Basics of Quality Improvement (QI)

Learning Objectives:
✓ Identify and categorize adverse outcomes
✓ Describe differences between structural, process, and outcome measures
✓ Become familiar with tools used for quality measurement and improvement
✓ Describe laws and regulations affecting quality improvement in health care

Overview:
• Definition of Quality:
  o Institute of Medicine (IOM) defines quality as “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”
  o US Agency for Healthcare Research and Quality defines quality as “doing the right thing, at the right time, in the right way, for the right person – and having the best possible results.”

• Quality health care should be: safe, effective, patient-centered, timely, efficient, equitable, and reliable

• Health care is expected to deliver “Standard of Care” and take measures to prevent “Negligence”
  o Standard of care:
    ▪ A diagnostic and treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance.
    ▪ In legal terms, the level at which the average, prudent provider in a given community would practice.
  o Negligence:
    ▪ The failure to use reasonable care.
    ▪ The doing of something which a reasonably prudent person would not do, or the failure to do something which a reasonably prudent person would do under like circumstances.
    ▪ Negligence is a ‘legal cause’ of damage if it directly produces or contributes substantially to producing such damage, so it can reasonably be said that if not for the negligence, the loss, injury or damage would not have occurred.
Quality Measurement-
- An integral part of QI is the recognition of barriers to quality and measurement of defects in order to improve:¹
  - **Underuse:** failure to provide a service when it would have helped the patient
  - **Overuse:** provision of health care services when potential for harm exceeds the potential benefit
  - **Misuse:** appropriate process of care is selected but a preventable complication occurs and patient does not receive the full benefit of service

- Systematic measurement of quality allows us to determine if improvement efforts:
  - Change outcome in the desired direction
  - Contribute to unintended results in other parts of the system
  - Require additional changes to “normalize” a process

- Donabedian describes design of quality in relation to structure, process, and outcomes:²
  - **Structural measures:**
    - Assess availability and quality of resources, management systems and policy guidelines
    - Look at how a health care system is organized and the conditions under which care is delivered
    - E.g. the decision to use intensivists in the ICU to decrease mortality
  - **Process measures:**
    - Use the process of health care delivery as the indicator of quality
    - Look at activities of frontline persons (physicians, nurses, etc.) to determine if guidelines are followed
    - E.g. determining the proportion of diabetics who have annual retinal examinations
  - **Outcome measures:**
    - Look at the end result of health care and also incorporate environmental, behavioral and genetic factors
    - Usually based on group results rather than individual outcomes
    - E.g. mortality data or patient satisfaction data

Tools for the Measurement of Quality-
- Differentiation of adverse outcomes¹
  - **Near miss:** “close call”; an event or situation that did not produce patient injury, but only because of chance
  - **Sentinel event:** an adverse event in which death or serious harm to a patient has occurred; usually unexpected or unacceptable (e.g. an operation on the wrong patient or body part)
  - **Adverse event:** any injury caused by medical care; undesirable clinical outcome resulting from some aspect of diagnosis or therapy (e.g. pneumothorax from central venous catheter placement); does not imply "error," "negligence," or poor quality care.
• Internal review/Quality scoring – HMC (Courtesy Dr. Schleyer)
  o Relationship between any identified variation in practice and event being reviewed
    ▪ 0: No quality of care concern identified
    ▪ 1: “Near Miss” +/- reached patient – low risk to patient
    ▪ 2: “Near Miss” +/- reached patient – high risk to patient
    ▪ 3: Event reached patient: required additional care or high risk
    ▪ 4: Event reached patient – potentially life threatening or disability
    ▪ 5: Event reached patient – life threatening or death
  o Clinicians with similar training would likely have optimally managed or made a timely diagnosis
    ▪ A: Virtually all the time
    ▪ B: Much of the time, but with variability among clinicians
    ▪ C: Rarely
  o Optional: Include a classification of error
    ▪ Patient disease
    ▪ Error in diagnosis
    ▪ Error in technique
    ▪ Error in management
    ▪ Error in judgment
    ▪ Error in communication/handoff
    ▪ Disclosed with patient or family?
    ▪ Standard of care?
  o Score determines further course of action/recommendations: peer review committee, etc

**External Influences on the Development of Quality Improvement**

• **Emergency Medical Treatment and Active Labor Act (EMTALA)** was passed as part of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986.
  o The rule: Any individual who comes to a hospital requesting an examination or treatment for a medical condition must receive an appropriate medical screening examination within the capability of the hospital's Emergency Department.
  o Addresses failure of a hospital to recognize an emergency condition due to inadequate screening procedures, and, if an emergency condition exists, the failure to properly stabilize, transfer or treat the patient in accordance with the hospital's capabilities.

• **JCAHO/Centers for Medicare & Medicaid Services (CMS) indicators**: national publicly reported performance measures required for accreditation were introduced in 1997.
  o Evaluation of performance in specific core areas of care in a health care organization
    ▪ Quantitative tools such as rate, ratio, index that indicate performance in relation to a specified process or outcome
    ▪ Goal is to identify trends and change processes to improve the outcome
- ORYX (performance measure named by JCAHO in reference to the animal “antelope”, unsuspecting of danger) core indicators:
  - Pneumonia
  - Heart failure
  - Acute myocardial infarction
  - Surgical infection
  - Pregnancy and related conditions
  - Indicators to come: nosocomial infections, VTE, patient satisfaction
- In order to get accredited, organizations must track and report outcomes in at least 3 of these clinical areas which should include 20% of their patient population.

- Public interest in health care QI was heightened when the Institute of Medicine published “To Err Is Human: Building a safer health system” in 2000.  
  - The report estimated 44,000 - 98,000 in-hospital deaths per year due to preventable medical errors: higher than deaths due to MVAs, breast cancer, and HIV/AIDS.
  - Other costs to society:
    - $17 bio - $29 bio per year total cost (additional medical costs due to error, lost income and household productivity, disability)
    - Patients’ loss of trust in the health care system
    - Health care providers’ loss of morale and diminished job satisfaction
  - The health care system lags behind other high risk industries in the area of safety and quality improvement

- Government and public responses to problems brought into light by the report have lead to more systematic QI strategies in hospitals:
  - The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) was enacted with the goal to improve patient safety by encouraging voluntary and confidential reporting of adverse events.
    - Patient Safety Organizations (PSOs) were created to collect, aggregate, and analyze confidential information reported by health care providers
    - Thus, patterns of failures are identified and measures to eliminate patient safety risks and hazards are proposed
    - Federal legal privilege and confidentiality protections to information reported to or developed by a PSO: penalties for violations of confidentiality or privilege protections.
    - Network of Patient Safety Databases as resource for providers, PSOs, etc.

Tools for Improvement of Quality-
- Traditionally, health care has focused on “Quality Assurance” (evaluating the delivery of services and quality of products) and “Quality Control” (verifying and maintaining a desired level of quality) → Not sufficient to improve outcome, not comprehensive
- Need to combine Quality Assurance with proactive QI or continuous QI (CQI): emphasis on process and focus on system rather than individuals.
• Different QI methods:
  o **FADE Model** –
    • Focus: define and verify the process to be improved
    • Analyze: collect and analyze data to establish baselines, identify root causes and point toward possible solutions
    • Develop: based on the data, develop action plans for improvement, including implementation, communication, and measuring/monitoring
    • Execute/Evaluate: implement the action plans, on a pilot basis as indicated, and install an ongoing measuring/monitoring (process control) system to ensure success
Plan-do-study-act (PDSA) – most commonly used method in health care for rapid cycle improvement, also called Deming Cycle
- Trial-and-learning approach or action-oriented learning where a hypothesis is made and tested on small scale before any changes are made to the system
- Tests a change by planning it, trying it, observing the results, and acting on what is learned

Steps in the PDSA cycle
- **Step 1: Plan**
  - Plan the test or observation, including a plan for collecting data.
  - State the objective of the test.
  - Make predictions about what will happen and why.
  - Develop a plan to test the change. (Who? What? When? Where? What data need to be collected?)
- **Step 2: Do**
  - Try out the test on a small scale.
  - Carry out the test.
  - Document problems and unexpected observations.
  - Begin analysis of the data.
- **Step 3: Study**
  - Set aside time to analyze the data and study the results.
  - Complete the analysis of the data.
  - Compare the data to your predictions.
  - Summarize and reflect on what was learned.
- **Step 4: Act**
  - Refine the change, based on what was learned from the test.
  - Determine what modifications should be made.
  - Prepare a plan for the next test.

Six-Sigma – designed by Motorola, Inc to reduce cost, decrease process variation, and eliminate defects: measurement-based strategy for process improvement and problem reduction through application of improvement projects.
- “Sigma” reflects the number of standard deviations a given process is from perfection
- At the level of six-sigma, a process has about 3.4 defects per million opportunities: virtually error free (99.9996%)
- Two Six-Sigma Models:
  - DMAIC (define, measure, analyze, improve, control) is an improvement system for existing processes falling below specification and looking for incremental improvement.
  - DMADV (define, measure, analyze, design, verify) is an improvement system used to develop new processor products at Six Sigma quality levels.
Steps in Six-Sigma

- **Step 1: Define**
  - Create a project charter (needs, goals, success criteria, deadlines, etc.)

- **Step 2: Measure**
  - Development of a data collection plan
  - Collection of data from several sources to determine the depth of defects or errors in the system

- **Step 3: Analyze**
  - Data analysis, identification of deviation from standard and sources of process variation

- **Step 4: Improve/Design**
  - Development of creative solutions and implementation plans

- **Step 5: Control/Verify**
  - Implementation of policies and guidelines to make reversion to old process impossible
  - Development of quality controls for monitoring of new process

A Comparison of the QI Models

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- Each model reflects a common thread of analysis and implementation
- Using a methodology ensures that critical steps are not missed
- No one method is best for everyone or all situations: Pick a method that makes sense to you and follow it.
References:


Quality Improvement Problem Set:

Problem #1: Categorize the following adverse outcomes into near miss, sentinel event, or adverse outcome.

Near  Sentinel  Adverse
Miss   Event    Outcome

○ ○ ○ ○ A diabetic woman with creatinine 2.5 mg/dL presented to surgery clinic with a large breast tumor. A CT scan of her abdomen and chest, with intravenous contrast, was ordered as part of her w/u. The ordering physician had missed her creatinine value in the outpatient clinic medical record but the Radiology technologist noted the problem and alerted the ordering physician to change the study.

○ ○ ○ Wound infection after total knee arthroplasty.

○ ○ ○ A patient with residual dysphagia after a CVA underwent G-tube placement for permanent feeding. The feeding tube was placed intra-abdominally and patient developed acute chemical peritonitis and died less than 48 hours post procedure.

○ ○ ○ A diabetic patient was started on rosiglitazone for improved glycemic control. Within a week of starting this medication he noted increased orthopnea, dyspnea on exertion and lower extremity edema. He was diagnosed with acute CHF exacerbation which required hospitalization.

○ ○ ○ A patient was admitted to the hospital by the overnight ER physician for EtOH withdrawal. The admitting team had already capped for the night and did not hear about this patient. The ER physician went off shift without signing out the patient to the oncoming team. Several hours later, the chief resident was alerted of the patient by the charge nurse and he was assigned to a medicine team for further care.

(1-Near miss, 2-Adverse outcome, 3-Sentinel event, 4-Adverse outcome, 5-Near miss)

Problem #2: For each of the following, indicate whether the measure is structure (S), process (P), or outcome (O).

S   P   O

○ ○ ○ Manufacturing capacity at the Rubber Duck factory.

○ ○ ○ Number of asthma patients with ED visits this quarter.

○ ○ ○ What percentages of children have received their immunizations?

○ ○ ○ Are there enough hospital in the event of a catastrophe?

○ ○ ○ How many of my diabetics are receiving yearly foot exams?

○ ○ ○ How many of my smoking patients have successfully quit?

(1-Structure, 2-Outcome, 3-Process, 4-Structure, 5-Process, 6-Outcome)

Problem #3: Your clinic manager asks you to come up with a way to improve management of the diabetic population blood sugar levels. How would you approach this problem using the PDSA format?