Special Article

Critical Care Delivery: The Importance of Process of Care and ICU Structure to Improved Outcomes: An Update From the American College of Critical Care Medicine Task Force on Models of Critical Care

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The American College of Critical Care Medicine (ACCM), which honors individuals for their achievements and contributions to multidisciplinary critical care medicine, is the consultative body of the Society of Critical Care Medicine (SCCM) that possesses recognized expertise in the practice of critical care. The College has developed administrative guidelines and clinical practice parameters for the critical care practitioner. New guidelines and practice parameters are continually developed, and current ones are systematically reviewed and revised.

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Abstract: In 2001, the Society of Critical Care Medicine published practice model guidelines that focused on the delivery of critical care and the roles of different ICU team members. An exhaustive review of the additional literature published since the last guideline has demonstrated that both the structure and process of care in the ICU are important for achieving optimal patient outcomes. Since the publication of the original guideline, several authorities have recognized that improvements in the processes of care, ICU structure, and the use of quality improvement science methodologies can beneficially impact patient outcomes and reduce costs. Herein, we summarize findings of the American College of Critical Care Medicine Task Force on Models of Critical Care: 1) An intensivist-led, high-performing, multidisciplinary team dedicated to the ICU is an integral part of effective care delivery; 2) Process improvement is the backbone of achieving high-quality ICU outcomes; 3) Standardized protocols including care bundles and order sets to facilitate measurable processes and outcomes should be used and further developed in the ICU setting; and 4) Institutional support for comprehensive quality improvement programs as well as tele-ICU programs should be provided. (*Crit Care Med* 2015; 43:1520–1525)

Key Words: critical care delivery; ICU; models of care; quality improvement

The best possible care of critically ill patients can be rendered when physicians of various specialties, nurses, and allied health professionals join forces and treat problems together.

Ake Grenvik, MD (1974)

In 2001, the Society of Critical Care Medicine (SCCM) published practice model guidelines that focused on the delivery of critical care and the roles of different ICU team members (1). The SCCM recommendations were based on six tenets: 1) Medical interventions should be provided by intensivists leading multidisciplinary groups; 2) Patient care should be directed by ICU teams using a "closed" format in which dedicated critical care teams take ownership of all aspects of care in the ICU; 3) ICU physicians should be available for medical and administrative tasks without competing clinical responsibilities; 4) ICU physicians and nurses should have critical care credentials; 5) Care teams should include critical care pharmacists and full-time respiratory care practitioners as well as ICU physicians and nursing staff; and 6) ICU governance should be conducted by multidisciplinary groups.

At the time, the 2001 SCCM Task Force identified several important but as yet unanswered questions that demanded further study. First, what aspects of critical care are directly linked to improvements in outcome? Second, can implementation of specific care protocols lead to improved outcomes, and if so, to what extent does the implementation of these protocols improve outcomes? Third, does dedicated team-based critical care reduce complications associated with critical illness? Fourth, does immediately available care at the bedside lead to improved outcomes? A Task Force on Models of Critical Care was convened to address some of these important unanswered questions.

METHODS

In 2009, a new Task Force on Models of Critical Care was convened by the SCCM. The new Task Force members consisted of 20 healthcare professionals and practitioners, including representatives from all of the disciplines that actively participate in the care of critically ill patients in the ICU. These professionals represented the practice of critical care in diverse settings, including nonteaching community hospitals, community hospitals with teaching programs, and academic institutions. Some members of the new Task Force were in private practice. Others were in academia. Others worked as consultants. A few members of the new Task Force had been members of the 2001 Task Force.

Members of the new Task Force were divided into three subcommittees, which were each asked to conduct reviews of the available literature pertinent to their assigned topics. The first subcommittee was assigned to examine the 2001 Task Force guidelines and identify studies published subsequently that either supported or refuted the 2001 recommendations. The second subcommittee was asked to identify studies addressing process improvement in the ICU. Several of the questions posed by the 2001 Task Force focused on the role of process improvement and protocol implementation in improving outcomes. One of the objectives for the second subcommittee was to consider whether there were key processes that might be considered essential for all ICUs. The third subcommittee was asked to identify studies that addressed integration of ICUs with other areas of the hospital and with regional healthcare systems. A primary objective for the third subcommittee was to evaluate nontraditional care models, such as telemedicine/telehealth systems. Each subcommittee met separately and brought their recommendations to the broader group in a series of telephone and in-person conferences. As a group, the new Task Force concluded that the published literature did not provide enough information to address all the questions posed by the 2001 Task Force. The new Task Force also concluded that there were insufficient data available to warrant a change in the recommendations published in 2001. The new Task Force, therefore, provided a series of statements refining the 2001 document. There is a hierarchy to the strength of evidence to guide practice and policy. Based on our analysis of the available literature, we determined that much of the evidence in this area is derived from study designs that have a lower level of reliability. As such, our recommendations should be viewed as a consensus of expert opinions. The structure of these refinements did not allow for Grading of Recommendations Assessment, Development, and Evaluation methodology evaluation (2).

The consensus of the new SCCM Task Force is that literature published since the 2001 guidelines suggest that both structure and process of care in the ICU are important for achieving optimal patient outcomes. Since 2001, several investigators

have published evidence that improvements in processes of care, ICU structure, and use of quality improvement (QI) science methodologies beneficially impact the outcome of critically ill patients and reduce the associated costs of care. The current literature is summarized below.

An Intensivist-Led, High-Performing, Multidisciplinary Team Dedicated to the ICU Is an Integral Part of Effective Care Delivery

Due in part to a controversy regarding "full-time presence" in the ICU versus "timely availability" of intensivists (particularly at night), the 2001 SCCM Task Force recommended that additional studies be conducted to evaluate factors associated with improved ICU outcomes. Since 2001, results were published from several single-center studies and multicenter cohort studies comparing outcomes and costs in ICUs with 24/7 intensivist staffing versus those without 24/7 intensivist staffing. The results are mixed. For example, Cavallazzi et al (3) performed a systematic review of the literature to assess whether admission to the ICU during the night or on the weekend (so-called "off-hours," i.e., when an intensivist might or might not be immediately available at the bedside) was associated with increased mortality. This group's pooled analysis of eight cohort studies with a total of 135,220 patients evaluating daytime versus nighttime admissions to the ICU showed no difference in the adjusted odds of death between critically ill patients admitted to the ICU during the daytime versus the nighttime. The presence of an intensivist physician on-site at night was associated with slightly lower but significant adjusted odds of death. There was significant heterogeneity in the quality of the studies evaluated. In a separate pooled analysis of six cohort studies with a total of 180,660 patients, an investigation of weekday versus weekend admissions was performed and demonstrated that the adjusted odds of death were significantly higher in patients admitted during the weekend as compared with patients admitted to the ICU during the weekday. Several factors that impacted the organizational/staffing structure of an ICU during the weekend may have explained the difference in risk of death. In another study, Wallace et al (4) conducted a multicenter, retrospective cohort analysis using the Acute Physiology and Chronic Health Evaluation clinical information system (2009–2010 data), combined with a survey of ICU staffing practices. This group included data from more than 65,000 critically ill adults admitted to 49 ICUs at 25 different hospitals. It found that nighttime staffing (i.e., 24/7 intensivist coverage) was not associated with improved outcomes in ICUs with high-intensity daytime staffing. Conversely, among ICUs with low-intensity daytime staffing, nighttime intensivist coverage significantly improved outcomes. With regard to costs, Banerjee et al (5) demonstrated that 24/7 intensivist staffing lowered direct costs for the sickest critical care patients. In a retrospective before-and-after comparison in a single PICU, transition to a nighttime attending intensivist coverage model was associated with a shorter duration of mechanical ventilation and a shorter ICU length of stay (LOS) (6). The reason for the mixed results of these studies is unclear. However, variability with regard to intensivist duties may have played a role (7, 8).

Wilcox et al (9) performed a systematic review of the literature to assess whether intensivist staffing patterns had an impact on clinical outcomes. Fifty-two observational studies, including the aforementioned study by Wallace et al (4), involving a total of 331,222 patients met the inclusion criteria. A pooled analysis of 34 studies reporting hospital mortality showed significantly lower mortality with so-called high-intensity staffing (transfer of care to an intensivist-led healthcare team or mandatory consultation with an intensivist) compared with low-intensity staffing. A pooled analysis of 18 studies reporting ICU mortality again showed significantly lower mortality with high-intensity staffing compared with low-intensity staffing. The effects on ICU mortality were similar between 24/7 intensivist staffing versus only daytime coverage by an intensivist. Kerlin et al (10) conducted a 1-year randomized single-center trial on the effects of 24/7 intensivist staffing ("intervention") compared with nighttime coverage by daytime intensivists who were available for consultation by telephone ("control"). The study involved a total of 1,598 critically ill patients randomized in blocks of 7 consecutive nights to either the intervention or control strategy. There were no significant differences in the primary outcome, ICU LOS, or in the secondary outcome of ICU mortality between groups. Finally, a recently published prospective, observational study by the United States Critical Illness and Injury Trials Group (USCIITG)-Critical Illness Outcomes Study involving 69 centers across the United States failed to show an association between severity-adjusted mortality and either 24/7 intensivist staffing or closed versus open ICU structure (11).

The 2001 SCCM guideline (1) stated that a "closed ICU" format, in which all patients in the ICU are cared for by a dedicated ICU team was preferable to an "open ICU" format, in which any credentialed physician can admit to the ICU and provide care. The results of the aforementioned study by the USCIITG contradict this recommendation, in that a closed format (40 of 69, 58% of ICUs in the study) was not associated with better outcomes compared with open or semiopen (mandatory consultation by the ICU team on all ICU patients). The investigators suggested that one potential explanation for their findings was that the vast majority of ICUs in their cohort had dedicated ICU medical directors (69 of 69, 100%) and nurse managers (68 of 69, 99%), as well as a large number of protocols (the median number of protocols per ICU was 19). Consistent with these findings, a systematic review and meta-analysis of 11 before-and-after observational studies suggested that telemedicine (specifically, intensivist-directed care remotely via telemedicine) was associated with lower ICU and hospital mortality among critically ill patients (12).

Based on the available evidence, the new SCCM Task Force concluded that an intensivist-led, high-intensity team is an integral part of effective care delivery in the ICU and can lead to improved outcomes. However, there does not appear to be any additional benefit from 24/7 intensivist staffing within a high-intensity staffing model. Furthermore, whether an

intensivist-led, high-intensity team involves direct supervision of all care on all critically ill patients in the ICU (in person or via telemedicine) or just mandatory consultation on all critically patients in the ICU remains an unanswered question.

Process Improvement Is the Backbone of Achieving High-Quality ICU Outcomes

In the ICU, the combination of effective process of care and appropriate structure increases the likelihood that every patient will receive the correct intervention(s) at the appropriate time(s) and that the interventions will be performed properly and cost effectively. Data published during the past decade suggest that together effective organizational process and appropriate structure improve patient safety, reduce ICU mortality, and decrease ICU LOS (11, 13–17). With regard to the impact of process of care and structure on ICU costs, data from the past decade are equally impressive. Implementation of ventilator weaning protocols by multidisciplinary teams, for example, was shown to save $13,132 per patient stay (18). Implementation of a pediatric ventilator-associated pneumonia (VAP) bundle reduced hospital costs by $2.3 million over 2 years (19). Use of a central venous line infection prevention strategy saved $1.9 million per year in an adult ICU (20), whereas a similar strategy reduced the total hospital costs by $1.3 million in a PICU (21).

Since 2001, an abundance of data has been collected, suggesting that adherence to best practice guidelines is an effective means of improving the process of care in ICUs. For example, one group of investigators (22) initiated a tele-ICU system in seven ICUs of an academic medical center and showed improved adherence to best practice guidelines for deep vein thrombosis prophylaxis (99% vs 85%; $p < 0.001$) and stress ulcer prophylaxis (96% vs 83%; $p < 0.001$). These improvements were associated with significant reductions in both hospital LOS (13.3 vs 9.8 d; $p < 0.001$) and mortality (13.6% vs 11.8%; $p = 0.005$). A follow-up multicenter study by the same group of investigators identified individual components of the tele-ICU system that were associated with lower mortality, reduced LOS, or both included adherence to ICU best practices with timely use of performance data (17). Other groups have observed that checklists produce similar results (23, 24). DuBose et al (24) demonstrated that use of checklists improved compliance with evidence-based infection control bundles (e.g., VAP bundles and central line infection care bundles) and reduced VAP and central line infections. Pronovost et al (25) demonstrated that ICU daily goal sheets helped ICU groups achieve similar results. Pronovost et al also demonstrated that use of daily goals sheets led to improved understanding of goals by nurses and residents (from 10% to 95%), which was associated with a decrease in ICU LOS from 2.2 to 1.1 days. Agarwal et al (26) showed that implementation of a daily patient goal sheet in a PICU improved communication between care providers and families and was associated with a trend toward decreasing ICU LOS. Again, the USCIITG outcomes study (11) cited previously suggested that daily review of care plans was associated with significant reductions in mortality.

Studies published during the past decade also suggest that ICU structure plays an important role in the success of process improvements (27). Several investigators have demonstrated that ICUs using a multidisciplinary team structure had shorter ICU lengths of stay, cost reductions, and lower mortality. For instance, Henneman et al (18) demonstrated significantly fewer mechanical ventilation patient days (4.9-d decrease), ICU LOS (4.5-d decrease), and median cost per stay in the unit ($13,132 decrease) after a ventilator liberation process was implemented by a multidisciplinary team. Kim et al (28) analyzed data from 112 hospitals (107,324 patients) and demonstrated that daily intensivist-led multidisciplinary rounds (including physicians, nurses, respiratory care specialists, and pharmacists) were independently associated with lower mortality in ICU patients. Significant reductions in mortality were achieved even after initiating multidisciplinary rounds with low-intensity physician staffing. Donabedian (27) suggested that both process and structure are necessary to drive improved outcomes. To this end, Lilly et al (17) assessed a tele-ICU intervention in over 118,000 critically ill adults admitted to 56 ICUs in 32 hospitals and found that there was a significant reduction in mortality, shorter ICU LOS, and shorter hospital LOS with the tele-ICU intervention compared with a control group. The individual components that were most important in improving outcome included intensivist case review within 1 hour of admission, timely use of performance data, adherence to ICU best practices, and quicker alert response times. The results of these studies support Donabedian's assertion in that both structure and process are important in driving improved outcomes in the ICU. The question on whether structure or process is more important has not been adequately studied at this time.

Standardized Protocols, Including Care Bundles and Order Sets, Facilitate Measurable Processes and Outcomes Which Can Be Modified and Improved as Needed. The Importance of Measurement Cannot Be Overemphasized

Understanding and using process improvement methodology to assess the impact of changes in ICU structure is essential (13, 14). Consequently, support for data gathering and analysis is crucial. Several investigators have used intermediate outcomes to evaluate the impact of process improvements. For example, Clemmer et al (29) evaluated implementation of initiatives to modify culture, thinking, and behavior of practitioners in a tertiary ICU. They found significant improvements in glucose control, enteral nutrition, antimicrobial use, use of ancillary tests, and appropriateness of sedation after implementing their program. These intermediate outcomes were associated with reductions in mortality and significant cost savings.

Micek et al (30) used a different approach. They conducted a before-after study. Micek's group evaluated outcomes before and after implementation of a process improvement (a standardized hospital order set for management of septic shock). Importantly, the order set was not initially used, so these investigators changed the structural components of their intervention to include the use of a dedicated sepsis rapid-response team.

They found that critically ill patients with septic shock received significantly more fluids in the emergency department prior to vasopressor initiation and were more likely to receive appropriate antibiotics after the process improvement was initiated. This group also demonstrated a trend toward shorter hospital LOS (12.1 vs 8.9 d; $p = 0.38$) and significantly lower mortality (48.3% vs 30%; $p = 0.04$) after initiation of the process improvement. Morris et al (31) used yet another approach. They evaluated the relation between process measures (compliance with four elements of a VAP prevention bundle) and outcomes (VAP rates, antibiotic use, and rates of methicillin-resistant *Staphylococcus aureus* acquisition). Significant decreases in all three areas were achieved after bundle implementation.

Measuring outcomes is a crucial part of determining the impact of QI initiatives; however, measuring outcomes can also be quite challenging. Importantly, outcome measures can include LOS, mortality, patient-reported health, quality of life, and cost. However, using mortality as an outcome measure typically requires larger samples and risk adjustment for fair comparison among providers and organizations. Patients typically are interested in outcome measures, such as survival and quality of life. Unfortunately, outcomes can be impacted by numerous factors, some of which may be outside the control of caregivers. Consequently, providers are often cautious about using such information (32, 33). Nonetheless, several institutions have developed comprehensive outcomes databases (34).

Institutional Support for Measurement Must Be Provided in Order to Optimize the Success of Process Improvement Efforts

Sustaining process improvements that drive change can be as difficult as implementing and evaluating them. Sustaining process improvements requires education of all ICU staff (35) and education of and support from hospital leadership (36). Some institutions have charged multidisciplinary task forces with these duties. Others have engaged bedside practitioners (37), which promotes grass roots ownership of process improvements. The latter strategy can also require revision of clinical practice policies (37–39). To improve the likelihood that process changes will be sustained, it is imperative that the changes be imbedded into the daily workflow and not be viewed as "extra" work. The following tools and practices may help with this endeavor: 1) flow sheets posted in the ICU illustrating how new processes have been incorporated into daily workflow; 2) formal protocols for educating float staff; 3) inclusion of new processes into daily checklists completed during multidisciplinary rounds; 4) use of auditors; and 5) staff evaluations that report how frequently staff comply with new processes (32, 40–42). Other methods reported in the literature include using triggers that initiate a re-evaluation of compliance with process improvement initiatives, real-time feedback on adherence, and intermittent unannounced surveys of compliance (37, 43). Periodic reassessment can also help sustain process improvements by helping identify shortcomings that need to be addressed.

A common pitfall in driving change implementing process improvements is the failure to establish a sense of urgency (e.g., the "burning platform"). This failure translates into a lack of motivation to change (44). Motivation can be positive or negative, and data can be used to get the attention of clinicians. For example, reports of increased compliance with a severe sepsis management protocol that results in a reduction of mortality can serve as a positive motivator (40). At most institutions, understanding the barriers to initiatives that improve the quality of care will be beneficial (41). Gurses et al (42) have developed an approach that identifies barriers to new process implementation and suggests ways to overcome impediments. The method is described as the Barrier Identification and Mitigation tool and offers practical approaches to successful implementation of process improvements and structural changes.

CONCLUSIONS

The SCCM practice model guidelines published in 2001 focused on delivery of care and the roles of ICU team members. Recommendations included critical care credentialed physicians (intensivists) leading multidisciplinary teams in "closed" ICU formats. During the past decade, it has been recognized that improvements in the processes of care and ICU structure as well as the use of QI science methodologies beneficially impact patient outcomes and reduce costs. Based on published data, a new SCCM Task Force on Models of Critical Care that was convened in 2009 offers the following recommendations:

- An intensivist-led, high-performing, multidisciplinary team dedicated to the ICU is an integral part of effective care delivery.
- Process improvement is the backbone of achieving high-quality ICU outcomes
- Standardized protocols including care bundles and order sets to facilitate measurable processes and outcomes should be used and further developed in the ICU setting.
- Institutional support for comprehensive QI programs as well as tele-ICU programs should be provided.

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