Quality Outcomes Database Spine Care Project 2012–2020: milestones achieved in a collaborative North American outcomes registry to advance value-based spine care and evolution to the American Spine Registry

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The Quality Outcomes Database (QOD), formerly known as the National Neurosurgery Quality Outcomes Database (N2QOD), was established by the NeuroPoint Alliance (NPA) in collaboration with relevant national stakeholders and experts. The overarching goal of this project was to develop a centralized, nationally coordinated effort to allow individual surgeons and practice groups to collect, measure, and analyze practice patterns and neurosurgical outcomes. Specific objectives of this registry program were as follows: “1) to establish risk-adjusted national benchmarks for both the safety and effectiveness of neurosurgical procedures, 2) to allow practice groups and hospitals to analyze their individual morbidity and clinical outcomes in real time, 3) to generate both quality and efficiency data to support claims made to public and private payers and objectively demonstrate the value of care to other stakeholders, 4) to demonstrate the comparative effectiveness of neurosurgical and spine procedures, 5) to develop sophisticated ‘risk models’ to determine which subpopulations of patients are most likely to benefit from specific surgical interventions, and 6) to facilitate essential multicenter trials and other cooperative clinical studies.” The NPA has launched several neurosurgical specialty modules in the QOD program in the 7 years since its inception including lumbar spine, cervical spine, and spinal deformity and cerebrovascular and intracranial tumor. The QOD Spine modules, which are the primary subject of this paper, have evolved into the largest North American spine registries yet created and have resulted in unprecedented cooperative activities within our specialty and among affiliated spine care practitioners. Herein, the authors discuss the experience of QOD Spine programs to date, with a brief description of their inception, some of the key achievements and milestones,
RELIABLE determination of clinical outcomes is essential to meaningful participation in the rapidly evolving patient-centered, value-based healthcare environment. However, a few years ago, several quality data experts realized that multiple challenges existed with respect to the proposed value-based healthcare approaches. Those challenges included the facts that medical “quality” remained poorly defined, that existing clinical classification schemes (i.e., diagnosis-related groups [DRGs] and International Classification of Diseases [ICD]) did not adequately reflect critical differences between various patient cohorts (particularly in procedural specialties such as neurosurgery), and that valid methods to continuously measure, promote, and report safety and quality in healthcare were grossly underdeveloped. Therefore, in 2008, the leadership of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) commenced the development of a national quality strategy, the core element of which was to build robust, novel information systems to measure clinical outcomes of relevance to all healthcare stakeholders and to apply those systems in high-yield value environments, such as spine care.\textsuperscript{10,11}

Between 2010 and 2012, the NeuroPoint Alliance (NPA), a not-for-profit corporation initially formed by the AANS and CNS in 2008, worked with relevant national stakeholders to develop a centralized, nationally coordinated effort to allow neurosurgeons and practice groups to collect, measure, and analyze practice patterns and neurosurgical outcomes. This effort was termed the “National Neurosurgery Quality Outcomes Database” (N\textsuperscript{2}QOD), later called the “Quality Outcomes Database” (QOD). The primary goals of this program were as follows: “1) to establish risk-adjusted national benchmarks for both the safety and effectiveness of neurosurgical procedures, 2) to allow practice groups and hospitals to analyze their individual morbidity and clinical outcomes in real time, 3) to generate both quality and efficiency data to support claims made to public and private payers and objectively demonstrate the value of care to other stakeholders, 4) to demonstrate the comparative effectiveness of neurosurgical and spine procedures, 5) to develop sophisticated ‘risk models’ to determine which subpopulations of patients are most likely to benefit from specific surgical interventions, and 6) to facilitate essential multicenter trials and other cooperative clinical studies.”\textsuperscript{11}

In order to execute these objectives, the NPA partnered with the Vanderbilt Institute for Medicine and Public Health (VIMPH) to establish a robust, HIPAA-compliant data collection platform, along with project operating procedures and data management strategies. The details of this collaboration have been described elsewhere.\textsuperscript{11,12} This alliance represented an unprecedented cooperative effort between organized neurosurgery and one of the most highly regarded clinical data and outcomes science programs in the world. Subsequently, an innovative program called the Practice-Based Learning Network (PBLN) was launched at VIMPH, which was composed of data coordinators and clinicians from all participating QOD sites. The objectives of this program were to engage all sites in an effort to uphold a learning culture, promote cooperation and communication among sites, and encourage all participants to share experiences regarding data collection methods. Through the PBLN and VIMPH, we (the QOD) subsequently generated periodic summary reports for participating institutions and practice groups related to our various clinical data efforts. These reports on short- and long-term clinical outcomes and patient-reported outcomes (PROs) were site-specific, risk-adjusted, and compared to average national benchmarks. These reports were then utilized by the sites for various purposes including, but not limited to, enhanced negotiation abilities with payers, bundled care contracting, local quality improvement (QI), and combination with cost data to help determine opportunities for individual surgeons to improve care efficiencies.

It is important to note that our data collection efforts were immediately distinguished from other surgical registry programs in two important respects. First, we made a routine commitment to the collection of PROs, which, despite evidence that these data elements are more accurately reflective of patient experience than physician observation,\textsuperscript{3} was uncommon at the time. Second, we routinely collected longitudinal data; this was considered essential to documenting the sustainability of treatment effects. Both of these characteristics dramatically strengthened the clinical and scientific value of our collected data. They also created certain practical and regulatory challenges, which will be described in the following sections.

**Principal Value Paradigm Opportunities in Neurosurgery: Spine Care**

Low-back and neck pain constitute two of the three most prevalent causes of disability in general, as well as job-related disability in the United States, together costing more than $50 billion per year.\textsuperscript{39,47} Although many patients with spine-related pain are successfully managed medically, some patients do require surgical therapies. A recent analysis from the Agency for Healthcare Research and Quality found spinal fusion to be the most expensive surgical procedure performed in United States hospitals,
with annual direct costs now totaling $180 billion. The Institute of Medicine and other observers have estimated that up to 25% of diagnostic and therapeutic spine maneuvers are unnecessary or ineffective.39 Two recent analyses of the National Inpatient Sample (NIS) have estimated a remarkable annual incidence for the two most commonly performed surgeries for lumbar and cervical spine degenerative disease: lumbar fusion and anterior cervical discectomy and fusion (ACDF). Martin et al. found that a total of 252,565 lumbar fusion surgeries were performed in 2015,31 whereas Saifi et al. found that a total of 127,500 ACDFs were performed in 2013 for degenerative conditions.43

Thus, surgical therapies for spinal disorders represent a particularly important opportunity to enhance value in United States healthcare because of the prevalence of spine conditions, the frequency with which surgical procedures are being performed, and the substantial associated costs.

Creation of the QOD Spine Program

In 2010, the NPA, along with a variety of other stakeholders, determined that a critical need existed with respect to defining the value of surgical spine care. Until that time, no nationally collaborative reporting mechanisms using validated outcome measures had assessed the extent to which spinal surgery impacts pain, disability, and quality of life while adjusting for bias and influential confounders such as variances in comorbidity, surgical approach, cultural factors, region, structure, and process of health services. Furthermore, national benchmarks of surgical morbidity and effectiveness, which define quality, had yet to be determined.

In subsequent sections in this paper, we describe our 8-year experience with and the key accomplishments of QOD Spine (formerly the N’QOD), a national collaborative registry of quality and outcomes reporting after low-back and cervical spine surgery. This program was designed to establish, for the first time, a robust national mechanism of quality reporting, risk-adjusted benchmarking, comparative effectiveness analysis, and evidence-based practice improvement for spine surgery. Of equal importance was the inclusion of essential preoperative patient characteristics, as well as prospective PROs, which were believed to aid in the identification of optimized care paradigms, refinement of surgical delivery to maximize treatment success, and objective determination of the value of spine surgery to the principal healthcare stakeholders who wish to deliver, consume, and/or purchase these services. As we will describe, the QOD also served as a tremendous data resource for cooperative QI and comparative effectiveness research. Our experience with the QOD will form the foundation of a larger, unprecedented national effort designed to make these data collection and analysis techniques available to spine surgeons in all treatment settings.

Early QOD Regulatory Challenges and Breakthroughs

In the early stages of the registry rollout, some of the QOD sites interpreted existing federal regulations pertaining to human subjects research as applicable to our prescribed processes, especially the direct patient contact for the purposes of collecting data, the longitudinal design, the gathering of data not considered to be standard of care in all settings (e.g., PROs), and the possible future use of the data for research purposes. Resolution of this issue has been described elsewhere.12,14 In short, the NPA led a multidisciplinary effort to engage the Office for Human Research Protections (OHRP) and the Office for Civil Rights (OCR) of the United States Department of Health and Human Services (HHS) to refine their guidance and ease the path to collecting longitudinal PROs outside of a “human research subject” setting. The ultimate result of this process was a determination that QOD data collection and analysis processes were not within the jurisdiction of the “Common Rule” (Human Research Subjects regulations, 45 CFR Part 46). After this guidance became available, virtually all sites across the country adopted the stance that the QOD was not human subjects research.

These early efforts enabled us to streamline our process of data collection in alignment with federal regulations. It also enabled us to appreciate various ambiguities that still exist in applicable federal guidance, leading to inconsistencies in local interpretations of the Common Rule and HIPAA Privacy Rule, which may limit opportunities that would otherwise promote data-driven practice improvements and thus enhance patient care.12

QOD Qualified Clinical Spine Data Registry

As part of Affordable Care Act reforms, physician and practice groups were mandated to meet certain quality metrics and standards in order to avoid penalties and negative reimbursements. To facilitate this, the Centers for Medicare and Medicaid Services (CMS) introduced the Qualified Clinical Data Registry (QCDR) reporting option, which helped specialty groups develop and report relevant measures of healthcare quality. A QCDR is a CMS-approved entity that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This program was thought to be particularly relevant to specialties such as neurosurgery, as most existing standardized quality metrics had been developed for primary care and more general practice (such as general surgery).41 Thus, in November 2014, the NPA initiated an effort to develop neurosurgery-specific quality measures. This effort resulted in the formation of a multidisciplinary team comprising healthcare policy experts, clinician-scientists, quality scientists (scientists who study quality), medical administrators, and epidemiologists. The team then created several unique measures by using a variety of resources including QOD data. Subsequently, in January 2015, the NPA submitted 21 preliminary measures to the CMS. In April 2015, the QOD officially became an approved QCDR in the Physician Quality Reporting System (PQRS) for the 2015 program year.41 This effort was significant in that it resulted in the first federally approved quality measures specifically relevant to the practice of neurological surgery. The measures remained in use until
Development and Implementation of Spine Specialty Modules

The first clinical data module to be established by the QOD was the lumbar spine module, which was piloted in 5 centers starting in February 2012. Detailed information regarding the sampling and data collection for the QOD was reported in previous publications. In March 2013, the QOD cervical module was established in collaboration with the Cervical Spine Research Society (CSRS) and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN). Finally, in January 2015, the spinal deformity module was officially incorporated into the QOD. The registry was launched to track patients with noncomplex kyphosis and scoliosis, as well as high-grade (Meyerding grade II and above) spondylolisthesis. The registry was established in collaboration with the AANS/CNS DSPN and the Scoliosis Research Society (SRS). Further descriptions regarding these modules are summarized in Table 1.

Key Scientific Accomplishments of the QOD

The QOD has proved to be one of the most successful cooperative scientific efforts in the history of our specialty, with over 40 peer-reviewed research publications, approximately 75 abstracts/national presentations, and many other methodological and/or policy publications resulting from this effort to date. Much of this research has been supported through generous grants from the Neurosurgery Research & Education Foundation (NREF) along with other private foundations and bio-industry partners.

Table 2 summarizes all the research publications to date using the QOD lumber and cervical modules, in addition to several focused efforts involving teams of researchers from select QOD centers. Table 3 lists the findings of a few representative scientific investigations of QOD investigators.

A Bridge Between Quality Data Collection and Continuous QI

Prominent healthcare researchers have convincingly suggested that “end results information (i.e., clinical outcomes data), although necessary for (healthcare quality) improvement, is not sufficient.” To the point, they contend that clinical data collection and analysis and applied QI are two distinct competencies. With this in mind, and with the idea that collected outcomes data are of little use if they cannot be applied to continuous QI, the AANS/NPA determined to promote a “national competency” in comprehensive QI using registry data. They specifically aspired to help QOD participating surgeons and other healthcare workers to complete the “cycle” of quality data collection, analysis, and application to clinical care (through well-developed methods of continuous QI). This broadened ambition for clinical data linked to continuous QI envisions an expanded role of clinical registries to define opportunities for QI, identify the major drivers of clinical outcomes, embed insights from registry data within continuous QI efforts (based on QI methods developed and validated by groups such as the Institute for Healthcare Improvement [IHI]; see below), create data portals for QI methods embedded in clinical workflows, and, finally, assess the impact of continuous QI on clinical outcomes (using the registry platform).

The NPA chose the IHI (Cambridge, MA) as a partner to help develop a tool kit for registry users to apply registry data to QI efforts. The IHI is a not-for-profit organization whose objective is to advance and sustain better outcomes in health and healthcare across the world. In late 2016, the NPA and the IHI with the support of the NREF engaged in a pilot QI project at 8 of the QOD participating centers. The objective of this pilot was to use IHI’s framework to develop a focused learning system for these sites, which could be used to apply data insights for real, on-the-ground improvement using improvement science.

Through this collaboration, the team developed an initial set of measures to address the outcomes of interest (spine surgery length of stay [LOS], readmission) and change ideas to be tested. Early experience has demonstrated excellent adherence to prescribed methods and patient satisfaction with standardized perioperative processes. Preliminary data suggest a positive influence on the selected outcomes, especially LOS. Implementation of these change ideas at additional sites to assess external validity remains to be done. Nevertheless, this effort represents a vital beneficial use of a registry platform to create a link between clinical data collection and processes of continuous QI. Applied QI through data collection should be the ultimate goal of any such registry effort.

Summary of Early QOD Experience: Lessons Learned and the Future of Spine Care Registries

The spine care QOD project was neurosurgery’s first attempt to create a national data system and an associated quality culture. Specifically, QOD Spine has served as an essential proof of principle regarding the feasibility of a continuous, national, cooperative quality data collection project involving clinicians in all practice settings: academic and community, rural and urban, large and small. Through this program, we have been able to nationally disseminate quality tools and techniques, and we have developed credibility in the quality data space among important stakeholders. The success of this program was highly dependent on cross-disciplinary and cross-specialty partnerships, and the importance of those partnerships was repeatedly validated over the course of the project through serial advances in data science, the evolution of collection and analysis methodologies, and increasingly relevant applications of the collected information to patient care and incentive systems.

2019. At that time, due to a variety of factors including constant CMS attempts to de-specify the elements and the lack of meaningful incentives and other methods for individuals and groups to participate in federal Alternative Payment Models (APMs), the program was discontinued. The NPA retains ownership of these measures, and it is highly likely that they will ultimately be applied to other specialty-specific quality and/or incentive programs.
The close of the decade and the eighth anniversary of the launch of this program give us occasion to reflect not only on the successes of this important effort, but also on the lessons learned and the possible insights into the future of spine care data collection. Perhaps the most important lessons realized from a methodological standpoint relate to data collection efficiencies. Although longitudinal recording of the patient experience and the collection of PROs add great value to the gathered information, routine commitment to the robust assessment of care sustainability and “the patient voice” creates significant burdens—cost, time, and other resources—when using standard data collection methodologies. Thus, only the largest QOD and best-funded centers have been able to collect large volumes of clinical data to this point in time. In that regard, data collection methodologies must be modified and, to a large extent, automated in order to allow for broader and more involved participation in spine data programs. With respect to the PROs themselves, we will likely need to consider an evolution in the use and application of these tools. In particular, there has been great emphasis on the part of many stakeholders on a consolidated set of national standards (e.g., PROMIS) to collect and compare information related to the patient experience.

Over time we have become aware that differential clinical data needs exist on the national, regional, and local level. More precisely defining our objectives (e.g., defining safety/effectiveness, QI, value demonstration, device utilization, public and private payer reporting, etc.) and aligning our programs to be in sync with those various needs will be essential going forward in order to meet the quality data needs of all stakeholders. Ideally, those objectives would be defined with an ever-growing group of strategic healthcare partners in order to maximize the relevance and applicability of the collected data. Our experience to date has reinforced the importance of breaking down legacy barriers to cooperative data collection and sharing among bio-industry, payers, regulatory groups, individual institutions, medical specialties, and others in order to achieve our collective national healthcare objectives.

Although we have collected unprecedented amounts of high-quality spine outcomes data, variability exists with respect to the adoption of prescribed national data collection standards. While some variability is to be expected in the creation of any national data program, routine variations in the quality and completeness of submitted data can have significant consequences in terms of data validity. There are a number of contributors to data collection variability including, but not restricted to, local resource restrictions, lack of automated data entry, and persistent ambiguities related to existing spine diagnostic categories. The latter limitation is particularly important, as inconsistent diagnostic identification can prevent valid comparisons related to the experience of various patient cohorts.

Finally, much has been made of the use of registry platforms for prospective science. We believe that we are only in the early phases of realizing the potential of subgroups of registry participants to leverage our infrastructures to advance evidence generation. In the future, we are committed to helping realize the vision of many leaders in healthcare science to use clinical data registries as “disruptive technologies” to overcome the practical limitations of traditional methods of evidence generation (i.e., randomized controlled trials). Nevertheless, it is important to be cognizant of some of the limitations of registries, particularly when they are missing any of the key characteristics that Klaiman et al. described as being integral to any registry. One of these characteristics is accuracy and completeness of data. Hence, registries should have robust methods and strategies in place to ensure completeness and accuracy of data. In the absence of adequate follow-up data or with unaudited or inaccurate data, inaccurate or flawed conclusions can be derived and may be counterintuitive. To that end, the QOD had a well-defined data collection plan for participating institutions that involved an audited, representative sampling methodology. These methods have been described previously. Although these techniques represented an essential advance in high-fidelity, collaborative prospective outcomes data collection, we believe that future programs relying on automated data collection can and should involve continuous enrollment of eligible patients, along with enhanced internal and external audits.

### TABLE 1. Details regarding the 3 modules of the QOD Spine registry

| Module (year) | Counts | Inclusion Diagnoses | Outcomes Collected | Focused Study |
|---------------|--------|---------------------|--------------------|--------------|
| **Lumbar (2012)** | 230 hospitals, 760 surgeons, 70,000 cases | Disc herniation, stenosis, spondylolisthesis, recurrent disc herniation, adjacent segment disease, pseudarthrosis | ODI, VAS, EQ-5D, NASS satisfaction, 30-day readmissions, & 30-day, 3-mo, 1-yr, & 2-yr reoperation | Impact of Fusion on Outcomes on Grade I Degenerative Spondylolisthesis (12 centers, 608 patients) |
| **Cervical (2013)** | 175 hospitals, 613 surgeons, 25,000 cases | Disc herniation, instability, pseudarthrosis, adjacent segment disease, stenosis (central/foraminal) | NDI, VAS, EQ-5D, mJOA, NASS satisfaction, 30-day readmissions, & 30-day, 3-mo, 1-yr, & 2-yr reoperation | Effectiveness of Surgery for Cervical Spondylolisthesis: Impact of Approach and Diagnostic Category on Pain, Disability, and Quality of Life (14 centers, 1256 patients) |
| **Deformity (2015)** | 108 hospitals, 300 surgeons, 2,500 cases | High-grade spondylolisthesis (Meyerding grade II & above), noncomplex kyphosis & scoliosis | ODI, VAS, EQ-5D, NASS satisfaction, 30-day readmissions, & 30-day, 3-mo, 1-yr, & 2-yr reoperation | Effectiveness of Surgery for Adult Spinal Deformity (High-Grade Spondylolisthesis and Moderate Scoliosis) (12 centers, 347 patients) |

mJOA = modified Japanese Orthopaedic Association; NASS = North American Spine Society; NDI = Neck Disability Index; ODI = Oswestry Disability Index; VAS = visual analog scale.
| Authors & Year | Patient Population | No. of Patients | Objective | Outcomes | Key Findings |
|----------------|--------------------|----------------|-----------|----------|--------------|
| Khan et al., 2019 | Patients undergoing elective surgery for DCR | 2,206 | Determine association of baseline & 12-mo NDI with patient satisfaction after elective surgery for DCR | 12-mo patient satisfaction | In multivariable analysis, after adjusting for baseline & surgery-specific variables, 12-mo NDI showed highest association with 12-mo satisfaction; level of satisfaction increases with decrease in 12-mo NDI regardless of baseline NDI |
| Asher et al., 2019 | Patients undergoing elective surgery for DCM | 1,963 | Determine influence of preop & 12-mo mJOA on satisfaction & understand change in mJOA severity classification after surgical management of DCM | 12-mo patient satisfaction | Comparing mJOA severity level preoperatively & at 12 mos: 55% remained in same category, 37% improved, & 7% moved to worse category; after adjusting for baseline & surgery-specific variables, 12-mo mJOA category had highest impact on patient satisfaction |
| Devin et al., 2018 | Patients undergoing cervical spine surgery for degenerative spine disease | 4,689 | Identify clinical factors associated with RTW at 3 mos among patients undergoing cervical spine surgery | 3-mo RTW after surgery | Patients less likely to RTW were older, were employed but not working, were employed part-time, had heavy- or medium-intensity occupation vs sedentary occupation, had workers' compensation, had higher NDI at baseline, were more likely to present with myelopathy, & had more levels fused |
| Sivaganesan et al., 2019 | Patients undergoing 1-level elective lumbar surgery | 8,834 | Present scheme for PRO-based, risk-adjusted rankings of spine surgeons & sites that perform elective lumbar surgery, using QOD | 12-mo PROs | Study represents first attempt to develop risk-adjusted, procedure-focused, large-scale, & PRO-based ranking of spine surgeons & practices |
| Sivaganesan et al., 2019 | Patients undergoing elective lumbar surgery for degenerative diseases | 33,674 | Develop predictive models for 3-mo medical & surgical readmission after elective lumbar surgery, based on a multi-institutional, national spine registry | 3-mo readmissions | Odds of surgery-related readmission significantly greater for patients with higher BMI, higher ASA status, females vs males, & African Americans vs whites, & for patients with severe depression, more involved spinal levels, ant-only surgical approaches, & higher baseline ODI |
| Sivaganesan et al., 2019 | Patients undergoing elective lumbar surgery for degenerative diseases | 11,897 | Analyze effect of day of the week for lumbar surgery on LOS | Hospital LOS | Among patients discharged home, significantly higher odds of longer LOS for those undergoing surgery on Friday vs Monday; among patients discharged to facility, significantly higher odds of longer LOS for those undergoing surgery on Wednesday, Thursday, & Friday vs Monday |
| Khan et al., 2019 | Patients undergoing elective lumbar surgery for degenerative diseases | 12,435 | Investigate factors associated with RTW in patients who achieved otherwise favorable outcomes after lumbar spine surgery | 12-mo RTW after surgery | Older patients had lower odds of RTW; females had lower odds of RTW vs males; patients with greater back pain & baseline ODI had lower odds of RTW; patients with longer duration of symptoms, more physically demanding occupations, workers' compensation claim, & short-term disability leave at time of surgery had lower odds of RTW independent of their good surgical outcomes |
| Khan et al., 2019 | Patients undergoing elective surgery for DCM | 2,156 | Utilize QOD to evaluate trajectory of outcomes in those operatively treated for DCM | Improvement on mJOA from 3- to 12-mo FU | Baseline mJOA categories had significant impact on whether a patient keeps improving in mJOA score from 3 to 12 mos post-surgery; patient w/ severe mJOA score at baseline had higher likelihood of improvement in myelopathic symptoms, vs patients w/ mild mJOA score |
| Kerezoudis et al., 2019 | Patients undergoing 1- to 2-level ACDF for degenerative spine disease | 4,148 | Decipher impacts of patient, surgical practice, & surgeon on patient satisfaction | 12-mo patient satisfaction | Baseline NDI, patient race, insurance status, symptom duration, workers' compensation status, & geographic region of hospital the most important predictors of long-term patient satisfaction after 1- to 2-level ACDF |

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### TABLE 2. Summary of studies using the entire QOD lumbar and cervical modules

| Authors & Year | Patient Population | No. of Patients | Objective | Outcomes | Key Findings |
|---------------|--------------------|-----------------|-----------|----------|--------------|
| Asher et al., 2019<sup>6</sup> | Patients undergoing surgery for 3- to 5-level DCM | 245 | Compare outcomes after ant & pst approaches using multicenter prospectively collected data | NDI, NRS for neck pain & arm pain, EQ-5D, mJOA, NASS satisfaction, LOS, 90-day readmission, & RTW | Patients undergoing ant approach had lower odds of longer LOS; 12-mo NDI, EQ-5D, NRS, mJOA, & satisfaction scores, 90-day readmission, & RTW did not differ significantly btwn ant & pst groups |
| Asher et al., 2017<sup>7</sup> | Patients undergoing elective lumbar surgery for degenerative diseases | 7,547 | Investigate whether association btwn known patient risk factors & disability outcome is differentially modified by patient smoking status for those who have undergone surgery for lumbar degeneration | 12-mo ODI | Adjusted odds ratio for risk factors & direction of improvement in 12-mo ODI scores were similar btwn smokers & nonsmokers |
| Wadhwa et al., 2017 | Patients undergoing elective lumbar surgery for degenerative diseases | 9,853 | Assess incidence & factors associated w/ 30-day reoperation & 90-day readmission | 30- & 90-day readmissions | Prolonged op time during index case the only independent factor associated w/ 30-day reoperation; higher ASA class & history of depression were factors associated w/ 90-day readmission |
| McGirt et al., 2017<sup>32</sup> | Patients undergoing elective lumbar surgery for degenerative diseases | 7,618 | Develop predictive model for 12-mo postop pain, disability, & QOL in patients undergoing elective lumbar spine surgery | 12-mo ODI, EQ-5D, NRS-BP, & NRS-LP | Most important predictors of overall disability, QOL, & pain outcomes after lumbar spine surgery were employment status, baseline NRS-BP scores, psychological distress, baseline ODI, level of education, workers’ compensation status, symptom duration, race, baseline NRS-LP scores, ASA status, age, predominant symptom, smoking status, & insurance status |
| Asher et al., 2017<sup>5</sup> | Patients undergoing elective lumbar surgery for degenerative diseases | 4,694 | Create predictive model of patients’ ability to RTW after lumbar spine surgery for degenerative spine disease | 3-mo RTW after surgery | Risk-adjusted predictors of lower likelihood of RTW were being preoperatively employed but not working at time of presentation, manual labor as occupation, workers’ compensation claim, liability insurance for disability, higher preop ODI, higher preop NRS-BP score, & demographic factors such as female sex, African American race, history of diabetes, & higher ASA status |
| McGirt et al., 2017<sup>33</sup> | Patients undergoing elective lumbar surgery for degenerative diseases | 6,921 | Develop grading scale that effectively stratifies risk of costly events after elective surgery for degenerative lumbar pathologies | Extended postop hospital LOS (≥7 days), discharge status (inpatient facility vs home), & 90-day hospital readmissions | Increasing point totals in Carolina-Semmes scale effectively stratified incidence of extended LOS, discharge to facility, & readmission in stepwise fashion in both aggregate QOD data set & when subsequently applied to CNSA/Semmes Murphey practice groups |
| Crawford et al., 2017 | Patients undergoing elective lumbar surgery for degenerative diseases | 10,967 | Determine if preop diagnosis of disc herniation, stenosis, spondylolisthesis, adjacent segment degeneration, or mechanical disc collapse impacts patient satisfaction after surgery | ODI, NRS-BP, NRS-LP, & patient satisfaction | Percentage of patients that would undergo same surgery again, by diagnostic group: disc herniation 88%, recurrent disc herniation 79%, spondylolisthesis 86%, stenosis 82%, adjacent segment disease 75%, & mechanical collapse 73% |

<sup>6</sup> CONTINUED ON PAGE 8
<sup>7</sup> CONTINUED FROM PAGE 6
# TABLE 2. Summary of studies using the entire QOD lumbar and cervical modules

| Authors & Year | Patient Population | No. of Patients | Objective | Outcomes | Key Findings |
|----------------|--------------------|-----------------|-----------|----------|--------------|
| McGirt et al., 2017 | Patients who underwent 1- or 2-level interbody lumbar fusion diagnosed w/ lumbar stenosis or grade I spondylolisthesis | 467 | Determine how MIS & traditional open technologies affect postsurgical outcomes & PROs | NRS-BP, NRS-LP, ODI, EQ-5D, RTW, & periop morbidity | After propensity matching, MIS cohort remained associated w/ reduced blood loss & shorter LOS for 1-level fusion (p < 0.05) but had equivalent LOS for 2-level fusion; outcomes in all other 90-day safety measures similar; in both unadjusted & propensity-matched comparison, MIS vs open technologies associated w/ equivalent RTW, patient-reported pain, physical disability, & QOL at 3- & 12-mo FU |
| Crawford et al., 2016 | Patients w/ lumbar stenosis (w/o spondylolisthesis or scoliosis) & baseline back pain score ≥5 out of 10 who underwent surgical decompression only | 726 | Determine if patients w/ lumbar stenosis & substantial back pain—in absence of spondylolisthesis, scoliosis, or sagittal malalignment—can obtain significant improvement after decompression w/o fusion or stabilization | 3- & 12-mo NRS-BP, NRS-LP, ODI, & EQ-5D | At 3 & 12 mos postoperatively, significant improvements from baseline for back pain (7.62 to 3.19 to 3.86), leg pain (7.23 to 2.85 to 3.07), EQ-5D (0.55 to 0.76 to 0.75), & ODI (49.11 to 27.20 to 28.38) |
| Onyekwelu et al., 2017 | Patients who had undergone decompression plus fusion & decompression alone for LSS | 1,791 | Ascertain any difference in clinical improvement or complication rates btwn obese & non-obese patients after decompression alone vs decompression plus fusion for LSS | ODI, NRS-BP, NRS-LP, & 30-day readmissions | No significant differences in ODI or leg pain improvement at 12 mos when comparing decompression w/ to decompression w/o fusion in either obese or non-obese cohorts; absolute improvement in back pain less in obese group when decompression alone performed; no significant differences in 30-day readmission rates among 4 cohorts |
| Asher et al., 2016 | Patients undergoing elective lumbar surgery for degenerative diseases | 3,073 | Analyze whether 3-mo outcome measurements sufficiently represent 12-mo outcomes for patients w/ degenerative lumbar disease undergoing surgery | Baseline & 3- & 12-mo FU ODI | In aggregate analysis of achieving MCID, 77% of patients concordant & 23% discordant in achieving or not achieving MCID at 3 & 12 mos; discordance rates of achieving or not achieving MCID for ODI were in range of 19%–27% for all diagnoses & treatments (decompression w/ & w/o fusion) |
| Carreon et al., 2016 | Patients undergoing TLIF & PSF | 101 | Evaluate relative cost-effectiveness of TLIF vs PSF | Health-related QOL measures & periop parameters | At 12 mos postoperatively, patients who had undergone TLIF had greater improvements in mean ODI & mean SF-6D scores but similar improvements in mean EQ-5D scores as patients treated w/ PSF |
| Glassman et al., 2016 | Patients undergoing TLIF & PSF | 1,722 | Compare outcomes of TLIF w/ those of PSF in patients w/ spondylolisthesis, spinal stenosis, & adjacent level disease | Op time, EBL, LOS, & 3- & 12-mo ODI | In spondylolisthesis group, there was greater improvement in ODI w/ TLIF vs PSF at 3 & 12 mos & in percentage reaching MCID at 12 mos; no differences in ODI improvement btwn PSF & TLIF in stenosis or adjacent segment disease groups |
| Parker et al., 2015 | Patients undergoing elective lumbar surgery for degenerative diseases | 4,370 | Compare effectiveness, morbidity, & quality of care associated w/ surgical management of degenerative lumbar spinal disorders in elderly vs nonelderly patients | LOS, complications, & 90-day readmissions | Hospital LOS & postdischarge inpatient rehab/nursing significantly greater in elderly; incidence of surgical complications & 90-day hospitl readmission similar |

ACDF = anterior cervical discectomy and fusion; ant = anterior; ASA = American Society of Anesthesiologists; CNSA = Carolina Neurosurgery & Spine Associates; DCM = degenerative cervical myelopathy; DCR = degenerative cervical radiculopathy; EBL = estimated blood loss; FU = follow-up; LOS = length of stay; LSS = lumbar spinal stenosis; MCID = minimum clinically important difference; MIS = minimally invasive surgery; NRS = numeric rating scale; NRS-BP = NRS for back pain; NRS-LP = NRS for leg pain; PSF = posterior spinal fusion; pst = posterior; QOL = quality of life; rehab = rehabilitation; RTW = return to work; SF-6D = 6-dimensional health state classification based on SF-36; TLIF = transforaminal lumbar interbody fusion.
| Authors & Year          | Objective                                                                 | Outcomes       | Key Findings                                                                                                                                 |
|------------------------|---------------------------------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Mummaneni et al., 2017 | Assess efficacy of open vs MI fusion for spondylolisthesis                | 12-mo PROs     | MIS associated w/ significantly lower mean intraop EBL & slightly longer op times in both 1- & 2-level fusion subgroups; change in functional outcome scores for patients undergoing 2-level fusion notably larger in MIS cohort for ODI; statistical significance shown only for changes in NRS-LP scores |
| Asher et al., 2018     | Determine MCID associated w/ surgical treatment for DLS                   | ODI, EQ-5D, NRS-LP, NRS-BP | Different calculation methods generated range of MCID values for each PRO: 3.3–26.5 points for ODI, 0.04–0.3 points for EQ-5D, 0.6–4.5 points for NRS-LP, & 0.5–4.2 points for NRS-BP |
| Chan et al., 2020      | Identify characteristics of subset of patients that would most benefit from surgery for DLS | NASS satisfaction questionnaire 12 mos postoperatively | Female sex (OR 2.9, p = 0.02) associated w/ most satisfaction                                                                                   |
| Chan et al., 2018      | Compare initial 12-mo outcomes data for patients undergoing fusion & those undergoing laminectomy alone for grade I DLS | 3- & 12-mo readmission rates, reoperation rates, & PROs | Fusion procedures associated w/ superior 12-mo ODI (β −4.79, 95% CI −9.28 to −0.31, p = 0.04)                                               |
| Chan et al., 2020      | Investigate impact of obesity on PROs after DLS surgery                  | 3- & 12-mo PROs | BMI independently associated w/ worse NRS-LP & EQ-5D at 12 mos (p = 0.01 & < 0.01, respectively) despite adjusting for baseline differences       |
| Mummaneni et al., 2019 | Construct predictive model for long-term patient satisfaction among those undergoing surgery for Meyerding grade I lumbar spondylolisthesis | Patient satisfaction ≥2 yrs | Older age, preop active employment, & fusion surgery most important predictors of attaining satisfaction w/ surgical outcome |
| Chan et al., 2019      | Compare 24-mo PROs after MI TLIF & MI decompression for DLS               | 24-mo PROs     | MI TLIF associated w/ greater blood loss, longer op time, & longer hospitalization; MI TLIF, as opposed to MI decompression alone, was associated w/ superior ODI change, NRS-BP change, & NASS satisfaction |
| Chan et al., 2018      | Investigate predictors of improved sex life postoperatively by utilizing prospective QOD registry | Sex life (assessed by ODI item 8) at baseline & 24-mo FU | Lower BMI associated w/ improved sex life; in younger patients (age < 57 yrs), lower BMI remained sole significant predictor of improvement; in older patients (age ≥ 57 yrs), in addition to lower BMI, a lower ASA status (I or II) & ≥4 yrs of college education predictive of improvement |
| Mummaneni et al., 2019 | Develop predictive model for factors associated w/ nonroutine discharge after surgery for grade I spondylolisthesis | Nonroutine discharge: discharge to rehab, post-acute care | Factors associated w/ higher odds of nonroutine discharge included older age, higher BMI, presence of depression, & occurrence of any complication |

DLS = degenerative lumbar spondylolisthesis; MI = minimally invasive.
in order to 1) reduce the opportunity for selection bias, 2) ensure data completeness and accuracy,15 and 3) maintain high-level data integrity, as well as minimize loss to follow-up of enrolled patients.

In light of the above, the leadership of QOD Spine concluded over the last 1–2 years that in order to more effectively (and rapidly) advance the relevance, practical application, and impact of its mission, it needed to leverage its insights and experience in the creation of advanced partnerships that would allow for dramatic scale and evolution of national spine care data programs. The result of our internal deliberations and mutual outreach between the specialties of neurosurgery and orthopedic surgery led to the development of a potentially paradigm-shifting collaboration—the American Spine Registry.

Transition to American Spine Registry

In September 2019, the AANS and the American Academy of Orthopaedic Surgeons (AAOS) announced the launch of the American Spine Registry (ASR), a jointly owned venture of the two organizations. In essence, the highly successful QOD Spine project will evolve into a more ambitious and far-reaching effort that will allow for the participation of all North American spine surgeons in a shared quality data collection platform.

The ASR will leverage the AANS/NPA’s unique data science expertise developed while administering the QOD, as well as the substantial operational expertise of the AAOS Registry Program (currently the world’s largest surgical registry program).1 The ASR, which is anticipated to quickly become the dominant international spine data collection platform, will allow both organizations to enhance the scalability, sustainability, end user ease of use, and relevance of national spine data collection efforts and will facilitate intelligent data use by engaging multiple healthcare stakeholders in their joint processes. Given that spine surgery is performed by both neurosurgeons and orthopedic surgeons, this program will provide an opportunity to bring together consistent, reliable, high-quality clinical and medico-economic information from a larger group of healthcare stakeholders including not only physicians but also patients, payers, regulatory groups, and industries.

The overarching vision of the ASR is as follows: “utilize data to inform the AANS and the AAOS care guidelines and to establish benchmarks to test clinical performance and the validity of various quality measures, which are efforts critical to a value-based health care system; provide feedback to providers that allows them to continuously improve their practice and health care outcomes using methods applicable to all practice settings; reduce data reporting burdens on physicians [largely due to enhanced, automated data extraction methods] and allow re-use of data for regulatory requirements and continuous QI programs; and help inform gaps in knowledge and define areas for further education and research.”16

Summary

In the short span of 8 years since its inception, the QOD Spine has become the largest spine registry in North America and has proved to be an instrumental platform for establishing benchmarks for outcomes in neurosurgery, engaging multiple stakeholders for executing QI initiatives, and generating evidence-based comparative efficacy research on some of the most important topics in contemporary spine surgery. The transition to the ASR, in collaboration with the AAOS, is another milestone in the evolution of value-based healthcare, which will further help us optimize care for patients requiring spine surgery.

In summary, an important primary intent of this effort, in addition to the development of important technological resources, was to promote widespread cooperation and create a “quality culture” within neurosurgery. By most objective measures, we have succeeded in that pursuit. The QOD is presently the largest continuous collaborative program within our specialty and, as detailed above, has resulted in substantial scientific insights, QI programs, and collaborative cross-specialty efforts. We have, in fact, gained significant traction in neurosurgery with respect to the ultimate goal of the science of practice, namely, to encourage the “habitual and systematic collection of data inseparable from practice, the analysis of practice data to generate new knowledge, and the application of that knowledge to processes of change in healthcare.”710 The culture of our specialty is enduringly altered, and quality data collection, along with its application, is embedded within the fabric of daily neurosurgical care. Our common data platforms now allow us not only to improve the outcomes of our patients but also to meaningfully engage other stakeholders in the value-care equation.

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Disclosures

Dr. Asher is the director of the Quality Outcomes Database and co-chairman of the American Spine Registry and receives study-related compensation from Stryker Corporation. Dr. Chan receives non–study-related research support from Orthofix Inc. Dr. Mummaneni is a consultant for DePuy Synthes, Globus, and Stryker; has direct stock ownership in Spinicity/ISD; receives clinical or research support from the NREF for the study described; receives support from AOSpine for non–study-related clinical or research effort; and receives royalties from DePuy Synthes, Thieme Publishing, and Springer Publishing. Dr. Glassman is an employee of Norton Healthcare and a consultant for K2M/Stryker and Medtronic; holds a patent with Medtronic; receives royalties from Medtronic and Stryker; received support from NuVasive, International Spine Study Group, Intelliriod, Pfizer, Cerapedics, Scoliosis Research Society, Medtronic, and Ortho Research & Educational Foundation for the study described; is the past president of the Scoliosis Research Society; and is the chair of the American Spine Registry. Dr. Foley is a consultant for Medtronic; has direct stock ownership in Digital Surgery Systems, Discgenics, DuraStat, LaunchPad Medical, Medtronic, NuVasive, Practical Navigation/Fusion Robotics, SpineWave, TDi, and Triad Life Sciences; holds patents with Medtronic and NuVasive; receives royalties from Medtronic; and serves on the Board of Directors for Digital Surgery Systems, Discgenics, DuraStat, LaunchPad Medical, Practical Navigation/Fusion Robotics, TDi, and Triad Life Sciences. Dr. Potts is a consultant for and receives royalties from Medtronic. Dr. C. Shaffrey has direct stock ownership in NuVasive; is a consultant for Medtronic, NuVasive, and SI Bone; holds patents with NuVasive, Medtronic, Simmer Biomet, and SI Bone; and receives royalties from NuVasive, Medtronic, Zimmer Biomet, and SI Bone. Dr. Haid has direct stock ownership in Globus Medical, NuVasive, Paradigm Spine, Remedy Health Media (formerly Vertical Health), and SpineWave; and receives royalties from Globus Medical, Medtronic, and NuVasive. Dr. Fu is a consultant for SI Bone, Johnson & Johnson, and Globus. Dr. Wang is a consultant for DePuy Synthes Spine, Stryker, Medtronic, Globus, and Spineology; holds a patent with DePuy Synthes Spine; has ownership in ISD; and has direct stock ownership in Medical Device Partners. Dr. Park is a consultant for Globus and NuVasive; receives royalties from Globus; and receives support from DePuy and ISSG for non–study-related clinical or research effort. Dr. Bisson is a consultant for nView, Stryker, and MiRus; has direct stock ownership in nView and MiRus; and receives support from the NREF and PCORI for the study described.

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Supplemental Information

Videos

Video Abstract. https://vimeo.com/400227507.

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