QUALITY IMPROVEMENT IN THE SURGICAL INTENSIVE CARE UNIT

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Ernest A. Codman, MD, was a Boston surgeon who became dissatisfied with the lack of outcomes evaluation for patient care provided at the Massachusetts General Hospital.[1] He firmly believed in recording diagnostic and treatment errors while linking these errors to outcomes for the purpose of improving clinical care. In 1911, Dr. Codman resigned his position at the Massachusetts General Hospital and opened his own hospital, focused on recording, grouping, and reporting of medical errors. In his lifetime, Codman's reforming efforts brought him ridicule, scorn, and censure and diminished his ability to earn a living. It is ironic that we now honor him as a hero and early champion of quality and patient safety.[2] Dr. Codman believed that "every hospital should follow every patient it treats long enough to determine whether the treatment has been successful and then to inquire 'if not, why not' with a view to preventing similar failures in the future."[3]

Overview of Medical and Surgical Quality System

Programs to support clinical benchmarking of surgical outcomes have grown dramatically over the past decade. These include programs administered by the American College of Surgeons (ACS): ACS-National Surgical Quality Improvement Program, ACS-Trauma Quality Improvement Program (TQIP), Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program, National Accreditation Program for Breast Centers, Commission on Cancer Accreditation Program, and the Surgeon Specific Registry.[4] The National Quality Forum (NQF) is the leading organization responsible for endorsing quality measures. Many organizations responsible for hospital accreditation and public oversight, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Centers for Medicare and Medicaid Services (CMS), rely on the endorsement of the NQF prior to applying a quality measure to practice in evaluating clinical performance.

Regional collaborative-based quality improvement (CQI) programs have gained in prominence over the last 10 years. Examples of these include formal statewide trauma systems, third-party payer–sponsored organizations, and physician-led voluntary surveillance systems. Blue Cross Blue Shield of Michigan and Blue Care Network (BCBSM/BCN) have sponsored a large number of innovative examples of CQIs on a statewide basis [*see Table 1*]. The Value Partnership Program of BCBSM/BCN, composed of 16 statewide clinical registry-based collaboratives involving multiple specialties, enrolls 200,000 patients annually, costs over $25 million per year to administer, and generated an estimated $1.4 billion in health care savings. To focus on improving the quality of care delivered to trauma patients, BCBSM/BCN supports the Michigan Trauma Quality Improvement Program (MTQIP).[5]

Examples of BCBSM/BCN regional CQI successes include a decline in risk-adjusted morbidity from 13.1% in 2005 to 10.5% in 2009 for general and vascular surgery patients ($p < .0001$) and a fall in overall complications for bariatric surgery from 8.7% to 6.6% associated with a significant drop in 30-day mortality from 2007 to 2009 ($p = .004$).[6] Improvements in quality were achieved in the interventional cardiology collaborative with reductions in contrast-associated nephropathy, stroke, and in-hospital myocardial infarction. Lastly, the cardiac surgery collaborative improved its composite quality score for Michigan participants from average on a national basis to achievement of a three-star rating from the Society of Thoracic Surgeons. This is indicative of aggregate performance that exceeds national norms with a 99% probability and falls within the top 10th percentile of all hospitals.

The Northern New England Cardiovascular Disease Study Group (NNECDSG) and the Surgical Care and Outcomes Assessment Program (SCOAP) in Washington are examples of regional voluntary consortiums.[7,8] The NNECDSG was founded in 1987 to provide information about the management of cardiovascular disease in Maine, New Hampshire, and Vermont. The group has made many significant contributions to the standardization of management for cardiac surgery patients in ways that have reduced mortatily.[9,10] The SCOAP is a physician-led, voluntary collaborative in the state of Washington that has created an aviationlike surveillance and response system for surgical quality. The program's goal is to improve quality by reducing variation in outcomes and process of care at every hospital in the region. The SCOAP has positioned itself as an opportunity for Washington State payers and health care administrators to work jointly with surgeons to improve the quality of care without turning over that responsibility to a national organization.[8]

Commercial proprietary programs to record and assess surgical outcomes are also available. The University Health Consortium (VHA-UHC Alliance NewCo, Inc., Irving, Tx; https://www.uhc.edu/) and The Leapfrog Group (Washington, DC; http://www.leapfroggroup.org/) are the two best-known commercial programs. The UHC is a coalition of academic medical centers across the United States, which over 30 years has developed objective data-driven metrics for global quality improvement at the hospital level. The Leapfrog Group is an employer-based partnership that advocates for improved transparency, quality, and safety in hospitals as part of a value-based purchasing initiative. Hospitals are rated on survey results and a hospital safety score. The hospital safety score is almost completely derived from measures related to surgical outcomes.

Programs designed to specifically evaluate performance and provide feedback for intensive care unit (ICU) quality have suffered from a lack of consensus over what to measure and how to organize this effort. The Institute of Medicine defines quality in health care as care that is safe, timely,

Scientific American Surgery
DOI 10.2310/7800.2260

Table 1 Blue Cross Blue Shield of Michigan/Blue Care Network–Sponsored, Registry-Based Collaborative Quality Initiatives

CQI Name	*Specialty*	*Basis*
Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE)	Anesthesia	Hospital
BCBSM Cardiovascular Consortium-Percutaneous Coronary Intervention (BMC2-PCI)	Interventional cardiology	Hospital
BMC2-Vascular Interventions Collaborative (BMC2-VIC)	Vascular interventions	Hospital
Michigan Arthroplasty Registry Collaborative for Quality Improvement (MARCQI)	Orthopedic surgery	Hospital
Michigan Bariatric Surgery Collaborative (MBSC)	Bariatric surgery	Hospital
Michigan Breast Oncology Quality Initiative (MiBOQI)	Breast cancer	Hospital
Michigan Emergency Department Improvement Collaborative (MEDIC)	Emergency medicine	Hospital
Michigan Hospital Medicine Safety Consortium (HMS)	Internal medicine	Hospital
Michigan Radiation Oncology Quality Consortium (MROQC)	Radiation oncology	Hospital
Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative (MSTCVS)	Cardiac surgery	Hospital
Michigan Spine Surgery Improvement Collaborative (MSSIC)	Spine surgery	Hospital
Michigan Surgical Quality Improvement Collaborative (MSQC)	General and gynecologic surgery	Hospital
Michigan Trauma Quality Improvement Program (MTQIP)	Trauma surgery	Hospital
Genetic Testing Resource and Quality Consortium (GTRQC)	Genetic Testing	Professional
Michigan Transitions of Care Collaborative (M-TC2)	Physician organizations	Professional
Michigan Urological Surgery Improvement Collaborative (MUSIC)	Urologic surgery	Professional

BCBSM = Blue Cross Blue Shield of Michigan; CQI = collaborative quality initiative.

effective, efficient, equitable, and patient centered.[11] Donabedian is responsible for describing the classic model of health care quality improvement, which includes three key components: structure, process, and outcomes.[12] Structure is indicative of the attributes of the setting or system in which health care is provided and these are typically hospital-level attributes (e.g., nurse-to-bed ratio, closed intensivist-managed ICU, trauma center verification). Process is the intervention provided in the clinical setting to the patient, such as time to antibiotic administration for sepsis. Adherences to processes of care are sometimes mandated, as well as their data collection (e.g., CMS Surgical Care Improvement Program). There are processes that apply widely to almost all surgical patients, such as measures to reduce surgical site infections; others are targeted to specific groups of patients (e.g., goal-directed therapy for sepsis resuscitation). Measurement of outcomes reflects the end result of care provided to the patient for the condition present. Outcomes can be interpreted in many ways: crude, stratified, or risk-adjusted rates are common approaches to presenting the data. Sample size and prevalence of adverse outcomes will also determine the usefulness of measurement and reporting for a particular outcome.

Within the discipline of critical care medicine, few performance measures have been implemented. The Critical Care Societies Collaborative (CCSC) has focused its efforts to address this gap in measurement. The CCSC Quality Improvement Task Force has identified and prioritized areas for performance measurement in critical care [*see Table* 2].[13] Commercial proprietary programs to record and assess ICU outcomes are also available. The Acute Physiology and Chronic Health Evaluation (APACHE) system (Cerner Corp., North Kansas City, MO) for tracking ICU outcomes is the most prevalent program used. Cerner Project IMPACT, Inc. (Bel Air, MD) was a joint venture between Cerner Corporation and the Society of Critical Care Medicine. Cerner Project IMPACT focused on the development of ICU improvement modules directed toward measurement and improvement of ICU performance. Cerner Corporation now owns APACHE and has incorporated Project IMPACT into this product, which is offered as a stand-alone piece of software or can be incorporated into the electronic medical record (EMR) environment.

One of the first critical care performance improvement projects to demonstrate success occurred when administrators from the Michigan Health and Hospital Association partnered with 108 adult ICUs throughout Michigan to form the Keystone Center for Patient Safety and Quality.[14] This initiative began in 2003 with participants beta-testing ICU core measures proposed by the JCAHO. These measures were targeted at decreasing complications in mechanically ventilated ICU patients. Adherence to process measures aimed at reducing ventilator-associated pneumonia, catheter-related bloodstream infections (CRBSIs), thromboembolic events, and gastrointestinal bleeding from stress ulceration was investigated. Each ICU provided data prior to these patient safety interventions and after each intervention had been implemented. The mean CRBSI rate dropped by 66% from 7.7 per 1,000 catheter days to 1.4 per 1,000 catheter days 18 months after implementation of the core measures.[14] Through ongoing participation, the rate of CRBSIs has continued to decline and is now at 0.6 per 1,000 catheter days as of 2011.[15]

Table 2 Critical Care Societies' CQI Task Force Priorities for Performance Measurement

Management of sepsis
Overuse in blood transfusions
Ventilator-associated pneumonia and mechanical ventilation
Risk-adjusted ICU outcomes
Therapeutic hypothermia
Daily chest radiographs in ICU patients
Screening of acute lung injury (ALI/acute respiratory distress syndrome)

ICU = intensive care unit

Identification of ICU policies and practices associated with good patient outcomes and efficient resource use can provide insight into relevant targets for ICU performance improvement. Using APACHE III data, the best-performing hospitals for mortality had decreased ICU length of stay and hospital length of stay and admitted fewer low-risk monitor patients. Hospitals with the shortest ICU and hospital length of stay had access to alternatives to intensive care and methods to facilitate patient throughput and used standardized protocols for high-volume diagnoses and care processes. These hospitals also continuously monitored resource use and screened potential admissions.[16]

Development of an ICU Quality Improvement Program

For an ICU to have a successful quality improvement program, there must be physician and nursing champions who are passionate about critical care performance. Quality improvement in critical care includes patient outcomes, patient and family satisfaction, and patient safety. ICU patients are more vulnerable to medical errors given the complexity and number of interventions, the severity of illness, time spent in hospital, and breadth of care being provided. Motivation to solve problems and a culture of ownership are crucial to the success of quality improvement efforts.

Review of one's own ICU data is the first step in the quality improvement process. There are many potential ICU quality measures, and these can be within the domains of structure, process, or outcomes [*see Table 3*]. Understanding how data are collected, relevant definitions, current care guidelines or best practices and when the ICU started each measure, case mix, and severity of illness measures are important in deciphering true changes over time. Regarding data collection, whether it is intended for a local project or a national collaborative, the data abstractor must be trained and provided with standardized data definitions for data elements to be collected. Whenever possible, the data entered should be audited for interrater reliability. Harnessing the power and efficiency of electronic data abstraction and entry should be considered, with the caution that periodic checks of data accuracy, completeness, and validity are vital to reliable use of data capture in this manner. An added benefit is that electronic data capture can help enforce compliance with protocols in real time, without the need for increased staffing for data collection.[17] Regular reporting of ICU outcome data and review of the data with representatives from the surgical and nursing teams along with the other ancillary services will help determine problem areas. Discussion of potential issues among those who directly care for patients is essential to understanding areas for performance improvement or what impediments may prevent successful implementation of new processes. If ongoing trends are identified, intervention with a detailed action plan is warranted.

Table 3 Possible ICU Quality Measures

Performance Measure	*Measurement*
Structure measures	
Procedure volume	Number
Intensivist-managed ICU	Yes/no
Nurse-to-patient ratio	Ratio
Trauma center designation	Yes/no/level
Daily huddle and goals of care	Yes/no
Line insertion cart	Yes/no
Viscoelastic testing	Yes/no
Process measures	
VTE prophylaxis	Type, timing
Stress ulcer prophylaxis	Type, timing
Ventilator-associated pneumonia prevention strategies	Adherence
Fluid resuscitation for sepsis (amount and timeliness)	Amount, timing
Antibiotic administration for sepsis (appropriate and timely)	Type, timing
Ratio of PRBCs to FFP in massive transfusion	Ratio
Line insertion checklist	Adherence
Indwelling urinary catheter removal	Adherence
Outcome measures	
Unplanned extubation rate	Rate
Ventilator-associated pneumonia rate	Rate
CRBSI	Rate
Ventilator days	Days
ICU length of stay	Days
ICU readmission	Rate
ICU admission rate	Rate
Mortality	Rate

CRBI = catheter-related bloodstream infection; FFP = fresh frozen plasma; ICU = intensive care unit; PRBC = packed red blood cell; VTE = venous thromboembolism.

Assembly of the quality improvement team within an ICU setting requires extensive insight into the mechanisms of change within one's own institution and the ability to provide leadership and structure without stifling innovation. The ICU director should think broadly and seek balance when selecting disciplines and individuals to populate the team [*see Figure 1*]. Pursue motivated people who work well with others, are already busy, and therefore are capable of getting things done. Ensure that mechanisms are in place to obtain advice, counsel, feedback, and criticism and to provide ongoing education. Tear down and destroy barriers that promote fear. Be sure to share credit for success widely and have

the ability to shoulder responsibility for failure if you are the leader. In the end, analytics are the tools of the trade (hammer, saw), the performance improvement process is the blueprint, and data are the raw materials. It is then up to the quality improvement team to construct a valuable result in an efficient manner.

Scoring Systems: Risk Assessment

Several predictive scoring and severity assessment systems are available in the critical care setting to gauge organ dysfunction and model patient outcomes [*see Table 4*]. The four major ICU predictive scoring systems used in the ICU setting are the APACHE system, the Simplified Acute Physiologic Score (SAPS), the Mortality Prediction Model (MPM), and the Sequential Organ Failure Assessment (SOFA). Additional scoring or outcome measurement systems have been developed for single organs (kidney: Risk, Injury, Failure, Loss and End-stage kidney disease [RIFLE]; liver: Model for End-Stage Liver Disease [MELD]), specialties (trauma: ACS-TQIP, MTQIP), and disease states (postinjury multiple organ failure: Denver Postinjury Multiple Organ Failure Score).

Predictive scoring systems work by taking known clinical variables and deriving a numerical or severity score for the outcome of interest. The derived severity score is typically entered into a mathematical equation where the solution yielded represents the likelihood of mortality for an ICU patient during hospitalization. Relationships between the severity score and mortality are determined empirically from large data sets. Hence, a predictive scoring system cannot reliably derive outcomes for types of patients that were not

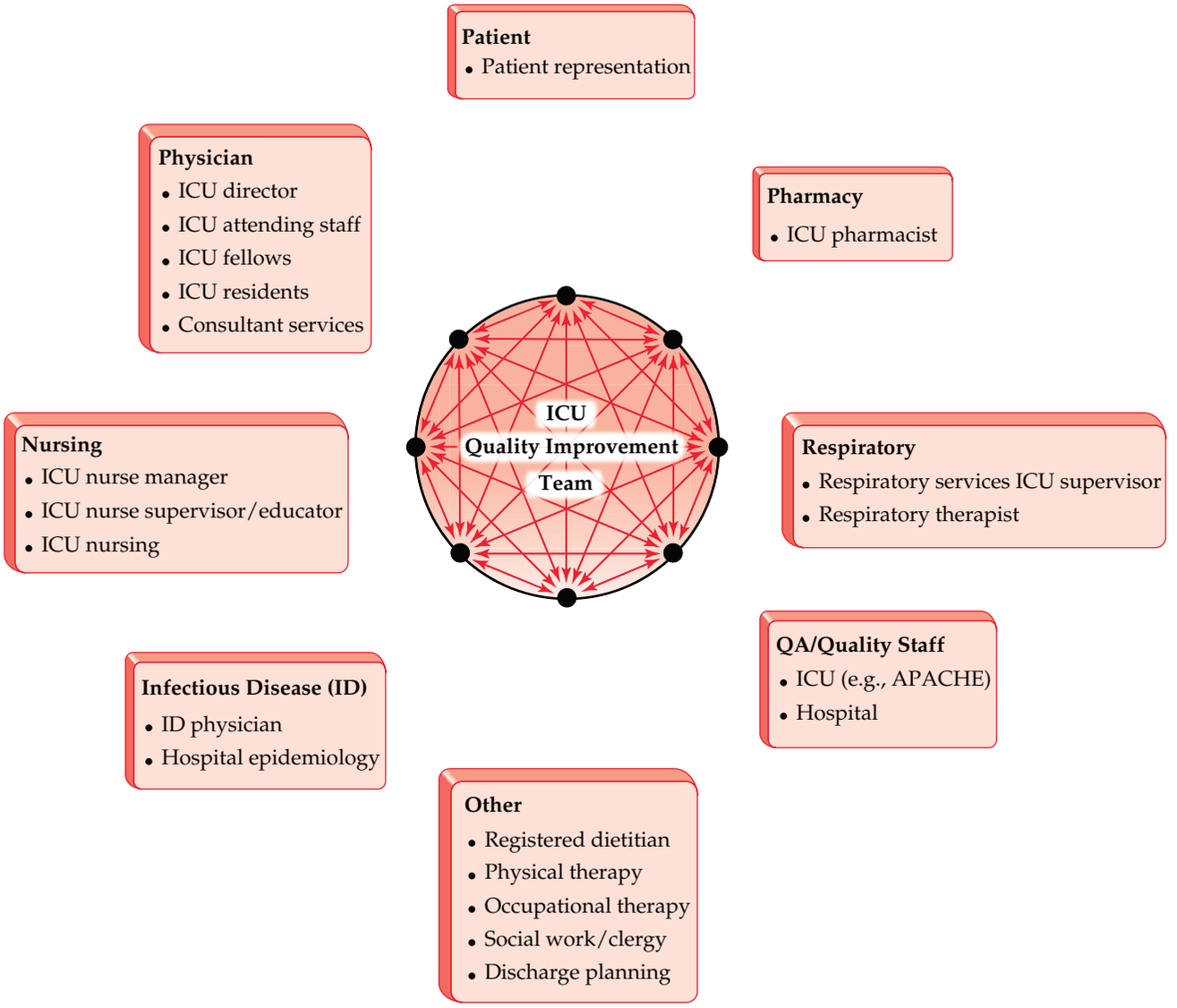

Figure 1 **Structure of the intensive care unit (ICU) quality improvement team.**
APACHE = Acute Physiology and Chronic Health Evaluation; QA = quality assurance.

Table 4 Predictive Scoring Systems

Name	*Acronym*	*Disease/Organ*	*Outcome or Measure*
Glasgow Coma Scale score	GCS	Brain	Level of consciousness after head injury
New York Heart Association functional classification	NYHA	Heart failure	Physical activity limitation, symptoms
Risk, Injury, Failure, Loss and End-stage kidney disease criteria	RIFLE	Kidney failure	Severity of acute kidney injury
Acute Kidney Injury Network classification	AKIN	Kidney failure	Staging system for acute kidney injury
Child-Pugh-Turcotte score	—	Liver failure	Mortality
Model for End-Stage Liver Disease	MELD	Liver failure	Transplantation planning
Ranson criteria	—	Pancreatitis	Mortality
American Association of Anesthesiologists physical status classification	ASA	Global	Overall physical health
Denver Postinjury Multiple Organ Failure score	Denver MOF	Global	Severity of multiorgan failure in trauma patients
Multiple Organ Dysfunction Score	MODS	Global	Mortality, ICU length of stay
Sequential Organ Failure Assessment	SOFA	Global	Mortality
Acute Physiologic and Chronic Health Evaluation system	APACHE	ICU	Mortality, ICU length of stay
Simplified Acute Physiologic Score	SAPS	ICU	Mortality
Mortality Prediction Model II	MPM II	ICU	Mortality
Abbreviated Injury Scale	AIS	Trauma	Anatomic severity of injury
Injury Severity Score	ISS	Trauma	Mortality, morbidity, length of stay
Trauma Score - Injury Severity Score	TRISS	Trauma	Mortality
Revised Trauma Score	RTS	Trauma	Mortality
American College of Surgeons Trauma Quality Improvement Program	ACS-TQIP	Trauma	Mortality, morbidity, length of stay
Michigan Trauma Quality Improvement Program	MTQIP	Trauma	Mortality, morbidity, length of stay

ICU = intensive care unit.

included in the derivation data sample, or in this case, outside the ICU setting. Essential features of a meaningful predictive scoring system are that it measures an outcome of importance and that the software or instrument is easy to use. Collection of vast amounts of data that do not contribute to the risk adjustment, measured outcomes, or processes of care employed is time consuming and costly.

Understanding how predictive scoring systems perform relies on the statistical principles of model discrimination and calibration. Discrimination is the ability of a scoring model to predict an outcome given the covariates measured and is assessed by the area under the receiver operating characteristic curve (AUC) or C-index. Discrimination ranges from 0.5 to 1.0, with 1.0 being perfect discrimination. If a scoring model predicts a mortality of 7% and the observed mortality in the same cohort is 7%, then the discrimination is 1.0 or perfect. In practice, a discrimination value greater than 0.7 is usually acceptable. Calibration describes how the model performs over a wide range of predicted values. Calibration is often presented as a graph of observed to expected values over the entire range of possible values for a measured outcome [*see Figure 2*]. The Hosmer-Lemeshow test assesses calibration as a goodness-of-fit statistic.[18] A highly calibrated scoring system is accurate at predicting outcomes over the entire range of possibilities: low, medium, and high rates. When using statistical modeling, this quotation from the British mathematician and professor of statistics George E.P. Block is important to keep in mind: "Essentially, all models are wrong, but some are useful."[19] Underlying this principle is the fact that actual outcomes are binary (true or false), whereas statistical model predictions are decimal values between 0 and 1.

Institutional ICU results are often expressed as the ratio of observed to predicted events (O/E ratio), which is called the standardized mortality ratio (SMR) when the benchmarked outcome is mortality. This is done by summing the observed patient mortality events (0 or 1) and dividing by the sum of the predicted mortality values (decimal between 0 and 1) for all of the patients in the cohort of interest. Statistical significance is then denoted by an associated confidence interval.[20] A confidence interval that spans across 1 represents average performance. A confidence interval greater than 1 is indicative of high outlier status, and a confidence interval less than 1 represents low outlier status. Multiplying the O/E ratio by the average percent mortality produces an adjusted mortality, which is sometimes easier for end users to interpret.

The most recent version of the APACHE system is APACHE IV. Many clinical variables are required and include age, diagnosis, previous treatment location, physiologic values, and chronic health descriptors. APACHE relies on the worst

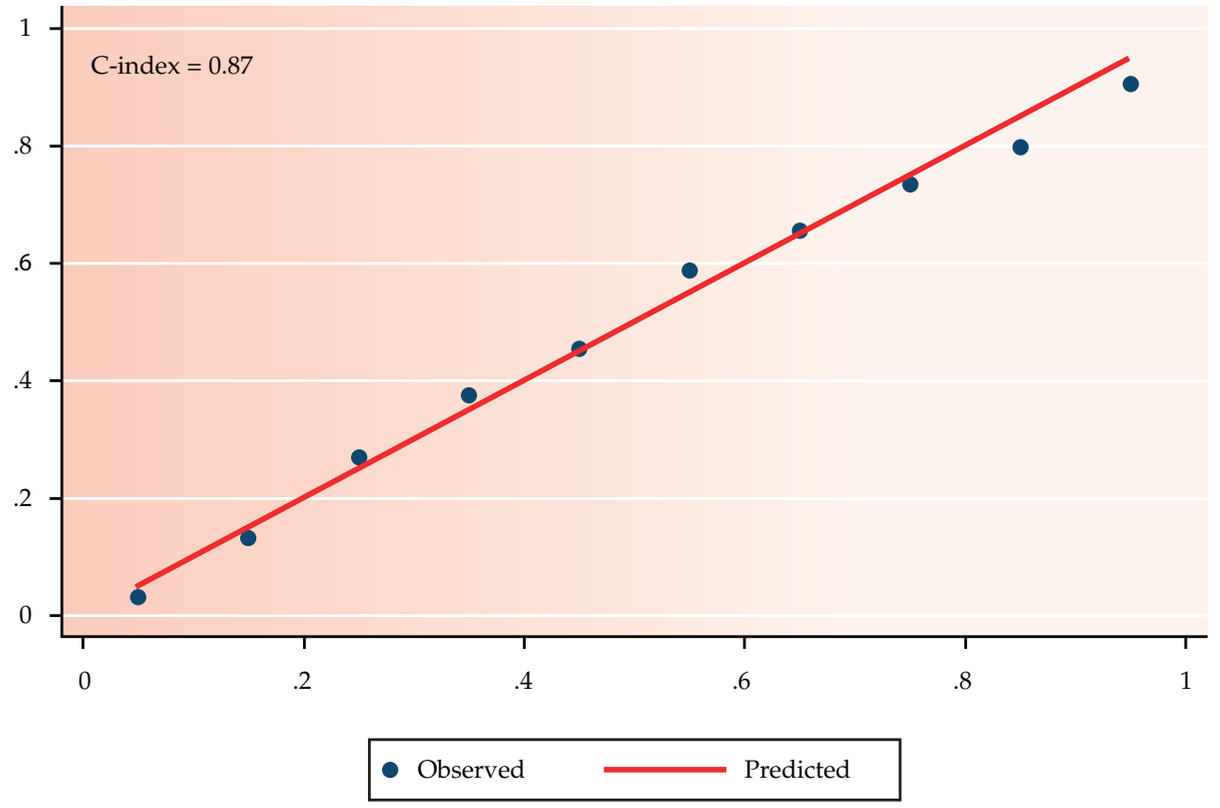

Figure 2 **The C-index statistic reflects the ability of a model to predict which patients will have the outcome of interest. A C-index of 0.5 indicates the model has discrimination power no better than the flip of a coin; a C-index between 0.6 and 0.7 has a limited discrimination power; a C-index between 0.7 and 0.8 implies moderate discrimination power; and a C-index of 1.0 indicates the model has perfect discrimination. For a model to have acceptable discrimination power, the C-index must exceed 0.7. Model calibration is a measure of how well the model fits the data at select levels of risk. Calibration is demonstrated by comparing observed and predicted outcomes across the range of risk for the outcome.**

values from the initial 24 hours after initial ICU admission. From the clinical covariates, a severity score is derived; this score is then entered into a logistic regression equation, and hospital mortality is the outcome predicted. APACHE models require periodic retesting and revision as their accuracy decreases over time due to changes in treatments and other factors affecting ICU mortality. APACHE IV predicts mortality better than APACHE III and also predicts ICU length of stay.[21,22]

The SAPS uses 17 variables collected in the initial 24 hours of ICU admission.[23] Twelve of the 17 variables are physiologic measures. The variables tend to be dichotomous (either present or absent; e.g., metastatic carcinoma) or are continuous variables that have been made categorical by designation of points to value ranges (e.g., age). A higher SAPS score represents a more severe level of patient illness, and the score is entered into a formula that predicts hospital mortality.[24] SAPS III has good discrimination but poor calibration in studies evaluating outcomes from multiple ICUs.[25,26]

In the MPM II, a severity score is calculated from 15 variables assessed at the time of ICU admission. With the exception of age, all of the model inputs are dichotomous and assigned a value of 1 point if present. The point total represents the MPM score, and this score, along with age, is entered into a mathematical formula, which generates a predicted mortality. The MPM score can be revised after 24 hours by updating seven admission values and adding results for six more variables. The MPM24-II prediction can be compared with SAPS and APACHE because all three of these predictive scoring systems are determined after the initial 24 hours of ICU admission.[27,28]

The SOFA uses a straightforward determination of major organ function in six different organ systems to calculate a severity score. Scores are compiled 24 hours after ICU admission and every 48 hours until ICU discharge.[29] The mean and highest scores are most predictive of patient mortality. A relative increase in the SOFA score by 30% is associated with a mortality of 50% or greater.[30]

ICU scoring systems have many limitations. Risk adjustment may or may not be present. The credibility of a scoring system is often closely linked to its ability to satisfy end users' desire for satisfactory risk adjustment based on patient factors. Acute physiologic parameters are used in some models employed to predict outcomes. For surgical patients, negative perturbations in laboratory studies and vital signs can often be improved prior to ICU admission due to operative intervention or emergency department/operating room resuscitation. These changes can lead to ICU admission scoring that is falsely low, highlighting the importance of scoring patients at time 0 into the system rather than at the time of ICU admission. Many surgical patients are not adequately scored within ICU indices because cardiac, pediatric, trauma, and burn surgery patients are often excluded from model creation data sets.

Lastly, unmeasured confounding (risk factors associated with the outcome that are distributed unevenly across groups of interest) can lead to biased conclusions.[31]

Evidence-Based Medicine and Protocols

The ICU is rife with studies examining how to improve outcomes for various disease states such as sepsis, hemorrhagic shock, myocardial infarction, and respiratory failure. In addition to reviewing one's own ICU data for specific areas that could be improved using the structure, process, and outcomes model, implementation of results from major evidence-based studies in critical care is extremely important. Two areas that have garnered much attention and have had a major impact for surgical patients are recognition/resuscitation for septic shock and resuscitation for hemorrhagic shock.

SEPSIS

Every year, over 1 million Americans experience severe sepsis or septic shock. Despite improved outcomes from sepsis, the rate of hospitalization for sepsis has more than doubled from 2000 to 2008.[32] In 2002, the Surviving Sepsis Campaign, a joint collaborative of the Society of Critical Care Medicine and the European Society of Intensive Care Medicine, was launched to promote the creation of evidence-based guidelines, implementation of a performance improvement program, and analysis of patient data for publication (http://www.survivingsepsis.org/). Best practices included screening for sepsis and performance improvement, diagnosis of infection, protocol-driven resuscitation, appropriate and early antibiotic administration, source control, and infection prevention.[32–35] These recommendations were primarily based on a single–center, prospective, randomized clinical trial of protocol-driven early goal-directed therapy (EGDT) versus standard care to patients presenting to the emergency department with early septic shock.[35] Despite disagreement about what particular aspects of care were most beneficial, this study demonstrated a 16% absolute reduction in 28-day mortality for patients who received early quantitative resuscitation in the emergency department. A multicenter trial in China confirmed this result with a finding of 18% absolute reduction in 28-day mortality for sepsis patients undergoing EGDT (survival rates 75.2% versus 57.5%, $p = .001$).[36]

To further assess which aspects of resuscitation contributed to improved mortality, three different groups, the Protocolized Care for Early Septic Shock (ProCESS) Investigators from the United States, the Australasian Resuscitation in Sepsis Evaluation (ARISE) Investigators from Australia and New Zealand, and the Protocolised Management in Sepsis (ProMISE) Trial Investigators from Great Britain, conducted multicenter, prospective, randomized clinical trials for EGDT of septic shock. The results from these three trials, published during 2014 and 2015, found that EGDT resuscitation using a defined protocol for septic shock did not improve mortality outcomes.[37–39] A commonality among these studies was administration of almost 2 liters or more of intravenous crystalloid fluid resuscitation prior to patient randomization. Hence, a clinical bias toward early fluid resuscitation was so predominant prior to initiation of these studies that all patients received and benefitted from crystalloid resuscitation. The additional adjunctive strategies in the protocol of central line placement and central venous pressure monitoring, central venous oxygenation saturation–guided resuscitation, and red blood cell transfusions were found to be not as important in determining mortality outcome.

Despite the nonsupportive study findings for the global EGDT process, the literature does continue to support early fluid resuscitation and timely antibiotic administration for severe sepsis and shock.[40] These processes are believed to be so vital to patient outcomes that the CMS has now instituted early sepsis management bundles that will require hospital compliance with obtaining lactate levels and blood cultures, broad-spectrum antibiotic administration, early fluid and vasopressor administration, and reassessment of volume status.[41] The first three components, lactate measurement, blood cultures, and antibiotics, are required within 3 hours of shock presentation, with the remaining components to be performed and documented by the end of 6 hours. Similar to the institution of the early Surviving Sepsis Campaign and ICU core measures, which both led to improvements in ICU outcomes, this mandate is based on positive outcomes data and would be advantageous for any ICU or hospital to implement.

MASSIVE TRANSFUSION IN TRAUMATIC HEMORRHAGE

Another important focus for evidence-based quality improvement in surgical ICUs surrounds the issue of blood product administration and ratios for trauma patients in hemorrhagic shock. Although a trauma patient with major hemorrhage may receive treatment in the emergency department or operating room prior to ICU admission, knowledge and provision of rapid, appropriate, ongoing resuscitation in the ICU are vital to patient outcomes. Using data from the Iraq and Afghanistan conflicts, the United States military demonstrated improved survival following massive blood product transfusion for combat-related injuries in patients who received a ratio of packed red blood cells (PRBCs) to fresh frozen plasma (FFP) of 1:1.4 or less.[42]

Based on this evidence, many civilian trauma centers adopted massive transfusion and damage-control resuscitation protocols that aim to deliver a set ratio of PRBCs to FFP consistent with a 1:1 or 1:2 ratio.[43] Damage-control resuscitation principles have been associated with improved outcomes compared with more traditional transfusion practices.[43–45] However, other studies report beneficial outcomes across a wider range of blood product ratios or using goal-directed approaches with viscoelastic monitoring.[46] Concerns about the safety of exposing injured civilian patients to large amounts of plasma-containing blood products led to the conduct of a multicenter, prospective, randomized clinical trial.[47,48] The Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR) trial was designed to address the effectiveness and safety of a 1:1:1 transfusion ratio (PRBCs, FFP, platelets) compared with a 1:1:2 transfusion ratio in trauma patients predicted to receive a massive transfusion.[49] The results from the trial showed that in patients with severe trauma and major bleeding, early administration of plasma, platelets, and red blood cells in a 1:1:1 ratio compared with a 1:1:2 ratio was safe and did not result in significant differences in mortality at 24 hours or at 30 days. More patients in the 1:1:1 group achieved hemostasis and fewer experienced death due to exsanguination by 24 hours.

Based on this evidence, trauma centers are encouraged to track and perform performance improvement with regard to blood products transfused and ratios achieved for patients with major hemorrhage. Benchmarking feedback is available in quality improvement programs on the national (ACS-TQIP) and regional (MTQIP) levels. The MTQIP collaborative tracks and scores the ratios of blood products achieved by participant hospitals as part of its hospital CQI performance index measure. The collaborative promotes sharing of best practices and techniques for massive transfusion protocol implementation and adherence. Smaller trauma centers often have unique barriers to ready availability of thawed FFP. Sharing of ideas has found that these centers can alter the ratios in massive transfusion protocol blood packs to achieve rapid catch-up (initial pack with PRBCs only and second pack with a high ratio of FFP to PRBCs). The MTQIP has also emphasized education of providers through presentations at meetings by national experts and dissemination of the published ACS-TQIP guidelines for massive transfusion.[50] Data reporting is provided to trauma centers on performance in aggregate and on an individual patient basis with regard to blood product ratios.

CAVEATS

There are many additional areas whereby surgical ICUs can improve patient care by drafting and implementing protocols of their own using evidence-based medicine. Taking available information in the medical literature and applying it to one's own ICU requires commitment and devotion of time. Successful implementation is dependent on provision of relevant education, communication with all stakeholders, clear demonstration of the rationale for change/standardization, and buy-in from participants called on to follow a new guideline or clinical pathway. The implementation, monitoring, and follow-up phase is where many failures occur. Starting with a known protocol where others have been successful at changing practices and improving outcomes is often easier than beginning fresh without a known template. Dividing the process into workable pieces and devising a timeline for assignments to keep the task on track and those responsible accountable are also advantageous.

Caution must be taken in instances where extrapolation of published work to new or broader populations may occur. An example of this occurring is in the widespread implementation of tight glucose control after a single study showing improved mortality and morbidity in the surgical ICU. Tight glucose control did not have an impact on mortality when applied to the medical ICU, and the practice was later found to be harmful in some patient groups.[51–53] Careful consideration of the specific patient group to be targeted and monitoring for adverse outcomes is essential when implementing a new practice guideline or protocol.

Quality Improvement Framework

Much of the conceptual approach to quality improvement can be traced back to W. Edwards Deming.[54] Deming was a mathematical physicist who traveled to Japan in 1947 to participate in the postwar rebuilding effort. The quality improvement framework exposed by Deming and others focuses on unnecessary variation, systems to improve processes, emphasis on workflow, and elimination of waste. Edwards Deming and Walter Shewhart created statistical process control, whereby a process is monitored over time by looking for variation that exceeds a desired level of performance. Plots of outcome rates over time with upper and lower confidence intervals are an ICU example of Deming and Shewhart's statistical process control [*see Figure 3*].

Returning to the structure, process, and outcome approach to quality and applying this concept to data collection in the ICU, we can see the benefits and pitfalls of each component. For the Keystone central line initiative, Pronovost and colleagues had to convince and ensure that the administration at each hospital would commit to and provide central line carts stocked with chlorhexidine skin preparation solution and the requested sterile supplies.[14] The central line cart with a specific list of required supplies is a structural element in the quality improvement process.

Use of the provided supplies every time in the standardized manner when inserting a central line is an example of adherence to a process. Documenting the process measures adhered to in each instance of insertion of a central line, using a checklist, is likely more amenable to monitoring

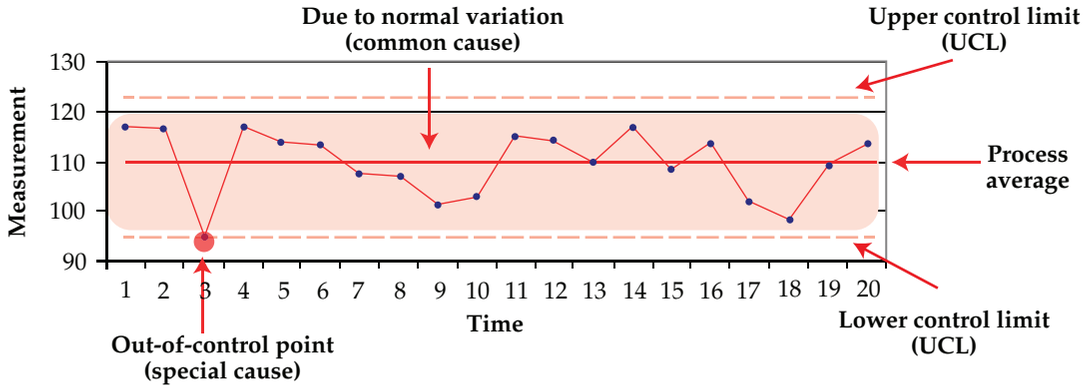

Figure 3 **Shewhart statistical process control chart.**

than recording outcomes for two reasons. First, the process measures are frequently present (use of full barrier precautions); second, the number of process events is significantly greater than the number of adverse outcome events (CRBSI). If a provider is not adhering to the checklist, it may take a substantial amount of time before the occurrence of a CRBSI is identified. However, the provider's adherence or nonadherence to the process can be observed immediately.

Outcomes are the component that patients and providers care about most. However, in practicality, they typically occur much later in the course of care than variations in process measures (e.g., mortality from sepsis due to poor source control, delayed antibiotic administration, and insufficient resuscitation may not occur until after days or months of ongoing progressive organ failure have happened). Some outcomes are very infrequent and do not lend themselves well to measurement compared with measurement/management of process or structure variables. The quality management tactical strategies of Deming and Shewhart to statistically monitor processes are most beneficial when integrated into the entire structure, process, and outcomes paradigm endorsed by Donabedian.[12]

The single most helpful and powerful quality improvement tool with which to implement statistical process control and structure, process, and outcomes principles is the Plan-Do-Study-Act cycle. This infrastructure was developed by Walter Stewart in the 1920s to focus quality improvement efforts on loop closure.[55] The subsequent clinical case example is meant to illustrate all of the principles covered in this review and demonstrate facets of one institution's approach to identifying a critical care problem, developing an action plan, implementing the plan, monitoring, and evaluating for the success or failure of the actions taken.

CASE STUDY

The Problem

In one of the MTQIP reports (Report #5), the University of Michigan Trauma Center was a high outlier for venous thromboembolism (VTE), with a crude rate of 5.6% [*see Figure 4*]. The University of Michigan previously exhibited average performance with a VTE rate between 4.0 and 4.8% and a 1.0 O/E ratio. In a subsequent report (Report #6), the crude VTE rate was even higher at 6.0%, which triggered an investigation, analysis, and performance improvement action plan.[56]

The Response

The response consisted of a review of the data by the University of Michigan Surgical Champion, the trauma medical director, and the director of the trauma and burn ICU. A list of potential circumstances responsible for this increase in VTE events was compiled:

- Deemphasis by providers in choosing enoxaparin 40 mg subcutaneous once per day as the preferred agent for VTE prophylaxis for trauma patients
- Electronic order entry pick-list placement of the order for heparin 5,000 units subcutaneous three times per day first and enoxaparin 40 mg subcutaneous once per day second on the list for trauma patient VTE prophylaxis
- Potential poor compliance with timely initiation of VTE prophylaxis once bleeding contraindications were alleviated
- No feedback on results or measurement of compliance with the existing trauma service guideline for VTE prophylaxis
- Excessive holding of VTE prophylaxis drug doses due to uncertainty surrounding operative interventions and procedures

It was decided to retrospectively abstract VTE prophylaxis drug type and timing for patients in a previous set of MTQIP data. An analysis was conducted to examine the relationship of drug type to VTE rates with adjustments made for timing of the first dose of VTE prophylaxis.

Data Analysis

Patients receiving enoxaparin experienced half the rate of VTE events when compared with those who received heparin following multivariate adjustment [*see Table 5*]. The same finding was obtained in a propensity-matched cohort.

The Plan

After accounting for injury severity and patient factors, prophylaxis with enoxaparin was associated with a significantly decreased rate of VTE events compared with heparin for patients admitted to the University of Michigan trauma service. The results of this analysis were shared widely with trauma service staff and other institutional stakeholders. An education session for providers was held with William H. Geerts, MD, an expert on VTE prophylaxis, during a visit to the University of Michigan specifically in regard to evidence supporting the use of enoxaparin (low-molecular-weight heparin [LMWH]) dosing of 30 mg subcutaneous twice per day in trauma patients.[57] The University of Michigan trauma service standard at the time was a single 40 mg subcutaneous enoxaparin dose with morning administration. However, use of a single morning dose led operationally to 48- to 72-hour lapses in VTE prophylaxis coverage, especially if a dose had been held for a procedure and the procedure was delayed until the subsequent day. Review of data at MTQIP meetings and survey results showed many trauma centers to be preferentially using LMWH as their pharmacologic VTE prophylaxis agent. Additionally, an article published by an MTQIP participant trauma center showed that traumatic brain injury patients can safely receive VTE prophylaxis once a stable clinical and radiologic examination is achieved.[58]

The following action plan was formulated and initiated:

- One drug for VTE prophylaxis: enoxaparin
- One dosage: 30 mg subcutaneous twice per day (am and pm administration)
- Education and inclusion of subspecialty providers (neurosurgery and orthopedics)
- The only exceptions to initiating VTE prophylaxis were bleeding contraindication, unstable traumatic brain injury/epidural hematoma, or low-risk patient (ambulatory and likely to be discharged home).
- We aimed to minimize holding of drug doses. For a next-day procedure, the last dose is 30 mg given in the evening the day before a schedule procedure. The dose due in the morning on the day of procedure is held. Dosing is resumed in the evening of the day of procedure unless problems are encountered (bleeding).

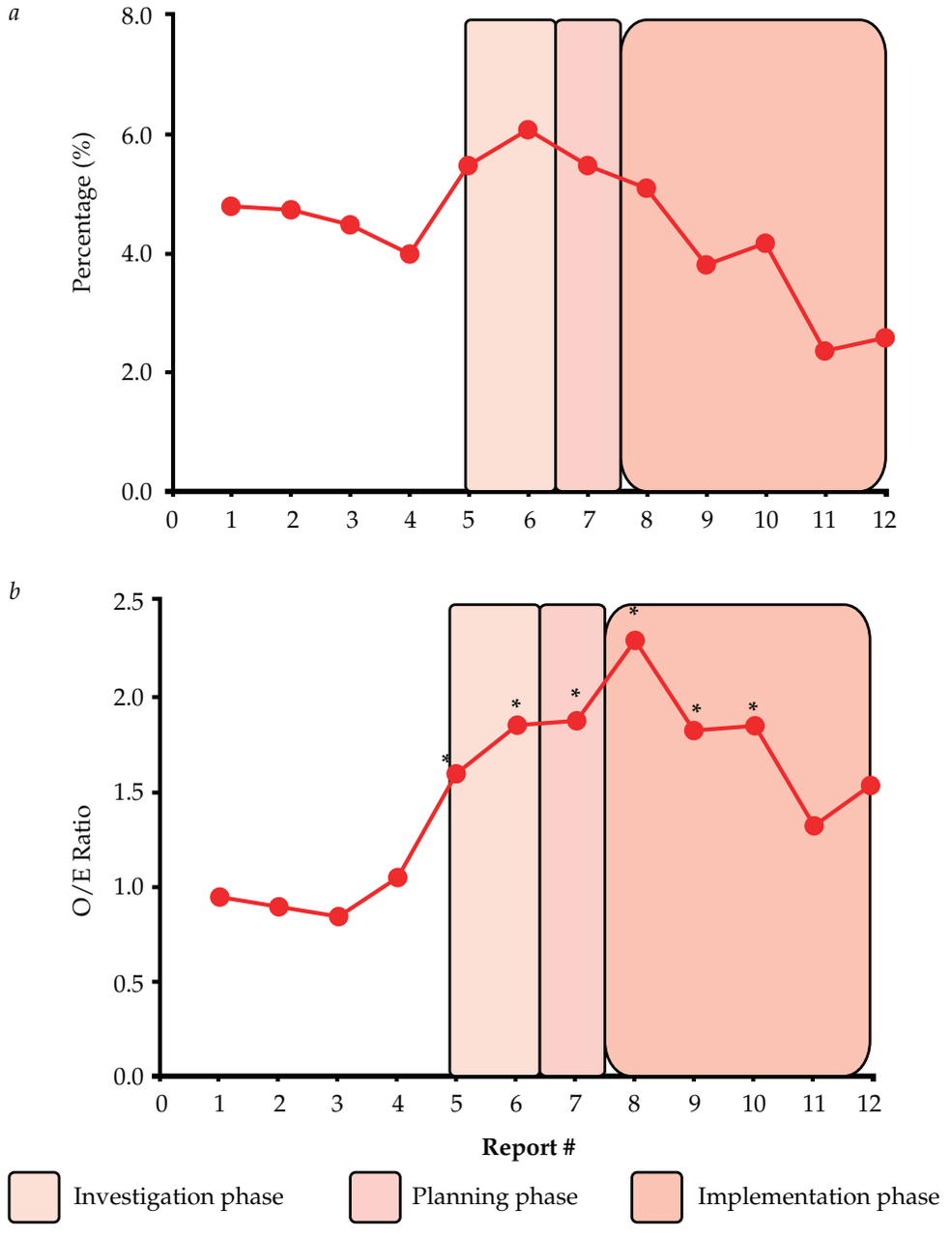

Figure 4 **Venous thromboembolism (VTE) events by report number. Benchmarking reports are distributed three times per year and cover a 1-year time period. (*a*) Crude VTE rate; (*b*) risk-adjusted VTE rate.**
***High outlier status when compared with the Michigan Trauma Quality Improvement Program (MTQIP) collaborative mean.**

Table 5 Multivariate and Propensity Score Analysis of the Michigan Trauma Quality Improvement Program Pilot Data for VTE Events and Type of VTE Prophylaxis

Analysis	*VTE Prophylaxis Agent*	*N*	*DVT, n (%)*	*PE, n (%)*	*VTE, n (%)*	*Odds Ratio*	*95% Confidence Interval*
Multivariate	SC heparin	552	41 (7.4)	14 (2.5)	49 (8.9)	—	—
	SC enoxaparin	381	13 (3.4)	5 (1.3)	15 (3.9)	0.46	0.25–0.85
Propensity	SC heparin	345	22 (6.4)	10 (2.9)	28 (8.1)	—	—
	SC enoxaparin	345	12 (3.5)	5 (1.5)	14 (4.1)	0.5	0.26–0.95

DVT = deep vein thrombosis; PE = pulmonary embolism; SC = subcutaneous; VTE = venous thromboembolism.

- Monitoring of VTE prophylaxis drug type and timing of first dose given was conducted using the MTQIP data platform.

Monitoring and Sustaining the Result

Following intervention, the crude VTE rate decreased from 6.2% (n = 36/year) to 2.2% (n = 14/year), and subsequent MTQIP feedback reports showed a return to average performance and elimination of being a high outlier for VTE events [*see Figure 4*]. Web-based MTQIP dashboard reporting allowed ongoing monitoring of compliance with the action plan after its implementation, by semester of the queried year. The use of enoxaparin as the preferred VTE prophylaxis drug increased in concert with a decline in the use of heparin and withholding of pharmacologic prophylaxis [*see Figure 5*]. Implementation of this performance improvement program for VTE prophylaxis allowed the University of Michigan to shift from high outlier status (2010) to average performance (2013) within the collaborative.

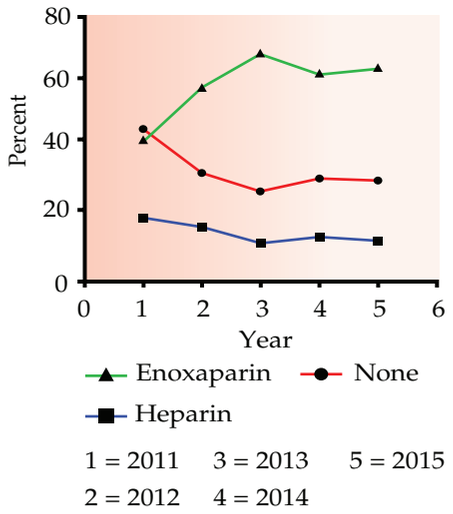

Figure 5 **Change in the type of venous thromboembolism prophylaxis agent administered over time.**

Summary

Selection of an appropriate project and preplanning with regard to strategy are often more important than management skill alone when undertaking and performing successful quality improvement in the ICU setting. The SMART goals template is a planning mechanism that seeks to clarify exactly what is expected and the measures used to determine if the goal is achieved and successfully completed.[59] A SMART goal is

- *Specific (and strategic).* Target a specific area for improvement. Link to departmental goals/mission and/or overall hospital/health system goals and strategic plans. Answers the question, "What?"
- *Measurable.* The success toward meeting the goal can be measured. Answers the question, "How?"
- *Assignable and achievable.* Specify who will do it. Goals are realistic and can be achieved in a specific amount of time and are reasonable. Answers the question, "Who?"
- *Relevant and realistic.* States which results can be achieved given available resources. Align goals with current projects and focus on one defined area.
- *Timely.* Goals have a clearly defined time frame, including a target or deadline date for when results can be achieved. Answers the question, "when?"

Financial Disclosures: Mark R. Hemmila, MD, has received support from Blue Cross Blue Shield of Michigan/Blue Care Network provided to the University of Michigan Medical School for operation of the Michigan Trauma Quality Improvement Program (MTQIP) coordinating center and serves as the medical director for the MTQIP. Wendy L. Wahl, MD, has no relevant financial relationships to disclose.

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Acknowledgment

Figure 1 Christine Kenney