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

Phase 1: The Cervical Spine Module

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[List all personnel involved with data collection and review]

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Date
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1.0 Rationale and Specific Aims

To date, no nationally collaborative reporting mechanisms utilizing validated outcome measures have assessed to what extent cervical 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 cervical 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 cervical 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 cervical surgery performed for primary cervical degenerative disease will be eligible for inclusion. Exclusions include but are not limited to spinal infection, tumor, fracture, traumatic dislocation, deformity (including kyphosis or scoliosis that is documented as > 20 degrees, moderate, large, or severe), prior cervical surgery at the same level, patients with presence of any neurological condition or deficit that would cause the interpretation of outcome to be unclear (chronic ulnar neuropathy, end-stage carpel tunnel syndrome), surgery involving occiput, C1 or any segment of thoracic spine below T2, < 18yrs of age, incarceration (prisoner), if informed consent is required by the local IRB, then refusal of consent. A standard of care outcomes questionnaire, which includes Neck and Arm Pain Scale, Neck Disability Index (NDI), Euro-Quol 5D (EQ-5D) (1, 2), Modified Japanese Orthopedic Association (mJOA) myelopathy scale 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).

2.0 Inclusion/Exclusion Criteria

Inclusion: Patients undergoing cervical surgery for Radiculopathy with or without neck pain, Myelopathy with or without neck or arm pain, or Mechanical neck pain from documented cervical instability, with underlying diagnosis of Cervical disc herniation, Central stenosis, Foraminal Stenosis or Cervical Instability involving vertabra C2-T2 by (Neurosurgery Practice Group) will be eligible for inclusion.

Exclusion: Patients undergoing cervical surgery for any diagnosis other than the four listed above should be excluded from the registry. Exclusions include but are not limited to spinal infection, tumor, fracture, traumatic dislocation, deformity (including kyphosis or scoliosis that is documented as > 20 degrees, moderate, large, or severe), prior cervical surgery at the same level, patients with presence of any neurological condition or deficit that would cause the interpretation of outcome to be unclear (chronic ulnar neuropathy, end-stage carpel tunnel syndrome), surgery involving occiput, C1 or any segment of thoracic spine below T2, < 18yrs of age, incarceration (prisoner), if informed consent is required by the local IRB, then refusal of consent.

3.0 Patient Enrollment

The first six eligible patients per week meeting the aforementioned inclusion criteria and scheduled to undergo cervical 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 enrollment 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.
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.

4.0 Data Elements and Related Procedures

Patient-Reported Outcome Instruments

A standard of care outcomes questionnaire (see appendix 1), which includes Neck and Arm Pain Scale, Neck Disability Index (NDI), Euro-Qol 5D (EQ-5D) (1, 2), Modified Japanese Orthopedic Association (mJOA) myelopathy scale and the NASS Patient Satisfaction Index (PSI) 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.

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 neck pain, arm pain, or both. Patients with the aforementioned symptoms can be further stratified based on radiographic presentation, including 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 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 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.

### 5.0 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.

### 6.0 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.

### 7.0 Statistical Considerations
The volume of enrollment at (Neurosurgery Practice Group) is intended to generate six cervical 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 cervical surgery patients per year and 3,750 patients per major diagnosis category. These numbers far surpass all prospective trials to date.

8.0 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.
Appendix 1. Patient reported outcome questionnaires used on pre-operative, 3-month, and 12-month post-operative patient interview.

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. Neck and Arm Pain Scale Scoring Instructions: I am going to ask you to rate your neck pain and arm 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 neck pain on a scale of 0-10 over the past 7 days.
   2. Now, please rate your arm pain on a scale of 0-10 over the past 7 days.

IV. Neck Disability Index Questionnaire

NDI Instructions: Next I am going to ask you to rate how your neck pain has affected your ability to manage everyday activities. Each item I read will have 6 possible responses. I will read them to you slowly. Please choose the response which most accurately describes your overall condition. Feel free to ask questions or choose a response at any time.
   1. Please rate the severity of your current pain:
      a. No pain
      b. Very mild pain
      c. Moderate pain
      d. Fairly severe pain
      e. Very severe pain
      f. The worst pain imaginable pain
   2. Please pick the response that describes your ability to care for yourself (washing, dressing, etc.)
      a. I can care for myself without causing neck pain.
      b. I can care for myself, but it causes extra neck pain.
      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 manage most of my personal care.
      e. I need help every day with most of my personal care.
      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 causing neck pain.
      b. I can lift heavy weights, but it causes extra neck pain.
      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 weights.
      f. I cannot lift anything.
   4. The next item asks you to rate your ability to read as much as you would like to.
      a. No pain in my neck when I read
b. Slight pain in my neck when I read
c. Moderate pain in my neck when I read
d. I cannot read as much as I would like to because of moderate pain in my neck.
e. Cannot read as much as I would like to because of severe pain in my neck
f. I cannot read at all.

5. The next item asks you about headaches.
   a. No headaches at all.
   b. Slight headaches come infrequently.
   c. Moderate headaches come infrequently.
   d. Moderate headaches come frequently.
   e. Severe headaches which come frequently.
   f. Have headaches almost all the time.

6. Next, rate your ability to concentrate.
   a. Can concentrate fully without difficulty.
   b. Can concentrate fully with slight difficulty.
   c. Fair degree of difficulty in concentrating.
   d. A lot of difficulty in concentrating.
   e. A great deal of difficulty in concentrating.
   f. Cannot concentrate at all.

7. Does neck pain interfere with your work?
   a. Can work as much as I want to.
   b. Can only do my usual work, but no more
   c. Can do most of my usual work, but no more
   d. Cannot do my usual work.
   e. Can hardly do any work at all
   f. Cannot do any work at all.

8. Does neck pain interfere with your ability to drive a vehicle.
   a. Can drive without any neck pain
   b. Can drive as long as I want with slight neck pain.
   c. Can drive as long as I want with moderate neck pain.
   d. Cannot drive as long as I want because of moderate neck pain.
   e. Nearly absent because of pain
   f. Can hardly drive at all because of severe neck pain
   g. Cannot drive at all.

9. Does neck 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 at all.

10. Next I will ask you whether neck pain interferes with your recreation activities.
    a. Recreation is normal and causes no extra pain.
    b. Recreation is normal, but does cause some extra pain.
c. Neck pain limits my recreation, but I still try to do as much as I can

d. Neck pain limits my recreation, but I still try to do some of it

e. Neck pain keeps me at home. I can hardly do any recreation

f. I do no recreation because of neck pain.

V. Modified Japanese Orthopedic Association Myelopathy Scale (modified Chiles version)

I am going to read out some questions. Each question has a choice of answers. Please tell me which answer best describes your own health state today.

1. Feeding and use of your hands and arms.
   Describe your ability to feed yourself.
   a. Unable to feed myself. (0)
   b. Unable to use both hands for knife and fork, but I am able to eat using a fork or spoon with one hand. (1)
   c. Able to use a knife and fork with much difficulty. (2)
   d. Able to use a knife and fork with slight difficulty. (3)
   e. Able to feed myself with no difficulty using both hands. (4)

2. Walking and use of your legs
   Describe your ability to walk.
   a. Unable to walk. (0)
   b. Can walk on flat surface with a cane or walker. (1)
   c. Can walk up or down stairs with support of a handrail. (2)
   d. Some trouble walking smoothly and problems with balance. (3)
   e. No problem walking. (4)

3. Loss of feeling or numbness in hands and arms
   Describe your ability to feel sensation in your hands or arms
   a. Severe loss of feeling in my hand or arm, loss of pain, touch or sensation. (0)
   b. Mild loss of feeling in my hand or arm. (1)
   c. No loss of feeling in my hands and arms. (2)

4. Loss of feeling or numbness in legs
   Describe your ability to feel sensation in your legs
   a. Severe loss of feeling in my leg. (0)
   b. Mild loss of feeling in my leg. (1)
   c. No loss of feeling in my legs. (2)

5. Loss of feeling or numbness in the trunk of my body
   Describe your ability to feel sensation in your body
   a. Severe loss of feeling in my body. (0)
   b. Mild loss of feeling in my body. (1)
   c. No loss of feeling in my body. (2)
6. Problems with Urinating
   a. Cannot urinate, void, or pee. (0)
   b. Severe difficulty because feeling of residual urine or retaining urine even after voiding or because of straining to go or just dribbling when urinating. (1)
   c. Mild difficulty because of problem with initiating or getting started or problem with urinating either too frequently or hardly ever. (2)
   d. No problems with urinating or peeing. (3)
Appendix 2. Summary of data variables to be collected for the National Neurosurgery Quality and Outcomes Registry—Cervical Module

N²QOD Variables

<table>
<thead>
<tr>
<th>Patient Variables</th>
<th>Clinical Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Security Number</td>
<td>Dominant Symptom: Neck Pain, Arm pain, Neck equal to Arm Pain, Motor Deficit</td>
</tr>
<tr>
<td>MR#</td>
<td></td>
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<tr>
<td>Patient name</td>
<td></td>
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<tr>
<td>Indication for Surgery</td>
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<tr>
<td>Underlying Pathology (Inclusion Criteria)</td>
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<tr>
<td>DOB</td>
<td>Duration of Symptoms (&lt;3mo, &gt;3mo, unknown)</td>
</tr>
<tr>
<td>Date of surgery</td>
<td>Ability to ambulate (independent, assistive device, non-ambulatory</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>
<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>Height (cm (or inches))</td>
<td>Cervical alignment</td>
</tr>
<tr>
<td>Weight (kg (or lbs))</td>
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<tr>
<td>Employment status</td>
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<tr>
<td>Activities status</td>
<td>Listhesis or dynamic instability (level of surgery)</td>
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<td>Smoking status</td>
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<td>DM</td>
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<tr>
<td>CAD</td>
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<tr>
<td>Depression and/or Anxiety Disorder</td>
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<td>Osteoporosis (yes/no)</td>
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<tr>
<td>Condition caused by work related or motor vehicle injury (yes/no)</td>
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<tr>
<td>Insurance payer</td>
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<td>Workers Compensation claim</td>
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<tr>
<td>Liability of disability Insurance claim</td>
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<td>Surgical Variables</td>
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<td>Date of Surgery</td>
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<tr>
<td>Surgical approach- Posterior, Anterior, Two-stage</td>
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<tr>
<td>Laminectomy yes/no Levels</td>
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<td>Arthrodesis yes/no Levels</td>
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<tr>
<td>Corpectomy yes/no Levels</td>
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<td>Arthroplasty yes/no Levels</td>
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<tr>
<td>Structural Variables*</td>
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<tr>
<td>Hospital, Practice, Surgeon</td>
<td>Posterior/Anterior instrumentation (N, Y-, company/brand specifics name</td>
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<tr>
<td>Urban, Suburban, Rural</td>
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<tr>
<td>Private vs. Public Hospital</td>
<td>Interbody Graft (Yes/No), How placed</td>
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<tr>
<td>Annual Volume (Practice, Surgeon)</td>
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<tr>
<td>Neurosurgery Residency</td>
<td>Length of surgery (minutes)</td>
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<tr>
<td>U.S. Region, State</td>
<td>ASA Grade</td>
</tr>
</tbody>
</table>
*entered once

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**N²QOD: CERVICAL SPINE MODULE V1.0**

<table>
<thead>
<tr>
<th>30-day Quality</th>
<th>3-month Quality</th>
<th>12-month Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of hospital stay</td>
<td>NDI (10 questions)*</td>
<td>NDI (10 questions)*</td>
</tr>
<tr>
<td>DC location</td>
<td>EQ-5D (5 questions)*</td>
<td>EQ-5D (5 questions)*</td>
</tr>
<tr>
<td>Readmission to Hospital (yes/no)-reason in pull-down menu</td>
<td>Neck and Arm Pain Scale*</td>
<td>Neck and Arm Pain Scale*</td>
</tr>
<tr>
<td>Return to OR (spine related) (yes/no)-reason in pull-down menu</td>
<td>mJOA (6 questions)*</td>
<td>mJOA (6 questions)*</td>
</tr>
<tr>
<td>Surgical Site Infection (yes/no) Treatment modality</td>
<td>NASS Patient Satisfaction Index (PSI)</td>
<td>NASS Patient Satisfaction Index (PSI)</td>
</tr>
<tr>
<td>DVT/PE (yes/no)</td>
<td>Work Status [No, Yes-part (mo), Yes-full (mo)] / Activities status*</td>
<td>Work Status [No, Yes-part (mo), Yes-full (mo)] / Activities status*</td>
</tr>
<tr>
<td>UTI (yes/no)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI/CVA (yes/no)</td>
<td>Revision Surgery – [No, Yes-same level, Yes-adj level]</td>
<td>Revision Surgery – [No, Yes- ]</td>
</tr>
<tr>
<td>Surgical Site hematoma (yes/no)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Neuro Deficit (yes/no)</td>
<td>Re-admission to hospital within 3 months-(yes/no)-reason</td>
<td></td>
</tr>
<tr>
<td>Dysphagia (requiring NPO or NG tube) (yes/no)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysphagia (not requiring NPO or NG tube) (yes/no)</td>
<td></td>
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<tr>
<td>Vocal Cord Paralysis (yes/no)</td>
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<tr>
<td>CSF Leak (yes/no)</td>
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<tr>
<td>Wound Dehiscence (yes/no)</td>
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<tr>
<td>Mortality (yes/no), cause</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Registry Details:

Inclusion – Cervical disc herniation, Central stenosis, Foraminal Stenosis or Cervical Instability involving vertabra C2-T2

Exclusion –

Patients undergoing cervical surgery for any diagnosis other than the four listed above should be excluded from the registry. Exclusions include but are not limited to spinal infection, tumor, fracture, traumatic dislocation, deformity (including kyphosis or scoliosis that is documented as > 20 degrees, moderate, large, or severe), prior cervical surgery at the same level, patients with presence of any neurological condition or deficit that would cause the interpretation of outcome to be unclear (chronic ulnar neuropathy, end-stage carpel tunnel syndrome), surgery involving occiput, C1 or any segment of thoracic spine below T2, < 18yrs of age, incarceration (prisoner), if informed consent is required by the local IRB, then refusal of consent.

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

Treatments – Laminectomy, Hemilaminectomy, Laminotomy, Foraminotomy, Facetectomy, Disectomy (Microdiscectomy, Open disectomy), Fusions (Anterior Cervical Discectomy and Fusion (ACDF), Posterior Fusion), Corpectomy, Arthroplasty (Artificial Disc Replacement)