The Science of Clinical Practice: Using Registries and Other Tools to Improve the Quality of Neurosurgical Care

AANS Annual Meeting
Practical Clinic
April 27, 2013
Ted Speroff, PhD
Vanderbilt University
Outline

- Changing Landscape
  - Value-Based Purchasing (CMS)
  - Patient-Centered Outcomes Research (PCORI)

- Registries
  - What is a Registry? What is a Quality Registry?
  - National Neurosurgery Quality and Outcomes Database (N²QOD)
  - Science of a Quality Registry
  - Successful Example of a Quality Registry

- Translation of Evidence into Decision Aids
- Science of Quality Improvement
Changing Landscape:
For the times they are a-changn’

Bob Dylan

Volume-Based Purchasing
- Fee for Service FFS
- Pass through of costs
- No transparency

CMS Alignment
- Public Sector
- Private Sector
- Professionals
- Frontline

Value-Based Purchasing
- Outcomes
- Accountability
- Triple Aim
  - Better Health Care
  - Better Health
  - Lower Costs
- Transparency

New Payment and Service Models:
Bundled Payments, Innovation Initiatives, Dynamic Learning Networks
Leadership, Focus on the Patient
Changing Landscape: Patient-Centered Outcomes Research (PCOR)

❖ Help people make informed healthcare decisions by providing information important to patients.

❖ Measuring outcomes that are noticeable and meaningful to them.
  ➢ Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?

❖ Producing results that help them weigh the value of healthcare options given their personal circumstances, conditions and preferences.
  ➢ What are my options and what are the potential benefits and harms of those options?
Research Priorities for PCORI

- Evidence on patient burden
- Gaps in evidence in clinical outcomes, practice variation, health disparities
- Potential to improve health, well-being, and quality of care
- Patient needs, outcomes, and preferences
- Relevance to making informed health decisions
- Effect on national expenditures
A Quality Registry is a Methodology aligning with the Triple Aim Initiative and PCORI
Registry Science: What is a registry?

Patient registry: an organized, structured system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, exposure, or procedure and that serves one or more predetermined scientific, clinical or policy purposes.

✓ Population focused
What is a Quality Registry?

- Quality improvement registries (QI registries) use systematic data collection and other tools to improve quality of care.

- Key features of a QI registry:
  - At least one purpose is quality improvement
  - An exposure of interest to health care providers & health care systems
  - QI tools are used in conjunction with data collection to improve quality
Registry Characteristics

✓ Based on medical care as it is actually delivered in real world situations in a naturalistic manner.
✓ Typically do not include control populations.
✓ Include multiple points of follow-up to obtain important long-term outcomes.
✓ Use standardized questionnaires.
✓ Include factors that predict who is more likely to experience the benefits and harms of different treatments.
✓ Issues of completeness of data collection and data quality.
✓ Confounding is a concern, registries must contain data elements that will allow for statistical controls for confounding.
Selecting Measures for a QI Registry

- Measure selection requires balancing the goals of the registry with the desire to meet other needs for providers (e.g., reporting to payers, accreditation)

- Parameters for selecting measures:
  - Measures are clinically relevant
  - Measures examine an area for which improvement is needed
  - Data for the measure can be captured without requiring significant changes to the care process
  - Actionable information that can be used to modify behaviors, processes, or systems of care must be readily available – this usually comes from process of care or quality measures

- QI registries must be able to adapt to continual sources of change
Reporting to Providers and the Public

- Reporting information to providers, and, in some cases, the public, is an important component of QI registries

- Many options for reporting exist:
  - Public reporting, confidential provider feedback, professional collaborations, state regulatory oversight

- Benefits must be weighed against potential negative consequences
  - Most common negative consequence is risk aversion, i.e., provider reluctance to accept high-risk patients
The primary goals of the N²QOD are to:

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

- Patient-Centered Outcomes at Baseline, 3 months, & 12 months
  - Pain (analogue scale)
  - Oswestry Disability Index (ODI), NDI, mJOA
  - EuroQol (EQ-5)

- Data Driven Practice-Based Learning
  - Biostatistics: risk-adjusted modeling reports
  - Shared decision making (Patients like me)
  - Quality Improvement
  - Comparative Effectiveness

- Policy Reports for Market-Driven Value-Based Care
  - Payors, Agencies, Markets
### Purpose Checklist of Standards

<table>
<thead>
<tr>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>N/A DNK</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Describe the specific health decision the study/registry is intended to inform.</td>
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<td>Describe and identify the specific population for whom the health decision is pertinent.</td>
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<td>Describe how study results will inform the health decision.</td>
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<td>Formulate the questions that pertain to the registry</td>
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<td>Specify at least one purpose of the registry</td>
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<tr>
<td><strong>State the objectives</strong></td>
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</table>
### Elements of Scientific Rigor: Standards of Good Practice

<table>
<thead>
<tr>
<th>Design Checklist of Standards</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>DNK</th>
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<tbody>
<tr>
<td>Develop a formal study protocol (purpose of the registry, data sources, measure of effect, standard dictionary, follow-up time)</td>
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<td>Select appropriate interventions and consider concurrent comparators.</td>
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<tr>
<td><strong>Define and confirm inclusion and exclusion criteria. Identify and assess participant subgroups.</strong></td>
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<td>Identify, select, recruit, enroll, and retain to ensure representativeness and address selection bias.</td>
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<td>Identify risk factors, covariates.</td>
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<td><strong>Measure outcomes that people in the population of interest notice and care about (clinically meaningful, patient centered, relevant).</strong></td>
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## Elements of Scientific Rigor: Standards of Good Practice

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<th>Governance Checklist of Standards</th>
<th>Yes</th>
<th>No</th>
<th>N/A DNK</th>
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<tbody>
<tr>
<td>Adherence to agreed-on enrollment practices</td>
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<td><strong>Unbiased and systematic data collection from all participants</strong></td>
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<td>Racial and minority groups, rural areas, low literacy, poor health care access, multiple disease conditions</td>
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<td>Advisory Board.</td>
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<td>Ethics and privacy.</td>
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<tr>
<td>Data safety and security.</td>
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</table>
Elements of Scientific Rigor: Standards of Good Practice

<table>
<thead>
<tr>
<th>Collaborative Network Checklist of Standards</th>
<th>Yes</th>
<th>No</th>
<th>N/A DNK</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>Maintaining collaborative data network across organizations and locations</td>
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<td><strong>Standard training and instructions.</strong></td>
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<tr>
<td><strong>Standardized terminology, controlled vocabulary. Collect data consistently (consistent standard instructions, clear definitions, standardized data).</strong></td>
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<tr>
<td>Data harmonization, equivalent data elements from different sources. Common data model and data dictionary.</td>
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<td>Feasibility assessment and fine-tuning.</td>
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<td>Linkage with external databases as appropriate.</td>
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## Elements of Scientific Rigor: Standards of Good Practice

<table>
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<th>Patient Reported Outcomes Checklist of Standards</th>
<th>Yes</th>
<th>No</th>
<th>N/A DNK</th>
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<tbody>
<tr>
<td><strong>Is the measure meaningful to patients?</strong></td>
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<td>How does the measure relate to health decisions? Rationale for the measure.</td>
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<td>How was the measure developed? Were patients involved in development?</td>
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<tr>
<td><strong>Measurement Properties:</strong> content validity, construct validity, reliability, responsiveness to change over time, score interpretability, meaningfulness of score changes.</td>
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<tr>
<td>Type of evidence supporting the measure.</td>
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<tr>
<td>Collect all items and components of composite scores.</td>
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<tr>
<td>Missing Data Checklist of Standards</td>
<td>Yes</td>
<td>No</td>
<td>N/A DNK</td>
<td>Comment</td>
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<tr>
<td>Protocol methods to prevent and monitor missing data: dropout, failure to provide data, data management issues.</td>
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<tr>
<td>Record all reasons for dropout and missing data. Describe expected loss to follow-up and potential effect on the results.</td>
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<tr>
<td>Completeness of information.</td>
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<tr>
<td>Monitor and take actions to keep loss to follow-up to an acceptable minimum (retention, reason for withdrawal).</td>
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<td>Strategies for interpreting missing data, sensitivity of inferences to missing data and interpretation.</td>
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</table>
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<table>
<thead>
<tr>
<th>Data Integrity and Validation Standard</th>
<th>Yes</th>
<th>No</th>
<th>N/A DNK</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Take appropriate steps to ensure data quality (structured training tools, data quality checks, data review and verification, plan for quality assurance).</td>
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<td>Document and explain any modifications to the protocol. Maintain an audit trail.</td>
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<tr>
<td>Enroll and follow patients systematically (describe how patients and providers were recruited into the study to understand selection bias).</td>
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<tr>
<td>Program data entry range and consistency checks.</td>
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<td>Compare data entry with patient records. Evaluate source of errors.</td>
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<td>Reproducibility of coding and data.</td>
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# Elements of Scientific Rigor: Standards of Good Practice

<table>
<thead>
<tr>
<th>Analysis Standard</th>
<th>Yes</th>
<th>No</th>
<th>N/A DNK</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Plan the data analysis to meet the objectives.</td>
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<tr>
<td><strong>Use appropriate statistical techniques to address confounding</strong> (identify confounders, evaluate impact of unmeasured confounders, assumptions made, strengths and limitations)</td>
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<tr>
<td>Multiple imputation method, validated method to deal with missing data</td>
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<tr>
<td>Evaluate selection bias. Compare registry with target population.</td>
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<tr>
<td>Describe data elements used in statistical models.</td>
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<td>Sensitivity analysis on models.</td>
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<td>Consistency of results with literature.</td>
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<tr>
<td>Review publications and presentations. Plan for generation of reports.</td>
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</table>
Understanding the Risk of Problems

**What is the risk of stomach bleeding with NSAID pills?**

All NSAID pills, including aspirin, block enzymes that protect the stomach. This can cause stomach bleeding. It is not possible to predict any one person’s risk. Research can’t tell how long you can use NSAID pills without bleeding. In general, stomach bleeding is more likely for people taking NSAIDs who:

- Are older, especially more than 75 years old.
- Take higher doses.
- Use NSAIDs for a longer time.
- Also take medicine to help prevent blood clots, like aspirin or warfarin (Coumadin®).

**Older people taking NSAID pills have higher risk of stomach bleeding**

- **For people age 16-44:**
  - 5 out of 10,000 people taking NSAIDs will have a serious bleed
  - 1 out of 10,000 people taking NSAIDs will die from a bleed

- **For people age 45-64:**
  - 15 out of 10,000 people taking NSAIDs will have a serious bleed
  - 2 out of 10,000 people taking NSAIDs will die from a bleed

- **For people age 65-74:**
  - 17 out of 10,000 people taking NSAIDs will have a serious bleed
  - 3 out of 10,000 people taking NSAIDs will die from a bleed

- **For people age 75 or older:**
  - 91 out of 10,000 people taking NSAIDs will have a serious bleed
  - 15 out of 10,000 people taking NSAIDs will die from a bleed
## Science of Decision Support: Decision Aide Checklist Standards

<table>
<thead>
<tr>
<th>IPDAS CHECKLIST CRITERIA</th>
<th>YES</th>
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<tbody>
<tr>
<td>CONTENT</td>
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<tr>
<td>Does the patient decision aid provide information about the options in sufficient detail for decisionmaking?</td>
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<tr>
<td>01  The decision aid describes the condition (health or other) related to the decision.</td>
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<tr>
<td>02  The decision aid describes the decision that needs to be considered (the index decision).</td>
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<td>03  The decision aid lists the options (health care or other).</td>
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<td>04  The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.</td>
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<td>05  The decision aid has information about the procedures involved (e.g., what is done before, during, and after the health care option).</td>
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</table>
Surgery Registries: Examples

- American College of Surgeons National Surgical Quality Improvement Program (NSQIP)
- Society Thoracic Surgeons (STS)
- Northern New England Cardiovascular Disease Study Group
  - Six Medical Centers: Maine, New Hampshire, Vermont, Massachusetts.
  - All Cardiothoracic Surgeons & Interventional Cardiologists
  - Observed Mortality Rate by Surgeon for All CABG over a 22 Month Period
Observed Mortality Rate by Surgeon for All CABG (22 month period)

O’Connor et al JAMA 266:803, 1991
New England Cardiovascular Disease Study Group

- Collect information on management of cardiovascular disease
  - Coronary artery bypass surgery (CABG), heart valve surgery, coronary angioplasty, myocardial revascularization
- Continuous data registry on every case
- Training in quality improvement
  - Learn from daily practice, use data for improvement
  - Meet > 3 times per year for QI in patient care
  - Peer site visits by surgeons/cardiologists to explore variations, form hypotheses, effect changes in the process of care, and evaluate comparative knowledge on the processes of care associated with outcomes, clinicians learn from each other about the Delivery of Health Care
- Benchmarking for learning
- Causes and correlates of postoperative mortality
Make Changes

- Standardized post-op management
- Implemented an extubation protocol
- Changed perfusion technique
- Decreased number of pre-op coag tests
- Changed type of prophylactic antibiotic
- Changed myocardial preservation techniques
- Standardized post-op care and transfers
- Critical pathways in care units
- Same day admission program
- Multidisciplinary work groups to reexamine clinical processes
- Redesigned existing operating rooms
- Relocated bypass pump in OR
- Dedicated operating room staff for cardiac surgery program
- Surgeon as a permanent first assistant
- One perfusionist rather than two
- Cross training of support staff
- Enhanced internal review of all deaths
- Assessment of surgeon resource utilization
Expected and Observed Mortality for All Patients Undergoing CABG

O'Connor et al JAMA 275:841, 1996
NECSG Publications

NECSG Publications

• Obesity and risk of adverse outcomes associated with CABG. Circulation 1998; 97(17).
• Geographic variation in the treatment of acute myocardial infarction. JAMA 1999; (281(7).
• Predicting the risk of death from heart failure after CABG surgery. Anesth Analg 2001; 92(3).
• In-hospital outcomes of off-pump versus on-pump CABG procedures. Ann Thorac Surgery 2001; 72(5).
NECSG Publications

• The association between heart rate and in-hospital mortality after CABG surgery. Anest Analg 2002; 95(6).
• Lowest core body temperature and adverse outcomes associated with CABG surgery. Perfusion 2003; 18(2).
• Development and validation of a prediction model for strokes after CABG. Ann Thorac Surg 2003; 76(2).
NECG Publications

• Multivariable prediction of renal insufficiency developing after cardiac surgery. Circulation 2007; 116(11).
• Does tight glucose control prevent myocardial injury and inflammation? J Extra Corpor Technol 2011; 43(3).
• How do centres begin the process to prevent contrast-induced acute kidney injury: a report from a new regional collaborative. BMJ Qual Saf 2012; 21(1).
Model for Quality Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?

PLAN

DO

STUDY

ACT

Langley et al., The Improvement Guide, 1996
The PDSA Cycle

**Act**
- What will we do with the results?
- What changes are to be made?
- Next cycle?

**Plan**
- Objectives
- Questions and predictions (why)
- Plan to carry out the cycle (who, what, where, when)

**Study**
- Complete the analysis of the data
- Compare data to predictions
- Summarize what was learned

**Do**
- Carry out the plan
- Document problems and unexpected observations
- Data Collection
## Pragmatic Science

<table>
<thead>
<tr>
<th>QI PDSA</th>
<th>Scientific Method</th>
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<tbody>
<tr>
<td>• Plan</td>
<td>• Framework &amp; Generate Hypothesis</td>
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<tr>
<td>• Do</td>
<td>• Design and Implement a Study</td>
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<tr>
<td>• Study</td>
<td>• Analyze and Interpret Results</td>
</tr>
<tr>
<td>• Act</td>
<td>• Contribution and Implications for Future Research &amp; Next Steps</td>
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PDSA Value Compass
Measurement of Health Outcome

Clinical Outcomes
- Mortality
- Comorbidity
- Complications
- Clinical Risk Factors

Costs
- Resource Utilization
- Direct Medical Costs
- Indirect Social Costs
- Market Share & Volume

Functional Health Status
- General and Disease-specific
  - Physical function
  - Mental function
  - Pain/Symptom Relief
  - Instrumental Life Activities
  - Quality of life
  - Well Being

Satisfaction
- Recommendation
  - Patient
  - Staff
  - Referring Physician
- Access, Retention & Loyalty
- Mutual Respect & Trust
- Role in Decision Making
- Informed and Activated
- Got what I want and need when I wanted it and needed it
National Quality Forum
Quality Measurement - Value Compass

**Health care Delivery**
- Clinical Outcomes & Cost
  - Performance in the provision of care
  - Evidence based criterion specified as a clinical performance measure

**Health Measure**
- Health Status & Satisfaction
  - Symptoms
  - Function
  - Quality of life
Data Registry:
Uses of Quality Measurement

- Quality/Performance Improvement
  - Change in health
  - Comparative effectiveness
  - Benchmarking

- Accountability
  - Consumer Decision Making
  - Performance-based payment
  - Professional Certification

- Research
Attributes of a Quality Measure

- **Importance:**
  - relevance, health importance, applicability to diversity and equipoise, potential for improvement, sensitive to change

- **Clinical Logic:**
  - Supporting Evidence, strength of evidence

- **Scientific Soundness:**
  - reliability, validity, comprehensible, interpretable, meaningful differences

- **Feasibility:**
  - response burden, literacy, data availability
Repeated Use of the PDSA Cycle

Hunches
Theories
Ideas

Changes That Result in Improvement
QI is a Science: Statistical Approach
Overall Improvement Strategy

Outcome

- Unstable process
  - Special causes present
  - Average is too high
- Stable process
  - Common cause variation is high
  - Average is too high
- Stable process
  - Common cause variation reduced
  - Average too high
- Stable process
  - Common cause variation low
  - Average reduced

Remove special causes
Process change
Process change
QI is a Science Defined Methodology

- Focus on systems (Systems theory)
- Develop ideas for change and test them (Scientific method)
- Use a balanced set of measures (Value compass)
- Understand the variation of data measured continuously over time (SPC)
- Systematic, Data-Driven Improvement (Sources of Variation, Diffusion of Innovation)
Neurosurgeons & the N²QOD Quality Registry

- Every system is designed to get the results it gets. If we continue to use the same system and process, we will continue to repeat the results we get.
- Neurosurgeons have unique clinical reasoning and knowledge of processes pertinent to improving clinical care.
- This Quality Registry approach will save lives, improve functional health status, and increase the efficiency of clinical care.