# Current and Emerging Payment Models for Spine Pain Care: Evidence-Based, Outcomes-Based, or Both?

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**Key Points**

- Payment for spine care is moving toward "value-based care" models.
- "Value" is defined as best outcomes at optimum cost.
- This chapter explores currently available models used by policymakers to define best outcomes.
- The Patient-Reported Outcomes Measurement Information System (PROMIS) is among the latest and most influential tools to assess ongoing population-based responses to treatment. Its limitations include lack of granularity with regard to specific treatment provided for each patient.
- "Evidence-based" medicine as a foundation of health policy including payment faces challenges with regard to generalizability of literature-based findings to guide treatments at the level of each individual.
- The US Federal insurance system has recently introduced a merit-based payment system (MIPS) requiring physicians to document specific treatment outcome and quality measures to justify a payment bonus or incur a payment penalty.

## Introduction

In contrast to the numerous workshops and handbooks describing methods to optimize payment for care rendered, virtually all academic texts, curricula [1], and monographs [2] about pain consider "translation" of basic findings to end with their clinical application. Rarely do they consider that interventions must be supported in a stable economic context, including paying for the time and effort of clinicians implementing them, if the interventions are to survive [3]. Other chapters in this volume present comprehensive accounts of the neuroscience of pain insofar as they help clinicians understand conditions affecting the spine and guidance as to patient selection when translating preclinical findings and clinical trial results into daily practice. However, none of these advances will persist as therapeutic options if the processes to ensure that they are paid for when applied appropriately fail to do so in an economically sustainable way. Many academic and tertiary pain care settings in which scientific advances are translated into clinical care already struggle to maintain profitability if not viability as healthcare payment evolves from fee-for-service to shared financial risk [4].

The present chapter reviews current and emerging payment models that, presently and in the near future, will provide economic support for the practice of spine care. Some general familiarity with the concepts of outcomes assessment and medical evidence is expected of the reader, not a high barrier, given the pervasiveness of both concepts throughout current medical training and practice [5]. We describe payment models based upon clinical outcomes achieved during the everyday care of real patients, as assessed by generic and specialized instruments such as the Patient-Reported Outcomes Measurement Information System (PROMIS) [6]. We describe other payment models based upon evidence-based methods that consolidate findings in prior published studies of previous cohorts or populations exposed to the same treatment [7]. We indicate that ongoing mandates aimed to contain ever-increasing costs of care are

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likely to result in a convergence of the two approaches as framed through Medicare payment models such as MACRA (see below). We conclude with a glimpse into how emerging technology may accelerate the routine collection of "big" data on a large scale to inform value-based care, including the application of blockchain methodology to aggregate detailed, individual patient data to inform population-based outcomes assessment while maintaining the security and confidentiality of individual records.

## Outcomes-Based Care and Payment

Efforts to heal disease and overcome the effects of trauma have been an integral part of civilization since before recorded history [8]. For those cultures with historical records of their approach to sickness, health, and healing, there is clear documentation that some healers and treatments were felt to produce better outcomes than others [9]. Well-regarded healers were accorded a higher status and in many cases paid more, than others. For example, Hammurabi's Code (c. 1695 BCE) stipulated the fee allowed for surgical procedures according to their complexity, the social and economic standing of the patient, the skill of the provider, and whether special equipment was employed [10]. However, this code punished surgeons whose operations were followed by the patient's death by amputation of both hands. Plato's dialogues contain many references to the practice of medicine in ancient Greece, including its two-tiered medical system. Citizens received time-consuming, individualized assessment and care, but slaves were treated in an empirical, hurried fashion in crowded clinics [9]. Physicians who treated citizens were state appointees with an annual term and high socioeconomic status. Their reappointment depended upon citizens' satisfaction with their results in the prior year, as voiced in a community gathering convened annually for this purpose. Socrates made reference to outcomes-based reappointment when he asked, "If you and I were physicians, and were advising one another that we were competent to practice, should I not ask you, and would you not ask me, well, what about Socrates himself, has he not good health? And was anyone else ever been known to be cured by him, whether slave or freeman?" [9].

Yet despite the foundational importance of health, sickness, and treatment to the human condition and references to illness or well-being for millennia not only in medical texts [10] but also in religion [11], systematic approaches to deciding upon the merit and value of specific interventions have been absent until recently. The term "outcomes movement" has been applied in many ways. Broadly, it refers to the use of prespecified measures to assess the effectiveness of medical care, often with an emphasis upon the patient's perspective and preferences as opposed to the function of one or another organ system [12]. Until the late twentieth century, results of medical interventions were as a rule reported in ad hoc, frequently intuitive ways. This approach was suitable for dramatic single cases or small series reporting prevention or cure of the fatal conditions such as diabetic ketoacidosis or scurvy [13], therapies whose real-world benefit was readily confirmed by some easily measured secondary function or physiological outcome or a vaguely phrased result such as returning to one's previous health (or in an Old Testament clinical trial of rich versus simple diets, displaying "fairer countenances") [14].

Multiple factors led to the introduction and now embedding of prespecified outcomes into medical research and health care [5]. These include the growing need to compare different treatments according to a common yardstick or yardsticks; the need to decide whether a treatment has a partial effect that falls short of being lifesaving but is nonetheless clinically significant, such as return to work; the cost of the treatment; and as above mentioned, the rise of consumer empowerment [15]. Consumer empowerment is manifest in medical care as patient-centeredness, reflected in part by the introduction of outcomes particularly important to patients such as quality of life, functional capacity, the medical condition's interference with daily life, mood, satisfaction with care, out-of-pocket costs to patients and families, or readmission to hospital [5, 16–18].

Outcomes assessment instruments have proliferated in recent years, owing to the increasing ease of capturing relevant data in real-world settings (e.g., by smartphones or activity monitors) [19] and the multiple purposes for which such measures may be applied. Such purposes include individual or population-based clinical or health services research, payment "for performance" in a cohort of insured patients treated in a single practice or health-care system, and monitoring the results of individual patients' care. There are generic outcome measures designed to capture health-related quality of life in a population without any single overriding health problem, and supplemental or condition-specific instruments relevant to a specific pathology or cluster of pathologies such as chronic pain or spine conditions [20–22]. Generic measures (particularly when compressed into as few questions as possible to reduce the burden of data capture) may lack the sensitivity to discern changes in outcomes of a patient cohort defined by having a specific pathology and often must be supplemented by questions relevant to that specific pathology [18–20, 23–26]. Alternatively, an adaptive testing instrument such as the Patient-Reported Outcomes Information System (PROMIS; see below) may be programmed to present supplemental questions exploring health-related quality of life and function in greater depth if the patient's initial responses indicate significant impairment. An idea of the range of chronic pain-related outcomes is reflected in consensus recommendations from conferences

**Table 3.1** Core domains for clinical trials of chronic pain treatment efficacy and effectiveness

| |
|---|
| Pain |
| Physical functioning |
| Emotional functioning |
| Participant ratings of global improvement |
| Symptoms and adverse events |
| Participant disposition (including adherence to the treatment regimen and reasons for premature withdrawal from the trial) |

Adapted from [27]
Note that the first five listed domains are also relevant to outcomes that assess the quality of clinical care

**Table 3.2** Recommended research standards prepared by an NIH task force on chronic low back pain ("cLBP")

| |
|---|
| Define the chronicity of the cLBP |
| Stratify the cLBP according to its intensity, interference with normal activities, and functional status |
| Report at least a minimum dataset: history and demographics such as employment status; physical examination; imaging studies; and self-report domains such as can be captured using the PROMIS measures |
| Measure outcomes drawn from the minimum dataset (among other sources) |
| Conduct research to refine the research standard |
| Disseminate the research standards through the National Institutes of Health Pain Consortium and the pain research community |

Adapted from [28]
Note: Many of the above proposed standards are also relevant to data obtained to document quality and value of clinical care outside of research

convened by the ACTION/IMPACT group [27] (Table 3.1) and a separate working group to identify a core set of outcomes for clinical research on spine-related conditions [28] (Table 3.2).

With regard to outcome measures as a driver of payment, a major impetus for this approach was the emphasis upon "value-based care" under the Affordable Care Act, where "value" is defined as improved clinical outcomes delivered "cost-effectively" (meaning reduced cost for similar outcomes or similar cost for improved outcomes). A current, widely used instrument for capturing outcomes in a variety of disorders including pain-related conditions relies upon computerized adaptive testing that as mentioned earlier minimizes the number of questions posed to respondents by having the choice of later questions depend upon the severity of symptoms and impairment revealed in the responses to earlier questions.

PROMIS was developed in 2004–2009 with funding from the National Institutes of Health [6, 29]. The self-reported outcomes for adults include measures of global, physical, mental, and social well-being. With the exception of global health status, the same measures for children are reported by proxy. Pain-specific domains include intensity, interference, behavior, and quality. Additional domains (e.g., fatigue or sleep disturbance) often associated with pain are also assessed. Initially, the validity and other psychometric properties of the PROMIS questions were categorized in longitudinal studies of six widespread, burdensome, and costly clinical conditions: congestive heart failure, chronic obstructive pulmonary disease, rheumatoid arthritis, cancer, back pain, and major depression. These initial studies characterized the responsiveness of the PROMIS measures to changes in health-related quality of life and function during treatment of each of these conditions [6, 29].

For example, the back pain study evaluated the impact of "spinal injections" on individuals with back and/or leg pain as assessed by the PROMIS pain measures. Similarly, the depression study examined the impact of standard treatments (medication, psychotherapy, or the combination of both) in a sample of individuals with clinical depression and evaluated their responses using the PROMIS measures of emotional distress (depression, anxiety, and anger). Such validation and outcomes studies of the PROMIS measures provide an initial framework for standardized, precise, and continuous measurement and improvement of outcomes. However, the information provided will require further comparative effectiveness studies (CERs) to provide practitioners, policymakers and third-party payers specifics with regard to treatment modalities that deliver the best outcomes in various cohorts of patients with chronic diseases. This is because the PROMIS dataset lacks the granularity of CER, e.g., to document which specific treatment was provided or what criteria drove the medical decision-making process. Thus, though we have made great strides in collecting data on outcomes, we have still not addressed the most important question for value-based care: "Which treatment or combination of treatments provide the best outcomes for this patient at the optimum cost?"

In summary, the rationale for outcomes-based payment lies with the opportunity to collect and monitor uniform, normative data, increasingly in real time, captured under real-world conditions of life and medical care. On the other hand, if an outcome instrument is used that is insensitive to the specific population and pathologies treated, a false-negative conclusion may be reached indicating that the treatment did not produce significant benefit. If one asks a greater number of questions to enhance the sensitivity of monitoring outcomes, this approach increases the burdens upon the respondent and clinician. Opportunities associated with routine outcomes assessment include the intuitively fair approach to care of paying for what works – as in Hammurabi's Code [30, 31] – and the prospect of collecting "big data" so as to refine care of populations by identifying opportunities for improvement. Threats and dangers to applying outcomes-based payment include incorrect or incomplete application of the primary sources dictating what the preferred outcomes are, for example, in misinterpreting the CDC Guidelines for

Opioid Treatment of Chronic Noncancer Pain [32] as stating in a blanket fashion that long-term use of opioids is necessarily a poor outcome. Further, any standardized instrument measuring health-related quality of life runs the risk of failing to assess personal abilities such as preparing a meal for a loved one, sitting through a religious service, or playing with a pet that may hold great meaning for the patient.

## Evidence-Based Versus Outcomes-Based Medical Care and Payment: "Chicken or Egg"?

A 1996 bellwether definition of evidence-based medical care was offered by David Sackett: "Evidence-based medicine is the conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services" [33]. Others have offered similar definitions, sometimes explicitly mentioning that the reduction of bias is one of EBM's (evidence-based medicine's) fundamental goals. To reduce bias in estimates of treatment efficacy, proponents of EBM have relied heavily upon randomized controlled trials, a method introduced into clinical investigation after the Second World War. Sackett's definition continued: "Current best evidence is up-to-date information from relevant, valid research about the effects of different forms of health care, the potential for harm from exposure to particular agents, the accuracy of diagnostic tests, and the predictive power of prognostic factors."

As pointed out above, prospective appraisals of individual outcomes of medical treatment date back at least as early as the Old Testament [14] and likely antedate the historical record. Yet until valid outcome measures were developed to capture the salient features of the disorder being treated, medicine's ability to predict the likely result of a treatment, assess its side effects, judge whether its cost is justified, and compare the effectiveness of one treatment versus another was quite limited. Arguably, the relationship between outcomes-guided care and evidence-based care is one of chicken and egg. The collection of valid, relevant outcomes is a foundation of clinical research, the aggregated results of which constitute "current best evidence." Awareness of current best evidence allows clinicians to prepare evidence-based guidelines, adherence to which is assumed to improve outcomes. Systematic collection of outcomes during clinical practice provides evidence to support continuous quality improvement [34]. Indeed, advances in outcomes assessment and clinical evidence have taken place concurrently in recent years.

Regarding the aggregation of data from multiple patients and sources, a fundamental stumbling block in translating clinical trial evidence to clinical care is that "the physician serves as advocate for the personal goals and subjective preferences of individual patients, not for classes of patients or for society as a whole" [13]. Decades ago, Louis Lasagna recognized that results obtained during everyday care of patients may not reflect the results of RCTs conducted to receive marketing approval [13]. The latter are typically conducted in artificially homogeneous populations without significant comorbidities, with few, if any concurrent medications, recruited and followed attentively – "hothouse medicine," in Lasagna's words. Therefore, he urged evaluation of new medications in the setting of everyday clinical practice, in what he termed a "naturalistic" fashion akin to what we now call "comparative effectiveness research." Critiques of the application of EBM to medical decision making have continued to appear in the subsequent decades [15, 35, 36].

Apart from questions regarding the generalizability of RCTs or their aggregated results reported in systematic reviews or meta-analyses, there are other reasons to question the use of this form of structured evidence as the basis for insurers' reimbursement for specific treatments [37]. Statistical methods for combining the results of clinical trials to reach a conclusion based upon the clinical literature were developed in postwar United Kingdom to help its government estimate resources required to support its newly declared policy of free health care for all [38]. Archie Cochrane was a public health physician who was instrumental in this early assembling of clinical trial evidence to support policymakers' decisions in the United Kingdom's National Health Service; the Oxford-based worldwide collaboration in EBM is named in his honor. The statistical decision support methods that Cochrane and colleagues introduced were population-based and by design decreased the weighting ascribed to results of individual outliers. On the other hand, patients referred for evaluation and treatment at specialized pain treatment centers are de facto outliers in that they have not responded adequately to efforts of their primary care providers. Therefore, prior approval or denial of payment based upon a systematic review or meta-analysis of the literature, showing no aggregate benefit for the experimental intervention compared with the control, may limit access by subgroups or individual patients who may respond to the treatment, albeit insufficient numbers to produce group differences in published outcomes between the active and control groups. For decades, clinical and health services researchers have recognized the merit of multiple sources of evidence beyond RCTs to aid in the evaluation of health effects, patient preferences, and costs of treatments [39] including novel technologies [13]. Examples of these non-RCT sources of evidence include case series, case studies, epidemiologic surveillance, cohort studies, decision analyses, mathematical modeling, group judgment methods, and administrative data. See Tables 3.3 and 3.4.

**Table 3.3** Technology assessment methods for evaluating safety and efficacy of proposed treatments, risks, costs, preferences, and current practice

| |
|---|
| Randomized clinical trial |
| Receiver-operating characteristic curve, relating true positive rate to false positive rate |
| Series of consecutive cases |
| Case study of a procedure, program, institution, or decision |
| Registers and databases |
| Sample surveys |
| Administrative data |
| Epidemiological methods: cohort studies, case-control studies, cross-sectional studies |
| Surveillance |
| Quantitative synthesis methods, including meta-analysis |
| Group judgment methods (Delphi, consensus conferences, etc.), sometimes incorporating literature reviews |
| Cost-effectiveness and cost-benefit analysis |
| Mathematical modeling |
| Decision analysis |
| Examination of social and medical issues |

Adapted from [13]
Note: Although presented in the context of technology assessment, the above methods and those in Table 3.4 are also relevant to evaluating the quality and value of clinical care

**Table 3.4** Examples of studies with effects on policy or practice

| |
|---|
| Randomized, controlled trials |
| Meta-analyses, systematic reviews, decision analyses |
| Prospective cohort studies |
| Retrospective cohort studies |
| Case-control studies |
| Cross-sectional studies |
| Ecologic studies |
| Pragmatic trials and large observational studies |
| Program-based evidence |
| Case reports and series |
| Registries |

Adapted from [39]

Variation in study designs of the available RCTs in clinical pain research, including interventions or outcomes measured and the timing of both, limits the strength of conclusions drawn from their pooled findings (meta-analysis). Except for a limited number of conditions, it has taken an inordinate amount of time to develop consensus treatment recommendations relevant to pain medicine, following EBM methodology [40–47].

## Applying Outcome Measures in Routine Clinical Care

There has been some move to address the gap between patient-reported outcomes and clinical recommendations. The acute pain arena lends itself to such detailed reporting of specific perioperative treatment provided while collecting outcome measures data [48]. This is exemplified in the PAIN OUT initiative [49, 50] under the auspices of the European Pain Federation (also designated as "EFIC"). Other initiatives apply tools specifically developed for patients undergoing total knee arthroplasty (TKA) or benchmarking of patients post hip surgery [51, 52]. Efforts are now under way to adapt the PROMIS measures into a 1-day timeline so as to develop a modified instrument suitable for acute pain outcomes studies (Kent M, 2018, personal communication). In the chronic pain arena, the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) developed by the Veteran's Administration [53] allows for routine data collection to guide clinical care, according to a framework that supports longitudinal outcomes assessment and comparison against a representative sample of the US population from the 2010 Census. PASTOR is based upon the PROMIS measures but extends them by adding problem screening questions to elicit (a) opioid abuse/misuse, (b) post-traumatic stress disorder, (c) health utilization – patient report of providers seen by type (primary care provider or pain specialist) – and (d) self-reported treatment history and effectiveness evaluation. The inclusion of the section in health utilization with self-reported treatment and effectiveness evaluation helps provide the information that closes the gap between actual treatment provided and changes in outcomes observed.

## How Do Policymakers Currently View the Issue of Physician Payment Models for Chronic Pain (Spine Pain Care)?

With the rising cost of health care globally, regulators and insurers worldwide are implementing policies to lower the cost of health care while maintaining quality and effectiveness or capping costs while improving health-related outcomes. In the United States, the efforts of the Congress illustrate the magnitude of the challenge. In October 2016, the Centers for Medicare and Medicaid Services (CMS) published a final rule for implementing the Medicare Access and Children's Health Insurance Plan Reauthorization Act of 2015 (MACRA). MACRA extended the efforts of the 2010 Affordable Care Act (ACA) that focused on physician payment reform as a mechanism for managing cost while realigning incentives to enhance health-related outcomes. The ACA expanded access to health care through insurance subsidies and Medicaid expansion and addressed health-care cost through delivery reform. In the lay media, the ACA's efforts to expand coverage have received greater attention than its impact upon delivery/payment reform although the latter is crucially important for clinicians providing care for spinal conditions [54]. MACRA established two new pathways for

Medicare payments to physicians and other health-care providers based on quality and value, superseding the prior traditional fee-for-service model in which physicians are paid for services rendered to patients. Policymakers' desire to move beyond the fee-for-service model was motivated by the aging of the population, driven by the baby boomers: the cost of care was outstripping the sustainable growth rate, a mechanism put in place earlier by the Congress to control cost of care for Medicare patients. The "game-changing" provision of MACRA is its mandate to implement a structured mechanism to report outcomes data. This standardized data is factored into a new payment model that provides a bonus for meeting target outcomes or, if they are not met, a risk for being paid less than under the current fee-for-service model. The new payment model is termed the "Quality Payment Program," within which MACRA has defined two main categories of physicians based on the size and location of the practice. Physicians who practice within an Accountable Care Organization will receive payment under the Advanced Alternative Payment Model (APM) pathway, and physicians who practice independently either solo or in varying sized group practices (urban, suburban, or rural) will receive payment under the Merit-Based Incentive Payment System (MIPS) [4, 55, 56].

## Merit-Based Incentive Payment System (MIPS)

### MIPS-Eligible Clinicians

Under the statute, physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists are all considered "eligible clinicians" and must participate in MIPS during 2017 and 2018 performance years (2019 and 2020 payment years).

Physicians are eligible to receive payment under MIPS as calculated by CMS according to performance in four main areas: (1) quality of care, (2) cost of care, (3) improvement activities, and (4) advancing care information (related to the use of the electronic health record (EHR) and information sharing practices). Stipulations have been made for how eligible physicians are to report the information in each of the categories, over what period, and what targets are to be met. The system is designed to provide CMS a 2-year lead time to evaluate the data reported by the eligible physicians so, for example, the initial reporting period started in 2017 and will affect payment made in 2019, and results from 2018 will be applied to payments of 2020. The system provides an adjustment that ranges from +/− 4% in 2019 to +/− 9% in 2022 and all future years based on performance measures in all the 4 areas outlined above [56]. CMS has reserved the right to modify these adjustments moving forward according to newly gathered information.

### Quality of Care

Of all the four areas, this has the most direct impact on patient outcomes. Key provisions include:

**Data Submission Requirements** For both solo physicians and group practices using the EHR, data must be submitted to a Qualified Clinical Data Registry (QCDR) and a Qualified Registry. Group practices will be able to use CMS's Web Interface (for groups of 25 or more physicians) and a CMS-approved survey vendor for Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CAHPS) data for MIPS.

**Minimum Data Submission** Eligible physicians are required to report at least six measures among which are at least one "cross-cutting" measure and one "outcome" measure. These measures are to be chosen from a list of all MIPS and specialty-specific measures provided by CMS. Specialist physicians may select outcomes from a specialty-specific measure set with no requirement to report a cross-cutting measure.

**Patient Experience Measure** The CAHPS survey counts as one patient experience measure and also meets the requirement to report a high priority measure. Of broader relevance to the issue of payment for treatments to relieve pain of spinal origin, in 2017 CMS announced that as of January 2018, all institutions' responses to the three HCAHPS questions related to in-hospital pain control were to be delinked from quality-based payment adjustments. The basis for this change lays in a suspicion (admittedly without supporting evidence, according to CMS) that asking inpatients to rate their pain intensity might ultimately result in greater quantities of prescription opioid analgesics being available with consequences such as substance abuse and overdoses. Regardless of the impact of this change for payment, it illustrates how pain treatment and payment for it have been affected by the recent epidemic of substance use disorder, particularly opioid abuse including overdoses.

**Global and Population-Based Measures** CMS requires group practices of 16 or more clinicians to report on all-cause readmissions (ACRs) within 30 days. Compliance with this measure is particularly important for multispecialty practices in which spine surgeons, physiatrists, and other physicians practice together, but between whom communication may not always be optimal. Patients managed surgically who are readmitted for poorly controlled pain or infection will adversely affect such scoring for all members of the practice. Alternatively, multispecialty practices that can demonstrate that patients move seamlessly from the primary care physician to the physiatrist or pain physician and then to the surgeon and back to the primary care physician in

the most expeditious manner will score highly for population health management and coordination of care. A minimum of 200 cases are to be reported to meet this requirement for reporting these 2 measures.

### Cost

CMS will evaluate physicians only on those cost measures relevant to their practice (where there are a minimum of 20 patients that can be ascribed to a specific physician or group). Two main value-based modifier measures are required for reporting cost measures: total cost per capita and the Medicare Spending Per Beneficiary. In addition, CMS included ten clinical conditions for which episode-based cost measures can be reported. These include (in the sequence as announced by CMS):

- Mastectomy
- Aortic/mitral valve surgery
- Coronary artery bypass graft
- Hip/femur fracture or dislocation treatment, inpatient-based
- Cholecystectomy and common duct exploration
- Colonoscopy and biopsy
- Transurethral resection of the prostate for benign prostatic hyperplasia
- Lens and cataract procedures
- Hip replacement or repair
- Knee arthroplasty

The episode measures include Medicare Part A (hospital, other health facility, or home care) and B (preventive or medically necessary services) payments for the reported treatment or procedure. Attribution of treatment or performance of a procedure to a clinician requires that the clinician bill for the procedure. For acute care, attribution is to the clinician billing for at least 30% of the inpatient billing codes. Individual clinicians or groups require a minimum of 20 cases to meet the reporting requirement for this measure.

### Improvement Activities Performance

CMS defines improvement activities as activities that an eligible clinician or group identifies as improving clinical practice or care delivery which ultimately enhances outcomes. These activities are to be reported with the same mechanisms for reporting quality measures. Such improvements include organizational activities designed to enhance care coordination to ensure that the patient has access to care and can navigate between primary care and specialist care seamlessly, minimizing waste due to unnecessary or dis-coordinated care. These activities also include changes in clinical practice through introduction or design of enhanced clinical pathways that improve patient outcomes.

## How Do Insurance Companies (Third-Party Payers) Currently View the Issue of Physician Payment Models for Chronic Spine Pain Care?

Precedents for payment set by CMS will ultimately be mirrored by other third-party payers. Unlike the MIPS-eligible clinicians, those practicing in large hospital settings meet the criteria for, and hence may elect to receive payment according to, the Advanced Alternative Payment Model (Advanced APM). CMS under the MACRA statute requires that participants "bear financial risk for monetary losses under the APM that are in excess of a nominal amount" [56]. CMS has further categorized financial risk into (1) the financial risk standard and (2) the nominal risk standard. Under the former, CMS can (1) withhold payments for services to the APM entity's eligible clinicians, (2) reduce payment rates to the APM entity and/or the APM entity's eligible clinicians, or (3) require the APM entity to owe payments to CMS. Regarding the latter (nominal) risk standard, CMS provided a three-part test for an APM to determine if risk for losses is "in excess of a nominal amount," which includes the following: (1) the specific level of marginal risk must be at least 30% of losses in excess of expenditure; (2) a minimum loss rate (MLR) must not exceed 4% of expected expenditures, and (3) total potential risk must be at least 4% of expected expenditures. As of the time of writing this chapter (mid-2018), MACRA is in the second year of performance; the APM as outlined herein will be applied in year 3 (2019).

Although there is no spine-specific model, by examining the next closest surgery (Comprehensive Care for Joint Replacement, CJR) one can gain insight into the APM process. Under the mandatory CJR model, CMS holds hospitals participating as Accountable Care Organizations (ACOs) under the APM financially accountable for the quality and cost of CJR episode of care for elective hip and knee surgery. The episodes start at admission and follow through till 90 days after hospital discharge. The episode includes all medical care and services billed to Medicare Part A and Part B for all Medicare fee-for-service beneficiaries. Between 2019 and 2024, hospital performance will be assessed each year for quality-adjusted spending targets, and the hospital with either receives a bonus for spending below target or pays a penalty for spending that exceeds the quality-adjusted target. Thus, in order to adapt to evolving expectations by CMS and by extension, private payers, ACOs must develop and implement value-based care delivery models in which well-designed clinical operation-provided care is coordinated throughout the hospital system to ensure that the right patient gets to the right provider at the right time for the best outcome at optimum cost.

## Meeting the Mandate for Value-Based Care Delivery Models that Are Evidence-Guided and Outcomes-Driven

An illustration of coordinated care that potentially meets the requirements for Advanced APMs and Medicare Bundled Payments for Care Improvements (BPCI) is the growth in musculoskeletal (MSK) service lines in most ACOs. These MSK service lines are complex, coordinated, multidisciplinary/interprofessional, outpatient/inpatient, value-based care delivery models that span the continuum of care. They include physical medicine and rehabilitation (PM&R) specialists on the front end to address acute/acute on chronic low back pain (duration <12 weeks), working with physical therapy and medication management. For patients who experience pain beyond 12 weeks, the above triage is supplemented by referral to an interventional pain medicine specialist. Some patients will also require care from a behavioral medicine specialist for treatments to enhance coping strategies and resilience. If necessary, then according to the triage protocol, the next step will include specialized imaging and referral to a spine surgeon for evaluation and possible surgery.

If surgery is required, protocolized care involving enhanced recovery after surgery (ERAS) and novel acute pain service-outpatient programs (APS-OP), transitional pain programs (perioperative surgical homes), and perioperative pain programs will facilitate patient progress through the continuum of care. For these novel models of care, value is measured by reduced length of stay, reduced inpatient complication rate, reduced acute readmission rates, and reduced post-acute care complications.

As of the time of writing this chapter (mid-2018), most ACOs are in the process of implementing these novel value-based care delivery models. There is abundant published evidence illustrating the efficacy and effectiveness of elements of these protocols, e.g., multimodal pain control. However, specific data on outcomes and cost-effectiveness of their implementation within CMS's MIPS framework of care delivery models is yet to accrue because the first year of data-based payment adjustment will be in 2019. MIPS-eligible physicians practicing solo or whose practices are not able to support participation in service line models (e.g., MSK service line) have been called on by CMS to propose measures that would meet similar quality performance goals. CMS suggests that such proposed measures should include but not necessarily be limited to (1) measures that are outcomes-based; (2) measures that address the domain for care coordination; (3) measures that address efficiency, cost, and resource use; (4) measures that identify appropriate use of diagnostics and therapeutics; (5) measures that address patient safety; and (6) measures that include submission methods beyond claims-based data submission. These measures should in theory enable MIPS-eligible clinicians to develop models of care comparable to those of ACO-based clinicians.

The assessment of the value of and ultimately future reimbursement for these models will be determined by how data is collected and analyzed. The data should demonstrate that improvements in patient outcomes and concurrent reductions in cost of care have to be readily attributed to enhancements in the care delivery models adopted. The challenge is that CMS has provided many options for data submission methods for both MIPS-eligible clinicians and ACS-based clinicians; the databases are varied and range from claims databases to QCDRs, electronic health records, and CMS Web Interfaces (for groups of 25 clinicians or more) to the use of a CMS-approved vendor for CAHPS for MIPS. These databases do not share the same architecture (compatibility or interoperability) so the data pooling necessary to decide upon population-wide, normative values or to stratify individual clinicians' results specifically will be a complex and ongoing challenge. Such challenges, however, represent opportunities for medical and surgical spine specialists to drive innovative solutions as to which outcomes are gathered and when and how best to collect, pool, and report such data.

## Coordination of MIPS Data Collection: Blockchain Technology?

Data will be accepted from MIPS-eligible clinicians, who may submit it using a wide variety of disparate systems. CMS will have access to this data and will analyze it and provide feedback regarding payment status, i.e., whether or not the physician meets the bonus payment criteria for the payment period. Current registries and reporting database systems meeting CMS requirements are not uniform in terms of format and compatibility, i.e., interoperability, and therefore additional work will be needed to achieve comprehensive population-based outcomes data to inform best practices.

Among the many creative solutions to overcoming the gap between the voluminous collection of data and its aggregation and analysis to improve outcomes, blockchain technology has been advanced as a partial solution. Blockchain technology can be defined as a "distributed peer-to-peer system of ledgers that utilize a software unit that consists of an algorithm which negotiates the informational content of ordered and connected blocks of data together with the cryptographic and security technologies to achieve and maintain its integrity" [57]. The technology was proposed in 2008 under the pseudonym Satoshi Nakamoto [58]. Bitcoin, the peer-to-peer electronic cash system, is the most popular current application of blockchain technology. Biomedical applications potentially include detailed analyses of comprehensive

data acquired from individual patients while maintaining the anonymity of the patients and the practices in which they are treated (except for those MIPS-eligible clinicians who are authorized access to such information).

The foundation for the transformational power of block-chain technology is its capacity to employ underutilized computers and harness their computational power by linking them within a peer-to-peer system. Two types of architectures have been described: (a) distributed, in which component computers are connected to one another without having a central element, and (b) centralized, in which all the component computers are connected to one central component [57]. Hybrid systems have been described, such as multiple distributed systems of computers that connect with a central node. Another hybrid variation is a centralized system in which all the peripheral computers are connected to a central node, within which lies a network of highly interconnected computers. The value of block chain is based on its ability to serve as a tool for achieving and maintaining integrity and anonymity in a distributed peer-to-peer system due to disintermediation (elimination of middleman CMS vendors). Specific examples include payment (managing ownership and creation of digital fiat currencies), cryptocurrencies (managing ownership and creation of digital instruments of payment that exist independently from any government or central bank), and records management (creation and storage of medical records that meet MACRA reporting requirements).

Blockchain technology using the appropriate software has the potential for using all the computing power computer of MIPS-eligible and advanced APM-eligible entities without the need for expensive registries or the use of middlemen vendors to transfer, store, analyze, and report outcome measures to and receive reports from CMS [59].

## Summary and Future Considerations

The answer to the question posed at the beginning of this chapter, "should evidence-based medicine or outcomes drive payments for spine pain treatment?" is "yes," i.e., both criteria together should drive payment! Both are two sides of the same coin. Evidence-based medicine is developed through rigorously designed clinical trials in carefully selected, often homogeneous cohorts. Outcome studies are driven by implementation of evidence-based clinical pathways aimed at achieving the desired health-related improvement in the patient population served. Despite steady improvements in both approaches to improving health care, the lead time from inception of an innovation until its acceptance as a new standard of clinical practice is significantly longer than in other industries (e.g., aerospace). Further, the standards for determining and updating optimum outcome measures for each diagnosis in spine care are yet to be fully developed and agreed upon by all stakeholder subspecialties and payer groups. For example, the outcome measures for two patients with post-laminectomy pain could be very different if one is a 70-year-old male with coronary artery disease and diabetes and the other is a 55-year-old otherwise healthy female with moderately severe osteoarthritis and osteoporosis presenting for care 6 months after her second spine surgery. Ongoing engagement with CMS by subspecialties involved in spine care will help shape future quality and outcome measures. Analyses of data that accrues from the measurement of outcomes of well-defined care will help reduce knowledge-practice gaps and identify areas for future research. Through the reorganization of practice engendered by the implementation of MACRA, one theme has become clear: the time has come to coordinate resources in care delivery and reporting of outcomes to ensure that value-based care can be delivered and quantified. As a practical matter, the issue of coordination of care may be more readily addressed by ACOs through internal structural changes (e.g., development of MSK service lines) and more difficult for individual or group-based MIPS-eligible clinicians.

This chapter has provided a glimpse at key concepts related to health care, with an emphasis on applicability to the treatment of painful conditions affecting the spine. The health-care industry is fast moving, and how payment is organized significantly changes. The key to survival (let alone success) lies in our ability as a specialty to improve care delivery models and outcomes through data-driven improvement in clinical operations: value-based care delivery models that leverage advances in health information technology.

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