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

A. T. Levinson
Division of Pulmonary, Critical Care, and Sleep Medicine, Warren Alpert School of Medicine at Brown University, Providence, RI, USA

Intensive Care Unit, Miriam, Hospital, Providence, RI, USA

M. M. Levy (✉)
Division Chief Pulmonary, Critical Care and Sleep Medicine, Warren Alpert School of Medicine at Brown University, Providence, RI, USA

Medical Intensive Care Unit, Rhode Island Hospital, Providence, RI, USA
e-mail: Mitchell_Levy@brown.edu

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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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