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ROLES OF REGISTRIES AND CARE PATHWAYS IN DEFINING VALUE FOR SPINE SURGERY

The National Neurosurgery Quality and Outcomes Database (N²QOD)

A Collaborative North American Outcomes Registry to Advance Value-Based Spine Care

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Study Design. National Prospective Observational Registry

Objective. Describe our preliminary experience with the National Neurosurgery Quality and Outcomes Database (N²QOD), a national collaborative registry of quality and outcomes reporting after low back surgery.

Summary of Background Data. All major health care stakeholders are now requiring objective data regarding the value of medical services. Surgical therapies for spinal disorders have faced particular scrutiny in recent value-based discussions, in large part due to the dramatic growth in the cost and application of these procedures. Reliable data are fundamental to understanding the value of delivered health care. Clinical registries are increasingly used to provide such data.

Methods. The N²QOD is a prospective observational registry designed to establish risk-adjusted expected morbidity and 1-year outcomes for the most common lumbar surgical procedures performed by spine surgeons; provide practice groups and hospitals immediate infrastructure for analyzing their 30-day morbidity and mortality and 3- and 12-month quality data in real-time; generate surgeon-, practice-, and specialty-specific quality and efficacy data; and generate nationwide quality and effectiveness data on specific surgical treatments.

Results. In its first 2 years of operation, the N²QOD has proven to be a robust data collection platform that has helped demonstrate the objective quality of surgical interventions for medically refractory disorders of the lumbar spine. Lumbar spine surgery was found to be safe and effective at the group mean level in routine practice. Subgroups of patients did not report improvement using validated outcome measures. Substantial variation in treatment response was observed among individual patients.

Conclusion. The N²QOD is now positioned to determine the combined contribution of patient variables to specific clinical and patient-reported outcomes. These analyses will ultimately facilitate shared decision making and encourage efficient allocation of health care resources, thus significantly advancing the value paradigm in spine care.

Key words: N²QOD, registry, spine, value.

Level of Evidence: 3

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Health care, as a proportion of US gross domestic product, has increased faster than any other industry.[1] The current third party insurance system insulates health care consumers from market forces and passes through costs generated by largely unconstrained consumer behavior. Value-based purchasing seeks to bend the cost curve and optimize population health by providing effective care while eliminating unnecessary services and avoidable expenses.[2]

Health care value is measured by comparing outcomes delivered against expenditure (costs) and can be examined from the perspective of multiple stakeholders.[1] In patient-centered

care, both observable and measurable health outcomes, along with patients' perception of health care quality, are evaluated. Critical to the determination and improvement of the effectiveness and efficiency of health care delivery is the acquisition of *valid and reliable* outcomes data. Such data can be used by providers to not only guide care and clinical decisions in real time but also examine the outcomes of care thereafter to identify opportunities for improvement. The current lack of such data limits providers' capabilities to improve care and patients' ability to make rational value-based decisions. Transparency of cost and quality data would allow patients and providers to choose those interventions that efficiently and effectively prolong life and improve its quality.[1]

PRINCIPAL VALUE PARADIGM OPPORTUNITIES: SPINE CARE

Low back pain is a highly prevalent and disabling condition that represents the most expensive cause of work-related disability in the United States.[3] Although many patients with low back and leg pain are successfully managed medically, up to 300,000 patients per year undergo surgical management for medically refractory pain. During the past 2 decades, there has been a 300% increase in the number of low back surgical procedures performed and a corresponding increase in the incidence and prevalence of lumbar fusions.[4–6] A study of Medicare patients found that the rate of complex surgery for spinal stenosis alone rose 15-fold from 2002 to 2007.[7] A recent analysis from the Agency for Healthcare Research and Quality found spinal fusion to be the most expensive surgical procedure performed in US hospitals, with annual direct costs now totaling $180 billion.[8] The Institute of Medicine and other observers estimate that up to 25% of diagnostic and therapeutic spine maneuvers are unnecessary or ineffective.[9,10] Surgical therapies for spinal disorders thus represent a particularly important opportunity to enhance value in US health care due to the prevalence of spine conditions, the frequency with which surgical procedures are being performed, and the substantial associated costs.

Numerous stakeholders are motivated to improve spine care—particularly payers, providers, and patients—and each has interest in properly defining its value. Quality, effectiveness, patient-centered outcomes, and accurate measures of true costs from the different stakeholder perspectives are 4 critical elements of value for which data are sparse. Surgical specialists have an opportunity to help define measures that reflect effectiveness and patient-centered outcomes, as well as cost, and thus contribute to true "value-based," rather than simply "cost-based," health care delivery, including purchasing decisions.

USING REGISTRIES TO DEFINE AND MEASURE VALUE IN SPINE SURGERY

Valid and reliable data are fundamental to understanding the value of delivered health care. The reported hospital safety, perioperative morbidity, resource utilization, and long-term outcomes after lumbar surgery vary widely in the literature. Currently, expected benchmarks of acceptable morbidity and treatment effectiveness are based on retrospective reviews or a limited number of tightly controlled studies. Although randomized clinical trials have long been the "gold standard" for high-quality medical evidence, they are generally costly and time-consuming. Furthermore, findings from randomized controlled trials do not always translate into real-world practice outcomes. Specifically, e*fficacious* treatments in research settings often fail to prove *effective* at the individual patient level when suboptimally applied in everyday care settings. Clinical registries are increasingly used to generate evidence and ascertain the effectiveness of clinical interventions in routine practice. Registries can also be used to identify patient or delivery system factors that are related to clinical outcomes providing guidance not only to improvements in health care delivery but also toward the more fundamental mechanisms of disease that could be driving such outcomes.

Patient care registries can be cost-effective, easily scaled to accommodate numerous users, and can rapidly and efficiently yield vast amounts of clinical data. Done with the proper design and rigor of implementation, such data can be both reliable and valid. Registries avoid the constraints of narrow eligibility criteria and may be used to directly evaluate a wide range of practice environments. In part for these reasons, health care policy makers, purchasers, and payers increasingly value high-quality registry data. Registries may represent the "next disruptive technology" in clinical research.[11]

To date, no nationally collaborative reporting mechanisms using validated outcome measures have assessed the extent to which lumbar spinal surgery impacts pain, disability, and quality of life (QOL) while adjusting for bias and influential confounders, including 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, have yet to be determined.

We describe here our preliminary experience with the National Neurosurgery Quality and Outcomes Database (N^2QOD), a national collaborative registry of quality and outcomes reporting after low back surgery. This program is 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 is the inclusion of essential preoperative patient characteristics, as well as prospective patient-reported outcomes, which will aid in 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 health care stakeholders who wish to deliver, consume, and/or purchase these services. The information presented here represents a descriptive analysis of 12 months of follow-up data on patients entering the registry during its first full year of operation.

N^2QOD METHODS

Detailed methods of the N^2QOD are described elsewhere.[12,13] Briefly, the N^2QOD is a prospective observational registry

recording 30-day morbidity and 3- and 12-month quality data for 5 common surgical lumbar spine diagnoses: first-time surgery for disc herniation, stenosis, and spondylolisthesis, as well as revision surgery for either recurrent disc herniation or adjacent segment disease.

Site-specific data extractors/coordinators are required to undergo training on data entry and N²QOD standard operating procedures. Patient enrollment into the registry *via* a sampling methodology is a standardized process across all sites. Potential patients meeting eligibility criteria are identified by the on-site data coordinators from the weekly posted surgery schedule. The first 6 patients meeting inclusion criteria are contacted in person at the clinic or by phone and their health status is assessed *via* interview. Once the first 6 surgical case patients meeting inclusion criteria have answered baseline questionnaires, no further patients are enrolled for that week. Start dates for each enrollment week are standardized across all sites and span a rolling 6-day cycle. Hence, the first day of each 6-day week falls on each weekday with equal frequency. This representative sampling method prevents a disproportionate volume of enrollment on any one day of the week or from any one surgeon's schedule, thus limiting potential enrollment bias.

Patients undergoing lumbar surgery performed for either primary or recurrent lumbar degenerative disease are eligible for inclusion. Exclusions include spinal infection, tumor, fracture, traumatic dislocation, deformity, pseudoarthrosis, same-level(s) recurrent multilevel stenosis, neurological paralysis due to pre-existing spinal disease or injury, less than 18 years of age, and incarceration. Patients whose past and/or present surgery will encompass construct of more than 3 motion segments are also ineligible.

A standard of care outcomes questionnaire, which includes back and leg pain (visual analogue scale [VAS]),[14–17] Oswestry Disability Index (ODI),[1,16,18–21] EuroQol 5D (EQ-5D),[22,23] and the NASS Patient Satisfaction Index are administered preoperatively and again at 3 and 12 months postoperatively. Information related to the patient's demographics, clinical presentation, diagnosis classification, perioperative medical care, and complications specific to their spine surgery is also collected. Recorded morbidity variables include but are not restricted to new neurological deficit related to index surgery, surgical site infection, symptomatic hemorrhage, unanticipated return to operating room, deep vein thrombosis/pulmonary embolism, myocardial infarction, mortality, urinary tract infection, and unanticipated readmission within 90 days.

HIPAA-trained data coordinators/extractors at each site enter data through a secure password-protected Web-based portal (REDCap—Research Electronic Data Capture) into a national aggregate database.[24] Data analysis and site reporting are subsequently performed by epidemiologists, health services researchers, and biostatisticians at the Vanderbilt Institute for Medicine and Public Health and the Vanderbilt Department of Biostatistics.

Data quality is maintained through a variety of methods. Data completeness and accuracy are assessed *via* automated and manual methods at the Vanderbilt Institute for Medicine and Public Health. Weekly missing data reports are sent to all participating N²QOD sites. Diagnostic accuracy is maintained through periodic surgeon-led self-audits that seek to correlate entered data with radiographical and clinical records. Ten percent of N²QOD sites undergo random on-site audits each year. Surgical schedule logs are reviewed both to ensure that appropriate case selection criteria were met and to help minimize the risk of intentional or inadvertent enrollment bias. The accuracy of diagnoses and treatment variables is confirmed *via* medical record audit. The accuracy of major perioperative safety endpoints with respect to morbidity and readmission is also examined.

The project is jointly funded by the American Association of Neurological Surgeons and participating sites. The American Association of Neurological Surgeons provided a major grant for registry infrastructure development; N²QOD sites assist with ongoing operational and data analysis costs through a subscription system. This funding model is similar to that used by other society-based registry programs.[25,26]

The HHS (US Department of Health and Human Services) Office of Human Subject Protections has previously determined that the N²QOD, as presently configured, is not subject to the jurisdiction of the Common Rule (45 CFR 46), and the HHS Office for Civil Rights has determined that N²QOD data methods are compliant with the Privacy Rule.[27] Existing relevant federal regulations, however, are not specific to quality registries, and varying regional interpretations of these regulations persist. For this reason, a detailed project description that outlines the proper use of protected health information, operational protocols, patient interaction, and reporting methods is routinely made available to sites for submission to their hospital's quality improvement office or institutional review board.

N²QOD: RESULTS TO DATE

Lumbar Spine Program Overview

The N²QOD lumbar module was launched in March 2012 at 3 practice sites. The program has expanded to 53 clinical centers in 29 US states and has recruited 7970 patients during 92 enrollment cycles (23 months). Forty-five percent of participating sites are academic centers; the remainder sites are private practices. The majority of centers (75%) are in urban settings. Total enrollment to date is 7300, making this the largest society-based North American cooperative spine surgery registry. Approximately 2780 patients have now crossed the 12-month follow-up threshold. At current data collection efficiencies (see the following), it is anticipated an additional 3300 patients will pass the 12-month threshold by fall 2014.

Data Characteristics

Baseline accrual [screened patients − (baseline exclusion + 30-day review exclusions)] is 91.6% of all screened patients. Total 3- and 12-month patient accrual to date is 4970 (81.0% of all eligible for follow-up) and 2067 (74.4% of all eligible for follow-up) patients, respectively. Conservative methods are used to determine follow-up rates, which do not include

data collected but not yet entered into the N²QOD REDCap database. These follow-up rates compare favorably with existing European spine registries (McGirt *et al*, Spine Focus, in press). Comparison statistics for other existing cooperative North American spine registries are not available.

Baseline data completeness is 98.1%. A successful contact was established within the specified target follow-up ranges with 85% and 88% of patients at 3 and 12 months, respectively. Sampling methodologies, as assessed at 2 representative centers by percent patients enrolled compared with percent eligible for enrollment, seem accurate within 2 to 3 percentage points. Random on-site audits of 10% of sites after completion of year 1 of patient enrollment revealed 97% diagnostic accuracy and 100% data completeness. Self-audits for accuracy of diagnostic assignment conducted in year 2 at 9 participating centers (956 consecutively enrolled patient records assessed) produced 7.3% overall change in primary diagnosis classification and 2.8% retrospective diagnostic exclusion. Methods to enhance diagnostic accuracy and consistency have been instituted project-wide, and this parameter will be reassessed at 6-month intervals.

Baseline Demographic and Clinical Characteristics

Baseline characteristics of enrolled patients are described in Table 1. Average age of enrolled patients was 58 years. The principal diagnoses were disc herniation (33%), recurrent disc herniation (6%), spondylolisthesis (20%), stenosis (34%), adjacent segment disease (6%), and mechanical disc collapse (1%) (the latter category was added after the first year of data collection). Forty-two percent of patients reported back pain equal to leg pain, whereas 35.7% had leg-predominant symptoms. Nearly 90% of the patients experienced their symptoms for longer than 3 months prior to surgery, and the mean baseline patient-reported outcome scores were consistent with a clinical history of chronic pain and significant functional impairment: VAS back pain (6.5), VAS leg pain (6.9), ODI (50%), and EQ-5D (0.53). More than half of patients were unemployed (53%), and 21% described themselves as depressed.

Patient Safety

Table 2 describes the observed overall 30- and 90-day surgical morbidity. Overall, the 3-month mortality was 0.3%. Three-month major adverse events were low overall but higher in patient groups more likely to undergo fusion. Overall, the 90-day hospital readmission rate was 8.9% and ranged from 7.1% (spondylolisthesis) to 12.5% (either type of revisions).

Patient-Reported Outcomes

Patient satisfaction with 12-month outcomes is described in Table 3. Overall, 60.5% of patients reported that surgery met their expectations and 81.3% stated they would undergo the same procedure again. A range of 29.5% (adjacent segment disease) and 14.6% (lumbar disc herniation) of patients stated they would not have the same surgery performed again. Eleven percent of all patients felt they were the same or worse as compared with before surgery. At 12 months, approximately

TABLE 1. Baseline Patient Characteristics

	N²QOD Total (N = 4970)
Sex	
Female	48.6%
Male	51.4%
Age, mean ± SD, yr	58.4 ± 14.1
Race	
Native American	0.4%
Asian	0.7%
African American	6.6%
Pacific Islander	0.3%
Caucasian	90.5%
Other	1.5%
Hispanic	2.3%
Education	
Less than high school	6.5%
High school	42.5%
2-yr college	18.3%
4-yr college	19.4%
Postcollege	13.2%
Insurance payer	
Uninsured	1.5%
Medicare	36.7%
Medicaid	4.0%
VA/government	2.6%
Private	55.2%
Liability	
Workers compensation	3.8%
Disability insurance	5.5%
Motor vehicle injury	1.9%
Employed and working	35.4%
Full-time	86.1%
Part-time	13.9%
Employed and not working	10.5%
On short-term disability	47.2%
On leave	52.8%
Unemployed	53.3%
On disability	19.4%
Due to spine problem	10.1%
Due to other condition	8.7%
Retired	64.4%
Homemaker	8.0%
None of the above	8.2%
Attending school	0.8%
Intend to work after surgery	93.9%
Participate in activities	
Outside of home	65.7%
Inside home	83.9%

TABLE 2. Overall 30- and 90-Day Surgical Morbidity, N²QOD Lumbar Spine Module

	30-d Major Adverse Events	30-d Readmission	90-d Reoperation	90-d Readmission
Overall (N = 4970)	2.2%	3.7%	2.3%	8.9%
First-time surgery				
Disc herniation (n = 1658)	1.4%	2.4%	2.7%	7.7%
Stenosis (n = 1686)	2.1%	4.9%	2.0%	9.8%
Spondylolisthesis (n = 1000)	3.1%	3.4%	1.6%	7.1%
Revision surgery				
Recurrent disc herniation (n = 297)	1.7%	4.0%	3.0%	12.5%
Adjacent segment disease (n = 280)	2.9%	4.6%	2.5%	12.5%

83% and 77% of all patients returned to employment and full activity, respectively. Occupation influenced likelihood of return to work and full activity (Table 4). Sedentary and heavy occupation workers reported 85% and 65% return to work at 3 months, respectively. This difference was less pronounced (87% *vs*. 83%) at 12 months. Return to full activity at 12 months in sedentary and heavy occupation workers was 83% and 70%, respectively. Return to work at 12 months by diagnosis ranged from 71% (recurrent disc herniation) to 87% (disc herniation).

Baseline patient-reported outcomes reflect severe baseline pain and disability in all diagnoses. Pain (VAS leg pain: 6.9 *vs*. 2.6; VAS back pain: 6.5 *vs*. 3.3), disability (ODI: 49.7 *vs*. 25.3), and QOL (EQ-5D: 0.54 *vs*. 0.76) on average were significantly improved 12 months after surgery (Table 5).

At 12 months, some patients reported no improvement in disability (12%), QOL (22%), back pain (23%), and leg pain (18%) (Table 6). Similar rates of failure to improve were noted in each of the individual diagnostic categories. Failure to report improvement over baseline ODI scores varied from 9.3% (spondylolisthesis) to 18.4% (adjacent segment disease).

Scatter plots illustrating individual patient outcomes (ODI, EQ-5D) at 12 months for patients with the primary diagnosis of lumbar disc herniation are shown in Figure 1. The diagonally oriented line represents the "status quo" (*i.e*., no difference in ODI between baseline and 12 months postoperatively). In the ODI plot, points above the line represent patients reporting worsened disability 12 months after surgery whereas patients below the line reported improved disability scores 12 months after surgery. The opposite is true in the EQ-5D plot (*i.e*., improvement in QOL above the line; worsened QOL below the line). Although cohort averages demonstrated an overall improvement in mean disability and QOL at the group level, a wide variation in preoperative disability, 12-month postoperative disability, and extent of 1-year improvement was observed at the patient level (Figure 1). Similar scatter plot patterns were observed for all diagnoses, in all procedures, and for all patient-reported outcomes. Patients underwent surgery for a wide variety of presenting symptoms, disability, and QOL (*x*-axis), likely contributing to the wide variation in surgical effectiveness (distance from the line of equivalence) observed here.

SIGNIFICANCE OF N²QOD DATA TO VALUE-BASED SPINE CARE

Each spine care stakeholder has unique interests in the objective determination of therapeutic value. Purchasers of health care services require valid and reliable information to accurately assess the extent to which providers and health care

TABLE 3. Twelve-Month Patient Satisfaction by Diagnosis

Patient Satisfaction (n = 1809)	Disc Herniation (n = 551)	Recurrent Disc Herniation (n = 111)	Spondylolisthesis (n = 377)	Stenosis (n = 671)	Adjacent Segment Disease (n = 98)	Symptomatic Mechanical Disc (n = 14)	Combined (N = 1822)
1	64.2%	56. 8%	66.4%	58.1%	41.1%	35.7%	60.5%
2	21.2%	21.6%	19.5%	19.9%	29.5%	28.6%	20.8%
3	5.5%	9.9%	5.9%	8.4%	13.7%	7.1%	7.4%
4	9.1%	11.7%	8.6%	13.6%	15.8%	28.6%	11.3%

Patient Satisfaction Index: 1, surgery met my expectations; 2, I did not improve as much as I had hoped but I would undergo the same operation for the same results; 3, surgery helped but I would not undergo the same operation for the same results; 4, I am the same or worse as compared with before surgery.

TABLE 4. Three- and 12-Month Return to Activity and Work by Occupation

	Sedentary (n = 761)	Light (n = 560)	Medium (n = 524)	Heavy (n = 426)	Combined (N = 2271)
Return to activity 3mo					
Yes	65.4%	68.-%	61.9%	54.4%	63.2%
No	34.6%	32.0%	38.1%	45.6%	36.8%
Return to work 3 mo					
Yes	86.3%	81.2%	74.6%	65.4%	78.3%
No	9.1%	13.0%	21.3%	31.9%	16.9%
Unknown	5.6%	5.8%	4.1%	2.7%	4.8%
	n = 294	**n = 202**	**n = 177**	**n = 152**	**N = 825**
Return to activity 12 mo					
Yes	82.9%	80.9%	69.0%	69.7%	77.0%
No	17.1%	19.1%	31.0%	30.3%	23.0%
Return to work 12 mo					
Yes	87.1%	81.3%	79.7%	82.6%	83.3%
No	4.7%	11.2%	16.5%	15.9%	10.7%
Unknown	8.2%	7.5%	3.8%	1.5%	6.0%

systems deliver care at expected standards of efficiency, safety, and effectiveness. Patients undergoing spine surgery require information that describes QOL after spine therapies, particularly the impact of care on relief of pain and amount of improvement in function. Clinicians require risk-adjusted data that allow for focused quality improvement and meaningful mechanisms to report and analyze quality data. Finally, all stakeholders benefit from data that improve outcomes prediction to promote informed decision making and efficient application of scarce health care resources.

The N^{2}QOD was developed to generate data relevant to the major value questions currently facing spine care stakeholders. Operational analyses confirm that the N^{2}QOD in its first 2 years has become a robust, reliable clinical outcomes platform for the collection and reporting of relevant quality data related to lumbar spine surgery. Longitudinal data collection and inclusion of patient-reported outcomes (unique among national surgical registries) now allow for a description of treatment effect, sustainability, and evaluation of patient-centered data not readily available within the traditional medical record.

N^{2}QOD results to date show that lumbar spine surgery has generally low rates of surgical morbidity and related events. In aggregate, the mean performance in routine practice revealed improvements in patient-reported outcomes, including ability to return to work. Initial treatment effects are sustained for at least 12 months, the limit of follow-up for these data. The majority of patients returned to work and full activity by 12 months after surgery and expressed that they were satisfied with their outcome and would have surgery again.

Not surprisingly, some patients do not show improvement with surgical therapies. For instance, 9% to 18% of patients enrolled in the N^{2}QOD do not report improvement from baseline ODI at 12 months and 17% of patients would not have the same surgery performed for the same condition. In general, *aggregate* outcome results reported here are similar to those reported in time-limited randomized clinical trials (Table 7). Furthermore, rates of patient satisfaction and major improvement observed here are higher than those described in previous analyses related to nonsurgical care (SPORT).[28,29] Unlike these evaluations, the effectiveness data reported here were generated in a broad clinical environment, reflective of diverse practice settings, not just research-intensive academic institutions.

The most striking finding in these data is the large variation in treatment response between *individual* patients. Similar patterns of variability are observed for all diagnoses, in all procedures, at all centers, and for all reported outcomes. Understanding the sources of this widespread variability represents the greatest opportunity for the N^{2}QOD to improve spine care outcomes. Specifically, assessing the interactive impact of multiple clinical variables on individual patient outcomes will allow clinicians to benchmark their care against their risk-adjusted expected outcomes. Similar analyses will power the development of predictive models to educate surgeons and patients on the personalized likelihood of various outcomes from spine surgery. In these ways, risk-adjusted modeling will allow for targeted quality improvement, practice-based learning, shared decision making, and more effective resource utilization. To these ends, we are presently developing multivariable

TABLE 5. Patient-Reported Outcomes for Pain, Disability, and Quality of Life

	Baseline			3 mo			12 mo		
	n	Mean	99% CI	n	Mean	99% CI	n	Mean	99% CI
Back pain									
Disc herniation	551	6.00	5.67–6.33	551	2.70	2.40–3.01	551	2.85	2.52–3.18
Recurrent disc herniation	111	6.53	5.86–7.20	111	3.39	2.68–4.09	111	3.50	2.78–4.23
Spondylolisthesis	375	6.92	6.59–7.25	375	3.17	2.80–3.53	375	3.04	2.65–3.43
Stenosis	670	6.46	6.18–6.74	670	3.00	2.72–3.28	670	3.43	3.12–3.73
Adjacent segment disease	98	7.33	6.67–7.99	98	4.59	3.75–5.43	98	4.99	4.10–5.88
Symptomatic mechanical disc collapse	14	8.0	6.82–9.18	14	4.79	2.86–6.71	14	5.71	3.20–8.23
Total	1819	6.48	6.31–6.65	1819	3.07	2.90–3.24	1819	3.28	3.09–3.46
Leg pain									
Disc herniation	551	7.04	6.76–7.33	551	2.16	1.84–2.47	551	2.37	2.03–2.70
Recurrent disc herniation	111	7.46	6.93–7.99	111	3.05	2.30–3.81	111	3.11	2.34–3.87
Spondylolisthesis	375	6.63	6.25–7.00	375	2.23	1.85–2.61	375	2.15	1.77–2.53
Stenosis	670	6.78	6.51–7.05	670	2.61	2.30–2.91	670	2.79	2.48–3.11
Adjacent segment disease	98	7.01	6.32–7.70	98	3.46	2.54–4.38	98	3.80	2.87–4.73
Symptomatic mechanical disc collapse	14	7.07	4.85–9.29	14	2.71	0–5.44	14	5.00	1.87–8.13
Total	1819	6.88	6.72–7.05	1819	2.47	2.29–2.65	1819	2.62	2.43–2.81
ODI									
Disc herniation	551	49.09	47.20–50.99	551	24.37	22.24–26.51	551	21.42	19.17–23.66
Recurrent disc herniation	111	53.16	48.84–57.47	111	31.51	26.44–36.57	111	27.93	22.64–33.22
Spondylolisthesis	376	48.91	46.73–51.09	376	29.59	27.07–32.11	376	23.68	21,11–26.26
Stenosis	671	49.01	47.38–50.64	671	28.17	26.23–30.11	671	26.41	24.36–28.45
Adjacent segment disease	98	56.20	52.06–60.33	98	41.14	35.47–46.80	98	39.35	33.43–45.27
Symptomatic mechanical disc collapse	14	60.71	47.98–73.45	14	42.40	25.25–59.55	14	43.41	24.46–62.36
Total	1821	49.74	48.73–50.75	1821	28.33	27.12–29.53	1821	25.26	24.00–26.51
EQ-5D									
Disc herniation	550	0.54	0.52–0.57	550	0.79	0.77–0.82	550	0.80	0.78–0.82
Recurrent disc herniation	111	0.47	0.41–0.53	111	0.71	0.65–0.77	111	0.72	0.66–0.78
Spondylolisthesis	377	0.53	0.50–0.56	377	0.75	0.73–0.78	377	0.77	0.74–0.80
Stenosis	670	0.57	0.55–0.59	670	0.78	0.76–0.80	670	0.76	0.73–0.78
Adjacent segment disease	96	0.44	0.38–0.50	96	0.67	0.62–0.73	96	0.64	0.57–0.71
Symptomatic mechanical disc collapse	14	0.49	0.32–0.67	14	0.68	0.49–0.87	14	0.65	0.42–0.88
Total	1818	0.54	0.53–0.55	1818	0.77	0.75–0.78	1818	0.76	0.75–0.78

Ranges for outcome metrics used. Visual analogue scale for back and leg pain: 0–10; ODI: 0–100; EQ-5D: −0.11 to 1.0.

CI indicates confidence interval; ODI, Oswestry Disability Index; EQ-5D, EuroQol 5D.

TABLE 6. Failure to Improve Over Baseline Scores at 12 Months

	m/N	%	95% CI	99% CI
Back pain				
Disc herniation	134/551	24.3	20.8–28.2	19.9–29.4
Recurrent disc herniation	22/111	19.8	13.1–28.7	11.6–31.6
Spondylolisthesis	70/375	18.7	14.9–23.1	13.9–24.5
Stenosis	157/670	23.4	20.3–26.9	19.4–28.0
Adjacent segment disease	31/98	31.6	22.8–41.9	20.6–45.1
Symptomatic mechanical disc collapse	4/14	28.6	9.6–58.0	7.2–65.0
Total	418/1819	23.0	21.1–25.0	20.5–25.6
Leg pain				
Disc herniation	83/551	15.1	12.2–18.4	11.5–19.5
Recurrent disc herniation	12/111	10.8	6.0–18.5	5.0–21.3
Spondylolisthesis	61/375	16.3	12.8–20.5	11.8–21.9
Stenosis	139/670	20.7	17.8–24.1	16.9–25.1
Adjacent segment disease	27/98	27.6	19.2–37.7	17.2–40.9
Symptomatic mechanical disc collapse	5/14	35.7	14.0–64.4	10.8–70.6
Total	327/1819	18.0	16.3–19.8	15.7–20.4
ODI				
Disc herniation	57/551	10.3	8.0–13.3	7.4–14.3
Recurrent disc herniation	16/111	14.4	8.7–22.7	7.5–25.5
Spondylolisthesis	35/376	9.3	6.7–12.8	6.0–14.1
Stenosis	94/671	14.0	11.5–16.9	10.8–17.9
Adjacent segment disease	18/98	18.4	11.5–27.7	10.0–30.9
Symptomatic mechanical disc collapse	2/14	14.3	2.5–43.8	1.7–52.2
Total	222/1821	12.2	10.7–13.8	10.3–14.3
EQ-5D				
Disc herniation	97/550	17.6	14.6–21.1	13.8–22.3
Recurrent disc herniation	28/111	25.2	17.7–34.5	15.8–37.5
Spondylolisthesis	65/377	17.2	13.6–21.5	12.7–23.0
Stenosis	171/670	25.5	22.3–29.0	21.4–30.2
Adjacent segment disease	26/96	27.1	18.8–37.3	16.7–40.5
Symptomatic mechanical disc collapse	5/14	35.7	14.0–64.4	10.8–70.6
Total	392/1818	21.6	19.7–23.5	19.2–24.2

m/N indicates number of nonresponders/number of total subjects; CI, confidence interval; ODI, Oswestry Disability Index; EQ-5D, EuroQol 5D.

methodologies to evaluate the contribution of patient and environmental factors to clinical outcomes.

Unlike time-limited randomized clinical trials, the N^2QOD will continue to accumulate patient data, further increasing the capability of its predictive models. The addition of data reflecting the outcomes of nonsurgical spine care to the N^2QOD in the near future will facilitate comparative effectiveness research. Finally, by combining cost data with

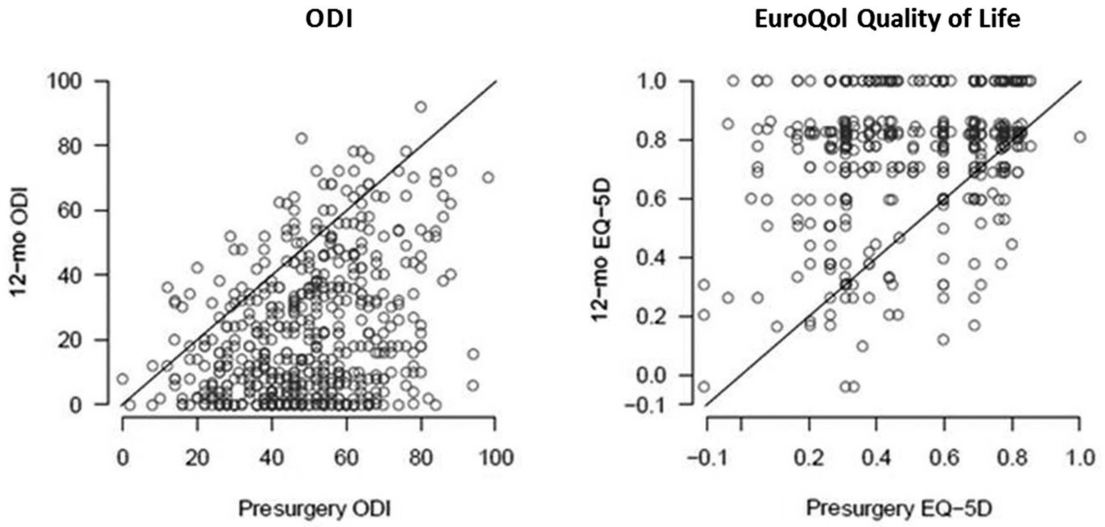

Figure 1. Variation in 12-month reported outcomes at the individual patient level (lumbar disc herniation). ODI indicates Oswestry Disability Index. EQ-5D indicates EuroQOL Quality of Life.

clinician- and patient-reported outcomes data, we hope to ultimately produce objective value data to inform effective allocation of scarce health care resources and promote the development of a sustainable health care system.

CONCLUSION

The N²QOD, a nationwide, prospective, patient-reported outcomes registry of surgical spine care, is now established in more than 50 major US treatment centers representing

TABLE 7. Previously Reported Patient-Centered Outcomes From Multicenter Spine Trials

	Follow-up Interval	Cohort	ODI (SE)	Return to Work, % (SE)	Post-treatment Satisfaction, % (SE)
Weinstein *et al*[28]	3 mo	Surgery	−36.1 (0.87)	77.0 (2.5)	68.1 (2.3)*
		Observation	−20.9 (1.5)	81.8 (3.6)	29.4 (3.7)*
		Treatment effect (95% CI)	−15.2 (−18.5 to −11.8)	−4.9 (−13.5 to 3.7)	38.7 (30.0–47.4)
	12 mo	Surgery	−11.2 (0.26)	89.3 (1.5)	71.1 (2.2)
		Observation	−8.6 (0.48)	80.0 (4.0)	44.7 (4.3)
		Treatment effect (95% CI)	−2.6 (−3.6 to −1.5)	9.3 (1.0–17.7)	26.4 (16.8–36.1)
Brox *et al*[30]	4 yr	Surgery	−15.3 (2.6)	26†	61‡
		Cognitive/exercise	−15.3 (2.8)	33†	65‡
		Treatment effect (95% CI)	0.0 (−8.9 to 5.6)	−7†	4‡
Fritzell *et al*[31]	2 yr	Surgery	−11.6 (0.80)	47§	62.6¶
		Observation	−2.8 (2.0)	33§	29.0¶
		Treatment effect	−8.8 (−26.5 to 44.1)	14	33.6

**Post-treatment satisfaction assessed as "very" or "somewhat satisfied" with symptoms.*
†Work status assessed at 1-year follow-up.
‡Patient overall rating assessed as "success."
§Working at follow-up regardless of baseline status.
¶Post-treatment satisfaction reported as "much better" or "better."
CI indicates confidence interval; ODI, Oswestry Disability Index; SE, standard error.

a diverse range of practice settings. In its first 2 years, the N²QOD has achieved outstanding benchmarks for the completeness and validity of its data collection. In the majority of nearly 8000 patients evaluated, surgery was found to be safe and effective at improving pain, disability, and QOL for 5 common lumbar diagnoses. However, significant numbers of patients did not report improvement in various standardized outcomes and marked variability existed in the effectiveness of surgical care at the individual patient level. Given the prevalence of spine conditions, the frequency with which surgical procedures are being performed and the substantial associated costs, analyses designed to identify best practices and predict outcomes based on patient and disease characteristics will be needed to reduce the incidence of ineffective surgical therapy for spinal diseases. The N²QOD registry thus holds promise to serve as a source of data to facilitate focused practice improvement and increase the overall value of spine care.

➢ Key Points:

- ❑ The N²QOD, a nationwide, prospective, patient-reported outcomes registry of surgical spine care, is now established in more than 50 major US treatment centers representing a diverse range of practice settings.
- ❑ In nearly 8000 patients, lumbar surgery proved safe and effective at improving pain, disability, and QOL for 5 common lumbar diagnoses. However, a significant number of patients did not report improvement in various standardized outcomes. Furthermore, significant variability existed in the effectiveness of surgical care at the individual patient level.
- ❑ Given the prevalence of spine conditions, the frequency with which surgical procedures are being performed and the substantial associated costs, analyses designed to identify best practices and predict outcomes based on patient and disease characteristics will be needed to reduce the incidence of ineffective surgical therapy for spinal diseases. The N²QOD registry thus holds promise to serve as a source of data to facilitate focused practice improvement and increase the overall value of spine care.

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