National Neurosurgery Quality and Outcomes Database (N²QOD): A Prospective Registry for Quality Reporting

Phase 1: The Lumbar Spine Module

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Date
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1.0 Background

Low back pain (LBP) is a highly prevalent and disabling condition that is associated with significant healthcare costs in the United States. Although many patients with low back and leg pain are successfully medically managed, as many as 300,000 patients per year require surgical management for medically refractory back and leg pain. Over the past two decades, there has been a 300% increase in the number of low-back surgeries performed and a corresponding increase in the incidence and prevalence of lumbar fusions (4, 6, 16). Revision lumbar surgery is also rising in prevalence. Compared to surgery for de novo LBP, physician-assessed outcomes and morbidity are worse after revision surgery (4). The reported hospital safety, peri-operative 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, not necessarily reflecting the “real world” environment and practice paradigms of national spine practice. In order to effectively determine risk-adjusted benchmarks of safety, quality, and surgical efficiency, as well as determine the comparative effectiveness of low-back surgical treatments, high volume data representing a multi-regional and heterogeneous population are required. Hence, a national collaboration of quality and outcomes reporting after low-back surgery will establish for the first time a robust mechanism of quality reporting, risk-adjusted benchmarking, comparative effectiveness analysis, and evidence-based practice improvement.

2.0 Rationale and Specific Aims

To date, no nationally collaborative reporting mechanisms utilizing validated outcome measures have assessed to what extent lumbar spinal surgery improves pain, disability, and quality of life while adjusting for bias and influential confounders, including variances in co-morbidity, surgical approach, cultural factors, region, structure and process of health services. Furthermore, risk-adjusted benchmarks of surgical morbidity and effectiveness, which define spine surgical quality, have yet to be determined.

In order to address these pressing needs, the NeuroPoint Alliance, Inc. (NPA) has developed the National Neurosurgery Quality and Outcomes Database (N2QOD). NPA is a not-for-profit corporation established in 2008 by the American Association of Neurological Surgeons (AANS) to coordinate a variety of national projects involving the acquisition, analysis and reporting of clinical data from neurosurgical practice using online technologies.

The N2QOD will allow any U.S. neurosurgeon, practice group, or hospital system to contribute to and access national aggregate quality and outcomes data. The N2QOD is primarily designed to serve as a continuous national clinical registry for neurosurgical procedures and practice patterns along the lines of the very successful Society of Thoracic Surgeons (STS) database.

The primary goals of this registry are to:

1) Establish risk-adjusted expected morbidity and one-year outcomes for the most common lumbar surgical procedures performed by spine surgeons. This would generate national benchmarks for 30-day morbidity, mortality, and 3- and 12-month quality data that are uniquely specific for individualized patient populations and practice settings.

2) 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, allowing measurements of health-services initiatives or practice paradigm shifts.
3) Generate surgeon- and practice-specific quality and efficacy data to support claims made to private payers.

4) Generate nationwide quality and effectiveness data on specific surgical treatments to support claims made to the U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services (CMS).

5) Demonstrate the comparative effectiveness of spine surgery procedures.

Brief Methods: Prospective observational registry recording 30-day morbidity and 3- and 12-month quality data. The first six adult patients per week undergoing lumbar spine surgery performed by spine surgeons at (Neurosurgery Practice Group) will be informed prior to surgery that they have been selected to be included in the registry. Patients undergoing lumbar surgery performed for either primary or recurrent lumbar degenerative disease will be eligible for inclusion. Exclusions include but are not limited to spinal infection, tumor, fracture, traumatic dislocation, deformity (including thoracic and/or lumbar kyphosis or scoliosis that is documented as > 20 degrees, moderate, large, or severe), pseudoarthrosis, same-level recurrent multi-level stenosis, patients diagnosed with neurological paralysis due to pre-existing spinal disease or injury, < 18 yrs of age, incarceration (prisoner), Laminectomy of > 4 levels (i.e. L2-S1 laminectomy) or fusion of > 3 motion segments (L2-S1), if informed consent is required by the local IRB, then refusal of consent, Spondylolisthesis grade 2, 3, or 4 (> Grade 1 (25%)), Patients receiving a surgery other than laminectomy, laminotomy, discectomy or fusion (examples of excluded procedures include laser disc ablation, Axia- lift), Patients who have a history of or whose current surgery includes an excluded device (examples include interspinous distraction device, spinal cord stimulator), will not be eligible. A standard of care outcomes questionnaire, which includes Back and Leg Pain Scale, (2, 3, 10, 12), Oswestry Disability Index (ODI) (3, 7, 8, 11, 12, 18), Euro-Quol 5D (EQ-5D) (5, 14), and the NASS Patient Satisfaction Index (PSI) will be administered pre-operatively and again at 3 months and 12 months post-operatively by a HIPPA- certified data extractor. Patient questionnaires will be completed in clinic or via phone interview. Standard of care reports on pre-operative clinic visits and radiographic images generated before the surgical procedure(s) and available through (Neurosurgery Practice Group) will be reviewed by a HIPPA- trained data extractor. Information related to the patient’s demographics, clinical presentation, diagnosis classification, and peri-operative medical care specific to their spine surgery will be collected from the patient’s medical record by the same data extractor. This data will be entered through a secure password-protected web-based portal into a national aggregate database maintained by the NPA (see section 10.0).

3.0 Previous Human Studies

PERTINENT LITERATURE REVIEW

Back pain is a highly prevalent and disabling condition that is associated with significant healthcare costs in the United States. Nearly 85% of the U.S. population will experience at least one episode of back pain with one and ten-year recurrence of 45% and 80%, respectively (1, 9, 19). LBP and leg pain remains the foremost reason why adults under 45 years of age limit their physical activity, is the second leading cause of physician visits, and is the fifth most common reason for hospital admission (20, 21). In the elderly (>65 years old), LBP affects between 30% to 50% of community dwelling adults and over 80% of nursing home residents (6, 17). The incidence of LBP is expected to increase considerably as the percentage of the U.S. population over 65 years of age dramatically increases over the next several years.
The economic burden of back pain in the U.S. is staggering. Direct costs of medical imaging, emergency services, social services, pain medication, physical therapy, caregiver services, and surgical intervention are estimated to range from $20-60 billion annually (1, 19-21). The marked physical disability, pain, and depression accompanying back pain has resulted in a much greater indirect economic burden. Indirect costs of lost work and social productivity resulting from back pain are estimated to range from $50-100 billion annually (1, 15, 19).

Although many patients with back pain are successfully medically managed, a substantial subset of patients requires surgical intervention for medically refractory back and leg pain. Current estimates suggest that up to 300,000 patients per year require surgical management for medically refractory back pain. In 2001, approximately 122,000 lumbar fusions were performed in the U.S. On a population basis, this represented a 220% increase from 1990. An equivalent rise has occurred over the past decade.

The reported hospital safety, peri-operative 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 a limited number of tightly controlled studies, not necessarily reflecting the “real world” environment and practice paradigms of national spine practice. These high-quality studies are only available for a small subset of lumbar surgical procedures. The effectiveness and expected surgical morbidity of most lumbar surgical procedures continues to be based on retrospective chart review studies, single center reports and other forms of low-level evidence. In order to effectively determine risk-adjusted benchmarks of safety, quality, and surgical efficiency, as well as determine the comparative effectiveness of low-back surgical treatments, high volume data representing a multi-regional and heterogeneous population are required. Hence, a national collaboration of quality and outcomes reporting after lumbar surgery could establish, for the first time, a robust mechanism of quality reporting, risk- adjusted benchmark calculations, comparative effective analysis, and evidence-based practice improvement.

4.0 Inclusion/Exclusion Criteria

Inclusion: Patients undergoing surgery for symptomatic herniated lumbar disc, lumbar stenosis, lumbar spondylolisthesis, symptomatic recurrent lumbar disc herniation, single level symptomatic mechanical disc collapse, or lumbar adjacent segment disease by (Neurosurgery Practice Group) will be eligible for inclusion. Lumbar surgeries included will be laminectomy w/wo fusion, w/wo instrumentation, or w/wo interbody grafting. Lumbar fusion alone w/wo instrumentation will also be included.

Exclusion:
Patients undergoing lumbar surgery for any diagnosis other than the six listed above should be excluded from the registry. Exclusions include but are not limited to spinal infection, tumor, fracture, traumatic dislocation, deformity (including thoracic and/or lumbar kyphosis. Or, scoliosis that is documented as > 20 degrees, moderate, large, or severe), pseudoarthrosis, same level recurrent multi-level stenosis, neurological paralysis due to pre-existing spinal disease or injury, < 18yrs of age, incarceration (prisoner), Laminectomy of > 4 levels (i.e. L2-S1 laminectomy) or fusion of >3 motion segments (L2-S1), if informed consent is required by the local IRB, then refusal of consent, Spondylolisthesis grade 2, 3, or 4 (> Grade 1 (25%), Patients receiving a surgery other than laminectomy, laminotomy, discectomy or fusion
examples of excluded procedures include laser disc ablation, Axia-lift). Patients who have a history of or whose current surgery includes an excluded device (examples include interspinous distraction device, spinal cord stimulator).

5.0 Patient Enrollment

The first six eligible patients per week meeting the aforementioned inclusion criteria and scheduled to undergo lumbar spine surgery performed by spine surgeons at (Neurosurgery Practice Group) will be informed prior to surgery that they have been selected to be included in the prospective observational registry. The potential participants will be identified from the weekly posted Operating Room schedule. The first six patients meeting inclusion criteria will be contacted in person at clinic, or by phone and their health status assessed via interview. Once the first six patients have answered the baseline questionnaires, no further patients will be enrolled for the week-period. A week-period will be defined as a six-day period so that enrolment will not always lie on the same operative weekdays. This method will allow for a representative sampling of patient experiences from the individual sites. At the conclusion of the six-day period, an additional six patients meeting inclusion criteria will be enrolled in the next six-day week period.

Note, the NeuroPoint Alliance in consultation with the N2QOD Scientific Committee, may conclude at the end of the feasibility phase of this project that certain sites, based on their clinical volume, may need to enroll more than 6 patients per week in order to allow for statistically valid conclusions to be drawn regarding individual site performance. In this respect, 6 patients per site per week represents the initial data collection objectives for the N2QOD Lumbar Spine Project.

All personal health information collected for the purpose of this study will be stored on a password-protected database with access granted only to team members listed in the project description.

6.0 Data Elements and Related Procedures

Patient-Reported Outcome Instruments

A standard of care outcomes questionnaire (see appendix 1), which includes Back and Leg Pain Scale (2, 3, 10, 12), Oswestry Disability Index (ODI) (3, 7, 8, 11, 12, 18), and Euro-Qol 5D (EQ-5D) (5, 14) will be administered pre-operatively and again at 3- and 12-months post-operatively by the designated data coordinator. All patient interviews will occur either in person at clinic, or over the phone.

The outcomes measures incorporated into this proposed study were chosen to facilitate a comprehensive assessment of pain, low-back specific disability, and quality of life. The Back and Leg Pain Scale will be used to allow patients to express their level of pain (range: 0-10). The Back and Leg Pain Scale has been demonstrated to have construct validity, internal consistency, responsiveness, and test-retest reliability in the setting of low back pain (3, 10, 12). The ODI measures a patient’s low back-specific functional disability. ODI has been demonstrated to have construct validity, internal consistency, responsiveness, and test-retest reliability in the setting of low back pain (7, 8). The EQ-5D is an instrument that measures preference-based general health
state and provides a utility measure in units of quality adjusted life years (QALYs) for cost-effectiveness and value assessment. The EQ-5D has also been demonstrated to have construct validity, internal consistency, responsiveness, and test-retest reliability (5, 12-14).

Patient, Diagnosis, and Treatment Variables

Standard of care reports on pre-operative clinic visits and radiographic images generated before the surgical procedure(s) and available through (Neurosurgery Practice Group) will be reviewed by a HIPPA-trained data coordinator. Information related to the patient’s demographics, clinical presentation, diagnosis classification, and peri-operative medical care specific to their spine surgery will be collected from the patient’s medical record by the data coordinator. All variables to be collected are listed in appendix 2 and include demographic, functional status clinical, radiographic, treatment, and health services structure and process variables. Furthermore, as the Medicare Physician Quality Reporting System (PQRS) requirements evolve, N2QOD will evolve with that program, allowing PQRS requirements to be met through N2QOD participation. Patients will be classified based on extent of symptoms from back pain, leg pain, or both. Patients with the aforementioned symptoms can be further stratified based on primary or recurrent pathology, as well as radiographic presentation, including lumbar stenosis, lithesis, degenerated disc pathology, disc height loss, or instability. Lastly, multiple surgical approaches and instrumentation will be recorded for each of the diagnostic sub-sets of disease characteristics.

Data Storage and Reporting:

All recorded data will be entered into a password-protected aggregate national database maintained by the Vanderbilt Institute for Medicine and Public Health (VIMPH) with access only by the (Neurosurgery Practice Group)’s clinical representative(s) and team members listed in the project description. The VIMPH is a nationally recognized leader in the field of health services research and quality improvement, with advisory positions and funding from the Agency for Health Research and Quality (AHRQ), the National Institutes of Health (NIH), and the Institute of Medicine (IOM). The VIMPH was chosen by NPA from a short list of leading national public health institutes due to their recognized expertise and experience facilitating multi-center quality improvement and health services research initiatives.

Aggregate pooled national data will be analyzed for risk-adjusted benchmarking by the NPA. These risk-adjusted analyses will serve as a foundation for quality reporting performance ratios (observed/expected).

All forms will be accessed and completed electronically by logging into a centralized registry platform (REDCap System® platform). The REDCap® platform is a highly scalable data capture, management and disseminating platform operating in a Linux environment with a MySQL back-end database.

All electronic case report forms (CRFs) will include edit checks, which will provide feedback in the event of inaccurate or incomplete data, and form controls, which will enable/disable fields based on the answers to other questions to prevent conflicting data from being entered. The system will control access based on user roles and identity, and will contain management reports for project monitoring, data reports for participant review, and site reports for practice review. Security of the system is achieved through application level controls, physical access controls and strong personnel training. All user interaction with the web-based system, from transmitting access passwords to entering sensitive patient data, is done via 128-bit encryption using the secure HTTPS protocol. Firewalls ensure that only the minimum traffic required for normal
operations is allowed to traverse the network of web and database servers. REDCap production servers are housed in secure institutional data center facilities and include failover protection designed to minimize potential for server downtime. Minimal required personnel are allowed direct access to production facilities. N²QOD data will remain secure and be maximally protected using REDCap production-level data center servers.

The inclusion of PHI is critical for longitudinal analysis at 3 months and 12 months post-operatively. Without unique patient identifiers, long-term quality measures cannot be accurately added to each patient’s registry entry. In addition, social security number (SSN) remains the only common patient identifier that allows linkage to other databases. These robust datasets that require SSN include the national Medicare and Medicaid claims database, claims datasets of private payers (i.e., Blue Cross Blue Shield, Aetna, and most others), and several national registries maintained by the National Cancer Institute and the National Institutes of Health. Maintaining SSN in the N²QOD registry will also create the potential to link N²QOD data with robust datasets that collect healthcare cost data. Such linkage would provide, for the first time, the ability to generate value measures of neurosurgical procedures. Linking 12-month quality adjusted life years (QALY) gained (EQ-5D) from the N²QOD dataset with 12-month cost data from a multitude of claims datasets via SSN will allow a cost per QALY-gained figure (i.e., a value measure) for all procedures performed in neurosurgery. Determination of value of care in this fashion is the exact request and aim of the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services, and the Institute of Medicine (IOM).

All PHI will be stored in the secure N²QOD data warehouse maintained by VIMPH with oversight by NPA, as detailed in the business associate agreement. Patients (case ID), surgeons (SID), practices (GPID), and hospitals (HID) will be assigned a numeric enrollment code by VIMPH. The unique subject identifier (patient registry ID) will be a concatenation of the the practice group’s registry ID and a case ID. The patient registry ID will be used as the primary patient identifier in datasets handled for analysis purposes. The “analytic dataset” thus developed by VIMPH will contain only these numeric identifiers. All protected health information, including social security number, will be securely stored at VIMPH and not included in any analyzed data sets or analysis reports. This HIPPA-compliant, limited dataset will represent the minimum data required for longitudinal analysis.

Data Analysis

The VIMPH will perform all advanced analysis of the limited dataset and generate overall and site specific reports of risk-adjusted benchmarks for all quality and outcome endpoints. These reports (lacking PHI) will be forwarded to participating sites every six months. VIMPH will also perform quality assurance analyses, correct for missing data, provide data compliance reports for both sites and the NPA, and, when requested by the NPA, facilitate links to administrative datasets. VIMPH will report monthly to the NPA on site enrollment compliance along with adequacy of baseline and follow-up data entry. They will also generate real-time recommendations to the NPA on potential data element revisions. All reporting and data transfers will be will be conducted in accordance with Data Use and Business Associates Agreements between the NPA, participating sites, and the VIMPH.

**Benchmarking Quality and Effectiveness:** For both site-specific and aggregate national data analysis, post-operative outcome scores will be compared with pre-operative scores via t-test and two-way ANOVA. One-year patient-reported outcomes (PRO) change scores will be calculated and used as a measure of effectiveness. Utilizing multiple regression analysis, variables
independently associated with PRO change scores will be identified. Utilizing this model and the variables identified as predictive of change in PRO, estimated expected effectiveness will be calculated specific for the (Neurosurgery Practice Group) unique patient population and surgical treatments, allowing an observed to expected ratio. Utilizing multivariate logistic regression analysis, variables independently associated with 30-day categorical morbidity measures will be identified and used to model expected morbidity specific for (Neurosurgery Practice Group), allowing an observed to expected ratio of morbidity and hospital safety.

Comparative Effectiveness: The relative effectiveness (PRO change scores) will be compared across multiple procedures for specific clinical and radiographic patient presentations utilizing a multitude of univariate and multivariate approaches. Furthermore, the relative effectiveness of specific surgical procedures will be compared across multiple pathologies and clinical presentations to determine the most appropriate patient populations for specific surgical procedures.

7.0 Risks

We do not foresee any circumstances where surgical patients will be placed at any kind of risk due to their participation in this quality reporting effort. Standard of care will be delivered in all cases. All personal health information collected for the purpose of this study will be stored in a password-protected database with access granted only to team members. The national aggregate quality data will be maintained by the NPA in a password-protected database managed by the VIMPH. While patient identifiers will be stored in this secure national database, aggregate data analysis for grant writing, peer-reviewed publication, or any use-specific reasons outside of the NPA’s quality reporting system will be allowed only after a separate IRB is approved and the NPA Data Access and Use Committee approves, at which point de-identified data will be shared with requesting centers.

8.0 Reporting of Adverse Events or Unanticipated Problems Involving Risk to Participants or Others

All N2QOD team members listed in the project description are required to have received training in HIPAA privacy and security rules and regulations.

9.0 Statistical Considerations

The volume of enrolment at (Neurosurgery Practice Group) is intended to generate six lumbar surgeries per six-day week, resulting in approximately 300 patients per year. We expect these 300 annual patients to fall within six major diagnostic categories (approximately 50 patients each). The aggregate data pool is expected to include 50 practice groups, generating approximately 15,000 lumbar surgery patients per year and 2,500 patients per major diagnosis category. These numbers far surpass all prospective trials to date. Using a mean (SD) pre-operative ODI of 41.7 as reported in the SPORT trial (22), 2,500 patients per diagnosis group is sufficiently powered to detect a statistically significant ODI change as small as 1% between treatment groups.

10.0 Privacy/Confidentiality Issues
All captured data will be analyzed and risk-adjusted models of expected morbidity, mortality, and 30-day, 3-month and 12-month quality data generated by the VIMPH. These reports will be reported back to (Neurosurgery Practice Group) every six months. The established safety protocol will be reviewed monthly and any compromise will be reported to the IRB and other relevant agencies. Participating patients will also be informed that they can withdraw their participation at any time should they become concerned about the safety of their personal health information.

All registry team members have been trained in HIPAA privacy and security rules and regulations. Our safety mechanisms and protocols will be reviewed monthly and any compromise to our data protection protocol will be promptly reported to the IRB or appropriate regulatory/oversight groups.

Prior to the onset of registry participation, a protocol in line with established guidelines will be discussed with all the members of the team. To ensure data accuracy, a second chart audit may be performed by an approved team member to confirm compliance and (where appropriate) inter-rater reliability. Also, the NPA may request de-identified operative reports and clinic notes to be mailed for review to confirm compliance and accuracy of data entry into the national quality registry. In these cases, no patient identifiers will be included in audited records.

Data will be entered into a national aggregate dataset maintained by the VIMPH, with oversight by the NPA, and reported back to (Neurosurgery Practice Group). Security of the system is achieved through application level controls, physical access controls and strong personnel training. All user interaction with the web-based system, from transmitting access passwords to entering sensitive patient data, is done via encryption using secure protocol. All new and modified data are carefully audited at the database level. Firewalls ensure that only the minimum traffic required for normal operations is allowed to traverse the network of web and database servers. Servers are housed in secured facilities, which are monitored 24 hours a day, seven days a week with access controlled by security personnel and/or biometric security systems. Only minimal required personnel are allowed direct access to production facilities, and remote access is strictly limited to senior production and technical staff.

11.0 References


20. Simon Dagenais D, PhD, Darren M. Roffey, PhD, Eugene K. Wai, MD, MSc, Scott Haldeman, DC, MD, PhD, Jaime Caro, MD, MSc: Can cost utility evaluations inform decision making about interventions for low back pain? A systematic review. *The Spine Journal*, 2009.


Appendix 1. Patient reported outcome questionnaires used on pre-operative, 3-month, and 12-month post-operative patient interview. Questions will be asked in the following order: EQ-5D, PSI, Back and Leg Pain Scale, ODI.

I. EuroQol EQ-5D Questionnaire

MOBILITY
Describe your mobility.
1. No problems in walking about.
2. Some problems in walking about.
3. Confined to bed.

SELF CARE
Describe your self-care.
1. No problems with self-care.
2. Some problems washing or dressing myself.
3. Unable to wash or dress myself.

USUAL ACTIVITIES
Describe your ability to perform your usual activities (for example work, study, housework, leisure activities).
1. No problems with performing your usual activities.
2. Some problems with performing your usual activities.
3. Unable to perform your usual activities.

PAIN/DISCOMFORT
Describe your pain or discomfort.
1. No pain or discomfort.
2. Moderate pain or discomfort.
3. Extreme pain or discomfort.

ANXIETY/DEPRESSION
Describe your anxiety or depression.
1. Not anxious or depressed.
2. Moderately anxious or depressed.
3. Extremely anxious or depressed.

EQ VAS Introduction
I would now like to ask you a different task.
To help you say how good or bad your health state is, I’d like you to try to picture in your mind a scale that looks a bit like a thermometer. Can you do that? The best health state you can imagine is marked 100 (one hundred) at the top of the scale and the worst state you can imagine is marked 0 (zero) at the bottom.

EQ VAS – Task
I would now like you to tell me the point on this scale where you would put your own health state today.
II. Patient Satisfaction Index (PSI)

1. Surgery met my expectations
2. Surgery improved my condition enough so that I would go through it again for the same outcome.
3. Surgery helped me, but I would not go through it again for the same outcome.
4. I am the same or worse compared to before surgery.

III. Back and Leg Pain Scale:

I am going to ask you to rate your back pain and leg pain when off your medication. Please rate your back pain and leg pain on a scale of 0 to 10, where Zero (0) means “no pain” and a ten (10) would mean the “worst pain imaginable”.

1. Please rate your back pain on a scale of 0-10 over the past 7 days.
2. Now, please rate your leg pain on a scale of 0-10 over the past 7 days.

IV. Oswestry Disability Index Questionnaire

ODI Instructions: Next I am going to ask you to rate how your back or leg problems affect your ability to manage routine activities. Each item I read will have 6 possible responses. I will read them to you slowly.

Please choose the response which most accurately represents your overall condition. Feel free to ask questions or choose a response at any time.

1. Please rate your current pain:
   a. No pain
   b. Very mild
   c. Moderate
   d. Fairly severe
   e. Very severe
   f. Worst pain imaginable

2. Please pick the response that describes your ability to care for yourself (washing, dressing, etc.)
   a. I can care for myself without pain.
   b. I can care for myself, but it is very painful
   c. I can care for myself, but it is very painful and I must move slowly and carefully.
   d. I need some help, but I can perform most activities.
   e. I need help daily with most of these activities.
   f. I cannot tolerate these activities and I stay in bed.

3. Please rate your ability to lift heavy weights.
   a. I can lift heavy weights without pain.
   b. I can lift heavy weights, but it is painful.
   c. I cannot lift heavy weights off the floor due to pain, but can lift when items are placed on a table or counter.
d. I cannot lift heavy weights due to pain, but can lift medium weight items from a table or counter.
e. I can lift only very light weight items.
f. I cannot lift anything.

4. The next item asks you to rate your ability to walk.
   a. Pain does not limit my ability to walk.
   b. Pain prevents me from walking more than a mile (about 16 blocks).
   c. Pain prevents me from walking more than a quarter mile (about 4 blocks).
   d. Pain prevents me from walking more than 100 yds (football field).
   e. I can only walk using a cane or crutches
   f. I spend most of my time in bed and I am unable to walk.

5. Next, I will ask you to rate your ability to sit.
   a. Pain does not limit my ability to sit.
   b. I can sit in my favorite chair without pain.
   c. Pain prevents me from sitting for more than 1 hour.
   d. Pain prevents me from sitting for more than 30 min.
   e. Pain prevents me from sitting for more than 10 min.
   f. Pain prevents me from sitting.

6. Next, rate your ability to stand.
   a. Standing does not cause extra pain.
   b. I can stand as long as I want, but it does cause extra pain.
   c. Pain prevents me from standing for more than 1 hour.
   d. Pain prevents me from standing for more than 30 min.
   e. Pain prevents me from standing for more than 10 min.
   f. Pain prevents me from standing.

7. Does pain interfere with your sleep?
   a. Never.
   b. Occasionally
   c. Pain limits me to less than 6 hours of sleep.
   d. Pain limits me to less than 4 hours of sleep
   e. Pain limits me to less than 2 hours of sleep
   f. Pain prevents me from sleeping.

8. This next item will ask whether pain interferes with your sexual activity. With regards to pain, how would you say your sex life is?
   a. Normal and causes no extra pain.
   b. Normal, but causes some extra pain.
   c. Nearly normal, but is very painful.
   d. Severely restricted by pain.
   e. Nearly absent because of pain.
   f. Not sexually active.

9. Next, I will ask you whether pain interferes with your social activity. With regards to pain, how would you rate your social life.
a. Normal and causes no extra pain
b. Normal, but causes some extra pain.
c. Pain limits my social life, but I still try to go out.
d. Pain limits my social life. I do not go out as often as I’d like.
e. I do not go out. Pain keeps me at home.
f. I have no social life because of pain.

10. With regards to pain, rate your ability to travel.
   a. I can travel without pain.
   b. I can travel but it does cause increased pain.
   c. I can tolerate travel over 2 hrs, but the pain is bad.
   d. Pain restricts my travel to less than 1 hour.
   e. Pain restricts my travel to less than 30 minutes.
   f. Pain prevents all my travel except to receive medical care.
### Appendix 2. Summary of data variables to be collected for the National Neurosurgery Quality and Outcomes Registry-Lumbar Module

**N²QOD Variables**

<table>
<thead>
<tr>
<th><strong>Patient Variables</strong></th>
<th><strong>Clinical Variables</strong></th>
</tr>
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<tbody>
<tr>
<td>Social Security Number</td>
<td>Dominant Symptom: Back Pain, Leg pain, Back equal to Leg Pain, Motor Deficit</td>
</tr>
<tr>
<td>MR#</td>
<td>Duration of Symptoms (&lt;3mo, &gt;3mo, unknown)</td>
</tr>
<tr>
<td>Patient name</td>
<td>Ability to ambulate (independent, assistive device, non-ambulatory)</td>
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<tr>
<td>Principal spine diagnosis (inclusion criteria)</td>
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<tr>
<td>Date of surgery</td>
<td></td>
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<tr>
<td>Gender (M/F)</td>
<td></td>
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<tr>
<td>Patient address/ phone number</td>
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<tr>
<td>Race/Ethnicity (White, Black or African American, Asian, Hispanic or Latino, American Indian, Other)</td>
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<tr>
<td>Level of education</td>
<td></td>
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<tr>
<td>DOB</td>
<td></td>
</tr>
<tr>
<td>Height (cm (or inches))</td>
<td>Prior Surgery at same level and side (Yes/No, unknown)</td>
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<tr>
<td>Weight (kg (or lbs))</td>
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<tr>
<td>Employment status</td>
<td>Disc Collaps (Yes/No) *level of surgery only</td>
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<tr>
<td>Activities status</td>
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<tr>
<td>Smoking status</td>
<td>Modic endplate changes (Yes/No) *level of surgery only</td>
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<tr>
<td>DM</td>
<td>Surgery within 12 mos. of Lumbar Procedure (y/n, type)</td>
</tr>
<tr>
<td>CAD</td>
<td></td>
</tr>
<tr>
<td>Depression and/or Anxiety Disorder</td>
<td>Disc herniation (Yes/No) *level of surgery only</td>
</tr>
<tr>
<td>Osteoporosis (yes/no)</td>
<td></td>
</tr>
<tr>
<td>Condition caused by work related or motor vehicle injury (yes/no)</td>
<td>Surgical Variables</td>
</tr>
<tr>
<td>Insurance payer</td>
<td>Date of Surgery</td>
</tr>
<tr>
<td>Workers Compensation claim</td>
<td>Surgical approach- Posterior, Anterior alone</td>
</tr>
<tr>
<td>Liability of disability Insurance claim</td>
<td>Laminectomy yes/no Levels (0,1,2,3)</td>
</tr>
<tr>
<td>Disc herniation (Yes/No)</td>
<td>Arthrodesis yes/no Levels (0,1,2,3)</td>
</tr>
<tr>
<td><strong>Surgical Variables</strong></td>
<td></td>
</tr>
<tr>
<td>Posterior instrumentation (N, Y-, company/brand specifics name)</td>
<td></td>
</tr>
<tr>
<td>Interbody Graft (Yes/No), How placed</td>
<td></td>
</tr>
<tr>
<td><strong>Structural Variables</strong></td>
<td></td>
</tr>
<tr>
<td>Hospital, Practice, Surgeon</td>
<td></td>
</tr>
<tr>
<td>Urban, Suburban, Rural</td>
<td></td>
</tr>
<tr>
<td>Private vs. Public Hospital</td>
<td>Estimated Blood loss</td>
</tr>
<tr>
<td>Annual Volume (Practice, Surgeon)</td>
<td></td>
</tr>
<tr>
<td>Neurosurgery Residency</td>
<td>Length of surgery (minutes)</td>
</tr>
<tr>
<td>U.S. Region, State</td>
<td>ASA Grade</td>
</tr>
<tr>
<td><strong>entered once</strong></td>
<td></td>
</tr>
</tbody>
</table>
## Registry Details:

**Inclusion** – Symptomatic lumbar disc herniation, lumbar stenosis, lumbar spondylolisthesis, symptomatic recurrent lumbar disc herniation, lumbar adjacent segment disease

**Exclusion** –
Patients undergoing lumbar surgery for any diagnosis other than the six listed above should be excluded from the registry. Exclusions include but are not limited to spinal infection, tumor, fracture, traumatic dislocation, deformity, pseudoarthrosis, same level recurrent multi-level stenosis, neurological paralysis due to pre-existing spinal disease or injury, < 18yrs of age, incarceration (prisoner), Laminectomy of > 4 levels (i.e. L2-S1 laminectomy) or fusion of >3 motion segments (L2-S1), if informed consent is required by the local IRB, then refusal of consent, Spondylolisthesis grade 2, 3, or 4 (> Grade 1 (25%), Patients receiving a surgery other than laminectomy, laminotomy, discectomy or fusion (examples of excluded procedures include laser disc ablation, Axia-lift), Patients who have a history of or whose current surgery includes an excluded device (examples include interspinous distraction device, spinal cord stimulator).

**note: inclusion/exclusion criteria are based on primary diagnosis and indication for surgery, and not secondary radiographic features**

**Treatments** – Lumbar discectomy, Laminectomy w/wo fusion, w/wo instrumentation, w/wo interbody, and fusion alone.