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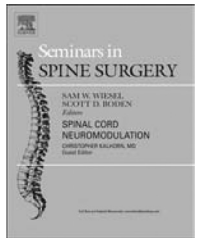

Value based spine care: Paying for outcomes, not volume

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A B S T R A C T

Spine pathology is among the most common, most disabling, and costliest disorders in the US health care system. Traditional reimbursement models in which volume of service rather than quality is incentivized has resulted in an unsustainable rise in cost. The focus for all stakeholders is now on value-based health care. Value is determined by the outcomes achieved per dollar spent to achieve those outcomes. Clinical registries and validated outcome tools are now making it possible for all spine practitioners to define and develop value-based care. Accurate measurement of outcomes and cost and identifying outliers are essential to improving the value in spine surgery.

1. Introduction

Spinal disorders are among the most common, disabling, and costly disorders in healthcare. An estimated 1 in 4 adults in the US report chronic low back pain, and back pain is the most common reason overall for a health care visit.[1] In 2010 the Global Burden of Disease study evaluated 291 conditions and found low back pain to be the most disabling disorder worldwide.[2] From 1998 to 2014 in the US, the total direct cost of treating patients with a spine condition rose by 129% to an estimated $315 billion. When compared on a per-case basis, cost of spine surgery is among the costliest procedures in the US health care system.[1,3] Despite the persistent rise in cost and clear impact on health, there has been no clear association with improved outcomes. For these reasons, the need for quality and cost improvement efforts in spine care has never been higher.

The Institute of Medicine estimates that up to 30% of health care spending is directed toward cost-ineffective approaches.[4] In response to this and the unsustainable trajectory of US health care expenditures due to overutilization and variation in quality and cost, the Patient Protection and Affordable Care Act (ACA), along with public, private and third-party purchasers (insurance companies and governments), have shifted the focus to value-based health care. Value in health care is determined from the patient perspective by measuring the benefit of treatment per dollar spent to achieve those benefits (*i.e.* outcomes/cost of delivering outcomes).[5] Importantly, volume or quantity of care, which has traditionally been incentivized, is not part of the value equation. High volume of spine surgery without regard to outcomes tends to drive up cost and diminish the value of spine care at the patient level. This approach inevitably results in wide variability in outcomes at the patient level.

Additionally, prior studies have shown wide variation in cost between surgeons and procedures at the patient level.[6-9] When measured at the population level, variation in outcomes and cost diminish the value of spine surgery (Fig. 1). Thus, value-based health care will weed out those delivering

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high quantity/low value care and ultimately reward those who are delivering superior outcomes with low variability.

2. Cost of delivering spine care

2.1. Traditional payment model

Spine care in the current healthcare system is organized around a fee-for-service model, which reimburses based on quantity. Interviewing stakeholders across the country working at institutions that annually perform 12,000 inpatient spine surgeries shows that this continues to be the predominant reimbursement system.[10] Under the fee-for-service model, we have seen a rise in the volume of spine procedures performed, leading to an increase in payments for spine care.[11-13] While this is in part due to an aging population that legitimately requires more surgical intervention, a fee-for-service system incentivizes clinicians to perform more expensive procedures that are reimbursed at higher rates.

2.2. Bundled-payment model

As costs increase, the government and insurers will increasingly look toward alternative payment models.[14] In 2016, The Health Care Transformation Task Force, comprised of several of the nation's most prominent insurers and health care systems, declared they would shift 75% of their business to organizations with incentives for quality and lower cost healthcare.[11] With this declaration, along with healthcare reform, spine surgeons should expect a transition to bundled payment models or similar reimbursement strategies in the future. Under bundled payment models, a fixed payment is made to the treating center for an entire episode of care. In the majority of early models, CMS was still billed in a fee-for-service manner, and the costs were reviewed at the end of the quarter. If the costs were less than the target price, a reward was issued. If the costs were more than the target price, the treating center had to repay CMS the amount of the loss. The goal of a bundled payment model is to shift a quantity-driven system toward a quality-driven system by discouraging unnecessary testing or procedures and encouraging efficiency.

The bundled payment model is still new for spine surgery. Early trials included the Bundled Payment for Care Improvement Initiative (BCPI), which included 20 hospitals from 2013 to 2015 with approximately 1000 episodes of care. They saw an increase in Medicare payments, with a decrease in mortality.[11] Ugiliweneza et al simulated what episode-based payment bundling might look like by collecting billing information from a national database and constructing hypothetical episodes of care for different diagnosis related groups (DRG). They found significant cost variation between DRGs, ranging from $11,880 to $107,642 and significant cost variation within each DRG due to the cost of treating patients with comorbidities. The largest portion of payments were to hospitals, accounting for 76%, while physician costs accounted for roughly 14%.[14] Physicians are often the ones most involved in developing successful strategies to decrease length of stay, reduce complications, and prevent readmissions. Therefore, as the "heavy lifters," appropriate incentives for physicians in this regard would likely lead to further improvements in cost. Alternatively, physicians could have a larger financial stake in the facilities providing care, which would create indirect incentive to take an extremely labor-intensive role at mitigating these adverse events.

Early studies suggest a theoretical increase in value with bundled-payment models, however the sustainability has been questioned. Specifically, the financial burden of post-discharge costs such as discharging to a facility and readmissions have been identified as substantial contributors to cost in the total joints literature. One study reviewing payments for total joints found that post-discharge payments accounted for 36% of all payments, and discharge to a post-acute care facility accounted for 70% of post-discharge payments.[15] A survey of joint arthroplasty surgeons in 2014 found that 84% of surgeons were still operating under a fee-for-service model and 61% planned on participating in bundled-payment models.[16] Many respondents expressed concerns about the sustainability of bundled-payments including uncertainty

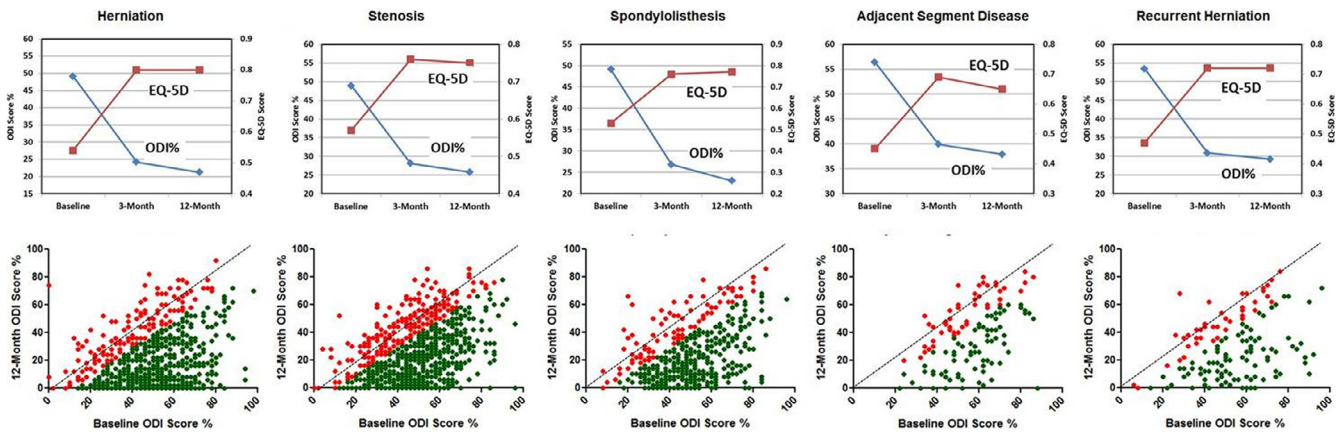

Fig. 1 – Insight has been derived from patient-reported outcome tracking. The top panels show that for several diagnoses patients achieve improvements in EQ-5D and when viewed from a population level. However, when this data is explored at the individual patient level (bottom panel scatter plots) marked variation in outcomes are observed.

regarding revenue sharing, current quality measures not reflective of outcomes, and, importantly, the potential disincentive for surgeons to operate on medically complex high-risk patients. The current model can create a race to the bottom, withholding care from the most disabled for which the procedures may have the biggest impact on quality of life.

2.3. *Drivers of cost*

The cost associated with spine care is incurred across a wide timeline and through multiple episodes of care. Generally, cost of care can be divided into direct and indirect costs. Indirect costs are from the societal perspective and include workday losses by the patient or family, and cost of a caregiver if needed. Direct costs are quantifiable and can be grouped based on the phase of care: pre-operative, operative, and post-operative. Pre-operative measures include office visits and non-operative treatment. The operative period consists of hospital fees (based on Diagnosis Related Groups, or DRGs), surgeon fees (based on Current Procedural Terminology, or CPT), and facility costs. Post-operative care includes rehabilitation costs, physical therapy, office visits, readmissions, complications, and medication fees.[17]

The operative episode of care provides the greatest opportunity for cost savings. In an analysis of patients who underwent laminectomy and fusions for degenerative lumbar disease, the total average cost was $27,800 with 83% of reimbursement for the hospital, 11% for the surgeon, and 5% for post-discharge health care resource utilization.[18] This is consistent with other models, which demonstrate that the hospital gets the majority of reimbursement after spine care.[14] When done safely, moving procedures to an outpatient setting can result in substantial savings. The total joint arthroplasty community has pioneered this move to outpatient surgery centers. Total knee arthroplasty procedures performed at an outpatient surgery center showed a cost savings of 30% with no major complications or readmissions at 1-year.[19] In the spine community, anterior cervical discectomy and fusion (ACDF) procedures have been safely performed in the outpatient setting with a post-operative observation period of 4-hours.[20,21] Outpatient lumbar microdiscectomies have a decreased complication rate in the outpatient setting and have a facility fee savings of 30%.[22] Focusing efforts on minimizing hospital costs, specifically on limiting length of stay and changing the surgical setting, are likely to yield the highest reduction in overall cost.

Surgeons' costs account for 11–14% of the total costs in spinal surgeries. Kazberouk et al examined 2,367 admissions for spine procedures at a single institution and found cost to vary by a factor of 1.31 after adjusting for patient characteristics and procedure types. The driving factors for low versus high cost physicians were a complex combination of operating room times, length of inpatient stay, anesthesia costs, and supply costs. The lowest cost physician had low supply costs, shorter inpatient stays, and shorter operating room and anesthesia times, resulting in an average cost savings of $1430 per procedure. In procedures requiring instrumentation, such as ACDF and posterior lumbar fusions, supply costs made up the largest overall total expense regardless of surgeon. In non-instrumented procedures operating room time contributed most to cost. Overall, this study demonstrated no single primary cost driver between surgeons, but instead showed variation based on the type of procedures performed.[23] However, if cost cutting by surgeons is undertaken, the surgeons compared must have similar safety profiles and patient reported outcomes and the analysis needs to account for patient comorbidities and complexity, creating an observed versus expected cost (Fig. 2).[8,9] A careful analysis such as this allows for a reasonable discussion amongst surgeons to develop effective cost-cutting measures. Cost-cutting measures without regard to safety or patient outcomes will cripple the value of spine surgery.

Patient-specific factors have been associated with increased risk of complication, and thus increased cost. Poor nutritional status is associated with prolonged hospital stay, increased complications, and a higher readmission rate at 30-days.[24] Smokers and patients with heart disease have an increased rate of readmission and subsequent costs.[18] Analysis of obese patients have shown an increased cost to achieve outcomes when compared to non-obese patients.[25] Chronic opioid use is of importance due to the known high risk of opioid-related adverse events and has recently been shown to correlate closely with complications, readmission and increased costs.[26] When developing bundled-payment models, considering drivers of cost variation is critical to implementing a sustainable system. Patient factors should be carefully considered and reimbursements adjusted for the expected increase in cost if they are to be included in a bundle. Alternatively, these factors could be used to define exclusionary criteria. Failure to do so, will likely result in some providers deferring treatment of high risk patients and falsely elevating the value provided.

3. Outcomes in spine care

Improving value in spine care relies on the ability to accurately measure and track meaningful patient outcomes. Like cost, outcomes should be measured over the entire phase of care for a disorder. Additionally, outcomes are condition-specific and cannot be entirely captured by a single outcome measure. For disorders of the spine, relevant outcome measures often are those measuring a person's function and participation in society, impairments, pain and quality of life.[27,28] There are several validated disease-specific outcome measures, but to compare different health conditions and different interventions (e.g. elective surgery vs cancer screening), the quality-adjusted life-year (QALY), is the recommended and most widely used tool to measure effectiveness of health care interventions.[29,30] The QALY, which incorporates length of life and quality of life, is estimated by multiplying the amount of time spent in each health state by its health utility score (0 = dead, 1 = perfect health). For example, if a patient lived the next 20 years with 10 years in perfect health (1 QALY x 10 years) and 10 years in moderate health with a utility score of 0.5 (0.5 QALY x 10 years), the total for those 20 years would be 15 QALYs. The QALY gained from a spine intervention can be estimated from questionnaires such as the EuroQol Group 5-Dimension Self-Report Questionnaire and the Short Form-12. Importantly, the outcomes relevant to the specific disorder must be defined.

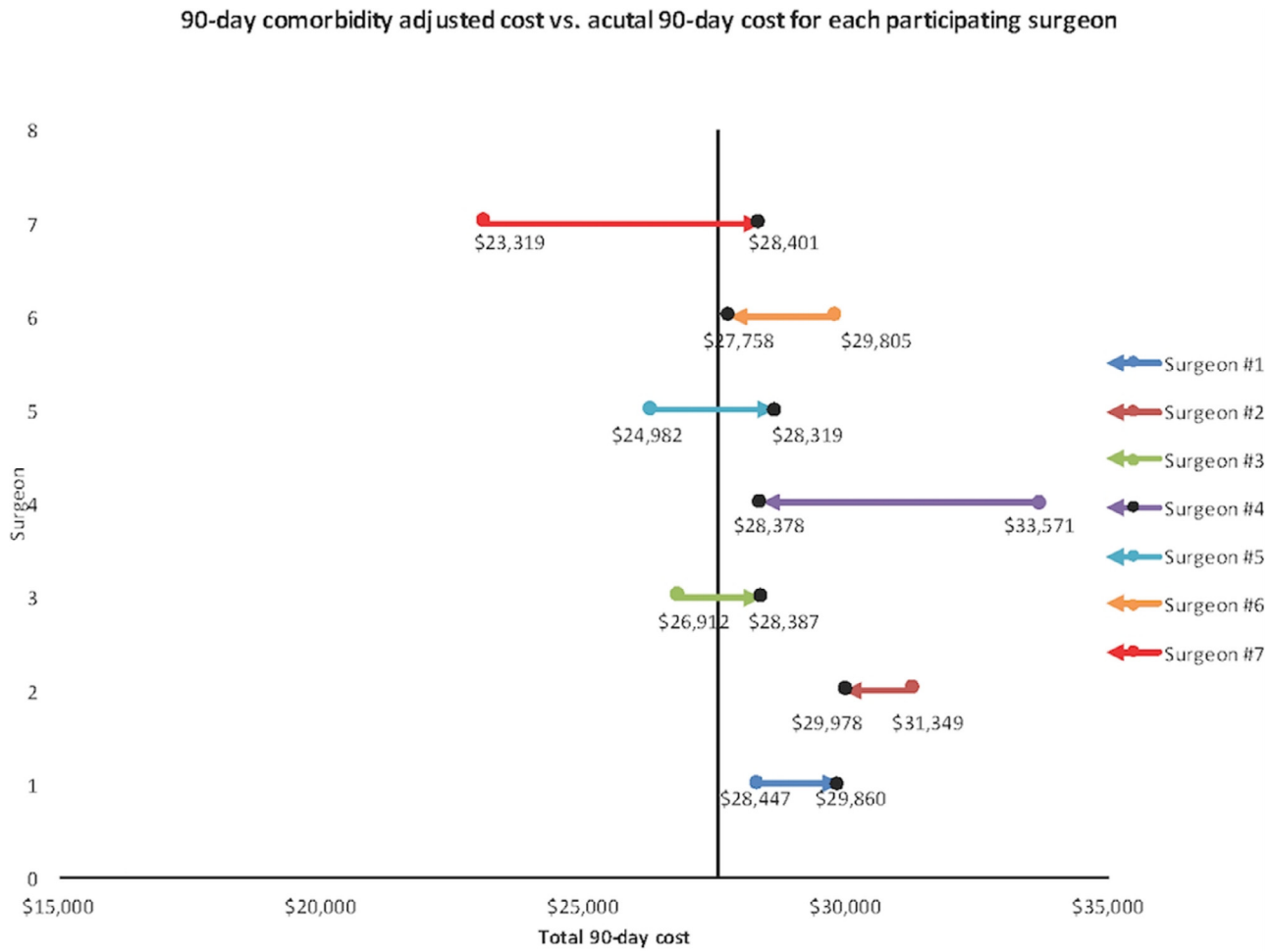

Fig. 2 – The 90-day adjusted cost vs actual 90-day cost for each participating surgeon. The vertical axis represents actual median 90-day cost ($27 565). The black dots represent mean comorbidity-adjusted 90-day cost for each surgeon and the colored dot represents the mean actual 90-day costs. The line joining the colored and black dots represents the difference between the actual and the adjusted cost. The adjusted cost was higher than the actual cost for surgeons #1 (P = .08), #3 (P = .002), #5 (P < .0001), and #7 (P < .0001), suggesting these surgeons were less costly than predicted. In contrast, the adjusted cost was lower for surgeons #2 (P = .128), #4 (P < .0001), and #6 (P = .44), which suggests that these surgeons were costlier than predicted after adjusting for comorbidities. Reprinted with permission.[8]

Because the goal of many spine interventions is to improve the quality of life rather than extend life, measuring and tracking improvements in quality of life and function is at the center of measuring and improving value in spine care. To accomplish this, a number of validated patient-reported outcome measures (PROMs) have been developed and validated, and long-term clinical registries have been designed for tracking outcomes. Transforming that information into actionable insights and identifying drivers of variation on an individual patient level, is the key to improving outcomes on a population level.

3.1. *Patient reported outcome measurement tools*

Patient-reported outcome measures are typically self-completed questionnaires that can be classified into general quality of life, pain, and disease-specific outcome measures.[31] The most commonly used general quality of life outcome assessment tools are the Short Form 36 (SF-36) and the EuroQol Five Dimension questionnaire. Both have been validated to measure overall health status across a broad spectrum of diseases.[32] In spine, pain outcome measures are often specific to back pain or leg pain visual analog scale (LP-VAS or BP-VAS) or the numeric rating scale (NRS). However, the literature has not demonstrated consistent or meaningful use for these scales in research settings. Spine disease-specific outcome measures are intended to link functional impairment to spinal disorders. For lumbar spine pathology, the most commonly used validated disease-specific outcome measure is the Oswestry Disability Index (ODI). The ODI is a questionnaire containing 10 subscales (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling), each scored for a total score expressed as a percentage (100% = worst disability, 0% = no disability). Relative to other outcome measures, the ODI has low responder and clinician burden as it takes roughly 5 minutes for the patient to complete and about 2 minutes for the clinician to

score. Several other disease-specific outcome measures exist in spine that are specific to cervical spine (Neck Disability Index or NDI) and myelopathy outcomes (Japanese Orthopaedic Association Scale or JOA). When tracking outcomes, a validated PRO in each of the three categories (quality of life, pain, and disease-specific) are recorded at baseline and again at defined points in the follow-up setting (e.g. 12 months after intervention). To track outcomes efficiently, a careful approach is needed to track the least amount possible yet including everything having a significant impact. An intervention should be followed for as long as necessary for patients to reach a static state, which varies by intervention. For example, those that undergo a discectomy should be followed for three months, whereas those that undergo a fusion should be followed for one year.[33] (Despite traditional thinking, evidence suggests it is not necessary to track patient outcomes out to 2 years following a fusion.[34]) Being sensitive to the comorbidities and patient characteristics that impact outcomes, a balance of the most efficient and sensitive patient reported outcomes administered, and the length of time patients are followed, reduces the cost and burden of this labor intensive exercise.

A considerable limitation of these tools is the absence of a direct, clinically significant meaning. To overcome this, the concept of a minimum clinically important difference (MCID) was introduced as the critical threshold needed for the intervention to be considered effective.[35] A range of MCIDs have been previously published for many of the disease-specific outcome PROs in spine. For example, a previously published MCID value for the ODI is 14.9.[36] While this concept is appealing from a clinical and research perspective, there are multiple methods for calculating MCID and a wide range for commonly used PROs have been determined depending on the method of calculation.[37] MCID, when anchored against satisfaction, is dependent on the baseline number for which the patient starts. Those that start with a very high baseline ODI (significant disability) require a much larger change score from the procedure to achieve satisfaction as compared to those that start with a lower ODI.[38] In response to this baseline effect, many have moved toward using a defined change score (e.g. >30%) to be considered substantial clinical benefit.[39]

In an effort to overcome limitations of current legacy patient reported outcome measures, the NIH-funded project produced the Patient-Reported Outcomes Measurement Information System (PROMIS).[40] PROMIS was developed to improve the reporting of patient's symptoms, function, and overall health status by testing domains of health, such as physical health, mental health, and social health. The use of item response theory (IRT) in the development of the questions (*i.e.* items) and the plan to use Computerized Adaptive Testing (CAT) allows for an efficient and reliable tool. Item response theory is a process of test development that ensures each individual question is reliable, of value to the whole, and precisely placed along the continuum of the trait being tested.[41] IRT allows each question to be unidimensional, testing a single trait and with minimal influence by other traits (e.g. a question that tests physical function is not influenced by depression). Computerized adaptive testing (CAT) is a testing format in which the response to a question determines the next question delivered to the examinee, allowing for the minimal number of questions needed. PROMIS utilizes a T-score as the output measure in which all PROMIS domains are normalized to the general population with the mean set to 50 and standard deviation set to 10 points. For spine patients, the Physical Function domain of PROMIS (PROMIS PF) is one of the most relevant and consists of 121 items (*i.e.* questions) on the continuum of very low to very high function. By using CAT, accuracy is often achieved with the delivery of 4–6 questions. The one challenge of utilizing CAT PROMIS is the need for constant high speed internet connectivity, which makes it challenging to be scalable across all types of practice settings. A 2014 study obtained PROMIS PF scores in addition to ODI and SF-36 PFD from a cohort of 1719 spine patients and found the PROMIS PF CAT to have better coverage and was quicker to administer.[42] While it is still unclear what a change in PROMIS scores mean clinically, a growing body of literature supports the superiority of PROMIS over traditional PROMs.

3.2. *Tracking outcomes: clinical registries*

With recent advances in health information technologies and statistical methodologies, new observational techniques are reconceptualizing the traditional evidence-based medicine paradigm. In particular, patient care registries are increasingly recognized for their value in powering health care quality improvement.[43] The term "registry" is used to describe centralized data collection of health care treatments, safety, and outcomes. The majority of these track hospital or payer/purchaser claims and billing records, which can provide population assessments and cost information. However, claims-based administrative databases are notoriously prone to coding errors and inaccurate at determining safety or effectiveness of care.[44] In contrast, a well-designed prospective clinical registry possesses many of the same characteristics as a randomized controlled trial and can produce level 1 prognostic evidence and level 2 evidence on effectiveness of care.[45] When compared to traditional methods of evidence development, registries are cost effective, reflect real world environments, and are increasingly supported by health care stakeholders. Hurdles to implementing a nationwide high-quality registry include the cost incurred to maintain data-collection infrastructure and to perform routine quality assurance.

An example of a national registry is the Quality and Outcomes Database (QOD).[46] The QOD is a prospective observational registry that records 30-day morbidity and 3- and 12-month quality data for surgical spine patients. In addition to collecting demographic data, diagnoses, complication and other perioperative factors, the QOD collects PROs including the BP and LP VAS pain scales, ODI, EQ-5D, and the NASS Patient Satisfaction index. These questionaries' are completed preoperatively and again at 3 and 12 months postoperatively. The QOD is now established in more than 100 major US treatment centers and data derived from the QOD has begun to generate evidence on cost and effectiveness of treatments for spine disorders. For example, repeat discectomy versus discectomy and fusion for the treatment of recurrent lumbar disc herniation has demonstrated similar short-term clinical outcomes but shorter operative times and length of

stay and significantly lower hospital charges for the repeat discectomy group.[47] With granular clinical details and relevant short- and long-term outcomes available through a national registry, powerful evidence such as these can be performed quickly and in a cost-efficient manner. Multiple mediums of data collection, including email, tablet or phone app, and by phone interview, need to be utilized to ensure high accrual and follow-up. When this effect has been analyzed, it was found that those who returned to work were less likely to participate in a phone questionnaire and were thus lost to follow-up. Once this working population was targeted with email or phone app, the follow-up rate improved.[48]

In addition to establishing superior treatment interventions for a specific disorder, data gathered from clinical registries in combination with advanced data analytics techniques are now being used to generate decision aids for predicting (before surgical intervention) which patients are unlikely to benefit from surgery or experience an adverse event.[49] As more data becomes available, predictive models will continue to become more accurate at predicting outcomes and costs associated with surgery based on a particular patient's baseline attributes and disease-specific factors, thereby reducing the uncertainty that currently surrounds value in spine care.

4. Paying for outcomes

Given the tremendous cost and high prevalence associated with spine disorders, the need for improving value in spine care has never been higher. Effectively reporting, measuring, and comparing outcomes are critical steps toward quality improvement and making safe decisions regarding cost of delivering outcomes.[50] While volume is not specifically part of the value equation, increased volume of the same condition can and will lead to improved efficiency and outcomes.

In place of alternative payment models, many private payers and employers are directing care toward "Centers of Excellence" (COE) that consistently demonstrate a high quality of care for a specific condition. Centers of Excellence, a type of Integrated Practice Unit (IPU), are multidisciplinary healthcare teams that accept joint accountability for outcomes and costs of treating a particular condition.[51] This model allows for rapid quality improvements throughout the entire phase of care surrounding a specific condition. For example, the IPU structure has been demonstrated to improve outcomes and decrease cost for geriatric hip fractures.[52] In theory, this is a more sustainable model, as it rewards physicians for their unique skills, appropriateness of care, and the cost-intensive process of tracking outcomes. Ideally, these centers should be readily identifiable by their superior outcomes and low costs via a common multicenter registry like the Quality and Outcomes Database (QOD). Certain hospitals are designated by the Centers for Medicare and Medicaid Services as centers of excellence but the selection criteria do not incorporate functional outcomes, which are crucial in evaluating outcomes in spine surgery. Initial studies comparing COE and other hospitals have demonstrated equivalent complication rates, readmission rates, and 90-day costs for spine surgeries, thus highlighting the need for critical evaluation of COE programs. Centers of excellence have the potential to resolve many of current health care issues, but more rigorous selection criteria and evaluation are needed, especially with regard to patient reported outcomes. While implementing a COE structure is no trivial undertaking, the longitudinal data that fuels continuous improvement and efficiency in this structure can now be achieved on a national scale using clinical registries.

Delivering high value spine care is a goal common to all stakeholders including payors, providers, and patients. To deliver on value, both outcomes and cost must be measured and considered over the entire phase of care for treating a disorder. Interventions (and providers) that improve outcomes must be identified and rewarded, while interventions that diminish outcomes must be identified and removed from the equation. For example, opioids are commonly used as a treatment for low back pain despite studies showing that preoperative opioid consumption correlates with worse quality of life and disability outcome scores, and increased costs following spine surgery.[26,53] Based on these results, decreasing or removing opioids from the treatment algorithm for preoperative pain management would be a step toward improved outcomes and ultimately decreased cost. Because cost-containment efforts are often developed without regard to outcomes but rather in response to cost of services provided, results are often ineffective and counterproductive when truly considered over the entire phase of care. Rather than measuring cost in terms of services provided, cost should be measured in terms of the disorder treated. Measuring the cost of delivering outcomes to a particular patient for a particular disorder will allow cost of patient factors at risk of complication or readmission to be established, and reimbursement appropriately risk-adjusted.

5. Conclusions

Establishing high value in spine care relies on quality, not quantity. Identifying and minimizing drivers of variation in outcomes and cost will accelerate the value of spine care. Improved patient-reported outcome tools, clinical registries, and advanced predictive technologies are now making it possible for all spine practitioners to participate in the development of high-value spine care. All stake-holders must recognize the changes and continuous adjustments necessary as data emerges. Reimbursement must be allocated to account for comorbidities and episodes of care, and surgeons must not be disincentivized to offer the best treatment to the medically complex. Finally, the heavy-lifters involved in driving true quality improvement and efficiency, must be appropriately incentivized to build a sustainable model over the long-term. Ultimately, true value-based health care will embolden those delivering on quality.

Disclosures

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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