Advancing Patient-Centered Spine Care Through Prospective Patient Care Registries

4 year experience with the National Neurosurgery Quality and Outcomes Database (N²QOD)

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NeuroSafe Symposium
7/16/2016
Disclosures

• Director, National Neurosurgery Quality and Outcomes Database
• Board of Directors, American Association of Neurological Surgeons; ABNS
• Surgery Steering Committee, National Quality Forum
• Chairman, Privacy and Research Task Force, AMA National Quality Registry Network
“AMERICANS spent $2.6 trillion on health care in 2010, a staggering 18% of GDP. Yet few of them have the faintest idea what any treatment costs or how it compares with any other treatment. Prices vary wildly and seemingly without reason…”
“About 30% of All Current Spending is Waste”

Source: Institute of Medicine: “The health care Imperative: Lowering Costs and Improving Outcomes - Workshop Series Summary”
“About 30% of All Current Spending is Waste”

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The Present Healthcare Environment

- Current healthcare costs are **unsustainable**
- Most stakeholders (correctly) believe that healthcare quality is inconsistent, and sometimes low
• *Value-based reforms* are being adopted by most stakeholders to help achieve sustainability of the current U.S. healthcare system

\[
\text{Value} = \frac{\text{Quality}}{\text{Cost}}
\]
Growth in Value-based reimbursement

United Healthcare

Total Value-Based Spend ($ Billions)

2011: $13
2015: $45+
2018P: $65+

Medicare

Alternative payment models: 90%
FFS linked to quality: 50%
All Medicare FFS: 100%
Value Care: Patient Perspective

Deductibles Rising Much Faster Than Premiums, Wages, and Inflation

- Overall Inflation
- Workers Earnings
- Single Coverage Deductibles, all Workers
- Single Coverage Premiums

NOTE: Average general annual deductible is among all covered workers. Workers in plans without a general annual deductible for in-network services are assigned a value of zero.

Challenges to Value-Based Approaches

• *Quality* remains poorly described
  – What would help: more focus on *outcomes*
  – Optimal healthcare outcomes for many medical conditions remain undefined from the perspective of *all* relevant stakeholders
Challenges to Value-Based Approaches

• Valid *methods* to continuously measure, promote and report safety and quality in healthcare are underdeveloped
  – Administrative datasets are ill-suited to advance quality improvement and science
National Strategy-Value Paradigm

• Build robust, novel information systems to measure clinical outcomes of relevance to all healthcare stakeholders

  – “The use of patient care data to measurably improve the quality of care and more efficiently allocate health care resources is reshaping modern medical practice, science and economics” Asher et. al., JNS 2013

• The only choice caregivers have is whether they will part of this process.
NPA Mission

- 501(c)(6)- Facilitate collection and analysis of clinical and economic data from practice for a variety of purposes using internet-based technologies
  - Research
    - CER
      - Public Reporting Requirements
      - Value-based purchasing
      - MOC
      - Quality improvement

Central Theme: Prospective Patient Registries ($N^2$QOD)
Clinical Registry

- *Observational* data collection systems designed to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure
  - Serves one or more predetermined scientific, clinical, or policy purposes.
  - Infrastructure can be adapted to other purposes.
Advantages of Registries for Quality Science and Healthcare Quality Improvement:

• *Easily scaled*
• *Cost-effective*
• *Continuous processes*
• *Wide variety of applications*
  – *QI*
  – *Evidence generation*
• *Yield data with strong external validity*
  – Registries typically have broad inclusion criteria and collect data in a comprehensive manner
    • Results can therefore be *generalized* to broad populations
“a disruptive technology.”

• “Today we can no longer afford to undertake randomized effectiveness trials that cost tens or hundreds of millions of dollars…today we also have registries and other powerful digital platforms.”

  – Dr. Michael Lauer, director of cardiovascular sciences at the National Heart, Lung and Institute, Bethesda, Md.

Clinical Registries are being increasingly used to promote value-based care and medical science

- Public and Private patient safety initiatives and quality reporting mandates
  - HHS (PQRS-QCDR)
    - 2/2/2015: HHS sets out to have “85% of all Medicare fee-for-service [FFS] payments tied to quality by 2016 or value by 2016, and 90% by 2018”
  - Private (e.g., BCBS distinction program)
  - Bariatric, orthopedic, cardiovascular and spine registry consortia

- **Board Certification**
  - ABMS MOC programs

- **Specialty society sponsored QI and Public Reporting**
  - AHA: “Get with the Guidelines”
  - STS: Voluntary performance reporting through Consumer Reports

- **Device registries**
  - FDA post-approval analyses

- **Comparative Effectiveness and Patient Centered Outcomes Research**
  - Federal Coordinating Council for Comparative Effectiveness Research
  - PCORI
Medicare Access and CHIP Reauthorization Act (MACRA)
• Proposed Regulations Released 4/2016
Key Elements

Consolidates Medicare Quality Programs:

- New Merit-Based Incentive Payment System (MIPS) program
  - Composite score (0-100)

*MIPS Components relevant to QCDR (Registry) Participation

- Quality (30%)
- Resource Use (30%)
- Meaningful Use (25%)
- Clinical Practice Improvement Activities (15%)
• Allow any neurosurgical or related specialty care provider, practice group or hospital to contribute to and access quality and outcomes data from a national registry

• Launched 3/2012
Value Opportunities in Spine Care

• *Spinal Disorders are the 2\textsuperscript{nd} most common reason for adult visits to medical provider*
  • LBP is the most common cause of work-related disability in the U.S.

• **Direct costs for Spine Care in the United States exceed $90 Billion annually**
  • Total costs may exceed $200 Billion*
  • Spinal fusion is the most costly O.R. procedure performed in US hospitals (AHRQ)

• **Utilization of common spine procedures has increased 150-600\% over the last decade**

• **Estimates are between 10 and 25\% of spine care (diagnostic and therapeutic) maneuvers are unnecessary and ineffective**
• Analyze 30-day surgical morbidity and 3 month/one-year improvements in pain, disability, quality of life and return to work after common spine procedures
  – Early emphasis on lumbar procedures
Stakeholder Engagement
Defining Quality
Diagnostic Classification/Inclusion

**Structural Pathology**
- Lumbar Disc Herniation
- Lumbar Stenosis
  - Central/Lateral
- Lumbar Spondylolisthesis
- Symptomatic Mechanical Disc Collapse
- Adjacent Segment Disease
- Recurrent Disc Herniation
- Scoliosis

**Symptoms**
- Back Pain Dominant
  - Acute/Chronic
- Leg Pain Dominant
  - Acute/Chronic
- Back=Leg pain
  - Acute/Chronic
- Neurogenic Claudication
Unique Aspects of N^2QOD
Relevant Methods and Measures of Outcomes

• Longitudinal follow up
  – Allow for the assessment of the sustainability of treatment effects

• Patient reported outcomes (PRO)
  – Key element in patient-centered care
  – May be more reflective of underlying health status than physician reporting
Human Research

Quality Improvement
Regulatory Summary

- 2011: Multi-society outreach to OHRP/OCR (HHS)
  - White House Meeting August, 2011
  - Written and verbal guidance-December 2011
- Summary of guidance
  - N²QOD is not subject to the jurisdiction of the common rule and its methods are compliant with the privacy rule (i.e, these activities do not constitute “human subjects research”)
  - Asher, A., et. al, Regulatory considerations for Prospective Patient Care Registries: Lessons Learned from the National Neurosurgery Quality and Outcomes Database (N²QOD) Neurosurg Focus. 2013, Jan; 34 (1): E5, 1-9
# The N²QOD Lumbar Variables

## Enrollment Variables:
**Patient, Structural, Clinical, Surgical**

<table>
<thead>
<tr>
<th>Patient Variables</th>
<th>Clinical Variables</th>
</tr>
</thead>
<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></td>
</tr>
<tr>
<td>Patient name</td>
<td></td>
</tr>
<tr>
<td>Principal spine diagnosis (inclusion criteria)</td>
<td></td>
</tr>
<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>
</tr>
<tr>
<td>Gender (M/F)</td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity (White, Black or African American, Asian, Hispanic or Latino, American Indian, Other)</td>
<td></td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
</tr>
<tr>
<td>Height (cm (or inches))</td>
<td>Prior Surgery at same level and side (Yes/No, unknown)</td>
</tr>
<tr>
<td>Weight (kg (or lbs))</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td>Disc Collapse (Yes/No) *level of surgery only</td>
</tr>
<tr>
<td>Ability to ambulate (independent, assistive device, non-ambulatory)</td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>Modic endplate changes (Yes/No) *level of surgery only</td>
</tr>
<tr>
<td>CAD</td>
<td>Surgery within 12 mos. of Lumbar Procedure (y/n, type)</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>Structural Variables*</td>
<td>Arthrodesis yes/no Levels (0,1,2,3)</td>
</tr>
<tr>
<td>Hospital, Practice, Surgeon</td>
<td>Posterior instrumentation (N, Y-, company/brand specifics name</td>
</tr>
<tr>
<td>Interbody Graft (Yes/No), How placed</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>*entered once</td>
<td></td>
</tr>
</tbody>
</table>

## Longitudinal Quality Data: Focus on Patient Reported Outcomes

<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>ODI (10 questions)*</td>
<td>ODI (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>Back and Leg Pain Scale*</td>
<td>Back and Leg Pain Scale*</td>
</tr>
<tr>
<td>Return to OR (spine related) (yes/no)-reason in pull-down menu</td>
<td>NASS Patient Satisfaction Index (PSI)</td>
<td>NASS Patient Satisfaction Index (PSI)</td>
</tr>
<tr>
<td>Surgical Site Infection (yes/no) Treatment modality</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>DVT/PE (yes/no)</td>
<td>Revision Surgery – [No, Yes-same level, Yes-adj level]</td>
<td>Revision Surgery – [No, Yes- ]</td>
</tr>
<tr>
<td>UTI (yes/no)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI/CVA (yes/no)</td>
<td>Re-admission to hospital within 3 months- (yes/no)-reason</td>
<td></td>
</tr>
<tr>
<td>Surgical Site hematoma (yes/no)</td>
<td>New Neuro Deficit (yes/no)</td>
<td></td>
</tr>
<tr>
<td>Mortality (yes/no), cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*also recorded at enrollment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**60 variables for risk adjustment**
Practicing Group Web Portal Provider

Online Data Entry

Reporting - Safety/Effectiveness

Quality control: Missing data, data validation & auditing

Aggregate & site specific data analysis

Secure Data Set Transfer

NEUROPONT ALLIANCE

est. 2008

VANDERBILT THE INSTITUTE FOR MEDICINE AND PUBLIC HEALTH

REDCap

Research Electronic Data Capture
The N²QOD Practice Based Learning Network

Welcome to The National Neurosurgery Quality & Outcomes Database (N²QOD)!

The National Neurosurgery Quality and Outcomes Database (N²QOD) serves as a continuous national clinical registry for neurosurgical procedures and practice patterns. Its primary purpose is to track quality of surgical care for the most common neurosurgical procedures, as well as provide practice groups and hospitals with an immediate infrastructure for analyzing and reporting the quality of their neurosurgical care.

Project Updates

N²QOD Quarterly Performance Reports Now Available The Quarterly Performance Reports have been uploaded to the Google Website. Please review these reports and share them with other members of N²QOD at your site. These reports highlight your...

Posted Mar 15, 2013, 2:50 PM by NPA Administrator

N²QOD in the February 2013 Issue of AANS Neurosurgeon

http://www.aansneurosurgeon.org/2210513/8/2737

Posted Mar 6, 2013, 5:49 PM by NPA Administrator

Data entry into the N²QOD formally commenced on February 22, 2012. To date, we have 35 contracted N²QOD sites and nearly 4,000 patients entered in the database.

The N²QOD has formally launched as of March 1, 2013! Training for sites is underway.
N²QOD Lumbar Spine Module:

- **Site Distribution**

- **78 Contracted N²QOD Sites**
  - 34 US States
  - 120 Hospitals
  - 6 new sites in activation

- **>950 Surgeons**
  - Neurosurgeon/Orthopedic

- **45% Academic**

- **55% Private Practice**
Representative Sampling

Table: Cycles of Six-Day Weeks for enrollment of surgical patients into the registry.

<table>
<thead>
<tr>
<th>Cycle</th>
<th>M</th>
<th>T</th>
<th>W</th>
<th>Th</th>
<th>F</th>
<th>Sat</th>
<th>M</th>
<th>T</th>
<th>W</th>
<th>Th</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
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<td>2</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
<td>X</td>
</tr>
<tr>
<td>3</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>5</td>
<td></td>
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<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
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<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Each cycle has a different start day for finding the first six consecutive surgeries. After Cycle 6, return to Cycle 1 and repeat.
Operations

- Data collection and quality assurance
  - Data collection
    - Link data from different sources
  - Data cleaning
    - Correction or amelioration of problems (missing/incomplete/incorrect/out of range)
      - Automated
      - Manual
  - Query reports
    - reports that relate to the quality of data received

Representative Sampling Methodology:
%enrolled /surgeon approximates %eligible
Audits for Data Quality and Validity

Audits demonstrate that data sampling methodology appears valid

<table>
<thead>
<tr>
<th>Enrollment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Data capture</td>
<td>98.1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Follow-up</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients contacted within 12m window</td>
<td>88%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data Integrity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Random Site Audits</td>
<td></td>
</tr>
<tr>
<td>Diagnostic Accuracy</td>
<td>97%</td>
</tr>
<tr>
<td>Data Completeness</td>
<td>100%</td>
</tr>
<tr>
<td>Self Audits</td>
<td></td>
</tr>
<tr>
<td>Diagnostic Accuracy</td>
<td>93%</td>
</tr>
<tr>
<td>(primary diagnosis corrected when necessary)</td>
<td></td>
</tr>
</tbody>
</table>
# Lumbar Spine Enrollment/Accrual

Initial 48 month experience (through 3/16)

## Enrollment

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened</td>
<td>20,197</td>
</tr>
<tr>
<td>Enrolled (after baseline and 30-day exclusions)</td>
<td>18,735</td>
</tr>
</tbody>
</table>

## Follow-up

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-month accrual</td>
<td>76.2%</td>
</tr>
<tr>
<td>12-month accrual</td>
<td>70.0%*</td>
</tr>
</tbody>
</table>

## Data Collection

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent variables</td>
<td>&gt; 4.0M</td>
</tr>
</tbody>
</table>

1/2016: >30,000 patients enrolled in all spine modules
Observations to Date
Spine Care Outcomes in a National Sample

• Spine surgery has never been broadly characterized in a comprehensive, prospective national database
  – Early descriptive analyses have yielded important observations that can be grouped into two categories
    • Opportunities to improve care
    • Experience of patient populations and individual patients
## Patient Satisfaction

**12 months**

<table>
<thead>
<tr>
<th></th>
<th>Disc Herniation N = 3126</th>
<th>Recurrent Disc Herniation N = 466</th>
<th>Spondylo-listhesis N = 1657</th>
<th>Stenosis N = 2826</th>
<th>Adjacent Segment Disease N = 404</th>
<th>Symptomatic Mechanical Disc N = 80</th>
<th>Combined N = 8559</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Satisfaction</strong></td>
<td>(N = 7506)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>70%</td>
<td>59%</td>
<td>71%</td>
<td>65%</td>
<td>54%</td>
<td>40%</td>
<td><strong>66.9%</strong></td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
<td>27%</td>
<td>19%</td>
<td>23%</td>
<td>30%</td>
<td>34%</td>
<td><strong>21.7%</strong></td>
</tr>
<tr>
<td>3</td>
<td>4%</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
<td>6%</td>
<td>11%</td>
<td>4.6%</td>
</tr>
<tr>
<td>4</td>
<td>6%</td>
<td>9%</td>
<td>5%</td>
<td>7%</td>
<td>10%</td>
<td>15%</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

**NASS 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 to before surgery
# Patient Satisfaction

## 12 months

<table>
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<th></th>
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<td></td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td>70%</td>
<td>59%</td>
<td>71%</td>
<td>65%</td>
<td>54%</td>
<td>40%</td>
<td>66.9%</td>
</tr>
<tr>
<td>2</td>
<td>20%</td>
<td>27%</td>
<td>19%</td>
<td>23%</td>
<td>30%</td>
<td>34%</td>
<td>21.7%</td>
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<td>3</td>
<td>4%</td>
<td>5%</td>
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<td>6%</td>
<td>11%</td>
<td>4.6%</td>
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<tr>
<td>4</td>
<td>6%</td>
<td>9%</td>
<td>5%</td>
<td>7%</td>
<td>10%</td>
<td>15%</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

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4. I am the same or worse as compared to before surgery
## Opportunities to Improve Care: Readmission

<table>
<thead>
<tr>
<th></th>
<th>30-day Major AE</th>
<th>30-day Re-admit</th>
<th>90-day Re-operation</th>
<th>90-Day Re-admit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OVERALL</strong></td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
<td>8%</td>
</tr>
<tr>
<td><strong>1st time surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disc Herniation</td>
<td>1%</td>
<td>3%</td>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>Stenosis</td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
<td>8%</td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
<td>7%</td>
</tr>
<tr>
<td><strong>Revision surgery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent Disc Herniation</td>
<td>2%</td>
<td>3%</td>
<td>3%</td>
<td>9%</td>
</tr>
<tr>
<td>Adjacent Segment Disease</td>
<td>3%</td>
<td>5%</td>
<td>2%</td>
<td>10%</td>
</tr>
</tbody>
</table>
Length of hospital stay

- Disc Herniation
- Recurrent Disc Herniation
- Spondylolisthesis
- Stenosis
- Adjacent Segment Disease
- Mechanical disc collapse
## Failure to improve over baseline

### 12 months

<table>
<thead>
<tr>
<th>Patient Reported Outcomes</th>
<th>m/N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back Pain</td>
<td>1838/8487</td>
<td>22%</td>
</tr>
<tr>
<td>Leg Pain</td>
<td>1495/8483</td>
<td>18%</td>
</tr>
<tr>
<td>ODI</td>
<td>962/8504</td>
<td>11%</td>
</tr>
<tr>
<td>EQ5D</td>
<td>1674/8463</td>
<td>20%</td>
</tr>
</tbody>
</table>
Analyses of Population Experience: Average Outcomes Over Time are Excellent and Sustained
However, there is Significant Variation in Effectiveness of Care at the individual patient level

What factors are driving outcomes at the individual patient level?
“Average” outcomes do not reflect the tremendous variability in response at the individual patient level.
Improving Value by Understanding Variation in Outcomes

Variation  ➔  Value

- Improve outcomes by understanding variation
- Conduct interventions and practice innovations for meaningful change in outcomes
Drivers of Outcome
Sorting out signal from noise

Multivariate analyses

• Analyzing the combined contribution of patient variables to specific outcomes
  – Determine expected benchmarks of care (to facilitate QI)
  – Facilitate informed decision making
    • Define “best care” for patient subpopulations

Figure 20: Nomogram calculating predicted 5m ODI score. For each predictor, read the points assigned on the 0-100 scale and add those points. Read the result on the “Total Points” scale and then read the corresponding predictions below it.
Facilitating **Meaningful** Comparisons Between Physicians and Patient Populations

Table 29: Site Variance – Return to Work

<table>
<thead>
<tr>
<th>Site</th>
<th>Rank</th>
<th>Observed</th>
<th>Expected</th>
<th>Obs-to-Exp Ratio</th>
<th>Rank of Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 9</td>
<td>1.0</td>
<td>0.889</td>
<td>0.782</td>
<td>1.14</td>
<td>2</td>
</tr>
<tr>
<td>Site 11</td>
<td>2.0</td>
<td>0.869</td>
<td>0.800</td>
<td>1.09</td>
<td>4</td>
</tr>
<tr>
<td>Site 14</td>
<td>3.0</td>
<td>0.842</td>
<td>0.651</td>
<td>1.29</td>
<td>1</td>
</tr>
<tr>
<td>Site 1</td>
<td>4.0</td>
<td>0.767</td>
<td>0.834</td>
<td>0.92</td>
<td>13</td>
</tr>
<tr>
<td>Site 15</td>
<td>5.0</td>
<td>0.765</td>
<td>0.827</td>
<td>0.92</td>
<td>12</td>
</tr>
<tr>
<td>Site 8</td>
<td>6.0</td>
<td>0.762</td>
<td>0.697</td>
<td>1.09</td>
<td>3</td>
</tr>
<tr>
<td>Site 4</td>
<td>7.5</td>
<td>0.769</td>
<td>0.832</td>
<td>0.91</td>
<td>14</td>
</tr>
<tr>
<td>Site 12</td>
<td>7.5</td>
<td>0.769</td>
<td>0.755</td>
<td>1.00</td>
<td>8</td>
</tr>
<tr>
<td>Site 6</td>
<td>9.0</td>
<td>0.759</td>
<td>0.726</td>
<td>1.03</td>
<td>1</td>
</tr>
<tr>
<td>Site 3</td>
<td>10.0</td>
<td>0.730</td>
<td>0.724</td>
<td>1.01</td>
<td>7</td>
</tr>
<tr>
<td>Site 7</td>
<td>11.0</td>
<td>0.714</td>
<td>0.697</td>
<td>1.02</td>
<td>6</td>
</tr>
<tr>
<td>Site 13</td>
<td>12.0</td>
<td>0.708</td>
<td>0.781</td>
<td>0.91</td>
<td>15</td>
</tr>
<tr>
<td>Site 10</td>
<td>13.0</td>
<td>0.696</td>
<td>0.716</td>
<td>0.97</td>
<td>9</td>
</tr>
<tr>
<td>Site 2</td>
<td>14.0</td>
<td>0.680</td>
<td>0.735</td>
<td>0.93</td>
<td>11</td>
</tr>
<tr>
<td>Site 5</td>
<td>15.0</td>
<td>0.562</td>
<td>0.593</td>
<td>0.95</td>
<td>10</td>
</tr>
</tbody>
</table>

Figure 10: Rank plot for 3m return to work rate.
Site-Specific, Risk-adjusted Benchmarks for Patient Reported Outcomes and Utilization
Web-based predictive model calculator

Baseline Variables

- Age (years)
  - 35

- BMI
  - 30

- Gender
  - Male
  - Female

- Ethnicity
  - Hispanic or Latino
  - Not Hispanic or Latino

- Race
  - White
  - Black
  - Other

- Level of Education
  - Less than High School
  - High School Diploma
  - Two-Year College Degree
  - Four-Year College Degree
  - Post-College

- Major Surgery in the Past Year
  - Yes
  - No

- Smoking Status
  - Current every day
  - Current some day
  - Former
  - Never

- Insurance Payer
  - Medicare
  - Private
  - Others

Diabetes
- No
- Yes, Type I
- Yes, Type II - Insulin dependent
- Yes, Type II - Non-insulin dependent

Coronary Artery Disease
- Yes
- No

Osteoporosis
- Yes
- No

Anxiety Disorder
- Yes
- No

Depression Disorder
- Yes
- No

Predominant Location of Symptom
- Back Pain
- Leg Pain
- Back Pain = Leg Pain

Did the Patient Have Any Motor Deficits
- Yes
- No

ASA Grade
- 1
- 2
- 3
- 4
- 5

Duration of Longest Standing Spine Symptoms (Months)
- Less Than 3 Months
- Greater Than 3 Months

Principal Spine Diagnosis
- Symptomatic Lumbar Disc Herniation
- Symptomatic Recurrent Lumbar Disc Herniation
- Lumbar Spondylolisthesis
- Lumbar Stenosis
- Lumbar Adjacent Segment Disease
- Symptomatic Mechanical Disc Collapse

Surgical Levels
- 1
- 2
- 3
- 4

Arthrodesis
- Yes
- No

Workers Comp
- Yes
- No

Surgical Approach
- Posterior Approach
- Anterior Alone

Workers Compensation Claim
- Yes
- No

Liability or Disability Insurance Claim
- Yes
- No

Was your Spinal Injury Caused by a Motor Vehicle Injury
- Yes
- No

Ambulation
- Independent
- With an assist device

Type of Occupation
- Sedentary
- Light
- Medium
- Heavy
- Disability
- Retired
- Others

Baseline ODI [0, 100]

Baseline EQ5D [-0.11, 1.00]

Baseline VAS-Back Pain [0, 10]

Baseline VAS-Leg Pain [0, 10]

Meaningful Improvement of ODI (optional)

PREDICT
A 35-year old white non-smoker male with BMI-30, lumbar disc herniation, higher education and sedentary job.

Baseline ODI 44; Patient is planned for a single-level discectomy.
- Patient’s baseline ODI: 44 (blue triangle)
- The estimated probability of this patient achieving ODI (15): 50%. (mean predicted outcome)
- SCB for ODI (25) : 78%
- MCID for ODI (31): 85%
- The probability of patient getting worse is 10 %
Estimating *Personalized Outcomes* to inform patient/physician decision making

**Complications/Re-admission**

<table>
<thead>
<tr>
<th>Patient 1</th>
<th>Patient 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1 Spondy</td>
<td>Grade 1 Spondy</td>
</tr>
<tr>
<td>Baseline ODI 30%</td>
<td>Baseline ODI 30%</td>
</tr>
<tr>
<td>2 level fusion</td>
<td>2 level fusion</td>
</tr>
<tr>
<td>40 year old Male</td>
<td>75 year old Male</td>
</tr>
<tr>
<td>BMI 25</td>
<td>BMI 50</td>
</tr>
<tr>
<td>Grad School</td>
<td>High school grad</td>
</tr>
<tr>
<td>1st Surgery</td>
<td>Revision Surgery</td>
</tr>
<tr>
<td>No co-morbidities</td>
<td>DM type I</td>
</tr>
<tr>
<td>ASA 1</td>
<td>ASA 3</td>
</tr>
</tbody>
</table>

**6% likelihood**

**48% likelihood**

**30-day Complication or Re-admit**
Prevent ineffective care before it occurs—or modify correctable factors with evidence-based decision support.
N²QOD Spine Projects

Summary

• Robust, reliable platform to define, measure and report clinical outcomes

• Risk Adjusted Modeling
  – Facilitate
    • Targeted quality improvement
    • Practice based learning
    • Shared decision making
    • Effective resource utilization

• Method to characterize “real” world care
  – Identify large scale improvement opportunities
  – Advance development of evidence
Related Activity 2014-16

- Other N²QOD Modules/New Development
  - Cervical Module
    - Activated March 2014 (26 centers)
    - > 7000 patients
  - Spinal deformity (with SRS/Spine Section)-fall 2015
  - Vascular (CV)-fall 2015
  - Tumor-2nd or 3rd quarter 2016
NPA Projects-Cooperative Registries

• **AANS-AAPMR Spine Care registry Project**
  – National comprehensive spine care project
  – Working group developing variables
  – Tentative start date: Fall 2016

• **Stereotactic Radiosurgery Registry with ASTRO**
  – National SRS outcomes registry
  – 30 centers; 3 year project
  – Start March 2015
  – Quintiles-data partner
  – Funding-BrainLab/Elekta
AAPM&R, AANS join forces to create Spine Patient Registry: 5 notes

The American Academy of Physical Medicine and Rehabilitation and the American Association of Neurological Surgeons are collaborating to establish a Spine Patient Registry, according to newswise.

Here are five notes:

1. The registry’s purpose will be to collect quality data for spine patients and track outcomes over time.

2. The registry will include surgical and nonsurgical spine patients.

3. The collected data will allow providers to evaluate the quality and value of specific treatments, from specific medicines to physical therapy to surgery.

4. The two organizations joined forces as they are "natural partners in caring for patients suffering spine disorders throughout the continuum of care," said H. Hunt Batjer, MD, AANS president.

Using the Evidence to Promote Quality
The IHI/NPA Re-admission project

• **Measuring Surgical Outcomes for Improvement: Was Codman Wrong?**
  – Donald M. Berwick, MD, MPP *JAMA*. 2015;313(5):469-470
  – “end-results information, although necessary for improvement, is not sufficient”

• Use major outcome drivers identified in N²QOD predictive models to improve care
  – First prospective project: designed to decrease re-admission rates following elective spine surgery in major centers
N²QOD: Advanced Applications of the Network

- Consolidation of reporting requirements
  - ABMS MOC
    - Registry approved for use in MOC Part IV
  - PQRS/VBM (CMS)
    - “QCDR”- 2015: specialty-specific, relevant data for use in value-based reimbursement programs
    - Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)
      - Merit Based Incentive Payment System (MIPS) and Alternative Payment Models (APM)
N²QOD QCDR/PQRS

• The National Neurosurgery Quality Outcomes Database (N²QOD) is an approved Qualified Clinical Data Registry (QCDR) for the PQRS 2015 reporting year.

• The N²QOD QCDR offers 21 unique measures that have been approved by CMS and from which an EP can choose to report for purposes of satisfying the PQRS.
  – First specialty-specific measures
  – Additional 9 spine care measures (non surgical) approved for 2016

• The N²QOD QCDR is open to all participating N²QOD registry physicians.

Introduction. Defining, measuring, and predicting quality in neurosurgery

Anthony L. Asher, Matthew J. McGirt, and Zoher Ghogawala

The use of patient care data to measurably improve the quality of care and more efficiently allocate health care resources is reshaping modern medical practice, and represents the future of health care. This issue of Neurosurgical Focus is dedicated to original scientific contributions focused on methods to define neurological quality from the perspective of multiple stakeholders, to accurately measure that quality, and to use accumulated data to predict and improve outcomes of care for individuals or patient populations.
Cooperative Science
Using Outcomes Data to Advance Medical Evidence

• Excellent clinical and economic effectiveness can be achieved in ambulatory surgery settings
• MIS may not have as many benefits as previously described
• Appropriately selected elderly patients may benefit from aggressive surgical interventions
• BMI does not seem to influence outcomes in lumbar decompression or fusion
• Excellent improvement in LBP can be achieved in decompression without fusion for lumbar stenosis
• Limited value to fusion versus revision discectomy for recurrent HNP
Inadequacy of 3-month Oswestry Disability Index outcome for assessing individual longer-term patient experience after lumbar spine surgery

Anthony L. Asher, MD,1 Silky Chotai, MD,2 Clinton J. Devin, MD,2 Theodore Speroff, PhD,4
Frank E. Harrell Jr., PhD,3 Hui Nian, PhD,3 Robert S. Dittus, MD, MPH,4,5
Praveen V. Mummaneni, MD,6 John J. Knightly, MD,7 Steven D. Glassman, MD,9
Mohamad Bydon, MD,9 Kristin R. Archer, PhD, DPT,10 Kevin T. Foley, MD,11 and
Matthew J. McGirt, MD1

• 3 month ODI outcomes reasonably predict 12 month outcomes at the population level
  – 3 month and 12 month *average* scores tend to agree (within 10 points)
  – 3 month scores reliably (85%) predict the direction of change
  – Achieving MCID or SCB at 3 months had a positive predictive value over 80% for maintaining the same status at 12 months

**Conclusion:** 3 month outcomes have potential value in a health policy context (e.g., predicting the likely effectiveness of various procedures)
Correlation between 3 and 12 month ODI
Individual Patients
Inadequacy of 3-month Oswestry Disability Index outcome for assessing individual longer-term patient experience after lumbar spine surgery

Anthony L. Asher, MD, Silky Chotai, MD, Clinton J. Devin, MD, Theodore Speroff, PhD, Frank E. Harrell Jr., PhD, Hui Nian, PhD, Robert S. Dittus, MD, MPH, Praveen V. Mummaneni, MD, John J. Knightly, MD, Steven D. Glassman, MD, Mohamad Bydon, MD, Kristin R. Archer, PhD, DPT, Kevin T. Foley, MD, and Matthew J. McGirt, MD

- 3 month ODI outcomes cannot reasonably predict 12 month outcomes at the individual patient level
  - ODI values for at least 20% of patients differed at least 20 points between 3 and 12 months
  - 25% of patients will experience significant changes in their disability status between 3 and 12 months (all diagnoses; all procedures)

Conclusion: 3 month ODI outcomes inadequately predict the direction and average magnitude of 12 month change for individual patients. They cannot be used to assess the experience of individual patients or performance of individual providers
Predictive Model for Return to Work after Elective Surgery for Lumbar Degenerative Disease

- 4,694 patients who underwent elective spine surgery for degenerative lumbar disease, who had been employed preoperatively, and who had completed a 3-month follow-up
  - Eighty-two percent of patients \((n = 3,855)\) returned to work within 3 months postoperatively.
  - The \(c\)-index of the model’s performance was 0.71 (“good” discrimination)
  - **Work-related factors contributed the most (33.3%) to predicting a patient’s chance of returning to work.**
    - In particular, preoperative work status was the most important predictor of RTW.
    - Other important predictors of RTW at 3 months were: manual labor job, need for fusion, education level, Workers’ compensation, liability insurance, race, symptom duration, gender, ASA score, baseline ODI score, history of diabetes, and baseline NRS-BP score.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Patient A</th>
<th>Patient B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>35</td>
<td>55</td>
</tr>
<tr>
<td>BMI</td>
<td>27</td>
<td>35</td>
</tr>
<tr>
<td>Gender</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Hispanic</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
<td>Black</td>
</tr>
<tr>
<td>Education</td>
<td>Less than high school</td>
<td>High school diploma</td>
</tr>
<tr>
<td>Prior Surgery</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Smoker</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Diabetes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>CAD</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Depression</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Dominant Symptom</td>
<td>LP dominant</td>
<td>BP dominant</td>
</tr>
<tr>
<td>Motor deficit</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>ASA score</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Symptom Duration</td>
<td>&gt; 3 months</td>
<td>&lt; 3 months</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>Stenosis</td>
<td>Spondylolisthesis</td>
</tr>
<tr>
<td>Number of Surgical Levels</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Interbody Graft</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Arthrodesis</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Approach</td>
<td>Posterior</td>
<td>Posterior</td>
</tr>
<tr>
<td>Insurance</td>
<td>Private</td>
<td>Medicare</td>
</tr>
<tr>
<td>Ambulation</td>
<td>Independent</td>
<td>With assistance</td>
</tr>
<tr>
<td>Occupation</td>
<td>Medium labor job</td>
<td>Heavy labor job</td>
</tr>
<tr>
<td>Employed and working</td>
<td>Employed but not working</td>
<td>Employed but not working</td>
</tr>
<tr>
<td>Compensation</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Liability</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Baseline ODI score</td>
<td>60</td>
<td>80</td>
</tr>
<tr>
<td>Baseline EQ-5D score</td>
<td>0.7</td>
<td>0.3</td>
</tr>
<tr>
<td>Baseline NRS-BP score</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Baseline NRS-LP score</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>Probability of RTW at 6 weeks</td>
<td>69.1% (56.4%–81.0%)</td>
<td>24.5% (17.6%–33.5%)</td>
</tr>
<tr>
<td>Probability of RTW at 3 months</td>
<td>99.8% (98.7%–99.9%)</td>
<td>77.0% (63.7%–88.1%)</td>
</tr>
</tbody>
</table>
Impact of Patients’ Functional Status on Satisfaction with Outcomes 12 months after Elective Spine Surgery for Lumbar Degenerative Disease

• Some groups have tried to use patient satisfaction as a surrogate for comprehensive care quality
  – Comprehensive assessment of quality of care is measured by patient-reported outcomes (PROs), the safety of the care delivered, and patients’ perception of overall care

• We correlated patient satisfaction (yes/no) with change in ODI
  – 5453 patients with 12 month f/u analyzed; 64% reported satisfaction
Relation Between Baseline ODI and 12-month PRO Parameters

Baseline ODI Functional Category

Percent

0~20 21~40 41~60 61~80 81~100

Expectations Met

MCID

SCB

Relation Between 12-month ODI and PR Parameters

Baseline ODI Functional Category

Percent

0~20 21~40 41~60 61~80 81~100

●

●

●

●

●

Expectations Met

MCID

SCB
Impact of ODI on satisfaction with outcome

NASS Satisfaction Index
Registries and the future of Medical Science

• “The expectation that every causal question in medicine be addressed with RCTs is unrealistic”

• “The original simplicity of RCTs has been lost…the unintended consequence has been to threaten the very existence of RCTs, given the operational complexities and ensuring costs”
  – “An ideal opportunity would be to embed randomization…into registries sponsored by societies.”
    • Antman E, Harrington et al., JAMA 2012;338:1743-4.
Site Specific Uses of Outcomes Data
Providing stakeholders with objective evidence of value
Length of Hospital Stay (Days)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Mean Number of Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar Non-Fusion</td>
<td>0.9</td>
</tr>
<tr>
<td>Lumbar Fusion</td>
<td>3.0</td>
</tr>
<tr>
<td>Anterior Cervical Diskectomy and Fusion</td>
<td>1.1</td>
</tr>
<tr>
<td>Cervical Laminectomy+Fusion</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Lumbar Surgery

Dotted line represents threshold for effectiveness of treatment reported in literature for each outcome measure.

30-Day Morbidity

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spine-Related Re-admission</td>
<td>2 (2.6%)</td>
</tr>
<tr>
<td>Non-Spine Related Re-admission</td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td>Surgical Site Infection</td>
<td>2 (2.6%)</td>
</tr>
<tr>
<td>DVT/PE</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Mortality</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

Cervical Surgery

Dotted line represents threshold for effectiveness of treatment reported in literature for each outcome measure.
Translate outcomes data to value

**ACDF Value**

<table>
<thead>
<tr>
<th></th>
<th>Inpatient Cohort n=59</th>
<th>Outpatient Cohort n=53</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Cost</td>
<td>$24,286 ± 6,442</td>
<td>$16,162 ± 2,592</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Indirect Cost</td>
<td>$5,980 ± 3,474</td>
<td>$4,674 ± 3,113</td>
<td>0.11</td>
</tr>
<tr>
<td>Total Cost</td>
<td>$27,123 ± 7,020</td>
<td>$20,043 ± 3,340</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**ACDF in ambulatory surgery center**

$11k savings/case with equivalent benefit (outcomes)
US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures

Each year US physician practices in four common specialties spend, on average, 785 hours per physician and more than $15.4 billion dealing with the reporting of quality measures. While much is to be gained from quality measurement, the current system is unnecessarily costly, and greater effort is needed to standardize measures and make them easier to report.
N²QOD: Challenges/Opportunities:
Blend data collection activities into workflow

• Achieve “lowest energy state” for data collection
  • Facilitated data acquisition at point of service
    • Standardized data presentation (op notes)
  • EMR integration
    – Pilot programs with Epic, Cerner, NextGen, RedCap
    – Automated data exports
• Automated methods for longitudinal data collection
  – Patient portals
N²QOD: Challenges/Opportunities:
Increase data value

• Combine outcomes data with economic data (cost/utilization)
  • Partnership with payers, hospital systems

• Individual provider level data

• Advanced (i.e., third party) audits and data quality “tiers”

• Non-surgical care data
  • Cross-specialty partnerships
Initial QOD Experience
Advancing Quality on a Broad Front 2012-2016

• Reduced regulatory barriers to collecting quality data
• Developed relevant measures of neurosurgical quality
• Built a novel, national data system
  – Disseminated quality tools and techniques nationally
  – Developed credibility among important stakeholders
• Identified important national QI opportunities
• Advanced cooperative, cross-specialty quality projects
• Used registry and registry data for
  – Advanced QI projects
  – MOC/Public reporting
  – Payer negotiations/Value-based contracting
  – Research
  – Evidence-based decision support
Projects: N²QOD

The National Neurosurgery Quality and Outcomes Database (N²QOD)

The National Neurosurgery Quality and Outcomes Database (N²QOD) serves as a continuous national clinical registry for neurosurgical procedures and practice patterns. Its primary purpose is to track quality of surgical care for the most common neurosurgical procedures, as well as provide practice groups and hospitals with an immediate infrastructure for analyzing and reporting the quality of their neurosurgical care.

The primary goals of the N²QOD are to:

1. Establish risk-adjusted national benchmarks for both the cost and quality of common neurosurgical procedures.
2. Allow practice groups and hospitals to analyze their individual morbidity and clinical outcomes in real-time.
3. Generate both quality and efficiency of neurosurgical procedures.
4. Demonstrate the comparative effectiveness of neurosurgical procedures.
5. Facilitate essential multi-center trials and other cooperative clinical studies.

http://www.neuropoint.org/
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