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Kevin Hines

Thomas Jefferson University

Nikolaos Mouchtouris

Thomas Jefferson University

John J Knightly

Atlantic Neurosurgical Specialists

James Harrop

Thomas Jefferson University

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A Brief History of Quality Improvement in Health Care and Spinal Surgery

Kevin Hines, MD¹ , Nikolaos Mouchtouris, MD¹ ,
John J. Knightly, MD², and James Harrop, MD¹

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Abstract

While medical and technological advances continue to shape and advance health care, there has been growing emphasis on translating these advances into improvement in overall health care quality outcomes in the United States. Innovators such as Abraham Flexner and Ernest Codman engaged in rigorous reviews of systems and patient outcomes igniting wider spread interest in quality improvement in health care. Codman's efforts even contributed to the founding of the American College of Surgeons. This society catalyzed a quality improvement initiative across the United States and the formation of the Joint Commission on Accreditation of Hospitals. Since that time, those such as Avedis Donabedian and the Institute of Medicine have worked to structure the process of improving both the quality and delivery of health care. Significant advances include the defining of minimum standards for hospital accreditation, 7 pillars of quality in medicine, and the process by which quality in medicine is evaluated. All of these factors have affected current practice more each day. In a field such as spinal surgery, cost and quality measures are continually emphasized and led to large outcome databases to better evaluate outcomes in complex, heterogeneous populations. Going forward, these databases will be instrumental in developing practice patterns and improving spinal surgery outcomes.

Keywords

Joint Commission on Accreditation of Healthcare Organizations, spinal cord injuries, outcome, National Academies of Science, Engineering, and Medicine (US) Health and Medicine Division, quality improvement, cost, structure, process

While medical and technological advances continue to shape and advance health care, these advances have not always directly translated to significant improvement in overall health care quality outcomes in the United States. Incorporating advancements into the health care models creates complex challenges in delivering high-quality medical care. In this article, we provide a brief outline on the history of such efforts and how they have changed health care systems.

Improving the quality of care rendered to patients has been a principle since the time of Hippocrates. Over time, there have been various advances in systems of care (Walter Letterman developing systems of triage of casualties in the American Civil War) as well as nursing (Florence Nightingale instilling Listerean principles of infection control in hospitals). However, the past century has seen many innovators and changes instrumental in the improvement in the quality of care in medicine. Understanding these recent contributions to quality improvement in health care frames future directions and emphasis in complex fields such as spinal surgery.

Abraham Flexner is an early contributor to the United States' effort in quality improvement in that he performed a retrospective analysis and review of the system. He constructed a *Report to the Carnegie Foundation*, which were published his results and recommendations in 1910. He described the poor organization of major hospitals and medical schools in the nation. With the aim of improving physician training, the report encouraged improving scientific method, and strengthening validity of medical licensure. This report resulted in

¹ Thomas Jefferson University, Philadelphia, PA, USA

² Atlantic Neurosurgical Specialists, Morristown, NJ, USA

Corresponding Author:

Kevin Hines, Department of Neurological Surgery, Thomas Jefferson University, 909 Walnut Street, COB Building, 3rd Floor, Philadelphia, PA 19107, USA.

Email: kevin.hines@jefferson.edu





Figure 1. American College of Surgeons met in 1917 outlining the 5 main objectives of “minimum standards” required to meet accreditation standards in hospitals nationwide.

restructuring of the medical education in the United States and resulted in the closure or merging of more than half the medical schools.¹

Meanwhile, Ernest Codman, an orthopedic surgeon from Boston, Massachusetts was championing changes for quality improvement through the use of patient registries and serial patient follow-up. He created a systematic protocol for following long-term patient progression and “end patient results.” Codman felt that all patients should be tracked in this manner and results be made public so that all patients could use the information in choosing their physicians and hospitals. While public reporting such as this may have incentivized hospitals to preselect patients to avoid bad results, Codman’s emphasis was largely placed on identifying effective versus ineffective implementation of health care treatments.²

Codman’s description of his end-result system inspired Dr Franklin Martin. He envisioned principles of patient outcomes assisting in surgeon and hospital standardization leading to an improvement in patient care. To address these needs, Dr Martin largely proposed and catalyzed the founding of the American College of Surgeons in 1913. The committee found it necessary to reject 60% of fellowship applications in its first 3 years of existence given the inability to determine clinical competency with the case records presented by the applicants.³

As the American College of Surgeons’ influence increased, John Bowman, PhD, the director acquired a large donation to fund a hospital standardization program. Over 300 fellows and hospital administrators met in 1917 to discuss an accreditation process and establish the “minimum standards” required of hospitals nationwide.⁴ Such standards included 5 main objectives: organize hospital medical staff, ensuring employment of only well-qualified and licensed physicians, ensuring regular staff and clinical performance review, maintaining thorough and organized medical records, and establishing facilities such as clinical laboratories and radiology departments (Figure 1). Using these principles, the Hospital Standardization Program was established and reviewed 692 hospitals with 100 beds or more. Unfortunately, only 89 hospitals met these minimum

standards for accreditation. While many hospitals were able to remediate and address their deficiencies, the report demonstrated the continued need for quality improvement in the United States’ hospital system and the “minimum standard” was officially adopted to firmly establish a hospital accreditation process. This was paramount in instituting and maintaining organized quality improvement in the United States.⁵

As the number of hospitals, nonsurgical specialties, and complexity of health care continued to grow, the size of the Hospital Standardization Program rapidly grew requiring over 2 million dollars in investment from the American College of Surgeons by 1950. It became apparent that support for this quality improvement initiative could not be sustained by the College alone and the scope of its involvement extended to many nonsurgical aspects of health care. As a result, the American College of Surgeons was joined by the American College of Physicians, American Hospital Association, American Medical Association, and briefly the Canadian Medical Association to form the Joint Commission on Accreditation of Hospitals in 1952. The independent, nonprofit organization began offering accreditation to hospitals in 1953 while upholding the values championed by the American College of Surgeons. The Joint Commission expanded the Hospital Standardization program by hiring surveyors and careful interviews and observation of medical staff and patient care issues. As the program expanded more hospitals continued to meet and maintain the “minimum standards.” As a result, the Joint Commission no longer felt that the standards were pushing hospitals to strive for higher levels of quality than already achieved.

Concurrently, others in the nation were looking to further quality improvement. Health Services Research Section of the US Public Health Service convened a meeting in 1965 during which leaders from many health-related fields convened to discuss social and economic research on public health and quality improvement. Among these leaders was Avedis Donabedian, considered by many to be one of the founders of the contemporary health care quality movement.⁶ Born 1919, in Beirut, Lebanon, his family moved to Palestine after fleeing the Armenian holocaust. Eventually attending American University of Beirut, he obtained his BA and MD. Using this training, he served as a general practitioner in Beirut and Jerusalem until 1954 at which point he moved to Boston. He obtained an MPH degree at Harvard School of Public Health and spent most of his career teaching at the School of Public Health at The University of Michigan. He was very passionate about the relationship between quality and systems in health care and felt that the skills of system management were not well taught in medical school.⁷ As such, he was commissioned to review the research on quality assessment. When he published his paper “Evaluating the Quality of Medical Care” in July 1966, the reception was enormous. It became one of the most frequently cited public health pieces over the next half century.

In his paper, Donabedian describes 7 pillars of quality in medicine:



Figure 2. Avedis Donabedian's standards for evaluation the quality of health care.

- Efficacy
- Efficiency
- Optimality
- Acceptability
- Legitimacy
- Equity
- Cost

The difficulty in the past was how to measure these goals. To accomplish this, he described three types of metrics for evaluating quality in health care: structure, process, and outcome (Figure 2). *Structure* includes credentialing of providers, adequacy of facilities, and administrative systems delivering care. *Process* observes which components of care are delivered and their appropriateness and competency of delivery. He recognized that it is rarely the individual that creates the problem but rather the process is a fault and needs to be changed for better results. *Outcome* involves evaluation of recovery, restoration of function, and survival. Measuring outcomes is necessary to determine what interventions are effective and should be implemented. Within these standards, he emphasized the need for clear presentation of these metrics (dashboards and scorecards) and broad quality measurements, including prevention, recovery, continuity of care, societal and cultural values, and economic efficiency. This way physicians can begin to truly understand evidence surrounding a problem and recognize issues affecting health care quality. This also provided the framework on which the interest in patient individualized outcomes and value-based care was developed.⁸

These advances largely structured health care improvement quality for several decades. During this time, the Institute of Medicine was founded in 1970 by the National Academy of Sciences. Originally formed in 1863, the Academy, a nonprofit private institution, was formed to advise the government on scientific and technological issues. Over time, the scope of the Academy's responsibilities began to include medicine and different aspects of health care. After Avedis Donabedian published his work, the concern over establishing a body advising the government on issues regarding social, economic, and political aspects of health care as well as medicine evolved. Out of this need the Institute of Medicine was founded in 1970. The members of this committee included not only major health profession disciplines but also economists, sociologists, engineers, writers, ethicists, and innovative business representatives with success in areas related to health care issues in the United States.⁹

Since its founding, the Institute of Medicine has continued to produce field defining publications. As an organization, it publishes roughly 50 well-vetted reports in medicine each year. One such publication, *America's Health in Transition: Protecting and Improving Quality*, was published in 1994. It asserts that health care quality is the degree to which health care improves outcomes and maintain consistency with current knowledge of practice. Obstacles to achieving this goal were outlined as unnecessary/inappropriate care, underuse of effective/appropriate care, and shortcomings in technical or personnel in care.¹⁰ This was followed by the Institute of Medicine's initiative proposing a coordinated effort to further examine quality improvement issues, devise measurements of quality improvement issues, all while paying special attention to vulnerable populations that do not traditionally receive the same quality of care as others in the United States.

While this launched a coordinated effort, it was not until the 1999 report *To Err Is Human* that the quality improvement initiative gained public traction.¹¹ Reporting that nearly as high as 100 000 preventable deaths per year occur during health care delivery due to medical errors. The leading causes of the death were medication and communication errors. This report outlined the need for improvement in medical electronic information systems and reporting of medical errors. The medical electronic information system remained far less developed than in other disciplines such as banking or the airline industry. In addition, liability without protection for health care workers inhibited error reporting and resulting improvements.¹¹ This spurred public awareness and catalyzed the Agency for Healthcare Research and Quality (AHRQ) to perform a review on quality assessment and improvement in US health care.

As this investigation was launched, there was an additional publication by the Institute of Medicine in 2001, *Crossing the Quality Chasm*, further demonstrated the discrepancy between the recommended delivery of health care and the reality of American health care in its current form. It described the factors that delivered inconsistent health care across the country regardless of insurance status, race, gender, geographic location of the patient. The Institute of Medicine report illustrated that medical information has irregular distribution secondary to poor information systems and lagging use of current technology. This prevents scientific advances from becoming uniformly available to practitioners across the country. From this discrepancy, new clinical education centered on increased interdisciplinary cooperation identified specific aims as drivers of health care change. These drivers were safety, efficacy, patient-centered care, timely, efficient, and equitable.¹² Overall, the report emphasized use of new technologies to deliver safer, more efficacious, and cost-effective care without financially penalizing individuals streamlining the care.

Since these publications defining the future direction of quality improvement, the Institute of Medicine has worked through three platforms: environmental, health care organization, and the interface between physicians and patients. Such efforts include redesigning primary care and care for patients with chronic conditions, restructuring insurance coverage and

malpractice in *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*.¹³ Another agenda laid forth ideas for educational reform, including establishment of core competencies, public reporting, and fostering training environments and oversight.¹⁴ It was also during this time that the Institute of Medicine emphasized institution of electronic health record systems with national standards for collection of this data.^{15,16} Finally, the Institute of Medicine outlined common and costly medication errors as well as a comprehensive approach to minimizing these errors in the report *Preventing Medication Errors*.¹⁷

Since its founding, the Institute of Medicine has changed its name to The National Academy of Medicine (<http://www.nationalacademies.org/hmd/>). It has been instrumental in launching a quality improvement initiative consisting of 3 phases. Already, in the first 2 phases, the Institute of Medicine has outlined and highlighted the discrepancy between current and ideal delivery of health care, made proposals on how to transform the health care system to close this gap. The final phase of this quality improvement initiative focuses on ongoing efforts to execute this transformation and the proposed mechanisms for quality improvement.

Understanding this history is vital for spine surgeons moving forward. Spine surgery has not been immune to the health care quality initiative. The quality improvement movement will define the future trajectory of major specialties such as spine surgery. All the concepts defined in the past century such as outcome-based care, standardization, and resource efficiency will guide future policy. Health systems are moving away from the fee for service model and pushing for a more sustainable system. This system is grounded in population health and preventative medicine, value-based care, and new payment models.¹⁸ Traditionally, the surgical management of patients with spinal disorders represented a very heterogeneous population with varied outcomes. Variability can be defined as both expected variation as well as unexpected variation.¹⁹ This unexplained variation can lead to excess waste and costs. Costs associated with surgical intervention may be very high and outcomes are poorly characterized. This is may be due to the homogenization of techniques that evidence-based medicine encourages. As prospective trials and studies with high levels of evidence require rigid inclusion/exclusion criteria with control of confounding variables, large studies quickly lose their generalizability. This makes higher level evidence costly and difficult to apply to patients with spinal disorders. This is an example of the Institute of Medicine's described discrepancy between current and ideal delivery of health care.

As such, there is opportunity for quality improvement as cost, efficacy, safety, and patient centered outcomes have yet to be fully defined for many treatment paradigms in existence. To address this deficiency, spine registries have gained popularity in parallel with growing emphasis on health care quality improvement. With a foundation laid upon Ernest Codman's work in "end result theory," registries represent a more scalable, cost-effective, alternative to randomized clinical control trials evaluating outcomes in a more generalizable context.

The first major registry established was the National Spinal Cord Injury Database. Started in 1973, the database was originally part of a project meant to demonstrate superiority of comprehensive spinal cord injury care over fragmented care across different centers.²⁰ As multiple centers joined the project, large volumes of data were generated for analysis. In the first 10 years alone, the National Spinal Cord Injury Statistical Center spurred advancements in spinal cord injury care in emergency, acute care, and rehabilitation settings. Rare for the time period, prospective data was collected on patient demographics, pathology, procedures, complications, implants, and patient-reported outcomes. Being one of the longer maintained databases, it has served as an example on the data that can be generated from years of follow-up on a variety of spinal pathology. Since then, many major registries have been established with ongoing enrollment since then. Such registries include the Swedish Spine Registry, Spine Tango, Rick Hansen SCI, N²QOD, British Spine, AOSpine, Kaiser Permanente, Vanderbilt Prospective Spine, North America Clinical Trials Network (NACTN), NASS and include various pathologies such as trauma, degenerative lumbar disease, and deformity among other conditions.^{21,22} As the scope of a registry gets larger, the follow-up tends to be shorter as the infrastructure required to maintain the database increases. As such, along with the Swedish Spine register, N²QOD (renamed as the QOD, Quality Outcomes Database) is a multicenter registry collecting prospective patient-reported outcomes with 12-month follow-up rates exceeding 75%. As these databases accumulate data, it is becoming apparent that while spinal surgery generally has low rates of morbidity and high rates of sustained treatment effects. However, there is a large degree of heterogeneity and significant variation in treatments as well as individual's response to treatment from patient to patient. It is important to note that there are wide variations in the design and data accumulated. Registries may have prospective versus retrospective designs, variability in follow-up and sample sizes, and different metrics used to evaluate outcomes. All of this must be weighed carefully as different clinical conclusions may be drawn from different data sets. However, understanding this will allow physicians to identify registries that best suit the population they serve when using them to enforce clinical decisions. These registries will become extremely important in improving quality care by identifying which cohorts of patients will or will not benefit from a particular surgery. Using data from a registry like QOD, a surgeon will be able to create a personalized predictive calculator for an individual patient's response to therapy.²³

As Donabedian noted late in his career, "There's lip service to quality and, goodness knows, propaganda, but real commitment is in short supply."²⁴ As clinical registry databases continue to grow, and the information technology platforms on which they are based improve, their predictive modeling capabilities and comparative power will continue to accumulate and drive quality improvement in medicine forward. They will provide invaluable data on comparative efficacy of various surgical and nonsurgical treatments for spinal disease.

The development of these quality improvement efforts will also improve the systems of care to patients at the local level. These registries represent invaluable adjuncts to randomized clinical trials that will evaluate rapidly changing heterogeneous populations and practices.²⁵ Using these tools, treatment paradigms may be altered so that the quality of spinal care delivered may be more efficacious, cost-effective, safe, and patient centered. As the history of quality improvement in recent years has shown, value-based and outcome-driven policy is becoming more important in every field, including spinal surgery. The future of spine surgery is interwoven with these quality improvement developments as the field searches for ways to improve the outcomes of these heterogeneous, complex patients.

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ORCID iD

Kevin Hines, MD  <https://orcid.org/0000-0003-1700-174X>
Nikolaos Mouchtouris, MD  <https://orcid.org/0000-0001-9495-9391>

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