures, etc.) to only the intensivist on service. Therefore, a more comprehensive classification is necessary to capture the spectrum on which modern ICUs must function.

When considering coverage of patients in an ICU, a range from patients never being seen by an intensivist to patients cared exclusively by an intensivist have been described. From an administrative perspective, the spectrum is summarized following four possible functional models. The fully open ICU model is one in which any staff physicians with hospital privileges can admit their patients in the ICU, where they are responsible for all aspects of the patient's management and eventual disposition. In such a model, there is no dedicated intensivist or ICU service, with the primary physician, or their service, being responsible for writing orders, performing procedures, and requesting consults if they want a specialist physician or service to see their patient. The next level of coverage is the elective consultation model, which is similar to the open ICU model in that the primary physician for the patient is responsible for all decisions, but an intensivist is available to be consulted for help and management recommendations if the primary physician desires. This is in contrast to the mandatory consultation model, where every patient admitted to the ICU is required to be seen by the intensivist, but the primary physician for the patient remains responsible for all decisions, and can decide how much help they would like from the intensivist including which consultant recommendations to implement. For both consultation coverage models, the details of the distribution and organization of care responsibilities between the intensivist and primary physician may vary significantly between individuals and institutions. However, communication and close collaboration between the intensivist and the primary physician, or their services, are key. A fully closed model of ICU care implies that the intensivists are responsible for all aspects of care for all patients in the ICU, including who is admitted and when they are ready to be discharged. To do so, the intensivist on service becomes the attending of record for the duration of the patient stay in the ICU, transferring back to the primary physician when they are ready to discharge the patient from the ICU.

Staffing Considerations

A second administrative focus when considering coverage of patients in the ICU needs to be the intensity of the physician staffing for the unit. Generally, ICU service staffing can be considered low-intensity or high-intensity [2]. The level of intensity is determined by the availability of intensivist, including whether there is

one on staff, whether there is one on site, and how long they are on-site for (e.g., morning rounds, 24-hour shift, etc.). One study found that being seen by an intensivist within 6 hours of admission was associated with decreased mortality and hospital length of stay, with a progressive decrease in hospital mortality over time [14].

A further determinant of staffing intensity includes the scope of the ICU service itself, such as whether it consists of a solo intensivist or whether the intensivist leads a multidisciplinary team and who is part of that team (e.g., pharmacist, respiratory therapists, dieticians, physical therapists, physician trainees, etc.). While there has been significant work on the impact of functional models on ICU care and outcomes, there has been relatively limited dedicated research on the direct impact of all the potential nuances of staffing intensity. Rather, the two are often conceptually lumped together, with the first two functional models (i.e., open and elective consultation models) being considered low-intensity staffing models and the latter two functional models (mandatory consultation model, closed ICU) being considered high-intensity staffing models [2].

Multiple studies have confirmed or found additional benefits of high-intensity physician staffing in the ICU in various settings. The exact reason for why intensivist involvement leads to better patient outcomes, or what that involvement entails is unknown, but is probably multifactorial. High-intensity physician staffing is considered as the most beneficial ICU staffing model, not only in medical and surgical ICUs but also in subspecialty units such as cardiac ICUs, neurosciences critical care units, and trauma ICUs [15–18]. A recent study assessed the association between a cardiac intensivist-directed care (high-intensity staffing model) and clinical outcomes in cardiac ICU patients [15]. Using a before and after study design, the high-intensity staffing model was shown to be associated with lower mortality after propensity score matching (3.7% vs. 7.5%, adjusted odds ratio 0.53 [0.32–0.86], $p < 0.001$) and lower ECMO-related mortality (22.5% vs. 54.5%, $p = 0.001$) compared to the low-intensity staffing model (no cardiac intensivist in cardiac ICU) [15]. In a neurosciences ICU, implementation of mandatory intensivist management was associated with decreased ICU length of stay (3.7 vs. 4.6 days, $p < 0.01$) and increased monthly admissions (142 vs 129, $p = 0.02$), but unchanged mortality [6]. A multicenter prospective cohort study of critically ill trauma patients compared mortality in open ICUs and ICUs utilizing the intensivist model (co-management by intensivist or management by intensivist-led ICU service). The intensivist model was associated with a lower mortality, especially in the elderly [RR 0.55 (0.39–0.77)], in units led by surgical intensivists [RR 0.67 (0.50–0.90)], and in designated trauma centers [RR 0.64 (0.46–0.88)] [7]. High-intensity physician staffing in a mixed ICU of a regional nonteaching medical center was associated with shorter hospital length of stay, better compliance with evidence-based practices, and a significantly lower mortality [19].

Of note, one retrospective study of 101,832 ICU patients reported counterintuitive results of higher hospital mortality and more interventions in patients managed by critical care physicians, even after adjusting for severity of illness [20]. The standardized mortality ratio was significantly higher in patients who received care provided by critical care physicians compared to patients who were managed in

ICUs where critical care physicians were not available (1.09, 95% CI [1.05–1.13] vs 0.91, 95% CI [0.88–0.94]). Potential explanations of the single contradictory manuscript include unmeasured confounders, obscure definition of critical care physicians, significant magnitude of missing data, and the nature of the data which was collected for a quality improvement project.

Importantly, a more recent systematic review that included the retrospective study described above reconfirmed the findings of the 2002 systematic review and showed that high-intensity physician staffing is associated with lower ICU mortality (RR 0.81, 95% CI [0.68–0.96]) and lower hospital mortality (RR 0.83, 95% CI [0.70–0.99]) [2, 21]. Although the systemic review implicated that the benefits of high-intensity physician staffing may be more evident in surgical and medico-surgical ICUs, a retrospective cohort study of medical ICU patients (n = 107,324) reported their lowest odds of 30-day mortality with high-intensity physician staffing and multidisciplinary care teams (OR 0.78, 95% CI [0.68–0.89]) when compared to low-intensity physician staffing without multidisciplinary care teams [22].

Despite the overwhelming body of literature (>40 reported studies) that support high-intensity physician staffing over low-intensity physician staffing, the precise rationale that translates high-intensity physician staffing into improved patient outcomes is unclear. Therefore, it is difficult to calibrate the components of high-intensity physician staffing toward better outcomes especially in circumstances where resources are limited. As in many situations in medicine, consistent and reliable delivery of care using evidence-based standardized protocols by experienced and trained personnel is likely to have contributed. In the retrospective cohort study of medical ICU patients, daily rounds by a multidisciplinary team was associated with reduction in mortality after adjusting for hospital and patient characteristics [22, 23]. Higher compliance with evidence-based practices, such as stress ulcer prophylaxis, deep vein thrombosis prophylaxis, and nutritional support, was reported to be associated with high-intensity physician staffing [19]. It is also possible that units that utilize high-intensity physician staffing models have better communication across the interprofessional teams and thus avoid complications that stem from poor communication. As multidisciplinary high-intensity physician staffing becomes the norm in most modern ICUs functioning with protocols and checklists, it has even become more challenging to tease out the impact of high-intensity physician staffing [24].

On a related note, a relatively recent study attempted to answer the question of optimal patient-to-intensivist ratio. The only previous study had suggested an increased ICU length of stay when the intensivist-to-bed ratio was 1:15, compared to 1:7.5, 1:9.5, or 1:12 [25]. The more recent retrospective cohort analysis showed that the relationship between patient-to-intensivist ratio and ICU/hospital mortality was U-shaped and a patient-to-intensivist ratio of 7.5 seemed adequate [26]. Although a ratio greater than 1:12 has consistently been associated with poorer outcomes, the optimal patient-to-intensivist ratio remains unclear in regard to patient outcome, reflecting the wide variety of possibilities and practices in place across ICUs based on local norms and resources.

A final consideration in adopting and staffing intensivist teams in the ICU is financial. A qualitative study in which chief medical officers and ICU directors were

interviewed from a range of ICUs across the USA delved into the factors associated with their decisions regarding implementation of the IPS standards recommended by the Leapfrog Group. Successful acceptance and adoption were associated with an existing hospital culture emphasizing patient safety and quality, support from administration, and a strong champion [27]. It was also noted from ICU directors that administrative and financial support was very important. These can take several forms, but usually take the form of having dedicated administrative staff and space, and financially supported protected time for intensivists to be able to focus on local quality assurance and performance improvement projects. While there are no definitive published numbers, the authors recommend 10–20% protected time for ICU directors and at least 5% protected time for staff intensivists to allow them to contribute meaningfully to local multidisciplinary practice improvements and policy updates. However, the impact of such commitments needs to be taken into account when determining staffing requirements.

24-Hour Intensivist Staffing

As the evidence supporting the benefits of high-intensity physician staffing has developed over the years, it has become the expected norm for ICU care delivery models in many high-income countries. There has been understandable discussion about what it actually entails and its potential expansion to further improve patient care in the ICU. Some institutions have attempted to move beyond the Leapfrog standards and toward 24/7 intensivist coverage or nighttime intensivist coverage [28]. A survey of ICU program directors in US academic medical centers with a relatively low response rate (37%) showed that one-third of the ICUs were covered 24/7 by board-certified or board-eligible in-house intensivists [29]. Most respondents believed that 24/7 coverage is associated with better patient care and better education for training fellows, although they did raise concerns about reduced autonomy and decision-making opportunities of fellows [29]. An important, but unproven, common assumption is that there is a grossly linear relationship between intensity of intensivist staffing and patient outcomes, such that increasing the former will improve the latter. Furthermore, the relationship between the magnitude of benefit and additional cost is largely uncharted. A randomized trial in an academic ICU running under a high-intensity physician staffing model compared additional nighttime in-hospital intensivist staffing with daytime intensivist available via telephone failed to show any difference in ICU or hospital length of stay, mortality, or readmission within 48 hours [30]. A retrospective cohort study showed that adding a nighttime intensivist to an ICU utilizing low-intensity physician staffing model during the day resulted in a reduction in mortality (OR 0.62, $P = 0.04$) [31]. The same reduction in mortality was not observed when nighttime intensivists were added to ICUs with high-intensity physician staffing during the day (OR 1.08, $P = 0.78$). Thus, the current body of evidence is not sufficient to justify 24/7 intensivist coverage based upon mortality alone, especially in ICUs with daytime

high-intensity physician staffing [32]. However, the existing evidence remains mixed as there are other reported benefits associated with 24/7 intensivist coverage including reduction in major complications after cardiac surgery, earlier decision-making regarding end-of life care, and possible improvement in the quality of end-of-life care [21, 33, 34].

Other Considerations

Despite the lack of clarity on causation, the benefits of having intensivist-staffed ICUs are well documented. However, achieving universal intensivist staffing or even availability to meet the tremendous need for critical care services is unlikely in the near future. It might be worthwhile to think about the possible mechanisms by which intensivists improve outcomes and other ways to try to achieve them. Potential reasons that can be combined into a conceptual framework include improved adherence to evidence-based best practices, an increased knowledge base about critical illnesses, and a proxy for organization factors and resources. Each aspect of this conceptual framework can be addressed individually by targeted interventions or collectively by multiple interventions at the same time.

Developing and utilizing protocols as decision-making tools is one way to try and improve care in ICUs. Whether in the form of checklists or algorithms, protocols allow for providing explicit directions for differential interventions based on patient factors and/or assessments. They can improve adherence to evidence-based best practices and minimize variability in care and have been shown to improve outcomes for a wide variety of ICU problems such as sedation, ambulation, central line infections, ventilator-associated harm such as lung injury and infections, and even sepsis [35–40]. Many protocols can be implemented by a variety of healthcare providers, from non-intensivist physicians like hospitalists to nurses, respiratory therapists, and pharmacists. While they provide a unique opportunity to improve care for patients who do have access to an intensivist, they cannot replace the breadth and depth of knowledge brought to the table by an intensivist as highlighted by the equivocal benefit protocol-based care provided in ICUs with high-intensity staffing [41].

Increasing the presence of providers with specific knowledge of critical illnesses and its managements is a challenge that can be potentially ameliorated in a couple of ways. One approach is through the use of advanced practice providers such as nurse practitioners and physician assistants who have obtained specialized training in critical care. Potential benefits include improving the efficiency of care in an ICU, for example, by allowing an intensivist to provide care to more patients than they could alone by off-loading tasks such as placing orders, writing notes, coordinating consults, or performing certain bedside procedures. They might also improve patient/family or nurse satisfaction by improving communication [42]. The literature regarding their impact on patient outcomes is building, with most studies supporting the fact that models of care including advanced practice providers are at least

equivalent to models utilizing resident physician staff [43–45]. However, almost all of these studies are based in the USA and are not true randomized trials. One recent prospective study comparing teams consisting of acute care nurse practitioners versus resident physicians got significant attention for showing decreased hospital length of stay for patients cared for by acute care nurse practitioners (7.9 ± 11.2 days) than for resident patients (9.1 ± 11.2 days) (adjusted OR, 0.87; 95% CI, 0.80–0.95; $P = 0.001$) as well as lower ICU mortality (6.3% vs 11.6%; adjusted OR, 0.77; 95% CI, 0.63–0.94; $P = 0.01$), but no difference in 90-day survival (adjusted hazard ratio, 0.94; 95% CI [0.85–1.04]; $P = 0.21$), hospital mortality (adjusted OR, 0.87; 95% CI [0.73–1.03]; $P = 0.11$), or ICU length of stay (3.4 ± 3.5 days vs 3.7 ± 3.9 days [adjusted OR, 1.01; 95% CI, 0.93–1.1; $P = 0.81$]) [46]. However, the study was performed in a highly staffed academic medical center, where a critical care fellow and intensivist were present on each team, limiting the generalizability to community ICUs with less resources.

Telemedicine offers another avenue for increasing the reach of intensivists and their expertise in taking care of critically ill patients. There is significant heterogeneity regarding the specific approach and technologies employed by a tele-ICU can vary, but most involve a combination of access to patient vitals and labs, the electronic medical record, and some form of audio and/or visual communication with the local bedside providers. The strategy on how to utilize the tele-ICU presence can also vary, from models ranging from direct intervention and order writing by the tele-ICU providers to just notification of local staff about any issues that might have been noted on monitoring. One study that compared three tele-ICU co-management strategies (direct intervention with notification, mixed methods, and monitor and notify) found higher levels of tele-ICU involvement to be associated with more orders being written per patient and significantly shorter acuity-adjusted hospital length of stay (0.68; 95% CI [0.65–0.70] vs 0.70; 95% CI [0.69–0.72] vs 0.83; 95% CI [0.80–0.86]) [47]. But the overall data is not definitive, with a meta-analysis suggesting that while tele-ICU care might lower ICU mortality (OR 0.80; 95% CI [0.66–0.97]; $P = 0.02$) and ICU length of stay (−1.26 days; [0.-2.21 to −0.30]; $P = 0.01$), there was no concomitant statistically significant improvements in hospital mortality or length of stay, limiting the benefit to the patient [48]. A complimentary area of potential benefit for ICU telemedicine is in the facilitation of quality improvement by enhancing compliance with best practices through a combination of vigilance, dedicating resources, and building a culture of awareness and safety [49]. However, the cost of setting up and maintaining a tele-ICU service can be substantial, with conflicting data regarding their cost-effectiveness based on the goals [50, 51]. Frank deliberation of local circumstances and goals is necessary prior to utilizing telemedicine systems for intensivist staffing.

Increasingly, the concept of regionalization, or routinely transferring critically ill patients to dedicated referral centers, has taken hold in the healthcare system. While it is difficult to find definitive evidence of the systemic benefits as pertains to ICU patients, there are observational studies showing that high-volume centers have better outcomes, particularly with certain higher-risk critical care issues like cardiovascular, respiratory, hepato-gastrointestinal, neurologic, postoperative, and severe

sepsis [52, 53]. An administrative analysis suggested that regionalization might allow thousands of lives to be saved [54], which might also lead to cost efficiency by promoting economies of scale. Other specialties like trauma and neonatal care have been able to do so successfully and might offer a blueprint for those interested in this approach [55, 56]. However, careful consideration is needed to avoid unanticipated consequences like overburdening of referral centers or leaving smaller referring centers unable to care for acutely ill patients.

Critical Care Transport

Care of the critically ill and injured frequently requires diagnostic tests, procedures, and/or interventions that provided outside of the physical ICU. However, this does not alleviate the need for ICU-level care as the patients remain critically ill and can have significant swings in physiologic parameters during transport that can require immediate management. Therefore, crafting appropriate transport approaches for the critically ill is important. Significant improvements in diagnostic and therapeutic modalities over the last several years have helped to improve outcomes for critically ill patients. However, this frequently requires the movement of patients from the ICU to other locations to be able to provide optimal care. This can potentially be extremely perilous given the need to maintain things like respiratory and hemodynamic support or other essential and time-sensitive therapies. Even ICU patients considered otherwise stable tend to have precarious physiologic reserves and even seemingly minor changes during transport having the potential to cascade into life-threatening complications. Due to the differences in error definitions and reporting, and the lack of focus on documenting accurately the number of opportunities versus the actual occurrence of errors, representative data is difficult to find. One study showed that 46% of intrahospital transports were associated with an adverse event, of which 26% affected the patient and 17% would be considered serious [57].

Transport of critically ill patients can be divided into two types: transport within the hospital (intrahospital) and transport between healthcare facilities (interhospital). Given the scope of this chapter, we will primarily be considering intrahospital critical care transport, which has historically received little attention compared to interhospital transport. This is despite the fact that intrahospital transport is expected to occur far more frequently than interhospital transport, and the in-hospital patients tend to be sicker than those transferred from other facilities [58].

Recommendations for personnel, equipment, and medications to facilitate the movement of patients exist but are mostly based on small observational and retrospective studies, or expert opinion [59–63]. Moreover, such information needs to be digested at the hospital and unit level, to account for local resources and context prior to conversion to policies which can allow for dissemination and consistency to reduce the likelihood of errors during transport.

A careful risk-benefit assessment of the need for the transport is always the first step. A review showed that diagnostic studies requiring transport resulted in a

change of therapies in 24–70% of patients [64]. The risks of transporting a critically ill patient can be reduced by increased awareness and education of appropriate staff, specialized equipment, and the use of tools like checklists. Despite recommendations by various societies, [60, 62] the specific composition of the transport team does not have a strong evidence base. Having team members with specialized training makes sense to ensure that they have the clinical abilities to adequately evaluate the patient and promptly initiate appropriate treatments if needed. A range of staffing models are used, from dedicated transport teams and unit-based personnel to on-call staff to transport ICU patients. Utilization of a dedicated transport team at Johns Hopkins resulted in a low adverse event rate of 1.7% [65]. However, using such a model is unlikely to be appropriate for widespread adoption due to the high cost of training and maintenance. At the least, a minimum of two clinical staff should accompany the critically ill patient, with another possible nonclinical person to assist with the logistics of moving the bed. Existing guidelines recommend that one of them be a critical care nurse, with a physician only being necessary for unstable patients [60]. However, a more recent study looking at teams led by critical care physicians versus critical care nurses was unable to establish non-inferiority of nurse-led teams [66]. Such recommendations do not consider the potential hidden costs of leaving the patients that would otherwise have been covered by that staff unattended, an area where further study is needed.

Current technology and equipment make it possible to replicate practically every aspect of the ICU environment during transport, but it is often different from that being used in the ICU. One study found that almost 16% of transports encountered technical problems with the equipment that the transport team had to deal with, leading to delays or even cancellation of patient transport [67]. Such studies highlight a couple of important issues. There is a need for technical expertise, or at least understanding, during the transport of a critically ill patient; being a qualified critical care practitioner does not necessarily equate to being qualified for critical care transport. There is also a substantial dependence on equipment when outside the stable physical environment of the ICU, making it all the more important to ensure its ongoing working condition.

Developing hospital policies and procedures can be of benefit by helping establish what constitutes an appropriate indication and conditions for transport. Pretransport checklists and in-transport monitoring tools are potential ways to help minimize the occurrence of adverse events during transport [68–71]. These can cover the assessment of the patient before and after transport, the review and checking of transport equipment, and the transfer of relevant patient related information during medical processes and testing.

Ultimately the goal should be to provide at least an equivalent degree of monitoring and care during the transport to what the patient was receiving before being moved. A comprehensive and systematic approach is needed to minimize the risk of errors and complications and to provide a safe transport of critically ill patients.

The ICU as a High Reliability Organization

The ICU is a dangerous place, with rapidly changing conditions, frequent situations where there is high uncertainty, and circumstances when quick decisions have to be made with incomplete knowledge. In this constantly changing environment, ICU clinicians need to diagnose, develop therapeutic plans, and deliver care. To minimize the risk of missed diagnoses and suboptimal therapeutic plans, ICU clinicians would do well to consider the high reliability organization (HRO) model.

The HRO model for healthcare was developed by looking for commonalities in other fields and industries where the tolerance for error is extremely low, such as the aviation and nuclear power industries. Despite having inherently high risks and consequences for error, they have excellent track records in safety. This is because such industries have utilized engineering approaches to create deliberate systems to improve task performance and manage the complexities of the technologies they use [72]. The ICU is a natural focal point of HRO functioning within healthcare due to the presence of the sickest patients and the use of the most complex therapies and technologies.

Administration naturally has a crucial role to play in setting the expectation and culture required for healthcare to function as a HRO. This is in line with the authors' beliefs that the greatest reduction in errors in the ICU requires a focus on the unit's organizational characteristics [73]. The emphasis on systems does not mean that individual skills are not important. Rather, the conceptual thinking is that the functional systems found in healthcare are made up of the people working in the organization [74]. In fact, well-functioning clinical "microsystems," such as the one found in a highly staffed, physician-led, closed ICU, may be the best current examples of HRO functioning in healthcare [75, 76].

There are many examples of using HRO principles in ICUs. With regard to problem detection and management, key characteristic principles of HROs include using failures/near failures to monitor the system, refraining from simple explanations to problems, focusing on each component and their potential to affect other components, developing capacity for responding to unexpected events, and deferring to expertise [77]. Although healthcare, especially the ICU, shares similarities with conventional HROs, there are constraints that make it difficult to function as such. Process improvement is likely the core component for ICUs to maintain high reliability as evidenced by improvements in certain preventable harms such as ventilator-associated pneumonia or central line-associated bloodstream infection [78, 79]. To facilitate measurable processes, standardized protocols such as sepsis bundles or ventilator-associated pneumonia prevention bundles and order sets should be used [80]. The intervention and its measurement should be supported by the leadership to optimize the institutional culture with visible interventions such as executive walk rounds which have been shown to have a positive impact on local unit culture or multifaceted interventions that can adapt to the circumstances of the unit like the comprehensive unit-based safety program [81–83].

Despite all the well-documented successes and benefits of current ICU care and models described and discussed earlier, they are dependent on the physician intensivist and their team performing all the core functions required for patient care. This model has evolved naturally over time with the development of critical care as a specialty, with the comparative improvements from intensivists probably owing much to their specialized knowledge of relevant diseases and systems, but it is ultimately reliant on the flawless performance of the individuals comprising the ICU team to optimize outcomes and minimize harm. Under the HRO and systems engineering paradigms, such an individual "heroism"-based model would be considered outdated, under-engineered, and aimed for failure at high frequency [84]. A system redesign focusing on the integration and management of technology, work processes, and culture into a healthcare ecosystem looking to serve the frontline provider's needs rather than being forced upon them might be needed to take the next step in delivering high levels of safety consistently to patients [85].

Conclusion

Peter Safar created the first physician-staffed ICU in 1958. He and Dr. Grenvik postulated that an intensivist-led ICU may translate into better patient outcomes in 1977 [86]. The evidence shows that high-intensity physician staffing, in various ICU settings, is associated with decreased ICU and hospital mortality, shortened ICU and hospital length of stay, and reduced costs. Moreover, 24/7 or nighttime intensivist staffing may be what the future holds, although the current body of literature is somewhat insufficient. Although many interventions including daily rounds by an intensivist [87], pharmacist consultation on ICU rounds [12], and lung protective ventilation [37] have been shown to be associated with improved patient outcome, thus far, high-intensity staffing in the ICU seems to be the most effective way of improving patient outcome in the ICU. However, the task of organizing high-intensity staffing may be challenging and will require careful consideration of individual circumstances surrounding each institution.

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Chapter 5
Quality Indicators: The Use of Metrics in Critical Care Medicine

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Quality has been described as the degree to which the delivery of healthcare increases the likelihood of desired patient outcomes and is aligned with best-known medical practices. Safety has been described as the absence of clinical errors, which includes doing the wrong thing (errors of commission) and not doing the right thing (errors of omission). The last 20 years have seen a move in healthcare from a fee-for-service-based healthcare system toward a pay for performance or value-based purchasing-based healthcare system [1]. One of the proposed benefits of this system lies in the alignment of incentives for healthcare providers, hospitals, and what is best, for patients. With this movement toward recognizing and paying for value in healthcare, an increased interest in the development of quality indicators and metrics has taken place [2]. Furthermore, a landmark publication from the Institute of Medicine on medical errors has served as a catalysts for the pursuit of safety in healthcare delivery [3]. Critical care provided in intensive care units is usually lower volume, higher acuity, higher resource demanding, and higher cost than other service lines/areas within the healthcare system [4]. Critical care consumes a disproportionate amount of resources, has a high rate of adverse events, and is delivered inconsistently with unwanted variability in adherence to the best established evidence-based practices [5, 6]. These factors make critical care a prime target for improvements in value and safety. Critical care professionals must understand how to evaluate the care they provide with valid metrics and to utilize these metrics to continually improve the value of care provided to ICU patients.

The goal of this chapter is to expose critical care practitioners and leaders to the fundamentals of measuring ICU value and quality of care. We will briefly describe the basic conceptual framework of value in healthcare, discuss the types and attributes of metrics for measuring quality in healthcare, discuss important factors for success, summarize common metrics utilized in the ICU, and finally discuss

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potential pitfalls in this process. We will not describe cost metrics in detail neither present a comprehensive all-inclusive list of currently utilized quality metrics in critical care. We believe that providing our readers with principles they can apply in their journey to improve quality is a better approach than a quick recipe of existing metrics.

Value in Healthcare

At a very high level, value in healthcare is defined by the formula V = Q/C, where V = value, Q = quality, and C = cost. Recognizing that the delivery of healthcare is complex, it is true that this single formula is unable to capture all the nuances involved in measuring quality and cost in healthcare. However, this basic formula is a useful conceptual framework to think about how quality and cost relate to the creation of high-value care in our ICUs. The highest value in healthcare is achieved by improving outcomes at a lower cost. Historically, clinicians have championed quality and ignored to some extent the cost portion of healthcare. Today we recognize that resources are finite and that high cost care is not always beneficial for patients. Critical care professionals need to own both parts of this equation if we want to drive high-value care in our ICUs.

Quality includes patient outcomes and patient experiences with the healthcare process. Patient outcomes are defined by the ultimate results of the interventions and care provided. Important patient outcomes include survival, preservation of limbs, and ultimately the ability to resume their lives with the same degree of functionality and independence they had prior to becoming critically ill. Additional patient outcomes include the development of hospital-associated infections and complications associated with the provision of critical illness. For years we have placed great emphasis on patients surviving critical illness. As important as this is, we are now recognizing that there are vast consequences of surviving critical illness with significant long-term issues related to cognitive capacity, functionality, and psychological well-being [7]. These are some of the patient outcomes that feed the quality component of the value equation. Patient experience measures the level of satisfaction patients and their families (very relevant for ICU care, since many of our patients have altered consciousness during their ICU stay) have with the experience of care they received in the ICU.

Cost includes both direct and indirect costs associated with the provision of care in the ICU. Direct costs also known as variable cost include drugs, diagnostics, and material costs. Direct costs are easily identified as the object cost and are attributable. Indirect costs in healthcare include both financial and nonfinancial costs related to an ICU stay. Financial costs also known as fixed cost (these costs would not change based on the number of patients in an ICU) are more difficult to measure upfront and are not always directly attributable. Indirect costs include the extensive hospital infrastructure required to provide critical care (includes hospital facilities, management, and personnel salaries). In addition, there are nonfinancial indirect costs of critical care associated with pain and suffering for patients and families,

burnout for ICU physicians and nurses, and lost productivity from patients and families dealing with critical illness (also known as the opportunity cost).

Framework for Assessing Quality

Two decades ago, Donabedian proposed a conceptual framework for assessing the quality of care that has been widely adopted and today is considered a standard [8]. This framework links three key domains: structure, process, and outcome (also known as the S-P-O model). The vast majority of quality indicators and metrics utilized in critical care will fall under one of these three domains. Structure refers to the conditions (organizational, infrastructure, materials, and personnel) that enable the delivery of healthcare. Process refers to the activities that take place during the delivery of care. In other words, what healthcare providers do while treating patients in the ICU. Process includes activities related to diagnosis, treatment, prevention of complications, and progression of care through different sites of care. Outcomes are the end results of the care patients receive in the ICU. Specific outcome measures that may be utilized in the ICU include mortality, morbidity, development of hospital-associated infections, and quality-of-life-related measures in survivors of critical illness.

There are unique aspects of each one of these domains (S-P-O) that make them useful for the basis of potential quality metrics in the ICU. Structures include aspects such as physical layout of an ICU or hospital which may be difficult to change for critical care leaders. On the other hand, structure also includes materials and how they are organized such as the development of an airway or central line cart. These aspects are usually within the control of an ICU leadership team. Staffing models and the organization of the ICU team fall within the structure domain. Intensivist-led teams, percent of ICU nurses with special critical care certifications, presence of dedicated clinical pharmacists and clinical nutritionist, and decision-making structure for admission or discharge are all examples of metrics that fall within this domain. Metrics that fall within the structure domain often are dichotomous and are either present or not. Furthermore, structure measures are important in creating value mostly through their influence in modifying processes of care. Therefore, they are not sufficient on their own to provide a balanced assessment of quality in an ICU.

Process measures evaluate the activities the ICU team is performing in the act of caring for patients. Every activity that occurs in an ICU during the care of critically ill patients is a process whether it is recognized as such or not and regardless if it occurs by design or by default. Multidisciplinary rounds, weaning patients from mechanical ventilation, placement of a central line, treating a patient in cardiac arrest, preventing deep vein thrombosis, initiating ECMO, and having goals of care discussions are all processes and can be measured. Process measures are important as they reflect the actions that ultimately impact the drivers of value in healthcare, patient outcomes, and cost. In addition, process measures can help focus individual critical care practitioners and ICU teams on the behaviors they need to implement to create value for patients.

Outcome measures represent the end result of the care we provide in the ICU. Because of this, they are usually the most relevant to patients, payers, and society. Outcome measures do pose unique challenges for ICU directors; they may be more difficult to measure, capture, or benchmark, and they may not always be modifiable by the actions of the ICU practitioner or team [9]. Mortality is a prime example of an important patient-related outcome that presents these challenges. What is the proper mortality for an ICU? We know that mortality is universal, so trying to quantify mortality for an ICU without qualifying severity of illness, patient values, and appropriate goals of care among other factors can provide a limited measure of quality. An avoidable death from a process error clearly represents low-value care. However, a peaceful and comfortable death in a terminal patient with care aligned with the patient's values represents high-value care. Outcome measures are most relevant and useful when paired with process and structure measures that provide broader context about the overall quality of care.

Utilizing the S-P-O model as a foundational basis for quality assessment in healthcare has been ultimately proposed by the Institute of Medicine summarizing major goals and key elements of high-quality healthcare [10]. High-quality healthcare should aim to be patient-centered, timely, effective, efficient, safe, and equitable [10]. Patient-centered care requires that all care be provided in a respectful and compassionate way with the patient's preferences and values directing the goals of care and clinical decisions. Timely refers to the delivery of appropriate care without delays and in the proper time window as to allow the best outcomes for patients. Effective care provides evidence-based care to all patients who will benefit from this type of care and avoids providing futile or harmful care to patients who do not benefit from a specific type of care. Effective care is meant to avoid both under and over utilization of medical interventions. Efficient care seeks to drive value by addressing both outcomes and cost of care. If two drugs provide the same outcome for a specific patient; efficient care would guide the use of the drug with a lower cost. Efficient care is critical in eliminating waste in healthcare. Waste is a significant area of opportunity in the ICU. Safe care refers to the avoidance of avoidable harm to patients receiving care intended to help. Medical errors are a large cause of mortality and morbidity in healthcare. Quality metrics measuring safety are prevalent in critical care. Finally, equitable care relates to the moral imperative that every patient receive the right care at the right time irrespective of factors such as socioeconomic status, race, gender, or location. With the use of the S-P-O model as a foundation and the goals proposed by the Institute of Medicine, critical care leaders can start building quality programs with metrics that will help move their ICUs toward providing high-value care.

Essential Attributes of Quality Metrics

The S-P-O model provides the basis for broad categories from which to create quality metrics. When moving to the creation of individual quality metrics for critical care, one must also consider specific attributes required for a robust and useful

Table 5.1 Essential attributes of a good ICU quality metric

Importance
Validity
Reliability
Responsiveness
Interpretability
Feasibility

metric. A good quality metric in critical care should be important, valid, reliable, responsive, interpretable, and feasible (Table 5.1) [11]. We will further discuss each characteristic and how they relate to the ICU.

An important quality measure should be associated with high prevalence outcomes or outcomes that lead to significant morbidity and mortality. For structure measures to be important, they must have a proven connection to clinically important outcomes. For example, studies have shown that ICU teams led by critical care specialists and that ICU teams with dedicated clinical pharmacists are associated with improved patient outcomes [12, 13]. Measuring the presence of these structural factors in an ICU would meet this requirement. Furthermore, to meet this requirement, a quality measure should be important from the perspective of different stakeholders (i.e., patients, clinicians, hospital administrators, and payers). For some quality measures, the importance might vary depending on a specific group of stakeholders. In these cases, the critical team should consider the different perspectives from all stakeholders and seek balance when selecting quality measures. However, the ultimate guiding principle should always be to pursue what is best for our patients.

A valid measure is one that ultimately quantifies what it is intended to measure. Validation might require comparisons of a new quality metric to a previously established standard (criterion validity) or to other measures or constructs that are expected to give similar results (construct validity) [11]. It is common for ICU teams to adopt quality measures that have already been shown to be valid. If developing new measures, following their performance for validity is recommended.

A reliable measure will yield the same result when assessed by a different rater and should yield the same result when the factor being measured remains unchanged. These are known as interrater and intra-rater reliability. Similarly to the case of validity, ICU teams generally will use measures that have been found to be reliable. In the case of newly developed measures, following their performance for reliability is recommended.

A responsive measure is defined by its sensitivity to capture the result of changes introduced by a quality improvement program [11]. A measure such as this can determine that the changes produce meaningful impact on a particular element of the care. Fundamental requirements for a responsive measure include the presence of room for improvement in the measure and that the measure be capable of identifying that improvement. It is recommended that a gap between current performance and desired performance be present. Implementing quality measures where there is no room for improvement (a topped-out measure) or measures that are unable to detect improvement are not useful in driving value.

Lastly, good quality measures must be interpretable and feasible. A quality measure that is interpretable is easily understood by the critical care team involved, by the hospital administration, by payers, and ideally by patients. Success for a given quality measure must be clearly defined and understood by all stakeholders. Feasibility is a key ingredient for practical reasons. The best quality measure is unlikely to be of any utility in creating and/or assessing value if it is not feasible to obtain. Many critical care teams propose quality measures that unfortunately they are unable to measure or obtain consistently. Feasibility ultimately is determined by local resources. A measure may be feasible in one ICU but may not be transferable to another ICU at a different institution due to a lack of resources needed to obtain the measure reliably. Critical care teams need to assess feasibility for each quality measure they are considering for their quality program.

Setting Your Quality Program Up for Success

There are a host of important factors that should be considered prior to initiating a quality program. These factors can contribute in a significant way to the success of the program. We will discuss the importance of understanding purpose when measuring quality metrics, the benefit of engaging all disciplines within the ICU team, and finally the value of setting priorities and focusing on less rather than more. We have chosen these specific factors as the representative ones understanding that there are many others that could be considered.

Carol Dweck has championed the concept of developing a growth mindset. This school of thought is based on the basic understanding that becoming is better than being. The primary purpose of measuring quality metrics in the ICU is to improve the care we provide. Quality scorecards are not about getting great marks but about producing change. A great quality program will move care forward by allowing us to identify areas of opportunity and measure the impact of our team-based solutions. Making sure the purpose is clear to all team members and that this purpose is always present is critical. Too often, ICU leaders favor quality metrics where they think they will "look good." If we only measure what is done well, we are failing our patients.

The ICU by its very nature is an environment that thrives and flourishes when the input and expertise from the multiple disciplines involved in critical care have the opportunity to work as one team [14]. Likewise, solid quality metrics should be chosen with the input from all disciplines involved in the ICU team. Having alignment and buy-in from the entire multidisciplinary ICU team is a fundamental factor for success. Engagement is significantly more likely when all disciplines are involved early in the process. Furthermore, the expertise of the different disciplines is likely to shed important insights. The multiple disciplines in the ICU need to be aligned on the quality metrics and develop a shred consciousness on those measures that are important to their particular ICU.

Finally, it is important to discuss the value of focus and being deliberate in choosing priorities. If everything is important, nothing is important. Many ICUs measure

a vast number of quality metrics. Unfortunately, in many cases this approach leads to a loss of focus within the ICU team reacting to the latest metric out of target. Less is often better. Fewer meaningful quality metrics are more likely to result in significant progress and change in the way care is delivered. It is upon ICU leaders to make sure the ICU team is working on the right number of metrics. Making choices is often hard but ultimately assures we are placing our efforts on the right quality metrics.

Examples of Quality Metrics in Critical Care

A comprehensive list of available and possible quality metrics for ICU leaders to use is beyond the scope of this chapter. We have deliberately focused on the foundational principles that guide the selection and use of robust quality metrics in the ICU. A solid understanding of these principles will arm critical care leaders with the tools to select and create useful metrics for their ICUs. There are many possible intensive care unit quality metrics to consider (Table 5.2). In this section, we will

Table 5.2 Possible quality metrics for intensive care units

Structure measures
Pre-established ICU minimum requirements
Intensivist staffing model
Critical care certified nurses
System to report adverse events
Process measures
Multidisciplinary intensivist daily clinical rounds
Patient handover and discharge
Deep vein thrombosis (DVT) prophylaxis
Stress ulcer prophylaxis
Ventilator-associated events prevention strategies
Central venous catheter bloodstream infection prevention strategies
Protocol-guided mechanical ventilation weaning
Severe sepsis and septic shock bundle implementation
Lung protective mechanical ventilation protocols
Palliative care
Timely family conferences
Advance directive and goals of care discussions
Early enteral nutrition
Appropriate blood transfusion thresholds
Outcome measures
Risk-adjusted mortality
Unplanned extubation rate
Hospital-acquired infection rate
Catheter-related bloodstream infections (CLABSI)
Catheter-associated urinary tract infections (CAUTI)
Ventilator-associated pneumonia
Intensive care unit readmission

review a sample of quality metrics that represent robust metrics with potential applicability in diverse types of ICUs. These are based on prospectively developed metrics by an international task force through consensus, as metrics that could be used to improve quality in a wide range of intensive care units [15].

Potential quality metrics within the structure domain include ICUs meeting a pre-established minimum requirement to provide critical care, staffing of the ICU with intensivists, and the presence of a system to report and evaluate adverse events. As we discussed above, structure-based quality metrics are usually binary (present or not). Structure-based metrics in the ICU are valuable if their presence helps drive improved delivery of critical care resulting in improved patient outcomes. ICU fulfills pre-established requirements to provide critical care. These requirements could be established at the national or regional level. The designation of a unit as an ICU results in standard resource allocation and reporting mechanisms. Studies have shown that critical care patient outcomes can be improved when cared by professionals trained in critical care [12, 16, 17]. Furthermore, the immediate availability of critical care expertise 24 hours a day can enhance quality of care, decrease morbidity and mortality, and improve length of stay of critically ill patients. Adverse events are common in medicine, and they are related to poor patient outcomes and increased cost of care. The presence of an adverse event reporting system in an ICU can be measured as a quality indicator [18, 19]. In order to understand the nature of the adverse events occurring in an ICU, a system to report and evaluate them must be in place. A systematic approach is necessary to identify the best solutions and changes needed to prevent adverse events from repeating themselves [20].

Process quality indicators are commonly utilized in the ICU. Two potential metrics in this domain are the presence of routine multidisciplinary clinical rounds in the ICU and standardized procedures for handover of patients leaving the ICU. Routine multidisciplinary clinical rounds for all patients admitted to an ICU can constitute a critical driver of quality [21, 22]. The value created for patients from a team approach where all disciplines contribute their expertise in the ICU is significant. Transitions of care from one unit to another within the hospital or healthcare system are points of tremendous vulnerability for patients. A standardized process to assure safe handover of patients leaving the ICU is a marker of quality [23]. Documentation for patients leaving the ICU is also a prime opportunity for standardization and improvement [24]. Evaluating and measuring this process is an attractive metric than can move the needle in quality and patient safety.

Many outcome measures are utilized in ICU quality programs. As we discussed, outcome measures probably capture best the final product of care and are driven by many factors. Factors such as structure and process of care are influenced by critical care providers. However, patient- and disease-specific factors may be out of our control. Some of the outcome measures to consider include reporting of standardized mortality ratio (SMR), ICU readmission rate, rate of central venous catheter-related bloodstream infections, and the rate of unplanned extubations. Raw mortality is not considered a strong quality metric because it is not risk adjusted and is unable to capture severity of illness [15, 25]. The use of a SMR calculated from an appropriately calibrated severity of illness score allows for more meaningful audits and

comparisons [26]. With proper benchmarking, it can provide the ICU leaders with observed versus expected mortality and can facilitate the identification of expected versus unexpected deaths. The readmission rate to an ICU within 48 hours is an outcome that reflects many processes underlying care [27]. A high early readmission rate suggests poor ICU discharge decision and processes [28]. Readmission to the ICU is an important outcome as it is associated with increased length of stay, morbidity, mortality, and overall cost of care [29]. The use of central venous catheters is widespread in the ICU. Catheter-related bloodstream infections are associated with increased morbidity, mortality, and resource utilization [30]. Catheter-related bloodstream infections are often preventable, and there are evidence-based interventions that have proven effective in drastically decreasing their incidence [31]. Measuring the rate of catheter-related bloodstream infections is a valuable quality metric when paired with the implementation of proven evidence-based practices [32]. The last example we will describe is the rate of unplanned endotracheal extubations. Unplanned extubations are associated with a high rate of re-intubation, increased risk of ventilator-associated pneumonia, and increased mortality [33]. The rate of unplanned extubations is closely associated with various processes of care such as proper management of sedation, delirium recognition, and proper transport protocols [34].

Potential Pitfalls to Avoid

Most ICU programs travel down the quality journey with the best intentions and a true impetus to improve care for patients. However, we have seen repeated examples of quality initiatives going of their initial goals and creating tension and problems within the ICU team. Two important pitfalls to avoid this situation are the potential effect of surrogation and the impact of small numbers.

Surrogation is the behavioral tendency to confuse what is being measured with the metric being used. Surrogation is a common behavior and is deeply imbedded in the way people think about metrics. It is prevalent in a wide spectrum of businesses and disciplines including healthcare [35]. In the ICU, surrogation can be seen when a team is trying to decrease hospital-acquired infections (HAI). They intend to measure the quality of care as expressed by their ability to impact HAIs, and they decide to use the rate of catheter-associated urinary infections (CAUTI) as a quality metric. The team starts measuring and reporting the rate of CAUTI every month. Surrogation quickly leads team members to start fixating on the metric itself as the goal. They become more concerned with the outcome (rate of CAUTI) than with implementing processes that would improve care and lead to significant reductions in preventable HAIs. Soon they are focusing on definitions, questioning the validity of the data, and gaming the system in terms of when cultures are obtained among other strategies focused on changing the metric and not improving the care. We control the process not the outcome. Therefore, if we want to impact the outcome, we must focus on managing and implementing the processes we believe will make a difference. We

can see similar patterns with sepsis mortality, bundles, ventilator-associated pneumonias, and many other quality metrics. Critical care leaders must focus and refocus the team on the goals of quality programs (i.e., reduce severe sepsis mortality vs. bundle compliance). It is also important that the team spend their efforts on implementing processes that are designed to improve care and that they learn from the metrics measured what works and where there is opportunity for further imporvement. Finally, from the perspective of regulatory agencies and other stakeholders, setting the appropriate targets for specific quality measures is critical.

Another important pitfall to avoid relates to the law of small numbers and our lack of insight into what numbers and statistics really mean in the real world. Confirmation bias is the behavior that leads us to interpret data or results in a way that fits a preexisting belief regarding what we are measuring instead of objectively assessing the measured data itself. This is common in science. We frequently see this manifest itself in quality metrics and quality improvement initiatives in medicine. On the one hand, if the measured metric implies high quality in our performance, we accept it on face value and believe we are doing great. On the other hand, if the measured metric result (data) implies poor performance, we often question the data's validity as opposed to seeking the opportunities to improve our performance. This is a recurring theme in ICUs and medical teams working with quality metrics. However, even when we are able to overcome our confirmation bias, we are prone to mistakes in interpreting data in the ICU as a result of the law of small numbers. The law of small numbers, described by Kanheman and Tveresky, is a judgmental bias that leads us to believe that samples based on small amounts of data represent accurately what is occurring in a larger population [36]. If an ICU has three consecutive months with no hospital-associated infections, the interpretation will lead the team to believe they are doing "very well." If on the fourth month there are two cases of HAIs, suddenly this interpretation shifts and now the team believes there is something wrong. The idea that predictions should be far less extreme than the data there are based on is counterintuitive. However, it has been shown that we are systematically biased toward placing excessive credence in dramatic results, even when they are derived from small samples (in statistical terms, the vast majority of data we use in the ICU for quality assessment is derived from a small sample). Critical care leaders must be cognizant of this bias and mindful of how the data they obtain best describes the reality of their ICU. A drop in mortality from 1 month to the other is most likely due to chance. However, consistent trends over time with larger data points may be a true reflection of changes in practice.

Conclusions

The healthcare landscape is rapidly changing. With a movement toward value-based payment models, the role of quality and cost has become prominent in managing our ICUs. Critical care leaders must understand the basic principles of measuring value in the ICU. Our roles today are centered on the creation of value for the critical

care patients we serve. Quality and safety are key determinants of value in healthcare. We have reviewed the basic framework that informs all quality indicators. In addition, we have described unique characteristics of robust quality indicators for critical care, briefly reviewed examples of quality metrics in the ICU, and finally discussed some potential pitfalls to avoid when implementing quality metrics. Critical care leaders are responsible for choosing the right metrics within the domains of structure, process, and outcomes for their specific ICU. Establishing quality programs that accurately measure these and more importantly help the team improve their practice patterns is essential to running a successful ICU.

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Chapter 6
Internal Financial Audits in the ICU

J. Christopher Farmer

Key Points

1. Performing an internal financial audit of ICU clinical services is a disciplined and structured process with well-described components mirroring other non-healthcare industries.
2. While most financial audits are performed by *external* agencies in order to validate internal assessments, this practice is not widely utilized in critical care. Currently, most ICU financial assessments are performed as *internal* audits only.
3. Internal ICU financial audit assessments are commonly limited to revenue and cost only and are incomplete management tools.
4. An ICU internal financial audit is not a management action plan; it is an analytical document that assesses fiscal activities documentation, business rules compliance, and nonclinical business regulatory oversight of an ICU.
5. The primary goal of an ICU internal financial audit should be to provide an overall review of a financial report that informs managerial and operational decision-making.
6. Some ICU internal financial audits also include clinical and quality performance data because cost, revenue, quality, and clinical performance are closely linked.

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Introduction and Overview

It has been stated, "no money, no mission." This is especially true in today's healthcare environment with difficult financial margins and little room for unexpected fiscal "bumps in the road." So, we routinely ask…what is the financial outlook for our ICU? Are we winning or are we losing? Are we measuring and managing the "right" things? What should we tally besides billing, coding, and revenue collection? Did we effectively and accurately measure our unit costs? What can we do better? Are others succeeding financially (benchmarking) where we are struggling? What are "they" doing differently? What was the value of the care that we provided in our ICU? What was the value of our ICU to the institution, is this quantified, or is it quantifiable?

These are commonly asked questions by ICU clinician managers about (nonclinical) fiscal management. This chapter is about fiscal assessment, more specifically the internal financial audit process. An audit is defined as "a formal examination of an organization's or individual's accounts or financial situation." [1] Unfortunately, our discussion cannot be a primer about how to "build" all of these comprehensive assessment tools, which is an entire book itself. Instead, we will exclusively focus on the internal audit process…is our system efficient, functional, and accurate?

A fiscal audit reviews financial data reporting and assesses accuracy and validity. An audit also assesses compliance with fiscal regulatory requirements. Finally, an audit assesses fiscal monitoring, fiscal risk management, and asset protection processes. These are different questions. Did we appropriately and accurately account, monitor, and report our ICU business activities? Did these data comply with written clinical and nonclinical business management strategies? Did we appropriately protect and maintain assets with monetary value, like medical equipment? And finally, did we assess and report the fidelity of these activities to our organizational leadership?

There are several important aspects of ICU fiscal management that are not typically assessed by an internal financial audit. Examples include:

- Quality improvement – a strong focus on quality and performance improvement is the most important approach to lower the overall cost basis of ICU patient care.
- Patient transfer processes – delayed transfer *out of* an ICU to a lower level of care results in excess utilization of ICU beds and increases ICU total fixed costs.
- Patient admission processes – delayed acceptance of clinically "borderline" non-ICU patients (ward and intermediate care unit) *into* an ICU commonly increases overall ICU length of stay, ICU care requirements, and ICU costs.
- Corollary: Early transfer of concerning patients to an ICU, even when their acuity of illness is somewhat lower, can "prevent" the need for complex ICU interventions requirements and thereby lower costs.
- Length of stay (LOS) – decreased ICU patient LOS does not automatically result in more patient care revenue that offsets costs. This is because fixed costs (personnel and facility costs) do not decrease unless the same volume of care is provided with less ICU personnel resource requirements, or increased numbers of patients (variable revenue) can now be admitted the that ICU.

The Internal ICU Financial Audit

Internal Versus External ICU Financial Audits An *internal* financial audit examines healthcare business practices and fiscal risks in the ICU. Conversely, an *external* audit is typically conducted by an accounting consulting firm that examines financial and other records and subsequently issues a detailed report analyzing the financial performance of the healthcare unit. Internal audits are conducted throughout the year, while external auditors conduct a single annual audit [2]. Additionally, data gathered from internal audit procedures are used as management tools for internal hospital and ICU leaders, while external audit reports are used by investors, creditors, and lenders to determine fiscal viability and regulatory compliance. It is very uncommon for ICUs to undergo external financial audits unless specific concerns are involved.

The Committee of Sponsoring Organizations of the Treadway Commission (COSO) How do we ensure that audit procedures are standardized, reproductible, and accurate? Ideally, healthcare and non-healthcare financial audits adhere to the published guidelines of the Committee of Sponsoring Organizations of the Treadway Commission (COSO). These guidelines emphasize appropriate corporate fiscal integrity, responsible corporate governance, reliable corporate ethics, effective corporate risk management, and requisite fraud surveillance. A COSO-modeled audit facilitates assessment of these nonclinical activities [3]:

- Internal control mechanisms – does the management team have efficient and effective financial reporting, compliance with regulations, and safeguarding assets?
- Risk management – does the management team effectively identify and manage unit strategic and operational risks?
- Control activities – does the management team have effective control mechanisms in place that ensure policies and procedures regarding daily operations are reliably performed and followed?
- Monitoring – does the management team monitor and gather data that reliably measure the effectiveness of these control activities?
- Information systems and communications – does the management team accurately report operational, financial, and compliance data to organizational leaders who direct business operations?

The COSO guidelines provide specific details regarding appropriate methods, correct analytical techniques, necessary audit content, and detailed final reporting.

The Elements of an ICU Internal Financial Audit In this chapter, we will exclusively focus on the accounting aspects of an internal ICU financial audit without regard to the direct and indirect impact of clinical quality, safety, and performance on fiscal outcomes. Additionally, before we can discuss the actual audit process, first we must enumerate the financial components of ICU operations. In a

well-functioning ICU with effective operations management, what are relevant financial metrics? What should we assess and where should we focus our efforts? Which financial metrics are most likely to improve performance and efficiency of the ICU? These are summarized in Table 6.1.

Table 6.1 Financial assessment of ICU operations [7–12]

Financial performance
Fiscal summary
Budget variance
Gross revenue
Net operating income
Net revenue per full-time equivalent (FTE), employed staff
Revenue per bed day
Net present value estimates
Other
Revenue cycle
Charge capture efficiency
Net collection rate
Denial rate
Days in accounts receivable
Average reimbursement rate
Evaluation and management (E & M) analysis
Charge description master (CDM) billable events versus payor disbursements
Other
Contracts
Physician contracts payments
Employed staff payroll
External contracts (part-time employees, third-party services, etc.)
Non-personnel investments
Pharmaceuticals utilization costs
Laboratory and imaging studies costs
Medical gases utilization costs
Medical equipment/devices purchase, rental, and maintenance costs
Facility costs (fixed cost per square foot)
Administrative overhead costs
Other
Fiscal compliance
Monitoring accuracy of provider billing and coding entries
Assessment of current fiscal key performance indicators (KPIs): are they relevant; are the data accurately gathered; and are the analyses and action plans appropriate?
Assessment of fiscal compliance with Centers for Medicare & Medicaid Services (CMS) and other payor regulations
Assessment of claims handling accuracy and completeness
Other
Financial risk mitigation planning
Is there a functional plan for issues with CMS compliance, CDM completeness, pricing, and reimbursement?
Managed care contracts, actual payments at variance with expected payments
Very high-cost pharmaceutical utilization tracking
Very long length of stay patients
Increased Private Pay, Medicare, and Medicaid patients significantly above projections
Unplanned large capital expenditures
Other

In a given ICU, most operations managers do not follow every one of the metrics/variables listed in Table 6.1. Rather, a fiscal operations scorecard is tailored according to the specific type of ICU, the clinical coverage model (e.g., employed physicians versus private group), other staffing considerations, the payor mix of patients, known specific fiscal risks, type of ICU (e.g., medical, surgical, cardiovascular, neurosciences, mixed, etc.), and other considerations [4]. In order to facilitate data analysis of these internal processes, these authors summarized the following, extracted from the Intensive Care Working Group on Costing, under the auspices of the Intensive Care National Audit and Research Centre (ICNARC) [5]. This "grouped" cost and asset approach has been in use for more than 20 years in the UK.

- Cost Block 1 (Capital Equipment): All assets that were valued >£1000, <10-year-old, and expected to last at least 1 year were identified.
- Cost Block 2 (Estates): Depreciation, maintenance, utilities, and so on were expressed as a percentage of total ICU floor area.
- Cost Block 3 (Nonclinical Support Services): Expressed as a percentage of hospital floor area.
- Cost Block 4 (Clinical Support Services): Pharmacy and dietetics services were subsequently excluded, as their contributions were both small and difficult to measure.
- Cost Block 5 (Consumables): These included drugs, piped gases, and equipment with a life span of <1 year.
- Cost Block 6 (Staff Costs): Allowances were made for the out-of-hours commitments of medical and technician staff and the additional costs of bank and agency nursing staff.

The Internal ICU Financial Audit Process An internal ICU financial audit is a thoughtful, well-structured, and disciplined process. Before an internal audit is accomplished, first ICU leaders and managers must ask, "Why are we undertaking this process? What are the specific concerns? Which ICU financial domains would benefit from evaluation and what sorts of information do we require in order to understand, reform, and improve? What don't we know that we need to know?" The emphasis point – while an internal ICU financial audit can be a panoramic view of the entirety an ICU's fiscal operations, in most circumstances the true goal of these processes is to address specific questions and concerns. Even more to the point and in my opinion, if ICU leaders and managers don't sufficiently know or understand the existing fiscal weaknesses of their operations, the availability of panoramic financial audit data is less likely to result in meaningful fiscal reform. The process of an internal ICU financial audit has well-choreographed steps. These are summarized in Fig. 6.1. We will describe each of these steps and phases.

Fig. 6.1 The sequential phases of an internal ICU financial audit [13]

Planning Initial planning activities include defining the specific goals of the audit; what questions need to be answered? For example, is payor mix negatively impacting net operating income? Is our charge capture efficiency where we want to be? Next, the audit is used to verifying compliance with independence requirements. For example, are we fully compliant with CMS guidelines for billing critical care time? Finally, define the audit team members, and then spell out methods to determine the nature, timing, and extent of analysis to be performed in order to conduct the audit in an effective manner. This is your opportunity to fully define audit processes, in detail, before intiation.

Risk Assessment The goal of this phase of audit planning is to identify, enumerate, and assess risks that could lead to a material misstatement during the assessment and analysis of ICU financial performance data. This requires a complete understanding of healthcare finances, known risks, reimbursement regulations, and compliance requirements. It also means that auditors must fully understand risks related to competitors, prevailing market forces, customers, and suppliers. For example, your ICU supports an advanced heart failure service line in your institution. What are the relevant financial risks that should be included in the audit process regarding ICU program solvency?

Audit Strategy and Plan Once this assessment is completed, auditors develop a detailed audit plan to address the risks of material misstatement in the financial statements and also data analysis missteps. Among other things, this includes designing a testing approach to various financial statement items, deciding whether and how much to rely on the company's internal controls, and allocating tasks to the audit team members. The audit strategy and plan are continually reassessed throughout the audit process and adjusted to respond to new information obtained about the business and its environment. Using the previous example, what data are required in order to comprehensively assess the ICU impact and fiscal status of an advanced heart failure program?

Data Gathering Directly quoted from PwC: "Auditors apply professional skepticism and judgement when gathering and evaluating evidence through a combination of testing the company's internal controls, tracing the amounts and disclosures included in the financial statements to the company's supporting books and records, and obtaining external third-party documentation. This includes testing management's material representations and the assumptions they used in preparing their financial statements. Independent confirmation may be sought for certain material balances such as cash." For example, E & M coding related to some specific providers seems to be significantly higher than those of other providers in the same work unit. Before concluding that "upcoding" may be occurring, first index acuity of illness indicators for patients cared for by these providers versus E & M coding.

Analysis and Action Plan Once these analytical processes are completed, the final steps are (1) achieve a majority opinion regarding the team's assessment of the

internal ICU financial audit findings and then (2) formulate a clear action plan, again endorsed by a majority of involved leaders. Oftentimes, in change management we attempt to change too much, too fast. This is especially true of when reviewing a comprehensive audit report with many findings, attempting to "do" too much and finishing nothing. Therefore, first prioritize the action plan. There are several considerations that influence these priorities. These other considerations include:

- Inter-unit and interservice politics.
- High complexity change management strategies required.
- Capacity to make the local unit changes (additional resources needed).
- Smaller local unit changes would require much bigger institutional changes.
- Everything costs money; even changes meant to save money.

It is tempting to exclusively focus on "the biggest leaks." Where are we hemorrhaging money, what is costing us revenue? That may be the correct approach, but it may not be when other considerations supervene. Consider this hypothetical example:

> Your institution initiated a left ventricular assist device (LVAD) program. An audit review of the first 6 months of ICU financial data indicate negative net operating income for implanted patients during their ICU stay. During the audit process, it was difficult to separate ICU costs from total hospitalization costs; some financial data modeling was required. When these findings are formally discussed with other involved clinical services, it is clearly a politically sensitive discussion. Furthermore, closer analysis of the data uncovers two patients, implanted early on in the program, both with very low body mass indexes (BMI) and limited mobility prior to surgery. They suffered very long ICU length of stays (more than 100 days). These two patients dramatically skewed cost data. The discussion now shifts to patient LVAD selection criteria rather than cost blame.

Summary

An ICU internal financial audit is merely a tool; it is not a solution. It was said, "If you don't know where you are going, any road can take you there." [6] An audit process can provide a detailed map of an area, but you and other leaders must choose the actual route. In this brief chapter, we have reviewed the definition, process, and analysis of an internal ICU financial audit. I have also included other references not directly cited in this chapter for your additional review.

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Chapter 7
Models of Staffing

Ruth Kleinpell and Stephen M. Pastores

Overview

Establishing the optimal staffing model for the intensive care unit (ICU) is an important consideration for critical care administrators. As critically ill patients often have the most complex care needs and highest mortality rates in the hospital, ensuring safe and high-quality care in the ICU is essential. The ICU is an area equipped with advanced technologies such as mechanical ventilators and personnel trained to provide intensive, advanced life-supportive care to critically ill patients [1]. ICUs can be general or specialized and can be organized by specific specialty or pathologies (e.g., medical or surgical ICUs or cardiovascular, neurological, burn, or trauma ICUs) or by age groups (e.g., adult or pediatric) [1].

According to the Society of Critical Care Medicine, patient care in the ICU is best provided by an integrated multiprofessional team of dedicated experts directed by a trained physician credentialed in critical care medicine (an intensivist). The ICU team may consist of intensivists, critical care nurses, pharmacists, advanced practice (non-physician) providers [nurse practitioners (NPs) and physician assistants (PAs)], respiratory therapists, resident/fellow trainees, hospitalists, and patients and their families. Other healthcare professionals such as nutritionists, occupational and physical therapists, social workers, case managers, and palliative care clinicians also provide care in the ICU. Several considerations for ICU staffing include the availability of intensivists, the ICU organizational structure, nurse staffing,

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integration of NPs and PAs, resident and fellow supervision, and use of hospitalists and telemedicine.

Intensivist Staffing

A number of studies suggest that the quality of care in hospital ICUs is strongly influenced by whether intensivist physicians are overseeing care [2–4]. There is also increasing support for having specialized intensivists for specific ICU populations (e.g., neurological, cardiac surgery) [5–7]. The Leapfrog Group in its recent report in 2019 outlines considerations for ICU physician staffing safety standards and defines intensivists as *one* of the following:

1. Board-certified physicians who are additionally certified in the subspecialty of critical care medicine.
2. Physicians board-certified in medicine, anesthesiology, pediatrics, emergency medicine, or surgery and who have completed training prior to the availability of a subspecialty certification in critical care and provide at least 6 weeks of full-time ICU care each year [8].

A systematic review and meta-analysis of ICU physician staffing models identified that when compared with low-intensity staffing, a high-intensity model with an intensivist responsible for day-to-day management of ICU patients was associated with lower hospital mortality (pooled RR, 0.83; 95% CI, 0.70–0.99) and lower ICU mortality (pooled RR, 0.81; 95% CI, 0.68–0.96) [9]. Other studies have supported this finding and also demonstrated that ICU patients receiving care in a high-intensity intensivist staffing model were more likely to receive evidence-based care, including prophylaxis for deep vein thrombosis and stress ulcer prophylaxis, and undergo spontaneous breathing trials while on mechanical ventilation [10–12]. Decreases in hospital length of stay and costs, ICU readmissions, and number of ICU complications as well as improvements in staff satisfaction and higher educational value for residents have also been reported [10–14].

However, full-time (24/7) intensivist coverage has not been shown to confer additional benefits with several studies in the United States demonstrating no improvement in mortality in teaching hospitals where there is on-site presence of senior physician trainees at nighttime and availability of intensivists by telephone for advice [13, 15–18].

In the United States, there are multiple perspectives and projection studies regarding the adequacy of intensivist staffing in the ICU with the majority projecting a growing shortage of critical care physicians [3, 19–23]. Using nationally representative intensivist workforce data derived from the American Hospital Association, Drs. Halpern and Pastores reported that there were nearly 29,000 privileged and approximately 20,000 full-time equivalent intensivists in the 1469 acute care hospitals with intensivists for fiscal year 2015 [24]. Nevertheless, the perceived shortage of intensivists has led to the integration of APPs into ICU teams and use of telemedicine.

ICU Organization

Staff organization in the ICU is another important consideration. Several different models exist including "open" and "closed" ICUs. In an "open" ICU model, patients receive care from a variety of physicians including surgeons, anesthesiologists, pulmonologists, and other specialists. Intensivist physicians are often available to provide consultation on management issues such as mechanical ventilation, vasopressor therapy, and treatment of high-acuity conditions such as shock. In a "closed" system, intensivists or critical care specialist teams provide exclusive oversight of patient care in the ICU.

Reviews of organizational structure and processes of care in the ICU have demonstrated that both organizational structure (i.e., the conditions under which patient care is provided) and processes of care (i.e., activities that constitute patient care) in an ICU directly influence clinical outcomes [25]. Structure-driven factors that are associated with clinical outcomes include the type of ICU, hospital and ICU case volume, open or closed ICU format, 24-hour presence of an intensivist, nurse staffing, and staff workload [25] (Table 7.1). As previously noted, some studies have shown the benefit of specialization of ICUs for certain fields [6] [7]; however, the literature does not support a survival benefit for specialized over general ICU care for common ICU admitting diagnoses such as ischemic stroke, pneumonia, abdominal surgery, or coronary artery bypass graft surgery [1].

Table 7.1 ICU staffing considerations

ICU bed volume
ICU organization Closed units Mandatory critical care consult in open or semiopen units
ICU staffing Intensivist in ICU 24/7 intensivist
Patient acuity levels
Presence of residents/fellows
Nurse-to-patient staffing ratio
Critical care specialty-trained nurses
Presence of respiratory therapists
Presence of a medical director
Presence of a nurse manager
ICU rounding practices Pharmacist on rounds Respiratory therapist on rounds Physical therapist on rounds Social worker on rounds Nutritionist on rounds Palliative care on rounds

Reference: Checkley et al. [25]

Critical Care Society Recommendations

Guidelines from the Society of Critical Care Medicine outline several recommendations for ICU staffing. These include:

- A high-intensity ICU model, characterized by the intensivist being responsible for day-to-day management of the patient, either in a "closed ICU" setting (in which the intensivist serves as the primary physician) or through a hospital protocol for mandatory intensivist consultation.
- A 24-hour/7-day intensivist model is not recommended if the ICU has a high-intensity staffing model (as described above) during the day or night.
- ICU nursing resources and nursing ratios should be optimized, taking into consideration available nursing resources (e.g., levels of education, support personnel, specific workloads), patients' needs, and patients' medical complexity.
- Because of current constraints on the availability and cost of 24-hour intensivist coverage, further studies are needed to address the efficacy of coverage with critical care-trained APPs, including nurse practitioners and physician assistants, and critical care telemedicine [1].

Nurse Staffing

A number of studies have established that a higher number of nursing care hours or a higher relative number of nurses to patients (or beds) is related to improved ICU patient care outcomes including lower mortality [26–31].

Typically, 1:1 and 1:2 nurse-to-patient ratios are commonly used for critically ill patients, depending on severity of illness, complexity of care, and patient care needs. There is growing evidence that inadequate nurse staffing affects delivery of basic care and increases the risk of in-hospital death [26, 27, 32, 33].

In a study of 69 ICUs exploring organization, size, volume, staffing, processes of care, use of protocols, and annual ICU mortality, the primary factors that were strongly associated with a lower ICU mortality were improved daily team communication strategies and a lower bed-to-nurse ratio (1.7 or less nurse-to-patient ratio) [25]. The use of critical care-trained and specialty-certified nurses has also been demonstrated to impact patient outcomes in the ICU including lower mortality rates [34, 35]. Additionally, the use of multidisciplinary team-based models of care including nurses can improve patient outcomes by decreasing adverse events and healthcare-associated infections and add to patient and clinician satisfaction [36].

Nurse Practitioners and Physician Assistants

In recent years, advanced practice providers (NPs and PAs) have increasingly been integrated to work in collaboration with intensivists and the ICU team to assist in patient care management, particularly in large academic medical centers [23, 37–39].

The APP roles are increasing, due in part to the complex medical care needs of acute and critically ill patients, increased bed capacity of ICUs, work-hour restrictions on physician trainees, workforce shortages, and safety and quality mandates.

Both NPs and PAs are prepared with advanced education and training. NPs are registered nurses who are prepared at either the master's or doctor's level, have an independent license, and are required to pass a national certification examination in most states to practice. Similarly, PAs are healthcare professionals who are certified by a national examination process and practice under the supervision of a responsible physician who must be available for consultation by phone or in person.

Role components of APPs include direct patient care management, diagnosing and treating illnesses, ordering and interpreting tests, initiating orders, and prescribing and performing diagnostic, pharmacologic, and therapeutic interventions including performing procedures consistent with education, training, state regulations, and site-specific requirements (Table 7.2). APP roles encompass other aspects of care including participation in or leading the integration of clinical practice guidelines, quality improvement initiatives, clinical research, and education of patients, families, physician trainees, and clinical bedside nurses [40, 41].

Table 7.2 Role components of APPs

Patient care management
Rounding
Obtaining history and performing physical examinations
Diagnosing and treating illnesses
Ordering and interpreting tests
Initiating orders
Prescribing and performing diagnostic, pharmacologic, and therapeutic interventions consistent with education, practice, and state regulations
Performing procedures (as credentialed and privileged such as arterial line insertion, suturing, and chest tube insertion, among others)
Assessing and implementing nutrition
Collaborating and consulting with the interdisciplinary team, patient, and family
Assisting in the operating room
Education of staff, patients, and families
Practice guideline implementation
Compliance with practice guidelines
Lead, monitor, and reinforce practice guidelines for ICU patients (e.g., central line insertion procedures, infection prevention measures, stress ulcer prophylaxis)
Lead quality assurance initiatives such as ventilator-associated pneumonia bundle, sepsis bundle, and rapid response team
Participate in/lead clinical research studies
Promote and enhance communication with ICU staff, family members, and the multidisciplinary team.
Discharge planning
Transfer and referral consultations
Patient and family education regarding anticipated plan of care and goals of care

Abbreviations: *APP* advanced practice provider
Adapted from Kleinpell et al. [40]

A number of studies have demonstrated the impact of NP and PA care in the ICU including promoting continuity of care, decreasing ICU length of stay, increasing adherence to clinical practice guidelines, and enhancing the training of resident physicians and critical care fellows [40–43].

Resident/Fellow Supervision

In academic medical centers, residents and fellows play an important role in direct patient care and care coordination activities in the ICU [44]. Finding the right balance between clinical service and education for these physicians-in-training can be quite challenging. Too often, the ICU rotations of the residents are relatively short to acquire an excellent understanding of the ICU's care processes and protocols and develop competency in performing ICU procedures [45]. At many teaching hospitals, residents and fellows from multiple departments with different supervision policies can be assigned to the same ICU. Thus, national accreditation guidelines require program-specific policies for supervision.

Hospitalists

In 2016, the Society of Hospital Medicine (SHM) documented that most hospitalist medicine groups care for ICU patients, with up to 80% of hospitalist groups delivering critical care, especially in non-academic centers in rural regions [46]. In some of these hospitals, hospitalists serve as the primary if not lone physician providers of critical care [47]. However, hospitalists are a highly heterogeneous workforce with varied exposure to and comfort with ICU practice, making it difficult to generalize their scope of practice in the ICU [48].

Telemedicine

Given the concerns that the rising demand for critical care services is outpacing the supply of intensivists in the United States, ICU telemedicine, the provision of care to critically ill patients by intensivists located remotely, has been growing steadily. At least 15% of ICU beds in the United States are covered by telemedicine programs [49]. Its appeal derives mainly from the potential ability to improve access to trained intensivists and the quality of critical care [50]. ICU telemedicine providers use electronic medical records combined with audiovisual technologies to assist bedside providers in patient care activities, including adherence to best practices, monitoring of clinical stability, and creation and execution of care plans [51]. However, given its cost and the challenges of determining how, where, and which

components of the intervention work best, local culture and resources should be accounted for when deciding whether to implement telemedicine in a particular healthcare system.

Summary

A number of factors need to be taken into consideration when planning for optimal staffing in the ICU. The high-intensity, intensivist-led model of care, with multiprofessional team-based care, has been demonstrated to result in best outcomes for critically ill patients in the ICU. However, 24-hour intensivist coverage may not be feasible due to the shortage of available intensivists, in addition to financial constraints. Ensuring adequate nursing staffing based on patient acuity and care needs is a crucially important consideration. The use of critical care-trained nurse practitioners and physician assistants can help to optimize team-based care in the ICU. However, additional research is needed on optimal coverage and roles in the ICU for these providers in order to obtain high-quality patient care and resident and fellow education. In many non-academic hospitals, hospitalists serve as the primary if not lone ICU physician providers. Finally, ICU telemedicine coverage has been growing in recent years, and while telemedicine may improve access to and quality of critical care, there is a paucity of high-quality evidence regarding its overall cost-effectiveness, and more research is warranted.

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Chapter 8
Tele-ICU

Zeid Kalarikkal and Shaun L. Thompson

Introduction

The US healthcare system is the most expensive in the world, and critical care services represent a significant fraction of this expense [4]. ICU services consume an estimated 10% of hospital costs at over $81 billion dollars annually [4]. Inpatient admissions requiring ICU stay cost approximately $61,800 on average, about 2.5 times more than a stay without ICU care [5]. Given the increased scrutiny of healthcare resources, newer methods are needed to improve the efficiency of care for patients in the ICU.

Care of critically ill patients by intensivists has shown to improve both ICU length of stay and mortality [6]. The Society of Critical Care Medicine recommends that an intensivist, usually unit-based, have the authority to intervene and directly care for critically ill patients in urgent and emergency situations [7]. The demand for critical care services in the United States is anticipated to increase due to aging of the population and the 35% shortfall of intensivists that is anticipated by 2030 [6].

ICU staffing models have been a subject of much debate. A systematic review and meta-analysis of 52 composite studies by Wilcox showed that access to intensivists and high-intensity staffing models are associated with reductions in ICU and in-hospital mortality [2]. However, around-the-clock staffing models still remain controversial as within the high-intensity staffing cohort, the same systematic review reported no survival benefit for continuous around-the-clock coverage versus daytime-only coverage [2]. These findings were also shown by Kerlin et al. in a systematic review and meta-analysis where nighttime intensivist staffing was not associated with reduced ICU patient mortality [8]. Realistically, it may be difficult

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for many hospitals to even have high-intensity daytime coverage due to lack of patient volume, lack of financial resources, and/or availability of intensivists. This disparity is magnified when focused on rural medicine. Rural populations are more likely to be underserved due to access to critical care services. Mohr et al. found that in Iowa, a state in the Midwest United States with a large rural population, most ICUs did not meet the Leapfrog standard for ICU staffing. This standard requires daytime coverage by board-certified intensivists and overnight access to an intensivist by telephone. It also requires a minimum 5-minute bedside response by a non-critical care physician, advanced practice provider, or specially trained nurse [9].

Tele-ICU is one of the ways the medical community hopes to solve the imbalance in supply and demand. It is defined as the provision of care to critically ill patients by healthcare professionals located remotely [10]. Tele-ICU services are meant to leverage, not replace, the need for bedside clinical expertise in the diagnosis, treatment, and assessment of various critical illnesses while allowing fewer intensivists to provide care to a larger number of critically ill patients. Modern telemedicine primarily occurs in centers that house intensivists, advanced practice providers, and nurses who either provide continuous around-the-clock coverage or during evening and weekend hours exclusively. They have the ability to access all patient data such as medical records, laboratory tests, and radiographic studies. Concurrently, they have the ability to remotely monitor vital signs and facilitate communication with bedside clinicians and other providers via computerized audiovisual approaches [11]. Additionally, Tele-ICU also requires a communication network to be established between the physical ICUs and the Tele-ICU monitoring center. These monitoring centers are typically located in areas with higher than average population densities of intensivists.

Models of Tele-ICU

There are three main models upon which Tele-ICU systems are designed: centralized, decentralized, and hybrid. Overall, there is much more literature available describing centralized models and review articles that describe implementation of a Tele-ICU system do so from the point of view of a centralized model [11].

Centralized Model

A centralized system is often referred to as a continuous high-intensity or active system. It is described as a team of healthcare care providers at a discrete site monitoring and intervening on a large population of critically ill patients. This closely resembles a hub-and-spoke model and offers clinicians the ability to integrate large

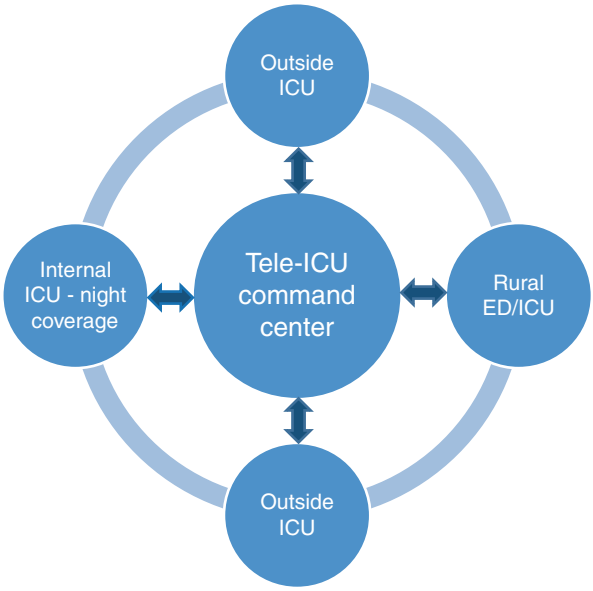

Fig. 8.1 Hub-and-spoke model of centralized Tele-ICU model

amounts of data from within a hospital system as well as from different hospital systems. It often provides computer-generated alerts, notifications, and clinical decision support algorithms [1]. It also provides the ability to highlight individual patients by acuity and to intervene on one patient at time while simultaneously monitoring a large patient population. Understandably, this more advanced system comes with associated higher costs and requires centralized location of the Tele-ICU team (see Fig. 8.1).

Decentralized Model

A decentralized system allows a remote intensivist to virtually visit one patient at a time from a remote location that can be anywhere the intensivist chooses. There is no established central monitoring facility, and monitoring is done from the providers' computer or laptop. It typically involves computers, tablets, and smart phones equipped with camera, speakers, and microphones located at sites of convenience for the physician [12]. The provider in this model communicates directly with an ICU team member who is at the bedside. This model provides much more limited information and lower-level intensity of interventions as compared to a centralized system, leading it to be referred to as a point-to-point passive system (see Table 8.1). This allows healthcare systems to provide intensive care at much lower costs. However, it is a reactive consultative model, without the ability to integrate different data streams.

Table 8.1 General comparison of the centralized and decentralized model

Characteristic	Centralized	Decentralized
Open architecture	Possible	Mandatory
Closed architecture	Most commonly	Not workable
Physical monitoring site	Yes	Not usually
Cost of installation	Higher	Lower
Operational costs	Higher	Lower
Complexity of installation	Higher	Lower
Smart alarms	Yes	Bedside RN functions as "alarm"
Concurrent EMR	Generally yes	No
Provider mobility	Not usually	Greater mobility

Reynolds and Bander [13]

Hybrid Model

The hybrid model is one that combines features of both the centralized and decentralized models. This model is not utilized as frequently and, thus, is not as well studied in regard to outcomes and effectiveness in comparison to centralized and decentralized systems. It resembles a centralized model; however the intensivists are separate entities that combine as a single virtual practice.

Staffing for Tele-ICU

Staffing may vary greatly depending on the Tele-ICU model being implemented with centralized models having more intense requirements. Additionally, the care model being used can have a significant impact on staffing needs. A continuous care model implies around-the-clock monitoring in real time that allows for monitoring of all ICU patients. A scheduled care model is also a type of care model used where dedicated times are previously identified for physician rounding and is typically set for 6 to 8 hours after a daytime ICU team has ended their shift. There is a reactive staffing model, where Tele-ICU staff respond on an as-needed basis such as for unstable patients, new admissions, or requests for ICU consultation [1, 12].

The centralized facility must be staffed by intensivists, nurses/advanced practice providers (APPs), and clerical assistants. This is independent of staffing at the ICU being monitored. The number of staff at each monitoring center depends on the total number of ICUs being covered as well as patients being monitored. Currently, recommendations suggest 60 to 125 patients for each intensivist, 30 to 40 for each nurse, and 50 to 125 for each clerical assistant [13].

Additional factors that can impact hours include academic versus community settings, availability of residents in-house, and hours of intensivist staffing at the bedside. Most centralized monitoring centers will provide continuous nursing and physician coverage 12 to 19 hours a day during the week and 24 hours a day on the

weekends. The nurses and clerical assistants typically cover 12-hour shifts, while intensivists work in shifts of 9 to 12 hours. Most intensivists maintain bedside clinical responsibilities as well when not scheduled to provide Tele-ICU service, while some intensivists choose to work Tele-ICU full time [3].

The intensivists' responsibilities can be categorized as routine and unscheduled. Routine responsibilities include evaluation of all new ICU admissions and monitoring of existing patients. Unscheduled responsibilities include responding to emergencies and identifying emerging problems [13]. As such, Tele-ICU physician engagement can be classified as high level or low level. High-level involvement includes emergency interventions such as direction of cardiopulmonary resuscitation, guidance for invasive airway management, and adjustment to other life-sustaining interventions. Low-level engagement of Tele-ICU intensivists includes non-emergent interventions such as reviewing results of blood tests ordered and electrolyte replacement. A low-level model would typically focus on emergency interventions and some minor interventions only; it typically would not include changes or modifications to existing therapies [1].

Financial Considerations

Every Tele-ICU program requires a well-developed financial business plan that can be significantly different for a centralized vs decentralized model. Areas of potential savings to a hospital system include decreased length of stay (LOS), decreased time on mechanical ventilation, and ICU triage 24 hours a day, among other indirect potential benefits.

The impact of Tele-ICU on overall ICU costs varies in the literature. Two previous studies reported detailed financial information that reported contradictory results as to whether Tele-ICU improved costs and clinical outcomes [14, 15]. Yoo et al. performed a cost-effective analysis of Tele-ICU systems and concluded that the current application of a centralized Tele-ICU is cost-effective under most circumstances [3]. However, this may have some variation based on severity of patient illness. A 2010 study on the cost-effectiveness of Tele-ICU across six intensive care units in a large healthcare system showed that the cohort of patients with lower disease severity had increased expense per patient and was not effective [15]. Patients with higher disease severity, however, showed decreased hospital mortality without increasing costs significantly. The authors showed that for this sub-group of patients, costs increased by $2895 per patient after Tele-ICU implementation which was not statistically significant while decreasing hospital mortality by 11.4% [15].

For rural hospitals, the importance of high ICU bed utilization is paramount as underutilization can represent a significant financial burden on a healthcare system. The primary aim of such hospitals is often to maintain an ICU at nearly full capacity with appropriate patients. Being part of a Tele-ICU program may allow a rural hospital to potentially retain patients who might have otherwise been transferred to a larger, higher-acuity facility. However, this purported benefit was not

consistent with the findings of Pannu et al. who noted that inter-hospital transfers actually increased post-implementation of a Tele-ICU program and were attributed primarily to transfers from less specialized ICUs. There was no relation to illness severity [16].

Tele-ICUs have mostly been unable to charge for intensivist services that they provide, so their costs can only be recouped through improved efficiency. However there have been significant efforts made to address this issue by the American Telemedicine Association. Breslow and colleagues showed that reductions in the patients' average length of stay (LOS) translated to a 24.6% decrease in cost per case, and this resulted in a $3.1 million benefit to the hospital over the 6-month study period [17]. A financial analysis of Tele-ICU at the University of Pennsylvania showed similar results with a decrease in ICU and hospital LOS leading to an estimated reduction in costs of up to $3.8 million dollars per year [18]. The most detailed financial analysis to date was performed by the Massachusetts Technology Collaborative in conjunction with the New England Healthcare Institute [19]. In this analysis, the University of Massachusetts Memorial Medical Center (UMMMC) implemented a Tele-ICU within its medical center and placed the technology into two smaller community ICUs. The change most affecting the financial results was the reduction in LOS, which decreased by approximately 20% [19]. The actual financial effects of a Tele-ICU are, however, difficult to measure because accounting systems are designed to measure direct billing and reimbursement rather than actual costs or indirect savings. Despite the paucity of financial analyses that have been conducted and completed, a number of healthcare systems have and continue to make large investments in Tele-ICUs which is likely due to the potential of a well-implemented Tele-ICU system to impact positive change on a healthcare system in terms of costs and quality of care.

Barriers to Implementation

There are five commonly cited barriers to adoption of a Tele-ICU system: high capital and operating costs, unproven return on investment, clinician resistance, lack of interoperability with EMR systems, and lack of documented outcomes [19]. It is estimated that establishing a Tele-ICU system can cost from 6 to 8 million dollars in upfront capital costs. On the other end, it can cost a single facility approximately $300,000–500,000 dollars to acquire and install the Tele-ICU technology required to allow monitoring by an established service. Also, reports suggest that it costs approximately 1–3 million dollars per year to maintain a command center [19]. The annual contracting fee to a command center for subscribing hospitals can vary from $23,000 to $40,000 per year [19]. Additionally, there are limited research findings available for hospitals to help guide the decision on whether or not to adopt a Tele-ICU program. Research that is available is mostly applicable to the particular ICU setting and hospital system in which they were studied [19].

Outcomes from Utilization of Tele-ICU

According to a consensus statement from the Critical Care Societies Collaborative, Tele-ICU outcomes should be evaluated from the perspective of the provider, patient, and healthcare system (see Fig. 8.2) [20].

Provider-Centered Outcomes

Tele-ICU can positively impact several important provider-centered outcomes. A systematic review of staff acceptance of Tele-ICU services found that it was viewed favorably by physicians and nurses. Nursing surveys report improved satisfaction from having access to an intensivist when needed [21]. Residents reported that Tele-ICU improved patient care and benefited their training specifically with regard to ventilator management, management of unstable patients, code supervision, and recognition of respiratory failure [22]. Romig and colleagues evaluated the impact of a nocturnal telemedicine service on staff satisfaction and perceptions of quality care. They found that nurses exposed to Tele-ICU responded more favorably than nurses who were not. Specifically, they reported a positive impact on communication with other healthcare workers, psychological working condition, and educational experience [23]. This likely translates to increased job satisfaction and decreased turnover. The bedside intensivist also benefits through decreased number of overnight shifts, increased sleep quality, and lower rates of burnout [6].

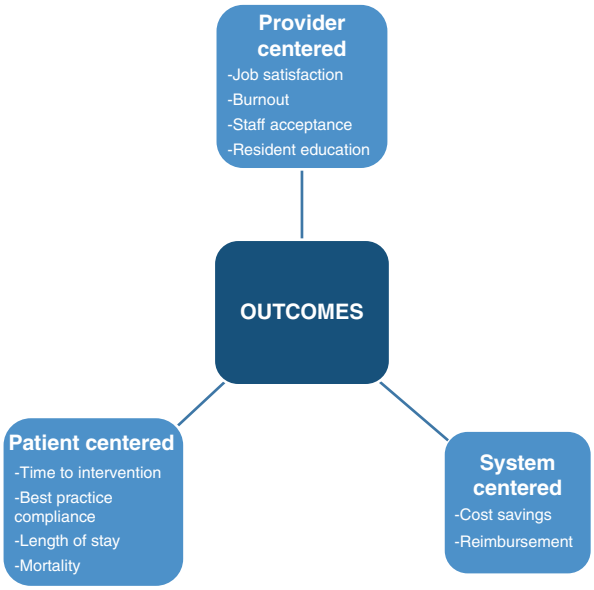

Fig. 8.2 Tele-ICU outcomes. (Venkataraman and Ramakrishnan [21])

Patient-Centered Outcomes

Several studies have attempted to address the impact Tele-ICU has on patient care. A great example of this can be seen with the impact of Tele-ICU on various best practices in the ICU such as stress ulcer prophylaxis, DVT prophylaxis, and adherence to VAP bundle. These practices are generally well accepted as favorably affecting ICU outcomes, yet there remains difficulty in achieving high rates of compliance. This was demonstrated by Lilly et al. who studied a large group of ICU patients and found generally low compliance rates [24]. The same investigators then conducted a pre-/post-Tele-ICU intervention study and reported an improved compliance rate with several common ICU best practices (see Table 8.2). In this study, they found that many potential complications were significantly reduced and ultimately would result in decreased patient morbidity and improved outcomes. This was verified due to the fact that they associated this improvement in best practice implementation with reduced adjusted odds of mortality and reduced hospital length of stay [10]. Youn demonstrated a Tele-ICU program-enhanced compliance with three ventilator bundle components, specifically head of bed elevation, deep venous thrombosis prophylaxis, and stress ulcer prophylaxis [25].

System-Centered Outcomes

Cost-effectiveness and reimbursement are two of the primary system-centered outcomes that have been studied.

Breslow et all showed that an effective Tele-ICU program can reduce ICU costs per patient by up to 25% [17]. This was attributed to increasing the number of ICU admissions per month as the average length of stay decreased after Tele-ICU implementation. This however is in direct contrast to the findings of Franzini et al. who concluded that average daily costs increased after implementation of a Tele-ICU system [15]. There is no definitive answer yet as to the economic viability of a Tele-ICU system, and future studies are needed.

Hospitals are currently unable to bill directly for Tele-ICU services that are provided as noted previously in this chapter. Telemedicine services outside of the ICU

Table 8.2 Best practice compliance pre- and post-Tele-ICU implementation

Best practice	Pre-Tele-ICU	Post-Tele-ICU	OR (95% CI)	P-value
Stress ulcer prophylaxis	83%	96%	4.57 (3.91–5.77)	<0.001
Deep venous thrombosis prophylaxis	85%	99.5%	15.4 (11.3–21.1)	<0.01
Ventilator-associated pneumonia (VAP) bundle	33%	52%	2.20 (1.79–2.70)	<0.01
Incidence of VAP	13%	1.6%	0.15 (0.09–0.23)	<0.01

Lilly et al. [10]

have been able to overcome some of the obstacles and can be easily reimbursed; however this has not trickled down to critical care. Given the uncertainties regarding the financial benefits of Tele-ICU, any progress on this front is unlikely to be seen for some time.

Conclusion

The use of telemedicine to provide intensive care coverage to underserved areas is a burgeoning field of medicine that can provide improved care and outcomes for patients. It offers a way to supplement and elevate traditional bedside care and allow healthcare systems to face the challenges of an ever-changing healthcare environment. While research is ongoing, there is a fair amount of evidence to suggest that when implemented appropriately, it can improve access to timely and quality critical care. There is still considerable room for advancement in terms of reimbursement for services provided and determining the optimal model to best service the needs of a healthcare system. However, the potential benefits and implications in helping to reduce morbidity, mortality, and healthcare costs are too significant to ignore, and further studies are required.

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Chapter 9
Digital Transformation: The Smart ICU

Javier Pérez-Fernández, Nestor A. Raimondi, and Francisco Murillo Cabezas

Digital transformation has come to stay. Technology is a major influencer of all aspects of our life, from banking to services and from the way we shop for groceries to the way we travel. Far from being just a fashionable aspect of current times, technology has flooded and penetrated medical practice. In less than a decade, practitioners have adapted their practice patterns to the use of electronic health records (EHR), voice recognition systems, automated drug delivery systems, simulation equipment, and other major technologic advancements some present and soon to come. Critical care, given its own nature, is the perfect environment for technological innovation. Critically ill patients require complex medical care associated to a myriad of medical devices and treatment aids that must be coordinated with advanced informatics. In addition, critical care is a very interactive world in which multiple information pathways and personnel collide to facilitate the management and care of the patient. Simplifying all those avenues of information, as well as improving patient care with a rational use of resources, is certainly the objective of the technologic advancements applied to critical care [1].

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The Cultural Factor

We witness a major change in the culture of healthcare. From the physician-centered environment or system-centered healthcare, we are moving toward the patient as the center of the healthcare system. Personalized healthcare is the core of the new delivery of care. A reviewed healthcare is directed by the four "Cs": culture, care, communication, and collaboration [2]. Current informatic systems work in collecting data, surveillance, and analytics to later cluster them to facilitate care based on average, mode, medians, etc. Healthcare metrics have been based on what happened to a population rather on what happened to the patient. Some have recognized this model as the "pret-a-porter" of the delivery of care, in which different pre-made "sizes" (treatments) are applied to conditions expecting that, for most patients, these will work.

This concept is in a similar way applied to the scientific method. In order for us to accept treatments or interventions, we require testing them into populations, even recognizing that the patients included on those studies might not be similar to our patients. In addition, the growing amount of collected data that we are able to manage has made a major impact in our decision-making capability. More and more variables are added to our analysis. However, not always more is better. And it is certainly the case when the practitioner is confronted with this huge amount of information that sometimes rather than facilitating the management complicates the decision-making. Nurses and bedside practitioners are exposed to a minacious monitoring of the patient's vital signs, with information coming minute to minute and every minimal change impacting the amount or nature of such information. All of that immersed in a myriad of vectors of information netted in our patient bedside, sometimes not interconnected and certainly not blended.

The Elements of the Digital Transformation

Understanding acute illness as part of a process rather than an episode of health is a change in our view of the disease. The integral concept of the patient challenges many of the views of the disease that have been dominating our practice. Acute respiratory distress syndrome (ARDS) is not a condition that affects the lungs. Moreover, a patient with ARDS is not the same as another patient with ARDS. We experience those singularities every day among our patients. Integral care therefore must focus on individual variability. But in order to do so, we must begin with a tight collaboration between different disciplines that can provide aspects of the care to that patient. That has been well-mastered in the ICU since the definition itself of a modern ICU includes multidisciplinary care team approach [3]. There are three factors that must be considered at this point:

First, the informatic systems implemented in ICU must have the ability to interconnect all aspects of the care, past and present, storing data in a reliable source of information, totally integrated and interoperable at a maximum level (Levels of

Information Systems Interoperability (LISI)) allowing the management of all aspects of care from a single application [4].

Second, processing and analyzing data. There is more and more data, more complex and rapidly accumulating, making our actual storage and processing systems inadequate for their purposes. Every day more and more institutions are using the cloud as a storage source, opening various concerns but at the same time increasing the possibilities to the user. Safety issues in one hand are being matched with positive aspects as the ability to share information among systems and even with other hospitals. The growing amount of information is reflected in the concept of *big data*. Analysis of *big data* introduces promising theories such as creating patient's profiles with individual characteristics shared by a few patients remotely located, disease evolution pathways, discovering adverse events associated with interventions otherwise unknown, as well as predicting responses to different therapies based on multiple patterns. Big data has become an integral part in the development of personalized medicine [5].

Finally, the use of artificial intelligence, aimed to create predictive algorithms, processes that will allow to confront situations and changes in condition with anticipative power and confidence. Predicting the development of sepsis, acute hypotension, or hypoxemia is subject of present research. Some are closer to reality than others, but undoubtedly, they represent a major development on medical care [6, 7].

Examples of digital advancements such as telemedicine and mobile health are currently present in our practice, and in some systems, they represent a significant portion of the delivery of care.

Benefits of the Digital Transformation

The multidisciplinary nature of critical care demands technical, financial, and social skills from the participants. These relevant factors must also be the driving points of the digital transformation.

Improving Patient Care

The ability to obtain a full array of clinical data, complete, reliable, timely, and sharable, is certainly attractive to most clinicians. Through simplification of the sources and filtering information, we must be able to decrease duplicity of services and accelerate therapeutic interventions in a safer environment.

Electronic health record (EHR) implementation has impacted patient safety by the decrease on medical errors. Writing and interpretation has been substituted by legible documentation, sometimes printed or in informatic support, providing a safer way of practice [8, 9]. Not only that, but through the integration of electronic tools such as medication reconciliation (MAR) or laboratory values, our practice has become also safer [10].

Additionally, electronic data sources allow the evaluation of the impact of interventions such as changes on ventilator parameters and could help to identify the need for resources or to modify protocols [11].

Tracking patients that have moved out of the ICU, for tests or treatments, is a major component of the digital transformation occurring in the ICUs. Everyday more our critical care is moving toward the delivery of ICU without walls. Connecting patients to the technology available at the ICU while collecting all information from them becomes then essential. Telemedicine has been advocated as a resource in this particular field [12].

Facilitating Administrative Workload

A greatly important portion of the practitioner time is spent in documentation in all of its forms.

Informatics is simplifying this aspect, sometimes by the preparation of "templates" with checkmark filling, sometimes by allowing verbal input of the information using voice recognition systems (with everyday more reliable transcription), or even by allowing the carrying of previous information into new documentation (with the consequent probability of transferring mistakes) [13].

Resource Utilization

Critical care clinicians are continuously scrutinized in regard to cost-effectiveness. Although ICUs are not "money makers," they can be great "money savers." Measuring data is necessary for the correct functioning of an intensive care unit as it helps to determine the performance, is an unvaluable tool for the standardization of care and will guide improvement initiatives [14]. The value of score systems and data collection has been highlighted as a performance improvement tool [15]. Reducing medical errors and adverse events might have enough impact on length of stay to justify the investment into technology for some institutions. Monitoring and analyzing costs with seasonal variations might also have impact on budgeting personnel expenses in areas with significant variable influx of patients.

Finally, we should not ignore the environmental impact that paperless informatic systems offer with the savings in paper and storage costs.

Expansion of Knowledge

Healthcare professionals are known to happily adapt applications that portend usefulness and improve care for their patients [16]. However, they might be resilient to adapt administrative tools, aimed to improve just utilization with a lack of clinical

value [17]. However, hospitals and health systems are continuously measuring the actions of the personnel by tools that are designed to help administrative and financial decisions rather than improve communication or facilitate clinical management.

Electronic applications that allow the "intervention" of the healthcare professional, whether inputting data or modifying some tools (adapting them to their particular practice) or those that are able to facilitate easy-to-absorb information and knowledge to be transmitted (i.e., hands off in shifts), are welcomed by all levels of professionals. Integrative systems, those enhancing interdisciplinary communication, form the nurturing environment for adequate transmission of knowledge, hence academic and research development. Interconnecting one ICU with others, sharing information and details with other professionals, and allowing data comparison (even if blindly obtained) might help such duties.

Finally, adding current evidence-base to treatment protocols or management algorithms must be part of the electronic solutions to allow the healthcare professional to better understand the rationale behind treatment recommendations and to facilitate standardization of care.

Communication

Social media has abruptly changed our way of communication. Healthcare professionals and systems must be prepared to the challenges presented by these forms of communication. Nowadays, press conferences might be surpassed by social media information, and both the institution and the professional must be ready to introduce themselves into those pathways of information.

Our ICU is portrayed more and more like a glasshouse in which everything that happens is exposed to the public and must be displayed with total transparency [18].

Telemedicine: Tele-ICU

Telemedicine and more particularly tele-ICU were born in response to the shortfall of intensivists and moved in great part by the need of quality-driven care on ICUs not served by specialists [19]. Moreover, the need for technology applied to the care of patients requiring critical care has also a reason to justify the development of telemedicine, while at the same time, the cost of technology and other financial challenges have limited its growth [20].

Tele-ICU allows access to intensive care specialists (both nurses and practitioners) in remote locations to facilitate care and implementation of protocols in ICUs. In particular, relieving professionals in nighttime periods has become a very attractive way to reduce burnout of those specialists and has been advocated as one of the benefits of tele-ICU [21].

Tele-ICU provided implementation of sophisticated early alarm systems, leading the response by a specialist. Examples include sepsis alerts, stroke alerts, etc. The

clinical impact of tele-ICU is still a subject of controversy mostly motivated by the high costs associated with its deployment and the lack of strong association between described benefits and the use of such technology [22, 23].

It is important to mention that tele-ICU was never designed nor developed as a substitution of the bedside care but rather as a complement.

New advancements in technology have the potential to make this tool more affordable, and we could expect changes in the delivery as well as, hopefully, reimbursement policies being revisited, making tele-ICU more attractive and expandable [24].

Smart ICU

Conceptually speaking, smart ICU is more than the word definition. Making an ICU *smart* entitles three major elements in the delivery of care: elimination of harm; engaging all professionals, patients, and families; and increasing proficiency and personalized care through the use of technology.

In the last decade, we have witnessed hospitals and health systems embracing projects aimed toward those aspects of care, in a full integral fashion or on a step-by-step basis. Examples include Project Emerge at the University of California in San Francisco or *Smart ICU*^{R} at Virgen del Rocio Hospital in Spain [25, 26].

Personalization of medical care is undoubtedly sought by all clinicians. As the healthcare environment is everyday more challenging, full of new discoveries and therapies, and our population ages and suffers multiple comorbidities, it is clear for all that treatments aimed to solve elements of the disease need to be integrated into singular care delivered to each patient. Therapies are changing, now being directed to "phenotype" or even genetically engineered for each patient. Critical care is not going to be different, and on a daily basis, we are being challenged with requests for a more accurate and agile delivery of care prioritizing patient safety and directed to a particular individual.

Critical care clinicians must turn into technology to answer some of those challenges. In the words of Dr. Max Harry Weil while describing critical care, "…it was the technology, and specifically the monitors and measurements, that increasingly distinguished themselves from their predecessors Intensive Care and Intensive Therapy" [27].

The "Techno" Problem

Lack of interoperability between technologies is as frustrating to the physicians as it is for most of us in daily activities. Who has not encountered those issues when simply downloading an application or a document into an application? One of the major problems of technology rests on the inability of informatic systems to com-

municate among them. Solutions are needed for solving multiple problems that medical care has, especially in the ICU. Medication systems are not fully connected to infusion pumps. Those are not connected to our EHR. Ventilators have a particular monitor system, but their data is not exported to medical record. Manual input of data is a common practice among healthcare professionals. All these aspects are calling for solutions to make the delivery of care safer and more effective.

The alarm fatigue is a major factor in patient safety [28, 29]. ICUs are continuously flooded by the noise of alarms announcing abnormal states or physiologic variables for our patients. In numerous occasions, those alarms do not result in meaningful response by the clinician or nurse, or they are simply ignored for a time, raising the concern regarding their value. Much has been said about alarm fatigue, but unfortunately it continues hitting our ICUs and distracting our professionals.

The amount of information delivered by our present technology comes many times unfiltered. Because of that, the clinician needs to exercise the decision of filtering and interpreting multiple variables in order to deliver care accordingly. Healthcare professionals used a limited amount of information to generate a clinical decision [30]. Clustering information might be an answer, but filtering and blending it is more attractive and likely to lead to safer and more effective delivery of care.

Workload and stress are factors limiting the effective time for our ICU professionals. Workload has been associated with increasing medical errors [31, 32]. In many circumstances, professionals are subject to tedious process of documentation and even duplicity of data entry as a result of the implementation of software or new informatics. Healthcare electronics would benefit from integral and easy-to-use systems that reduce the time spent by the professional in documenting, allowing more time for the care of the patient.

Stress is undoubtedly inherent to the job of a critical care clinician. Stress is fed by multiple sources, including the multiple interactions with different professionals, many times from multiple specialties, and the different aspects of the critical care. In addition, critical care professionals are subject to continuous scrutiny in an environment in which they are required to perform under major pressure, and they are expected to deliver answers with precision and celerity. Finally, technology could be a factor for stress, adding more requirements to the professional by increasing the amount of unfiltered data and alarms and even documentation requirements [33].

Systems' Interoperability

Perhaps one of the major caveats of modern ICU delivery of care is the lack of interconnection among different monitoring systems and medical equipment devices.

Interoperability signals should blend safety systems, informatics, medication delivery and storage (pharmacy), equipment, and other supplies and interact and feed information to and from medical record, telemedicine, and remote accessibility. All this must be achieved in a highly secured environment [4].

The concept of smart ICU requires the patient being the center of all these interconnections. That means our ICU must center on the patient and all the systems must work for the patient, connected and without the need to modify the delivery of care based on the available systems. To achieve this, a five-step process has been suggested [4]. First, wiring (or wireless coverage) of the entire ICU; second, connectivity ports and accesses in all rooms; third, automatic identification tags on all data sources; fourth, adapters in all equipment and data-generating devices so they can transmit and communicate; and, fifth, addition of middleware, allowing communication among systems and devices. Middleware is classified by FDA into class 1 or medical device data systems (MDDS) and class 2, offering active monitoring and alarms.

Why Do We Need Smart ICU?

Patients in critical care receive care from multiple avenues. Information is also obtained from multiple sources. Multidisciplinary care is the rule and not the exception in ICU. Interoperability must be a major achievement of modern informatics. Through mastering the ability to interconnect and allowing diverse systems to act and receive information, we are setting the basis for the smart ICU. There are five major reasons why smart ICUs will result in a safer and more efficient environment for the delivery of care: capacity to analyze data from a very extensive database (e.g., big data); development of protocols from the data analysis; acquisition of real-time, contrasted information; ability to separate meaningful data from non-essential; and the possibility to develop predictive algorithms with degrees of autonomy.

The Components of Smart ICU

First, as defined previously, smart ICU must have the ability to interconnect all data and monitoring systems within the same software, with language interpretation and analytics. The system must be able to store data, and for that reason, and given the multiple sources and amount of data, the use of remote storage systems must be considered (cloud), as well as mirroring data for security purposes. One of the obstacles found in today's systems is that data is collected to later be analyzed. Sometimes even the input of the data into the system is delayed, not allowing real-time analysis. For instances, many electronic records require ventilator data to be manually input or nurse's entries and data from the pumps to be manually added. Those circumstances limit the ability to interpret or analyze real-time information allowing room for human mistakes in the transcription of those entries. An informatic system, smart, must be able to collect all data and transmit it and interconnect it, real-time, directly from each software or equipment. In addition, the smart infor-

matic system should allow the creation of virtual communities (i.e., iv pumps or ventilators) from which data can be abstracted and analyzed in a simple fashion [34].

Second, the smart ICU system must be user-friendly. One of the buying points for users of any new technology is how easy it is to use such technology. Software systems must be universally accessible and allow entrance to all levels of participants, sometimes including patients and families. In the previously mentioned Project Emerge, families have the ability to entry different preferences for their relatives, such as music or diet. The system allows the recognition of those preferences and sets up approaches to the caregiver to facilitate the delivery of those preferences when possible [25]. It is not unusual on the actual software systems that the level of skills required for accessing most of the beneficial applications is high, limiting in many instances the adequate usage and requiring costly and time-consuming training sessions for all personnel [35].

Third, smart ICU systems must start building alarms with meaningful value and with the ability to evolve on those values [36]. For example, an alarm for blood pressure will be continuously activated in a patient with a hypotensive episode with no purpose once the episode has been recognized. However, the episode could be triggering two aspects to the alarm system. The first should be the recognition of the situation by the equipment, hence the ability to silent the alarm (after the clinician intervention has occurred) and possibly the reaction with some therapeutic intervention (as described below). In a similar way, systems must perfectionate to be able to separate contamination versus real alarm situations. It is a common event to walk into a patient room and see and hear the monitor alarming for an arrhythmia that refers to movement of the leads or respiratory excursions. It is important to reflect that in medical care, an alarm is effective when it is activated if a serious or meaningful problem occurs (that most times has been previously identified and set by the professionals working in the ICU and thus must be "modifiable" and adaptable to different scenarios), it is recognized by the clinician with the right meaning (it requires familiarity with the concept and values of normal by the professional), and it is accompanied by a solution for the problem (an alarm that only tells us the immediate proximity of a catastrophic event might not have other purpose than "alarming" and causing chaos). It is not unusual to observe that in multiple circumstances, ICUs do not have protocols for determined changes in physiologic variations notified by the alarms. The implementation of protocols should be very helpful in this particular matter. Finally, alarms should have the ability to react using a confidence interval previously determined in a similar fashion that the plane's autopilot varies in course and altitude according to variations on weather on the flight-path. This concept is certainly better attained upon understanding and implementing artificial intelligence as mentioned below.

Fourth, the smart ICU system must have the ability to learn from previous events, big data analysis and protocols added. This concept refers to artificial intelligence, and this will be subject of discussion below. Value in the form of action-reaction or predictive algorithms is a major avenue for research at the moment [37–39].

Fifth, the smart ICU system must be mobile. According to the concept of modern ICU, critical care is not a place but is the care delivered and must not be limited to

a certain area but expanded to all the hospital, also known as ICU without walls. Once a patient is evaluated and is determined the need for critical care, we should be able to extend our care delivery to any area with full guarantees and standards of care. That must include informatics. Thus, a smart ICU system must be mobile and portable and require minimal hardware to function at full capacity. One of the requirements for such task is the availability of real-time locating systems (RTLS). These systems presently used mostly to locate devices (mobile asset tracking) can also be utilized to monitor inventory and of course to map location for patients and personnel [40]. They also have the potential to track compliance with regulatory policies such handwashing protocols, encounter times, etc.

An additional point for discussion is communications. Nowadays most hospitals use several communication systems (e.g., portable in-house phones, cell phones, hard-line phones, paging systems, etc.). However, the systems are not, most of the time, interconnected or much less connected to the main informatic system and rarely will be communicating with the EHR. An ideal scenario is to have all forms of communication interconnected allowing the documentation of those communications and also the ability to interchange the methods according to the needs and circumstances. In that environment, any form of communication will be recorded in a central system, and one provider will have a single way of access (i.e., a single number) that will transfer from method to method according to the location of the provider (location that could be tracked using RTLS).

Artificial Intelligence (AI)

There have been a significant number of publications regarding the use of AI in all aspects of our life in the most recent years [41]. For some, the word artificial intelligence is becoming synonymous with augmented intelligence. In great part due to our unmet needs of delivery of precision care, with celerity while at the same time personalized, AI has become a sought development in critical care. The concept of smart ICU cannot be understood without advanced technological tools with some degree of autonomy and capacity of learning [42]. Let's take for example the ICU room and some of the aspects related to the care of the patient in such environment. Patient identification is now manually input. Safety measures used two or even three identifiers including technologic aid (band scanning) for any procedure. By using modern technology, patient face recognition could substitute most of those with a tremendous accuracy and safety. By the same token, we could even identify body positions that will impact on protocols such as head elevation, extremity movement, etc. [43, 44]. Moreover, aspects related to the room's environment can also be detected and intervene on, such as light intensity, noise level, family presence, etc. It is extremely difficult to control all these aspects without a very advanced, autonomous system.

Conceptually, there are three major aspects on artificial intelligence applied to medical care. The first relates to the ability of the systems to select information from

the cascade of influx data that minute to minute all medical systems are feeding to the central intelligence. This concept is tightly associated with the quality of information summarized in the four Vs: volume, value, variety, and velocity. The volume of received information is growing every day. Collecting all data results in astringent amounts of information from multiple sources. The ability to classify, control, and structure the information depends on advanced informatics. Value is probably one of the most important aspects in medical care. If data could be classified and "digested" to serve a particular clinical purpose, it would determine a significant advancement in medical care. For example, if changes in the respiratory frequency could be matched to changes in respiratory pattern and associated with particular mechanical ventilation changes, the resultant data could have much more clinical value for the clinician. The variety of the information is also a factor of clinical importance as data for a physiologic variable could be obtained from different sources allowing contrasting and validating results. This, far from increasing the time spent by the clinician, could be achieved using technology, facilitating the recognition of any changes. Finally, real-time information is needed. Multiple times, the clinician is bombarded by data from a past period of time. How many clinicians have the ability to determine the number of their patients in a given moment in the ICU that are on a spontaneous breathing mode? How many can tell what dosages of vasopressors are their patients receiving in a singular moment? Acquiring data in real time and having access to that information could be crucial in some aspects of the decision-making process.

The second aspect relates to the autonomy of the system for action-reaction. Alarms are an integral part of the medical care, moreover in the ICU. Anytime an alarm is triggered is should be associated to a significant event, it should be recognized with such meaning and should carry the activation of a plan of action. Alarms flood our ICUs, and in multiple circumstances, one of those three characteristics is not achieved being responsible of the alarm fatigue, a factor that impacts patient safety, and it is the object of serious personnel dissatisfaction. Artificial intelligence has the capability to learn from episodes, cultural aspects, and individual variations. Systems can adapt alarms to pre-determined circumstances and facilitate the filtering of those with less clinical significance or not important at that particular moment to then minimize the contamination of information or even allow the system to alter those filters according to newly developed situations. Action-reaction protocols can be included in the alarm system, a part of the response phase. This will be similar to a plane's autopilot, that in order to maintain the flight path and following a pre-established variation range is able to adapt variables such as speed, altitude according the the wheather conditions [45]. Aspects of the critical care such as response to modifications on the oxygenation (measured via pulse oximetry) of a patient on a ventilator or variation in blood pressure in patients with a continuous infusion of a vasoactive substance, with a consequent change in the therapy in an automatic fashion, can only be achieved through the integration of those aspects and the help of AI.

The third aspect is the development of predictive algorithms. The availability of big data has opened the door to the access of shared information. Now, aspects of

the care of patients can be matched to many other patients and locations and even clustered based on individual characteristics such as gender, age, race, etc. Artificial intelligence can not only store and analyze those data points but also create commonalities in some of those aspects leading to predictions of actions. It is not obscured to all of us that predictive models are being used on marketing and other information aspects of our life [46]. Prediction of physiological variables has been the subject of many investigations [47, 48]. In response to personalization of medical care, predictive algorithms portend increasing value. The ability to determine the response to a particular therapeutic agent for each individual, the odds for a therapy to be effective, or even the possibilities for a successful admission or discharge to the unit are subject of many queries. Not only based on clinical value but also on due financial implications, the use of AI in the development of predictive algorithms and protocols is highly on demand. Moreover, multiple determinations of the value of a medical intervention are based on observational data. Even on studies that are well-randomized and prospective, most of the studied variables depend on the observations by nurses or clinicians. Repetitive patient assessments, a very time-consuming and subjective element of the care, can be substituted by AI interventions while integrating and interpreting results at the very same time [49].

There are additional factors attributed to AI that will need further contrast such as the ability of saving time for professionals (beyond the time savings already granted by the use of technology) or reducing stress for clinicians through facilitating medical decisions. Although these factors could easily be extrapolated from the characteristics of AI, more evidence is needed to determine the actual impact of artificial intelligence on those.

Conclusions

Critical care medicine is evolving from disease-centered and physician-centered to patient-centered delivery of care. Personalized medicine is the medicine of the future, medical care characterized by the “6 Ps”: prevention, prediction, participation, precision, panoramic access, and personalization.

Technological advances have made medical care safer, faster, and more reliable. However, the actual systems, more directed toward administrative, documentation, and financial aspects, will need to evolve toward more intuitive, integrative, and innovative ones.

Converting our ICUs to smart ICU requires the precise use of technology centered in the patient, with the ability to filter information, personalize care, and facilitate interoperability of the different systems. Artificial intelligence will be a very important tool in the delivery of care in the near future, and although all these aspects might not be operational in the present time, many of the characteristics are already impacting the delivery of critical care of the twenty-first century.

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Chapter 10
Protocols, Policies, and Procedures: Tools for Quality Improvement in Critical Care

Andrew T. Levinson and Mitchell M. Levy

Introduction

Quality and safety have become central issues in health care in the last two decades. Prior to the release in 2000 of the Institute of Medicine report *To Err is Human*, many in health care assumed quality care was the norm and mistakes and poor care were very rare [1]. The report emphasized that medical errors were quite frequent and the ones that made the public eyes were not just outliers.

Compounding medical errors is the fact that providers often are not able to make accurate self-assessments of performance. In truth, there is a gap between our perception of how we are doing and how we are actually doing. The gap between perception and true performance is well described in the literature [2, 3]. Deaths and complications significantly increase if best practices such as appropriate antibiotics and low tidal volume strategies are not followed, yet without audit and feedback, clinicians believe themselves to be doing a much better job than is factually accurate.

Patient safety and quality improvement (QI) or performance improvement (PI) are now central to both individual intensivist daily practice and health-care institution system wide. The quality of care is dependent upon the application of best practices following the best available evidence, for the purpose of limiting practice variability. Through the use of measurements of provider and provider team

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performance, the goal of all successful quality improvement programmes is to improve overall care and decrease deviations from best practices.

An efficient and highly reliable intensive care unit (ICU) requires the development and continuous refinement of policies for the delivery of care. Checklists, protocols, bundles, and guidelines are powerful tools to implement and improve ICU policies. Essential to the improvement of ICU policies and procedures is the ongoing collection and dissemination of both process and outcome measures. Essential to QI is the process of measuring the performance and then providing ongoing audit and feedback. Audit and feedback addresses the gap between clinician-reported perception of practice and actual performance.

The accurate measurement and reporting of quality data is becoming even more important as it is becoming increasingly widely distributed and recognized by the public and policy makers and being linked to financial reimbursement.

Tools to Implement ICU Policies and Procedures

Protocols, checklists, and bundles that reflect up-to-date guidelines are essential tools used to implement new ICU policies and procedures designed to improve the quality of care. When effectively utilized, these tools decrease variability in care and enhance the translation of evidence-based medicine to the bedside.

Protocols are precisely detailed plans that guide therapy aimed at improving clinical care. Protocols are of varying complexity and drive behaviour towards a common standard. Their prescriptive nature facilitates use in both routine bedside care and clinical research.

Checklists are the least complex tools and have been shown to facilitate efficient, high-quality care. Checklists are simple reminders to facilitate routine care patterns, such as the provision of deep vein thrombosis (DVT) prophylaxis.

Guidelines are recommendations derived from systematic review of relevant literature, which aim to provide a minimum standard of care for clinical management of various disease states. Often less proscriptive than protocols or checklists, guidelines serve as a general framework for clinical management.

Bundles are a set of interventions, distilled from evidence-based guidelines, which target specific disease management. The assumption underlying the development of bundles is that ‘bundling’ proven interventions together should result in better outcomes than when implementing them individually. Monitoring compliance (audit and feedback) is the key to successful implementation of care bundles to drive change in clinical behaviour [4, 5]. It is important to emphasize that these tools serve to enhance, not replace, the skills of the bedside clinician. They aid in bridging the gap between the discovery and publication of new knowledge and clinical implementation. This path of knowledge translation can help lead to a broad-based application of best practices for appropriate patients.

Two examples of multifaceted interventions in the ICU to improve care include the Surviving Sepsis Campaign’s (SSC’s) performance improvement initiative for

sepsis management and the Michigan experience with an intervention to reduce central line-associated bloodstream infections (CLABSI) [6, 7]. These projects used local interdisciplinary teams, introduced education, and monitored performance using checklists (CLABSI) or bundles (SSC). Local commitment allowed for large-scale implementation. In 29,470 patients with severe sepsis and septic shock worldwide over a 7.5-year period, the SSC initiative demonstrated that increased compliance with sepsis performance bundles was associated with a 25% relative risk reduction in mortality rate, the success of which were confirmed in a recently published state-wide initiative in New York [8]. In Michigan, the median CLABSI rate dropped from 2.7/1000 catheter days to 0 at 3 months and was sustained over the next 18 months.

More recent similar multifaceted interventions have demonstrated improvement in the use of appropriate antibiotics in sepsis [9], reduced mortality in patients with severe sepsis or septic shock [10], and a reduction in ICU adverse events by increasing engagement and satisfaction of ICU patients and family members [11].

Despite these and other quality metrics successes, not all of the results have been positive. Decreased time from knowledge acquisition to bedside care may lead to unintended consequences. The first example of this is in the treatment of CAP. The Joint Commission established a 4-hour goal for antibiotic administration in response to two large retrospective studies, demonstrating improved outcomes with earlier antibiotic administration [12]. As an unintended consequence, the accuracy of a clinical diagnosis for CAP declined, leading to excessive antimicrobial use and misuse [13]. The Joint Commission has since added a diagnostic category of 'diagnostic uncertainty' and increased the time goal to 6 hours.

A second example of the potential deleterious effects of widespread application of quality metrics is the story of tight glucose control. In 2001, Van den Berghe reported that normalization of glucose in critically ill cardiac patients, i.e. tight glucose control, was associated with decreased mortality. This was rapidly translated into clinical practice in medical and surgical ICUs worldwide. Over the next 9 years, studies suggested these findings may be less pronounced in the medical patients, culminating in the NICE-SUGAR trial, which demonstrated harm to these patients, attributable to much higher rates of severe hypoglycaemia in the intensive insulin group [14].

These stories serve to remind that ongoing refinement of measures and evaluation of outcomes is central to the quality movement. Rapid translation of evidence into clinical practice can sometimes result in unintended consequences. Ongoing evaluation and reassessment is important to recognize and address unanticipated results.

Overview of Policy Development and Establishing a Quality Improvement Committee and Programme

Hospitals and ICUs worldwide have embraced the field of quality improvement (QI). Policy development should be based on a vigorous quality improvement programme.

QI includes four essential phases: development, implementation, evaluation, and maintenance. Each phase has key features. The first step of the development phase is to establish a collaborative interdisciplinary leadership group or quality improvement committee. This group is central to the success of the QI project, and members need to be selected thoughtfully. Representatives from all stakeholder groups likely to be affected by the potential intervention should be represented, including ICU nurses, respiratory therapists, clinical managers, social workers, spiritual care counsellors, local experts, and multidisciplinary providers. Ideally membership should include representation from all shifts (days, evenings, and nights) and varying levels of seniority and include a community/patient representative. A hospital senior manager should be on the committee or be a designated sponsor/liaison to help ensure adequate institutional commitment. This team should guide the process and needs to have shared commitment to both QI and a collaborative approach.

Understanding the target environment is important for the initiation of a QI project. Characteristics of the target ICU, size, hospital and ICU type, regional culture, and other factors are essential in the success of a QI initiative. A mature and high-functioning ICU with prior QI experience may perform differently than a QI-naive ICU. Prior experience with successful QI initiatives can help guide data measurement and the form of feedback that works best for a specific ICU team. Pre-existing, administration-supported teams for data entry and monitoring as well as tracking and reporting programme implementation can decrease the project costs and help ensure sustainability. Goals should be achievable; thus understanding baseline practice is essential. Specific QI efforts should target process issues and clinical outcomes for which the specific ICU is not performing well. If an ICU is already doing well with regard to a specific process or outcome measurement, investing significant time and effort in a QI project will likely be very low yield [15].

Implementation of Policies

After establishing the scope and goals, making a plan for implementation is the next step. Understanding the target environment will aid the process, utilizing existing assets and targeting potential barriers to shape implementation. A 2019 analysis of the initial implementation of ICU quality improvement programmes in six community-based hospitals found that key components essential for successful implementation included assessing staff and organizational readiness for change, ensuring existence of external collaborators and mentors, and having committed nurse and physician champions [16].

Another study by Deborah Cook and colleagues demonstrated that barriers to implementation are not necessarily complex, but easily overlooked [17]. Poor communication between the bedside nurse and physician was one of the main reasons for inconsistent use of semi-recumbency. Through an understanding of process and barriers, solutions may be identified to improve compliance.

Multifaceted interventions are more effective than single interventions for influencing behavioural change. Guidelines and education alone are unlikely to make substantial changes, so the addition of audit and feedback systems is important [18]. While designing an audit and feedback system, both outcome (long-term) and process (short-term) measures should be considered. There are arguments both for and against the use of either one; thus understanding the benefits of each becomes important. Examples of outcome measures include incidence of ventilator-associated conditions (VACs), catheter-related bloodstream infections (CR-BSI), ICU length of stay, and mortality. Tracking and reporting outcome data is usually quite feasible as most institutions collect these data, but demonstrating change may be more difficult. Therefore, process measurement, i.e. a marker of 'what we do' (such as time to antibiotics), is more difficult to track and may require new systems, personnel, and financial investments. However, process measures are more likely to show change and success over a short period of time. Outcome measures are often better accepted, because they are more obvious measures of patient care. Linking process measures to patient outcomes may facilitate acceptance of specific performance metrics and lead to improved compliance.

The final piece of a QI programme is sustaining the effort. Depending on the complexity of the intervention and level of success, sustaining the initial process may require variable work. Balancing cost in terms of manpower and financial resources with value or impact is essential. Not all achievements will decay at the same rate, so the maintenance phase has to be dynamic, and institution-specific, similar to implementation [19].

Running a successful QI project requires sustained but incremental interdisciplinary teamwork. At the heart of its success and maintenance is leadership and perseverance—continuous pursuit of improvement and sufficient resource allocation to allow it to succeed and persist over time. A full review of QI implementation is beyond the scope of this chapter, and a useful resource is the 'how to' guide published by Curtis et al. [20].

Measurement of Performance

Essential to the quality movement is the process of measuring performance. Developing and revising ICU policies and procedures should be based on the ongoing measurement of performance.

Physicians can have unrealistic expectations around their own competency and performance when compared with external assessments. They also may have inflated views around the adequacy of care they provide [2]. A survey of ICU directors comparing perception of care provided versus actual care delivered demonstrates this gap. Perceived adherence to low tidal volume ventilation and tight glycaemic control was 79.9 and 65%, while actual adherence was 2.6 and 6.2%, respectively [3].

Physician reporting and clinical experience can play a role in patient care, but evidence suggests that objective evaluation provides a better assessment of practice patterns and therefore a better basis for informing high-quality and reliable care.

There is significant practice variability that may not be detected unless an ongoing performance measurement is implemented. In a classic study, only 54.9% of 6712 patients in the United States received care that was compliant with recognized best practices for preventive care [21]. This variability in performance may be due to the complexity of patient care, individual patient physiology, professional values, cost, or other important processes. When deviation is due to knowledge deficits, oversight, or the faulty application of knowledge, it is unacceptable. Variability linked to poor outcomes has been demonstrated in the ICU. Adherence to Infectious Disease Society of America guidelines for the treatment of severe community-acquired pneumonia (CAP) was only 57.8% in a cohort of 529 ICU patients [22]. Mortality was higher in the guideline-non-adherent population. Other deviations are frequently linked to worse outcomes [23, 24].

Limiting variability is central to the quality movement but has been met with resistance. Standardization of care is seen as an attack on physician and patient autonomy and a minimization of the importance of physician experience. Some feel that the experience garnered cannot be replaced with quality metrics. Reliance on clinical experience has been called into question. In a systematic analysis of 62 published studies, the majority of these studies suggested a steady decline in both physician competency and patient-centred clinical outcomes after completion of training [25]. Thus, dependence on accrued knowledge, i.e. ‘experience’, alone may not ensure high-quality care.

Accurate quality measurements can be logistically and technically challenging. There is the potential for surveillance bias and other potential confounding. Any proposed measure needs to be validated and scrutinized to ensure avoidance of unintended consequences [26]. For example, hospitals are compared for their venous thromboembolism (VTE) prophylaxis rates and subsequent risk-adjusted VTE rates. However, one recent study demonstrated that in hospitals with high rates of VTE prophylaxis, and therefore higher-quality scores for VTE prevention, there was also increased use of non-invasive imaging to look for VTE, and this results in higher risk-adjusted rates of VTE in these hospitals [27].

Quality measurements are increasingly relevant for practitioners and hospital systems [28]. In the United States, the National Quality Forum (NQF) is a public-private partnership that endorses consensus standards for performance measurements. Performance measures are selected based on their scientific acceptability, clinical importance, usability, and feasibility. To be endorsed by the NQF, the measures must be evidenced-based, tested and validated, and supported by key stakeholders as well as community representatives. Endorsed measures are adopted by both public and private funders and health-care systems. Examples of current NQF measures relevant to critical care practice include appropriate antibiotic selection for community-acquired pneumonia (CAP), spirometry testing for patients with COPD, and 30-day all-cause mortality following hospital admission for COPD.

Communities with limited resources face particular challenges when it comes to quality measurement. A retrospective study of rural critical access hospitals (CAHs) in the United States found that they were less likely to have high scores on key process of care measures. CAHs also had higher 30-day mortality rates for common ICU diagnoses such as pneumonia, CHF, and acute myocardial infarction [29]. One potential benefit of the increase in widespread quality measurement is the potential for improvements for all patient populations, including those in minority groups with historically limited access to quality care. One study found that since the introduction in the United States of tracking for the adherence to process of care measures for myocardial infarction, pneumonia, and CHF, there has been a significant improvement in the quality of care delivered to all patient populations and a narrowing of the gap between the quality of care provided to members of minority groups in the United States [30].

Compliance with Physician Reporting

In the United States, reporting of physician and hospital data on quality measures is becoming increasingly common and available to the public, policy makers, and payors. It is no longer unusual for outcomes reporting to be mandated and performance tied to the reimbursement of both hospitals and individual providers. One of the factors that makes interpreting quality reporting particularly challenging is that there is significant regional practice variation on Medicare quality indicators.

The potential positive impact of required physician reported is exemplified by the 2013 New York State initiative requiring state-wide reporting of sepsis care. All hospitals in the state were required to submit data on compliance with recommended sepsis care. An analysis of the initiative found a significant reduction in risk-adjusted sepsis mortality after the implementation of required reporting [8].

Even prior to the implementation of the landmark Affordable Care Act (ACA), in the United States, there have been significant national efforts to collect and disseminate information on quality measurements. The Deficit Reduction Act of 2004 authorized the Centers for Medicare and Medicaid Services (CMS) to develop data infrastructure and to involve various stakeholders in identifying and validating key performance indicators. The ultimate goal is linking payments to individual physician and hospital performance.

Key components of the Affordable Care Act (ACA) approved by US Congress in 2010 include identifying quality and performance gaps in the health-care system, approving and utilizing quality measures developed by independent groups, and then utilizing them for public reporting and linking them to payments. Currently over 76 inpatient quality reporting measures are being reported, including those that relate to management of acute myocardial infarction (AMI), congestive heart failure, and pneumonia. In addition the Centers for Medicare and Medicaid Services (CMS) require hospitals to report adherence to the National Quality Forum's severe sepsis and septic shock management bundle [31].

The effectiveness of required mandated reporting of quality mesures has been mixed. A recent analysis of a cohort of patients with sepsis found no difference in mortality after adjusting for severity of illness between the patients who received all of the recommended required CMS measures for sepsis care and those who did not receive all components [32]. In contrast, an analysis of data from recent demonstration programmes funded as part of the ACA documented significant financial savings and improvements in core quality measures when health-care organizations were given financial incentives and increased flexibility in the delivery of care not tied to fee-for-service payments [33, 34].

With inpatient quality reporting, significant improvements in rates of achievement for process measures in the management of heart failure and pneumonia have been achieved. For example, 93% of patients in 2006 with AMI received aspirin on arrival to the hospital, but this increased to 99% in 2010. Similarly, only 55% of patients with AMI received cardiac catheterization percutaneous intervention (PCI) within 90 minutes of presentation in 2006, but this increased to 91% by 2010.

While there has been significant progress on reported compliance with process measures with the advent of required reporting of quality measures, there has not always been a corresponding improvement in outcomes, including mortality.

A 2015 study evaluating the effect of hospitals participating in the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) did not yield positive results. The study used propensity score matching to compare mortality data and information on serious post-surgical complications (myocardial infarction, pneumonia, acute renal failure) for over a million patients in 263 participating NSQIP hospitals and 526 nonparticipating matched hospitals. While there was a trend towards improved outcomes in both the hospitals that participated in the quality reporting programme and those that did not, enrollment in the programme was not associated with any significantly improved post-operative outcomes or reduced costs [35].

Conclusion

Developing and maintaining effective policies, procedures, and protocols is truly of critical importance in ensuring a smoothly operating and efficient ICU. Ongoing quality improvement using quality measurements is becoming increasingly important in caring for the critically ill.

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Chapter 11
ICU Design

Paul C. Yodice

There have been a number of publications in recent years as well as in the distant past regarding intensive care unit design. Most begin with a description of a planning phase, the time required for planning, designing, evaluating, and implementing the said designs [1, 2, 3]. Published abstracts, manuscripts, and books present concerns for patient psychosocial issues, family comfort, staff accommodations, and other amenities. There are sections regarding consultants, architects, administrators, finances, financiers, and finally the composition of clinician contributors to the design of a unit/floor/wing to care for the critically ill person [4, 5, 6].

As any institution embarking upon a redesign or new construction will employ a team of non-clinical experts to consider each and all of these topics, I will not touch upon some of that herein. The manuscripts and books enumerated in the bibliography as well as consultants hired by the reader's institution will provide some financial and regulatory insights [7, 8]. Instead, as an intensivist dedicated exclusively to the care of critically ill people for more than two and a half decades in ICUs of various vintage, the most important question of immediate concern is "Do I have all that I need to help this person?" This question is often followed by "Am I able to use that (whatever *that* may be) safely in this area in the care of my patient?" Design of the intensive care unit affects the multidisciplinary approach, clinical effectiveness, and well-being of both the staff and of the patients for whom they care [9, 10].

Most of those who read this will not have the luxury of a "clean slate," a new building or wing, a tabula rasa from which to build an entirely new unit to house all of the current, anticipated, and conceivable technology. We are all too often saddled

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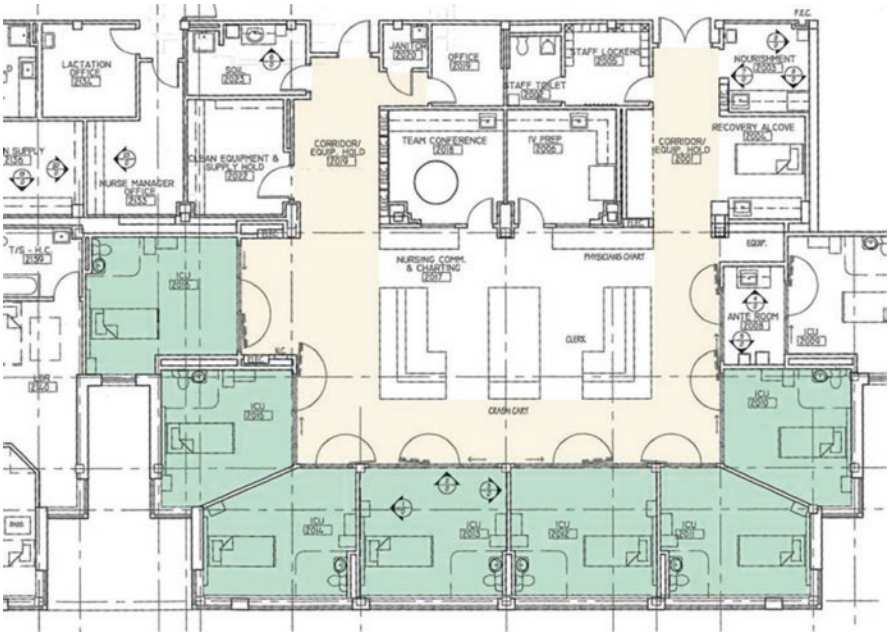

Fig. 11.1 ICU design. Used with permission from TM Osborn Associates

with space that was dedicated to decades-old concepts, and even then, the room footprint was an afterthought [5] (Fig. 11.1).

Thus, we begin this chapter where clinicians begin their assessment of a patient: in a patient room at the bedside.

The Patient Room

Although the modern patient room must be organized to best accommodate and manage the individual patient, current technology allows for and necessitates the management and monitoring of patients elsewhere in the intensive care unit. Thus the patient room must accommodate a single patient [11–15] to maintain infection control; readily allow access to evaluative, management, and support technology; provide means to communicate within ICU and throughout the institution; and maintain physical and psychological comfort of patient, visitors, and staff [16–26]. While every ICU director, nurse manager, and staff member desires a newly constructed intensive care unit, we more frequently must develop a plan based upon a preexisting structure subject to relatively unyielding dimensions. In the United States, the average ICU room size is 259 square feet [21], and it is within this space that all of our care with all of our technology must be delivered.

A. Core [27, 28, 29].

The "core" of the patient room is the source or sources that supply the technology supporting the patient and equipment. The distribution of electrical, data stream, gas, suction, and select supplies is often considered in three traditional floor plans:

1. Headboard configuration – in which the gas supply, data stream cables, suction, and majority of electrical outlets are supplied on one wall at which the head of the bed is usually aligned.
2. Column(s) configuration – one or more pillars or columns on which the same sources are placed. These columns are in some instances mobile: an advantage as additional technology is brought into a patient's room.
3. Boom(s) configuration – ceiling or wall affixed articulating arms from which electrical, gas, and data stream emanate (Fig. 11.2).

As flexibility improves from headboard to column to boom configuration, so too does complexity, maintenance requirement, infection prevention protocol, and risk of failure. This must be considered at the time of planning.

B. Technology [30].

The devices of universal implementation in an intensive care unit include:

1. Patient bed:
   - Capability considerations include bariatric, rotational, percussion, imaging (MRI, fluoroscopy, etc.) compatibility, and orthopedic fixation.
2. Physiologic monitor [30–36]:
   - Interface with EMR, backward compatibility with older technology, communication with central and telecommunication stations, two-way interface with other technology (ventilator, infusion pumps, etc.), interface with local and distant physiologic alarms, etc.
3. Infusion pumps – intravenous, nutrition, body cavity [37–39, 47–49]:
   - Bidirectional feedback with EMR and physiological monitor
   - Interface with local and distant alarm system
4. Oxygen and compressed air:
   - Source must be readily accessible from either side of the patient.
   - Must be readily and uniquely identifiable as oxygen and distinct from compressed air.
   - Supplies for administration must be readily at hand at oxygen source.
5. Suction – must have multiple sources:
   - Patient requirements (nasogastric suction, wound drainage, thoracostomy drainage systems, etc.)
   - Procedure related (endoscopy, bronchoscopy, etc.)

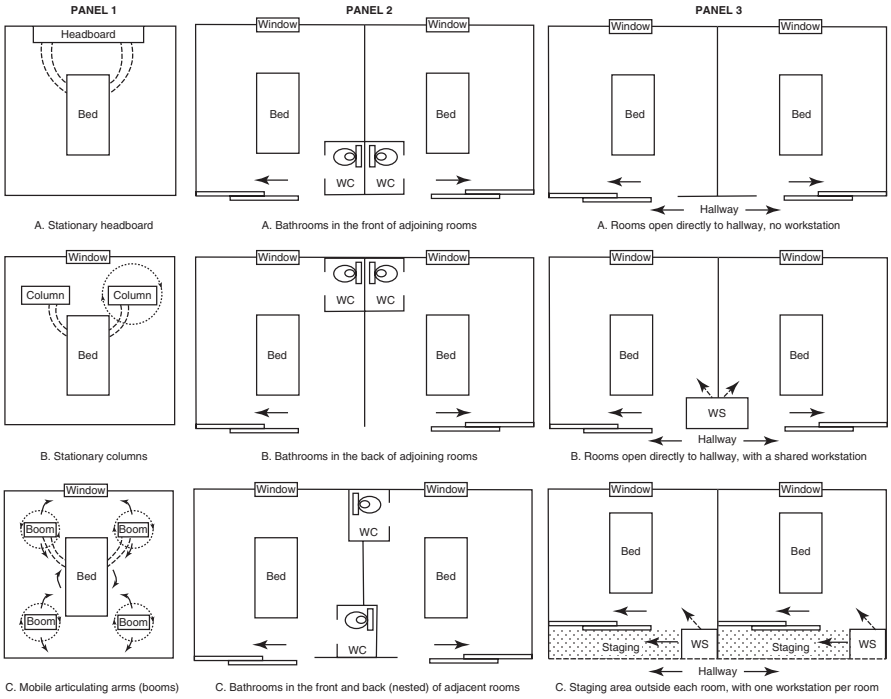

Fig. 11.2 ICU utilities and equipment (panel 1) are mounted on a stationary headboard (A), stationary (left side) or rotating (right side) columns (B), or mobile-articulating columns (booms) (C). The booms can be attached to the walls or ceiling and at any corner of the bed and swivel and move horizontally or vertically. In panel 2, the ICU patient room bathroom (WC) can be located in front of the room ("inboard") (A), back of room ("outboard") (B), and in the front of one room and the back of the adjacent room ("nested") (C) [22]. Although these decisions may be based upon the availability of plumbing, the impact on patient visualization from the hallway, window availability, and workflow should be considered by the design team. Panel 3 shows that patient rooms may open directly into the hallway without any workstations (WS) (A) or with a shared workstation for the two rooms (B). Alternatively, the rooms can be set back to provide a staging area in front of each room with one workstation per room (C). (Modified with permission from CHEST. Halpern [96])

6. Electronic medical record for documentation and order entry. The evolution of this matter is fast paced, but for consideration, we have [40, 50, 51]:
   - Traditional desktop computer workstation.
   - Workstation (or computer) on wheels (WOW or COW).
   - Handheld laptop-type devices.
   - Notepad devices – these have become more powerful and capable with all of the features and capabilities of their larger counterparts.
7. Two-way communication [52, 53]:
   - Patient to staff
   - Staff to patient
   - Staff to staff

8. Telemedicine – now accepted in many areas of medicine especially neurosciences and radiology [41–46, 52–61]:
   - Critical care has witnessed the successful application of telemedicine in the management of the most critically ill. As the value of well trained critical care physicians is now more universally accepted, the availablilty of same remains inadequate to meet the need with a physical presence at all times in all institutions. The ratio of skilled critical care practitioners to critically-ill patients in need of those skills is inadequate. Thus, the technology of real-time, high-definition, two-way audiovisual correspondence, interaction, and examination must be included in the planning of an ICU renovation or construction.
9. Mobile over-bed or bedside table
10. Specimen label printer
11. Ceiling-mounted lifting device [61–65].
    Although these common devices – patient monitors, infusion pumps, and computer entry devices – are becoming more compact and efficient, ever more technology is introduced to ICU for point of care management [82–85]. Thus, the 259 square foot patient room must accommodate:
    a. Mechanical ventilators
    b. Continuous renal replacement therapy (CRRT)
    c. Extracorporeal membrane oxygenation (ECMO and ECCoR)
    d. Ventricular assist devices (IABP, LVAD, RVAD, BiVAD)
    e. Ultrasonography [81–83].
    f. Continuous video electroencephalography (CVEEG)
    g. Mobile CT scanners [66, 67].
    h. Patient lift equipment
    i. Patient mobilization equipment (walkers, wheelchairs, etc.)
    Other as yet undefined technology will require real estate within the patient room, while patient care must remain unimpeded, thus the necessary strategy of planning with intent.

C. Environment

1. Supplies
   Emergency supplies must be easily and readily accessible to staff within the patient room:
   a. Personal protective equipment: gloves, masks, gowns, face shields, etc.
   b. Patient care materials: sterile gauze, tape, saline, nasal cannula, oxygen mask, ambu-bag, etc.
   Non-emergency supplies:
   c. Bed linen, patient hygiene, bathing, etc.
2. Storage
   a. Adequate for the non-emergency supplies
   b. Patient belongings

c. Small safe for patient item security
d. Flashlight for emergency use

3. Lighting (67–71)

   a. Patient controlled for general atmosphere and focused for reading and meal
   b. Staff-controlled general room lighting must be of a quality that is both comfortable to patient and visitors but adequate for overall clinical evaluation;
   c. Staff-controlled general and staff-focused, bright lighting adequate for procedures as well as detailed examination of all aspects of the patient and surrounding environs
   d. Natural lighting through windows
   Must have means of control by both patient and staff

4. Visitor seating

   a. At least two chairs dedicated for visitor use [72, 73].

5. Privacy

   a. Easily decontaminated or replaceable curtains to visually isolate patients from exterior environs

6. Sink [74–78].

   a. Preferentially located near entrance to patient room
   b. “No-touch” activated
   c. “No-touch” soap dispenser in immediate proximity
   d. “No-touch” hand sanitizer
   e. Hand towel dispenser with appropriate waste bin exclusively for this purpose

7. Waste disposal [79, 80].

   a. Must prevent aerosolizing of material as eliminated

8. Soiled linen bins

   a. Rolling device for easy mobility in patient room
   b. Readily accessible to staff during linen change

9. Trash bins

   a. Standard
   b. Infectious
   c. Sharps

10. Temperature control
    Adjustment may be made to address:

    a. Patient clinical requirements
    b. Patient comfort

11. Clock
12. White board/electronic board in line of sight of patient
    Provides up-to-date information to patient, visitors, and staff
    a. Patient Name
    b. Contact person name and details
    c. Location
    d. Clinical team member names (physician, nurse, respiratory therapist, physical therapist, dietician, clerk, etc.)
    e. Date
    f. Outdoor weather
    g. Activities allowed
    h. Patient medical tests/travel planned
13. Board for visitor use in line of sight of patient
    a. Surface upon which messages can be written
    b. Surface upon which notes, cards, photos, and drawings can be hung
14. Television
    a. Internet capabilities
    b. Radio capability
    c. Closed caption capability
    d. Control
        i. Traditional handheld device
        ii. Voice control capability
        iii. Wireless keyboard
15. Access
    Curtains, sliding doors, hinged doors, and breakaway doors each meet some of the requirements below. Each of these requirements can be met with adequate consideration in the redesign of established ICU space.
    a. Must be large enough to simultaneously accommodate:
        i. Patient on stretcher or bed in transport
        ii. All of the patient's necessary equipment
            1. Infusion pumps on rolling stands
            2. Ventilator
                a. Along with alternative gases and associated equipment (NO, heliox, etc.)
            3. Cardiac support devices (VAD, ECMO, etc.)
            4. *Personnel* (too frequently forgotten)
                a. Physician(s)
                    i. Managing patient stability, cardiac support devices, etc.

b. Nursing staff (often two)

i. Managing infusion pumps, drains, and stabilization equipment, managing patient vital signs, etc.

c. Respiratory therapist

i. Manage airway, ventilator support, gas supply, etc.

d. Transport personnel

i. Coordinate movement of equipment, transfer of patient from stretcher/bed to ICU bed, positioning of patient and equipment and patient in room, etc.

b. Must allow for privacy

c. Must meet infection prevention/infection control requirements

i. Policy and procedure must be in place for all surfaces and technology within the patient room.

1. Compatibility with techniques and efficacy of decontamination routines must be validated with manufacturer recommendations and independently on a regular basis by the institution.

ii. Surfaces must be accessible for ready decontamination.
iii. Decontamination must be achievable in rapid fashion for patient readiness.
iv. Decontamination must be isolated to the room intended so as not to put other patients, visitors, and staff at risk of exposure.
v. Egress with materials must not put other patients, visitors, or staff at risk of exposure or contamination.

16. Infection control requirements
i. Positive pressure capabilities for select rooms
ii. Negative pressure capability for select rooms
iii. Decontamination anteroom

1. Designated room(s) – must meet all of the above described requirements yet have adequate area for safe decontamination without risk of cross-contamination or exposure to others. Such a chamber may reduce the already limited footprint in an already established ICU.
2. An alternative to establishing such a space within a patient room is to configure this decontamination anteroom outside of an already developed patient care room. This may be a modular or readily constructed chamber assembled by hospital engineers and tested for safety and efficacy.

The Corridor Outside of Patient Rooms

As with the patient rooms themselves, we are often faced with limitations imposed by structural elements such as support columns, fire walls, and conduits for plumbing, electrical support, and data transfer that prevent substantive changes in the dimension of the space in which we practice.

Nevertheless, reconfiguring the allocation of available space can afford reasonable improvements in efficiency, throughput, and satisfaction.

There are a number of published manuscripts that speak to the value and efficiencies of "pod" distribution of individual staff, workspace, and associated equipment. While the underlying rationale is sound – maintain focus on the assigned patient(s) without distraction from colleagues – it is counter to very nature of multidisciplinary patient care and inconsistent with human behavior. Clinicians who practice in units developed with individualized workspace enclaves for nurses, therapists, and physician staff have found instead, these areas abandoned in favor of a more localized area in which disciplines congregate for the very purpose we have brought them together – shared responsibility, shared experience, shared observation, shared support for patients, and for each other. While an individual may briefly "chart" data in that nicely appointed modern alcove, it isolates the staff member physically and psychologically (Fig. 11.3).

Thus, the corridors outside of each patient room should make available:

1. Supplies that would be commonly required when entering a patient room
   These supplies can be placed in wall-mounted racks or enclosed boxes at a height that does not interfere with patient bed/stretcher movement through the corridor
   a. Waterless hand sanitizer
      i. Easily accessed by clinicians and visitors
      ii. Visually obvious to all as to purpose and requirement
      iii. Auditory cue that agent has been dispensed
      iv. Ready access when exiting patient room (or alternative dispenser or sink within the room as presented earlier in this chapter)
   b. Non-sterile, non-latex gloves in three sizes
   c. Personal protective equipment
      i. Non-sterile barrier gowns for clinicians and visitors
      ii. Masks
      iii. Eye protection
         1. Mask with face shield
         2. Goggles
         3. Glasses with side shields
2. Sinks of sufficient depth and shape to prevent splash back and aerosolization [74–78].
   a. Non-touch activation
   b. Soap dispenser with non-touch activation

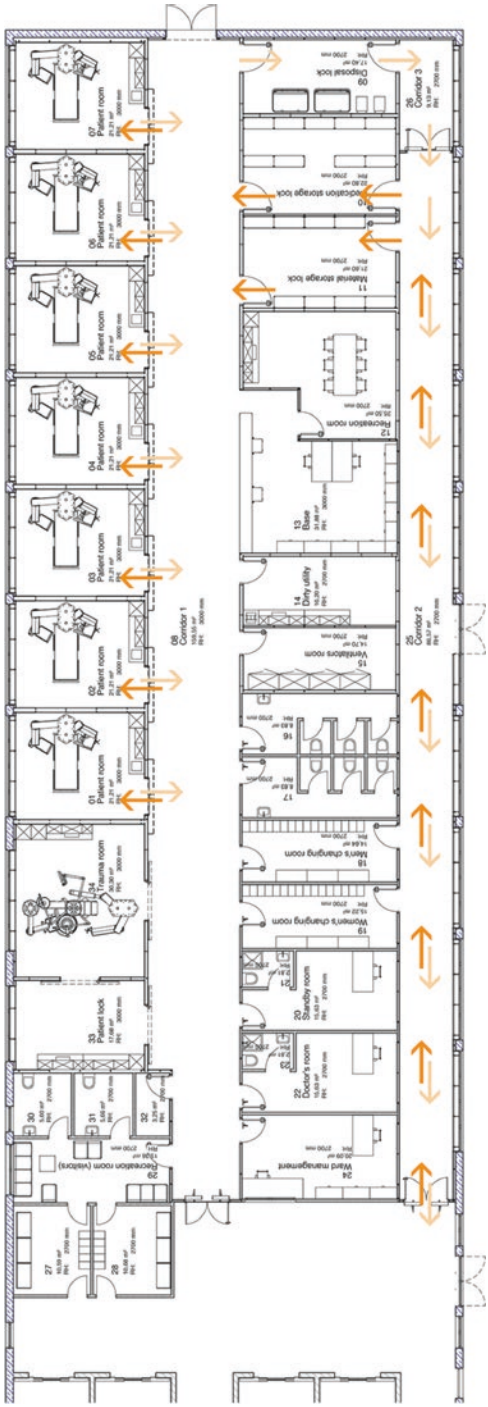

Fig. 11.3 Workflow material. Used with permission from the Getinge Group

c. Dispenser for single-use paper towels
d. Trash bin for paper towel disposal

3. Patient monitoring

a. Alarms

i. Patient activated
ii. Clinician-specified parameter deviation
iii. Clinician activated

1. From within patient room
2. From site outside of patient room

b. Monitors [54–60]

i. Individual patient
ii. Clinician-assigned patient group
iii. Entire ICU

c. Patient location board

i. Bed assignation
ii. Staff assignation
iii. "Current" location of patient

4. Code carts – must be:

a. Immediately accessible
b. Easily identifiable by non-clinicians
c. Mobile
d. Uniform in contents
e. Self-contained

i. There should be no assumption that any required element will be available or functional if not present on the code cart itself.

f. Readily usable within or outside of patient room

i. Monitor/defibrillator wires adequate to meet patient requirements
ii. Compatible with "routine" ICU equipment

1. Defibrillator and ICU monitor cables
2. Injectables with ICU infusion tubing
3. Oxygen supplementation/intubation equipment

At least two full and unused code carts should be present in the ICU at any given time. As one is being used, a replacement should be requested and delivered promptly given the nature of critically ill patients and the unexpected frequency with which life-threatening events occur.

5. Procedure carts
   - Central line, tube thoracostomy, intubation, ECMO, thoracotomy, neurosurgical intervention, etc.
6. Trash and linen bins
7. Mobile electronic medical record/order entry devices utilizing secure wireless connection to the institution's infrastructure

   a. The flexibility afforded by mobile devices for order entry (COE)/EMR is favored by clinicians over the more traditional fixed, desktop configurations.
   b. Computers (or workstations) on wheels consist of robust but compact mobile computer, large monitor, a keyboard, and a mouse or mousepad mounted to a mobile stand often with desktop area for handwritten documentation.
   c. Easily height adjustable, the clinician can access COE and EMR function from either standing or sitting position.
   d. Mobility allows use from anywhere.

The location of mobile carts, workstations, and bins when not in use can be cause for considerable consternation. Their very mobility may lead to the perception that the devices and carts need not have a designated station or "home" which then leads to corridor clutter and impediment to patient, staff, and visitor flow. Thus, reasonable thought should be given to such landing pads for the carts, workstations, and bins though mobile.

Traditional ICU design has numerous countertops with cabinet space beneath. This below-counter space is all too frequently itself filled with clutter and unused detritus of life past and present. In the modern era of "open plan" architecture, such cabinet space should be considered for reclamation as under-counter space for storage of mobile devices, carts, workstations, etc. which may be accessed from either side of said countertop. Utilization of this under-counter space for this purpose results in unobstructed corridors which allows ease of throughput as well as the freedom for multidisciplinary, family-inclusive intensive care rounding style now accepted as standard. The accessibility of devices from either side of the countertop potentially affords more rapid utilization throughout the unit in which it is housed.

Unit Configuration

The concept of intensive care unit design of configuration is again predicated and limited on the structural requirements of that still in existence. Columns, structural walls, and ingress/egress will affect the proposals available for consideration. With that background, there has and continues to be debate of centralized work area vs distributed or "pod" work areas situated more closely to individual or grouped patient rooms. Proximity to critically ill patients is paramount for rapid intervention; thus the configuration, whether central or distributed, must afford rapid delivery of hands-on care. Similarly, the ability to visualize patient, equipment, and environment must be seamless, simultaneous, and frequently necessary for more

than one patient for a single caregiver. Frequent rounding with intention in concert with bidirectional telemedicine utilized within the ICU erodes the distinction and benefits of one design configuration over the other for patient care purposes. Mobile devices for documentation, order entry, and data collection/integration/display further diminish the necessity of fixed bedside proximate workstations intended to maintain staff-patient cohesion. In practice, it is anathema for most people, particularly those dedicated to the care of others to sit apart from colleagues with whom they share a common goal and common foe. The practice, whether central or pod distribution of work area, is for health-care providers to congregate, often based on the color of their scrubs, which frequently corresponds to their vocation or dedicated role in the ICU. This social aspect of humanity, whether health-care providers or otherwise, is irrelevant save for the reality that it will occur regardless of the intent of ICU design. Therefore, the design must allow for best patient care – observation, investigation, management, intervention, and access – while simultaneously recognizing this most human of behaviors. Modern technology as herein described inherently provides for both.

The traditional "Nursing Station" – which is alternatively called central hub, central station, administrative area, and interdisciplinary team center and, for the purposes of this section, will be referred to as the "Central Nursing Station" among other designations – provides an opportunity for clinical and non-clinical health-care providers to:

1. Coordinate care.
2. Review data, images, and clinical results.
3. Populate data fields on required documents.
4. Develop action plans for anticipated and potential events among other purposes.

The Nursing Station may actually be represented by several satellites depending upon the size and configuration of the ICU given the main tenet is that patient visualization, access, and intervention from this space is prime.

The unit clerk or ward clerk or administrative assistant is frequently situated in a position of first contact with those entering the ICU. He/she is frequently charged with the responsibility of greeting and directing new entrants and responding to and directing telephone calls. The surrounding space should allow the administrative assistant to support staff, visitors, and interested parties. Technology readily available to the admin includes workstation to locate patients present in ICU and patients anticipated to arrive as well as the locations of patients that have transferred out of ICU. The admin is also often responsible for generating ICU census documents, patient identification, visitor identification, and specimen labels and generating documents including required forms, policies, and procedures necessary for ICU practice and patient care.

Thus, the unit clerk/ward clerk/administrative assistant space will have:

1. A desktop computer and screens
2. Printers with scanning and fax capability

3. Patient label and identifier reproduction technology
4. Telephone and alternative communication devices

The Central Nursing Station is also the area in which the following often reside:

1. Pneumatic specimen, pharmacy, and blood bank system
2. Bidirectional patient audiovisual technology
3. Patient physiological monitor and alarm repeater
4. Radiology transfer and large-format viewing technology
5. Point of care specimen analyzer
6. Fixed, large-format clinical documentation and order entry workstations
7. Desktops/countertops with chairs on which staff can share thoughts, notes, documents, concerns, and comfort

The last of these items speaks to the inherent nature of caring for the most critically ill. Contrary to media portrayal of professional health-care providers, we suffer along with our patients and their families yet must maintain professional decorum and provide unhindered medical care, unencumbered by our own personal, emotional investment. Thus, the requirement to have an area where "we who must do it all" can do the same for each other while continuing to fulfill our responsibilities to our patients and their families. The traditional Nursing Station, an area to congregate with the ICU "family," as diverse yet as cohesive as any, is as necessary to the survival of the team and team members as it is to the care we provide to patients and to and their families.

Non-clinical Space

Although this section might be considered within the arc of unit configuration in the course of reconfiguring already established ICU space, it amounts to repurposing or re-designating non-patient space. Some of these areas can be integrated if appropriate safety precautions are incorporated while others are by necessity and obviously isolated.

1. Clean utility/supply room
    a. Readily accessible
    b. Unhindered by patient, technology, equipment, or personnel
    c. Technology enabled – computerized dispensaries integrated with patient information services and institutional inventory utilization/availability
2. Equipment storage: devices and technology utilized on an as-needed basis; accessible only by appropriate personnel
    a. Ultrasound equipment
    b. ECMO/VAD/etc.
    c. Bottled gases
    d. Replacements for/additional as-needed ICU technology (pumps, modules, stands, poles, monitors, cables, etc.)

3. Pharmacy
    a. Quickly accessible by appropriate staff
    b. Unhindered by patient, technology, equipment, or personnel
    c. Technology enabled – computerized dispensaries integrated with patient information, central pharmacy, EMR, and COE
4. Staff lavatories
5. Staff lounge with amenities for personal items, technology for personal food storage and re-heating, personal electronics charging stations, and computer with access for personal use Substantial effort, energy, and expense should be designated to the staff lounge in perspective of the environment in which an ICU staff devotes his/her own life. A brief respite in a personal healing environment is paramount to the ability of that staff member to successfully and fully reengage the ICU world.
6. Conference room
    a. Of sufficient size to accommodate educational needs of all ICU disciplines
    b. Capable of utilizing all telecommunication, bidirectional audiovisual, and electronic display technology available to remain available and in contact with ICU staff and patient information
    c. Capable of accommodating staff involved in multidisciplinary ICU QI/QA meetings
    d. Ready access to patient care areas of ICU
7. Patient family support room
   This represents a conference room to be used for clinician-family interactions, discussions, and decision-making. It should be appointed in consideration of the gravity with which some discussions must be undertaken and with sufficient accommodation to provide comfort for an extended period of time.
8. On-call rooms
    a. Must adhere to Graduate Medical Education (GME) and Accreditation Council of Graduate Medical Education (ACGME) requirements for students and residents
    b. Gender-specific or preferentially private call rooms for non-student ICU practitioners required to remain on-site for extended periods of time:
        i. Lockable storage for personal items
        ii. Capable of utilizing all telecommunication, bidirectional audiovisual, and electronic display technology available to remain available and in contact with ICU staff and patient information
        iii. Access to sink and shower
9. Visitor waiting room
    a. Close proximity to the ICU
    b. Close proximity to visitor lavatories
    c. Appointed with at least two chairs per patient bed

d. Ample electrical outlets for visitor personal devices
e. Nearby vending machines for soft drinks and snacks
f. Display of Policy and Procedure for ICU visitation in all appropriate and required languages
g. Language translator services

10. Signage and wayfinding [86].
The value of unambiguous, simple, and direct signage cannot be overstressed. Visitors are often overwhelmed with grief and fear as well as overburdened with both patient-related and non-patient-related responsibilities. Comprehension is diminished by distraction from these diverse demands; thus, no burden must be added by a complex "dance routine" in order to share a moment with a beloved. Signs must be simple, direct, obvious, and clear to any and all.
11. Mourning
When we are no longer able to help a person in our care to live, we must keep that person comfortable and help beloved to survive their loss. As we have moved toward integrating family presence into our daily ICU bedside routine [5, 87–97], rounds, and codes, so too has the discussion of goals of care, end of life, and the process of withdrawal moved from one of isolation to family inclusion.

The aforementioned family support room is one venue in which to have discussions and is frequently used for establishing goals of care while care is being maximized. It is used too when sharing circumstances with those who may not have been aware as a beloved's condition deteriorated. Recent practices, though, have led to discussions with more involved family and friends at the bedside, inclusive of the ICU staff who has been intimately involved with the care of the person in that bed.

With this change in practice comes a change in perspective, and appropriate preparation for this begins with the ICU design. Adequate seating for all involved must be made quickly available at the bedside to ensure these most serious moments are kept solemn and respectful as well as safe for all. Monitor alarms must be silenced though may or may not continue to record and display information to those within the room. The display of information must be an integral component of the discussion. Staff not involved in that discussion must be informed that this solemn experience must not be interrupted, and arrangements made by the ICU team leader to have a surrogate assume responsibilities while discussions are ongoing.

That this subject is part of ICU design may seem at odds, but it calls to the concept that clinicians are the key to success of the concept of ICU design. Chairs, tissues, water, cups, and snacks are some of the items that must be readily available for the family. It is not uncommon for a friend or family member to feel overwhelmed, thus the need for mobile blood pressure cuff, heart rate monitor, and pulse oximeter as well as a policy and procedure for transport of that individual to an appropriate triage area. Following their passing, consider-

ation for transport of the patient's body in a manner that least disrupts care of others is of considerable value but is subjugate to the respect required toward that patient, the beloved, and other patients and visitors in ICU and throughout the institution. This moment is no less important than all which came before.

Final Thoughts on ICU Design

There are a number of excellent manuscripts and books that more completely address ICU design issues including those which begin with a tabula rasa. You will find these in the bibliography of this chapter, and I implore you to read each and many of the references found in their own bibliographies. The approach taken in this chapter has been one of practical application of current standards to an already established intensive care unit environment. A word of caution here: substantial changes to the size and structure of a room, unit, or facility may have significant regulatory compliance implications, whereas more subtle rearrangements may not trigger or necessitate the same. Institutional engineers and architects have regulatory expertise that cannot be underestimated and must be called upon early in the conceptualization of possible ICU design alternatives. By our very nature, we critical care practitioners are creative, innovative, introspective, sensitive, comprehensive, collaborative, and stoic. We are also, on occasion, firmly set in our ways. As you read through this chapter, you very well may have said "I do that"; "We have that"; "That's not new." And so, it may be and likely is. If instead you thought "We can't do that," well I suggest you read the chapter or one of the myriad in the bibliography. We are critical care practitioners. Of course, "We can" or at least we can try.

Thank you GRVMC and JPF.

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Chapter 12
Disaster Preparedness and Management

Lewis J. Kaplan and Samuel Tisherman

Disaster Fundamentals

Disasters occur in two forms – natural and man-made. The nature of a disaster is that its needs may rapidly exceed the capabilities of the individuals, facility, system, or network that is impacted by, or responding to, the disaster. Therefore, a disaster is an internal event that causes significant damage that limits the ability of the hospital to function normally or an external event that leads to an influx of patients and overwhelms the hospital's normal functions. Within this broad framework, healthcare facilities in general, and ICUs in particular, must prepare for how disasters may impact operations, supplies, communication, documentation, and care. Since disasters may be external to a healthcare facility (i.e., hurricane, mass shooting, CBRN attack) or internal to it (i.e., fire, cyberattack, active shooter/active killer), an all-hazard approach is warranted [1]. As ICUs are one of the hubs around which hospital operations revolve, their preparation to respond to disasters is essential for facility performance and excellence in patient care.

While hospital workers and administration members view their facility as a place of refuge and safe harbor, hospitals have been specifically targeted for attack [2]. Terror organizations have practiced attacking hospitals in training camps, and major city attacks that have been thwarted identified hospitals as targets [3]. Recently, a hospital-based ambulance coordination center was targeted in 2015

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[3]. Hospital-directed attacks are sufficiently common that the World Health Organization tracks such events ([4], Fig. 12.1). Therefore, hospitals should prepare for being targeted and, in particular, to mitigate the risk of insider-driven or insider-supported attacks [5].

Unlike reinforced and highly secured federal facilities and military bases (hard targets), hospitals – like schools, transportation hubs, and arenas – are all soft targets. Soft targets are easily accessible, accommodate large numbers of people, deploy only limited security assets, and utilize limited protective measures during routine operations [6]. Soft targets are therefore vulnerable to a wide variety of potential attacks. The security of a soft target such as a hospital is crucial to ensure that the facility is able to participate in external disaster management and to mitigate as well as effectively respond to an internal disaster [7]. Resources and guides provided by the US government (and others) may be effectively grouped into those that (1) address process, (2) provide education, and (3) detail specific tactics to defeat threats such as unmanned aircraft (including drones), explosives, active shooter/active killer, and vehicle ramming attacks. Together these domains form a violent event response and recovery framework that is usable by healthcare facilities.

Disaster preparation requires a direct assessment of potential threats, vulnerabilities, potential responses, and training for response to external and internal disasters. The Federal Emergency Management Agency offers a useful guide – Threat and Hazard Identification and Risk Assessment (THIRA) – that dovetails with exercises such as those of the National Exercise Program [1, 8]. These exercises are designed to assess preparedness fitness and identify core capabilities. It is clear that disaster preparedness is a shared responsibility between the public, government, industry, volunteer associations, and owners/operators of soft target/crowded place venues.

Partnership with security, as well as law enforcement, is essential in forming a disaster response approach as well as for training [9]. Such partnerships help to harden soft targets such as hospitals against direct threat but also craft pre-planned responses that enable traffic control, limit access, and protect workers during a disaster response where the facility is engaged in the response. In this way, ICU preparation forms a smaller part of the larger facility preparation and is equally important. In order to effectively participate in a hazard and vulnerability analysis, formulate mitigation strategies and tactics, and effectively utilize resources – including staff – to save lives, ICU leaders and team members must be well-prepared disaster response planners, leaders, and participants.

Staff and Leadership Preparation

Preparing for disaster or crisis response may be divided into three linked domains. Programmed education and training for disaster response ideally address skill sets and capabilities for (1) care, (2) supervision, and (3) leadership. Leaders should be thoroughly prepared for every role, while everyone else should understand how their role interfaces with all others. Since training and skill maintenance require

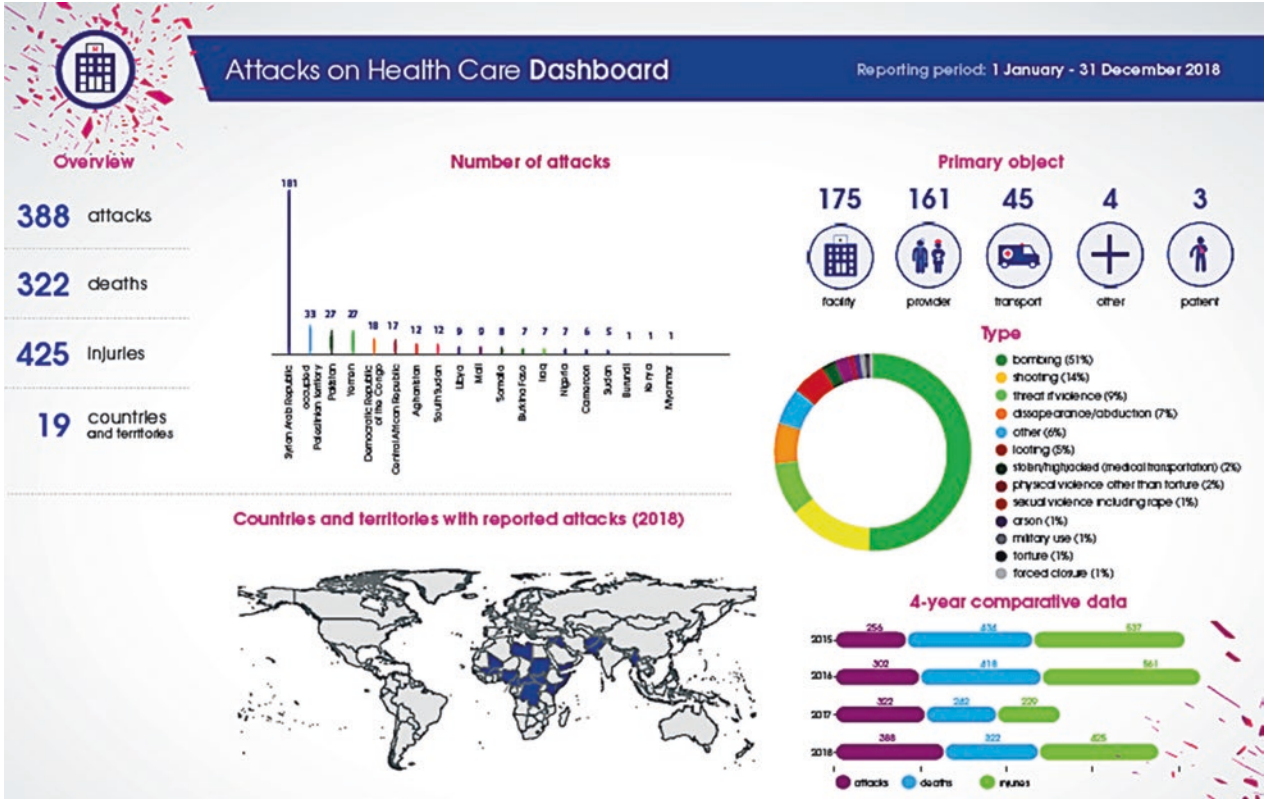

Fig. 12.1 Infographic from the World Health Organization (WHO) demonstrating attacks on healthcare clinicians, facilities, crews, and patients during calendar year 2018. Note that facilities and providers were attacked with nearly equal frequency and that bombings outstripped all other means of attack

time investment, administrative support for these activities as a signature aspect of the facility is essential. Administration must view disaster preparedness on par with their commitment to care quality, center of excellence status, and patient reviews. In the absence of administrative commitment, disaster preparation is apt to be underfunded, under-valued, under-staffed, under-coordinated, and under-practiced. High reliability and successful US programs often incorporate disaster preparedness into a facility's trauma program such as that verified by the American College of Surgeon's Committee on Trauma [10]; other facilities work disaster preparedness into their outreach programs for community support. At the basic level, ICU team members must be prepared to care for an influx of patients, expand available and covered beds, and maintain care quality. Preparation for care is the base tier of disaster preparation and is a knowledge and skill set suitable for all team members.

Preparation for Care

ICU team members include all of those who routinely participate in multiprofessional rounds as well as the supporting teams. Team members relevant for disaster response training include but are not limited to intensivists (regardless of parent training discipline), critical care nurses, PharmDs, respiratory therapists, registered dietitians, physical therapists, social workers, case managers, palliative care practitioners, radiology technicians, radiologists, lab technicians, infection preventionists, and a host of medical and surgical consultants. Of note, members related to the Operating Room are equally important in disaster preparation. These members include surgeons, anesthesiologists, perfusionists, blood bank technicians and consultants, as well as post-anesthesia care unit nurses. Transportation technicians, security personnel, and pastoral care team members play vital roles in team-based training and response. While some of these team members may be more remote from the ICU during daily operations, they have expanded roles during disaster response. It is equally important to note that some of these members may be viewed as key members of other teams as well. Thus, it is essential to establish the number of available personnel at any given time of a possible disaster. This issue should be addressed and planned as part of the team-building and response training.

Basic skills in disaster response should be taught to everyone in the facility. These skills include recognizing that there is an Incident Command Structure (ICS) [11], where the individual exists within the ICS chart, who would serve as their immediate supervisor during a disaster. All members should understand how they will be communicated with and what is specifically expected of them during each phase of a disaster. Who to turn to with questions, what the facility expects of them with regard to time commitment, and what the facility will provide for them during a disaster if extended duty is required should all be taught and provided in a readily accessible document, electronically and in print, in case of power disruption.

Changes in duty assignment or performance that accompany disaster footing should be reviewed. Such changes may include abbreviated charting, care outside of the home unit, and adopting a minimum acceptable level of care as opposed to the highest level of care as a philosophic and practical approach. Relocation of essential equipment such as monitors and ventilators is a task that must be specifically assigned so that when a disaster is declared, expanded bed locations may be appropriately equipped (i.e., the "hallway bed" in the ED or the ICU) [12]. Everyone should be part of an emergency personnel alert and recruitment system – aka "call tree." This system should be both high and low tech in nature to plan for hazards that disable facility or regional electronic communication including amateur radio platforms [13]. Device-to-device communication and other cloud-based or fog-based methods of communication have been explored when cellular communications are unavailable [14, 15]. Even unmanned aerial vehicles have been modeled to support disaster-based communications [16].

Since the ICU typically serves as the safety net for inpatients (the ED does this for outpatients during normal operations), during disaster, the ICU may be overwhelmed without a plan for rapid decompression of those less ill. The ED may be overwhelmed during the disaster with inpatients awaiting a bed during a disaster response as well. Decompression is aided by suspension of elective OR cases and rapid conclusion of in-process cases reducing the expected number of admissions. Relocation to other areas of the hospital requires a carefully constructed plan so that the destinations are already identified; spaces may need to be repurposed during the disaster. For example, the PACU may serve as an impromptu ICU, as may the inpatient dialysis unit. OR or ICU rooms may be temporarily repurposed as an OR at need. Hallways may rapidly become virtual "rooms," and the lobby may be a holding area as those who may be discharged may have no safe way out of the hospital. Other examples may be readily imagined, and all will require coordination with other services that may be otherwise overlooked such as environmental services, food services, outpatient medication availability, and lavatory access and capacity.

Communication with Incident Command Structure members who funnel information to the Command Center is essential and should be regularly scheduled as well as on-demand; an only on-demand plan does not allow the Incident Command Structure to plan for evolving issues if their sole notice is after the issue is established. Finally, a method to communicate that the disaster has been successfully managed and that team members should resume normal operations is as important as the signal to begin disaster response. Each of the knowledge and skills identified above should be previewed in orientation, refreshed on a yearly basis, and practiced. It is the regular team-based practice that is credited with the smoothness and effectiveness of the hospital disaster response operations in the 1 October Las Vegas, Nevada, active shooter disaster [17]. Regular team training develops transactive memory – team members can anticipate what other team members will do since they have repeatedly performed those actions together [18]. Just as being a team member requires training and practice, so too does supervising a disaster response team.

Preparation for Supervision

Supervisors should receive basic training in hospital operations as well as Incident Command Structure education. The US Federal Emergency Management Agency (FEMA) offers a series of courses that prepare supervisors for participation in incident command (https://training.fema.gov/nims/). While supervisors may undertake training that would qualify them for a leadership role, the full panoply of courses is not required at the supervisor level. Supervisors may benefit from ICS-100 (Introduction to ICS), ICS-200 (ICS for Single Resource and Initial Action Incidents), and ICS-300 (Intermediate ICS for Expanding Incidents). FEMA also offers position-specific training that may be appropriate for supervisors in different settings.

Other agencies also offer courses that prepare team members and supervisors for disaster response. Examples include Fundamentals of Disaster Management offered by the Society of Critical Care Medicine (https://www.sccm.org/Fundamentals/FDM), as well as the Disaster Management and Emergency Preparedness offered by the American College of Surgeons (https://www.facs.org/quality-programs/trauma/education/dmep). As of the time of this writing, both courses are being updated. Supervisors should participate in regularly scheduled meetings with supervisors of other areas of the facility that will need to work together during a disaster response. These meetings afford the opportunity to examine and reexamine contingency plans and identify vulnerabilities and solutions. It is an opportunity to walk supply routes, find areas of the facility where cell signals are known to have limited penetrance, and discover potential problem areas such as whether there are sufficient electrical outlets to power monitors for those placed in "virtual" beds. On a less frequent basis, supervisors should share findings with the local facility planning group to update plans, improve policy, and share findings that may influence physical plant revision, staffing, or budget elements.

Preparation for Leadership

Leaders should be competent at team member roles as well as those of the supervisors who they guide. The next level of FEMA courses is useful in this regard and includes ICS-400 (Advanced ICS for Command and General Staff), ICS-700 (National Incident Management System: An Introduction), ICS-701 (NIMS Multiagency Coordination System (MACS)), ICS-703 (NIMS Resource Management), ICS-706 (NIMS Mutual Aid), ICS-800 (National Response Framework: An Introduction), G-191 (ICS/Emergency Operations Center Interface), G-402 (ICS Overview for Executives/Senior Officials), and G-775 (EOC Management and Operations). Clearly, preparation for disaster response leadership is much more involved, requires more time, and reflects a dedication

to disaster management that must be supported by administration as a key aspect of the facility's public profile.

Leaders should meet on a regular basis with the facility planning group in a parallel fashion to that of the supervisor group. However, the unique and highly trained leadership group should regularly interface with the city (or region) and statewide disaster planning groups for coordination, drill planning, and interagency cooperation assessment. A disaster requires interagency management without siloes or boundaries in order to save lives [19]. It is ideal – but not required – that leaders also participate in professional society activities, especially those that focus on disaster planning and management to help ensure that their facility is exposed to emerging technologies, processes, and plans, especially those that may be garnered from groups remote to their own. In this way, a novel approach from across the country, or in a different one, may be rapidly brought to one's home facility *and* have a specific individual to whom one can turn to advice about that process. Existing standards, policies, and protocols, as well as new approaches, all inform the planning process for one's facility and how it will interface with external agencies such as law enforcement, EMS, public health, the media, as well as intelligence and military resources when required.

Planning

All-Hazard Approach

Using an all-hazard approach is much more efficient than crafting individual plans for specific scenarios. Moreover, there are so many commonalities between plans that leveraging core responses allows a facility's team to repeatedly train in the same way to develop core competencies. Those skills may be supplemented as needed for a unique scenario that is not addressed in an all-hazard approach – although such a need is anticipated to be a rare. Increasingly, social media (SoMe) is a hazard as well as events are often advertised and shared along those lines. Furthermore, individuals with an issue that is relevant to the facility may share their displeasure using SoMe. Therefore, monitoring SoMe is essential for facility security and disaster mitigation and an avenue that may not be routinely included in disaster planning as most facilities primarily focus on receiving disaster victims from the outside, not caring for them from the inside [20]. Additionally, SoMe communication during a disaster may be disruptive for first responders [21]. The WHO data above supports needing to plan for internal disaster management with regard to violence, but equally important is to plan for fire, biologic agent dispersal, chemical release (including formaldehyde), and electrical failure [22, 23]. Understanding how many things may trigger a disaster within a facility, let alone outside of it, makes using an all-hazard approach essential.

Key Local Events Including Weather

Public events such as the Olympics, championship sport contests, concerts, rallies, and dignitary visits should all prompt potential receiving facilities to be on heightened alert. Since most of these are well forecast, there is time to plan for some of the specifics of such events, as well as craft contingency plans. For instance, when the Pope visits a city, the exact route he will take may not be known well in advance, but where he will speak is clearly defined [24]. Therefore, local agencies can plan for potential disasters related to that event using knowledge of proximity to the closest facility – and then the next closest – and so on [25]. Planning should include all elements of the city or region's emergency services as well as advance elements of any security that accompany to visiting dignitary (i.e., US Secret Service for the US President) and coordinate with appropriate agencies from the local government such as the Public Health Service. Plans must be crafted to not disenfranchise other patients who are already receiving care, or those who need care, on the basis of a dignitary who require care in the same ICU [26]. SoMe monitoring may be important in supporting internal disaster mitigation in this unique circumstance.

Anticipated weather-based disasters – such as flooding in New Orleans – should inform disaster planners, especially when such events are recurrent. Tornado-specific plans that identify tornado shelters make sense for the US "tornado alley" (southern plains of the US) but would be unnecessary around Anchorage, Alaska. Such weather knowledge informs building design, the location of electrical units, locations of helipads, and evacuation plans among other elements too numerous to mention. California wildfires are well known and help guide the need for the number of burn units, their location, and staff recruitment [27].

Physical Plant Considerations

The physical layout of the entire hospital as well as that of each ICU should be examined to plan where overflow patients may be managed and where those who are being discharged early (so-called reverse triage) may be moved to accommodate incoming critically ill patients both adult and pediatric [28, 29]. Power outlets, handy hygiene stations, Wi-Fi coverage for workstations on wheels, and vacuum and oxygen lines are all key determinants of where patients may receive care. Some ICUs have a procedure room that may be used as an isolation room, or an impromptu OR. Areas where additional supplies may be delivered and stored should be identified as the existing stores may prove inadequate during a disaster. Since many ICUs are keycard locked, disaster management may necessitate entry for individuals who do not normally require entry. A plan to afford them entry should be developed but should not compromise the integrity of the locking mechanism. Unlocking the ICU doors to provide unrestricted access is not recommended.

Charting and Documentation

Charting and documenting care may be equally problematic, especially during a cyberattack or during a power failure. A plan to utilize "downtime" charting will capture care and may be scanned into the electronic health record at a later time. The degree of completeness achievable during normal operations is often impossible to maintain due to patient influx beyond typical staff/patient ratios, normal number of occupied beds, and increased time during which staff are engaged in bedside care. This departure from the usual standard is appropriate during disaster management and should be anticipated [30, 31]. The use of hard charts should be embraced using abbreviated documentation forms as well.

Communication

Communication with other areas of the hospital such as Pharmacy, Radiology, and Blood Bank may be crippled during power outages since orders and electronic alerts serve as the primary mode of contact in most facilities in developed countries, especially tertiary or quaternary care centers. During a cyberattack or electrical outage, normal communications will fail. In that situation, low-technology solutions are required for patient care. Runners to deliver orders or request aid is a low-tech but high human capital mechanism that may be supplanted, or supported, by battery-operated local walkie-talkies between key sites. Relocation of emergency supplies from Pharmacy may reduce the need for pharmacy requests; a disaster pack of specific agents may be assembled once a disaster is declared and delivered to the ICU. Antibiotics, analgesics, sedatives, and resuscitation medications including steroids could form the nucleus of such a medication grouping. Relatedly, on-site preparation of vasoactive infusions – a process that has been principally moved to the Pharmacy that is typically outside of the ICU (except those that have a satellite pharmacy in the ICU) – may be required for timely care.

An often-overlooked element of communication is that of discourse with law enforcement or military command during a disaster. Pre-defined communication channels and radiofrequencies should be planned so that it does not need to be established in an on-demand fashion. Communication should also address how individuals (patients, staff, EMS workers) will access the hospital through a security cordon (see below) [32].

Water, Linens, Food, and Supply Chain Maintenance

Water supply interruption must be planned for as well to include potable and non-potable supplies. Consideration for the use of chemical toileting facilities is important if toilets and urinals are unable to be flushed. Linen management will be an

issue if the water supply is interrupted as well. Staff sleeping spaces, food delivery, and patient food delivery will all require plans and contingency plans if access to the hospital is compromised or restricted. Earthquakes, volcano eruptions, hurricanes, and explosive devices may all disrupt roadways. Since supply delivery will be equally important for Pharmacy, external partnerships must be included in contingency plans to maintain a supply chain, evacuate those who cannot be cared for at your facility (see below), and bring in available staff for care continuity. When roadways are not passable, helicopter delivery may be required utilizing air ambulance services or the Army National Guard (or equivalent), for example. Novel approaches such as adventure motorcycle transport of volunteer medics may be leveraged as it is currently done in Israel [33]; delivery of essential medical supplies could be readily envisioned. Emergency blood is routinely delivered by motorcycle in the United Kingdom during normal operation due to two-wheeled vehicle superiority in navigating traffic snarls [34]; they even deliver donated breast milk to undernourished premature infants.

Evacuation

Evacuation planning requires both an internal and an external plan. Internally, how patients are to be moved (bed, sled, or other), by who (ICU nurse plus aid(s)), to where (staging area), and in what order must be clearly articulated and practiced [35]. Plans should be developed assuming an operational power grid – and elevators – as well as one in which there is no power or in which the elevators should not be used (i.e., fire). Escape routes should be well mapped and demarcated. Staff should review fire exit locations including how many steps fire exits are located from any ICU bed – and which direction – as smoke and darkness will obscure the location. While flashlights are commonly available, they require a hand to hold and use them. Flashlights that clip on to a shirt pocket or a belt, or, ideally, a headlamp, is a better option as it leaves both hands free and the light moves with the wearer's head and eyes. The option of a red filter lens is great for preserving night vision during a power outage. There are a variety of reports of well-coordinated evacuations as well as tools for evaluating the efficiency of an ICU evacuation [36].

Access

Hospitals may be rapidly overwhelmed by the influx of individuals presenting for care outside of EMS transport. This occurred most recently during the Las Vegas, Nevada, shooting by way of example. Traffic flow and control is essential to achieve three goals: (1) establish a triage center outside of the ED, (2)

establish a security perimeter, and (3) control access to the facility. It is during triage that the ICU practitioner may engage in the initial aspects of a disaster response. Triage rules apply, and the intensivist must hew to those rules as resources may be quite limited. Recall that the extent of the disaster, the number of people who will present for care, and the kind of care that will be required are unknown at the outset.

Service Animals

Individuals who are supported by service animals may also present for care. The Americans with Disabilities Act (ADA) provides facility access for those with service animals exclusive of sterile areas or those that require isolation [37]. Only service animals are permitted access. Service animals are dogs or miniature horses in the United States, who must perform a specific task for their dyad partner. Emotional support animals are not so authorized nor are they covered by the ADA and, accordingly, need not be granted access. At present, human facilities do not provide service animal care if the service animal is injured. Additionally, the facility need not provide routine care for the service animal – a family member or a service animal agency must provide that care – and may drive specific partnerships to be developed as part of the facility disaster plan.

Drills and Location

After planning, practice is the next most important element of disaster preparation and cannot be overemphasized ([38], Fig. 12.2). Tabletop exercises alone are insufficient to prepare a facility or a set of individuals. Plans need to be enacted, routes

Fig. 12.2 Graphic representation of one method of preparedness that leverages an all-hazard planning approach. The three interwoven elements include a vulnerability analysis, a risk reduction program, and a plan for frequent disaster drills

need to be traversed, and communication trees need to be activated, and each of these needs to be debriefed immediately afterward to identify what worked well and what needs to be improved. While most drills are forecast, some should be impromptu as a means of assessing durable knowledge, strengths, and weakness that occur in the absence of notification. While mannikins can be moulaged to simulate patients, human volunteers make the drills more "real" for participants. A moving "patient" coupled with spontaneous or solicited verbalizations evokes a visceral response from participants in a way that a mannikin cannot. Local schools including nursing, medical, dental, and allied health profession students make ready volunteers as "disaster victims." Drills should occur during daytime as well as at night as disasters are unscheduled. Weekday and weekend testing is equally key as staffing may be less than during the week. A templated approach to drill performance should be utilized to compare unit performance from one evolution to another. Drills should practice what to do if your facility is remote from the disaster as well as if your facility is at its epicenter.

Debriefing is another highly valuable method of improving ICU disaster preparation and performance. Unlike how we generally evaluate code team performance, the disaster "team" that works together should have their performance immediately critiqued in parallel to how professional special response teams engage in an "after action report" [39]. This method ensures that the information is fresh and that all participants have an opportunity to contribute to the drill evaluation. This data should then be used by supervisors and leaders to decide what skills need to be reinforced, which one should be celebrated, and what elements should be revised. When there are skills that need to be reinforced, high-fidelity simulation offers a highly successful platform from which to provide that training [40]. Furthermore, by having teams engage in routine debriefing after team-based events, the use of a debrief permeates ICU culture and crafts an expectation of participation that is seriously considered and valued.

Simulation is increasingly utilized for planning and drills as it affords the opportunity to change the base conditions and then determine how the planned response will fare [41]. Base conditions to change may include time of day, staffing, season, temperature, patient volume, and injury type; many other conditions can also be changed depending on the robustness of the simulation program [42]. Augmented reality programs are being developed within the military for care and care coordination across combat geographies and are likely to filter into civilian use quite rapidly. This is akin to running trials in silico and has been well utilized in response planning with regard to nuclear weapon-based conflict. Facility, city, region, and state disaster drills are essential to model coordination and evaluate for gaps in preparation. The facility-based ones may be most important for the ICU as it may deliver "patients" to the ICU where the rest tend to deliver patients to the facility grounds and the Emergency Department. Of necessity, each facility needs partners for drills. Even if the ICU does not have direct interaction with many of the partners, ICU leadership needs to understand which partners exist and their capabilities. That understanding may specifically impact decisions and actions around supplies, evacuation, and security as noted above.

Partners

Common partners that include fire, EMS, law enforcement, Red Cross, and local/state/federal government agencies all bring specific capabilities that may not be housed within an individual facility. They also bring coordination capability across multiple agencies and may lead to novel solutions such as a freestanding ICU within a freestanding ED [43]. These capabilities may be particularly essential in the event of a chemical, biologic, radiologic, or nuclear exposure (CBRN). Many of these agencies also have an explosive agent detail using human, canine, as well as robotic resources to address potential unexploded devices. Since those with exposure are likely to require critical care, ICU leadership should be conversant with the range of services available from partner agencies. A superb way to do this is to invite leaders from partner organizations to visit your ICU, examine your space and capabilities, and offer insights from their point of view. It is surprising how an external view can find opportunity that may not be readily identified by those who regularly use that same space.

Legal and Administrative Support

Legal

Codifying how authority is distributed within an institution during a disaster as well as how working conditions and time frames may be altered is important. As many facilities employ people who participate in unions, negotiation with union leadership is essential and should be articulated in a legal document that serves as a contract. Orientation of new employees should familiarize themselves with the terms of the contract as well. Little other legal support is required as the overwhelming majority of directives that guide disaster response are established by local, state, and federal law.

Partner relationships often benefit from governance within a Memorandum of Understanding or a Transfer Agreement. These are key in moving patients between institutions – or between institution ICUs – during a disaster. The MOU or Transfer Agreement should also reference the disaster plan as its foundation for use. These need to be regularly updated (at least every 3 years) and may be also improved out of cycle (new findings, new institution, leadership changes, etc.) as needs arise.

Administrative

Administrative support, however, is not secured by law but is a cornerstone of a successful disaster preparedness program. Administrative aid takes three distinct forms: (1) designated time for clinical leaders (including those in the ICU) to spend in

training for disaster management, (2) designated time for leaders to spend in disaster management drills and coordination exercises, and (3) institutional commitment and financial support of a comprehensive disaster management program. All three work together to establish disaster preparedness as a major thread in the fabric of clinical care. If an institution is to be a disaster preparedness and management hub, outreach – and an outreach coordinator – to support partners, and space for them when they are in the institution, is equally important in sustaining a program. The outreach coordinator also helps with the bidirectional flow of follow-up information and queries as part of a performance improvement program.

Roles Outside of the Institution

ICU leaders are generally teachers in a number of capacities. It is optimal if the ICU leadership also serves as instructors within the disaster space. Note that there are teaching roles for all of the team members regardless of parent discipline, including teaching partner organizations and associations. Some teaching opportunities require a credentialing process (FDM, DMEP, and others), but many simply flow from a desire to share knowledge. Often, the process of inviting partner organization leaders into the ICU leads to being invited into the partner organization space, especially in support of information and knowledge sharing. It is generally easier to work with people in a high stress environment such as a disaster, when there is a relationship upon which those interactions rest. While political activity or advocacy may be embraced by those engaged in disaster preparation, such activity is not necessary to build a strong, flexible, and high reliability ICU disaster response program [44].

Conclusion

ICU disaster preparedness and management offers a role for everyone involved in critical care. Responding to an internal or external disaster remains a team-based event. As such, team members must be prepared for care, supervision, and leadership. Like other skill sets used on a more frequent basis, the skills required for an efficient, safe, and effective ICU disaster response are perishable. Therefore, regular planning, training, and drilling are required to ensure smooth team performance to support care excellence. Partnerships at the local, state, and federal level are essential whether regardless of disaster type and location. An all-hazard approach is the optimal method by which to plan for success regardless of disaster type. ICU disaster planning is a microcosm of facility disaster planning, and critical care leaders must be integrated into the Incident Command Structure to ensure that the ICU's response is well-coordinated with that of the rest of the facility. Therefore, administrative support for ICU leader training and participation in disaster preparation is

essential. In sum, disaster planning, preparation, and response define a role for everyone in the healthcare facility, will stress the resources and capabilities of the ICU, and are a reality for which the entire ICU team should be specifically trained.

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Chapter 13
Critical Care Educational Modeling

Jason L. Bartock and R. Phillip Dellinger

The first established intensive care unit (ICU) can be traced back to 1953 in Copenhagen, Denmark [1]. The integration of knowledge, skills, attitudes, and behaviors with a sound ethical and profession framework has led to groundbreaking advancements in patient-centered outcomes over the past 66 years. The modern critical care service model now finds itself in a new era of significant growth by specialty, technology, complexity, and acuity. This must be met with an educational model that is both systematic and adaptive in its effort to compliment novel services, new training program requirements, and alternative staffing models.

Critical care training and education varies worldwide in context, content, assessment, and duration. Whether you practice in an academic teaching program or in a community medical center, there are parallels drawn between the quality of care provided and the quality of education available. Providing teaching that is measurable and translatable to staff, trainees, patients, and caregivers is more challenging now than ever before. Success can be found in building a systematic approach to a learner-centered model, with competency-based training, compassionate coaching, and performance review.

Staff Education in the Modern Training Environment (Learner-Centered Model)

ICU education is designed to provide a comprehensive understanding of topics delivered and reinforced through visual, verbal, and tactile educational modalities.

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Learners

1. ICU Staff Physicians
2. Critical Care Trainees
3. Advanced Practice Providers
4. Nursing

Educational Modalities

Bedside Rounding
Curriculum-Based Lecturing
Targeting Teaching/Small Group Huddles
Simulation Training
Research and Study Design
E-Learning (Podcasts and Web Series)
Professional Development

Teaching responsibilities have grown outside the comfort zone of the ICU. We feel the pressure to deliver a more personalized experience. This experience not only includes medical trainees but other colleagues, advanced practice providers, and patients and their caregivers. Targeting a universal curriculum and distributing education through various education modalities alone do not ensure that concepts are translatable and provide the tangible understanding, professional growth, practical application, and improved patient outcomes we strive for.

Traditionally, the framework for medical education and training has been time-based, and learners are assessed periodically to determine a specific grade. In this model, equal weight was given to both the process and the outcome of the learning [2]. Emphasis was placed on understanding a concept or principle, and skills were evaluated globally [2, 3]. Transitioning to a competency-based approach is believed to provide more individualized and flexible training with transparent standards and an increased public accountability [4].

Building a collective educational program that is sharable for learners at different levels is not unrealistic. The multidisciplinary critical care team is comprised of learners from different backgrounds and varying levels of experience and expertise. Defining competencies, providing compassionate coaching, and delivering a workplace-based assessment of competence are applicable to each type of learner regardless of background. This learner-centered model allows for both the learners and teachers to exchange expectations and actively take responsibility for the learning process (Fig. 13.1).

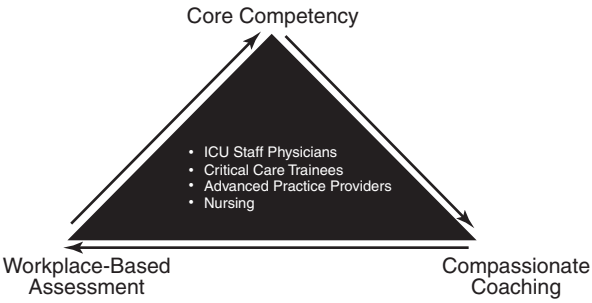

Fig. 13.1 Standardized approach to staff education

Competency-Based Training

Competency-based medical training is a method for describing the knowledge, skills, attitudes, and behavior expected from a care provider [4]. Medical education has begun to modify its training programs from syllabus-based and examination-driven systems to programs built around competencies assessed in the workplace [5].

Applicable competencies can be identified and implemented in several ways. In critical care medicine, the CoBaTrICE project has been a widely accepted platform for provider competencies [4, 6]. CoBaTrICE is an international partnership of professional organizations and critical care clinicians working together to enhance training in intensive care medicine worldwide [7]. The CoBaTrICE project featured consensus techniques comprised of an extensive international consultation process using a modified online Delphi involving more than 500 clinicians in more than 50 countries. Also included was an eight-country postal survey of patients and relatives and an expert nominal group to define the core competencies required of a specialist in the ICU [4].

There are practical concerns surrounding competency-based training. A list of competencies provides a summary of capable tasks but does not guarantee a provider's ability to synthesize these competencies to deliver comprehensive care. Practical concerns also exist in determining core competencies for continued professional growth. With advancements in technology and an evolving scope of practice, attending physicians are required to show competency in core skills while being pressured to rapidly acquire new skills (ECMO training, point-of-care ultrasonography). Practices should customize competencies that complement the needs of their individual learners as well as their critical care service line.

A key advantage to competency training is placing the focus on the ability to "perform tasks" rather than receiving credit for "time served" [4]. This allows learners to progress at their own pace. One must remain aware that these competencies need to be acquired within a fixed training period and to remain mindful of the "learning process" so that medical education does not give way solely to "medical training" [2].

Compassionate Coaching

Critical care education has long been cemented in Socratic methodologies. ICU teaching is often comprised of argumentative dialogue through which we ask and answer questions in an effort to stimulate critical thinking and work to identify knowledge deficits. Although this may be effective in identifying knowledge deficits, the psychophysiological effect is thought to be equally detrimental in leadership development and professional growth [8]. A platform for the development of future ICU leaders can be found by utilizing a more holistic approach through compassionate coaching [8].

Coaching with compassion requires a caring relationship between the teacher and the learner. Compassionate coaching emphasizes empathy of the learner and requires a willingness to act in response to a learner's needs in an effort to achieve the desired educational goal [5]. A coach takes on the role of teacher, mentor, and friend in order to achieve a desired educational goal for his/her learner. Coaching with compassion may require training staff to retool their role, perspectives, and attitudes [5]. Coaching with compassion is felt to be a more powerful methodology in engaging the learner, stimulating independent thought, cementing competencies, and building emotionally developed future leaders [5].

Workplace-Based Assessment

Historically too much emphasis has been placed on learner's ability to show knowledge and pass some forms of examination. There is too little emphasis on whether they can perform in their expected role [7]. Objective structured clinical examinations (OSCEs) have been widely utilized in medical education but can limit the provider-patient encounter by isolating aspects of the clinical encounter along with the type of cases that can be simulated. OSCEs also lack the universal applicability to patients and caregivers who do not share a common clinical background [7].

Workplace-based assessments can be used to validate the teaching curriculum, teaching methodology, clinical context, application, and impact on patient care. Assessments can be customized to a specific learner to validate a competency goal. For example, a learner's ability to interact with a patient, build a care plan, or carry out the difficult conversation is traditionally assessed through a one-on-one evaluation by a faculty member tasked with overseeing that learner's time in the ICU. This "traditional" form of feedback provides the learner with insight into an observed behavior or procedural skill set and offers the opportunity for improvement. Unfortunately, it is one-dimensional. One-dimensional feedback may lack the diversity of experience and practice we seek to impart on the ICU learner to best shape a core competency. In contrast to "traditional feedback," Multisource Feedback (MSF) in an example of a workplace-based assessment that compiles

Table 13.1 Workplace-based assessmt tools

Assessment tool	Design	Advantages
Direct Observation of Procedural Skills (*DOPS*)	Direct observation of the learner performing diagnostic and interventional procedures during clinical practice	Assessment during everyday work in real-life scenarios Observes technical ability as well as professional interactions and behaviors
Mini-Clinical Evaluation Exercise (*Mini-CEX*)	15–20-minute snapshot of a clinical encounter designed to assess clinical skills, attitudes, and behaviors essential to the provision of a desired competency	Can be used in different clinical settings depending on the target learner Easy to design around specific clinical competencies Short interactions provide the ability to be done repeatedly over a fixed teaching period
Case-Based Discussion (*CbD*)	Discussions between the learner and the educator about how a clinical case or scenario was managed Provide real-time feedback	Detail into decision-making and competency application Tests higher-order thinking and synthesis within the framework of actual practice
Multisource Feedback (*MSF*)	Patients' or colleagues' interpretation of the learner's professionalism, knowledge, and procedural skills	Real-time feedback obtained from a perspective external to that of the clinical educator

feedback from multidisciplinary providers (ICU physicians, consultants, nurses, and other trainees) as well as the patients and their families. Pooling experience and perspective to develop multidimensional feedback allows the ICU learners more opportunities to shape goal competencies and comply with best practices. MSF and other workplace-based assessments are outlined in Table 13.1.

Medical education is moving away from cumulative marks and moving toward gathering evidence of conceptualization, clinical competence, and professional behavior. Common workplace-based assessments include Direct Observation of Procedural Skills (DOPS), Mini-Clinical Evaluation Exercise (mini-CEX), Case-Based Discussion (CbD), and Multisource Feedback (MSF) [4].

Patient and Caregiver Education (Family-Centered Model)

Learners

1. The Patient
2. The Caregiver

Educational Modalities

Bedside Rounding
Printable Educational Materials
Digital/Web-Based Content
Multidisciplinary Meetings

In an effort to maximize patient outcomes, providers must use their acquired competencies to match the needs and individual characteristics of the critically ill patient and their caregivers. *The Society of Critical Care Medicine*, as part of its family-centered care program, has recommended that family education programs be included as part of the clinical care [9]. Family presence at the bedside enhances engagement, and when coupled with an educational program, it has been shown to improve outcomes [10]. Family education programs have also demonstrated beneficial effects for family members in the ICU by reducing anxiety, depression, post-traumatic stress, and generalized stress while improving family satisfaction with care [9, 11].

A patient's care team, support devices, and clinical condition can change minute by minute in the ICU. Implementing educational content that provides a patient and caregiver with the knowledge to remain engaged with each other, make the best informed decisions, and feel satisfied with care can be very challenging. Similar to a learner-centered model, the patient-centered model should start by identifying core competencies or concepts that every patient or family member can accomplish during their stay. Competencies may vary from institution to institution depending on the clinical expertise of that unit and its patient population. Collective competencies that prove to be translatable across ICU specialties, as described by the AACN, are competencies related to ICU arrival, ICU understanding and partnership in care, and ICU transitions (Fig. 13.2) [11].

Competencies

Learning validation and the assessment of educational demonstrations, diagrams, reinforcements, reviews, electronic resources, and support systems is critical. Providers must use tools to anticipate the needs of the patient and family based on cultural, cognitive, and physical differences [11]. Family-centered educational assessments are often obtained in real time by learner teach-back or through unit-based surveys. These assessment tools help the care providers realign modalities to best target a competency-based strategy [9, 11].

Simulation Training

I hear and I forget; I see and I remember; I do and I understand. –Confucius, circa 450BC

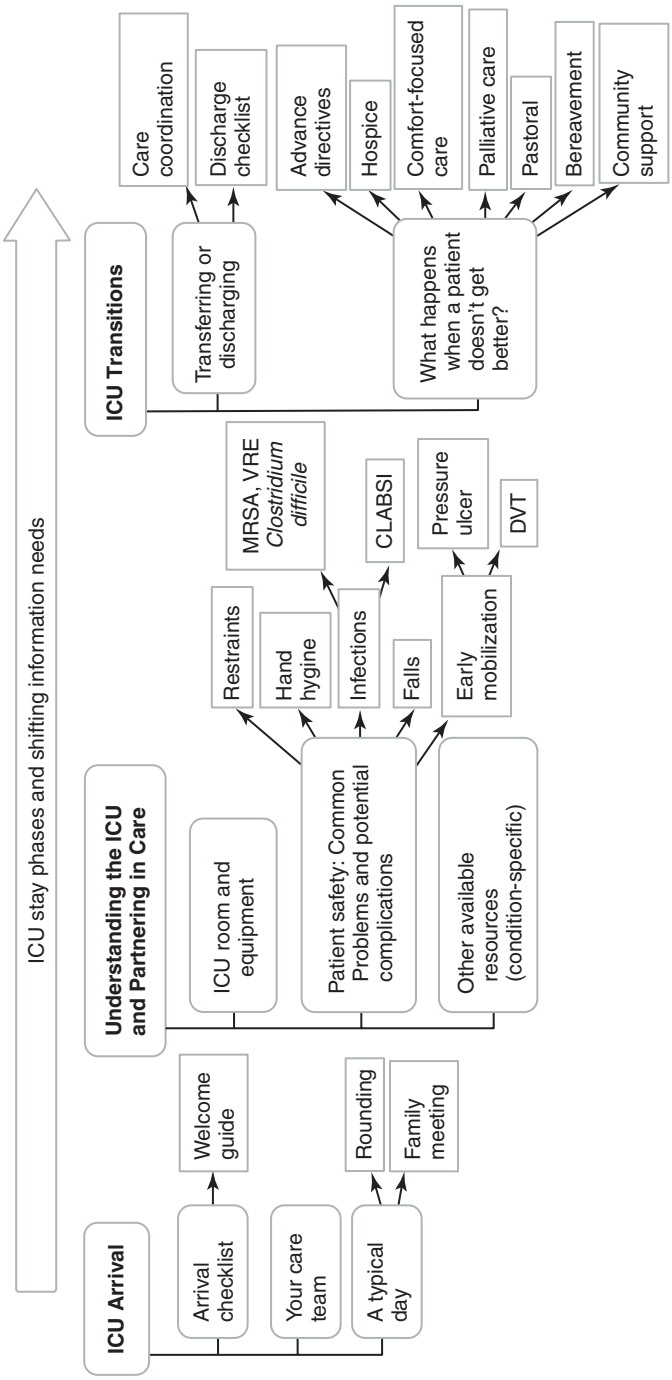

Fig. 13.2 Competencies and information pathway. (Adapted from Schnock et al. [11]. Copyright 2017)

Learners

1. ICU Staff Physicians
2. Critical Care Trainees
3. Advanced Practice Providers
4. Nursing

Outline

1. Select a category of learner
2. Identify an educational objective
3. Choose an appropriate fidelity
4. Build the scenario
5. Debrief and evaluate the experience

Simulation refers to the artificial (and almost always simplified) representation of a complex real-world process with sufficient fidelity to achieve a particular goal [12]. Simulated clinical environments have been documented throughout historical texts, dating back to the birthing phantoms of ancient Rome and continuing through the use of vivisection to advance surgical techniques in the nineteenth century [4]. Patient care and family interactions carry the expectation of perfection. However, many of these interfaces do not occur with the regularity to ensure competency and are carried out within the confines of an imperfect system. Additionally, health care is now regarded as an industry with greater emphasis on accountability, transparency, and quality assurance [12, 13].

Experience-based training in clinical emergencies and acute pathology is difficult due to the fact that many of these encounters are rare or do not warrant a delay in management to allow for teaching. Emphasis must be placed on repeated protocol-based training practices in the appropriate management of a clinical situation. This aims at reducing the margin of error for an unexpected emergency. Simulation training in the critical care environment affords us the opportunity to "fail for success": training toward competency and proficiency while at the same time identifying system errors and providing safe and timely care for all.

The use of simulation is growing rapidly; the Society for Simulation in Healthcare (SSH), the largest academic society for simulation, has experienced a 16-fold increase in membership since its inception in 2004 and an average annual growth of 25% in the past 5 years. The Agency for Healthcare Research and Quality has allocated more than $9 million in support of simulation research [13]. Results from a survey of program directors in emergency medicine demonstrated 91% of responding programs in 2008 used simulation in their training programs [13]. Teaching hospitals throughout the USA use simulation to teach, assess, and evaluate core competencies in medical education. Emphasis is

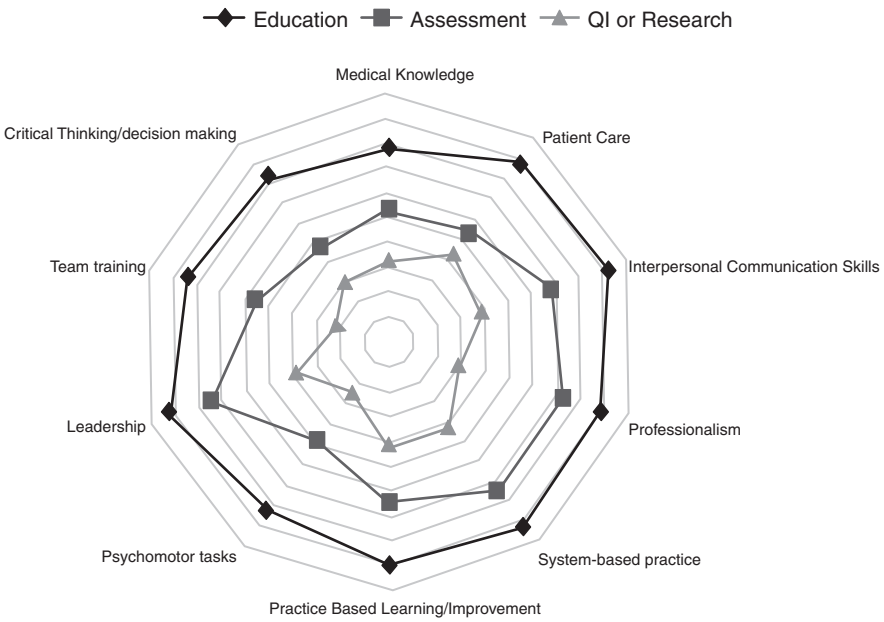

Fig. 13.3 Core competencies for simulation training. (Adapted from Huang et al. [13]. December 2012)

placed on multifaceted domains of leadership, system-based practice, and practice-based learning/improvement (Fig. 13.3) [13].

The aim for ICU educator is to facilitate learning through immersion, reflection, and feedback [12, 13]. Fidelity is a common industry term used in simulation to describe the degree of realism and technical complexity for a chosen scenario. Low-fidelity models can be developed and updated rapidly in contrast to high-fidelity models which offer added flexibility but cost significantly more to engineer and maintain [12]. Higher-fidelity modeling is not always necessary. Educators should tailor the fidelity of their simulation to the degree of immersion necessary to highlight a desired competency and deliver impactful learning (Tables 13.2 and 13.3) .

Failing in a simulated learning environment is failing in a safe environment and learning in the process. The capacity to fail through complex clinical scenarios or high-risk patient encounters and improve through feedback provides immersive and impactful learning which reduces the likelihood of future errors.

Teaching at the Bedside and During ICU Rounds

Teaching during ICU rounds is challenging due to time pressure and distraction (both warranted distraction related to the illness being dealt with and frequent interruption). Carlos et al. offer the CARE framework as a method to incorporate ICU

Table 13.2 Classification of simulators as per type

Simulation types	Specifications	Examples
Educator driven	Task trainers replicating a particular part of the anatomy Varying levels of sophistication are used to practice specific procedures or interventions	Intravenous-insertion arms, central line insertion mannequins, urinary catheter trainers, airway management heads Store-bought animal anatomy such as pig tracheas or cricothyroidotomy training and pig feet for suturing
Event driven		
Standardized patients	Trained actors, role-play, history taking, physical exam, communication skills	Situational simulation, mock emergencies and disasters
Hybrid simulation	Combination of standardized patients and part-task trainers	
Computer-based simulators	Mouse-and-keyboard navigation for multiple pharmaco-physiological models	

Adapted from Datta [12]. April 2012

Table 13.3 Classification of simulator by fidelity

Classification of simulator by fidelity	
Low-fidelity simulators	
Screen-based text simulators	Create scenarios with user selecting one of several responses User choice results in a new text narrative with more management choices *For example*, scenario involving a patient with chest pain; the user may be offered the options of selecting pain medication or obtaining an ECG
Static mannequins	Used for hands-on practice *For example*, intubating airway mannequin
Medium-fidelity simulators	
Screen-based graphical simulators	Demonstrating physiological modeling and pharmaco-kinetic and dynamic processes associated with drug administration *For example*, ACLS Training Center®
Mannequins with mechanical movement	Mannequin and software which can simulate the interaction between a student and teacher *For example*, AMBU® Man CPR trainer
High-fidelity simulators	
Non-physiologic (static) programming	Manually set parameters dependent on an operator
	Parameters reset after each intervention *For example*, ventilator connected to a test lung
Physiologic programming	Parameters change from baseline dependent on intervention and independent of the operator
	Automatic generation of appropriate physiological responses to treatment interventions *For example*, SimMan®

Adapted from Datta [12]. April 2012

teaching at the bedside [14]. This methodology includes *C*limate (setting patient/family expectations and seek permission, set learner expectations, avoid one-upmanship), *A*ttention (plan in advance, remain focused on the moment, keep content relevant for all members of the rounding team, be democratic as to leadership style), *R*easoning (encourage hypothesis-driven examination, avoid "read my mind" questions, give formative feedback), and *E*valuation (avoid individual criticism, provide feedback). We would also refer the reader to a manuscript on practical tips for ICU bedside teaching by Santhosh et al. that includes discussion of the CARE approach as well as other bedside teaching methodologies [15].

Summary

Critical care education aims to build better multimodal critical care service lines targeting the best practices and outcomes for those patients who are the sickest. With evolution in critical care service and staffing models, we have been asked to provide measurable and translatable education experiences which promote professional growth, improve patient outcomes, enhance family engagement, and engender patient satisfaction. By taking a systematic approach to a learner-centered and a family-centered educational model, with immersion though simulation training, we can provide a framework on which to construct comprehensive educational experiences for all learners.

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Chapter 14
Humanizing Critical Care

Gabriel Heras, Jerry Zimmerman, and Jorge Hidalgo

What Is Humanization of the Intensive Care Units?

- The model is centered on the person which includes patients, family members, and health professionals.
- The model emphasizes the respect to dignity of every human being.

People Are at the Center of Humanization

The humanization of intensive care movement was launched in Spain in February 2014 with the Project HU-CI [1]. It is an international research project that seeks, from the scientific evidence, a paradigm shift in healthcare toward a more friendly and people-centered model [2].

Probably many readers are surprised and feel like this humanistic trend represents a contradiction, since perhaps this essential quality in the health professions

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should never have been lost. But the truth is that when professionals become actual users of the system, as families or patients, it is then when we really appreciate the need to invest in improving the patient-healthcare provider relationship. At the same time, in the setting of constant, multivariable stress, critical care health professionals experience high rates of professional burnout [3]. It has actually been suggested that the intensive care unit may represent one aspect of hell [4]. While this comparison may be a bit hyperbolic, if we fail to listen to all the members of the interdisciplinary care system, we will lose an important opportunity to improve, just as in any other field of knowledge.

Therefore, taking note of all the parties that coexist in the health system on a daily basis (patients, relatives, and professionals) becomes a necessity, and this activity provides a path toward the ideal state healthcare system and forces everyone to focus on the particular problems of each protagonist, to respond to their individual needs, and to understand that the balance depends on the well-being of all involved. This charge becomes everyone's responsibility. Although we cannot cure all patients, we can certainly optimize the care that we provide. To address this challenge, we must focus our attention on preserving the dignity of the person, as this becomes the golden rule in our interactions.

The professional and technical development of ICU providers and ICU physical plant capabilities over the past few decades is impressive. Proof of this are the increasing survival rates associated with critical illness [5]. On the other hand, development of intensive care as a subspecialty at the technological level has outpaced progress in the human aspects of critical care. This inequity not only affects patients. In many circumstances, the organizational and architectural characteristics of an ICU can create a hostile environment for everyone: patients, families, and even critical care professional. Therefore, humanization must also include structural changes [6].

Different Views of Humanization

To humanize is defined as the action of "attribute human qualities or to adapt to human nature or use." The same conceptual definition can be found in various languages [7, 8]. That is, we could humanize everything we set out to do, and if we focus on healthcare, regardless of whether we are patient, family, or professionals, we could ask ourselves one or more of the following questions:

- Can I humanize my relationship with others?
- How can I humanize my day-to-day activities to be happy?
- Can I humanize the space in which I personally work?
- Can I humanize the management team with whom I interact?
- Can I humanize my hospital or health center?

And this list of questions could be as long, personal, and individually unique as we want it to be [8].

According to one of the references in humanization in Spain, José Carlos Bermejo (director of the Center for Humanization of Health of Madrid), humanizing means:

> humanizing means that everything is done to promote and protect health, to cure diseases, to guarantee an environment that favors a healthy and harmonious life at a physical, emotional, social and spiritual level. To speak of humanization demands the intrinsic dignity of every human being and the rights that derive from it. It is for this reason that it becomes a vitally important need and transcendence [9].

In addition, humanizing represents fighting for "what we have not yet" reached: how we should live to fully realize ourselves as people and feel that way in every situation and in every place. Humanizing healthcare means betting on a healthcare system that is more friendly and people-centered, regardless of their role. Humanizing also means personalizing assistance by listening to what patients and family members need, not promoting what we think they need, but attending to their needs, even if these needs do not coincide with ours, and directing this culture change into a clinical process where attitude is fundamental. Humanizing is also understanding and accepting that professionals are fallible and vulnerable and that we also need to be listened to since we, care providers, represent the basic capital to humanize the healthcare system. A system becomes humanized when it prioritizes service to all people involved in the chain of health: patients, family members, and professionals.

Care Provider Skill Set

Healthcare requires not only professional competence and training but also individuality, emotional sensitivity, collaboration, and ethics. It requires great communication and relationship skills that include empathy, active listening, respect, and compassion. But historically, health professionals have curricular defects in training in "human tools," the so-called soft skills. The affective-effective model [10] inspired by the work of Albert Jovell has been summarized: "It is the way to care for and cure the patient as a person, based on scientific evidence, incorporating the dimension of the dignity and humanity of the patient, establishing an attention based on trust and empathy, and contributing to their well-being and to the best possible results in health." This supports the idea that just because we are human, we are not necessarily humane nor we have the knowledge of how to deliver human care.

Scope of Humanization

Humanization is not a simple issue and certainly has its own history, including the fact that humanization of healthcare is considered by many as "fashionable." As noted previously, humanization includes patients, families, and health personnel, as well as managers and health authorities. In the largest sense, humanization encom-

passes culture, politics, society, economics, ethics, and justice. And the scope of humanization transcends people and behaviors. Humanizing requires not only attitude but also a human touch to structure and technology.

The actual adventure of humanizing sometimes generates considerable controversy, perhaps because it puts us in contact with ourselves and our differential views of what is involved in humanization.

It is undeniable that humanization involves change and movement and it is certainly not static. With respect to other disciplines of healthcare, humanizing involves not only studying a technique or a procedure and putting it into practice but also requires deep and continuing reflection. To humanize consists of becoming aware of oneself: where am I; what can I do? It requires that each of us take a journey into our inside. It requires a personal commitment to clarify our reality, our relationships, and our personal environment.

Talk to Me

If we make a halt in our journey in life to listen to the patients, to the families, and to our colleagues, and if we could embrace their points of view, we would probably have addressed the key to the issue. And this activity would be absolutely reproducible anywhere in the world. Basically, effective communication between all parties is the most essential element of humanization.

Aspects included in this communication are:

- Those related on how to improve the care we deliver, focusing on patient's well-being and satisfaction, integrating both aspects of the care as a priority, physical and emotional.
- Those related to facilitating empowerment and engagement of families in the care plan, listening to their needs, as well as encouraging their presence and participation in patient recovery.
- Those related to recovering the vocations of experienced professionals, exhausted and discouraged with the excess workload and stress and the continued cuts in pay, materials, or benefits.

What Are We Waiting For?

Humanization seems so obvious; it is such a common sense that the question arising is why have we not realized it previously? This question might not be as simple to answer, and a more suitable question might now that we have realized the importance, what are we waiting for before we implement it?

In a down-to-earth approach, we believe that effective communication is again the key, and through listening to the different players involved, we will be able to

Fig. 14.1 Project HU-CI: areas of improvement and research [12]. Used with permission

deliver humanized care. Employing a collaborative network research model, the Project HU-CI aims to evaluate different aspects of humanization and to implement the corresponding improvement actions. These quality improvement and research initiatives, summarized in Fig. 14.1, were identified through active listening and shared reflection on thousands of opinions of a variety of stakeholders and resulted in a Humanization Plan of the ICUs in Madrid, Spain [11], and has been recognized by *New England Journal of Medicine* Catalyst [12] as a change in the healthcare model.

The Integration of Intensive and Palliative Care

One area of research for Project HU-CI is the care at the end of life, which includes 22 good practices across 6 areas of interest: (1) protocolization of end-of-life care, (2) management of physical symptoms, (3) provision of presence and companionship, (4) awareness of emotional and spiritual preferences, (5) protocol for limiting life support treatments, and (6) multidisciplinary involvement in the decisions involving life support limitations [13].

In general terms, one in each ten patients admitted to the ICU dies [5], and in up to 70–90% of those cases, their death is preceded by some life support treatment limitation (LSTL), either by not starting or by withdrawing treatments [14].

The decision about the care limitation should be shared by the provider team and should include the patient. When the individual, affected by the severity of the con-

dition, is unable to make informed decisions, those need to be discussed with relatives or representatives [15]. Decisions of this interdisciplinary team should respect what the patients previously have expressed to their families either verbally or through advance directives.

Once there is a consensus on the limitation of care, the primary objective becomes alleviation of symptoms and the provision of emotional support both to the patient and family facilitating a dignified death [16], making special emphasis on alleviation of pain and dyspnea, and in the company of loved ones. Healthcare professionals who serve critical patients have a double commitment, namely, administering necessary treatments and procedures to avoid death and optimizing quality of life for those who survive while identifying those who will not achieve these objectives and integrating palliative care as an essential aspect of intensive care [17].

Despite the variability of the published studies, it seems clear that long-term care planning and the integration of a palliative care program reduce the number of admissions and the average duration of stay in the ICU [18]. Coexistence of such a technological field as ICUs, but comprehensive intensive care can only be realistically conceived if, in addition to the prevention, diagnosis, monitoring, and treatment of critical illness, palliation is also available for patients who would benefit from it [19, 20]. Palliative care is not about patients entering the ICU to die, but rather is about ensuring that those who will not be able to recover pass under the best possible circumstances.

At present, end-of-life care and PC practices vary widely among hospitals, regions, and countries [21].

When life support treatments are considered useless by the healthcare team, and there is agreement with the patient or their representatives about this limitation, the care plan must shift focus to avoid suffering, respect the dignity of the sick person, and prevent or resolve conflicts derived from difficult decision-making. Therefore, palliative care involves not only the administration of appropriate drugs to alleviate pain or dyspnea but also the engagement by relatives or close friends of the patient, attention to their needs, and provision of an environment as comfortable as possible avoiding noise or unnecessary alarms [22, 23]. This frameshift results in gradually directing more importance to the care itself instead of the treatments or diagnostic tests. This change in strategy must include the patient's family, not only during the dying process but also during the grief process once the patient has passed away.

Fundamental components of palliative care in the ICU can be summarized as follows:

- Communication about the patient's current situation, prognosis, and treatment options
- Establishment of a plan of care that takes into account the values and preferences of the sick person
- Relief of symptoms
- Emotional support for family members, including bereavement care
- Prioritization of continuity of care
- Recognition, prevention, and treatment of professional burnout

Table 14.1 Difficulties and solutions to integrate palliative care in the ICU [25]

Challenges	Solutions
Little training in and lack of knowledge about PC among ICU providers	Plan for awareness and training of PC in the ICU
No problems or deficiencies are identified	Establish PC as a priority area for quality improvement
Absence of collaboration with other professionals	Convene a multidisciplinary working group
Critical care and PC are viewed as two exclusionary areas	Establish a joint care plan
Unrealistic healing expectations by the healthcare team and family members	Consult or collaborate with PC in the ICU
Absence of recommendations or protocols	Compose clinical standards with joint clinical sessions
Suffering of relatives not taken into account	Share all relevant information with family members
Risk for professional burnout, moral distress, and compassion fatigue	Develop interprofessional recommendations for end-of-life care

Despite the fact that the ICU has traditionally been considered a place to treat seriously ill patients, if comprehensive PC concepts are applied, the ICU can also be a place for a dignified death. Appropriately trained providers not only treat symptoms but also engage with and support both the patient and the family [24]. This model represents a paradigm change that broadens the range and improve the quality of services provided at the end of the life for critically ill patients.

Any change inevitably involves overcoming some barriers. Table 14.1 summarizes the main challenges and possible solutions for integrating PC in ICU.

Quality improvement projects aimed at integration of PC with intensive care medicine have prioritized five areas:

1. Training of professionals to improve their knowledge about the principles and practice of PC in intensive care medicine
2. Collaboration with specialists in PC to promote change in end-of-life care
3. Identification of the challenges that prevent improving the care at the end of life and propose solutions
4. Review of quality criteria in the care of dying patients and their families
5. Preparation of supporting documents such as LSTL forms, information brochures to family members, etc.

Requesting the collaboration of health personnel from PC services can be a great help to update protocols and recommendations in order to improve the quality of care in the dying process [26, 27]. The benefits derived from the integration of PC in the ICU can be summarized in the following principles:

- Early identification of PC needs for patients and families
- Improvement in the training and awareness of PC among critical care professionals
- Establishment of a defined plan of care

- Decrease in non-indicated costs and treatments, with consequent decrease in healthcare spending
- Prevention and treatment of professional burnout associated with the care of dying patients and grieving family members
- Assurance of continuity of care if the patient is discharged alive from the ICU

In summary, professionals who serve critically ill patients have a double commitment: administering the necessary treatments and procedures to avoid death and maintaining a quality of life for acceptable patients while being sensitive to those who will not survive by integrating PC as an essential aspect of critical care. This must include respecting advanced directives, reviewing the content, identifying the legal representative, and facilitating difficult decisions based on the patient's preferences. In the absence of advanced directives, critical care providers must proactively engage in conversations with both the patient (if possible) and the family regarding medical care preferences and encourage them to participate in decision-making, especially for patients with chronic diseases or terminal illnesses. In the midst of modern ICU technology advances, humanizing care for both the survivor and the dying patient will ultimately benefit all.

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Chapter 15
Billing and Coding

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Introduction

Critical care billing and coding is instrumental in the financial sustainability of intensive care services. Whether care is delivered in a private, fee-for-service model, or in a single-payer system (state or country level) adequate coding and billing is needed not only to provide financial support for the system and its individual components but also to determine the budget required for any given period.

Critical care spends more than 30 percent of the financial resources of a hospital system while typically accumulates less than 15 percent of the hospital beds [1]. Moreover, technology and specialization of care as well as aging of the population are factors that impact the cost of care of those patients admitted to the ICUs, prolonging their length of stay and allowing more and more costly tests and procedures [2].

Amid those important factors, every country and even sometimes every area in each country presents different challenges related to financing and provision of services in the ICUs. While some provide critical care services in the setting of a bundle-care model, others continue experiencing the so-called fee-for-service model with separation of charges and compensation for the institution and the clinician (physician or advance practitioner).

In addition, there is much confusion and information regarding documenting and billing for critical care, what entitles and what needs to be there. Organizations such as the American Medical Association or the Society of Critical Care Medicine have published guidelines and define terminology for providers to allow critical care time documentation and billing according to the Centers for Medicare and Medicaid Services requirements [3, 4].

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This chapter will aim to simplify billing and coding aspects for critical care providers and will make references to the updated information available online by Centers for Medicare and Medicaid Services [4].

Disease-Related Group

Medicare Severity Diagnosis Related Group (MS-DRG) is also known as DRG. It is an inpatient prospective payment system and determines how hospitals get paid. Attempts to reflect the hospitals case mix, including the type of patients the hospital treats, severity of medical issues, and the number of resources needed to be used to treat those patients. It is based on ICD 10 [5].

DRGs apply to inpatient services offered but lately have included some outpatient surgeries [5].

For a hospital to get paid, in a simplified way, depends on two main factors, the DRG assigned to the patient (reason for hospitalization) and the hospital payment rate per case. In addition, there is weight factor associated with the DRG based on the average amount of resources to take care of that particular patient (based on average DRG data). The higher the weight factor, the more the payments for a particular DRG. In general, many factors influence the payment rate per case, also known as base payment rate. It includes labor and nonlabor portion. Location area for the institution is factored into the labor portion according to a cost of living adjustment.

Although clinicians are not directly affected by DRG-associated reimbursement, accurate and complete documentation will make a better justification for patient's ICU admission and treatment and provide better financial return to the institution. The International Classification of Diseases-10 (ICD 10) has made imperative for providers to maintain accurate and specific documentation. Inpatient hospital depends in a great portion on that. In addition, The Affordable Care Act requires providers not only to demonstrate medical necessity but also document the patient encountered in detail.

Critical Care Services

In the United States, Medicare has determined strict criteria for billing critical care services. Most private insurances follow Medicare rules, with only few exceptions and pilot projects in which bundle services are in place. Even on those, documentation criteria must be met.

Critical care treatment is billed using the Current Procedural Terminology (CPT) codes 99291 and 99292 of the evaluation and management services bill (E&M) **(1,2)**. In order to meet criteria, the patient must be critically ill or injured with impairment of one or more vital organs and/or there is a high probability of immi-

nent or life-threatening deterioration of his/her condition. Critical care involves high complexity decision-making. In addition, critical care must be medically necessary and reasonable.

According to Centers for Medicare and Medicaid Services, critical care must encompass the treatment of a vital organ and/or prevention of further life- threatening deterioration of the patient's condition. A patient that is admitted to the ICU after surgery might not qualify for critical care services unless there is a real potential deterioration risk. Typical examples of organs involved that have that potential include central nervous system failure, circulatory failure, shock, or renal, hepatic, metabolic, or respiratory failure.

It is important to mention that just because a patient is critically ill or is admitted to a critical care area does not justify that critical care services are or need to be provided. Examples of situations in which patients admitted to ICU do not warrant critical care services include:

- Daily management of patient on chronic ventilator
- Management of dialysis care related to a patient receiving dialysis for end-stage renal disease
- Patients admitted to ICU because of no other beds available
- Patients admitted to ICU for close observation and monitoring of vitals
- Patients admitted to ICU because hospital rules require certain treatments to be administered in the ICU

Critical care codes are based on a patient's condition and the intensity of services provided and not the location of the service. Following this statement, critical care services could be billed in the medical-surgical ward, ED, recovery area, and of course ICU among others.

Critical Care Time

Critical services, as a difference to other E&M codes, are time-based, representing the time spent by the clinician evaluating, treating, and managing the patient. The time might be spent bedside or elsewhere in the unit or in the grounds nearby as far as the clinician is immediately available to the patient (as an example cannot be seeing other patients on the floor). That determines how time need to be accounted for patient-care interventions such as reviewing test results, discussing care with nursing staff or other physicians (including phone conversations while on the unit), completing orders or documentation, arranging transfers, and even discussing care with family members (only if the patients are unable to make informed decisions and those are needed for treatment purposes) [6].

Code **99291** is applied to the first 30–74 minutes and **99292 for each** 30 minutes. If less than 30 minutes are spent, then an E&M evaluation code must be used. Total time per day must be documented. The time must be continuous or intermittent and aggregated in time increments spread over a calendar day. Time for procedures that

Table 15.1 Services bundled into adult critical care codes (with CPT codes)

Interpretation of cardiac output measurements (93561–93562) Chest x-ray, professional component (71010, 71015, 71020) Blood gas interpretation (99090)
Interpretation of data stored (ECG, vital signs, laboratory, etc.) (99090) Nasogastric or orogastric intubation (43752–43753)
Pulse oximetry (94760–94762)
Temporary transcutaneous pacing (92953)
Vascular access (noncentral) (36000, 36410, 36415, 36591, 36600)

Table 15.2 Reporting critical care services

Less than <30 minutes	Appropriate E&M code
30–74 minutes	99291
75–104 minutes	99291 × 1 and 99292 × 1
105–134 minutes	99291 × 1 and 99292 × 2
135–164 minutes	99291 × 1 and 99292 × 3
165 minutes and longer	99291 × 1 and 99292 as appropriate

require different billing (i.e., intubation, line placements) must be carved out from the total time. Some procedures are included in the critical care service and must not be reported separately (Table 15.1).

Initial critical care time, billed as code 99291, must be met by a single practitioner, in a single period of time, or be cumulative by the same practitioner on the same calendar date. An example of correct reporting of critical care services is seen below (Table 15.2).

Subsequent critical care visits performed on the same calendar date are reported using CPT code 99292. The service may represent aggregate time met by a single practitioner or practitioner in the same group with the same medical specialty in order to meet the duration of minutes required for CPT code 99292. The aggregated critical care visits must be medically necessary, and each aggregated visit must meet the definition of critical care in order to combine the times.

It is also important to clarify that two practitioners cannot bill critical care at the same time. So, if a critical care physician and a neurologist are seeing a patient between 09:00 and 10:00, only one of them can bill critical care time for that hour. However, if the critical care physician sees the patient at 09:00 and the neurologist sees the patient at 10:00, both can bill critical care time as long as they are managing different conditions (very important to have clear documentation of accurate diagnosis).

Billable services that can be carved out of the critical care time are summarized below (Table 15.3). When documenting critical care time, it is important to describe these services as a separated procedure and explain that the time spent on these is not accounted into the critical care time billed.

Table 15.3 Separately billable services (with CPT codes)

Insertion of Swan-Ganz catheter	93503
Temporary transvenous pacer	33210
Thoracentesis (with or without imaging guidance)	32554–32555
Pleural drainage (insertion of catheter with or without image)	32556–32557
Placement of central vascular access	36556
Tracheostomy	31600–31603
Endotracheal intubation	31500
Arterial puncture	36600
Arterial catheterization	36620
Pericardiocentesis	33010–33011
Cardiopulmonary resuscitation	92950

Shared Time-Split Time

A split/shared E&M service performed by a practitioner of the same group practice (or employed by the same employer) cannot be reported as critical care services. The critical care service reported should be billed under an individual practitioner.

Once the initial critical care visit (99291) has been documented, critical care services times are additive (99292) even when performed by different practitioners in the same group. According to CMS when "more than one member of a physician group provides ICU (99291 and 99292) care to the same patient in the same day… the physicians should bill as if all of the services were provided by one of the members of the group" [4].

To add critical care time, practitioners must work in the same group, but if they have different taxonomic backgrounds (i.e., physician/nurse practitioner), shared billing can be applied in some areas although it is recommended to insert the appropriate provider identification number (NPI) with the submitted claim [7]. This has changed from previous CMS guidelines and it is applicable to some regions. Thus, practitioners must know and be familiar with the regulations applicable by your different payers.

Teaching Time

In academic centers it is common that patients are initially evaluated and managed in some medical aspects by residents and fellows to a later evaluation by the attending practitioner. Teaching practitioners can report critical care time only if that time has been devoted entirely to the patient together with the resident and fellow. If the teaching practitioner is not present, then critical care time cannot be billed based on

the resident or fellow documentation. It is however accepted a combination of teaching practitioner documentation and the resident or fellow documentation to support the services provided (linked documentation). In that case, the teaching practitioner must document a statement that he/she personally spent the time providing critical care. That statement should include documented time, rationale for the services, and the teaching practitioner medical plan of care. In addition the teaching practitioner should apply the modifier GC (this service has been performed in part by a resident under the direction of a teaching physician).

Nonphysician Practitioner (NPP) Billing

The Balanced Budget Act of 1997 recognized NPPs as healthcare providers. NPP direct billing is typically subject to a decreased Medicare allowable down to 85% of the physician's rate [8]. There are three particular scenarios, incident-to-billing, direct, or split/shared encounters that we will be reviewing here.

Incident to Billing

Service provided by the NPP but billed by the physician using the physician NPI number. This scenario does not apply to critical care or other hospital settings. It is restricted to office encounters when physician is physically present.

Direct Billing

Occurs when NPP provides the entire service. It can occur in all settings. The patient can be new or established, and there is no need to have a plan of care determined prior to the visit. The service is billed under the NPP NPI and is reimbursed at 85% of the physician's fee schedule for Medicare reimbursement. This might be different for other payers.

Split/Shared Billing

Current CPT guidelines do not allow split/shared visits for consultations or for critical care services. Direct billing rule must be applied.

A split/shared visit may occur for E&M services provided by same group practitioners (physician and NPP). The service must be within the NPP scope of practice and may occur jointly or independently on the same calendar day. Both NPP and

physician must have a face-to-face encounter with the patient. If the encounter is billed under the physicians NPI, it is reimbursed at 100% fee. If no face-to-face encounter occurs, even if the physician participated on the reviewing of the patient's record and delineation of the plan of care, then the services must be billed under the NPP NPI.

Documentation guidelines for these encounters include:

- The split/shared visit must have documented face-to-face encounter by both NPP and physician on the day of service.
- Both should document their participation in the medical record.
- The NPP must be employed by the physician practice (otherwise the services cannot be considered shared/split)
- The physician cannot state "review and agree" without seeing the patient personally.
- The physician must document the three components of the E&M service (history, examination, and medical decision-making).

According to previously discussed and following CMS rules, only one practitioner can bill for critical care during any single period, and the initial CPT code 99291 applies to a single practitioner intervention [4]. Any care beyond 74 minutes is billed using the add-on code 99292, and the care can be provided by a physician or an NPP of the same group of practice.

Conclusions

The complexity of critical care coding and billing makes the financial part of critical care many times obscured for many albeit is essential to the justification and reimbursement for our services.

Attempts have been made to simplify and to justify all elements of the critical care. New changes will likely attempt to embrace new challenges to practice such as tele-ICU, predictive models, and even simulation and training. Those are yet to come. Meanwhile it is essential that the practitioner familiarizes themselves with the rules and regulations in their area of practice and documents with flawless determination the care provided.

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Chapter 16
Intensive Care Burnout

Cory Franklin

History

For over a century, psychologists and psychiatrists have realized the physical and emotional effects of job stress can be debilitating. As far back as the late nineteenth century, the recognition and treatment of these conditions had profound social and economic implications across the European continent, when Germany pioneered workers' compensation in the 1880s [1]. Patients with nervous disorders who suffered industrial accidents at their jobs often filed claims, and if German insurance boards rejected the claims, survivors would often feel doubly traumatized, first by the accident and then by years spent appealing the decisions. Nevertheless, this was a significant breakthrough in public recognition of health problems emanating from job-related stress.

In World War I, British surgeons recognized a dreaded complication of combat referred to as "shell shock" [2]. (The term was replaced in World War II by "battle fatigue," and today is recognized by the diagnosis post-traumatic stress disorder or PTSD.) Neurologists and psychiatrists employed hypnosis, electric shock, and psychological coercion, often to no avail. Many men were too psychologically damaged to respond and were eventually consigned to asylums.

In our current society, a number of occupations including law enforcement, firefighting and first responders, teaching, financial management, and professional sports can lead to incapacitating job stress. In healthcare, nurses and physicians who work in the intensive care unit (ICU) are especially susceptible to the "burnout syndrome." As ICUs developed from their evolution in the 1950s until today, burnout has become a well-recognized occupational hazard for physicians and nurses who work there (while most literature employs the academic term "burnout syndrome," this chapter will use the more common, simplified term "burnout") [3].

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Burnout was first described in two articles published separately in 1974, one by Herbert Freudenberger and the other by Sigmund Ginsburg [4, 5]. Freudenberger, a German-born American psychologist and psychotherapist, described a condition he observed in himself and his colleagues as burnout. Specifically, his experience resulted from the stressful conditions he experienced when he worked in a New York City free clinic.

For those wishing to study burnout in the modern ICU, Freudenberger's original article is particularly instructive. He described burnout as occurring when the workplace makes excessive demands on energy, strength, or resources. He noticed that burnout was most likely to occur in those who were dedicated and committed to their jobs and that it was often manifested by headaches, fatigue, exhaustion, gastrointestinal symptoms, sleeplessness, or shortness of breath. Sufferers experienced depression, anger, or frustration and often resorted to alcohol or drug abuse. While there is still no universally accepted definition of ICU burnout, almost a half century later his work remains a good starting point [6].

Definition and Measurement

Freudenberg's description of burnout was qualitative, but quantitative research soon followed. In the next decade, social psychologist Christina Maslach and her colleagues published groundbreaking literature focused on defining and measuring burnout more precisely. Her major contribution was the Maslach Burnout Inventory (MBI), the first and most successful attempt to identify burnout by using a self-reporting questionnaire. The MBI attempts to identify three common characteristics generally associated with burnout: *exhaustion*, *depersonalization*, and *reduced personal accomplishment* [7, 8].

Exhaustion is characterized as fatigue after devoting excessive time and effort to tasks that appear to have little or no benefit. The most common situation in the ICU where this occurs is when staff are caring for patients who they believe have little chance of recovery. *Depersonalization* is the cynical attitude that develops when caregivers become callous about their work. It manifests in negative comments about patients, families, or other staff; blaming patients for their medical problems; or lack of compassion over patients' deaths. *Reduced personal accomplishment* is a combination of a lack of professional self-esteem and feeling incapable of doing work well or effectively. Respondents to the MBI are asked to identify how often they feel this way about their jobs by answering 22 questions, with answers graded on a seven-point scale. If a respondent scores above a cutoff value, he or she is diagnosed with burnout.

In the last two decades, there has been an exponential increase in research on burnout, which has demonstrated limitations to the MBI, including the fact there is no general agreement on diagnostic cutoff values for critical care professionals. More recent questionnaires have pointed out the difficulty in identifying individuals with burnout. The difficulties include questioning the underlying assumption of the three characteristics MBI is looking for; other criteria such as lack of expected

reward for an occupational task might describe burnout just as accurately. The MBI itself has contributed to the dilemma because its widespread use has deterred alternative interpretations of the syndrome. In addition, the syndrome may exist on a continuum – burnout may be partial or evolving – and the MBI is often used as a black and white discriminator between individuals with burnout and those without, even though this was not the original intent of the survey tool [6, 9, 10].

Prevalence

In 2016, the American Thoracic Society (ATS), the American College of Chest Physicians (CHEST), the American Association of Critical Care Nurses (AACN), and the Society of Critical Care Medicine (SCCM) prepared a joint statement addressing burnout syndrome among ICU healthcare professionals. Their findings and recommendations were published in their respective journals. In 2017, a national summit was convened by the Critical Care Societies Collaborative (CCSC) to address prevention and management of burnout in the ICU with members from each of the aforementioned organizations present. These efforts are an indication of the severity of the problem of ICU burnout in the 10,000 critical care physicians and 500,000 critical care nurses working in the United States [11, 12].

The preliminary figures from the CCSC findings indicate:

Up to 45% of critical care physicians reported a symptom of burnout, while 71% of those specializing in pediatric critical care reported symptoms.

Approximately 25–33% of critical care nurses manifest symptoms of severe burnout, and at least 86% have one of the three classic symptoms.

The high burnout rate in critical care professionals is attributed to the stressful environment in the ICU caused by high patient morbidity and mortality, changing daily work routines, and regular encounters with traumatic and ethical issues.

Burnout in critical care health professionals may result in PTSD, alcohol abuse, and even suicidal thoughts.

In nurses, burnout is associated with reduced quality of care, lower patient satisfaction, increased numbers of medical errors, higher rates of healthcare-related infections and higher 30-day patient mortality rates.

Risk Factors

Those suffering from burnout in the ICU tend to be more highly motivated and younger. The fact that younger workers are more prone to burnout in the ICU is counterintuitive, because the ICU is a physically demanding job: it is primarily a "young person's job," which becomes more difficult as caregivers get older. Perhaps older physicians and nurses develop effective coping mechanisms over the years to avoid burnout. An inadequate personal support system – no close family, spouse, partner, children, or friends – is also likely to be a risk factor for burnout in ICU personnel.

It is important to recognize that while the risk factors for critical care nurses and critical care physicians are often similar – excessive responsibilities, sleep deprivation and disruption, lack of control, continuously facing ethical dilemmas/end-of-life issues, caring for notorious patients, and increased documentation requirements with the electronic medical record – there is a difference between burnout in the two groups. Physicians encounter many patients for brief periods of time, while nurses are continually involved with smaller numbers of patients for longer periods. This creates different patterns of stress. Critical care physicians may have the highest rate of burnout among doctors. The reasons may include long working hours, night call, and infrequent vacations. For critical care nurses, stress leading to burnout is often related to organizational problems in the ICU, staffing issues, moral dilemmas, and difficulty with end-of-life care policies. These differences in root causes mean that not all solutions to burnout are applicable to both groups. There is no one-size-fits-all fix [13, 14].

Consequences

The costs, direct and indirect, of ICU burnout are significant. Nurses and physicians can both suffer terrible consequences from burnout, including substance abuse, depression, and even suicidal ideation. Critical care nurses, in particular, have an incidence of PTSD at a rate of 15–30% associated with burnout (it is not clear whether burnout triggers PTSD or whether the two coexist). Besides the tragic human costs to healthcare personnel, burnout results in suboptimal job performance, which directly affects patient care [15–18].

It goes without saying that burnout causes healthcare workers to leave their professions at higher rates. The costs for hospitals and society are substantial. Continuity of care suffers when ICU physicians leave their practices or retire, and it may cost several hundred thousand dollars to replace each one of them. The consequences of nursing turnover are likely to be even more costly. The CCSC report cited the cost of replacing one ICU nurse at more than $65,000, but with a turnover rate of 15–20% per year, the cost to a hospital could easily exceed $one million annually. This does not take into account the added deleterious effect on staff morale when personnel leave the ICU, creating a "snowball effect." Burned out nurses leave, creating staffing issues for the ICU, which then places more stress on remaining nurses, who are ultimately prone to burnout and leaving the ICU themselves [19, 20].

Solutions

An editorial in Lancet suggested that ICU burnout is a societal problem: "an inevitable product of our times and our society, a result of increasingly stressful work environments and longer working hours." The editorial continued that "improved

awareness especially among policymakers, funders, and hospital administrators, and better communications within teams with structured individualized interventions, together with increased research and resources, will be small steps in the right directions" [14]. These types of anodyne platitudes will be small steps indeed – and likely of little help to the individual critical care physician or nurse.

The solutions to the omnipresent problem of ICU burnout must come primarily from those most affected – the hospitals, the specific ICUs, and most importantly the practitioners themselves. For nurses, where burnout is often a consequence of factors beyond their immediate control, they must have lectures and in-services on the signs and symptoms of burnout. *The hospital and ICU must make this part of every nurse's initial job training – any hospital or ICU that does not do this is failing to hold up its end of its bargain with the employee. Psychotherapists trained in emotional understanding should be part of every ICU and available to everyone.*

Early recognition of burnout by oneself or one's colleagues can lead to increased communication and support from coworkers, realigning personal and professional goals, and balancing work/home priorities. The nurse who understands he or she is facing burnout can be empowered to take active measures to counteract the situation. This might take the form of reducing hours, changing shifts, taking more vacations, seeing a trained professional, or actively engaging in meaningful stress reduction such as yoga, cognitive behavioral therapy, or some other effective personal physical or mental approach. Any good coping skill or stress reduction mechanism should focus on the fact that the nurse is not simply an extension of his or her job. He or she has a life outside the ICU.

But, especially in the case of the nurse, avoiding burnout is rarely accomplished by the practitioner alone. The hospital or ICU where the practitioner works may contribute to the problem and thus must act to remediate the situation. Many nurses feel significant stress from overwork, caused by staff shortages or frequent cross-coverage assignments in other units. Hospitals must ensure that ICUs are staffed appropriately with sufficient numbers of competent personnel, especially on off-hours. Short-term financial cutbacks by administrators often lead to greater long-term expenses with increased turnover and disgruntled staff. Going cheap on ICU staffing is rarely a prudent strategy. Moreover, improving working conditions – better breakrooms, parking, greater continuing education, and opportunities for professional advancement – can be the difference between a satisfied nurse and a dissatisfied one. Adequate compensation is necessary but not sufficient – administrators must understand that money alone is rarely a source of satisfaction, but lack of money is often a source of dissatisfaction.

The ICU head nurse or nurse manager plays an important role. He or she is like a military commander, who is responsible for the well-being of his or her troops, ensuring their physical and mental comfort. ICU nurses are occasionally engaged in conflicts with patients, families, or physicians, and in those situations, the nurse manager must support the nurse when he or she is in the right and instruct him or her when in the wrong.

In the context of lack of control of one's environment, ICU policies – often end-of-life or transfer policies – are a common source of stress for nurses. A neurosur-

gery policy that automatically accepts cases from other hospitals of head trauma or severe cerebrovascular accidents who are not candidates for surgery places nurses in the uncomfortable position of caring for patients unlikely to survive but still requiring significant nursing care. This can be an exceedingly stressful situation. The ICU nurse manager is often the point person to forge a reasonable compromise with the physicians and administrators on such a policy. ICU nurses should also have some input on hospital do-not-resuscitate and end-of-life policies, because those nurses are essential to policy implementation.

As mentioned before, ICU physicians are subject to different stresses, including heavy workloads and important clinical decisions. In limiting intensivist workloads, it is difficult to accommodate physician responsibilities with the demands of complex patients. The ICU is not comparable to the emergency department, where cases are self-limited and resolve or are admitted to the hospital usually within 24 hours. In this respect, the emergency department lends itself to shift work. ICU cases often take days to weeks to resolve, and it is inevitable in such cases different physicians will take charge of the decision-making; shift work may be necessary but it is not as desirable. An optimal solution must balance reasonable working hours for intensivists with continuity of care. The in-house intensivist should not work too many hours a week and must devote especial attention to sleep and outside life. The on-call intensivist who is part of a team can rarely work more than 3 weeks at a time without a couple of days off. At some point of course, vacations are essential.

Decision-making is another part of physician stress in the ICU. Intensivists are routinely called upon to make life or death decisions. Because the stakes are so high for the patient, the physician may become overconfident after making successful decisions; naturally, it is exhilarating to save someone's life. By the same token, the physician can become hesitant when a previous decision costs a patient his or her life. After this happens, the doctor may fail to act when action is indicated; the cat who sits on a hot stove will never sit on a hot stove again, but it will never sit on a cold one either. Likewise, intensivists are often called upon to perform stressful tasks like terminal extubation or termination of care. No matter how often one does this, it is not easy – that is to say, it should never become easy. One of the keys to practicing intensive care and avoiding burnout is the quality as described by the legendary Sir William Osler more than a century ago: *Aequanimitas*, i.e., coolness and presence of mind under all circumstances, calmness amid storm, and clearness of judgment in moments of grave peril [21].

One more thought for intensivists. To avoid burnout, it is probably a good idea for the ICU physician to do something professionally outside the ICU. The ICU has been compared to a black box, and being confined to a black box all the time can be stultifying and on occasion claustrophobic [22]. Talking to patients is an essential aspect of medicine, and it is difficult to do this in the ICU if most of the patients are in coma or intubated. The medical intensivist should do a clinic, office practice, or ward rounds at least once a week. The surgical intensivist and the anesthesiologist should be involved in the operating room or the clinic weekly as well. Practicing medicine outside the ICU can clear the mind and refresh the spirit.

Finally, nurses and physicians must work together to avoid burnout. Collaboration and communication are central to avoiding the loss of control that both groups sometimes experience (it is sad but true that administration is occasionally seen as the common enemy). One essential is a combined ICU conference, with bedside nurses, physicians, the nurse manager, and ICU director attending. It is routinely difficult to get the necessary staff together for such conferences because of conflicting schedules and the hectic ICU atmosphere. But both groups should make such a conference a priority for at least an hour once a month. The conference should be an uninhibited forum where attendees can discuss problems, air grievances, and propose solutions. Occasionally enmity is generated, but it is far outweighed by the sense of mission and the opportunity for all personnel to speak freely and express their thoughts.

Conclusion

Any discussion of ICU burnout should acknowledge that while burnout is a constant threat, working in the ICU can be fulfilling and deeply satisfying. The aforementioned Lancet editorial published the comments of one physician who said that long hours with a good team can be less stressful than shorter hours with a mediocre team where the physician or nurse is under more pressure to make sure they "don't drop the ball" [14]. There are many different types of ICUs, from trauma to burns to pediatric to cardiothoracic, and none is immune from staff burnout. While there is no surefire way to prevent burnout completely, the best defense is a team approach – with a common mission, shared goals, and a spirit of cooperation by all involved.

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Chapter 17
Complementary Therapies

Marie R. Baldisseri

Introduction and Definitions

Many clinical practitioners as well as patients have recognized for some time that traditional and conventional medical patient care with general treatment principles based on specific disease processes can often be wholly inadequate. In the past, there was a rift between traditional and conventional medicine and other holistic and complementary practices. After the 1990s there has been a move toward other options that give patients and their health caregivers additional humanized treatment options. These are particularly seen in cases of terminal diseases and chronic diseases and in critically ill patients in the ICU when the disease may or may not be terminal but the need for alternative therapies for pain, fatigue, depression, delirium, weight loss, and depression is paramount to the patient. These symptoms can be devastating to the patient because they directly affect the day-to-day quality of life of the individual and his or her qualitative functional status. The medical and nursing teams have often been amenable to these approaches as alternatives when traditional medications and medicine have failed [1]. Cancer patients and ICU patients are living longer lives because of many of the therapies now available to them [2]. However, these survivors are now having to deal with the issues of living such as pain, fatigue, and depression. For many patients who survive an ICU hospitalization, it has been well documented that these patients are traumatized with the very real ICU memories of pain, loneliness, depression, anxiety, and fear [3–6]. Ultimately outcomes are worse for ICU patients who suffer additional trauma after ICU hospitalization because of these factors [7, 8]. Post-ICU psychosis has been recognized by the ICU caregivers as a known complication of the ICU stay, but too often, sedatives, anxiolytics, antidepressants, and antipsychotic drugs become the mainstay of treatment to avoid

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these complications. However, these drugs themselves can often exacerbate symptoms, particularly in the elderly, leading to a vicious cycle of medications and even additional medications to treat the side effects of many of these drugs.

A holistic approach to medicine has been the standard practice for many years, especially dating back to the 1970s in the USA [9]. The holistic approach advocates a "whole-body" approach to the practice of medicine and surgery. The patient is treated with special attention not only to the physical aspects of the disease but to the mental and spiritual aspects as well. In many ways, alternative and complimentary therapies are an extension of the holistic approach and an amplification of the methods used in the holistic approach. In Dossey's theory of integral nursing, the patient is seen as a whole physical, mental, social, spiritual, and emotional being. This theory of integral nursing forms a framework that can easily incorporate the principles and practice of complementary therapies (CM) [10].

Complementary and alternative therapies (CAT) are defined as nontraditional and nonconventional healthcare solutions as compared to traditional and conventional treatments for patients with illnesses [11]. The National Center for Complementary and Integrative Health (NCCIH) has defined CAT as healthcare approach outside of mainstream Western conventional medicine. They have categorized complementary health approaches (CHA) into three main areas [12]:

1. Natural Products
    - Plants
    - Vitamins
    - Probiotics
    - Dietary supplements
2. Body-Mind Interventions
    - Massage
    - Hypnotherapy
    - Relaxation techniques (breathing exercises, imaging, meditation, progressive muscle relaxing applications)
    - Movement therapies (the Feldenkrais method, the Alexander technique, Pilates)
    - Yoga
    - Chiropractic
    - Osteopathy
    - Acupuncture
    - Tai chi
    - Qigong
    - Healing touch (HT)
    - Reiki
    - Reflexology
3. Other Methods
    - Ayurveda
    - Traditional Chinese medicine

- Homeopathy
- Neuropathy

Complementary medicine (CM) and complementary therapies (CT) usually supplement and augment the traditional treatment practices rather than replace them [11, 13]. Alternative therapies (biologically based, homeopathic) are those which are used instead of conventional and traditional treatment practices [1]. This chapter will be primarily devoted to the use of complementary therapies rather than the use of alternative therapies. The main goal of many of the traditional treatments used for patients is primarily the control of the disease, cure, or alleviation of symptoms such as pain and other chronic symptoms. CAT is designed to alleviate stress and induce a level of comfort and relaxation and a sense of well-being to ultimately improve the patient's overall quality of life.

Familiarity with the practice of CAT has led to increased usage and demand by practitioners who not only have some experience with these therapies but are also open to the concept of using supplemental methods to treat a patient's disease. The development of CAT has been driven by consumer demand [14]. Many patients have some personal experience with these modalities and expect to continue these treatments during an illness or disease at home, during acute hospitalizations, or during terminal and palliative care. In addition to helping to treat the disease or the illness, these therapies can be used to alleviate the stress associated with office visits, hospitalizations, surgeries, medications, and family-related issues. Requests for CAT have been found to occur most frequently for the acutely ill or critically ill patient at three junctures during their hospitalization: on admission to the hospital, continuing specific home therapies (directed at control of pain, nausea, and sleep difficulties), and when end-of-life care has been initiated [14, 15]. Their use in the ICU has been affected by transmission of information and belief in their effectiveness by ICU nurses [16].

Prevalence

The practice of using complementary therapies in the care of patients has gained in popularity in the USA over time [17, 18]. It is estimated that between 30% and 40% of American adult patients and 12% of children use one or more complementary or alternative therapies at an annual expenditure of 13.7 billion [11, 13, 18]. The use of complementary therapies is reported to be significantly higher in cancer patients with rates of up to 91% [19].

Nurses and CAT

The American Academy of Nurse (AACN) has prioritized complementary therapies as an important adjunct to traditional therapies for the critically ill [20]. Although CAT have been used for many years by nurses in clinical practice, there is relatively

little information concerning nurses' perspectives about the use of complementary medicine in the ICU, and only smaller studies showed a positive benefit of CAT [1, 21, 22]. A survey was performed in 2005 to determine the perspective of more than 700 critical care nurses toward the use of CAT from 50 US states and from 5 geographical areas. This study showed that relatively uniform practices were seen throughout the various geographic regions of the USA and that most ICU nurses were receptive to the idea of introducing the concepts of complementary medicine for their ICU patients [23]. In this study, the therapies seen as most popular and legitimate in their efficacy included counseling, prayer, music and pet therapies, exercise, diet, meditation, relaxation techniques, and behavioral medicine [24].

CAT can be practiced and implemented into a patient's care plan by a multidisciplinary team of physicians, nurses, social workers, physical and occupational therapists, family members, friends, and patient caregivers, among others. The approach to nursing and their beliefs in the use of complementary medicine has been a focus of many studies [22, 23, 25]. Nurses who use these complementary therapies in their own lives are more receptive to using these same therapies for their patients in the critical care venue [26]. Most popular among these techniques are diet, exercise, relaxation techniques, and prayer [24]. In a small survey of critical care nurses at two local hospitals, diet, exercise, prayer, relaxation, and counseling were viewed as the most "legitimate" of all the most well-known CAT available [22]. In a survey of London critical care nurses, similar results were seen, especially in the use of CAT in the neonatal ICU setting where neonatal massage was often used [21].

In 2015, a summary of 15 studies examining nurses' perceptions and attitudes toward CM showed that the majority of nurses (66%) had a positive attitude toward CM but up to 68% believed they did not have sufficient knowledge or training to adequately provide information to patients and families and make it a daily part of their nursing practice [27]. Similar results have been seen in studies done in Asian countries [28, 29].

CAT in the ICU

In the practice of critical care in the ICU, the demand and need for alternative and complementary therapies has been increasing. Critically ill patients and their families endure a very high level of stress and angst in dealing with their disease; their ICU and hospital stay; the fear of future hospitalizations; the fear of dependence; and, ultimately, the fear of death [25]. The ICU environment is often frightening and stressful to patients, families, and friends not only because of their current illness/disease they are dealing with and the uncertainty of the ICU stay and their future but also the fear and stress induced by the physical and emotional environment of the ICU itself [16]. Multiple loud alarms, high-tech equipment, busy personnel, pain, disturbance of the normal sleep-wake cycle, nausea, invasive procedures, and mechanical ventilation create an additional layer of stress and anxiety to patients and families who are emotionally vulnerable [30]. There have been several studies that have validated the use of complementary therapies and the positive benefit in the critically ill population [1, 26, 31].

Table 17.1 Complementary therapies

Mind-body interventions
Diet
Exercise
Behavioral medicine
Assisted-animal intervention (AAIN) (pet therapy)
Art therapy
Music therapy
Meditation
Guided imagery meditation
Prayer and spiritual guidance
Counseling and psychotherapy
Hypotherapy
Relaxation techniques
Biofeedback
Energy therapies (therapeutic touch and electromagnetic/magnetic applications)

The perception and attitudes of healthcare professionals may likely influence the practice of CAT in ICUs. The perception of legitimacy and efficacy of additional therapies play a role in how receptive healthcare professionals will be likely to use them in with their patients. Those most comfortable with CAT have had personal experience for themselves or have used them previously in their clinical practice [22, 26]. Those professionals who have additional training in CAT are also more likely to use them in their practice as well. In a 2005 nursing survey by Tracy and Lindquist, they found that most ICU nurses were very receptive to the use of CAT but were limited by a lack of knowledge and training in their use [23, 24]. Similarly in 2017 in a study of oncology nurses, most nurses thought that CAT could improve the quality of life of cancer patients but felt that they lacked knowledge and training in applying these principles and integrating them in their nursing practice [32]. In this survey, 35% of nurses had practiced CM for personal use, but only 25% had some general knowledge of the applicability in patient care, but up to 66% believed that CM should be incorporated into their nursing scope of practice [32].

Most CM used in the ICU have centered primarily on mind-body interventions including massage, music therapy, aromatherapy, and reflexology. Many of these and others are listed in Table 17.1.

Evidence-Based Support for CM

Previous criticisms of CM were based on the fact that there were few, if any, strong evidence-based studies to support the use of CM in practice. However, during the past decade, there have been a number of randomized controlled trials (RCTs) that have looked at various methods used in CM. Most studies are relatively small in numbers of patients but have shown statistical improvement with various complementary therapies. Studies on *massage therapy* have shown effectiveness in decreasing anxiety,

tension, and postoperative pain, inducing relaxation, and relieving some of the physical and psychological ICU-related problems associated with critical illness and demonstrated an effect on stabilizing vital signs [33–36]. RCTs on *aromatherapy* have demonstrated a decrease in anxiety and improvement in the quality of sleep for ICU patients. This has been shown in general ICU patients, coronary ICU patients with ischemic heart disease, and those patients undergoing coronary invasive procedures [33, 37–40]. *Music therapy* has shown to decrease anxiety and pain, provide relaxation, and improve comfort in ICU patients as reported in several ICU studies, some including mechanically ventilated patients [41–47]. *Touch therapies* have shown significant benefit, especially for calming premature infants in the neonatal ICU as well as in stabilizing vital signs [48–51]. In adult patients, touch therapies decreased anxiety and hospital stay duration in patients who had undergone coronary artery bypass surgery [52]. *Reflexology* techniques in critically ill patients improved relaxation as well as blood pressure, heart rate, and oxygen saturation [21, 53]. In addition, foot reflexology was found to be effective in shortening the duration of mechanical ventilation [54]. *Acupuncture/acupressure therapy* has been shown to have many positive effects in ICU patients, including decreased levels of anxiety, decreased heart rates and respiratory rates, and a decrease in the sensation of dyspnea, particularly in mechanically ventilated patients [55, 56]. Acupuncture/acupressure also helped with improving the quality of sleep in the ICU with increased duration of sleep and decreased frequency of waking-up episodes [57, 58]. *Mediated prayer* has been reported to have a positive effect in decreasing the intensity and severity of disease symptoms [59, 60]. There are no large RCTs of *animal-assisted intervention* (AAI), but there are several pilot studies and posttreatment crossover studies that showed positive results when patients are allowed the use of this intervention in the ICU. These studies suggest that AAI decrease anxiety, depression, and pain and promote engagement and motivation, particularly in the rehabilitation phase of their illness [61–65].

In heart failure patients, both yoga and tai chi have been recognized and shown to be effective in reducing cardiovascular risk factors and levels of hypertension and improving cardiovascular symptoms (increased strength endurance and flexibility and decreased anxiety), mood, exercise self-efficacy, and cardiovascular quality of life [66–68].

Although many studies have shown immediate short-term benefits to ICU patients and others, there is relatively little information concerning the long-term impact of CAT on patient outcomes.

Educational Programs

Educational programs that increase the knowledge of these therapies will ensure increased familiarity with them and increased usage as practitioners become more accustomed to supplementing traditional treatments with alternative choice [25]. It is important that healthcare professionals explore the science of many of these alter-

natives so that our patients are well informed prior to making decisions about using them in their care plan [23].

As demonstrated in several studies, there appears to be a discordance between the positive attitudes of many nurses toward CM and the lack of knowledge and training and application into clinical practice. This discordance underscores the importance of improving CM education at the undergraduate and postgraduate levels of nursing training [69–71].

Coupled with improved nursing and physician CM training, there need to be established guidelines from professional healthcare societies, commonly accepted standards of care and practice parameters, as well as state regulations and legislature. In order to be more readily accepted and, most importantly, applied into daily clinical practice, we must rely on a combination of education and propagation of guidelines and standards at the state, national, and international level [32]. Education with both CAM didactic and experiential activities has been inconsistent. It has been reported that between 64% and 84% of US medical schools offer some exposure to CAT in the form of didactics or simulation training. However, these numbers have not been consistent [72–74].

Centers for Integrative Medicine have been increasingly prevalent in the USA with over 27 US states having at least 1 to several centers of excellence [75]. Many of these centers, in addition, have consultation services within the acute care hospital for management of pain, delirium, sleep disorders, etc. Palliative care services are now widely accepted at all community and academic centers. Palliative care services rely predominantly on methods to alleviate pain, duress, and stress and are often involved in end-of-life and hospice planning.

Consequences

It is important to evaluate CM practices similar to all other practices in medicine and surgery in terms of the unknown or harmful effects versus the potential beneficial effects. Similar to all therapies including medications, radiographic tests, and surgeries, alternative treatments must be evaluated and examined for potential complications, unsafe use, overuse, drug interactions with prescribed mediations as well as other nonprescribed drugs, side effects, and negative outcomes [76–78]. In addition, evaluation of efficacy, cost-effectiveness, workload, and feasibility also needs to be seriously considered in all therapies regardless of how “organic” or “holistic” they may appear to be. Obviously, cost is always a consideration in a healthcare system that is already burdened by costly treatments to the patients and their families. Patients may use and request CAT regardless despite there being little scientific evidence of their efficacy. This must be balanced to some degree with the lack of strong evidence-based literature and the possible inherent biases of the healthcare team. Ethical issues arising concerning economic costs must also be considered.

Regardless of the CM therapies provided to patients, adherence to safety and infection control principles must be employed [14]. However, there are no standardized national or state regulations regarding the usage nor the credentialing of healthcare providers in their use [79]. There is relatively little information concerning the long-term impact of CAT on patient outcomes.

Conclusions

CM and CT have long been a part of practice in the history of medicine, but it is not until recently that they have gained in popularity among patients and caregivers. Although now considered slightly more mainstream, the concerns about lack of familiarity and proof of their scientific and personal value still abound. Healthcare professionals seem inclined to use them but are stymied by the lack of information and training available to them concerning the effects of these therapies. Complementary and alternative therapies need to be incorporated into conventional and traditional acute care in a responsible, safe, and ethical manner [80, 81]. Concerted, multidisciplinary approach to optimize patients, particularly during times of stress, such as during an ICU hospital stay, needs to incorporate these interventions. They carry intrinsic value since they have been shown to decrease suffering (pain, mood, and loneliness), increase patient engagement and motivation, and decrease the physiologic burden of disease and illness by stabilizing heart rate and blood pressure and decreasing the need for sedatives and other drugs. These interventions can motivate the patient and positively reinforce their participation in their recovery [61].

CAT has potential to become a major tool for health promotion and health prevention. Thus, medical and nursing professional societies need to be proactive in creating standards of care and practice guidelines so that healthcare professionals, patients, and their families are informed about the different options in terms of efficacy, safety, and short- and long-term effects [82].

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Chapter 18
Establishing a Research Program in the ICU

Laurence W. Busse, Alex Hall, and Jonathan Sevransky

Introduction

Intensive care units (ICUs) are robustly staffed with clinical personnel and replete with high-cost, life-sustaining technology. Much of this infrastructure has evolved from clinical experience and training, leading to heterogeneous care that varies both between sites and within sites [1, 2]. Clinical research, which is the testing of a hypothesis, permitting conclusions to be drawn, and thereby developing or contributing to knowledge, is the mechanism by which these disparate practices are compared, ultimately leading to emergence of a standard of care [3]. Additionally, the immense financial cost and burden of critical illness highlights the necessity for clinical research to better determine which costly treatments are effective and, conversely, which may not be [4]. The speed of progression of illness and recovery and the immediacy of many of the interventions and therapies deployed in critical care provide tremendous insight to the clinician-scientist into the disease state [5]. Accordingly, there is no better setting in which to devise and develop new strategies for the fight against critical illness [6].

While there are many reasons to expand the knowledge base in critical care, some challenges to performing and completing research in the critically ill need be addressed. First, clinical research can be expensive and cumbersome, making it difficult to cover the resources required [7]. Moreover, trial execution is complex and challenging, resulting in significant difficulties in bringing novel ideas to fruition [8]. In addition, clinician-scientists are burdened by competing demands on their

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time, resulting in impediments in completing and supervising trials [8]. Finally, critically ill patients are frequently unable to provide informed consent, and the investigator often must rely on surrogate consent under time-limited circumstances. In combination, these challenges result in substantial barriers to conduct successful critical care research [9, 10, 11].

This chapter will provide guidance on establishing a research program and methods to mitigate common pitfalls and obstacles encountered in a variety of settings. The primary objective is to provide insight on building an infrastructure that will attract and execute high-quality trials, produce results, act ethically, and become sustainable.

Types of Research Programs

The character of the clinical research program may be dictated by the institution (i.e., academic center, community hospital) and the type of research being conducted (i.e., randomized controlled trials [RCTs], case reviews, etc.). Examples of research performed in the ICU include performance improvement projects (designed to improve the care of patients within that ICU), investigator-initiated clinical trials (which test a hypothesis within a limited patient population), and multicenter trials (which enroll patients with a specific illness in order to test interventions to achieve generalizability). Multicenter trials are commonly sponsored by industry, governmental funding agencies, foundations, or institutions. The setting of the hospital (i.e., academic, community, governmental, or military) will define the patient population as well as the potential resources available to staff a study.

Academic institutions usually have a robust network of resources to assist the clinician-scientist. One primary challenge in an academic setting is learning to navigate the complex network of administrative red tape that comes with initiating a study. In addition, the complex nature of critically ill patients at tertiary or quaternary academic centers can result in difficulty recruiting the proposed patient population. Conversely, community hospitals are very limited in the administrative and personnel resources available to the clinician-scientist; however, the nimble and flexible structure frequently make the initiation phase quicker and straightforward. In addition, community hospitals often have the ideal patient populations being studied and allow the clinician-scientist to achieve immediate success in establishing a research infrastructure.

Within the applicable setting, the clinician-scientist must determine the type of research to pursue. RCTs are the most academically rigorous endeavor and seek to establish efficacy of a therapy. However, RCTs require the most effort in terms of resources, time, and regulatory and safety oversight. Case control and cohort studies may not establish causality, but are hypothesis-generating and easier to conduct from a regulatory perspective. Retrospective chart reviews and epidemiological studies require relatively little regulatory oversight but can shed light on population-based health trends and the effects of newly adopted care practices. External funding

is typically weighted on the potential impact of the proposed study. Participation as a site for an industry-sponsored RCT can result in substantial funding for investigators and in some cases subsidize future research endeavors. Lastly, any research may be considered in conjunction with graduate medical education and may provide clinician-scientist with additional manpower and resources in exchange for valuable experience.

Research in the Community Setting

The assimilation of research into the largely community-based US healthcare system provides ample opportunity for the nonacademic clinician-scientist to continue to participate in research activities. Nonetheless, a 2012 discussion article by the Institute of Medicine highlighted several obstacles to conducting research in the community setting, including lack of patient demand due to the pluralistic and fragmented nature of the healthcare system, financial issues (e.g., insurance and reimbursement limitations), clinician hesitation, and poor communication between the clinician-scientist and the other clinicians [7]. Hospital-level hurdles are granular and frequently result of hospital administrators focused on the potential financial strain of conducting research [7]. Therefore, establishing a research program in the community setting requires attention to common themes:

- Inclusion of all stakeholders in discussions regarding the need/desire to perform research
- Recognition that clinical research can coexist with high-quality care
- Acknowledgment of economic incentives for performing research
- Implementation of a cohesive research strategy and infrastructure

A successful community-based research program will merge clinical research into the framework of patient care, align financial and nonfinancial incentives for study participation, harmonize and simplify procedures for study execution, and build demand for participation from patients and providers.

Many intensivists gain exposure to clinical research during fellowship training and then continue their efforts at academic institutions with established research programs [12]. However, a large proportion of intensivists establish employment in the community setting [13]. Research in a community setting is uncommon, as many clinicians do not actively engage or refer patients for trial participation [14]. Despite these limitations, community-based intensive care may provide the ideal setting for clinical research; common patient populations and disease conditions are abundant, and thus impactful research developments would potentially be far-reaching. The abundance of common disease states present in community-based ICUs may help overcome significant recruitment and enrollment hurdles [15]. Finally, recognizing that the majority of patient care in the USA is delivered in the community setting, ensuring the inclusion of community sites will improve the generalizability and external validity of the research.

Collaborative Research

The diversity of available trials, limited resources for building and training a team, and limited time available to spend with prospective enrollees represent real-world logistical and operational obstacles for the clinician-scientist seeking to conduct clinical trials in a community setting [16]. One potential way to overcome these issues is to join a research consortium or to engage in multicenter trials. A research consortium oversees collaborative research among multiple sites and offers a number of advantages, including strategic planning, study development, negotiation of contracts, data collection, and funding [17]. The Canadian Critical Care Trials Group (CCCTG) was an early consortium focusing on critical care research and has successfully supported investigator-initiated research since its inception in 1989 [18]. CCCTG members are self-funded and through participation in the consortium can facilitate recruitment and enrollment of a large number of patients, which may counteract small expected treatment effects and the inherent heterogeneity of critical care patients (www.ccctg.ca) [18]. Other successful consortia include the Australian and New Zealand Intensive Care Society (ANZICS; www.anzics.com.au), the European Society of Intensive Care Medicine (ESICM) Trials Group (www.esicm.org/research/trials/trials-group-2), Brazilian Research in Intensive Care Network (BRICNet; www.bricnet.org), and Discovery, the Critical Care Research Network of the Society of Critical Care Medicine (SCCM, www.sccm.org/Research/Research/Discovery-Research-Network).

Multicenter trials offer economies of scale with regard to trial execution and logistical support, since they are able to centralize study activities, and thus eliminate duplication of efforts and associated costs that may occur at each individual site [19]. For example, multicenter trials in oncology are able to utilize a central IRB (cIRB) provided by the National Cancer Institute and the Office of Human Research Protections [20]. Multicenter trials can be investigator-initiated or commercially backed and usually involve a number of organizing bodies, such as a steering committee, data safety monitoring board (DSMB), data coordinating center, clinical coordinating center, an investigational drug service, and a central laboratory [21]. The makeup and overlap of these groups varies between trials but individually provide unique skillsets to ensure the successful execution and completion of a trial. As a participating site, the clinician-scientist who participates in a multicenter trial will have to undergo thorough protocol training and regulatory compliance and ensure appropriate data collection and quality efforts. Study activities are monitored rigorously, and predetermined expectations for recruitment and enrollment will be set by the sponsoring organization.

Identifying Opportunities for Research

The researcher needs to consider multiple issues when starting a research program, including available resources, time, commitments, and the ratio of desired versus available patient population. Single-center quality improvement efforts may have

the lowest barrier to entry but still require substantial time and resources. Moreover, these projects are not commonly funded through external agencies. Conversely, larger clinical trials that are funded have additional personnel and operational burden. A clinical trial must not only fulfill the scholarly objectives of the clinician-scientist but also be financially viable and self-sustaining.

Funding for such clinical trials falls into four main categories: federally funded studies (i.e., NIH, DoD, etc.) industry-funded studies (i.e., pharmaceutical companies or device manufacturers), foundation- and nonprofit-funded studies, and investigator-funded studies (i.e., no external funding). Each funding source comes with benefits and drawbacks to the investigator. Clinical research funded by industry entities, for example, can offer newly created clinical research programs adequate revenue for their efforts and even may allow for accumulation of funds for future investigator-initiated efforts. However, these studies are typically more restrictive and involve research questions that are predetermined and in line with the commercial entity's interests. Although arrangements between an investigator and the company vary widely, the protocols are usually tightly controlled and regulated. Alternatively, a clinician-scientist can seek funding through government or nonprofit grants. Though more difficult, this pathway may be more in line with the scholarly intent of the clinician-scientist.

The landscape of funding sources has evolved over the last two decades, with government funding for the biomedical sciences remaining flat or decreasing from 2004 through 2015, before experiencing an increase from 2016 to 2018 [22]. In contrast, private sources of funding have increased significantly from 46% in1994 to 58% in 2012 [23]. Moreover, commercially funded early-stage research has declined in favor of medical devices, bioengineered drugs, and later-stage clinical trials [23]. Self-funded research is difficult to quantify, but remains the backbone of clinical research, likely feeding both commercially and government-funded efforts. For example, preliminary work for the intravenous angiotensin II for the treatment of high-output shock (ATHOS) trial was funded from residual monies from previous investigator efforts and subsequently resulted in the industry-funded Angiotensin II for the Treatment of Vasodilatory Shock (ATHOS-3) trial [24, 25]. The Sri Lankan Clinical Trials Registry reported on 210 registered trials successfully conducted over a 10-year period, a large portion of which (41.9%) were self-funded by the investigators [26]. However, with the increasing cost and complexity of research, a fledgling research program will likely not get far without external funding [27].

There is no shortage of commercially sponsored critical care studies. In 2016, biopharmaceutical companies invested about $90 billion in research and development in the USA, with thousands of new therapeutics currently in development [28]. While industry studies are financially more lucrative, there are fewer opportunities for publication and may not be as intellectually stimulating as the alternatives. Nonetheless, if the clinical question posed by an industry-backed study resonates with the clinician-scientist and the other parameters of the study coincide with the culture and practice patterns of the research program of the ICU, industry-backed studies can be quite fulfilling. Opportunities for participation may arise via word of mouth, as a result of networking with other clinician-scientists and mentors in the field. Additionally, pharmaceutical companies may seek out clinician-scientist with

a desired expertise. For an example, an expert in the field of non-cystic fibrosis bronchiectasis may be contacted for participation in an industry-funded RCT evaluating a new therapeutic for this disease due to the limited population and treatment facilities. Finally, a new clinician-scientist may inquire about participation from a sponsor or other trial investigators to determine if additional investigators and sites are sought. All sponsored studies of human volunteers performed in the USA are required to be registered in the ClinicalTrials.gov database maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH) [29]. ClinicalTrials.gov is a registry of both federally and privately funded clinical trials conducted under investigational new drug applications to the US Food and Drug Administration. Sponsorship information and the name and contact information of the principal investigator are included in this registry.

The task of identifying the right opportunity starts with a reflection of the traits of the ICU, such as the demographics of the patient population, common diseases, and the expertise of the staff. For example, a cardiovascular ICU is unlikely to perform well in a sepsis study, and a general medical-surgical ICU is unlikely to perform well in a complex cardiothoracic study. In addition, ICUs in which the clinicians do not follow commonly accepted treatment paradigms may find it difficult to conduct a study which is dependent on those paradigms (e.g., sepsis studies which rely on standards of care outlined in the Surviving Sepsis Guidelines) [30]. Moreover, ICUs in which clinicians lack equipoise regarding certain experimental procedures or clinical questions will not be able to study these procedures or clinical questions objectively. Table 18.1 highlights some important factors to consider when identifying study opportunities. Appropriate research opportunities should be matched with patient, ICU, and hospital demographics (e.g., incidence of disease in question, required pharmacy and coordinator time, ICU type), so that screening and enrollment, study execution, and regulatory restrictions will not conflict with local limitations.

The Business Plan for Research

As an initial exercise, the investigator should create a business plan, which may assist in elucidating the projected resources as well as the needs of the new research program [21]. This business plan should identify contemplated studies, as well as projected study-associated expenses, revenues, and deficits. Study expenses and revenues are highly variable and dependent on individual study-specific logistics. Therefore, the budget will need to be estimated based on initiation costs, projected enrollment, and execution requirements.

Unfortunately, depending on the funding source, per-patient revenue does not always cover the actual costs of conducting a trial [16]. After start-up funding (i.e., IRB, training, etc.), all other expenses are usually cost-reimbursable, meaning that study teams only receive further funding after a patient has been enrolled and certain procedures performed. A 2003 study found that the average per-patient cost for

Table 18.1 Clinical characteristics of an ICU

Characteristic	Variable	Study implications
Patient demographics		
Patient age	Young versus old	Screening and enrollment
Case mix	Incidence of disease in question	Screening and enrollment
Common comorbidities	Inclusion and exclusion criteria	Screening and enrollment
Socioeconomic status	Medical literacy, family support	Consent and post-discharge compliance and follow-up
ICU demographics		
Number of beds	Large versus small	Screening and enrollment
Coverage model	Open versus closed, full-time intensivist versus intensivist consultancy	Screening, study execution
ICU type	Medical-surgical, surgical, cardiac, cardiovascular, trauma, neuro	Screening and enrollment
Protocols followed	Standardized practice habits, adherence to established and widely adopted protocols	Study execution, data integrity, generalizability
Hospital demographics		
Coordinator bandwidth	Full versus part time	Screening and enrollment, study execution
Pharmacy capabilities	Capabilities and hours of research pharmacist	Study execution
Weekend coverage	Capabilities and hours of research pharmacist, coordinator, and intensivist	Screening and enrollment, study execution
Regulatory culture	Liberal versus conservative	Study selection, consent, reporting requirements

participation in a clinical trial was estimated at $6000, whereas per-patient reimbursement was only $2000 [31]. Per-patient reimbursements for industry-sponsored studies are generally more generous than for government-sponsored studies [21]. The clinician-scientist needs to identify and pursue studies where projected per-patient revenues supercede per-patient costs, with margins to be applied to fixed costs and excess monies going to fund future efforts. Broadly, budgeted study costs should include per-patient efforts of study personnel (e.g., obtaining medical histories, performing physical exams, coordinating study procedures), per-patient procedures which are performed in the context of research (e.g., blood draws, radiological or endoscopic evaluations), and consumables (e.g., study and placebo drugs) [21].

Fixed costs include compensation for research team personnel, which are incurred by the entity's research department or institution. Therefore, performance and gross per-patient reimbursement will need to exceed the costs of the personnel to a loss. As an example, an anticipated study may be projected to pay $7000 per patient, with direct patient-specific costs (e.g., medications, laboratory testing,

Research RN Coordinator - Business Plan

Assumptions:

- Research RN Coordinator Salary: $105,000, including fringe benefits
- Start-up costs should be paid by the sponsor and average $5,000 to $20,000 for individual studies (i.e., IRB fees) and are not shown
- Reimbursement numbers are estimates based on industry ranges
- Patient and enrollment rates should be based on census numbers
- Conservative enrollment rate is used (10% of eligible patients)
- Period covers 24 months with 4 months of enrolling in year 1 and 12 months of enrolling in year 2
- Patient care (non-personnel), research specific tests (i.e., labs), and PI support are not shown; however, variance can cover these costs
- Budget covers one full time RN coordinator covering 3 diffierent clinical trials
- Timeline to hire:
  - Month 0 – 2: Screen candidates
  - Month 2 – 4: Hire, credential coordinator
  - Month 0 – 4: Feasibility, site visits
  - Month 1 – 6: Regulatory Submissions and contracting
  - Month 0 – 10: SIV, Receive start-up funds (1-3 studies, @ $5,000-20,000)
  - Month 2-12: First Enrollees @ $5,000-10,000

Expected shortfall in the first 12 months may be mitigated through:

- Shared coordinator from another site or department
- Temporary cost-share with department support to hire candidate prior to funding notices

Fig. 18.1 Example of a new research program business plan

interventions) estimated to be 50% of this total cost, and the remaining revenue needed to cover study team salaries. The number of patients expected to be enrolled will dictate whether fixed costs can be adequately covered and should be based on the current and projected ICU census, the local prevalence of the disease state being studied, and site-specific accrual rates [32]. Figure 18.1 is an example of a budget plan for a new research program.

The Research Team

An ICU research program requires a committed team to be successful. Clinical research is time-consuming, and the start-up phase is often the most significant hurdle for a new program [33]. It is important to achieve buy-in from all of the stakeholders whose professional activities intersect with patient care [33]. Clinical research in an ICU is usually multiprofessional and requires the participation of medical and nursing leadership, respiratory therapists, nurses, pharmacists, advanced practice providers (APP), and intensivists. The research program will need to be promoted throughout these various departments, while simultaneously, care must be taken to ensure that research efforts will not be disruptive in established workflows [34]. As such, continuous marketing is needed to highlight the positive attributes of

the research program, including opportunities for publication, acquisition of knowledge, advancement of cutting-edge care models, and the prestige for having participated [35, 36]. The clinician-scientist needs to be adept at interpersonal skills, as different goals will be a motivation for different stakeholders [37].

Once consensus is achieved that a research program should be initiated at a particular site, work must begin to assemble a dedicated research team, consisting minimally of a clinician-scientist and a research coordinator. Challenges at this stage usually involve scarcity of resources, including time and money. A recent survey of intensivist workload noted that the median annual workload was 169 days per year [38]. Extrapolating the workload to a standard 40-hour work week, surveyed intensivists work the equivalent of 50.7 weeks per year. Moreover, the vast majority of intensivists were noted to engage in nonclinical endeavors, which for all intents and purposes are uncompensated [39]. The time commitment for clinical research should also be considered in the broader context of efforts within the US healthcare system to determine safe physician-to-patient ratios, avoid physician burnout, and minimize expenditures [39]. Intensivist staffing is often guided by this third principle via calculations of return on investment (ROI) [40]. However, this ROI is calculated at the health system level, not at the level of the individual intensivist, whose job satisfaction may be guided by nonfinancial factors [41]. An intensivist, for example, may wish to reduce compensated clinical time requirements in order to perform research efforts. Aside from the financial implications, alteration of an intensivist's work schedule is often difficult in an ICU setting where shift-work schedules are determined well in advance. Therefore, early efforts toward the establishment of research program may occur outside of acquired clinical responsibilities, on an intensivist's own time, with both financial- and time-based constraints.

The Investigator

A new ICU-based research program will require a motivated clinician-scientist, typically a practicing intensivist, but can also be a nurse or pharmacist investigator. For each of these types of investigators, it is important to allocate the adequate time needed for the effort, either by reducing the investigator clinical time or, alternatively, conducting all research-related efforts on personal time. In order to reduce clinical time, the investigator may seek to subsidize a portion of his or her salary through funded study efforts. Funding may come through successful grant or scholarship applications, including those from government, industry, and/or local sources [42–44]. Local (e.g., departmental or hospital) funds may also be available, depending on the type of entity within which the research program is being established [16]. The initial responsibilities of the investigator are to build and manage the research team, identify study opportunities, and generate consensus among the other stakeholders in the ICU. The principal investigator (PI) for a study is typically a physician but can alternatively be a nurse or pharmacist. The PI oversees all

aspects of a given study, including execution, education of the clinical staff, patient recruitment, and regulatory activities (i.e., subject safety and ethical conduct of the study, data quality and accuracy, and follow-up compliance). The PI may need to interact with regulatory bodies (e.g., liaisoning with representatives from the US Food and Drug Administration during study design to achieve Investigational New Drug approval) and ultimately decides upon deliverables from research (i.e., publication).

The Research Coordinator

An ICU research program will not succeed without an astute clinical research coordinator (CRC). Given the disease complexity of many ICU studies, it is recommended that the CRC be a critical care nurse with clinical and research experience [45, 46]. Many critical care studies will require bedside nursing involvement (i.e., medication administration, physical examination); therefore, a CRC with experience in critical care setting will be more likely to accomplish study-related activities in collaboration with the bedside nurse. Primary responsibilities of the CRC can vary but typically involve interacting with the study sponsor, establishing budget and executing contracts, completing regulatory requirements, screening and recruiting patients, study execution, data gathering and synthesis, and submission of results for publication [47]. Ultimately, substantial flexibility is necessary during the initial establishment of a research program, as a large proportion of responsibilities are shared between the CRC and PI. Notably, there are three main challenges with hiring of the right CRC, including the identification of the ideal candidate, tailoring the job to suit the career objectives of the candidate, and allocating funds to cover salary costs. Identifying the right CRC is rarely as simple as matching the list of required skills to those of the potential candidate. Because the CRC plays such an integral role in a new research program, considering a non-experienced candidate with the goal of on-the-job learning is suboptimal. Figure 18.2 is an example of a job description for a CRC with requirements that would fulfill the needs of a newer research program. Finding the ideal CRC requires both skill and luck. Word-of-mouth recommendations are often one successful strategy when initiating a candidate search. Strategic networking with other research program personnel may provide increased opportunities in locating the right person. Medical societies often allow a mechanism for employment solicitation, and regional or national conferences may assist in matching job-seekers to potential employers or provide a means for the clinician-scientists to share ideas, including coordinator opportunities. The Association of Clinical Research Professionals (ACRP) provides a career portal for research coordinators (https://acrpnet.org/career-center/) and may be an additional resource.

One important factor that leads to the overall program's success is identifying and ensuring a paradigm that leads to the CRC's job satisfaction. A 2004 survey of 49 ICU-based research coordinators inquired as to the 'best' and 'worst' aspects of

Clinical Research Nurse II

Job Description
POSITION OVERVIEW:
The Section of Pulmonary, Allergy, Sleep and Critical Care Medicine is increasing its participation in inpatient and outpatient pulmonary and critical care studies and is in need of a dedicated nurse/coordinator to assist in these efforts. This clinical research nurse position would primarily function in the coordination and management of multiple studies under the direction of the Principal Investigator.

Candidates for this position would be expected to coordinate, implement and evaluate the Section's clinical research trials, studies and projects. Additionally, the candidate would be expected to contribute to the development of research protocols, recruit and screen potential study participants, and develop and conduct patient and family education. This person will also perform patient evaluations, administer medications and research instruments and provide nursing support in the performance of specialized diagnostic, therapeutic and surgical procedures.

Regulatory and administrative responsibilities include management of research project databases, development of study related documents, and completion of source documents/case report forms. The candidate will ensure compliance with research protocols and prepare regulatory submissions. Interaction with the Institutional Review Board, Research Administration Services, and Clinical Research Offices, among other regulatory and administrative offices, will be frequent.

As operations grow, this candidate may provide direction and may supervise other Research Nurses or other support members. Employees in this classification may be required to work with, take specific precautions against and/or be immunized against potentially hazardous agents.

MINIMUM QUALIFICATIONS:
- Licensed as a Registered Nurse in the state of [program location]
- Three years of related nursing experience
- Critical care nursing experience preferred
- Clinical research experience preferred

This position involves working with human blood, body fluids, tissues, or other potentially infectious materials.

Fig. 18.2 Example of job posting for a critical care research coordinator

the role and identified four thematic clusters in both categories: (1) "How the job was structured," (2) "The worth of the job," (3) "What the work involves," and (4) "Who I work with" [48]. While there was significant variation among respondents, autonomy, respect, and intellectual stimulation were the most valued parts of the job. In contrast, isolation, under-recognition, high workload, and insufficient compensation were the worst aspects of the position. A recent 2018 survey explored the question of why research coordinators entered the field and found that almost a third (31%) of the 121 nurse coordinators who responded stated that an interest in research itself was the primary attraction of a research post, while an even larger proportion of participants (37%) wanted a change from their current post. Finally, a third of respondents highlighted advancement or better fit with family obligations

[49]. The clinician-scientist will need to emphasize the positive aspects to the CRC candidate on an individual basis.

The CRC's salary is a new fixed cost and is usually the most challenging aspect when starting a research program. Solving this dilemma often requires creativity. During a program's infancy, when there may be a small number of projects or studies being pursued, sharing a CRC with another department may be optimal [8]. For example, a program that lacks CRC infrastructure may elicit other programs that have already an established research presence to determine if arrangements can be made to cost-share for a CRC who may have available time. Interdepartmental cost-sharing and payment must be negotiated and is usually done based on projected study time requirements. Ideally, external funding sources (grants, industry-sponsored studies) will ultimately facilitate the hiring of a CRC within the new program. Appropriate payment for this important role, including compensation for weekend and night coverage, remains an important driver for success [50].

Other Team Members

There are many iterations of what makes up the optimal research team, and each program will have its own needs based on the means available and the underlying culture and structure of the program. For example, a community-based hospital that is also affiliated with a major academic institution will typically offer a substantial research administration infrastructure (i.e., budget and contract negotiation, sponsored programs office, and technology transfer office). However, many nonacademic community hospitals may lack this robust infrastructure. Invariably, the infrastructure of any research program may include or intersect with several entities, including study steering committees, data safety monitoring boards (DSMB), the study sponsor, the IRB, and other necessary trial services, such as a data coordinating center, a clinical research organization, and central and/or local laboratories [21]. Other important members of the research team include a research pharmacist, project manager, nurse unit directors, and clinical nurse specialists, who can facilitate ICU and hospital buy-in and training. Depending on the design of the study, other allied health providers may play critical roles. For example, a study with an extubation outcome is more likely to involve protocols and additional study training for respiratory therapists to facilitate appropriate and timely extubation of patients. For drug trials, the pharmacist plays a central role including preparing and delivering study drugs, maintaining study medication administration logs, interacting with centralized pharmacies, and recording an accurate study drug inventory [51]. In addition, pharmacists help to ensure the safety of human subjects and must be familiar with regulatory, ethical, and legal requirements of the study [52]. Table 18.2 outlines potential members of a research team with associated responsibilities.

Table 18.2 Cost analysis for three concurrent studies *(industry funded, participating site)*

Study	Analysis	Yr 1 *(4* months *of enrollment)*	Yr 1 *(12 months of enrollment)*
Sepsis study 1	**Monthly enrollment estimates** *(10% of eligible)*	**1.5**	**1.5**
	Annual septic shock population across ICU(s)	365	365
	Monthly septic shock population across ICU(s)	30	30
	Estimated monthly # eligible (50% of monthly total)	15	15
	Annual revenue projections	**$45,000**	**$135,000**
	#Months enrolling/active	4	12
	Average per-subject payment (low $5000, high $10,000, avg $7500)	$7500	$7500
	# Enrollments per month	1.5	1.5
	***Minimum* annual expense projections** *(coordinator support only)*	**$14,061**	**$42,183**
	# Months	4	12
	% Coordinator effort	30%	30%
	FT coordinator cost per month	$11,718	$11,718
	Coordinator monthly salary ($85,000/yr)	*$7033*	*$7083*
	Fringe benefits (27.25%)	*$1930*	*$1930*
	Indirects (30%)	*$2704*	*$2704*
	Projected variance *(revenue – expense) Balance can be opened to PI effort and/or banked as residuals*	**$30,939**	**$92,817**
Sepsis study 2	**Monthly enrollment estimates** *(10% eligible)*	**1.5**	**1.5**
	Annual septic shock population across ICU(s)	365	365
	Monthly septic shock population across ICU(s)	30	30
	Estimated monthly # eligible (50% of monthly total)	15	15
	Annual revenue projections	**$49,200**	**$147,600**
	# Months enrolling/active	4	12
	Per-subject payment ($8200)	$8200	$8200
	# Enrollments per month	1.5	1.5
	***Minimum* annual expense projections** *(coordinator support only)*	**$14,061**	**$42,183**
	# Months	4	12
	% Coordinator effort	30%	30%

(continued)

Table 18.2 (continued)

Study	Analysis	Yr 1 *(4* months *of enrollment)*	Yr 1 *(12 months of enrollment)*
	FT coordinator cost per month	$11,718	$11,718
	Coordinator monthly salary ($85,000/yr)	*$7083*	*$7083*
	Fringe benefits (27.25%)	*$1930*	*$1930*
	Indirects (30%)	*$2704*	*$2704*
	Projected variance *(revenue – expenses) Balance can be applied to PI effort and/or banked as residuals*	**$35,139**	**$105,417**
Ventilator study 1	**Monthly enrollment estimates** (*10% of eligible)*	**1.5**	**1.5**
	Annual population across ICU(s)	350	350
	Monthly septic shock population across ICU(s)	29	29
	Estimated monthly # eligible (50% of monthly total)	15	15
	Annual revenue projections	**$60,000**	**$180,000**
	# Months enrolling/active	4	12
	Per-subject payment ($10,000)	$10,000	$10,000
	# Enrollments per month	1.5	1.5
	***Minimum* annual expense projections** *(coordinator support only)*	**$18,748**	**$56,244**
	# Months	4	12
	% Coordinator effort	40%	40%
	FT coordinator cost per month	**$11,718**	**$11,718**
	Coordinator monthly salary ($85,000/yr)	*$7083*	*$7083*
	Fringe benefits (27.25%)	*$1930*	*$1930*
	Indirects (30%)	*$2704*	*$2704*
	Projected variance *(revenue – expenses) Balance can be applied PI effort and/or banked as residuals*	**$41,252**	**$123,756**
Total projected variance across three studies		**$107,330**	**$321,990**

Please note that "expense" figures *do not* include PI support or other non-personnel expenses (i.e., investigational pharmacy, lab costs, etc.). Level of effort will vary by study, and salaries, fringe rates, and indirect rotes are all meant as examples only and should be confirmed at each institution

Role of the Program Manager

The role of the research program or project manager (PM) is dependent on the needs of the research team and/or clinical trial. If an investigator is undertaking complex research (e.g., a multicenter randomized controlled trial), the PM is key to the

successful execution and completion of the project. From the proposal phase through trial completion, the PM is typically the navigator of the entire project and should have advanced knowledge in research methodologies, grants and finance management, and trial logistics and operations. The PM serves as the chief counselor to the PI and ensures the smooth day-to-day operations of a clinical trial. In addition, the PM interacts with the study sponsor, clinical coordinating center, data coordinating center, site staff, and other relevant personnel. The ACRP identifies six content areas for a successful PM: (1) ethical and participant safety considerations, (2) regulatory requirements, (3) clinical trial operations, (4) study management, (5) scientific concepts and research design, and (6) business management, leadership, and professionalism. (Source: detailed content outline acrp.net)

Finding a qualified PM is largely dependent on the size and scale of the research project. For example, large multicenter, multinational RCTs require a PM that has substantial experience in overseeing similar trials. Navigating the complex legal, regulatory, and budgeting involved in a major project is a massive undertaking, and recognizing the unforeseen potential complications is a valuable resource to the PI, funder, and other important stakeholders. During the planning phase, the PM is expected to assist in the development of the protocol, case report forms (CRFs), budget, standard operating procedures (SOPs), study database, and regulatory planning, including investigation and development (IND) or investigational device exemption (IDE) applications or waivers, and site planning. During the execution phase, the PM is expected to ensure study logistics run smooth, maintain appropriate expenditure accounting and fiscal responsibility, organize and assist with special meetings and presentations, develop reports to assess data accuracy and study performance (i.e., data entry, site activation performance, recruitment expectations, etc.), ensure ongoing regulatory compliance, provide necessary support for ancillary studies, and conduct site visits. During the closeout phase, the PM participates in regulatory closeout reports and data verification and lock, identifies discrepancies, may assist with statistical analysis and publication, and ensures the proper expenditures are finalized (Table 18.3).

Study Execution in an ICU

Start-up activities usually commence in parallel with study selection. These include completion of site questionnaires and projected budgets, signing of contracts, preparation and submission of the protocol to the IRB, conceptualization of screening and recruitment processes, training of study and clinical personnel, establishment of data collection and submission methods, and clarification of remuneration. Successful study execution is contingent upon many factors. First, anecdotally, an ICU with a full-time, dedicated intensivist practice model may operate more efficiently with regard to study activities as compared to an open ICU with multiple practice models. Study-related training and communication is more effective in a closed unit, where simplified and targeted efforts can enhance compliance with

Table 18.3 The research team and other important stakeholders

Clinician-scientist	Typically an MD, but can be any motivated stakeholder	Manages the research program Builds institutional consensus Establishes the research team Reviews and selects studies Acts as the principal investigator Oversees study execution May consent patients[a] Participates in publication of results
Research coordinator	May or may not be an RN	Interacts with regulatory bodies (IRB) Interacts with study sponsor May negotiate budget[b] Trains bedside clinicians Screens patients and may perform consent Enrolls patients and liaisons with pharmacist Performs study activities Collects and submits data
Research pharmacist	PharmD	Trains pharmacy staff on study-related activities Randomizes enrolled patients Delivers study drugs to bedside providers
Project manager	Typically a research coordinator by training and may be an RN or others	Ensures that regulatory requirements are met Guides trial operations and logistics Assists in study management and execution Assists with study design Performs business management and fiscal stewardship
Budgeting office	Common in academic institutions	Negotiates budget Designs and implements payment and disbursement efforts
IRB	May be local or central, usually includes MDs from multiple specialties	Reviews and approves protocol Reviews and approves informed consent Provides ethical oversight to study
DSMB	Comprised of independent experts	Provides oversight of patient safety Provides oversight of data integrity May stop a study for futility or harm
Steering committee	Associated with multicenter trials and consists of global principal investigators, content experts, and some site investigators	Performs study design Determines site selection Manages centralized data collection (DCC) Oversees study execution (CCC) Coordinates central pharmacy efforts Determines publication strategy
Study sponsor	May be industry (pharmaceutical company), governmental (NIH), nonprofit (Kaiser Family Foundation), or the investigator	Pays for study activities May support research program costs unrelated to any particular study (salary support)

[a]May be done by research coordinator
[b]May be done by budgeting office or project manager

study requirements. Existing literature favors the use of clinical trials units (CTU) or specialized entities that design and conduct high-quality trials in an efficient, impactful, and inexpensive manner [27]. It is likely that a closed ICU approaches the characteristics of a CTU more than an open ICU. Second, the culture of practice of an ICU and its adherence to established standards may undermine a study result if significant deviations from the standards exist [53]. For example, a sepsis study that may utilize standardized resuscitation strategies in accordance with Surviving Sepsis Campaign guidelines would expect these strategies to be carried out across all participating sites [30]. Departure from this practice may introduce variability that threatens the overall integrity of the data and final conclusions. Third, hospital-related limitations can greatly restrict study activities. For example, smaller hospitals may not have full-time availability of investigational drug services. Lack of these specialized pharmacists can limit the ability to enroll during off-hours, especially for hyperacute trials that have short enrollment windows, limiting potential enrollment in a timely fashion. Fourth, the regulatory culture can dictate processes. A conservative or inexperienced IRB in regard to critical care research may be hesitant to approve studies where the risks versus benefits are perceived to be equivocal and may limit the ability to obtain consent remotely (e.g., by phone, email, or fax) from legally authorized representatives (LAR) [54]. The use of e-consent platforms (i.e., smart phones) greatly streamlines the consenting paradigm in hyperacute, randomized clinical trials [55].

Protocol Submission

Start-up activities include protocol creation and submission. A protocol must include a compelling hypothesis which compares one intervention against another. An interventional clinical trial protocol requires the identification of a target population, an intervention and a relevant comparator, and an appropriate outcome that will be sufficient to demonstrate the impact of an intervention [21]. The protocol also requires a detailed statistical analysis plan (SAP), including sample size calculation, the level of significance, and the handling of missing data. In an industry-funded study, a fully developed protocol is typically provided and only requires minor clarifications when submitting to local regulatory and institutional guidelines. However, investigator-initiated studies will require the full development of a protocol and SAP. Poorly written protocols are common [56–58] but can be improved by including a minimum set of scientific, ethical, and administrative elements as outlined in the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) international initiative [59]. Additionally, new drug or device trials may require submission of an IND or IDE application to the FDA. Additional resources for writing a protocol and navigating the IND/IDE landscape should be examined to assist the new investigator ensuring success [60, 61].

Screening and Enrollment

After start-up activities have been completed, enrollment commences, which brings its own set of challenges. In a critical care setting, the likelihood of identifying, screening, consenting, and enrolling the required number of patients is dependent on may factors, including the availability of research staff, the window of time for enrollment, lack of an available LAR or proxy, family dynamics, and language barriers [62]. Accordingly, the number of eligible patients is usually higher than the number of consenting participants [63]. The time constraints in the schedule of the research coordinator can limit screening and enrollment, especially if nights and weekends are not covered [64]. Poor health literacy may also be an obstacle when discussing complex critical care studies. The paradox of disease state prevalence and patient recruitment has been well described and disproportionately affects poorer patients, whose socioeconomic status is correlated with poor health literacy [65, 66]. Recruitment is further complicated when patients are unable to provide informed consent due to being in extremis from critical illness [62].

Surrogate consent is commonly obtained from family members, who also may lack medical literacy and who are often under considerable stress in the acute stage [67]. Additionally, inadequate family support (e.g., when a patient is homeless) may pose a challenge when trying to identify an appropriate LAR for informed consent discussions. The option of waiver or exception from informed consent in emergency research has encountered resistance from regulatory criteria and a high barrier to entry, as well as ethical issues [63]. In a 2009 study of survivors of critical illness, nearly half of patients disagreed with a waiver of consent, and up to 20% disagreed with delayed consent [68]. However, other more recent studies of patients and surrogates who participate in emergency research have positive experiences [69], although good clinical outcome of patients may be associated with positive thoughts about the experience [70]. Finally, degree of risk or uncertainty of the proposed intervention is usually inversely correlated to study enrollment and should be considered when developing a study portfolio [62].

Tools for successful patient recruitment include optimizing study personnel work hours to cover all potential enrollments, frequent communication with clinical staff regarding the presence or absence of a patient's LAR, and providing consent forms in other common languages [62]. Direct involvement of the PI in the consent process may enhance the likelihood of success, though there is conflicting data on this approach [71]. Additionally, obtaining consent electronically may facilitate enrollment when family members are remote, though local policies may prohibit this practice. However, most IRBs permit telephone or facsimile consent and are slowly adopting e-consent practices [63].

Despite these limitations, the actual process of screening and enrollment is largely study-specific, and each trial contains unique challenges. Recruitment obstacles to consider upfront include the following: (1) What is the process for daily screening, including frequency? (2) Who is screening daily (i.e., research teams,

clinicians, or both)? (3) What notifications can be automated to prompt research teams? (4) What is the plan for after-hours screening? (5) Who performs the informed consent discussion? Although these considerations are universal, the answers are multifactorial and vary depending on individual site infrastructure, experience, and team strengths and weaknesses. Often, when deploying effective recruitment strategies, processes are dynamic, and iterative improvements are made through trial and error. Effective recruitment may hinge upon efforts of targeted groups in key positions (i.e., the clinical pharmacist or respiratory therapists), depending on study details. For example, the ICU clinical pharmacist may be able to screen for a study with inclusion criteria pertaining to vasopressors and can easily alert the PI or research team with minimal impact on his or her daily workflow. Novel approaches, including use of e-consent, preemptive consent, or alternative consent models, may also prove successful [63].

Publication

Opportunities for publication differ between study types and should be considered before developing a study portfolio. Dissemination of study results represents a fundamental obligation of the PI for both the greater good of the medical and scientific community and as an ethical obligation on behalf of the patients and families who agreed to participate. In addition, regulations often require some publication of trial results through a national registry (e.g., clinicaltrials.gov) or in a peer-reviewed journal. For multi-investigator collaborations, with or without external funding, a publication plan should be established at the onset of the study and should include timeline after study conclusion, primary authorship, data availability outside of investigators, as well as considerations for the desired audience and the potential implications of the results. While manuscript submission is beyond the scope of this work, the quality of study design and execution can influence its potential acceptance in a publication [36, 72].

Ethical Considerations

Critically ill patients are considered a vulnerable population and therefore require special consideration when designing a clinical trial [5]. Important issues include (1) assessment of a patient's ability to consent, (2) whether a conflict of interest exists when an investigator also acts as the patient attending physician, (3) determining trial recruitment priorities when there are multiple studies (co-enrollment), and (4) whether to enroll patients who are at a high risk of dying.

Attending and Enrolling Simultaneously

The practice of critical care (in which a clinician primary objective is to benefit the individual patient) and critical care research (in which the investigator primary interest is to gain knowledge) are different, but can be aligned [73]. Research and clinical practice often occur simultaneously; however, the clinician-scientist must be aware of the potential conflict of interest. When a clinician-scientist has financial or tangible personal interest in a product (i.e., drug or device) or could benefit monetarily from the results of a trial, a third-party oversight committee (i.e., institutional conflict of interest committee) should make determinations about involvement at an individual patient level. Aside from financial considerations, the clinician-scientist working in the ICU may unduly influence a patient's decision to participate because of an existing clinical relationship with a patient [73].

Additionally, it is important to avoid misleading a patient or the LAR into thinking that participation in an investigational study guarantees therapeutic benefit (e.g., therapeutic misconception) [74]. Therapeutic misconception can undermine the informed consent process and suggests that the clinician-scientist may lack clinical equipoise, or the general state of uncertainty regarding the competing treatments [75]. Clinical equipoise is a requirement for the ethical comparison of multiple interventions (i.e., comparative effectiveness trial which can only be undertaken when the superiority of two or multiple treatments is unknown); thus the clinician-scientist upholds the principle of "do no harm" and allows the chance to determine treatment assignment with the understanding that either arm is as likely as the other to achieve the therapeutic intent [76]. However, it may be such that one treatment assignment may be preferred over another for a particular patient or circumstance, and upholding a randomization assignment in this setting would put the clinician-scientist in a position of potentially compromising individual patient care.

Attending in an ICU while simultaneously acting as an investigator has affected physician behavior [77]. When a clinician-scientist is faced with conflicting goals, strict adherence to a study protocol can often be at odds with clinical practice preferences. For example, a sepsis trial protocol may require volume resuscitation by administering 30 mL/kg of intravenous fluid, but a local site may practice more conservative resuscitation strategies. Understanding how a trial protocol can lead to changes in clinical care is a crucial step and should be weighted with the appropriateness for individual patients (e.g., altering medication dosages or allowable adjunctive therapy) [76]. Indeed, the clinician-scientist should have a working understanding of established research principles concerning the rights of the patient and prioritizing the safety, principles of informed consent, as well as how a study protocol may diverge from desired practices for each patient enrolled in a study [34]. Finally, steps should be taken to maintain a position of equipoise and minimize the risk of therapeutic misconception. To this end, the American Thoracic Society published recommendations titled *The Ethical Conduct of Clinical Research Involving Critically Ill Patients in the United States and Canada* and state that "[when] practitioners serve as investigators and clinicians for the same patients…,

other persons (e.g., co-investigators, research coordinators, or persons not involved in the study) should explain the research to potential study participants and obtain their consent" [73].

Co-enrollment

A heterogeneous patient population combined with multiple stringent inclusion and exclusion criteria are inherent limitations in critical care research, and enrollment rates are consequently affected by these limitations. Simultaneous enrollment into multiple studies may be considered however, understanding the associated risks including unexpected interactions between study interventions, protocol violations effecting data integrity, and stress or fatigue on the patient or family [78]. A survey by Cook et al. [5] on prevailing views on co-enrollment noted that the practice is not universally endorsed [5]. Regardless, if this avenue is pursued, adjustments in study design may mitigate some identifiable risks. The clinician-scientist should consider anticipated covariates (e.g., unrelated trial interventions, parallel or factorial trial design) and psychosocial factors (e.g., family dynamics) when deciding on whether to offer co-enrollment [5]. An assumption exists that patients experience undue "burden" when approached for participation in multiple studies [79]. However, limited evidence supports this assumption [80]. Typically it is at the clinician-scientist discretion whether or not to disclose the possibility of enrollment into more than one trial, even when a subject is eligible for participation in multiple studies [78]. Clinician-scientists should use caution when considering co-enrollment in interventional (i.e., drug or device) studies due to increased risk to the patient, the complexity of adhering to multiple protocols, and the risk to the integrity of the data Additionally, most sponsored trials preclude enrollment in another trial; therefore, this practice is generally discouraged when establishing a new research program.

Enrollment of Patients at High Risk of Death

Studies involving critically ill patients are complicated due to a higher risk of death. Critically ill patients with very high probability of death are typically referred to as "moribund." When a patient is deemed moribund, the clinical team(s) has determined that it is unlikely that any known intervention will substantially alter the clinical course or outcome of death. Many clinical studies involving critical care often involve patients that approach moribund status, but in whom definitive efforts to avoid death have not yet been terminated. In these circumstances, there are both benefits and risks when considering enrollment into a clinical trial. For example, when designing a trial where the primary outcome measure is mortality, the inclusion of moribund patients may dilute an efficacy signal due to unlikelihood that any

intervention would result in a change in that outcome. However, investigators should consider including moribund patients in a study in circumstances where absolute mortality risk remains uncertain (i.e., survival is possible, even anecdotally) and survival is achievable and of high interest. It is important to consider that patients with multiple comorbidities may die from factors unrelated to the disease of interest. Furthermore, a pragmatic study may attempt to enroll all type of patients, including those who are moribund, which may decrease a potential effect of the intervention, but improve the external validity of the trial [73]. When confronting the extremely high likelihood of death, moribund patients and their surrogates often feel that there is nothing left to lose and will want to participate. Therefore, it is important to avoid therapeutic misconception in describing potential study involvement to these patients or their surrogates. Careful consideration should be given to the vulnerability of moribund patient and their surrogate decision-makers [81]. Patient autonomy should be preserved, even when there is little or no hope of survival [82]. To confound the issue, prediction of moribund status in the critically ill patient is difficult. Physicians have been shown to be poor prognosticators with regard to mortality [83]. In the currently active Vitamin C, Thiamine and Steroids in Sepsis (VICTAS) trial, investigators did not preclude patients with clinical prognostication of moribund status as an exclusion criteria, but rather elected to maintain a pragmatic approach for inclusion and exclusion criteria while still seeking to achieve an improved mortality outcome, even in the extremely critically ill patients [84]. In contrast, moribund patients were excluded from the ATHOS-3 trial; however, this trial was not powered to detect a mortality difference. Instead, the ATHOS-3 trial sought to elucidate a blood pressure response in a fairly homogenous population of septic shock patients [25].

The Institutional Review Board (IRB)

An IRB reviews any research involving human subjects and approves research in accordance with the Belmont principles of beneficence, respect, and justice [85]. The IRB is tasked with the essential job of ensuring patient safety and autonomy [76]. The IRB also conducts study oversight in accordance with federal, institutional, and ethical guidelines [76]. For many trials, the local IRB will evaluate the trial according to local rules and patient interests. However, there is an increasing amount of standardization of local IRB activities and guidelines. Additional information about IRB and human subjects protection can be found on the Association for the Accreditation of Human Research Protection Programs (AAHRPP) website (www.aahrpp.org). Larger multicenter trials may rely on a central or single IRB (cIRB), which can streamline the review process and administrative redundancy across sites [86]. Many government agencies and clinical trials consortia endorse the use of cIRBs to improve study efficiency and eliminate the possibility of variable interpretation of the protocol and informed consent among site-specific local IRBs [87]. Central IRBs are bound by the same ethical standards as local IRBs, and

in fact, any reliance agreement between a cIRB and local IRB must be approved by both parties.

Many clinician-scientists may find the interaction with the local IRB to be intimidating, lengthy, and complicated [85]. The relationship between the IRB and the clinician-scientist can also be seen as acrimonious or burdensome. Nevertheless, IBR review of the protocol prior to study initiation and the evaluation of possible adverse events and protocol violations during study execution are an important aspects of the ethical conduct of a study [88]. Indeed, the IRB should halt any study that fails to meet set standards regarding beneficence, respect, and justice. Therefore, the clinician-scientist should recognize the positive role the IRB plays in clinical research and how it can provide substantial guidance and mentorship [89].

Informed Consent

In addition to the previously discussed barriers surrounding informed consent in the critically ill patient, there are also ethical considerations involving informed consent. Patients who have life-threatening critical illness may need urgent intervention within a short period of time, with unacceptable risk associated with delayed care [6]. These patients may also be candidates for ongoing trials, participation in which may require expedited consent. However, critically ill patients are often unable to consent to participate, requiring the involvement of a surrogate decision-maker. While participation *without* consent is clearly unethical, consent by proxy may constitute a loss of individual autonomy in research [90]. The suitability of surrogate decision-making may be clouded by a variety of factors, including psychological stress, guilt, and financial concerns [75]. More importantly, the principle of substituted judgment, in which surrogate decision-makers decide which course of action would represent the patient's best interests, is a subject of debate [91, 92]. Reasons for participation in clinical trials may differ between a patient and their surrogate decision-makers. Patients tend to be more altruistic about participation, whereas surrogate decision-makers are more likely to consider participation as a therapeutic option [63]. Debate exists as to whether critical care research should be excused from informed consent requirements [6]. A 2008 survey of critical care researchers' experiences, beliefs, and practices noted that respondents believed that modifications to the consent process, including waived or deferred consent, were appropriate in the right setting [5]. Deferred or advance consent may allow for patients with *anticipated* critical care needs. For example, anticipated exacerbation of chronic diseases such as chronic obstructive pulmonary disease or congestive heart failure may allow for a patient to provide advance consent and thus avoid the need for surrogate consent. Finally, it is important to understand that the informed consent process and informed consent form are different. Informed consent process is a communication of mutual understanding between the clinician-scientist and the enrollee, whereas the informed consent form is a legal contract [85]. Underlying the signed consent form requires many assumptions [85]:

- The purpose of the study has been described.
- Participation and withdrawal from the study is voluntary.
- Confidentiality will be maintained.
- Risks and benefits have been explained.
- Methods for communication and feedback by study participants (including complaints) have been provided.

It is incumbent upon the clinician-scientist to reassess regularly whether continued participation in a study is desired by a patient and whether it is still in the patient's best interest [73]. In many cases, re-consent of a patient upon improvement in clinical condition is warranted and sometimes required even if study activities have concluded.

Metrics for a Research Program

The primary goal of an ICU research program is to improve the care of critically ill and injured patients. A secondary goal is to improve the job satisfaction of the clinicians involved, as well as to promote the culture of learning in the ICU. This culture of learning may lead to retention of clinicians and can be a factor promoting the ICU and the hospital as a desirable place to seek care. In order to achieve these goals, the research needs to be financially sustainable and fit within the workflow of the ICU. Additionally, any well-conducted research should lead to the publication of accurate and unbiased results [36], even if the results do not show a treatment effect [93–95].

Improving Patient Outcomes

The establishment of a research program theoretically benefits patients who are not involved in any research efforts [34]. Ozdemir et al. [96] found a lower overall patient mortality in centers that are more active in research compared to less active sites [96]. Although the underlying mechanism for this remains unclear, improved outcomes may stem from rapid adoption of evidence-based practices, higher cumulative knowledge, and a more robust and embraced research infrastructure and greater available resources (more doctors, nurses, critical care beds, and operating rooms). Further evidence suggests that trial participation, regardless of treatment assignment, may lead to improved outcomes. Eligible but non-enrolled patients into the OSCILLation for ARDS Treated Early (OSCILLATE) trial were found to have a higher odds ratio for increased mortality (adjusted odds ratio, 1.39; 95% confidence interval, 1.06–1.84; $P = 0.02$) [97, 98]. Similarly, the Conventional ventilation or ECMO for Severe Adult Respiratory failure (CESAR) authors found that for patients enrolled in their trial, merely being transferred to a center specializing in extracorporeal membrane oxygenation (ECMO) conferred a mortality benefit, whether or not a patient was actually placed on an ECMO circuit [99].

Supporting Future Opportunities

The clinician-scientist must take a structured, practical, and businesslike approach when designing and executing a study [36]. Like any new enterprise, a nascent research program should perform a return on investment (ROI) analysis in regard to budgeting and sustainability. Lessons learned about recruitment and financial viability from a first-time participation in a study should be applied to the next study opportunities. Each study can require substantial investments of limited resources and requires renewal of these resources for ongoing operations [100, 101]. Beal [102] provides detailed resources for helping determining an appropriate budget for a contemplated study [102]. Other forms of ROI include strategic positioning for future endeavors, downstream revenue associated with patient care after the trial activities are completed, market share and the perception by consumers that an ICU offers clinical trials, and altruistic reward [103]. After evaluating these factors, a business case must be made for establishing an ICU-based clinical research program. At a minimum, the research program should demonstrate a neutral or positive ROI to sustain organizational support.

Summary

Critical care research can be highly rewarding endeavor for the clinician-scientist. However, the complexity involved in establishing an ICU-based research program may complicate the development of a successful research program. A thorough understanding of the clinical trial landscape is important in devising and designing a research agenda. The clinician-scientist must know the key stakeholders, including relevant regulatory bodies, potential funders, and other institutional team members, to achieve consensus for the effort. When successful, a clinical research program can add value to the careers of the investigators, to the ICU, and even to the institution in which it occurs.

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Chapter 19
The Safety of Patients in Critical Care

María Cruz Martín Delgado

Introduction

Patient safety is a challenge and a priority of all health systems. International policies have been implemented with the precise objective of reducing the number of incidents related to patient safety (IRPS) [1]. Despite this and the effort made, there are still many patients who suffer damages derived from healthcare [2]. Its impact extends not only to relatives but also to professionals and to institutions elevating health costs and creating a financial burden.

The majority of studies conducted in patient safety have been directed to know the epidemiology of adverse events (AEs), to know their causes and their consequences [3]. Many safe practices have been promoted to reduce the risks related to healthcare incidents [4].

Recently, aspects related to post-AE performance have become more relevant. Risk management involves, among other actions, the identification, notification, and analysis of the AEs with special emphasis in the root cause analysis of such events with the ultimate goal of establishing performance improvement initiatives aimed to prevent their recurrence. These strategies have been incorporated into institutional policies becoming the center of the culture of safety. Nonetheless there are areas requiring improvement such as our capacity to inform patients and their families about AEs and the support offered to professionals involved in AEs.

Finally, patient safety calls for the unrestricted commitment of the professionals in embracing the culture of safety in their work environment [5]. The culture of safety involves the organization understanding of the sum of values, attitudes, perceptions, competencies, and individual and group behavior patterns. Moreover, the organization must be committed to accept the different styles determined by all

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those characteristics, competencies, and different environments to promote the culture of safety [6].

Patient Safety: Definitions

Patient safety is defined by the avoidance of unnecessary harm or potential injury associated with a healthcare activity most commonly defined as adverse events [7]. Complication is defined as a negative outcome derived from the natural course of the disease. The AE is an unintentional damage caused during or as a result of a healthcare intervention, and it is not related to the evolution of the patient's illness. The damage associated with an AE includes injury, disability, prolonged hospital stays, and ultimately death. An incident could occur without producing damage. These incidents occur between 3 and 300 times more frequently than AEs and undoubtedly define a system failure, described in the model of iceberg or pyramid proposed by Heinrich [8]. No-harm incidents constitute the base of the pyramid, at the tip of which would be the most severe AEs those carrying a risk of death. Both AEs and no-harm events share the cause or the "unsafe practice," thus becoming essential the analysis of all the events as learning from the no-harm events could be extrapolated to the AEs [9]. The IRPS can be avoidable or unavoidable. The former is attributed to errors or unsafe acts (actions or omissions) favored by failures in the system, and the second ones are considered risks inherent to clinical practice. These, however, after full root analysis demonstrate modifiable factors that could have determined a safer practice. Avoidable or potentially avoidable IRPSs are frequent (34.3–83%) [10], and all carry a very high economic impact [11].

The Genesis of Incidents and Adverse Events

Error is defined as a failed action that is not done as planned or the wrongful use of a plan to achieve a goal. An error can occur in three conditions: by the performance of unnecessary actions, by the poor execution of useful and necessary maneuvers, or by the omission of beneficial interventions. Those conditions have been termed overuse, misuse, and underutilization, respectively. The first two would include the errors of commission and the last one the errors of omission [12]. Errors can also be classified as latent or active. Active errors are insecure actions (forgetfulness, lapses, failures, or transgressions of protocols) that depend directly on the operator, and their effects are observed immediately. Possible errors, on the other hand, do not depend on the operator, and their effects are not simply observed including defects in design, installation, maintenance, and others. When analyzing errors, the natural tendency is to take into account the former and ignore the latent conditions, which can lead to the recurrence of errors and the AEs [13]. Human errors can be approached in two ways [14]: The personal approach focuses on the errors and

failures of individuals. The corrective measures are aimed at professionals. It tends to simplify the psychological complexities of people, raising causes linked to lack of motivation, forgetfulness and carelessness, lack of care, negligence, or recklessness. The answers are punitive (fear, disciplinary measures, threats, blaming, or shaming those involved). This personal approach, focused on guilt-punishment, has prevailed in many organizations until recently [15]. The modern vision considers the highly complex health system, where many elements and factors interact and where responsibility does not depend only on one of them. The majority of AEs are usually generated in a causal chain that involves resources, processes, patients, and professionals, most of the times being the result of failures in the system rather than individual ones. The theory of the "Swiss cheese" as the genesis of the AEs, postulated by Reason [13], establishes that in complex systems there should be different defense and security barriers whose objective would be to protect potential victims from possible harm. These mechanical, personal, or organizational barriers, effective when intact, can weaken at certain times, producing holes in the manner of a "Swiss cheese," the most frequent causes of deterioration being active failures and latent conditions. These holes, individually considered, usually would not cause damage and only if they were aligned would draw a trajectory that would allow the AEs to occur.

Different studies analyze the causes of AEs by identifying the variables that contribute to increasing their risk [16]. Factors emphasized in those studies include the inexperience of the professional, the introduction of new procedures and techniques, the lack of protocolization or systematic approach, administrative failures such as insufficient resources, the complexity of care, the need for urgent interventions, aging of the population, prolonged stay, deficient interpersonal skills, and psychological pressure on the professional.

Patient Safety in Critical Care Services

Adverse events are frequent in intensive care medicine. In the USA, 148,000 AEs are reported annually [17].

In the study Safety and Risk in the Critically Ill (SYREC) in Spain, the probability of a patient suffering from at least one IRPS was 62%. The rate of occurrence of AE was 2.04/100 patients/hour of stay in intensive care. Seventy-four percent of the incidents were related to medications, appliances, medical care, vascular access and probes, airway management, and mechanical ventilation. Sixty-six percent of the IRPS resulted in no harm, and 34% were AEs; 29.5% caused temporary damage and 4.28% permanent damage, which compromised the patient's life or contributed to death. Ninety percent of the incidents without harm and 60% of the AEs were considered avoidable [18].

The IVeMVA [19] study (incidents related to mechanical ventilation and airway) performed in 104 Spanish ICUs for 7 days concluded that mechanical ventilation (MV) is a high-risk procedure for critically ill patients. 2492 incidents (41% AEs)

were reported in 1267 patients. 73.7% of the incidents were related to the MV process, 9.5% with the tracheostomy, 6.2% with the noninvasive MV, 5.4% with the MV weaning process, 4.4% with the intubation, and 0.8% with the use of prone position. The incidents were considered avoidable in 73% of the cases, and 0.8% produced an injury that placed the patient's life at risk or contributed to his death.

Internationally, other studies have found similar results [20, 21, 22], which shows that the critically ill patient is especially vulnerable to suffer AEs.

Valentin et al. [20] in a multicenter study, in a 24-hour incidental cut in 305 ICUs from 29 countries, identified 584 AEs (defined by 5 types of sentinel events) that affected 391 patients. The observed rate of AEs per 100 patients per day was 14.5 related to tubes, catheters, and drainages, 10.5 related to medications, 9.2 to equipment, 3.3 to airway devices and management, and 1.3 to alarms. A second study [21] focused on AEs related to parenteral medications in 113 intensive care units from 27 countries detected 861 medication errors that affected a third of the patients studied. The incident rate was 74.5 per 100 patients/day. 0.9% of the patients presented permanent damage or died due to a medication error. Antimicrobials, sedatives, and analgesics were the drugs in which a higher proportion of incidents were found, with the most common types of errors being the frequency of erroneous administration and the omission of doses.

In 2010, the results of a multicenter study conducted in France, the Selected Medical Errors in the Intensive Care Unit (IATROREF) [22] in 70 ICUs, were published. 1192 incidents were detected, affecting 1369 patients, of whom 367 (26.8%) experienced at least 1 incident (2.1 per 1000 patients/day); the most frequent was related to medication errors (185.9 per 1000 days of insulin treatment). 183 (15.4%) errors were AEs and affected 128 (9.3%) patients. The presence of two or more AEs was an independent risk factor for mortality in the ICU. This study established a relation between AEs and mortality, although it pointed out the difficulty of proposing this association in patients with severe illnesses and multiple comorbid factors that may have contributed to their death.

In 2013, a study conducted in 57 ICUs in Austria, Germany, and Switzerland [23] using a voluntary notification system evaluated the incidence of medication-related errors; the accidental removal of catheters, tubes, and drainages; as well as their relation to the environment of safety and workload. 795 patients were included, and 641 errors were reported, affecting 33.8% of the patients, with a rate of 49.8 errors per 100 days/patient. The workload was related to a higher number of errors; on the contrary, the culture of safety contributed to a reduction of the incidents.

There are many factors in critical care related to the increase in the risk of AEs: the severity of the conditions, the number of interventions such as diagnostic and therapeutic procedures, the increasing use of high-risk medications, the volume of data generated in their care, the use of newly developed technology, situational stress, the workload, the need for teamwork and effective communication, the multiple transfers of information, and professional burnout are just some of them [24].

In 2009, the Vienna Declaration was published. It was promoted by international scientific societies, and gathered governments, representatives from industry, and

patients. The Vienna Declaration recognized the inherent risk for AEs associated with intensive care medicine and called for increasing our work aimed to patient safety and care [25].

Safety Practices

In recent years, many safe practices related to the critically ill have been established showing reduction in damages associated with healthcare events. A safe practice is defined as the one that is carried out based on the best scientific evidence available to date, to avoid or minimize the risk of causing an IRPS. The National Quality Forum (NQF) in the document "Safe Practices for Better Health Care" summarized the practices to be implemented with high priority based on the existing evidence regarding effectiveness in relation to the patient safety. Most of the 34 recommended safety measures have application in the ICU [26]. The Agency for Healthcare Research and Quality (AHRQ) in the report Making Health Care Safer II - An Updated Critical Analysis of the Evidence for Patient Safety Practices [27] updated a series of recommended safe practices that have been prioritized for its application in clinical practice [28].

Hand hygiene is the practice with greater evidence in reducing healthcare-associated infections. Despite the evidence it has been demonstrated that such safe practice is only suboptimal in its compliance with rates reported between 30% and 75% [29]. Different initiatives, based on the implementation of measurement packages, have been shown to reduce catheter-related [30] bacteremia, ventilator-associated pneumonia [31], and infections related to urinary catheters [32]. In Spain, Zero projects have been shown to significantly reduce infections related to the use of devices in patients admitted to the ICU, including not only clinical measurement packages but also specific actions in patient safety [33, 34]. The prevention of multiresistant germs with the adequate use of antibiotics [35] and the diagnosis and early treatment in sepsis and septic shock have an important impact on the safety of critical patients [36].

Pharmacotherapy in critical patients is complex, characterized by polypharmacy, high-risk drugs, and intravenous administration with frequent modifications. In addition, dynamic changes in distribution volumes make pharmacokinetics and pharmacodynamics more complicated. Therefore, given the severity and complexity of the critical patient, the risk of suffering damages due to adverse events related to medication errors is more significant. Medication errors represent the leading cause of AEs in critically ill patients, increasing mortality and impacting financially institutions and healthcare in general [37, 38]. The use of technology such as computerized prescription (CPOE), clinical decision support systems (CDSS), bar codes, and smart pumps, together with the incorporation of a pharmacist in the ICU team, are some of the practices that have been shown to reduce medication errors [39]. The reconciliation of medication reduces the number of AEs related to medication in the ICU [40].

The use of adequate thromboembolic prophylaxis reduces thromboembolic events in critically ill patients [41]. Much has been learned regarding the use of systematic stress ulcer prophylaxis, and current recommendations call for avoidance of such practice in patients without risk factors for bleeding, a measure that can lead to less AEs [42].

Other clearly preventable adverse events are related to care such as pressure ulcers [43], the use of mechanical restraints [44], or falls [45] or those related to tubes, catheters, drainages, and other devices.

Teamwork and effective communication are essential elements of patient safety [46, 47]. The transfer of information can lead to information losses that result in AEs. Recommending structured procedures such as the use of mnemonic tools that ensure an effective handover have been called as safe practices [48]. Multidisciplinary rounds have been shown to improve communication and reduce AEs [49]. Perioperative intensive care medicine based on enhanced recovery after anesthesia (ERAS) protocols, in a multidisciplinary environment, adds value to the surgical process [50] and can reduce the frequent damage associated with these procedures in the critical surgical patient [51].

The use of ultrasound allows invasive procedures to be performed more safely, and its use is recommended to reduce the AEs associated with the insertion of venous catheters [52].

Recently, initiatives such as "choosing wisely" have led to adopting more restrictive policies regarding unnecessary interventions that can put the patient's safety at risk [53, 54]. Other initiatives such as the implementation of rapid response teams and ICU models without walls can detect patients at risk of deterioration early, reducing cardiac arrest and readmissions not scheduled in the ICU [55, 56].

Early diagnosis and prevention of post-ICU syndrome in patients and families through measurement packages such as the implementation of the ABCDEF bundle have been shown to reduce many of the adverse events in critical patients improving the results (days of mechanical ventilation, delirium, muscle weakness) and reduce the sequelae derived from admission to the ICU [57].

Other aspects related to the humanization of intensive care such as the flexibilization of the ICU schedules [58], the participation of the patient and the relatives in the care, and the prevention of professional [59] burnout have demonstrated their impact in the patient safety. The incorporation of palliative medicine in end-of-life care improves the results on patients who die in the ICU by reducing the related AEs [60].

The training of professionals using clinical simulation has demonstrated its effectiveness in acquiring specific skills in patient safety and improving the safety of certain procedures in critical patients [61]. The competence and certification of nursing professionals have been related to patient safety [62].

In the near future, big data and machine learning can help predict which patients can benefit from specific treatments and in which damage can occur [63].

Finally, the evaluation of the patient safety through quality [64] indicators and other risk management tools [65] can lead to improvement in the actions aimed to reduce the AEs.

Notifying Patients and Relatives of an Incident Related to Patient Safety (IRPS)

Ethical and professional guidelines establish the obligation to report errors made during healthcare, especially if they result in harm to patients. The Joint Commission [66] in 2001 established as a standard of accreditation the need to inform patients of AEs. Progressively, the number of institutions that have established specific policies to inform about the AEs has increased, and some countries have published guidelines and recommendations on how to carry out the process [67]. In some areas, specific legislation has been developed to promote the information process. Despite this, the systematic concealment of errors has been the usual practice until recently, and its impact on clinical practice is limited. Much needs to be learned about gaps existing on how to effectively carry out this process.

Disclosing an AE includes the process of recognizing openly and sincerely that unintended damage has occurred; the damage that has happened is reported; and the consequences for the patient, the result of the investigation of the causes that have influenced the AE, and the actions that have been placed to avoid its recurrence. The need to include an expression of empathy as saying "I am sorry" is recommended [68].

There is a duty to inform patients about any AEs, if such information significantly affects the care of the patient [69]. The ethical and legal bases supporting the disclosure of AEs include the respect to the autonomy of the patient, the right to receive information, the right to participate in the decision-making, the professional responsibility, and, also, an obligation toward the health organization. Reporting errors benefits patients, since it allows for early and appropriate solutions in order to prevent future damages, reduces stress by knowing the causes, allows the patient to participate actively in decision-making, compensates for losses, and improves the healthcare relationship. For the professional, it can reduce the stress to be "forgiven," narrow the care relationship, reduce claims and litigation, or even improve the position of the defendant if they occur; it also allows us to learn from mistakes and accept responsibility and can, as a consequence, change unsuccessful clinical practices. Patients want and require that their physical, emotional, and informative needs be covered after an AE through care, emotional support, and information related to the event (what, how, and why). They demand extensive and detailed information and express the need to be informed on time. They want to receive an apology, and they want real and objective explanations about the events that occurred, why it happened, that corrective actions (changes in the system) are made that prevent future AEs and in some cases show the desire to identify the professional responsible for the AE, or that corrective measures are applied when necessary [70]. The perception of errors and AEs has a negative effect on patient satisfaction, primarily if an adequate communication process does not occur. Patients usually respond positively to the process, which improves the care relationship and confidence in the health system and may even decrease lawsuits [71, 72].

A significant percentage of professionals acknowledge having been involved in a severe AE, particularly in some specialties [73]. Despite considering the need to communicate when an AE happens, they manifest the difficulty of carrying out the information process [74].

The content of the information provided by the professionals expresses a wide variability. It does not cover all the elements that constitute the complete information process (admission of the error, discussion of the event, the link between error and immediate effect, immediate effect, the link between error and damage, the damage produced), which influences when considering whether this information has been carried out or not [75]. Their main expectations are receive support from colleagues and the institution, training, and help in the disclosure of the AE, understanding, and forgiveness on the part of affected patients, a nonpunitive attitude, confidentiality of the process, and changes in the system that avoid the recurrence of AEs [76].

The professionals consider it essential to receive emotional support and training to deal with the problem adequately [77]. Communication with patients and family members could have a positive effect on professionals [78]. The acceptance of mutual criticism and the existence of constructive feedback on AEs could reduce the negative impact they have on health professionals. Discussing AEs among colleagues can affect learning and constitutes emotional support for the professionals involved. The recognition of errors by professionals involves [79] constructive changes in clinical practice. Although professionals consider AEs information process favorable, they acknowledge that they do not usually do so [80]. Different barriers have been identified, as well as facilitating factors when it comes to informing patients and relatives [81] about AEs. The main barriers to informing the sick and their relatives are ignorance; lack of skills and training to do so; the fear of losing trust, reputation, privileges, professional status, and even the license to practice; and the feeling of lack of protection or the fear of legal actions [82]. The lack of training and skills in communication processes is one of the main barriers identified by professionals when not communicating AEs to patients [83]. Training in this type of skills and abilities is rare [84]. Only 17.4% of physicians and 19.1% of nurses have received specific training to inform a patient about AEs.

It is necessary that in each institution, the process is contemplated within the framework of institutional policy, as well as to prepare and have guidelines that establish recommendations in relation to the AEs information process. For this, it is essential to improve the culture of safety of all the actors involved (patients, professionals, and other agents) [85]. Finally, it is necessary to more research regarding the communication and how to process information on AEs to patients and relatives [86].

Legal Aspects

One of the main barriers that limit the implementation of information policies to patients and relatives about AEs is the fear of professionals to be involved in a lawsuit or litigation or to feel unprotected at the time of doing so [87]. Some countries

have legislated the duty to inform patients about AEs that occur during healthcare treatments [88]. Others have regulated the protection of part of the content of the information provided to patients through specific laws ("apology laws") [89] that protect expressions of apology. The laws of qualified privilege have been developed in some legislations to confer protection to the members of the quality committees that know information related to the analysis of AEs [90].

In relation to the impact of AEs communication policies on the number of lawsuits and litigation, the results are inconclusive. Although some studies have shown that these policies reduce the number of demands, it seems reasonable to consider that, by increasing the knowledge about a significant number of patients, the number of demands could be increased [91]. Several experiences have shown that the open and honest communication of the AEs results in a reduction in the economic costs related to health lawsuits [92].

Support for Professionals Involved in an Adverse Event

The term "second victim" (SV) was introduced by Wu [93] in 2000 to refer to the professional who participates in an unavoidable AE and who is traumatized by that experience or who is not able to deal emotionally with the situation. Subsequently, Scott et al. [94] extended this term to any health professional who participates in an AE, a medical error, or an unexpected injury related to the patient and who becomes a victim in the sense that she or he is traumatized by the event. Its prevalence has been estimated that it can reach up to 50% of health professionals [95]. Recently, the term "SV" has been questioned as inappropriate, since it can convey a lack of responsibility for what more accurate words are looked for [96]. Different studies describe a series of immediate reactions of these professionals involved in AEs, such as acute stress response with re-experimentation symptomatology (repetitive episode memories, dreams, nightmares, intrusive thinking), alertness (subjective sensation of inadequacy, fear of repeating the error), and avoidance, along with feelings of guiltiness, shame, and depersonalization. Some professionals present symptoms on the sphere of affect (sadness, irritability, emotional lability, confusion, sleep disturbances, lack of concentration) or anxiety. Specific alterations may occur such as loss of confidence, sense of incompetence, fear of being wrong, or losing recognition, reputation, or prestige. All these can lead to personal and professional consequences in the medium-long term as a risk of harmful substances consumption, changes in attitude toward work, abandonment of the profession, or even suicidal behaviors [97].

These consequences can appear as an initial response to the incident or the reaction of other professionals, during the investigation process, or during a legal process, in cases where it occurs. The professionals who suffer a malpractice claim have significant emotional consequences that affect their performance [98].

Support strategies have been described for professionals that must be given at the individual and organizational level [99, 100], immediately and over time. The priority

is to offer support, understanding, and a nonpunitive attitude, especially by the other professionals or peers, together with those responsible for the institution. The discussion and analysis of the AEs should be always focused in recognizing the causes and applying changes to prevent recurrences. The preferred environment should ensure confidentiality and must facilitate support by experts and external resources such as legal and psychological, in cases where necessary. There are different initiatives of support programs for the SV that should be developed and extended to cover the needs of the professionals involved in AEs [101–102].

All these initiatives should promote and encourage the health system to provide the necessary support to patients and their families, professionals, and the institutions that are involved in AEs while continuing to work on offering a safer healthcare environment.

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