

Advancing the Culture of Patient Safety and Quality Improvement CME

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ABSTRACT: The American health care system has many great successes, but there continue to be opportunities for improving quality, access, and cost. The fee-for-service health care paradigm is shifting toward value-based care and will require accountability around quality assurance and cost reduction. As a result, many health care entities are rallying health care providers, administrators, regulators, and patients around a national imperative to create a culture of safety and develop systems of care to improve health care quality. However, the culture of patient safety and quality requires rigorous assessment of outcomes, and while numerous data collection and decision support tools are available to assist in quality assessment and performance improvement, the public reporting of this data can be confusing to patients and physicians alike and result in unintended negative consequences. This review explores the aims of health care reform, the national efforts to create a culture of quality and safety, the principles of quality improvement, and how these principles can be applied to patient care and medical practice.

INTRODUCTION

Over the last century, advances in medicine and surgery have dramatically transformed life expectancy and quality of life. Yet despite the many great successes of the American health care system, there continue to be opportunities to improve quality, cost, and access. According to the Organization for Economic Cooperation and Development, per capita health care spending in the United States is almost twice the average of other developed countries. Increased health care spending would be acceptable if it resulted in universal access, improved outcomes, and better health of the entire population, but unfortunately, higher cost has not correlated with overall increased quality. On the contrary, the United States has worse outcomes than other developed countries when assessed by infant mortality, unmanaged diabetes, and life expectancy.¹ Among peer countries, the United States has the second-highest death rate from ischemic heart disease.

As the leading cause of death in the United States and globally, cardiovascular disease accounts for much of the total health care spending. In fact, one of every six US health care dollars is spent on treating cardiovascular disease, and it's no wonder.^{2,3} In the last 50 years, risk factor modification, medical therapy, interventional techniques, and surgical management of heart disease can all be credited with improving the survival and quality of life for countless patients, and this comes with a hefty price tag. For the US health care industry, cardiac care is a very profitable business model in the current "fee-for-service" environment, where the direct costs are approximately \$215 billion annually.⁴ However, the increasing cost of care may not be sustainable.

THE FEE-FOR-SERVICE PARADIGM SHIFT

The diagnostic and therapeutic armamentarium in cardiac care has grown tremendously. And while the ability to diagnose and treat the spectrum of heart disease has exploded in recent years, so have the costs. Fee-for-service care incentivizes more services, more tests, more procedures, and more hospitalizations, all of which result in more reimbursements for providers.

The paradigm in American health care is changing from fee-for-service to value-based care, where value is defined by the health outcome achieved per dollar spent.⁵ In 2010, Harvard Business School economist Michael E. Porter envisioned the concept of value-based care as follows:

"Value should always be defined around the customer, and in a well-functioning health care system, the creation of value for patients should determine the rewards for all other actors in the system. Since value depends on results, not inputs, value in health care is measured by the outcomes achieved, not by the volume of services delivered, and shifting focus from volume to value is a central challenge."⁶

THE CULTURE OF QUALITY AND SAFETY

In 1999, The Institute of Medicine released a sobering report titled *To Err is Human: Building a Safer Health System*, which stated that an estimated 98,000 hospitalized patients die each year from medical mistakes.⁷ The report was not intended to blame providers or hospitals but, rather, to clarify that bad systems of care (and not bad people) were largely responsible for these deadly mistakes. Furthermore, the report hoped to rally health care providers, administrators, regulators, and patients

around a national imperative toward creating a culture of safety and developing systems of care to improve health care quality. In a subsequent report, the Institute of Medicine published *Crossing the Quality Chasm: A New Health System for the 21st Century*, which described the institute's six aims for health care reform:⁸

- First, health care must be **safe**. “Primum non nocere” (first do no harm) should no longer be the sole burden of individual providers. Instead, hospitals must be held accountable for maintaining systems of care that ensure patient safety.
- Second, health care should be **effective**. Health care providers must use evidence-based medicine and evidence-based practice. Since the best science and clinical practices in medicine continue to evolve, every practitioner should be expected to participate in life-long learning through continuing medical education to remain up to date. Reliance on tradition and anecdotal personal experience should no longer be acceptable practice. The phenomenon of “illusory superiority”—otherwise known as the “Dunning-Kruger effect”—highlights that poor performers often lack the skills and knowledge to identify their own poor performance.⁹ Medical staffs and hospital leaders should ensure that all health care providers have the appropriate decision-making support tools, and leaders must be forever vigilant to assess and ensure that all patients in their facility are receiving evidence-based and guideline-directed care.
- Third, care should be **patient centered**. “For the secret of the care of the patient is in the caring for the patient.”¹⁰ High-quality care needs to be respectful of the patient's values and receptive to the patient's input. All care decisions and therapeutic plans—including the rationale, risks, costs, and benefits—should be proactively explained to the patient. The “best possible outcome” is optimally decided through shared decision making by a highly competent care team and a well-informed patient.
- Fourth and fifth, care should be **timely** and **efficient**. Unnecessary delays and prolonged waiting times can be frustrating and dangerous for patients depending on their underlying medical conditions. In addition to caring for their patients' welfare, all care providers should be good stewards of valuable health care resources. After an attentive patient evaluation, any blood tests, diagnostic imaging, and invasive procedures should be tailored to confirm or refute the provider's differential diagnosis specific for that individual patient. Whenever possible, decisions and plans should avoid wasting valuable equipment and precious time.
- Lastly and arguably most importantly, care must be **equitable**. The quality of care should not vary based on a patient's personal characteristics, gender, race, religion, geography, or socioeconomic status. Every person across the country should have access to high-quality value-based care.

In order to improve the US health care system, Donald Berwick, former administrator of the Centers for Medicare and Medicaid Services (CMS), has argued that we must simultaneously focus on three aims¹¹: improve the individual experience of care, improve the health of the population, and reduce the per capita cost of care for populations. In Berwick's opinion, the barriers to an integrated health care system are not technical but political. To be successful, political and economic leaders will need to partner with payors, employers, health care systems, providers, and patients to align the appropriate incentives and disincentives for healthy lifestyles and affordable quality health care.

DEFINING QUALITY CARE

How do we define, let alone measure, quality health care?

There are numerous consulting companies—including four major organizations (U.S. News and World Report, LeapFrog Hospital Safety Grades, Consumer Reports, and Healthgrades)—that grade, rate, and report the quality of hospitals and providers. Although the rating systems of the above well-respected consumer-focused organizations evaluate the same hospitals, they seem to arrive at different conclusions, perhaps because they each employ different rating methods or focus on different metrics.¹² As a result, more than 700 hospitals are stated to be in the “Top 100 Hospitals.” However, no hospital is rated as a high performer by all four major ranking programs, and only 10% of hospitals rated as a high performer in one system are rated the same in another system. As a result, rather than providing clarity, these public reporting programs add to the confusion of the public and their payors. In the absence of a consistent definition or agreement on quality care, are we left to the rationale of US Supreme Court Justice Potter Stewart, who said “I know it when I see it”?

In the words of W. Edwards Deming, “Without data, you are just another person with an opinion.” Although not a physician, Deming is considered to be the pioneer of quality improvement in industry with many valuable applications to health care systems. Deming refined his observations of how organizations work through the four components of his System of Profound Knowledge:^{13,14}

- The first is appreciation for a system, which acknowledges that action in one part of the system will have effects in the other parts (“unintended consequences”). The more one understands the system, the more likely he/she is to avoid the unintended consequences and optimize the entire system.
- Second is knowledge of variation. To improve quality, systems should strive to reduce variation. Although autonomous practice by individual physicians was once considered sacrosanct, this often leads to suboptimal application of

evidence-based care and, therefore, poor patient outcomes. Ironically, adherence to the cherished value of individual autonomy has resulted in less overall autonomy for the profession of medicine.¹⁵

- Third is the theory of knowledge, which requires that one understand the difference between theory and experience. Although the practice of medicine is an art, quality care requires the scientific method to test theory and predictions to prove and improve outcomes.
- Fourth is an understanding of psychology. Change management and process improvement require understanding how people learn and interact within a system.

The Deming Cycle, otherwise known as the “Plan-Do-Check Act” (PDCA) cycle (Figure 1), is a four-step model for continuous performance improvement. The “plan” recognizes an opportunity or a need to enact a change. In medicine, this opportunity might arise from an interest in applying a new therapy or from recognizing a need for performance improvement. Using evidence-based medicine or guideline-directed recommendations, a practice change can be planned for piloting. The “do” requires an ability to test the proposed change through a small-scale pilot study. To “check” requires the ability to collect, organize, and analyze data. The “act” takes the lessons learned from the collected data and acts on those lessons. If the change was successful, the practice can be implemented on a larger scale. If the change did not work, the cycle begins again by formulating a different plan. The PDCA cycle is the engine that perpetually moves performance improvement.

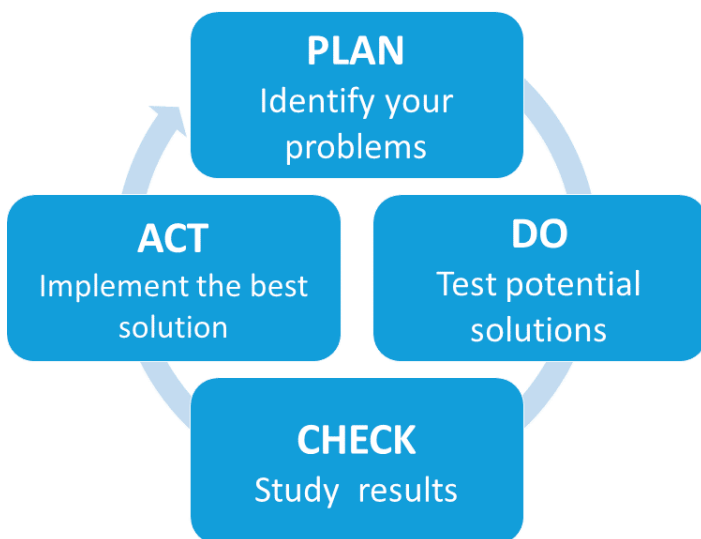


Figure 1.
The Deming Cycle: Plan-Do-Check-Act.

SYSTEM OF CARE

The care of an individual patient is best performed within a larger system of care that provides a method for evaluating patients, an arrangement for labs and imaging, a reliance on best medical evidence, and a process to ensure that individual patients are responding to treatment as expected. System-based practice, practice-based learning, evidence-based medicine, evidence-based practice, quality assurance, and a rigorous process for performance improvement are all essential components of high-quality care. Evidence-based medicine is defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” exemplified by randomized controlled trials.^{9,16} Evidence-based practice uses clinical information, diagnostic tools, management strategies, and appropriate therapies linked to outcomes that can be measured, analyzed, and modified.¹⁷ Data collection and decision support tools are necessary to continuously employ the Deming cycle of PDCA.

PERFORMANCE IMPROVEMENT IN CARDIAC SURGERY

Beginning in the 1970s, the rate of coronary artery bypass grafting (CABG) surgeries exploded across the country and dramatically increased health care costs, which led to increasing scrutiny of CABG results. Consequently, the Health Care Financing Administration (HCFA) began to publish CABG mortality data derived from administrative claims data that could not be risk adjusted.¹⁸ In 1989, the Society of Thoracic Surgeons (STS), the largest professional society of cardiothoracic surgeons and providers in the world, established the Adult Cardiac Surgery Database (ACSD) to address the limitations of unadjusted CABG mortality reporting. Currently, the STS ACSD collects 95% of data on all cardiac surgeries performed in the United States and includes 1,111 participant hospitals and more than 3,800 physicians, including surgeons and anesthesiologists, representing more than 90% of the groups that perform cardiac surgery in the United States.¹⁹

As a result, information from more than 6.9 million surgical records provides a robust data set for analysis and reporting. Using weighted statistical models, prospective patient-specific risk-assessment calculations can be performed at the bedside of preoperative patients. Comprehensive STS risk models have been developed based on the most contemporary data available with the primary goal of optimizing the predictive accuracy for case-mix adjustment.^{20,21} Furthermore, 30-day risk-adjusted program-specific outcomes that are benchmarked against national data are regularly reported to each participating hospital and physician. In addition, 10% of all cardiac surgery programs are independently audited each year to ensure that their institutional data is complete and accurate.²²

Using regional data from the STS ACSD, the Michigan Society of Thoracic and Cardiovascular Surgeons developed a system to evaluate cardiac surgical deaths with the hope of potentially avoiding future mortalities.²³ They started with the concept that cardiac surgical deaths are initiated by a seminal event that triggers a cascade of deterioration ultimately leading to the patient's death. They then reasoned that by reviewing individual clinical events, therapeutic decisions, and interventional practices, they may be able to identify and avoid interdependent patterns and thereby prevent future deaths. In reviewing 1,905 patient deaths out of 53,674 patient operations (3.5% mortality), they did a phase of care mortality analysis to determine where the seminal event occurred (ie, preoperative, intraoperative, postoperative ICU, postoperative floor, or discharge). In the judgement of the reviewing surgeons, 41% of the deaths were deemed avoidable. The largest number of both actual and potentially avoidable deaths occurred in the preoperative phase, which prompts the thought that perhaps better judgement regarding appropriate patient selection and/or improved preoperative patient optimization by the surgeon would have resulted in fewer deaths. A phase of care mortality analysis should be an integral part of cardiac surgical programs so that these processes of care can be continuously assessed and improved.

In addition to mortality, the STS ACSD reports other quality metrics for CABG, valve, and CABG–valve procedures, such as prolonged ventilation, postoperative renal failure, postoperative stroke, cardiovascular reoperation, and deep sternal wound infection. For isolated CABG procedures, it also reports metrics related to process compliance (eg, preoperative beta blockade administration, internal mammary artery utilization, and discharge prescriptions of antiplatelet agents, statins, and beta blockers).²²

There's no doubt that all surgical procedures have risks, but assessing risk based entirely on instinct can lead to over- or underestimation of adverse events.²⁴ For this reason, the STS developed an online Adult Cardiac Surgery Risk Calculator (riskcalc.sts.org) that identifies and stratifies the morbidity and mortality risks associated with specific cardiac surgical operations. In addition to its utility in patient counseling and shared decision making, scores that are higher than expected can be used to identify patient-specific risk factors that might be managed and optimized to potentially reduce the risks. The Houston Methodist DeBakey Heart & Vascular Center has created and instituted preoperative optimization protocols in an effort to reduce the risks of mortality from prolonged ventilation (Figure 2).

Optimizing patient safety and outcomes are the prime directives for all quality assurance and performance improvement

CONSULT FOR CARDIAC SURGERY

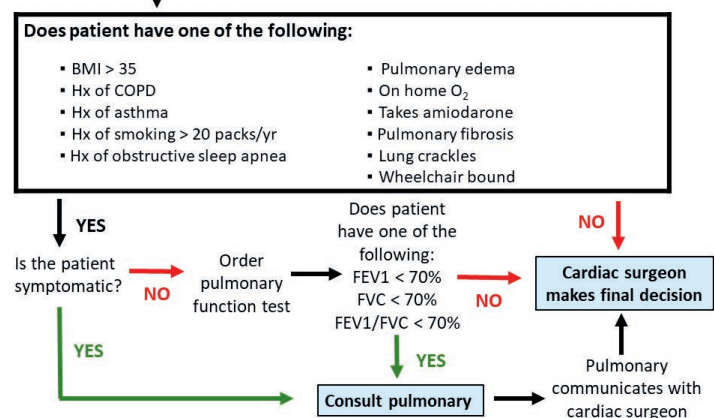


Figure 2.

The Methodist DeBakey Heart & Vascular Center preoperative prolonged ventilation prevention algorithm. BMI: body mass index; Hx: history; FEV1: forced expiratory volume in one second; FVC: forced vital capacity

processes. In value-based care discussions, there is often an unspoken concern that efforts to reduce costs might compromise patient care. Rather than attempting to reduce cost while maintaining quality, it is better to focus on increasing quality, which will ultimately reduce complications, and therefore costs, associated with cardiac surgery. The Virginia Cardiac Services Quality Initiative (VCSQI) is a regional collaborative group of programs that share their STS ACSD data as well as their hospital cost data. Through this unique ability to link quality and cost, the VCSQI has observed a direct correlation between complications and cost. For patients undergoing CABG, for example, each major complication related to CABG exponentially increases hospital costs compared with those who have no CABG-related complications.²⁵ Some people have questioned why prolonged ventilation should be reported as a complication. Studies of efforts to decrease time on the ventilator have been shown to decrease not only other complications but also death, length of stay, and total hospital costs.²⁶ Conversely, the frequency of prolonged ventilation in patients undergoing cardiac surgery at VCSQI hospitals increased CABG costs by approximately \$60 million over a 10-year period.²⁵

Prolonged mechanical ventilation (> 24 hours) after cardiac surgery is a value-based care problem because it impacts both cost and quality (in terms of increased morbidity and mortality). Although some patients require extended ventilatory support after cardiac surgery, the majority of them can be expeditiously awakened, weaned, and extubated.²⁷ Traditional thinking dictated that postoperative cardiac surgery patients were safest

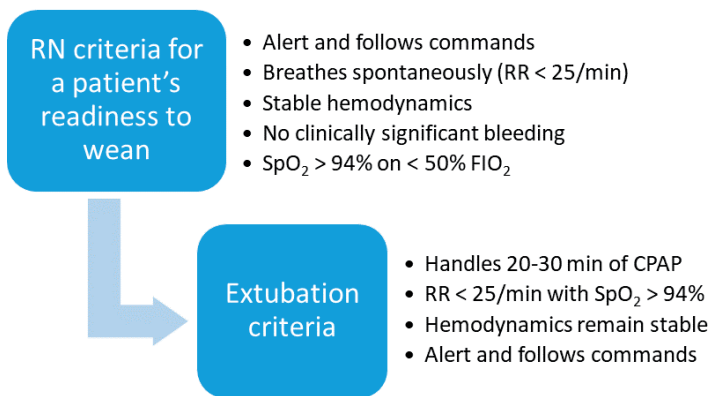


Figure 3.

Suggested fast-track weaning and extubation from the ventilator. Adapted from Chan et al.²⁹ RN: registered nurse; RR: respiratory rate; SpO₂: blood oxygen saturation level; FIO₂: fraction of inspired oxygen; CPAP: continuous positive airway pressure

on the ventilator until they could demonstrate stability with incremental weaning. However, traditional methods to reduce ventilator support actually increased time on the ventilator rather than increasing patient safety.^{26,28,29} Dogmatic reliance on measuring respiratory mechanics have been replaced with simple clinical assessment (Figure 3). "Fast-tracking" protocols directed primarily by nurses and respiratory therapists have been successful in improving the rate of early extubation (< 6 hours) and decreasing mean ventilation times without a significant change in reintubation or 30-day mortality.²⁹ Simultaneous efforts to optimize preoperative pulmonary function combined with reducing unnecessary hours on the ventilator have tremendous value by both increasing quality and reducing costs.

The STS ACSD remains the gold standard of medical database registries. Although participation in the database is voluntary, it captures 95% of all cardiac surgery procedures. Given the size, penetrance, completeness, and fidelity of the data, the STS ACSD provides an unparalleled platform for cardiac surgery research. Nevertheless, the stated purpose of the STS ACSD is to provide accurate and relevant information to surgeons for self-assessment and quality improvement.²² With the use of these valuable data collection and decision support tools, individual surgeons, hospital-based programs, regional collaboratives, and the entire specialty have the ability to access and analyze cardiac surgery data and risk-adjusted outcomes. In fact, regional collaboratives have successfully used these data to share best practices, improve outcomes, and lower costs.^{30,31} Among medical specialties, cardiac surgeons are recognized leaders in quality assurance, performance improvement, patient safety, and public transparency.

ACCESS TO DATA AND PUBLIC REPORTING

As noted above, the intended purpose of the STS ACSD and other cardiac databases was for self-assessment of outcomes, quality, and research. Individual participants voluntarily submitted data with the understanding that program-specific benchmarked outcomes would be confidentially returned for their own personal quality assessment. The practice of public reporting began in 1989 when the New York State Department of Health began to collect surgeon-specific mortality rates for CABG.³² Although this information was meant to be confidential, *Newsday* filed a Freedom of Information Act petition and began to publish the surgeon-specific information. Shortly thereafter, other states and media outlets also began to publish physician- and program-specific cardiac surgery and interventional cardiology outcome data. Numerous entities now collect, analyze, and rank medical information using various measures and methods.¹² While this information is meant to inform the public, regulators, and payors, contradictory results and ratings can confuse and mislead the various stakeholders.

There are strong arguments to support public reporting. Transparency and accountability are morally imperative to maintain the public's trust. Health care consumers could use the data to make better-informed choices for themselves and their families. Disparities in outcomes would encourage low-scoring providers to enact performance improvement programs that would elevate the quality of care. Regulators, employers, and payors could use the information for accrediting and contracting decisions. But transparency can be a double-edged sword. Data that is inappropriately collected, analyzed, and reported can be confusing, deceiving, and damaging to both patients and providers. Administrative claims data are frequently flawed, and therefore the conclusions are appropriately suspect.³³ Even high-fidelity risk-adjusted data, depending on how it is displayed, can be easily misunderstood by the public and result in a misinformed decision with adverse consequences.³⁴ Even with accurate information, patients commonly disregard the outcome data and prefer to rely on proximity or referral.

Public reporting in general can contribute to many unintended consequences.^{12,32} An effective but frowned-upon method for physicians to improve quality outcomes is to avoid high-risk patients and procedures; thus risk aversion threatens the ability of high-risk patients to receive appropriate care. Risk aversion also jeopardizes lower socioeconomic or racially diverse communities by limiting access to care for genetic or acquired comorbidities. Ironically, high-performing institutions may be unwilling to take on riskier patients for fear of compromising their publicly reported ratings. Conversely, public reporting can punish providers and hospitals who are willing to care for complicated patients and perform high-risk procedures.

Recently, several hospitals have been forced to close their congenital heart surgery programs and their surgeons have been publicly humiliated as a consequence of publicly reported outcomes ratings.³⁵ Regardless of how well intended or how carefully designed, there is no perfect public reporting system, and all will have flaws and glitches. The goal of outcome assessment should continue to be identification of opportunities for improvement rather than punishment.

Finally, as observed by Collins et al., are we sacrificing the future for the sake of the present?³⁶ Might training of future physicians and surgeons be compromised by discouraging or even forbidding them from seeing higher-risk patients to avoid bad outcomes? Throughout our history, intrepid physicians and surgeons have greatly advanced the medical care of populations because they had the courage to innovate and act when the high risk of doing nothing for their patient was unacceptable. Advancing the culture of patient safety and quality improvement does not require that we cower from challenging patients or problems. On the contrary, it demands that we have the strength and commitment to learn from our previous patients so that we can provide better care for our future ones.

KEY POINTS

- In the American health care system, the fee-for-service paradigm is shifting toward value-based care to increase quality and decrease cost.
- The Institute of Medicine has set six quality aims for health care reform. Health care should be safe, effective, patient centered, timely, efficient, and equitable.
- The care of an individual patient is best performed within a larger system of care that includes system-based practice, practice-based learning, evidence-based medicine, and evidence-based practice.
- The culture of patient safety and quality requires rigorous assessment of outcomes. Numerous data collection and decision support tools exist to assist in quality assessment and performance improvement.
- Unintended consequences of transparency include risk aversion that can negatively impact individual patient- and population-based care.

Conflict of Interest Disclosure:

The author has completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and none were reported.

Keywords:

value-based care, patient safety, outcomes, evidence-based medicine, practice-based learning

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