The Past, Present and Future of Health Care Quality

Urgent need for innovative, external review processes to protect patients

By Martin D. Merry, MD, & Michael G. Crago, PhD

The history of the health care quality process hit a critical turning point barely one month before the worldwide millennial celebration in November 1999.

Americans who lauded the remarkable technical capability of modern medicine—“miracle” drugs, transplants, genome therapy—were astounded by the Institute of Medicine’s landmark report, “To Err Is Human.”

It turned out the same system accomplishing technical miracles was also responsible for 44,000 to 98,000 deaths annually in hospitals due to medical errors. As the IOM report made painfully clear, the health care system itself was between the fifth and ninth leading cause of death in the United States.

And while the IOM report met with criticism and its numbers were recently disputed in a new study reported in the Journal of the American Medical Association, the issue of safe patient care and high quality still remains at the forefront of medical debate.

In a consumer-driven world that demands and receives ever-higher levels of quality and value in virtually all other industries, how could health care mount such frightening statistics?

As one senior manufacturing executive stated, “For the past decade every one of our suppliers—except health care—has offered us higher quality at lower costs. Health care alone continues to offer us lower quality at ever-increasing cost!”

Why is health care so far removed from the economic mainstream when it comes to quality?

The answer lies in the strange saga of how health care quality systems developed in total isolation from the rest of the American economy.

History of health care quality

Three historical traditions influencing the evolution of health care quality are depicted in Figure 1. They illustrate both the isolation of health care quality development and how it evolved.²

Until 1987, health care quality concepts remained isolated within a learning science tradition dating to Hippocrates (3rd century B.C.). Medicine was then, and still is, taught and learned as a craft.

The modern physician is the product of a long textbook, classroom and apprenticeship process. Quality is based almost solely on the skills of the craftspeople. And craft traditions are virtually blind to systems issues central to Column 3’s management science.

Medicine traditionally relies on the unique truism that “patients may die, despite consummate skills of the practitioner.” No other field has this ready, plausible
explanation for poor outcomes. “My patients are sicker!” has been a nearly impenetrable defense for fending off serious inquiry into the sickly statistics.

With the exception of a few isolated and marginally influential researchers, only during the year since the release of the IOM report has the truth penetrated health care’s consciousness.

It is not patient variation, but inconsistent quality of care that generates these widely variable patient outcomes from region to region, health system to health system.

**Learning science**

Quality assessment began during a remarkable period of reform within the medical profession.

The American College of Surgeons (ACS) was founded in 1913 to address great variations in the quality of medical education and the competence of physicians.

By 1917, the ACS developed the Hospital Standardization Program.3 HSP was a set of uniform, high standards to apply to physicians practicing at hospitals seeking the distinction of achieving the standards.

By the mid-1930s, only about half of hospitals seeking HSP distinction achieved it, and failure was not dishonorable. The unit of quality assessment under HSP was peer case review.

Properly conceived and executed, this process can be a valuable learning experience. Following a death or other adverse outcome, physicians gather to review the record and discuss the case. They assess whether the outcome might have been preventable.

Literature of the period suggests this learning-based model of quality assurance successfully improved hospital standards throughout the early decades of HSP. But in the

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1950s and ‘60s, something went seriously awry with peer review.

**What went wrong?**

As modern elements of Column 1 evolved, Column 2 effectively split into two channels. One channel of the learning column tracked true. It maintained the learning science origins and continues today with great vigor in academic medical centers.

It persists primarily in the form of morbidity, mortality and other educational information:

- Avedis Donabedian’s structure-process-outcome quality model
- Paul Ellwood’s outcomes measurement concepts
- Modern case management systems

The second channel of this split came under the influence of Column 1’s regulatory mindset and practices, and increasingly distant from Column 2’s learning tradition.

The origins of Column 1 are even more ancient, dating to the 2100 B.C. Code of Hammurabi—when the penalty for surgical malpractice was to amputate the hands of the surgeon!

This code focused historically on “bad care,” and more recently the establishment and maintenance of minimum standards.

Three fundamental characteristics distinguish modern Column 1 players:

1. They establish comprehensive, general standards external to the institutions/practitioners actually providing care. Examples include licensure criteria, accreditation standards and laws.

2. They measure or survey the provider entity against these standards, typically through onsite inspections, often supplemented by data analysis.

3. If they judge a provider in non-compliance with standards, they can hold the provider accountable through mandatory recommendations, sanctions, financial penalties, and even imprisonment.

This is a far cry from learning. It is fear.

Not surprisingly, this motivational base has a spotty effect on actual quality at the bedside. The IOM explicitly labeled the “culture of blame” as a major impediment to improving health care quality systems.

The point here is not to condemn Column 1 practices; few question their importance in preventing practitioners and institutions from falling below minimum expected standards of practice. But can a process heavily associated with a “culture of blame” genuinely inspire excellence?

Column 1 players are inevitably in the “minimum standard” business, holding provider entities accountable when they slip below recognized standards. Excellent performance in Column 1 responsibilities assures a basic level of quality standards and complements the more excellence-oriented aspirations of Columns 2 and 3.

As the ACS transferred ownership of the original HSP to the Joint Commission on Accreditation of Hospitals (now Healthcare Organizations, JCAHO) in 1951, Column 1’s legal and regulatory processes became more influential.

How do current health systems leaders view Column 1 approaches?

Some leaders are abandoning non-compulsory JCAHO review, and others are seeking innovative external review, such as the Baldridge and ISO 9000. A new era is at hand.

**Health care and other industries**

To fully comprehend the IOM’s findings, compare health care’s quality statistics with those of other industries.

To compete in world-class markets, manufacturing and service industries must operate with quality systems capability in the range of 5-6 Sigma—that is, between 230 and 3.4 defects per million opportunities.

According to recent studies, the quality capability of the systems derived from Figure 1’s Columns 1 and 2 in health care today range from 2 Sigma to 4 Sigma.

That translates to somewhere between 308,000 defects per million—the number of cardiac patients who would benefit from aspirin administration daily, but who don’t receive it—and 6,210 defects per million—the current rate for hospital medication ordering and administration practices.

The only known health care exception to these startling numbers is anesthesia mortality. Through a unique effort combining the knowledge of committed anesthesiologists and pervasive use of virtually foolproof equipment, anesthesia mortality presently approaches 6 Sigma.

**Column 3 and the future**

This huge health care “Sigma gap” sets the stage for a genuine quality revolution in health care. And the earliest skirmishes of the revolution are already under way.

Columns 1 and 2 remained impenetrable to the quality methods of Column 3’s management science until 1987. Then, some pioneering
physicians, hospitals and other health care organizations combined with quality experts from manufacturing and service industries to launch an ambitious experimental introduction of Column 3 management practices.

This experiment was a definitive success, proving that management science-based techniques could duplicate in health care exactly what it had done in all other industries. With proof that process improvement can simultaneously improve quality and lower cost, the continuous quality improvement wave in health care was under way. Organizations spent millions on continuous improvement processes, realizing impressive results and some failures.

But the wave passed by. Modern quality management science failed to take hold in a critical mass of health care organizations. Most that experimented with Column 3 reverted to the more familiar practices of Columns 1 and 2. And they unwittingly locked their institutions into the 2-4 Sigma quality capability of today's health care system.

Renaissance of Column 3

On a positive note, Column 3 remains alive and well in a number of incubator organizations. Those who continued to learn and lead Column 3 development are well positioned for a renaissance.

Part of the renaissance of Column 3 management science will be an organizational post-mortem on why the 1987-1995 experience did not embed itself in health care. Typically, the reasons for failure surround:

1. The deeply embedded culture that is the legacy of Columns 1 and 2 was simply not ready for the invasion of so alien a culture as that surrounding modern quality science. The traditional Column 1 and 2 health care cultures responded to this invasion with a powerful “immune reaction,” effectively “banishing” this new science back to exile in Column 3.

2. The business case for quality science was never effectively presented. Though it was clear that process improvement could reduce costs and improve quality, few health care organizations were able to leverage this as a significant strategic advantage. Two other problems were at work:
   a. Since health care quality measurement has been so rudimentary, higher quality was often opaque. Purchasers and patients couldn't yet really distinguish high quality from mediocrity.
   b. Payment systems were not geared to reward value. Fee-for-service simply paid for doing more—sometimes a sign of poor quality with slow/incorrect diagnosis, excessive testing and complications that generated higher bills and more revenue.

3. Inadequate time to mature. Those involved with the introduction of Column 3 quality science to health care in the late 1980s still remember the admonitions of the “wizened veterans” of manufacturing's world-class quality competition. “This transformation will take five to ten years to truly embed itself as your new way of doing business.”

In health care, other pressures intervened before even the most stalwart supporters of Column 3 could truly accomplish their organizations' quality management goals.

Health care’s crises with falling provider payment, balanced budget implications, ambulatory fixed payment systems, rising costs and insurance premiums are relentlessly forcing health care provider organizations to move beyond Columns 1 and 2.

The renaissance of Column 3 is inevitable. The most progressive health care organizations will embrace it as rapidly as possible. Only Column 3 can bridge the gap from 4 to 6 Sigma quality. It also is the only body of knowledge that addresses the cost element of the cost/quality/value equation and the only column that leaders can use to address the economic issues.

A call to action

It is time for health care to mature as a true, value-adding industry.

For this to happen, Column 3 management science must emerge as both a survival and strategic leadership commitment for health care provider organizations—as well as an ethical imperative in moving from 4 to 6 Sigma quality.
Five elements of a successful transition to Column 3 include:

1. **Maintaining the best values of medicine’s Column 2 learning science tradition**, even as its practices are updated to embrace the information age. This means detoxifying medical peer review practices now extant in the vast majority of hospitals and restoring a learning-based peer case review, now supplemented by rigorous data analysis by physicians and others regarding practice patterns.

2. **Understanding, creating and managing organizational culture.** Nobody planned the “culture of blame” that IOM identified as a major impediment to current quality transformation. But culture fights to maintain itself and Columns 1 and 2 are deeply embedded in health care and very powerful. Successful health care organizations will develop effective strategies that honor the power of historic health care culture and consciously create new, positive and collaborative cultures to accomplish the clinical integration needed for 6 Sigma quality.

3. **Developing new leadership concepts and practices.** It’s not surprising that relatively few leaders whose heritage stems from Columns 1 and 2 have the depth of understanding and concomitant skills to master integration of modern quality science with health care practices. Even many who successfully embraced Column 3 during the “CQI glory years” have been battered by a combination of quality management decline, merger-mania, high level power struggles, increasing financial pressures, and health system downsizing. The good news? Research and the literature are overflowing with promising new leadership theory and practices. This literature suggests old-style, top-down hierarchical leadership has virtually no place in the present revolution.

4. **Integrating Column 3 management science with clinical care and care system design.** This involves a body of knowledge pervasive in the airline industry, but virtually unknown in health care: human factors science. This focuses on a deep understanding of how error occurs in complex human systems, and how communications protocols and other sophisticated techniques can virtually eliminate human imperfection as a source of error and injury in complex systems. The successful integration of Columns 2 and 3 holds promise in creating higher quality, more humane and far more healing environments than Columns 1 and 2 alone ever contemplated.

5. **Establishing innovative external review processes that can genuinely help committed organizations achieve their 6 Sigma quality goals.**

### External review

As health care becomes increasingly market-driven, those purchasing and using its services will define health care quality and value.

Patients will have a major voice in the future evolution of health care. But non-consumer-based quality assessment will remain vital to health care organizations.

Optimal future quality will emanate from organizations that integrate the best of Columns 1, 2, and 3 into their external review systems.

Quality practices related to the three columns will evolve along different tracks, though ultimately some convergence is likely.

### Column 1

The IOM report has placed the players of Column 1 in an extraordinarily difficult position.

These public guardians of health care quality are presiding over an industry with 2-4 Sigma quality. They must find a way out of their dilemma. Society needs minimum standard certifiers. But historical players in this column must take a serious look at their practices and innovate them.

Good regulation and competition may stimulate innovation and excellence in Column 1 external review. The greatest hope probably lies in enlightened innovation in such organizations as:

- JCAHO
- The National Committee for Quality Assurance (NCQA)—focusing on managed care plans
- The Peer Review Organizations (PRO)—focusing on Medicare/Medicaid

If JCAHO can reform its processes and innovate to offer greater value to its constituents, it might emerge as an important element in the future quality equation for health care organizations.

For all the deficiencies of its current image and processes, it is deeply embedded in health care culture. JCAHO could become a beacon of transition for health care organizations still within its diminishing sphere of influence.

A recent article suggests that JCAHO is indeed actively acknowledging and willing to work in a complementary fashion with newer external review frameworks.

The NCQA and PROs also have positive potential. While maintaining their primary role of safeguarding
minimum standards, many have moved on to establish more collaborative relationships with health care systems.

With their vast data capability, the best PROs are already offering these systems both information support and technical consultation on how to improve systems.

**Column 2**

Because health care is offered from one human being to another human being one-at-a-time, review of individual patient care will never disappear.

It will be important to conceive case review not simply as a narrowly defined, cost-generating process, but one that complements and supports the overall medical center quality/cost/value improvement strategy and practice.

Perhaps most of all, physician leaders face an urgent imperative to detoxify peer case review. Negative peer review evokes fear, anger, resistance and professional conflict. It is antithetical to the original learning intent of case review and leaders are well advised to abolish this toxicity unequivocally.

**Column 3**

The external review frameworks for Column 3 quality management presently are ISO 9000 and Baldrige.

The Baldrige system of external review is based on criteria derived from the United States Baldrige National Quality Award, a highly prestigious achievement in the realm of world-class quality. Health care organizations are now using the Baldrige framework in two contexts:

1. Actually pursuing the award
2. As a template for quality systems development

Few health care systems are striving for quality awards. Many more systems are seeking comprehensive frameworks to improve quality systems capability.

It's impossible to predict exactly what combination of Column 1-3 external review systems will prove optimal for both health care providers and the communities they serve.

ISO 9000 and Baldrige took many industries to world-class quality: automotive, aerospace, information technology, telecommunications, machinery, electrical products, pressure equipment, and transportation.

Perhaps these Column 3 review systems will help move health care down the path toward world-class, 6 Sigma quality, as well. ●

**References**

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