

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

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Practical Clinic

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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

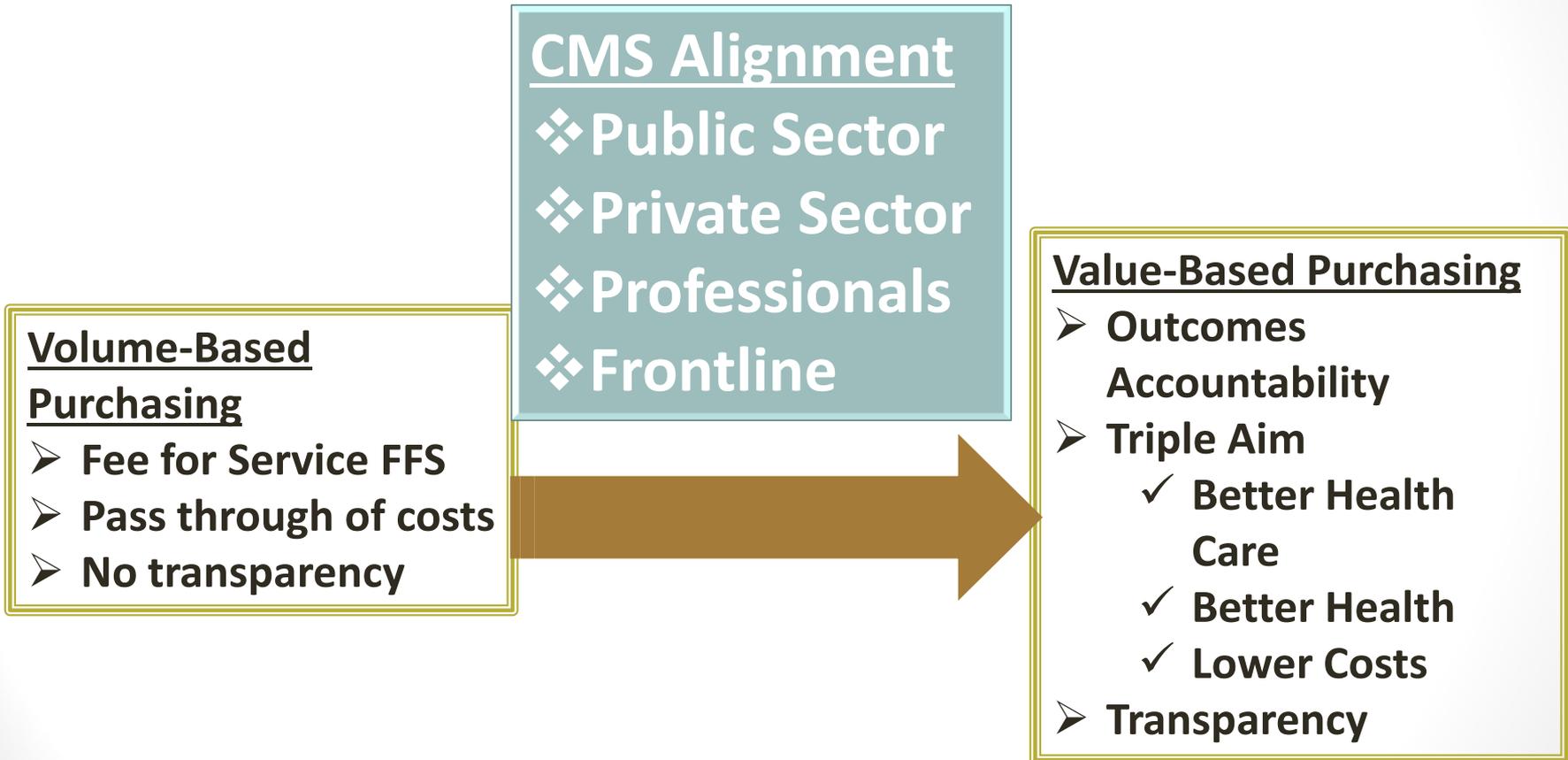
❖ Translation of Evidence into Decision Aids

❖ Science of Quality Improvement

Changing Landscape:

For the times they are a-changn'

Bob Dylan



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.
 - What works best? For Whom? Under what circumstances?
- ❖ 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

N²QOD 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

Elements of Scientific Rigor: Standards of Good Practice

Purpose Checklist of Standards	Yes	No	N/A DNK	Comment
Describe the specific health decision the study/registry is intended to inform.				
Describe and identify the specific population for whom the health decision is pertinent.				
Describe how study results will inform the health decision.				
Formulate the questions that pertain to the registry				
Specify at least one purpose of the registry				
State the objectives				

Elements of Scientific Rigor: Standards of Good Practice

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

Elements of Scientific Rigor: Standards of Good Practice

Governance Checklist of Standards	Yes	No	N/A DNK	Comment
Adherence to agreed-on enrollment practices				
Unbiased and systematic data collection from all participants				
Racial and minority groups, rural areas, low literacy, poor health care access, multiple disease conditions				
Advisory Board.				
Ethics and privacy.				
Data safety and security.				

Elements of Scientific Rigor: Standards of Good Practice

Collaborative Network Checklist of Standards	Yes	No	N/A DNK	Comment
Maintaining collaborative data network across organizations and locations				
Standard training and instructions.				
Standardized terminology, controlled vocabulary. Collect data consistently (consistent standard instructions, clear definitions, standardized data).				
Data harmonization, equivalent data elements from different sources. Common data model and data dictionary.				
Feasibility assessment and fine-tuning.				
Linkage with external databases as appropriate.				

Elements of Scientific Rigor: Standards of Good Practice

Patient Reported Outcomes Checklist of Standards	Yes	No	N/A DNK	Comment
Is the measure meaningful to patients?				
How does the measure relate to health decisions? Rationale for the measure.				
How was the measure developed? Were patients involved in development?				
Measurement Properties: content validity, construct validity, reliability, responsiveness to change over time, score interpretability, meaningfulness of score changes.				
Type of evidence supporting the measure.				
Collect all items and components of composite scores.				

Elements of Scientific Rigor: Standards of Good Practice Standards

Missing Data Checklist of Standards	Yes	No	N/A DNK	Comment
Protocol methods to prevent and monitor missing data: dropout, failure to provide data, data management issues.				
Record all reasons for dropout and missing data. Describe expected loss to follow-up and potential effect on the results.				
Completeness of information.				
Monitor and take actions to keep loss to follow-up to an acceptable minimum (retention, reason for withdrawal).				
Strategies for interpreting missing data, sensitivity of inferences to missing data and interpretation.				

Elements of Scientific Rigor: Standards of Good Practice

Data Integrity and Validation Standard	Yes	No	N/A DNK	Comments
Take appropriate steps to ensure data quality (structured training tools, data quality checks, data review and verification, plan for quality assurance).				
Document and explain any modifications to the protocol. Maintain an audit trail.				
Enroll and follow patients systematically (describe how patients and providers were recruited into the study to understand selection bias).				
Program data entry range and consistency checks.				
Compare data entry with patient records. Evaluate source of errors.				
Reproducibility of coding and data.				

Elements of Scientific Rigor: Standards of Good Practice

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

Decision Support



Choosing Pain Medicine for Osteoarthritis



*A Guide for
Consumers*

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

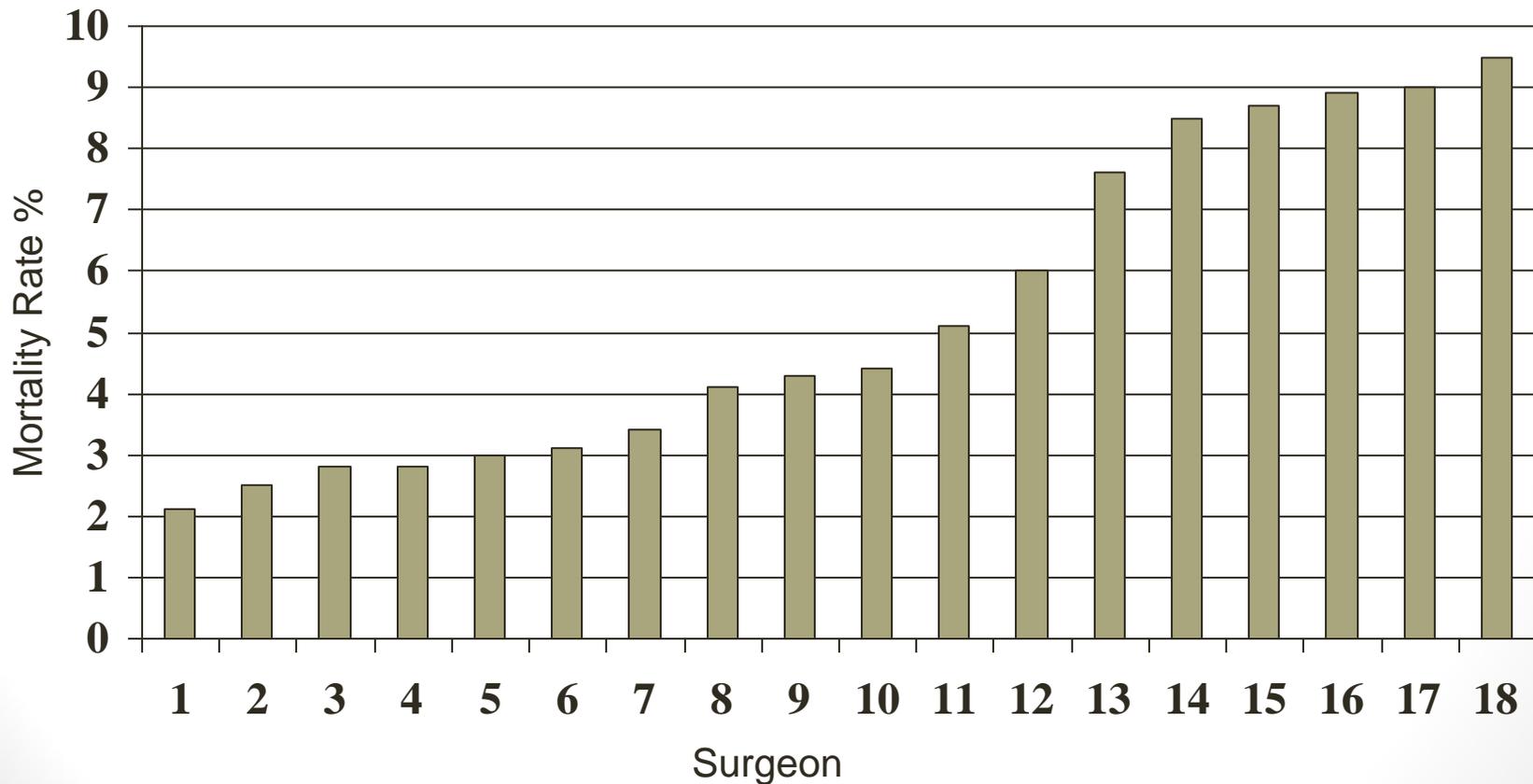
Science of Decision Support: Decision Aide Checklist Standards

IPDAS CHECKLIST CRITERIA		YES	NO	N/A	COMMENTS
CONTENT					
Does the patient decision aid provide information about the options in sufficient detail for decisionmaking?					
01	The decision aid describes the condition (health or other) related to the decision.	●			
02	The decision aid describes the decision that needs to be considered (the index decision).	●			
03	The decision aid lists the options (health care or other).	●			
04	The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.	●			
05	The decision aid has information about the procedures involved (e.g., what is done before, during, and after the health care option).	●			

Surgery Registries: Examples

- ❖ **American College of Surgeons National Surgical Quality Improvement Program (NSQIP)**
- ❖ **Society Thoracic Surgeons (STS)**
- ❖ **Northern New England Cardiovascular Disease Study Group**
 - ✓ Gerald O'Connor, Steve Plume, Jack Wennberg. Started 1987.
 - ✓ 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)



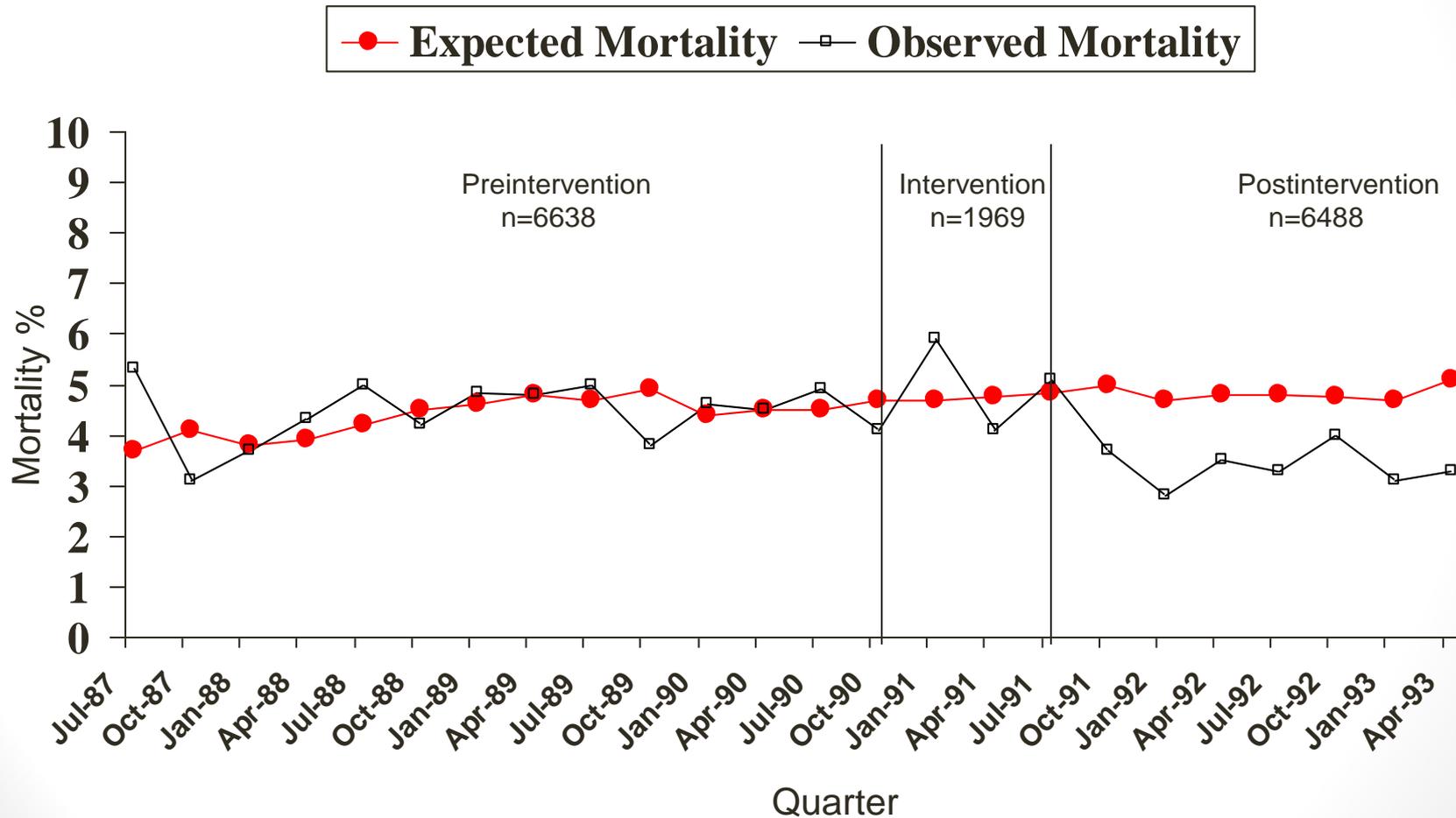
New England Cardiovascular Disease Study Group

- ❖ 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



NECSG Publications

- **A regional prospective study of in-hospital mortality associated with coronary artery bypass grafting.** JAMA 1991; 266(6).
- **Multivariate prediction** of in-hospital mortality associated with CABG surgery. Circulation 1992; 85(6).
- **Regional organization for outcomes research.** Ann NY Acad Sci 1993; 31.
- Differences between men and women in hospital mortality associated with CABG surgery. Circulation 1993; 8(5).
- **Identification of preoperative variables** needed for risk adjustment of short-term mortality after CABG surgery. J Am Coll Cardiology 1996; 28(6).
- The New England Cardiovascular Disease Study Group: a regional **collaborative effort for continuous quality improvement** in cardiovascular diseases. Jt Comm J Qual Improve 1998; 24(10).

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)).
- Risks of morbidity and mortality in dialysis patients undergoing CABG surgery. *Circulation* 2000; 102(24).
- Decreasing mortality for aortic and mitral valve surgery in Northern New England. *Ann Thorac Surg* 2000; 70(2).
- Physician leadership in cardiac outcomes reporting. *Ann Thorac Surg* 2000; 70(3).
- Effect of preoperative aspirin use on mortality in CABG patients. *Ann Thorac Surg* 2000; 70(6).
- Predicting the risk of death from heart failure after CABG surgery. *Anesth Analg* 2001; 92(3).
- Survival of patients with diabetes and multivessel coronary artery disease after surgical or percutaneous coronary revascularization: results of a large regional prospective study. *J Am Coll Cardiol* 2001;37(4).
- In-hospital outcomes of off-pump versus on-pump CABG procedures. *Ann Thorac Surgery* 2001; 72(5).

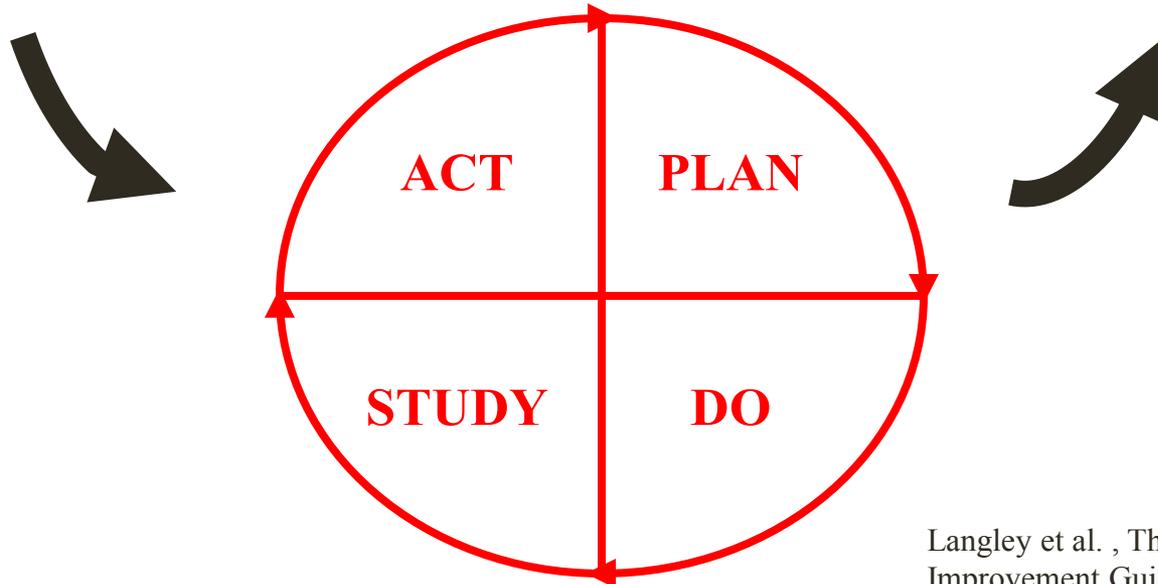
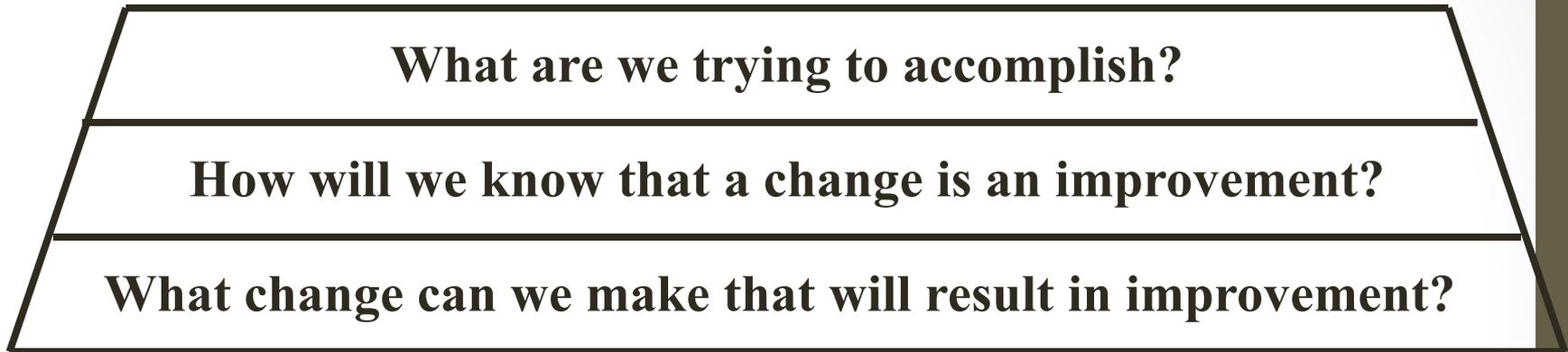
NECSG Publications

- The effect of comorbid illness on mortality outcomes in cardiac surgery. *Ann Surg* 2002; 137(4).
- 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).
- A multicenter comparison of intraaortic balloon pump utilization in isolated CABG surgery. *Ann Thorac Surg* 2003; 76(6).
- Multivariable prediction on in-hospital mortality associated with aortic and mitral valve surgery in Northern New England. *Ann Thorac Surgery* 2004; 77(6).
- Effect of diabetes and associated conditions on long-term survival after CABG surgery. *Circulation* 2004; 110(11).
- Intraoperative and postoperative variables associated with strokes following cardiac surgery. *Heart Surg Forum* 2004; 7(4).

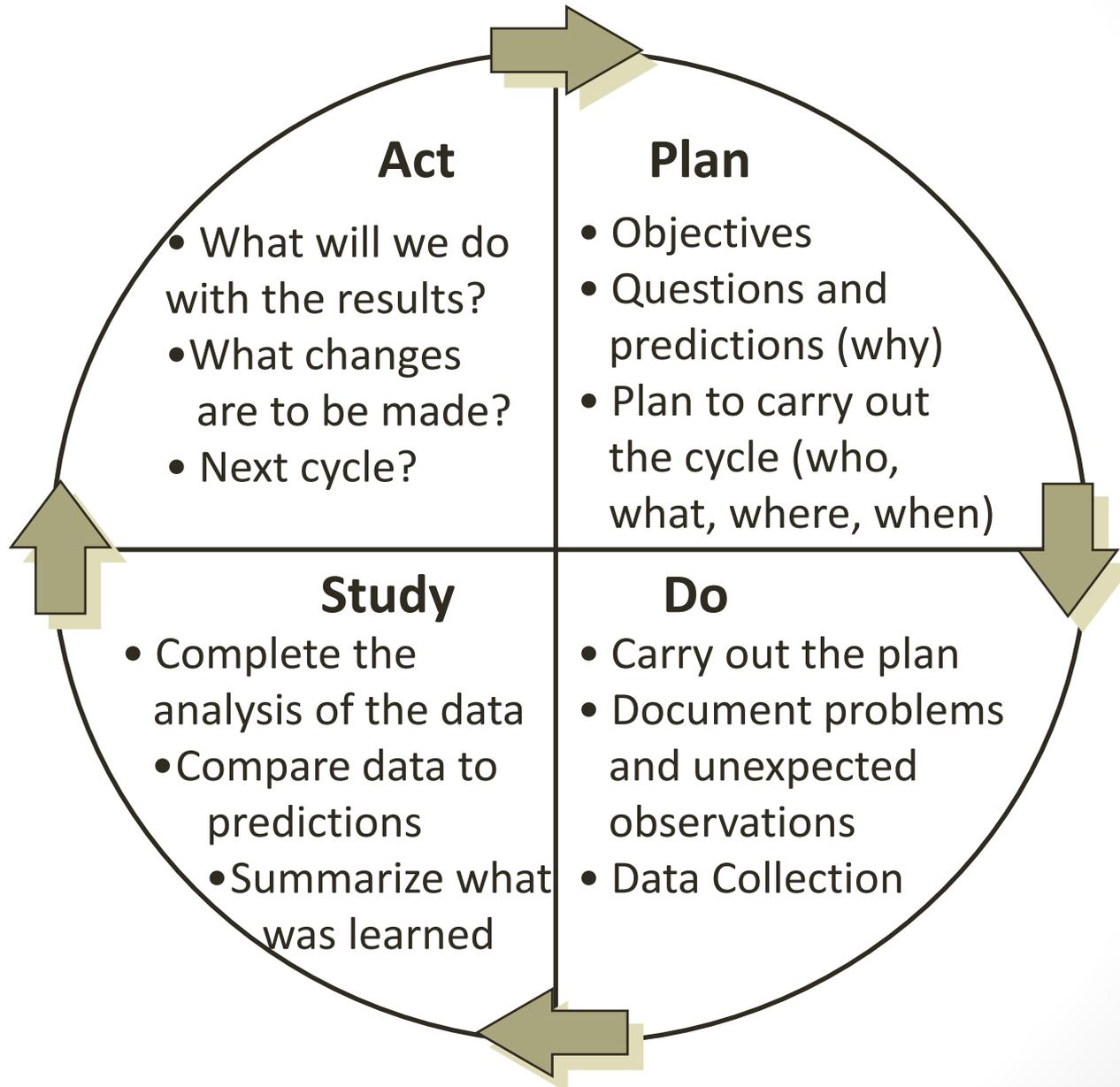
NECG Publications

- Perioperative stroke and long-term survival after CABG surgery. *Ann Thorac Surg* 2005; 79(2).
- The identification and development of Canadian CABG surgery quality indicators. *J Thorac Cardiovasc Surg* 2005; 130(5).
- Comparison of three measurements of cardiac surgery mortality for the Northern New England Cardiovascular Disease Study Group. *Ann Thorac Surg* 2006; 81(4).
- Multivariable prediction of renal insufficiency developing after cardiac surgery. *Circulation* 2007; 116(11).
- Long-term survival of the very elderly undergoing CABG. *Ann Thorac Surg* 2008; 85(4).
- Cardiopulmonary bypass recommendations in adults: the northern New England experience. *J Extra Corpor Technol* 2008; 40(1).
- Appropriateness of CABG surgery performed in northern New England. *J Am Coll Cardiol* 2008; 51(24).
- Using biomarkers to improve the preoperative prediction of death in CABG patients. *J Extra Corpor Technol* 2010; 42(4).
- 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



The PDSA Cycle



Pragmatic Science

QI PDSA

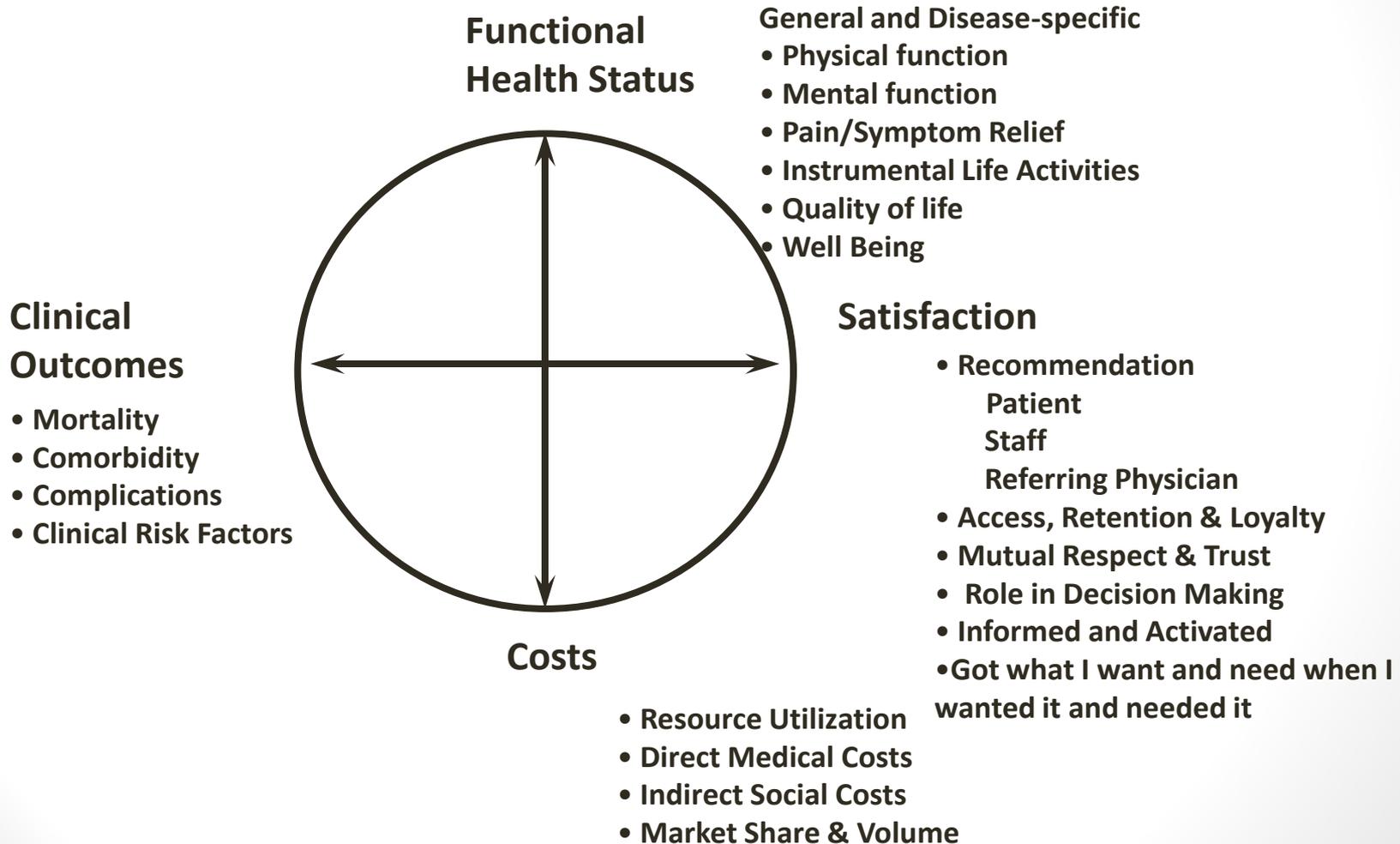
- Plan
- Do
- Study
- Act

Scientific Method

- Framework & Generate Hypothesis
- Design and Implement a Study
- Analyze and Interpret Results
- Contribution and Implications for Future Research & Next Steps

PDSA Value Compass

Measurement of Health Outcome



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

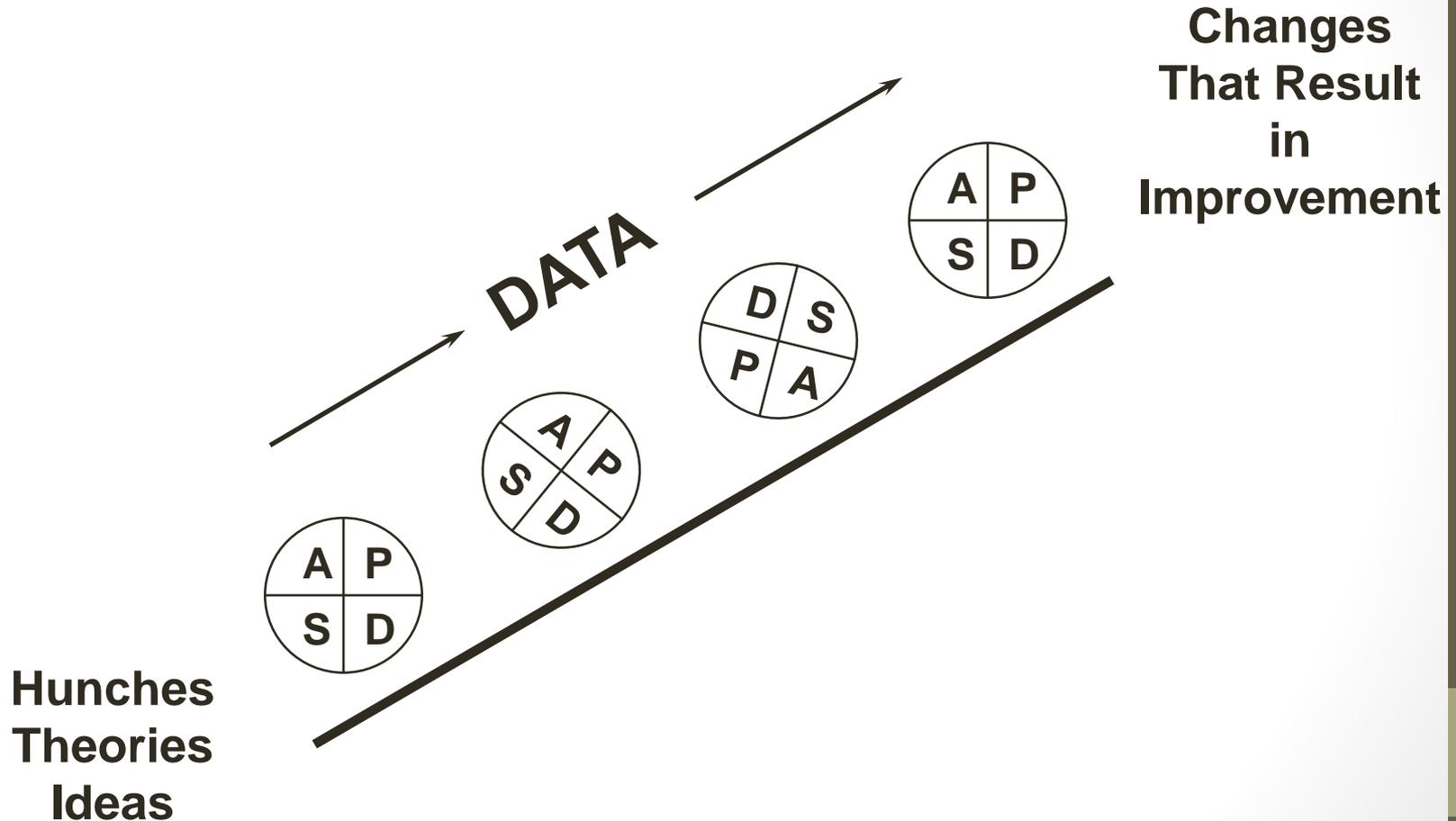
❖ Scientific Soundness:

- reliability, validity, comprehensible, interpretable, meaningful differences

❖ Feasibility:

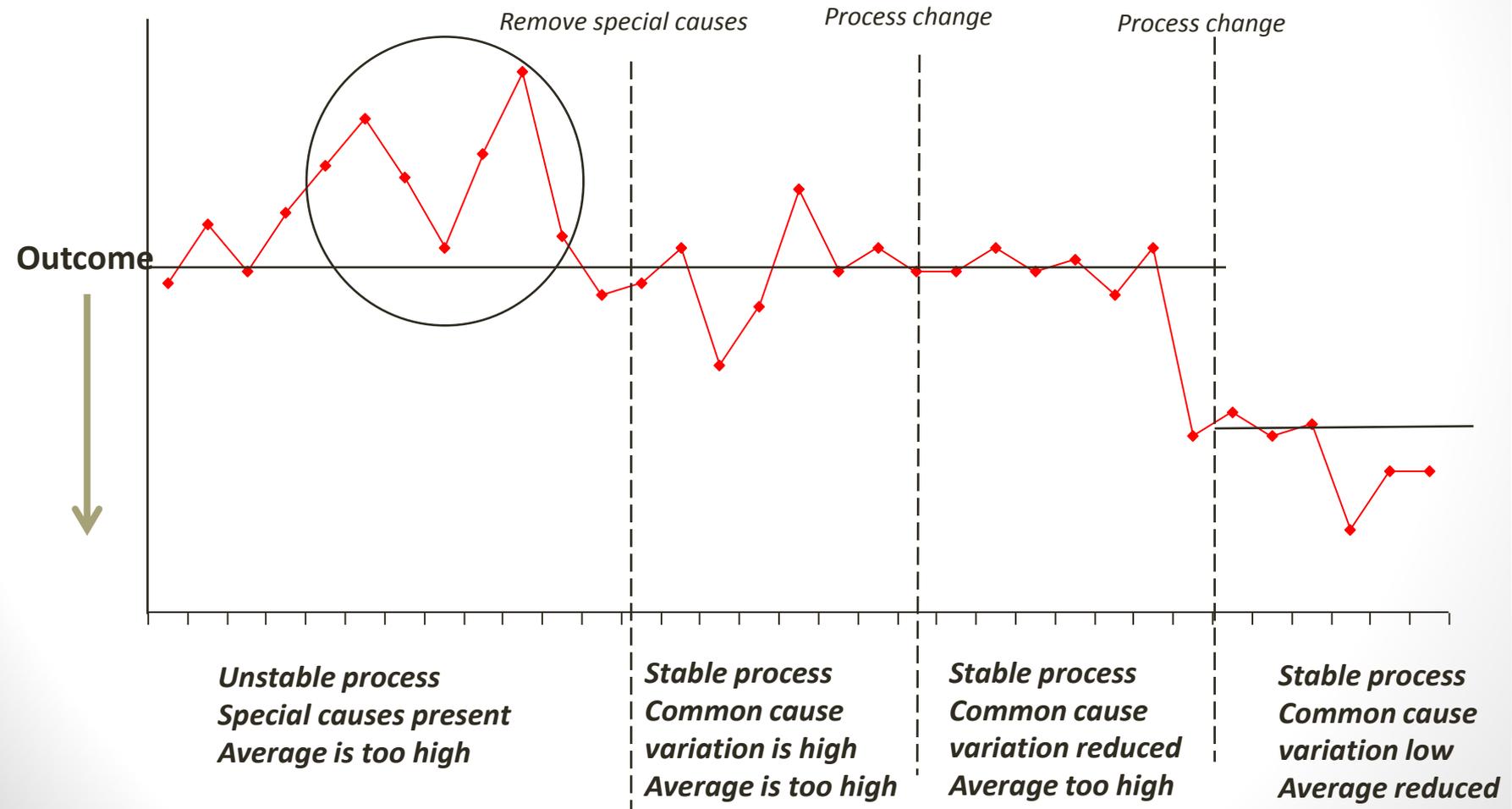
- response burden, literacy, data availability

Repeated Use of the PDSA Cycle



QI is a Science: Statistical Approach

Overall Improvement Strategy



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.