

## 2C: Healthcare Quality Improvement

**Bimal R. Desai, MD, MBI, FAAP, FAMIA**

Children's Hospital of Philadelphia

# Clinical Informatics Subspecialty Delineation of Practice (CIS DoP)

## Domain 1: Fundamental Knowledge and Skills (no Tasks are associated with this Domain which is focused on fundamental knowledge and skills)

### Clinical Informatics

- K001. The discipline of informatics (e.g., definitions, history, careers, professional organizations)
  - K002. Fundamental informatics concepts, models, and theories
  - K003. Core clinical informatics literature (e.g., foundational literature, principle journals, critical analysis of literature, use of evidence to inform practice)
  - K004. Descriptive and inferential statistics
  - K005. Health Information Technology (HIT) principles and science
  - K006. Computer programming fundamentals and computational thinking
  - K007. Basic systems and network architectures
  - K008. Basic database structure, data retrieval and analytics techniques and tools
  - K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])
  - K010. Development and use of transaction standards (e.g., American National Standards Institute X12)
  - K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)
  - K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System [LIS])
  - K013. Development and use of data model standards
  - K014. Vocabularies, terminologies, and nomenclatures (e.g., Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine – Clinical Terms [SNOMED-CT], RxNorm, International Classification of Diseases [ICD], Current Procedural Terminology [CPT])
  - K015. Data taxonomies and ontologies
  - K016. Security, privacy, and confidentiality requirements and practices
  - K017. Legal and regulatory issues related to clinical data and information sharing
  - K018. Technical and non-technical approaches and barriers to interoperability
  - K019. Ethics and professionalism
- ### The Health System
- K020. Primary domains of health, organizational structures, cultures, and processes (e.g., health care delivery, public health, personal health, population health, education of health professionals, clinical research)
  - K021. Determinants of individual and population health
  - K022. Forces shaping health care delivery and considerations regarding health care access
  - K023. Health economics and financing
  - K024. Policy and regulatory frameworks related to the healthcare system
  - K025. The flow of data, information, and knowledge within the health system

## Domain 2: Improving Care Delivery and Outcomes

- K026. Decision science (e.g., Bayes theorem, decision analysis, probability theory, utility and preference assessment, test characteristics)
- K027. Clinical decision support standards and processes for development, implementation, evaluation, and maintenance
- K028. Five Rights of clinical decision support (i.e., information, person, intervention formats, channel, and point/time in workflow)
- K029. Legal, regulatory, and ethical issues regarding clinical decision support
- K030. Methods of workflow analysis
- K031. Principles of workflow re-engineering
- K032. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)
- K033. User-centered design principles (e.g., iterative design process)
- K034. Usability testing
- K035. Definitions of measures (e.g., quality performance, regulatory, pay for performance, public health surveillance)
- K036. Measure development and evaluation processes and criteria
- K037. Key performance indicators (KPIs)
- K038. Claims analytics and benchmarks
- K039. Predictive analytic techniques, indications, and limitations
- K040. Clinical and financial benchmarking sources (e.g., Gartner, Healthcare Information and Management Systems Society [HIMSS] Analytics, Centers for Medicare and Medicaid Services [CMS], Leapfrog)
- K041. Quality standards and measures promulgated by quality organizations (e.g., National Quality Forum [NQF], Centers for Medicare and Medicaid Services [CMS], National Committee for Quality Assurance [NCQA])
- K042. Facility accreditation quality and safety standards (e.g., The Joint Commission, Clinical Laboratory Improvement Amendments [CLIA])
- K043. Clinical quality standards (e.g., Physician Quality Reporting System [PQRS], Agency for Healthcare Research and Quality [AHRQ], National Surgical Quality Improvement Program [NSQIP], Quality Reporting Document Architecture [QRDA], Health Quality Measure Format [HQMF], Council on Quality and Leadership [CQL], Fast Health Interoperability Resources [FHIR] Clinical Reasoning)
- K044. Reporting requirements
- K045. Methods to measure and report organizational performance
- K046. Adoption metrics (e.g., Electronic Medical Records Adoption Model [EMRAM], Adoption Model for Analytics Maturity [AMAM])
- K047. Social determinants of health
- K048. Use of patient-generated data
- K049. Prediction models
- K050. Risk stratification and adjustment
- K051. Concepts and tools for care coordination
- K052. Care delivery and payment models

## Domain 3: Enterprise Information Systems

- K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
- K054. Institutional governance of clinical information systems
- K055. Information system maintenance requirements
- K056. Information needs analysis and information system selection
- K057. Information system implementation procedures
- K058. Information system evaluation techniques and methods
- K059. Information system and integration testing techniques and methodologies
- K060. Enterprise architecture (databases, storage, application, interface engine)
- K061. Methods of communication between various software components
- K062. Network communications infrastructure and protocols between information systems (e.g., Transmission Control Protocol/Internet Protocol [TCP/IP], switches, routers)
- K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
- K064. Clinical system functional requirements
- K065. Models and theories of human-computer (machine) interaction (HCI)
- K066. HCI evaluation, usability engineering and testing, study design and methods
- K067. HCI design standards and design principles
- K068. Functionalities of clinical information systems (e.g., Electronic Health Records [EHR], Laboratory Information System [LIS], Picture Archiving and Communication System [PACS], Radiology Information System [RIS] vendor-neutral archive, pharmacy, revenue cycle)
- K069. Consumer-facing health informatics applications (e.g., patient portals, mobile health apps and devices, disease management, patient education, behavior modification)
- K070. User types and roles, institutional policy and access control
- K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed loop communication)
- K072. Security threat assessment methods and mitigation strategies
- K073. Security standards and safeguards
- K074. Clinical impact of scheduled and unscheduled system downtimes
- K075. Information system failure modes and downtime mitigation strategies (e.g., replicated data centers, log shipping)
- K076. Approaches to knowledge repositories and their implementation and maintenance
- K077. Data storage options and their implications
- K078. Clinical registries
- K079. Health information exchanges
- K080. Patient matching strategies
- K081. Master patient index
- K082. Data reconciliation
- K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
- K084. Non-regulated medical devices (e.g., consumer devices)
- K085. Telehealth workflows and resources (e.g., software, hardware, staff)

## Domain 4: Data Governance and Data Analytics

- K086. Stewardship of data
- K087. Regulations, organizations, and best practice related to data access and sharing agreements, data use, privacy, security, and portability
- K088. Metadata and data dictionaries
- K089. Data life cycle
- K090. Transactional and reporting/research databases
- K091. Techniques for the storage of disparate data types
- K092. Techniques to extract, transform, and load data
- K093. Data associated with workflow processes and clinical context
- K094. Data management and validation techniques
- K095. Standards related to storage and retrieval from specialized and emerging data sources
- K096. Types and uses of specialized and emerging data sources (e.g., imaging, bioinformatics, internet of things [IoT], patient-generated, social determinants)
- K097. Issues related to integrating emerging data sources into business and clinical decision making
- K098. Information architecture
- K099. Query tools and techniques
- K100. Flat files, relational and non-relational/NoSQL database structures, distributed file systems
- K101. Definitions and appropriate use of descriptive, diagnostic, predictive, and prescriptive analytics
- K102. Analytic tools and techniques (e.g., Boolean, Bayesian, statistical/mathematical modeling)
- K103. Advanced modeling and algorithms
- K104. Artificial intelligence
- K105. Machine learning (e.g., neural networks, support vector machines, Bayesian network)
- K106. Data visualization (e.g., graphical, geospatial, 3D modeling, dashboards, heat maps)
- K107. Natural language processing
- K108. Precision medicine (customized treatment plans based on patient-specific data)
- K109. Knowledge management and archiving science
- K110. Methods for knowledge persistence and sharing
- K111. Methods and standards for data sharing across systems (e.g., health information exchanges, public health reporting)

## Domain 5: Leadership and Professionalism

- K112. Environmental scanning and assessment methods and techniques
- K113. Consensus building, collaboration, and conflict management
- K114. Business plan development for informatics projects and activities (e.g., return on investment, business case analysis, pro forma projections)
- K115. Basic revenue cycle
- K116. Basic managerial/cost accounting principles and concepts
- K117. Capital and operating budgeting
- K118. Strategy formulation and evaluation
- K119. Approaches to establishing Health Information Technology (HIT) mission and objectives
- K120. Communication strategies, including one-on-one, presentation to groups, and asynchronous communication
- K121. Effective communication programs to support and sustain systems implementation
- K122. Writing effectively for various audiences and goals
- K123. Negotiation strategies, methods, and techniques
- K124. Conflict management strategies, methods, and techniques
- K125. Change management principles, models, and methods
- K126. Assessment of organizational culture and behavior change theories
- K127. Theory and methods for promoting the adoption and effective use of clinical information systems
- K128. Motivational strategies, methods, and techniques
- K129. Basic principles and practices of project management
- K130. Project management tools and techniques
- K131. Leadership principles, models, and methods
- K132. Intergenerational communication techniques
- K133. Coaching, mentoring, championing and cheerleading methods
- K134. Adult learning theories, methods, and techniques
- K135. Teaching modalities for individuals and groups
- K136. Methods to assess the effectiveness of training and competency development
- K137. Principles, models, and methods for building and managing effective interdisciplinary teams
- K138. Team productivity and effectiveness (e.g., articulating team goals, defining roles of operation, clarifying individual roles, team management, identifying and addressing challenges)
- K139. Group management processes (e.g., nominal group, consensus mapping, Delphi method)



# Knowledge Statements from the DoP

---

K032. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)



# Healthcare Quality Improvement

---

## Distinguish Quality Assurance (QA) from Quality Improvement (QI)

- Quality Assurance
  - Focused on the individual
  - Inspection, critique, correction of performance, but no focus on system change
  - Tends to “punish,” doesn’t delve into root cause
- Quality Improvement
  - Systems-focused
  - Fallibility is recognized and errors seen as opportunities to improve
  - Peer review of errors is encouraged to identify and improve systems

# QI Historical Perspective

---

Informed by work in manufacturing, process control

## 1890s – Frederick Taylor

- “**Scientific Management**” movement
- By modern standards, he thought poorly of workers
  - *“In the majority of cases this man deliberately plans to do as little as he safely can”*
  - *“When he tells you to pick up a pig and walk, you pick it up and walk, and when he tells you to sit down and rest, you sit down. You do that right through the day. And what's more, no back talk”*

## 1930s –Walter Shewhart, Western Electric Co.

- **Statistical Process Control**
- Creator of control charts



clipart credit: <http://flaticon.com>



# QI Historical Perspective

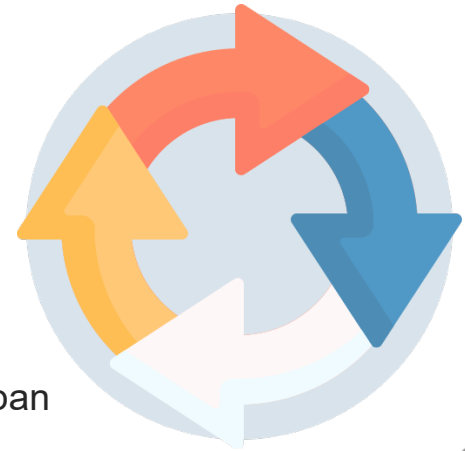
---

## 1950s – Taiichi Ohno

- Developed Toyota Production System, aka “**Toyota Lean**”
- System focuses on removing all activity that has no value, contributes to waste or “*muda*”

## 1970s – W. Edwards Deming

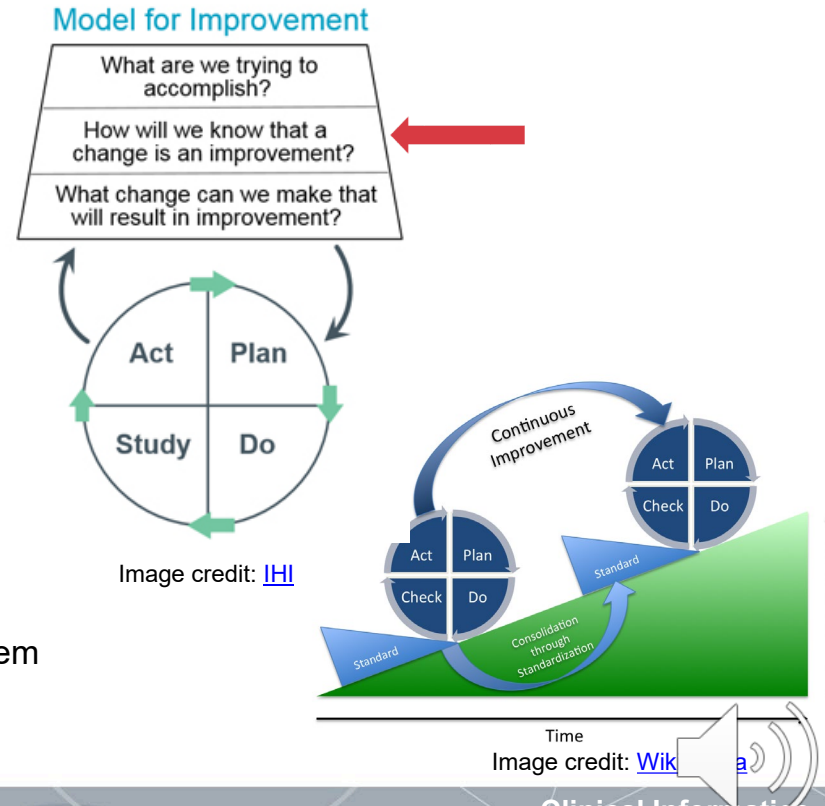
- **Theory of Improvement**
- **Plan-Do-Study-Act** cycle for learning and improvement
- Hired as consultant to improve production methods in post-WWII Japan



clipart credit:  atcon.com

# The IHI Model for Improvement

- Developed by Institute for Healthcare Improvement (IHI) in 1996, based on work by W. Edwards Deming (1900-1993), based on the work of Walter A. Shewhart (1891-1967)
- While model is attributed to Deming, he called it the “Shewhart Cycle”
- Uses rapid-cycle process called Plan Do Study Act (PDSA)
- Model starts with defining the problem, a strategy for measurement of magnitude/improvement, and a test of change
- Then, you plan the test of change (plan), implement it (do), evaluate whether it worked (check/study), and disseminate or adjust (act). The new standard solidifies the improvement, prevents backsliding
- In this way, you continuously and incrementally improve a system



# The Importance of Measurement

---

*One day when I was a junior medical student, a very important Boston surgeon visited the school and delivered a great treatise on a large number of patients who had undergone successful operations for vascular reconstruction.*

*At the end of the lecture, a young student at the back of the room timidly asked, "**Do you have any controls?**" Well, the great surgeon drew himself up to his full height, hit the desk, and said, "**Do you mean did I not operate on half the patients?**" The hall grew very quiet then. The voice at the back of the room very hesitantly replied, "**Yes, that's what I had in mind.**"*

*Then the visitor's fist really came down as he thundered, "**Of course not. That would have doomed half of them to their death.**" God, it was quiet then, and one could scarcely hear the small voice ask, "**Which half?**"*

- E.E. Peacock, 1972  
in Tufte Data Analysis for Politics and Policy





# Measurement is the Foundation of QI

---

## What to measure – Donabedian Framework

- Structure?
  - Process?
  - Outcome?
- 
- Lagging vs. Leading Indicator
  - Characteristics of a good quality indicator

# Donabedian Quality Framework

**Structure** – Attributes of setting in which care occurs

- Number of specialists for a given patient population
- Number of clinical guidelines implemented

**Process** – How care is actually provided and received

- Proportion of diabetic patients who are screened for proteinuria
- Proportion of children with otitis media who are treated appropriately with narrow-spectrum penicillins

**Outcome** – Effects of care on patient status

- Intermediate measures
  - HbA1c results for diabetic patients
  - Lipid profile results for patients with hyperlipidemia
- End measures
  - Quality of life for patients with degenerative joint disease
  - Functional status for stroke patients
  - Patient satisfaction



Donabedian, A. Evaluating the quality of medical care. 1966. *Milbank Q.* **83**, 691–729 (2005).

# The Same Quality Indicator, Measured Differently

---

**Goal: “All emergency department rooms should be stocked with equipment for bag-mask ventilation”**

- **Structure:** “does your hospital have a policy or standard that specifies what equipment should be in every room in the ED”?
- **Process:** “In weekly audits of ED rooms, what percent of the time is a room found to be improperly stocked?”
- **Outcome:** “How many occurrences are there annually of trauma/resuscitation events in the ED where a bad outcome was attributed to missing airway equipment?”

# Lagging vs. Leading Indicators

---

**Leading Indicator:** An indicator that anticipates future events, changes detectable before the events occur.

- Examples: physical activity, weight, immunizations, antibiotics given prior to surgery, timely corticosteroid treatments for acute asthma, etc.

**Lagging Indicator:** An indicator that follows an event.

- Examples: infections (lagging) caused by hand washing rate (leading); ventilator acquired pneumonia; complication rates, asthma hospitalization or revisit rates

Compare “Leading” to “Process” & “Lagging” to “Outcome”

- **Process/Leading:** rate of pediatric immunization
- **Outcome/Lagging:** rates of pertussis and measles in a community

# Attributes of Good Indicators

---

- Definitions are **agreed upon**
- Optimally **sensitive** and **specific**
- **Valid** – does the indicator **discriminate** between good and bad quality?
- **Reliable** – are **repeated measurements** stable, reproducible, consistent?
- Relates to **identifiable user events** (cause → effect)
- **Permits useful comparison**
- **Evidence-based**



# Error-Proofing Tools and Concepts

---

- High Reliability Organizations
- Checklists
- James T. Reason's "Swiss Cheese" Model
  - Latent and active failures are like "holes in the cheese"
  - Processes, safeguards, and workflows are "layers of cheese"
  - Accidents / errors occur when the latent and active failures in different layers line up, allowing hazards to lead to losses.
- Failure Mode and Effects Analysis (FMEA)
- Statistical Process Control (SPC) Charts

Reason JT. The Contribution of Latent Human Failures to the Breakdown of Complex Systems. Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences 327 (1241): 475–484.

[Abstract](#)

# High Reliability Organizations

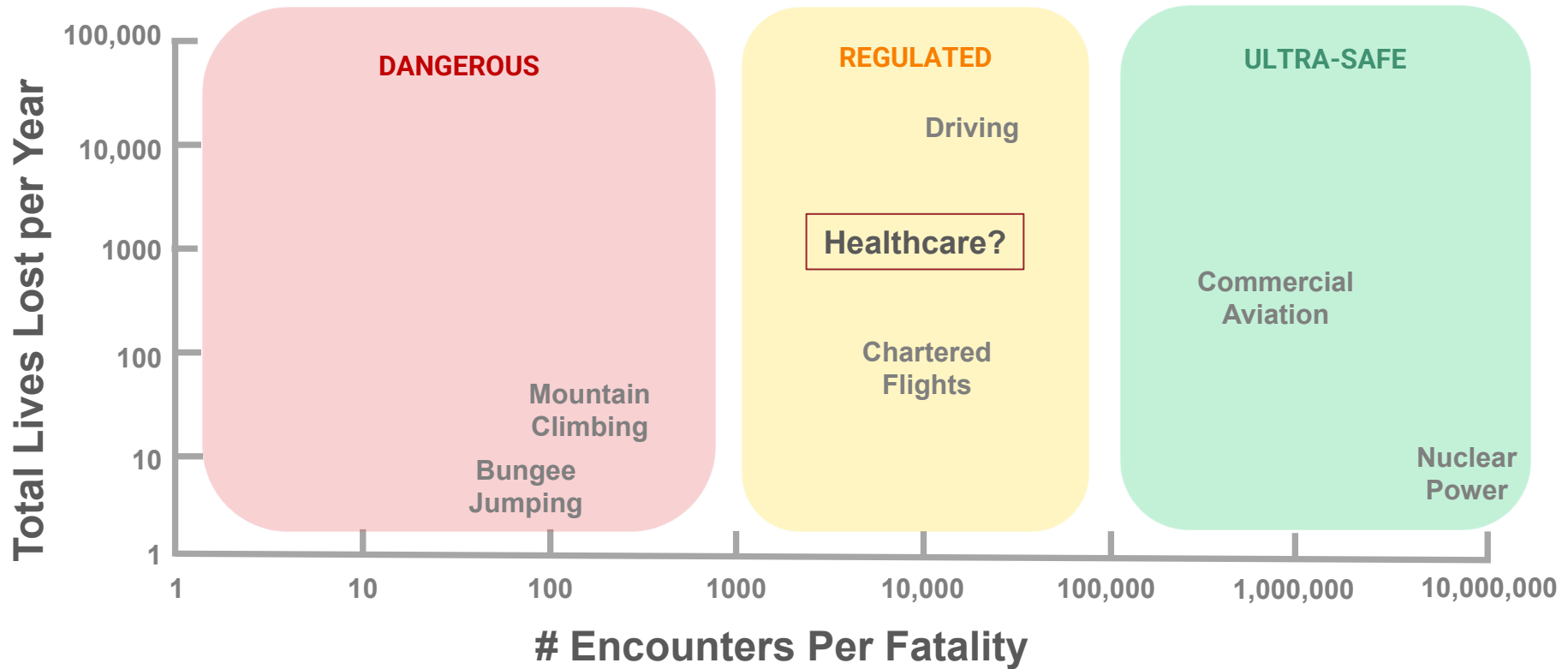
---

- Features of high-hazard industries (like healthcare, aviation) that ensure they can operate for extended periods without serious accidents or catastrophic failures.
- Characteristics of High Reliability
  - Preoccupation with Failure – vigilance, practice with a questioning attitude, escalation
  - Reluctance to Simplify – look for systemic causes, not superficial explanations
  - Sensitivity to Operations – vigilance to state of work, emerging issues, input from staff
  - Deference to Expertise – people closest to work are most knowledgeable
  - Commitment to Resilience – rapid assessments of threats, respond or mitigate quickly



Source: [AHRQ High Reliability Primer](#)

## How Do Healthcare and Aviation Compare in Terms of High Reliability?



Graphic adapted from Leape, Amalberti, 2001





# SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▶▶▶▶▶▶▶▶ Before skin incision ▶▶▶▶▶▶▶▶▶▶▶▶▶▶ Before patient leaves operating room

## SIGN IN

- ☐ PATIENT HAS CONFIRMED
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ SITE MARKED/NOT APPLICABLE
- ☐ ANAESTHESIA SAFETY CHECK COMPLETED
- ☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING

### DOES PATIENT HAVE A:

#### KNOWN ALLERGY?

- ☐ NO
- ☐ YES

#### DIFFICULT AIRWAY/ASPIRATION RISK?

- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

#### RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?

- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS  
AND FLUIDS PLANNED

## TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE  
INTRODUCED THEMSELVES BY NAME AND  
ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL  
AND NURSE VERBALLY CONFIRM
  - PATIENT
  - SITE
  - PROCEDURE

### ANTICIPATED CRITICAL EVENTS

- ☐ SURGEON REVIEWS: WHAT ARE THE  
CRITICAL OR UNEXPECTED STEPS,  
OPERATIVE DURATION, ANTICIPATED  
BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE  
ANY PATIENT-SPECIFIC CONCERNS?
- ☐ NURSING TEAM REVIEWS: HAS STERILITY  
(INCLUDING INDICATOR RESULTS) BEEN  
CONFIRMED? ARE THERE EQUIPMENT  
ISSUES OR ANY CONCERNS?

### HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?

- ☐ YES
- ☐ NOT APPLICABLE

### IS ESSENTIAL IMAGING DISPLAYED?

- ☐ YES
- ☐ NOT APPLICABLE

## SIGN OUT

### NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE  
COUNTS ARE CORRECT (OR NOT  
APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED  
(INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT  
PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL  
AND NURSE REVIEW THE KEY CONCERNS  
FOR RECOVERY AND MANAGEMENT  
OF THIS PATIENT



# WHO Surgical Checklist

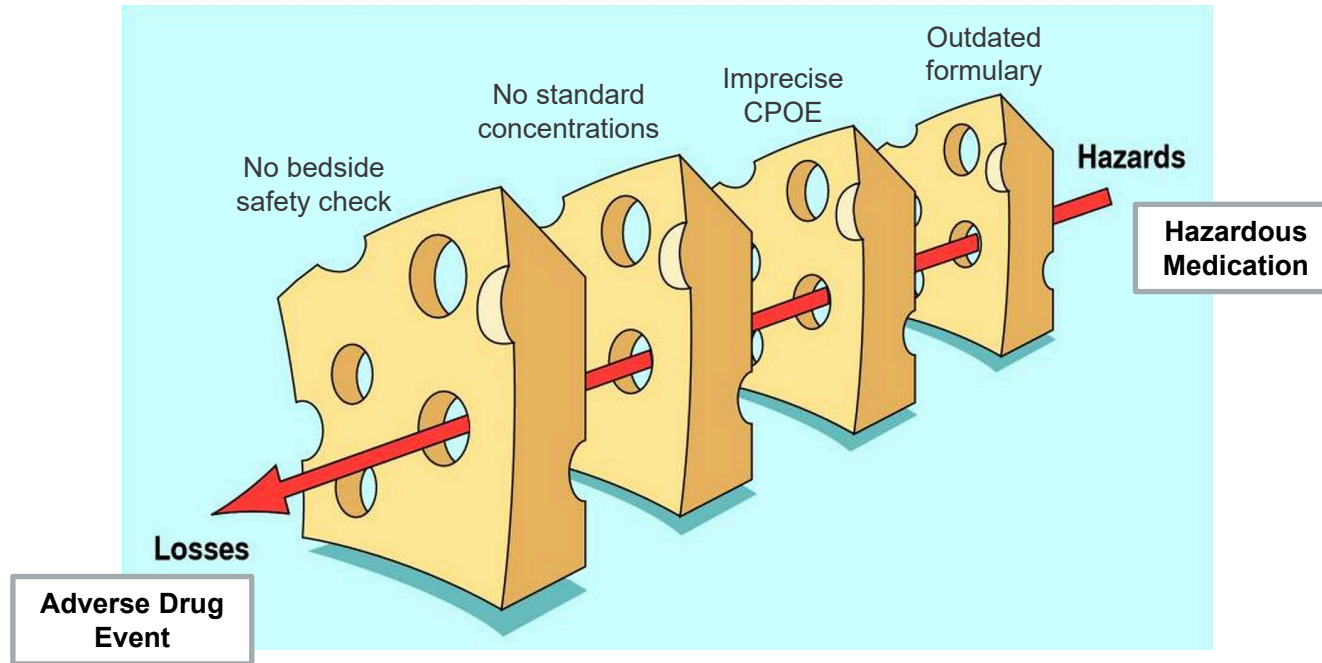
---

Weiser TG, Haynes AB, et al. **Effect of a 19-item surgical safety checklist during urgent operations in a global patient population.** Ann Surg. 2010 May;251(5):976-80. [[Abstract](#)]

1750 consecutively enrolled patients >16 years old at 8 hospitals across the world

*“The complication rate was 18.4% (n=151) at baseline and 11.7% (n=102) after the checklist was introduced (P=0.0001). Death rates dropped from 3.7% to 1.4% following checklist introduction (P=0.0067). Adherence to 6 measured safety steps improved from 18.6% to 50.7% (P<0.0001).”*

# Reason “Swiss Cheese” Model



Original image from: Reason J. Human error: models and management. BMJ. Mar 18, 2000; 320(7237): 768–770.

# Failure Mode & Effects Analysis

---

## “FMEA”

- Devised by the US Military in 1949
- Used in aerospace, automotive industry
- Later adopted for healthcare use

Modes of failure in a process can be risk-prioritized according to **severity** of the failure, frequency of **occurrence**, and **detectability**

# Failure Mode & Effects Analysis

---

**Step 1:** Create detailed flow diagram of a process

**Step 2:** For each step, describe what happens if process fails

**Step 3:** Rate each failure on a standardized scale x 3

- Severity of harm if failure occurs (**S**)
  - 1=none; 5=fatal
- Likelihood of occurrence (**O**)
  - 1=rare; 5=common
- Inability of existing controls to detect failure (**D**)
  - 1=easily detectable; 5=failure would not be evident

**Step 4:** Calculate Risk Priority Number ( $RPN = S \times O \times D$ )

**Example:** A fatal, but rare and detectable error =  $5 \times 1 \times 1 = RPN 5$



# Shewhart / Control Charts

---

- Not a hypothesis test
- Definitions of “common cause” and “special cause” are based in statistics
- When monitored over time, an indicator will fluctuate around an average value, defined by upper and lower control limits. This fluctuation is called **“common cause”** variation.
- Improbable patterns of fluctuation suggest the process has changed due to some special reason, hence then name **“special cause”** variation.



# Shewhart / Control Charts

**Upper Control Limit (UCL)** = +3 sigma limit

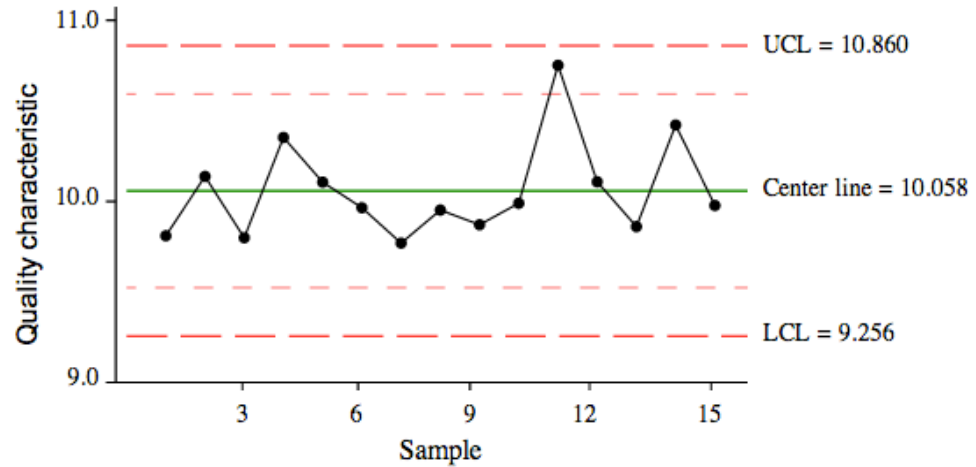
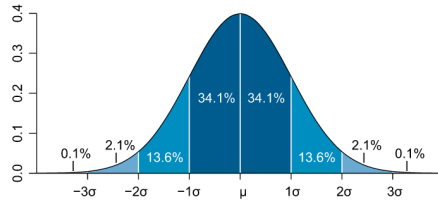
**Lower Control Limit (LCL)** = -3 sigma Limit

99.73% of observations should fall within +/-3 sigma

**Upper Warning Limit (UWL)** = +2 sigma limit

**Lower Warning Limit (LWL)** = -2 sigma limit

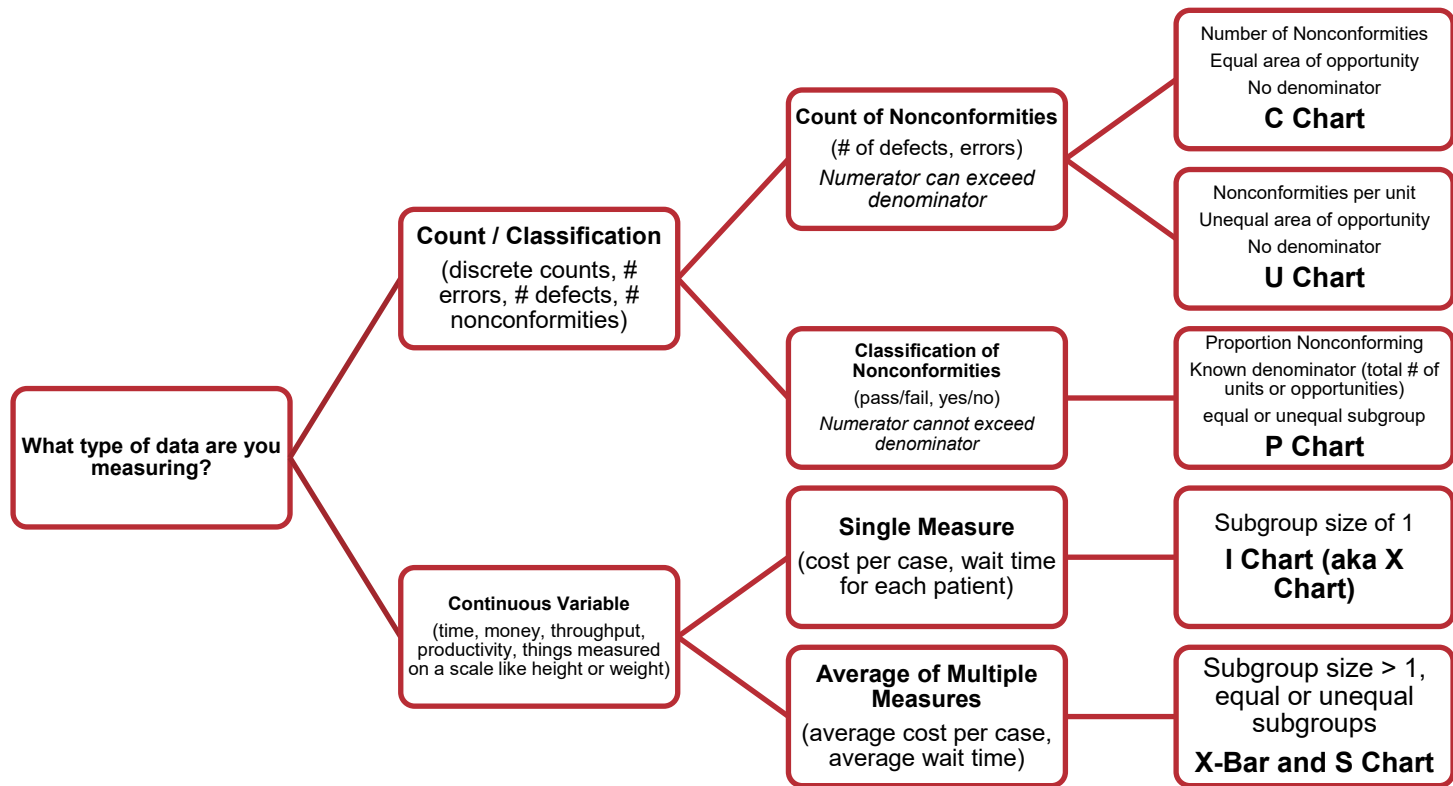
95% of observations should fall within +/-2 sigma



Formula for calculating those limits depends on type of data and type of control chart

# UCL/UWL Calculations Determined by Chart Type

See **SUPPLEMENT** for healthcare examples of these





# Control Chart Center Line

---

## “Common Cause” Fluctuation

- Within UCL and LCL (99.73% of random fluctuation should fall within 3-sigma)
- **AND** has no unnatural patterns

## “Special Cause” Fluctuation

- Falls outside UCL or LCL
- **OR** meets criteria for any “Special Cause” pattern

# Special Cause Patterns

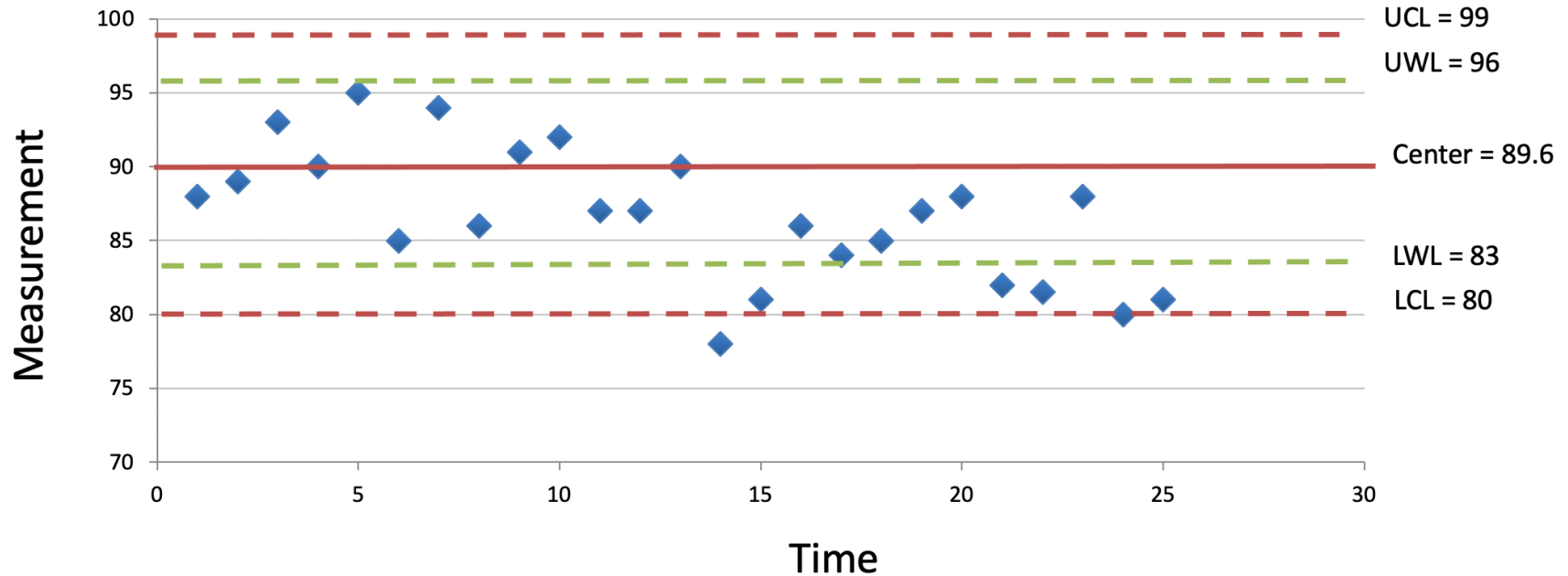
---

They all describe statistically improbable events or series of events

Definitions differ, but some commonly accepted patterns:

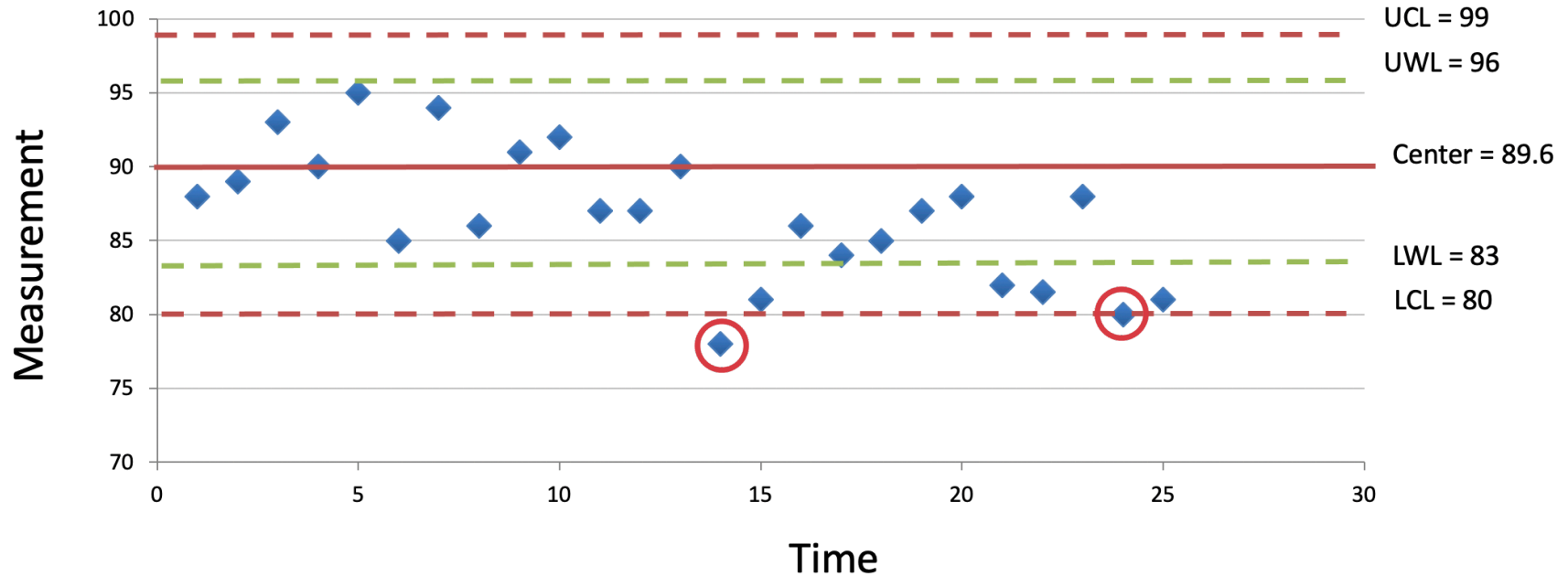
- Any single point outside 3-sigma
- Two out of three points between 2 and 3-sigma
- Four out of five consecutive points beyond 1-sigma on the same side of the centerline
- Eight consecutive points on the same side of the centerline
- Six in a row continually increasing or decreasing (drift)
- And the list goes on...

# Special Cause Examples



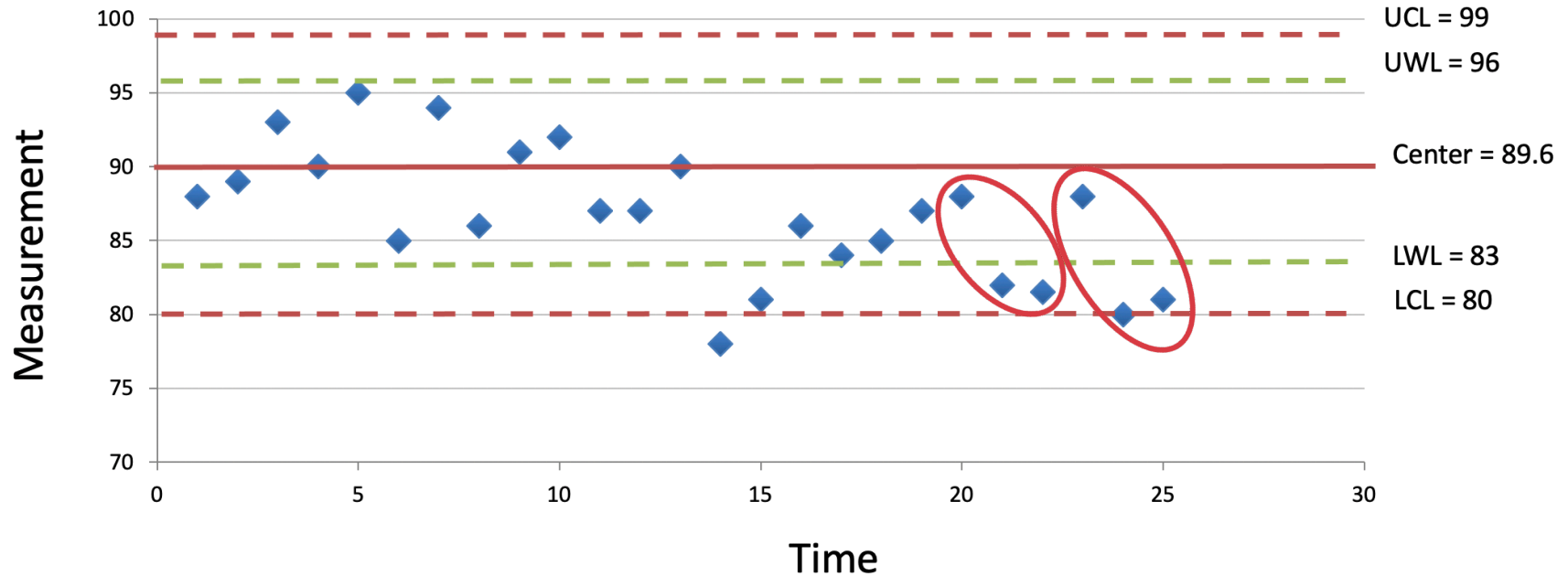
How many special cause patterns can you identify in this graph?

# Special Cause Examples



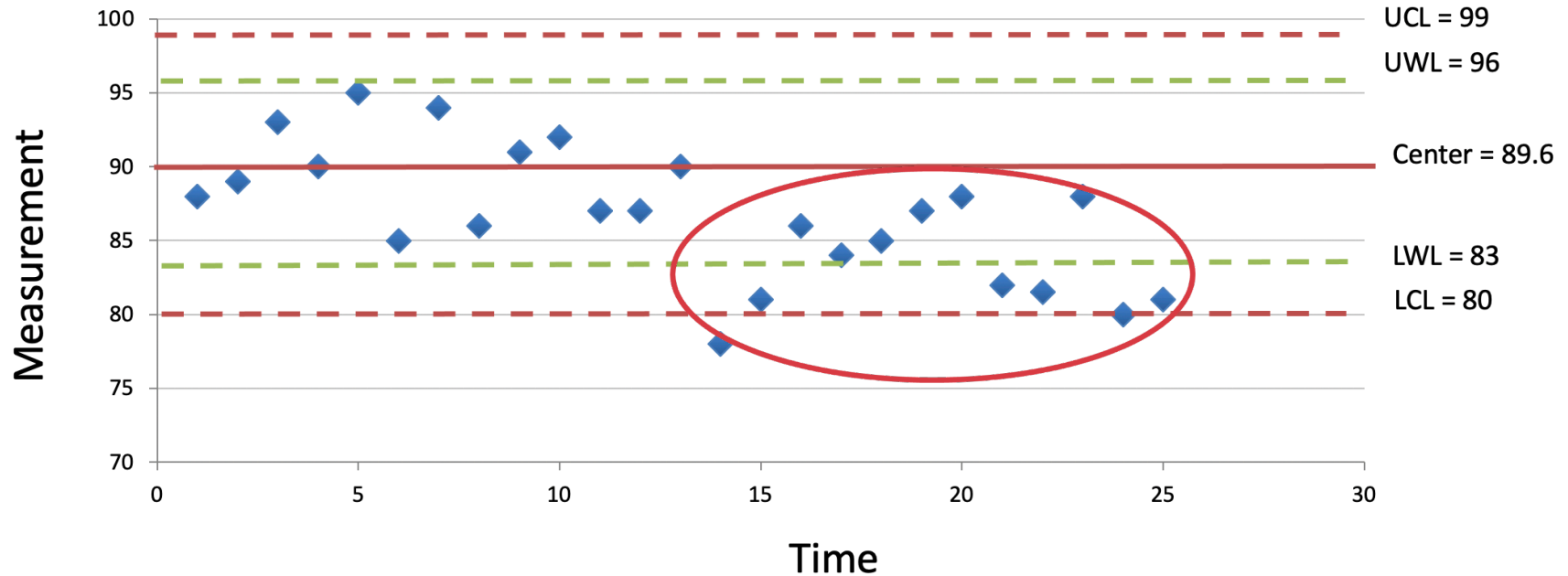
**Any single point beyond 3-sigma is due to “special cause”**

# Special Cause Examples



**Two out of 3 points between 2- and 3-sigma**

# Special Cause Examples



Eight consecutive on the same side of center line

# Other Special Cause Terminology

---

**Shift** – “a run of 6 or more points on same side of center line”

**Trend** – “five consecutive points going in same direction”

**Run** - “too few or too many events crossing the center line”

**Cycle** – periodicity in data suggests special cause

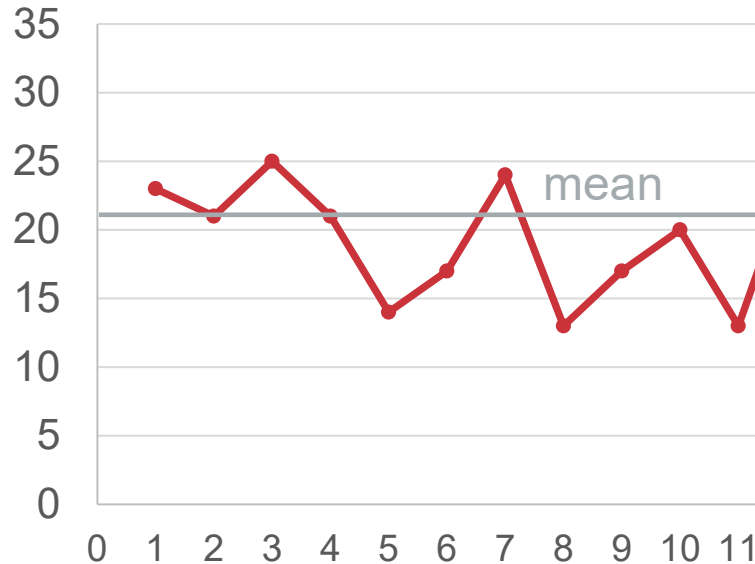
- Eg: “difference in STAT lab delays during night shift”

**Pattern** – cycles in data attributable to other factors besides time

- Eg: “higher override rates when a specific pharmacist is on duty”

# Value of Using Control Charts

Process Defects



For a QI project, you're trending defects in a process over time.

After 11 months, you calculate the mean to be about 21 defects/month

new goal

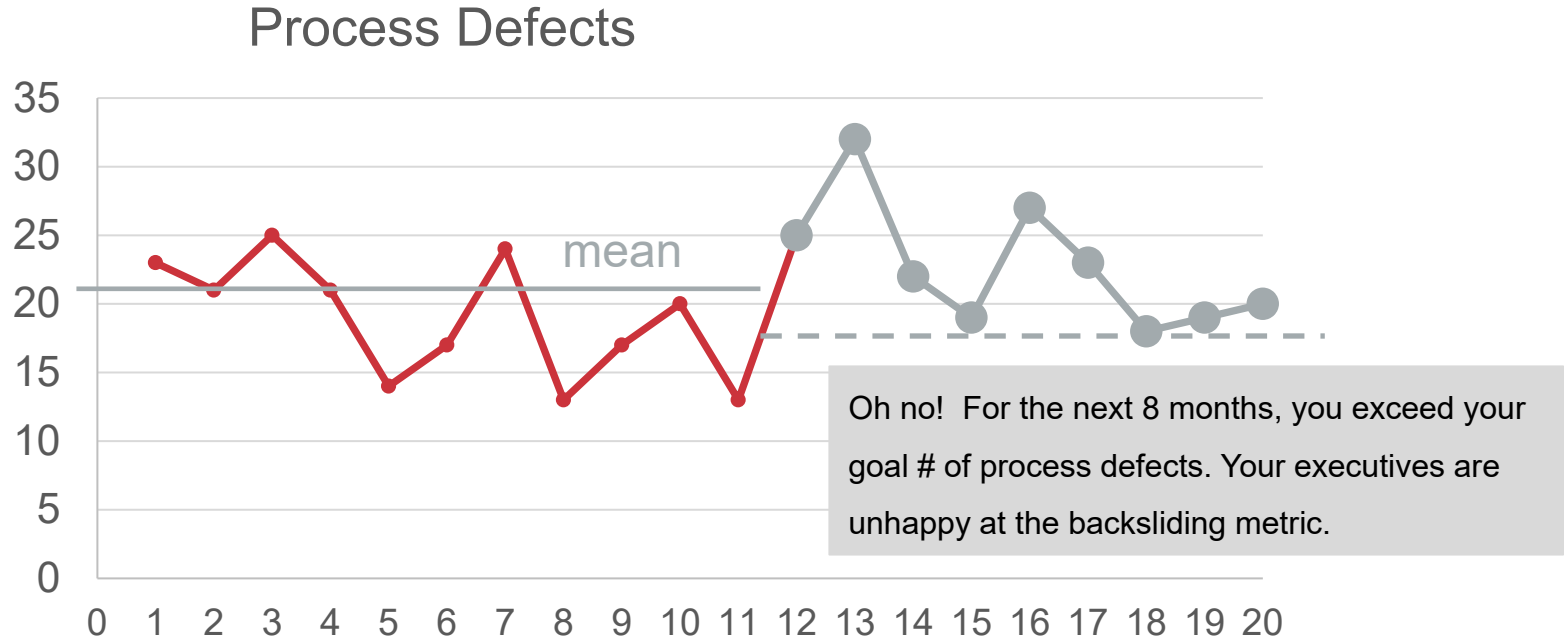
You choose a target for improvement that is 10% less, or about 18.

Courtesy Ron Keren, MD • Used with permission



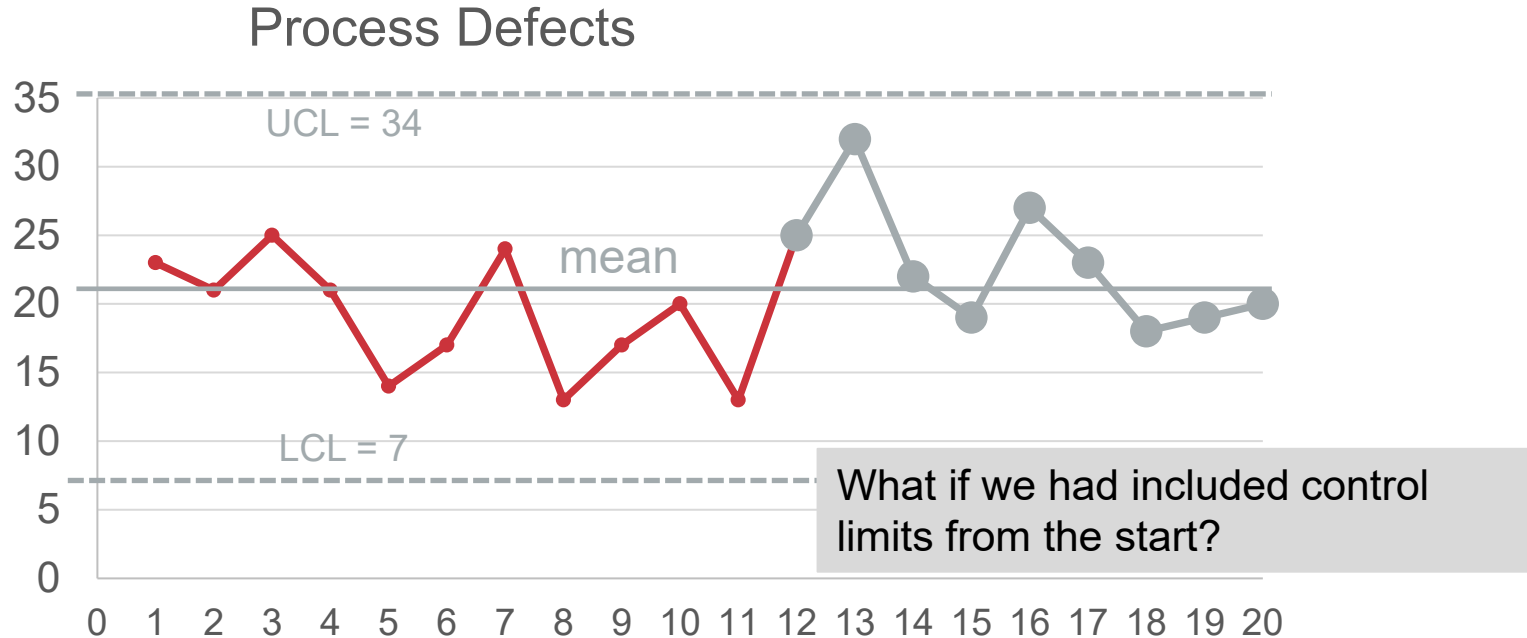


# Value of Using Control Charts



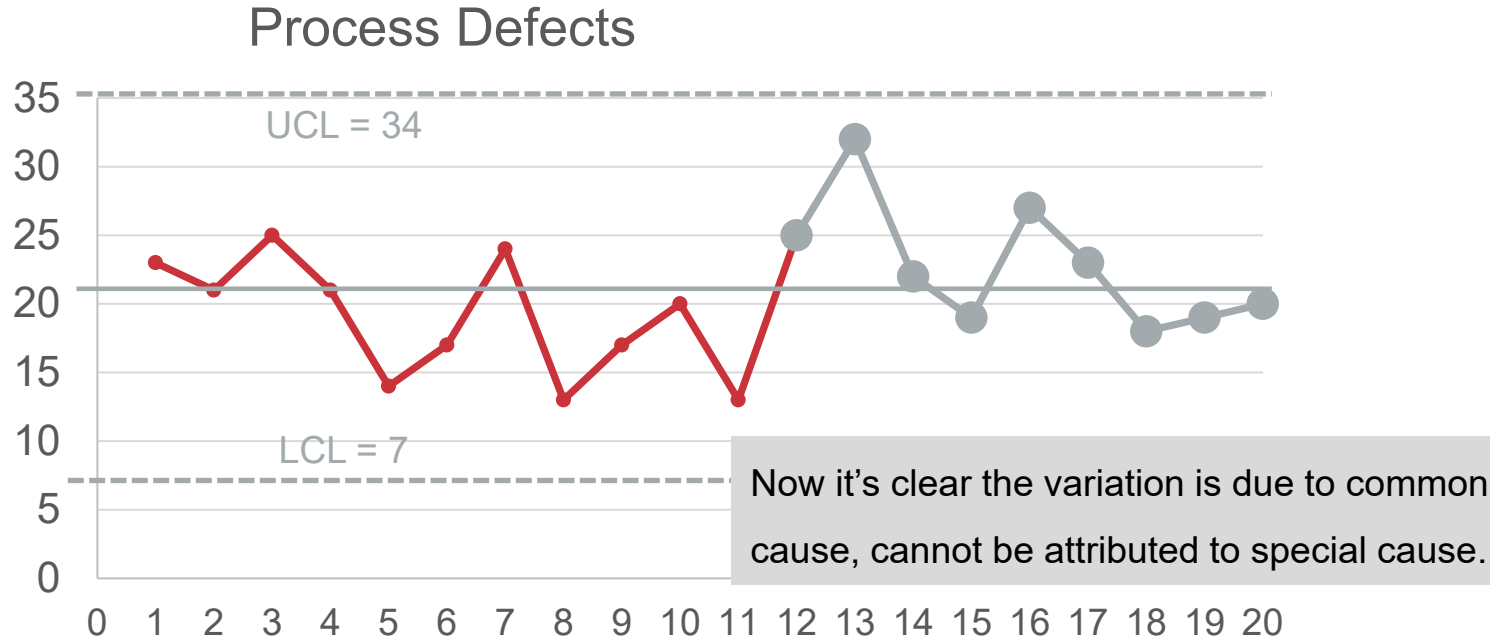
Courtesy Ron Keren, MD • Used with permission

# Value of Using Control Charts



Courtesy Ron Keren, MD • Used with permission

# Value of Using Control Charts



Courtesy Ron Keren, MD • Used with permission

# Other QI Tools

---

## Flowchart

- Graphically represent a process step-by-step
- Model of workflow and cognitive steps with inputs, decisions, outputs

## Cause-Effect / Ishikawa / Fishbone diagram

- Identify possible targets for improvement
- Trace back to root cause by asking “Five Whys”
- Represent as an outcome (head) and domains (bones)

## Pareto Chart

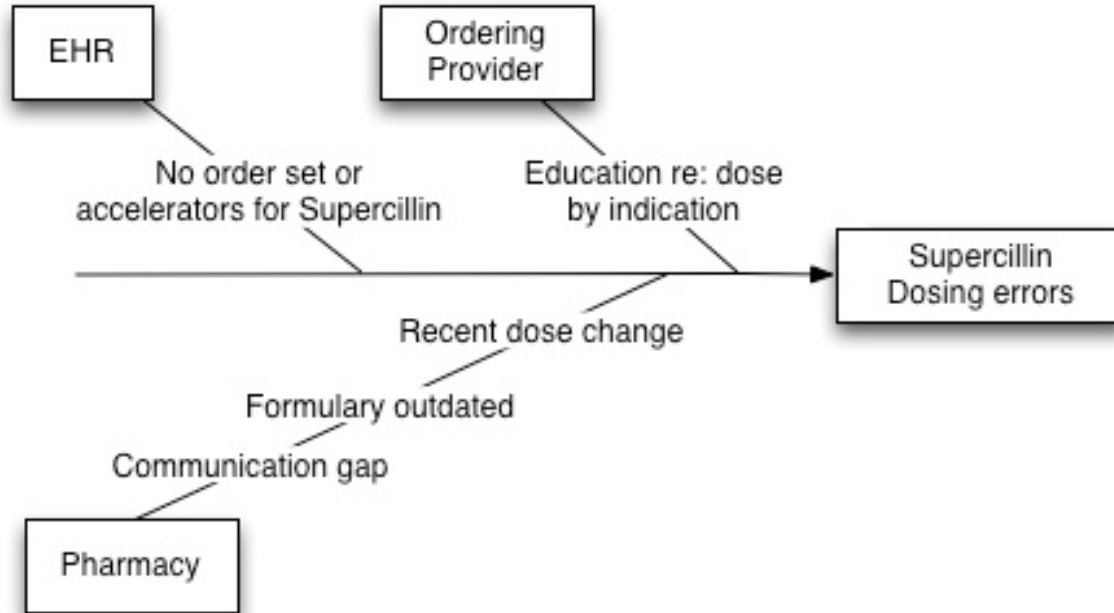
- Frequency-sorted graph of events with a cumulative percent line
- Origin of the “80:20” rule
- Used commonly to identify the most valuable targets for improvement

## Key Driver Diagram

- Establishes a causal pathway between the intervention and the aim
- Work backwards from Outcomes to Drivers to Changes
- User to identify measurable tests of change

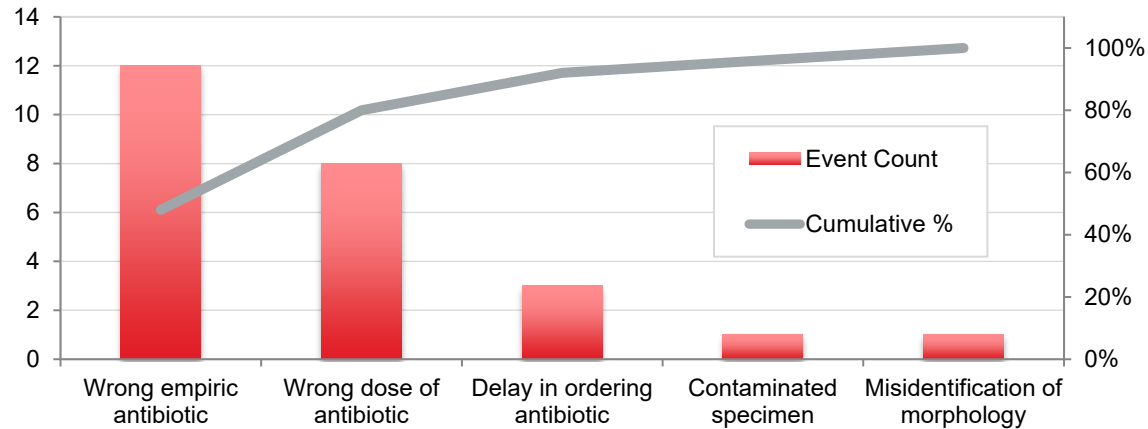


# Ishikawa Example



# Pareto Chart Example

## Causes of Errors Related to Antibiotics for Urinary Tract Infections



# Five Whys Example

---

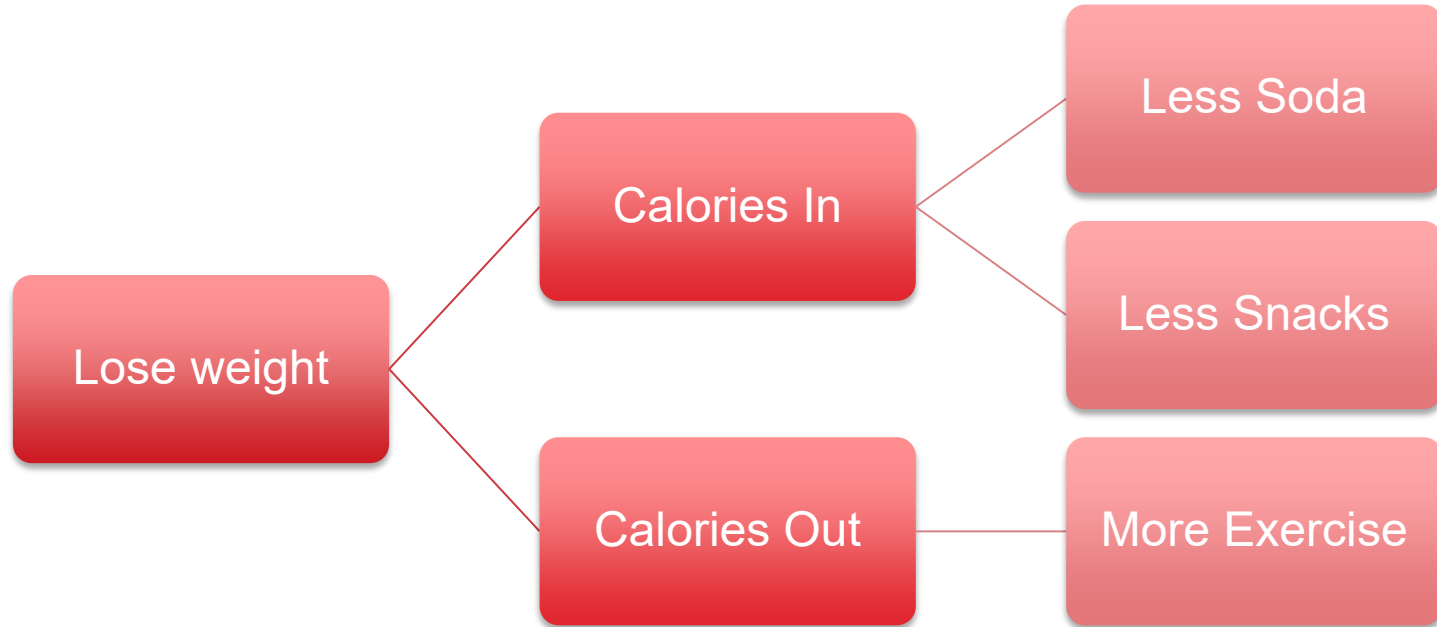
(source: [https://en.wikipedia.org/wiki/Five\\_whys](https://en.wikipedia.org/wiki/Five_whys))

## Problem: The vehicle won't start

- 1<sup>st</sup> Why? The battery is dead
- 2<sup>nd</sup> Why? The alternator is not functioning
- 3<sup>rd</sup> Why? The alternator belt is broken
- 4<sup>th</sup> Why? The alternator belt was well beyond its useful service life and not replaced
- 5<sup>th</sup> Why? **The vehicle was not maintained according to the recommended service schedule (Root Cause)**
  - **Solution: start to maintain according to schedule**
- 6<sup>th</sup> Why? Replacement parts are not available because of the extreme age of the vehicle (optional footnote)
  - **Solution: purchase a different vehicle that is easier to maintain**



# Key Driver Diagram



Example adapted from IHI Open School website: <http://www.ihl.org>



# Improvement Methodologies

---

PDSA = “Plan – Do – Study – Act”

- (aka “PDCA” or “Plan – Do – Check – Act”)

Six-Sigma

Toyota Lean and related strategies

Supplemental reading: Varkey P, Reller MK, Resar RK.

**Basics of quality improvement in health care.** Mayo Clin Proc. 2007;82(6):735-739. [[Abstract](#)]



# Plan Do Study Act (or Plan Do Check Act)

---

Key to improvement is small, repeated cycles to select targets, improve on a small scale, implement widely, and measure outcome

- IHI reference: <http://www.ihi.org/knowledge/Pages/HowtoImprove/>
- Steps:
  - Form the team
  - Set Aims – time specific and measurable
  - Establish measures (ideally, these should be good indicators)
  - Select target for change/improvement (use FMEA, Pareto, Fishbone, and other techniques to identify targets)
  - **Plan – Establish objectives, processes, expectations**
  - **Do – Implement the plan, collect data for analysis**
  - **Study / Check – look at the results and compare against expected results**
  - **Act – request corrective actions, disseminate results to all areas**



# Example in Practice

---

A children's hospital wants to encourage appropriate 1<sup>st</sup> line antibiotic prescribing for community acquired pneumonia

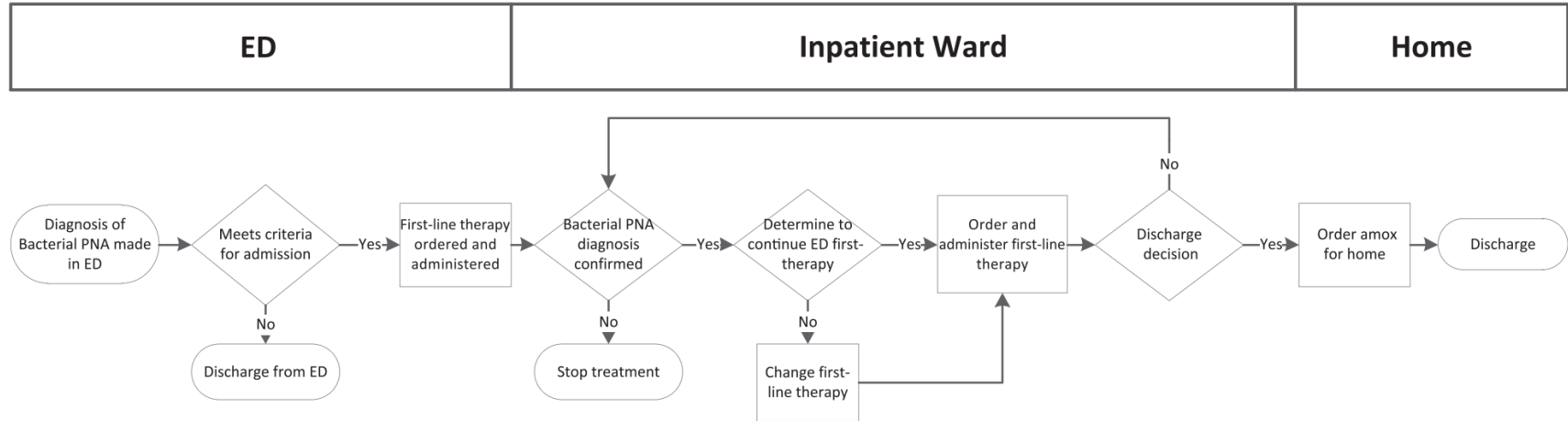
1: Form a team: hospitalists, ED, ID, pharmacist, and others

2: Develop aims: increase percent of patients admitted with community acquired pneumonia (CAP) on appropriate antibiotics from baseline of 0% to 80%

*Ambroggio et al, Pediatrics 2013*

# Example in Practice

## 3: Create a process map to understand current workflows



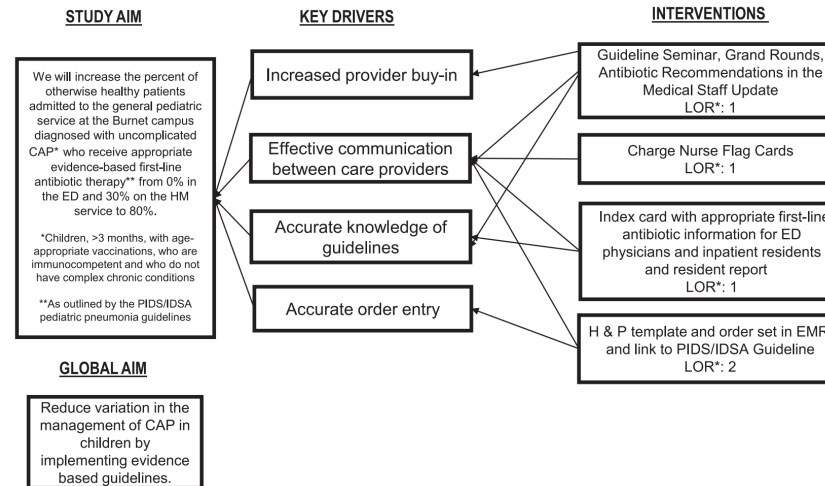
**FIGURE 1**

Process map of antibiotic prescribing for a patient being admitted for CAP. Amox amoxicillin; PNA, pneumonia.

*Ambroggio et al, Pediatrics 2013*

# Example in Practice

## 4: Conduct FMEA and determine key drivers



**FIGURE 2**

Key driver diagram summarizing the project aim and interventions implemented to achieve the study aim. H&P, history and physical examination note; LOR, level of reliability.

*Ambroggio et al, Pediatrics 2013*



# Example in Practice

---

## 5: Plan and do the intervention(s)

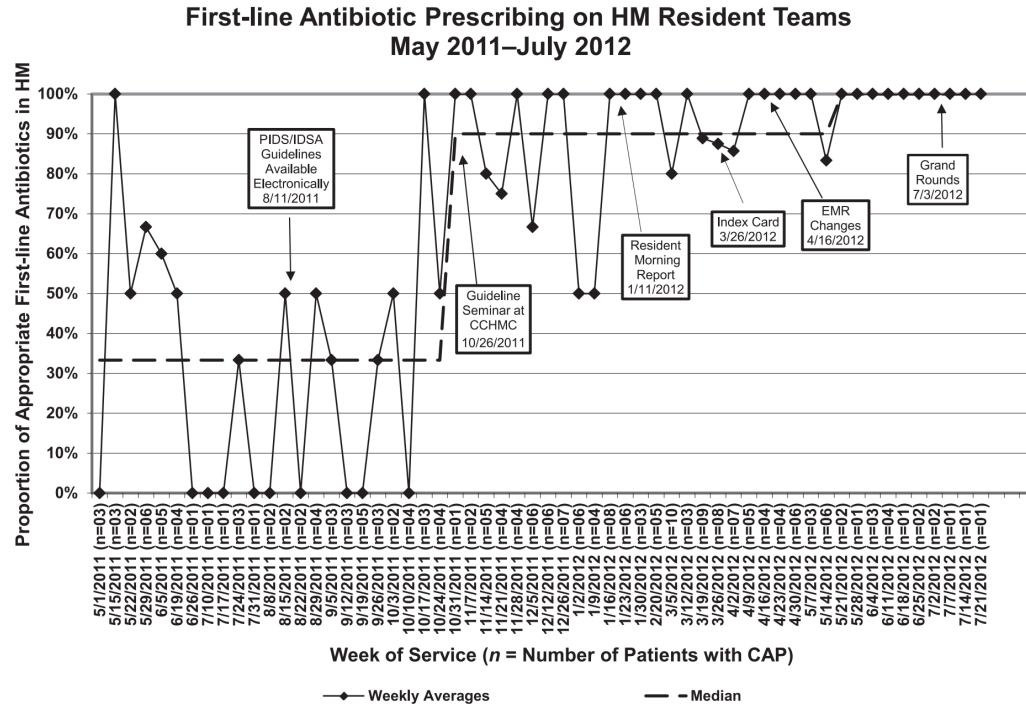
- Educational seminars re: ID guidelines
- 4x6 index card with recommendations in bullet points
- Included recommendations in housestaff guide
- Incorporate CAP guidelines into an existing CAP orderset, with links to guidelines
  - Default orderset to recommended 1<sup>st</sup>-line antibiotics
- Update EHR note templates to reflect guideline-based plan of care

*Ambroggio et al, Pediatrics 2013*



# Example in Practice

## 6: Measure the change using run chart



Ambroggio et al, *Perceptions* 2013

# Six Sigma

---

Developed by Motorola in the 1980s

Name comes from ideal of having a process in control within six-sigma (“perfect” process) – 3.4 defects per million opportunities, or 99.999% error free.

Steps – DMAIC (note some similarities to PDSA/PDCA)

- **Define** – project charter, needs, scope, goals
- **Measure** – data collection plan, sources of data to measure defects, design control charts to monitor process
- **Analyze** – identify deviation from standards, sources of process variation
- **Improve** – identify creative solutions, implement plans
- **Control** – process is updated; policies, guidelines, error-proofing put in place



# Lean Methodology

---

Taiichi Ohno, Toyota Motor Corporation Engineer in 1950s

Remove all non-value added activities

- *Muda* – “uselessness, wastefulness”
- *Mura* – “irregularity, unevenness”
- *Muri* – “unreasonable, burdensome work”

# Seven Types of *Muda*

---

1. Overproduction / underproduction
2. Inventory (ex: too much inventory of a perishable good in stock)
3. Repairs / rejects (assembly mistakes)
4. Motion (poor work area ergonomics)
5. Processing (e.g. outdated policies, procedures)
6. Waiting (patients languishing in a waiting room)
7. Transport (transporting patients unnecessarily)

# Lean: Value Stream Mapping

---

Graphical depiction of inputs, throughputs, outputs

Highlights opportunities for improvement

Frontline staff bring forth ideas for improvement

Tests of change implemented as “kaizens” or “change for the better” – small improvements, rapid adaptation to results, continuous quality improvement

# Lean: Kaizen

---

Standardize operational activities

Measure operation

Compare measurements to requirements

Engage frontline staff in identifying opportunities to improve

When improvements work, make them the new standard

Repeat

# Lean: Supporting Conventions

---

## **Kanban** cards

- Visual indicators that a supply is empty
- Ex: red flip tabs on the top of hand sanitizer dispensers



## **Andon**

- Visual indication that indicates production status / alerts when assistance is needed
- Ex: “X-Ray In Progress” light

## **Poka-yoke**

- “mistake avoiding” in design or process
- Intentional incompatibility of refill spouts for inhaled anesthetics
- Color-coding of medical gases - yellow for air, green for oxygen
- The notch on your SIM card that only allows it to be inserted in one orientation





# Your Homework

---

Review the [PDSA Tutorial](https://www.albany.edu/cphce/neo_public/pdsa_tutorial.pdf) on the New York State Perinatal Quality Collaborative website

[https://www.albany.edu/cphce/neo\\_public/pdsa\\_tutorial.pdf](https://www.albany.edu/cphce/neo_public/pdsa_tutorial.pdf)

Pick a hypothetical clinical quality improvement project of your choosing and use the guide to design a PDSA project (you can stop at the “PLAN” stage for this exercise).

---

# End of Lecture

# Supplement: SPC “Count” Examples

---

## Number of workplace injuries per month

- Count data → number of injuries, unknown denominator (employee can be injured multiple times)
- “Equal area of opportunity” → workplace doesn’t change size, time period is fixed
- Therefore, you would use a C Chart (think “Count”)

## Number of line infections per 1000 patient days

- Count data → # of line infections, but unknown denominator (no limit on # of infections per patient day)
- “Unequal area of opportunity” → # patient days changes per observation period
- Therefore, you would use a U Chart (think “Unequal”)

## Proportion of patients who had medication reconciliation performed per encounter

- Count data with known denominator → total number of patients/encounters is known
- Numerator can’t exceed denominator → Med Rec only performed once per encounter
- Therefore, you would use a P Chart (think “Proportion” Chart)



# Supplement: SPC “Continuous Variable” Examples

---

## Variation in Patient Days per month

- Not a count or classification of nonconformities
- Has a “scale” (days, time)
- Measurement is individual patient days, not an average → subgroup size = 1
- Therefore, you would choose an I Chart (think “Individuals”)

## Time from ED to OR for sequential cases of isolated femur fracture

- Scale = time
- Individual, sequential measurements (x-axis is each femur fracture case in sequence)
- Therefore, you would choose an I Chart

# Supplement: SPC “Continuous Variable” Examples

---

## Average turnaround time for STAT CBC tests per month

- Time is continuous scale
- Measurements are an average, not individual / sequential observations
- Therefore, you would choose an X-bar Chart (X Chart) —

## Average cost per appendicitis case per month

- Scale = cost
- Average of multiple measures —
- Therefore, you would choose an X-bar Chart (X Chart)

# Supplemental QI Materials

---

Institute for Healthcare Improvement Open School

- <http://www.ihl.org/Pages/default.aspx>
- <https://www.youtube.com/user/IHIOpenSchool/videos>

Example of QI tools in action

- Ambroggio L, Thomson J, Murtagh Kurowski E, Courter J, Statile A, Graham C, Sheehan B, Iyer S, Shah SS, White CM. **Quality improvement methods increase appropriate antibiotic prescribing for childhood pneumonia.** Pediatrics. 2013 May;131(5):e1623-31. PubMed [PMID: 23589819](https://pubmed.ncbi.nlm.nih.gov/23589819/)

# Suggested Additional Reading

---

Mainz J. **Defining and classifying clinical indicators for quality improvement.** *Int J Qual Health Care* 15, 523–530 (2003). [[Article](#)]

Ransom SB, Joshi MS, Nash DB. **The healthcare quality book.** Chicago: Health Administration Press, 2005. 495 p.

Varkey P, Reller MK, Resar RK. **Basics of quality improvement in health care.** *Mayo Clin Proc.* 2007;82(6):735-739. [[Abstract](#)]

**How to Improve [Internet].** Cambridge (MA): Institute for Healthcare Improvement; [cited 2020 Aug 21]. Available from: <http://www.ihl.org/resources/Pages/HowtoImprove/default.aspx>

Hughes RG. **Tools and Strategies for Quality Improvement and Patient Safety.** In: Hughes RG, editor. *Patient Saf. Qual. Evid.-Based Handb. Nurses* [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK2682/>