# Historical Aspects of Quality in Healthcare

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## Introduction: Quality in Healthcare

> *Quality. 1. [noun] the standard of something as measured against other things of a similar kind; the degree of excellence of something.* [1]

Optimization of patient value should be at the center of any successful healthcare system [2]. This can be achieved by maximizing the quality of care while minimizing costs. This is demonstrated in Michael Porter's healthcare value equation (value = quality/cost) in which value is a function of benefit and cost.

In a patient-centered healthcare system, the numerator, quality, should be measured in terms of outcomes that matter to patients [3]. The most widely used clinical measures for quality, such as the Physician Quality Reporting System, are process measures. Although process measures are easier to obtain than outcomes measures and are valuable in assessing diagnostic and procedural practices, they do not necessarily correlate with outcomes [4]. In order to create treatment algorithms based on outcomes rather than process, the Patient Protection and Affordable Care Act has created provisions such as the Patient-Centered Outcomes Research Institute to identify the most effective forms of treatment [4, 5].

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J. Ratliff et al. (eds.), *Quality Spine Care*,
https://doi.org/10.1007/978-3-319-97990-8_1

The International Consortium for Health Outcomes Measurement (ICHOM) was founded on the principles described in Michael Porter's and Elizabeth Teisburg's *Redefining Healthcare* principles. ICHOM works with physicians, patients, and registries, to create a global standard for outcome measures according to medical condition.

Porter stratifies outcomes that matter to patients into a tier system to better define healthcare quality for patients. This comprehensive assessment of quality includes the direct outcomes (mortality and degree of recovery from the medical condition), failures in the treatment process, time of recovery, and long-term outcomes [3]. Improving quality in any of these realms can reduce cost and increase the value of care. A recent version of the equation has incorporated "service," or patient satisfaction (value = (quality+service)/cost), to include the patient's evaluation of the care received [6].

Many approaches exist to reduce cost, the denominator in the value equation. One approach is to focus on reducing costs in the highest-cost patients [5]. Porter and ICHOM's approach is to measure cost as the total expense incurred for the full cycle of care for the specific medical condition across specialties, rather than dividing cost by specialty or type of service. This allows for a patient-centered measurement of cost [7].

Although patient value should be at the center of the healthcare system, it is important to consider the impact that quality of care has on other stakeholders as well.

## Stakeholders in Quality of Care

Quality of care can be considered in terms of three stakeholders: the patient, the payer, and society.

### The Patient

Quality of healthcare is determined by the system's ability to meet the patient's individual needs. Most important is the ability to provide well-planned care and manage a patient's medical condition by providing necessary treatment options. For example, a patient who suffers from severe back pain due to metastatic spinal disease may not be able to sustain open back surgery but may benefit from minimally invasive techniques such as cement augmentation or separation surgery [8]. The availability of such options helps to meet a patient's needs and increase the quality of provided care.

Another patient interest to consider is functional status. Not only does it affect a patient's autonomy and quality of life but also his or her ability to earn wages and provide for one's family [9].

Although providing service that leads to patient satisfaction is important, the patient's perception of quality of care does not necessarily correlate with health status. In a study that examined the relationship between quality of surgical spine care and patient satisfaction, improvement in quality of life and improvement in general health were not associated with patient satisfaction [10]. In addition, perception of quality of care may be influenced by socioeconomic status, educational, and cultural backgrounds [11].

## The Payer

In short, payers foot the proximal costs of health treatments – the literal common denominator of the Utah value equation. Naively, one expects payers to work to minimize costs. Yet payers in the United States represent a heterogenous group: the American healthcare system is an amalgam of different payer entities. Thus what constitutes cost minimization, and therefore value maximization, for payers in practice is a nuanced question affected by incentives unique to each group. Here we will consider three views of the payer perspective of value in spine care: from large government agencies like Medicare, from private insurance companies, and from society as a whole.

### Government Agencies

The US government runs two massive healthcare payer agencies in Medicare and Medicaid. Across all programs, the government is responsible for paying for the care of roughly 107 million people at a total cost of $1.2 trillion/year [12]. Several factors make government agencies particularly sensitive to emphasizing high-value, high-quality procedures. Foremost is the dual challenge of rising enrollment and rising medical costs in the setting of the political impossibility of significant budget expansion. Moreover, Medicare patients represent an elder segment of the US population; medical expenditures for those 65 and older are roughly three times higher than someone closer to the median US citizen ($18,988 vs $6632) [13]. Finally, Medicare cares for patients over the long term – essentially from enrollment to the grave. These pressures likely account for the recent heavy focus on quality assessment with the Performance Quality Rating System (PQRS). From a neurosurgical perspective, PQRS is notable for its emphasis on measuring and explicitly improving functional outcomes after treatment along the neuraxis. In effect, the Centers for Medicare and Medicaid Services (CMS) has challenged spine surgeons to demonstrate the value of their procedures.

### Private Health Insurance

Private health insurance remains the majority payment model in the US health system. Estimates vary, but roughly two thirds of Americans are covered by private health insurance plans at a total cost of $1.1 trillion dollars per year. Probability of private coverage is associated with both income and full-versus-part-time working status; thus the privately insured population tends to be wealthier (and therefore healthier) than the publicly insured. Moreover, insurance is closely tied to one's employment: around 80% of all private insurance policies are employer-provided policies.

This has interesting consequences for the incentive structure of private insurance companies. The customers of private insurance companies are most often not patients themselves but their employers. For publicly traded companies, ultimate responsibility lies with creating value for shareholders. Moreover, in the modern economy, employment durations may be brief; loss of employment leads to loss of coverage. Indeed, in a 3-year period from January 2009 to December 2012, 35.1 percent of Americans were uninsured for at least 1 month. The average period without insurance was 17.4 months, or more than half of that period. Thus a single private insurance company is relatively decoupled from the long-term consequences of a given procedure. An efficacious procedure from the perspective of private insurance is one with minimal operative costs for a given indication, short recovery time, and proven efficacy in the near-to-middle term. All told, private insurance companies wield significant influence in shaping current practices via selective reimbursement of procedures. These factors likely shape the apparent arbitrariness with which these decisions are reached [14].

### Society

Ultimately, society bears the cost of all healthcare expenditures. Every dollar spent on healthcare is one not spent on infrastructure, science, or education. All told, the United States spent $3.3 trillion on healthcare expenditures in 2016. This represents outlays of roughly $10,350 per person, or 17% of gross domestic product. These numbers are only projected to grow. It is a tired fact by now that on a per-dollar basis, health outcomes in the United States are significantly worse than similar western industrialized countries.

As political and economic pressure builds to address these disparities, surgeons can play a leading role in ensuring system-wide quality. The public requires surgeons who offer validated, reliable procedures only when indicated. We must continue our efforts to minimize complications and prevent reoperations. While these are characteristics common to good surgeons, perhaps less appreciated are their cumulative effects on the health system as a whole.

## Society

The interest of the entire population must be considered when evaluating quality of care in terms of society as a whole [15]. Because society spans across more than one generation, the goals for achieving high-quality care are long term [16]. For example, a society may invest in preventative care to decrease healthcare expenses of preventable diseases.

Clear guidelines on patient selection for treatment are beneficial to prevent unnecessary costs to society. In a study of elderly patients who underwent surgery for lumbar spinal stenosis, comorbid disease and increasing age were shown to be associated with an increased risk of major complications, rehospitalization, and discharge to skilled nursing facility; all of which are costly to society [17].

In addition to reducing direct medical care expenses, careful patient selection may prevent loss of productivity. A study examining risk factors for loss of work productivity after surgery for lumbar disc herniation revealed that patients with severe disability and poor motivation to work were more likely to require an extended time off work [18]. The study suggests that patients who are at risk of a poor outcome should receive vocational counseling and early rehabilitation in order to prevent a loss of employment. Incorporating measures to prevent unemployment into healthcare may help patients return to work sooner and continue to contribute to society.

## Historical Perspectives on Assessing Quality in Spinal Surgery

### Introduction

Over the years, surgeons care deeply about providing their patients high-quality procedures; patients themselves must trust their surgeons to provide high-quality care. Ongoing assessment of quality in spinal surgery remains fundamental to ensuring acceptable outcomes, solidifying trust between patient and provider, and improving the practice altogether. Toward these goals, spine surgeons require tools to assess current practices and new procedures. Ideally, such measures should be objective, easy to administer, and standardized to facilitate comparison.

While today discussions of quality of care may be dominated by the Centers for Medicare and Medicaid Services' Physician Quality Reporting System (CMS PQRS), physicians have been interested in the objective assessment of the effectiveness of their interventions throughout the history of modern medicine. In this section, we will trace the evolution of objective quality assessment in spinal surgery from the twentieth century to the present. As we will see, this development occurred in a saltatory fashion. It remains interesting to consider societal and resource constraints driving development.

### Early Period (1930s–1980s)

The earliest modern tool for assessing outcome quality in bony surgery is the Massachusetts General Hospital Anatomic Economic Functional Rating System (MGHAEF) [19]. Developed in the late 1920s by the Fracture Service at MGH, it was popularized during the early 1930s during the height of the Great Depression. Originally applied to measure outcomes of reduction of compound fracture of the lower limb, this scale is remarkably modern. Authors of MGHAEF recognized the need to report the multidimensional outcomes of surgical treatment, both on the bone itself and on the life of the patient.

The scale consists of three dimensions, each scored from zero to four. The anatomic limb exploited the then-recent proliferation of medical X-ray imaging to evaluate the success of intervention on bone healing, with aligned healing as the

**Table 1.1** The Massachusetts General Hospital Anatomic Economic Functional Rating System as applied to spinal fusion surgery

| Anatomic | | Economic | | Functional | |
|---|---|---|---|---|---|
| A0 | Pseudarthrosis | E0 | Completely invalid | F0 | Pain worse than before surgery |
| A1 | Unilateral pseudarthrosis | E1 | No gainful occupation | F1 | Pain the same as before surgery; can perform daily tasks of living |
| A2 | Insufficient unilateral fusion mass | E2 | Able to work but did not return to previous occupation | F2 | Low level of pain; able to perform all activities except sport |
| A3 | Contiguous fusion mass without hypertrophy | E3 | Returned to previous occupation in limited status | F3 | Rare, brief recurrences of pain or sciatica |
| A4 | Solid fusion with hypertrophy | E4 | Returned to previous occupation without restriction | F4 | No pain even during sport |

Data from Vanti et al. [20]

best outcome and pseudarthrosis as the worst. The economic outcome dimension evaluated a patient's capacity to return to work at >1 year, with return to work without restriction as the desired outcome and completely invalid as the least desirable. The functional limb concerned a patient's pain. On this scale, highest scores were awarded to pain-free patients, and lowest scores were assigned to patients whose pain increased following surgery. Complete scores were recorded in compound notation: thus a patient with a perfect outcome would be reported as $A_4E_4F_4$, a convention that would carry forward.

Over decades, this scale was modified ad hoc to suit the needs of inquiring surgeons on their area of expertise. A complete, modern version of MGHAEF applied to spine fusion surgery is demonstrated in Table 1.1 [20].

## Modern Assessments (1980s–Present)

During the 1980s, as aging baby boomers began to experience the consequences of spine degeneration, spine surgery quality metric assessments were revisited. The first conceptually significant example is work done by Dawson et al. [21] in a case series of 58 patients undergoing lumbar arthrodesis via autologous bone graft. Patients were graded via a modified MGHAEF scale both pre- and postoperatively; as the goal of surgery was not to achieve normal preoperative anatomy, the anatomic scale was dropped from preoperative assessment. Importantly, though successful fusion was observed in 92% of cases, economic and functional improvements were noted in only 70–80%.

To critics of the MGHAEF method, this suggested that ultimate impact on the patient may be a more salient feature of quality assessment, even as surgeons strive for technical perfection. This idea was likely at the forefront of the mind of Donald

**Table 1.2** The Prolo scale

| Economic | | Functional | |
|---|---|---|---|
| E1 | Completely invalid | F1 | Total incapacity (or worse than before operation) |
| E2 | No gainful occupation (including housework or retirement activities) | F2 | Mild-moderate level of low back pain and/or sciatica (or pain the same as before but able to perform ADLs) |
| E3 | Able to work not at previous occupation | F3 | Low level of pain; able to perform all activities except sport |
| E4 | Working at previous occupation at part time or limited status | F4 | Rare, brief recurrences of pain or sciatica |
| E5 | Able to work at previous occupation without restriction | F5 | No pain even during sport |

Data from Vanti et al. [20] and Prolo et al. [22]

J. Prolo, MD, as he developed his eponymous scale for quantitative assessment of lumbar surgery outcomes [20]. Originally outlined in a case series of 34 patients undergoing posterior laminar interbody fusion (PLIF), the Prolo scale is bidimensional: only economic and functional outcomes contribute to a patient's score. Explicit rating of anatomical outcome is dropped completely. Along the remaining dimensions, outcomes are classified along a scale from 1 to 5. Along the economic axis, these outcomes range from E1 (complete invalid) to E5 (able to return to work without restriction). Along the functional axis, outcome rage from F1 (total incapacity, or worse than before surgery) to F5 (complete recovery, no pain even with sport). Outcomes are also noted in compound notation; thus the best possible score on the Prolo scale would be reported $E_5F_5$.

This approach has distinct advantages. First, it is aligned with clinical reasoning: mild anatomic imperfections not causing symptoms are by definition clinically insignificant; conversely, a patient presenting with pain would only have anatomy evaluated secondarily. Moreover, without an imaging requirement, the scale is significantly cheaper and easier to administer. It is robust to retroactive application even in the face of incomplete records. Third, without specific anatomical scoring, the scale is easily generalizable to multiple regions of the body. Finally, non-zero integer notation allows for ratiometric comparison of functional status before and after surgery within single patients. The complete Prolo scale is demonstrated in Table 1.2.

## Legislative Assessments of Quality

The development of spine-specific metrics for quality assessment occurred in parallel to an evolving social and legal framework for evaluating quality of medical care more generally. As these considerations tend to dominate discussions of quality, it is worth briefly discussing their development here.

The creation of Medicare and Medicaid in 1965 led to a need to ensure basic measures of quality and consistency of medical care. To this end, Congress created a set of "Conditions of Participation" or requirements hospitals must meet to receive payments from these programs. Such requirements included round-the-clock nursing and complete staff credentialing and submission to utilization review. This practice review was performed by a rotation of several official bodies: In 1972, the task fell to Utilization Review Committees (URCs), which were widely seen as ineffective due to absence of formal evaluation criteria. Soon after, URCs gave way to Professional Standards Review Organizations (PSROs), networks of physician-run nonprofits mandated to evaluate provided quality of care. Unable to contain costs, PSROs were replaced Peer Review Organizations (PROs) in 1983. These new PROs had a more specific mission to reduce complication, readmission, and mortality; moreover, they were given authority to implement solutions. The PRO model is generally accepted to be more successful than prior review bodies and continues to play a role under Centers for Medicare and Medicaid Services. These efforts by Congress to ensure care quality via legislation are supplemented by nonprofit organizations, including the Joint Commission on Accreditation of Hospitals (JCAH) and the National Academy of Medicine (formerly the Institute of Medicine).

Contemporary efforts toward quality improvement have trended toward incentivized public reporting. Surgical teams lead this trend with the establishment of the Surgical Care Improvement Program (SCIP) in 2003. Aimed at reducing surgical complications and mortality, SCIP constituted a voluntary reporting database with payments provided by Medicare for participation. The SCIP blueprint was used to develop the Physician Quality Reporting System (PQRS) created by Congress with the passage of the Affordable Care Act (ACA) in 2010 [4].

## Future of Quality Assessment

### Current Quality Assessment Metrics

Several methods are available to assess the quality of life of patients. These quality assessments may be collected at any point during a patient's medical or surgical treatment plan. Metrics typically utilized for quality assessment include patient questionnaires such as the SF-36, EuroQol, or Oswestry Disability Index [23–25]. These metrics serve as markers of efficacy for clinical interventions or may be mathematically converted into health utility scores such as quality-adjusted life years (QALYs) providing a more robust means of measuring clinical outcome than with longevity alone.

Given the diversity of terminology and metrics used in quality-of-life questionnaires, the National Institutes of Health (NIH) in 2004 led a multicenter initiative to develop the Patient-Reported Outcomes Measurement Information System (PROMIS) to further standardize, validate, and enhance patient-reported outcomes (PROs) across multiple medical conditions [26]. Embracing the electronical health record (EHR), PROMIS utilizes computer adaptive tests (CATs) to assess for severity of numerous symptoms such as pain, fatigue, depression, anxiety, and physical functionality for patients with diverse medical conditions [26, 27]. PROMIS has the potential to unify PROs in an efficient, computerized manner with consistent recorded values and terminology to serve as a universal quality assessment for all patients [28].

### Integration of Quality Metrics into EHR Systems

The future of quality assessment lies in the capacity of the EHR to serve as a data repository for PROs to capture quality-of-life information for millions of patients at different intervals of their treatment. Efforts such as PROMIS offer the possibility of creating a universal quality assessment language to describe patient quality of life during any treatment plan for any medical condition in any healthcare setting. As clinicians become more familiar with quality assessment, these metrics and questionnaires will become routinely collected clinical variables similar to the collection of vital signs or physical exam findings. Prior investigations have demonstrated the feasibility of collecting quality assessment data utilizing the EHR as part of routine clinical work flow without prolonging average visit time for each patient [29]. Big data analytics of this large volume of clinical data will provide greater validity and public access to these clinical parameters and will bring greater insight into nuances in treatment plans that may enhance quality of life for particular patient groups.

### Cost-Utility and Cost-Effectiveness Research

As patient quality-of-life information becomes increasingly available to clinicians and health professionals, utilization of this data will lead to greater quality-driven care. Health utility models and cost-effectiveness studies are already increasingly utilized to capture the cost-efficacy of neurosurgical interventions and provide quantification of the quality of life impact as well as social cost implications of surgical interventions [30]. Investigations in cost-effectiveness of interventions allow for mathematical modeling to determine if the gains in quality of life after medical or surgical interventions justify the individual or social costs incurred by that treatment [31, 32]. Through having consistent, high-quality data that captures quality of life before and after interventions, quality of cost-effectiveness studies will further guide patient management and health policy.

## Conclusion

It is evident that in the new era of medicine, assessment of quality will continue to be vital in patient counseling and the overall care provided. Profound understanding of quality should be emphasized early on during medical education. Moreover, better integration of quality metrics into clinical practice will improve overall patient care and outcomes.

Creation of a more comprehensive quality measure will require more perspectives from other healthcare systems to be obtained. Understanding the architecture, success, and challenges faced by other systems will aid in assessing scalability of quality assessment internationally.

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