Patient Safety and Quality Improvement 101

GLOBAL HEALTH CONFERENCE

NOVEMBER 2020

Objectives

- To understand why Patient Safety and Quality Improvement is foundational to today's healthcare delivery
- To know the meaning of the basic vocabulary of patient safety/quality improvement
- To Understand the basic PS/QI methods

Traditional Patient Safety/Quality Improvement

"To Cure Sometimes

To Relieve Often

To Educate Unceasingly

To Comfort Always"

Overarching Aim for HC

 In the patient's words: "They give me exactly the help I need and want exactly when I need and want it"

•Thus the ideal 21st Century HC System evaluates the care through the patient's eyes

Why Bother with Pt Safety/Quality?

 Do You Have an Ethical Responsibility to Consistently Provide Good Patient Care?

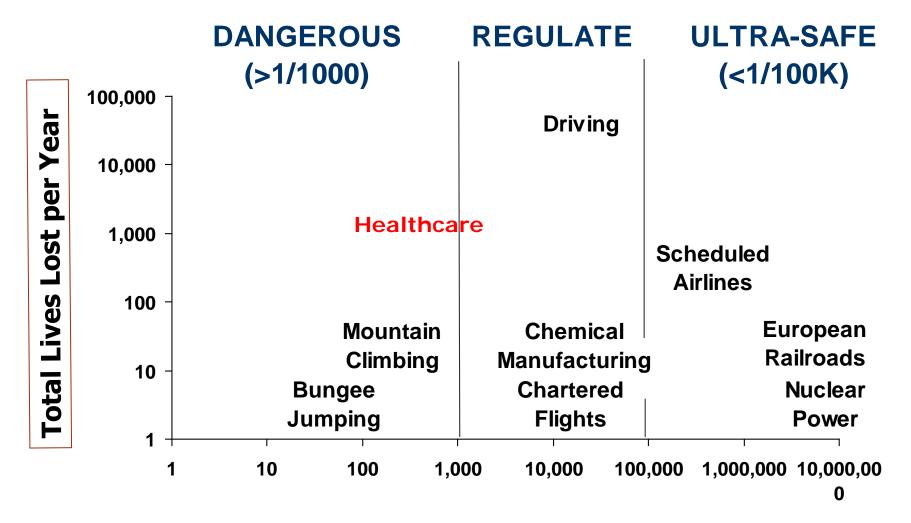
Is your community better off because your healthcare facility is present in it? Questions to ask in Evaluating Healthcare Outcomes – Evidence Based Medicine

- 1. What portion of your patients are receiving care in line with current best practice (evidence-based medicine)?
- 2. How does the healthcare you provide need to change to reflect best practice (evidence-based medicine)?
- 3. Do your healthcare professionals / managers have the skills and support to make these necessary changes?

Which is the Most Dangerous?



How Hazardous is Health Care?



Number of encounters for each fatality

Patient Safety

•HC has two implicit moral/ethical promises to patients that entrust their care to us, we promise to:

• Do everything possible to help them

Not hurt them

Patient Safety

- Patient Safety is the prevention of medical errors and adverse events
- Integrating PS into practice is a very complex process in that it interacts with both clinician practice and the institutional "System"
- •HC systems must be built on a "Culture of Safety"
 - A system designed to prevent errors while empowering individual staff members to promote safety and recognize and respond to errors that occur

Patient Safety

•An 80-90% success rate to an institution sounds "great"

- But from a patients' standpoint, it is unacceptable
 - For the individual patient, reliability is an "all-or-none" matter

• Safety is Quality for an "n" of one

•Optimal Patient Safety requires a framework for improving reliability - standardized protocols for care that are evidencebased and widely agreed upon is essential

Current Variation in Practice

- Study of Content of Care to Adults between 1996 and 1998:
- •Only 55% of patients received "recommended" care (439 process-of-care measures)
- Up to 10,000 lives per year savable from pneumonia could be prevented annually

•The "Gap" between what we know works and what is actually done is so large it requires attention

McGlynn, Asch, Adams, Keesey, Hicks, De Christofaro and Kerr NEJM 348;(26) 2635-2645 June 26, 2003

Patient Safety – Systems Thinking

- •No system will ever be able to "eliminate all errors."
- •A key principle: all patient safety programs that are focused exclusively on eliminating errors will fail
- •We are human. We will never eliminate all errors. The real goal is to prevent harm to patients
- •How: by taking a systems approach to problem solving

Medical Errors

•IOM Definition:

"The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (including problems in practice, products, procedures or system)"

- "A Process that does not proceed the way it was intended by its designers/managers"
- A more practical definition:

"Freedom from accidental injury due to medical care"

Patient Safety Errors

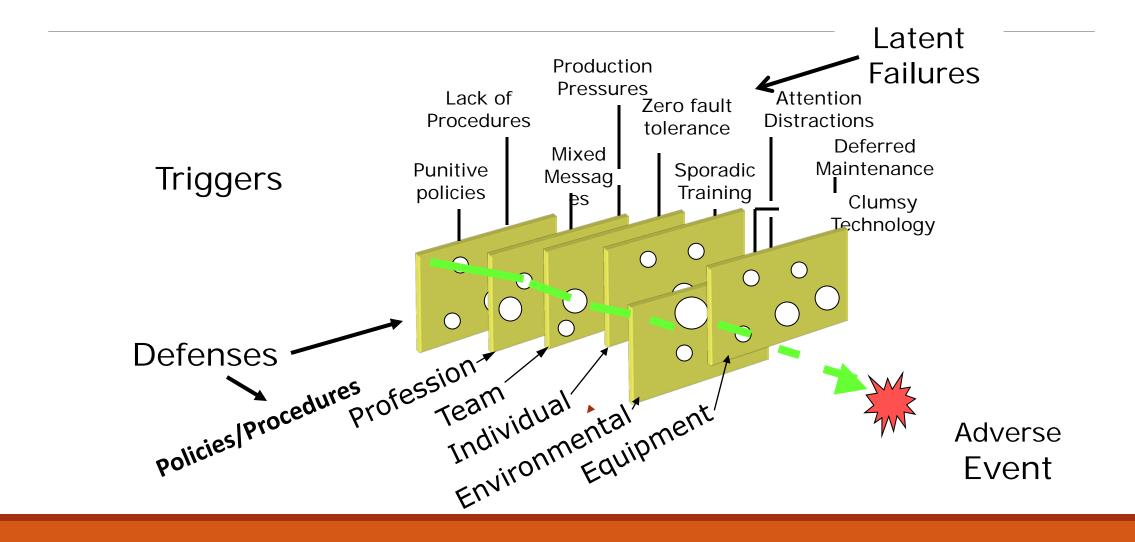
•Preventable harm is the third leading cause of death

•Medicine squanders ~ 30-40% of monies spent on HC

•Surgical instruments left in patients, overdoses in pediatric patients with blood-thinners, Operates on the wrong side of the body, delivers appropriate therapy (all of them) only about 55% of the time, and kills ~ 100k per year.

 About 17% of hospitalized patients suffer a diagnostic error and ~ 7% suffer a med error

The Swiss Cheese Model (Reason, 1991)



Sentinel Event

An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof

Serious injury includes loss of limb or function. "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome

"Near Misses"

 "Near misses are the huge iceberg below the surface where all the future errors are occurring"

- •Close calls are given the same level of scrutiny as adverse events that result in actual harm
 - They are 3 to 300 times more common than actual adverse events
- •A willingness and an way (means) to report problems is essential to safe care because you can't fix what you don't know about
- •As important, if not more important to evaluate a new miss than evaluating an actual misadventure that resulted in patient harm

Normal Response to a Medical Error

•Go directly to the staff members involved (the sharp end of the chisel)

- The Physician/medical residents
- The Nurse

•However, this is counter to a Safety Culture ("Just Culture") concept:

- Do not automatically blames the caregiver
- Instead, thoroughly investigate the incident
- Root Cause Analysis:
 - RCA is the process that seeks to explore all of the possible factors associated with the incident by asking what happened, why it happened and what can be done to prevent it from happening again

Just Culture

An atmosphere of **trust** in which people are encouraged (even rewarded) for providing essential safety-related information. Individuals trust that they will not be held accountable for system failures; but, are also clear about where the line must be drawn between acceptable and unacceptable behavior

System Characteristics That Promote a Culture of Patient Safety

•Culture Change: is it <u>Safe</u> to report adverse events?

•<u>Simple</u>: one-page (or less) report

 Share Feedback: in an <u>Effective</u> system – adverse events are analyzed by experts and all share in feedback

Patient Safety and QI Gurus

- •Walter Shewhart: first to describe the PDSA cycle and statistical control
- •W. Edwards Deming: focus on process improvement, management has the final responsibility for quality
 - Special Causes of variation: unnecessary variation associated with specific causes: equipment, people
 - Common Causes of variation: those associated with systems aspects such as design, training, machines or working conditions
- •Joseph Juran: QI is a never-ending process, Quality goals must be specific
- •Ishikawa/Taguchi: statistical techniques / quality tools
- •Paul Betalden, Donald Berwick, Lucien Leape, and Brent James

The Catalyst



"To Err is Human" 1999

~ 98,000 preventable deaths

This was the "what"

"Crossing the Quality Chasm" 2001 Quality as a **systems** issue This was the "**how**"

	The Six Aims For Improvement	
L	Safe	Effective
	Patient-centered	Timely
	Efficient	Equitable

Patient Safety Goals

- 1. Improve the accuracy of patient identification:
 - a. Two patient identifiers
 - b. "Time Out Process:" Prior to the start of any invasive procedure conduct a final verification process to confirm that all team members understand:
 - 1. You have the correct patient
 - 2. You are doing the correct procedure
 - 3. On the correct site,
 - 4. With the availability of appropriate ancillary data
 - 5. "Time-Out" is documented



BY STAYSKAL FOR THE TAMPA TRIBUNE

Patient Safety Goals

2. Improve the effectiveness of Communication among caregivers:

- Verbal and telephone orders or critical test results require "read-back" verification
- Never document with unapproved abbreviations, acronyms or symbols ("Do Not Use" list)
- Reporting and receipt of critical test results and values must be timely (<60 minutes)
- Standardize "hand off" communications including time to ask and answer questions (such as SBAR)

Communication: <u>SBAR</u>

- •<u>S</u>ituation:
 - "I am calling about Mrs. Smith; I am worried about her vital signs"
- •<u>B</u>ackground:
 - She was admitted 2 days ago with chest and abdominal trauma"
- •<u>A</u>ssessment:
 - "She is hypotensive and tachycardic; I think she is going into shock"
- •<u>R</u>ecommendation:
 - "I need to you come see her NOW. Are you available?"

Patient Safety Goals

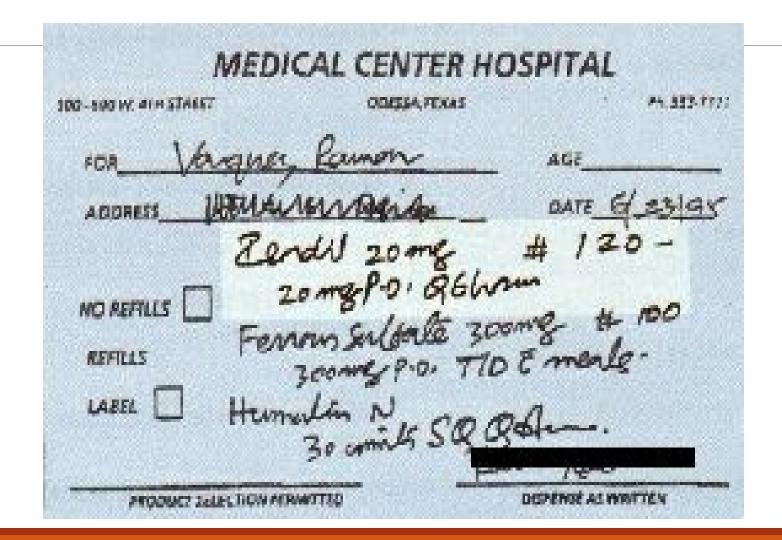
- 3. Improve medication safety:
 - Drug concentrations have a standardized list that limits the amount that can be given
 - Actions are taken to prevent look-alike and sound-alike medication errors
 - Label all medications and solutions used in OR and Procedure areas
- 4. Reduce the risk of health care-acquired infections
 - Comply with hand hygiene guidelines: wash hands for at least 15 seconds before and after delivering care or use alcohol-base hand gel
 - Manage all unanticipated death (s) or major permanent loss of function associated with a healthcare acquired infection as a sentinel events

Written Medication Orders: Illegible Handwriting

- •16% of physicians have illegible handwriting.¹
- •Common cause of prescribing errors.^{2, 3, 4}
- •Delays medication administration.⁵
- •Interrupts workflow. ⁵
- •Prevalent and expensive claim in malpractice cases.³

Anonymous. *JAMA* 1979; 242: 2429-30; 2. Brodell RT. *Arch Fam Med* 1997; 6: 296-8;
 Cabral JDT. *JAMA* 1997; 278: 1116-7; 4. ASHP. *Am J Hosp Pharm* 1993; 50: 305-14;
 Cohen MR. *Medication Errors. Causes, Prevention, and Risk Management;* 8.1-8.23.

Can you read this?



Medication Errors

PRESCRIPTION I	FAULTS:
----------------	---------

- Inappropriate prescribing
- Underprescribing
- Overprescribing

Duplicative errors

Prescribing drugs that interact

Given to the wrong patient

PRESCRIPTION ERRORS:

- Error in drug dose
- Route of administration
- Frequency of use
- Duration of therapy

Surgical Check List

•A 2007 WHO effort to reduce the number of surgical deaths

•Aim: to reinforce accepted safety practices and foster better communication and teamwork between clinical disciplines

•A tool for clinicians to improve the safety of their operations and reduce unnecessary morbidity and mortality

Patient Safety Errors – Hospital-Acquired Infections

- •CLABSI checklist: in SICU (Johns Hopkins) resulted in a 70% reduction in CLABSI in the 100 ICUs in Michigan:
 - But the checklist is only one aspect
 - Culture and Behavior change with Robust measurement

•9 preventable harms: adverse drug events, CAUTI, CLABSI, Fall injuries, Pressure ulcers, Venous Thromboembolism, VAE, Obstetrical adverse events

Systems Thinking:

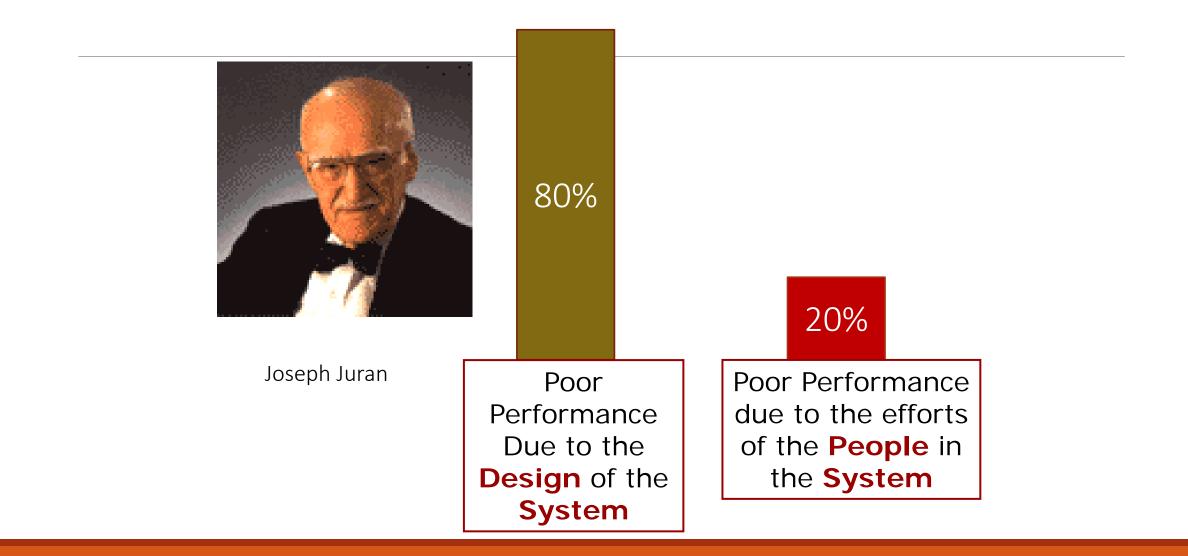
- •Systems thinking is not easy
- •Not a natural act: we see the parts not the whole
- •But to master the art of Quality (system) Improvement we must have a deep and fundamental understanding of how the parts are connected in our entire complex Healthcare system
- "We must accept human error as inevitable and design around that fact." - Don Berwick, M.D.
- "The Search for zero error rates is doomed from the start"

Systems Thinking

"Running a Hospital isn't Brain Surgery....

It's Harder!"

Systems Behavior



System Thinking

"Healthcare Organizations are the most complex organizations to manage"

Peter Drucker

Quality Improvement (QI)

•Quality is the "extent to which the clinician or organization meets or exceeds the needs and expectations of patients"

•QI involves the systematic and continuous implementation of changes that measurably improve patient care

 QI is based on the understanding that it is easier to improve that which can be measured, thus QI entails monitoring and assessment

Continuous Quality Improvement

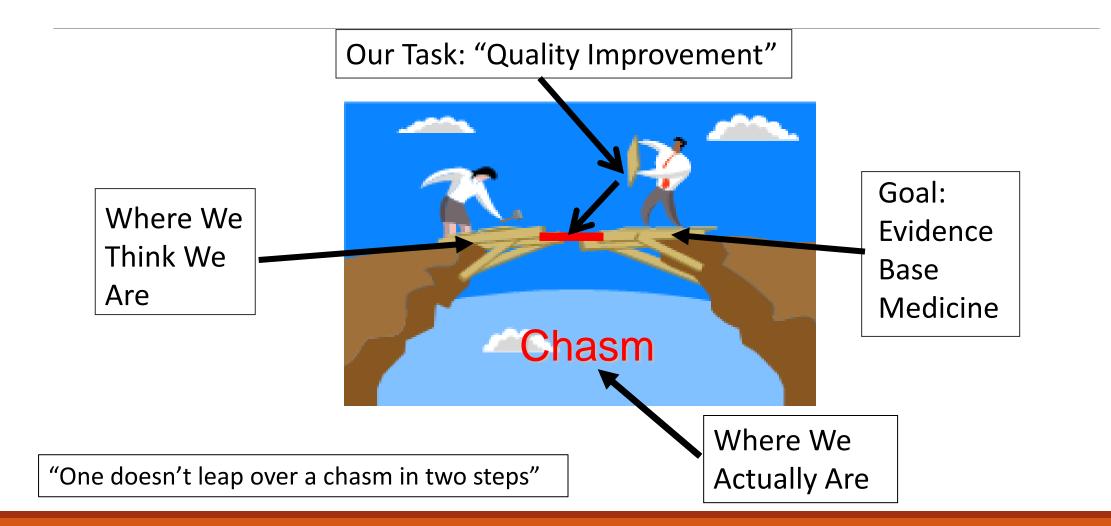
•CQI is both a management philosophy (management's job is to optimize the system" Deming) and a management method:

- It is rigorously based in fact-based decision making
- It is systems-based
- It involves unit-based teams
- It emphasizes continuing the system analysis and improvement
- It is organization learning
- It uses Quality Tools
- It is based in a facility-wide Quality Council
- It is based on Senior Management Commitment to make processes effective
- It uses Statistical analysis
- It uses appropriate benchmarking (peer comparisons) to identify best practices

The 6 Fundamental Domains of Quality

- 1. Safety: as safe in healthcare as in our home
- **2.** *Effectiveness*: matching care to science; only "Appropriate" care avoiding overuse of ineffective care and underuse of effective care
- **3.** Patient (Person) Centeredness: honoring the individual, and respecting choices
- 4. Timeliness: less waiting for both patients and those who give care
- 5. *Efficiency*: reducing waste: "Improving my work is my work"
- 6. Equity: closing gaps in health status amongst groups

"Crossing the Quality Chasm"



Classic Way to Define Impaired Quality

•Overuse (of procedures that cannot help) [Up to 15% of actions]

•Underuse (of procedures that can help) [Up to 50% of actions]

•Misuse (errors of execution)

"Science of (Q) Improvement"

•Basically the Scientific Method:

- Measure the current process (baseline status)
- Analyze the steps in the process (process mapping)
- Create a "Hypothesis" (change part of the process)
- Experiments changing the process (RCI: PDSA Cycle)
- Measuring the new results (QI and Pt safety)
- Analysis: accept (incorporate into your processes) or reject the change studied

The "First Law of Q Improvement"

[Step #1]

• "Every System is perfectly designed to get the results it gets" Paul Betalden, M.D.

•This reframes Performance from a matter of *effort* to a matter of system *design* (change from existing form)....

If you want to improve results you must change the system!

Second "Law of Q Improvement:" Transparency

- Be open and honest about "failed" tests:
 - These are often the most valuable RCIs
 - It is natural for humans (HC workers) to want to forget about experiments that don't work

•But all scientists know that learning from failure is just as important as learning from success

Third "Law of Q Improvement:" Attitude

•To learn something new is **Humbling**. It requires that we put aside our "expert" status and become learners: disciples, open, teachable, obedient

•We don't like feeling stupid; we'd much rather be the Teacher, the one with all the answers, but first we must embrace the humility discipleship requires

•Willingness to Fail

Fourth "Law of Q Improvement:" Agility

How do I implement this the new information in this Thursday's *Lancet* into next Tuesday's new practice?

"What can I do by Next Tuesday?"

Fifth "Law of Q Improvement" is "Team Based"

Staff need a culture that acknowledges that the best care comes from people working as a team, not as "lone rangers" with the sole responsibility for the success or failure of their actions

- T ogether
- E veryone
- A cheives
- M ore

"Doctors still perceive that they are the

center of the healthcare universe. Healthcare

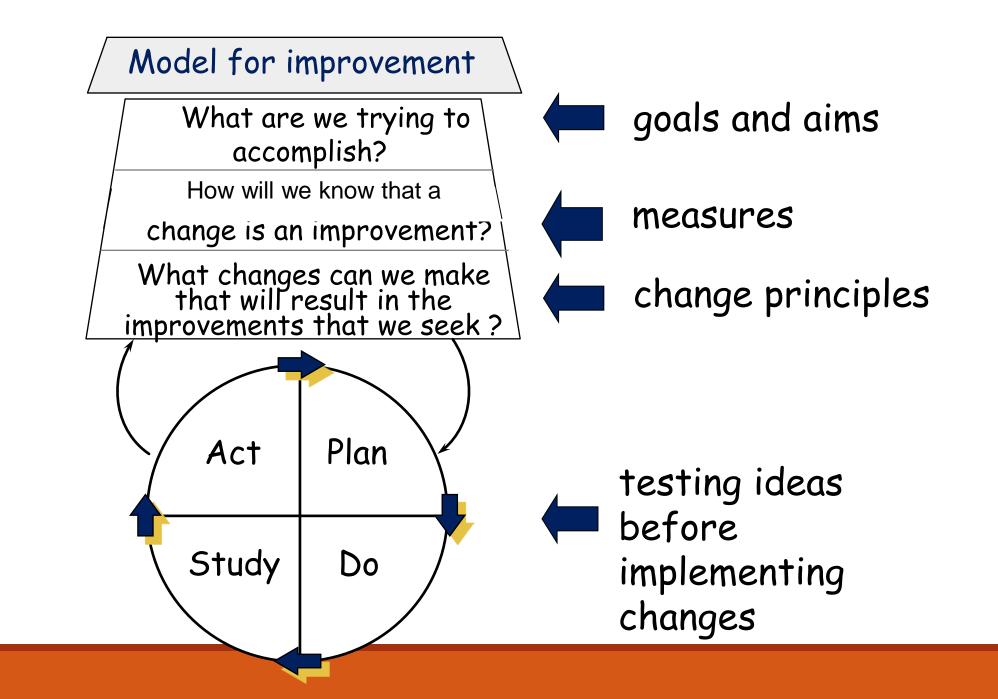
is a team sport, and we don't optimally work in teams"



	Project Name:					
	Date Chartered	Start Date:	Target Completion Date:			
	Project Team	Phone	Title			
		!				
	Fill in team members names and					
	contact information	÷				
		i				
	Process Owner	Phone	Title			
Team						
rearr	Problem Statement					
Team Charter	 Describe the problem, opportunity, or objective in concise, measurable terms. 					
Charter	 Include a summary of the problem and impact (a.k.a. PAIN). 					
	Goal Statement					
	 Describe the team's improvement objective Begin with the words "reduce, eliminate, control" Should be 'SMART' – specific, measurable, attainable, relevant, timebound Project Scope Where does the process under investigation start? Where does this process stop? 					
	 What is inside of the project scope? What is outside of the project scope? 					
	 Deliverables What end result(s) do are expected to be achieved from this project? 					
		low will you know that any changes have resulted in improvements?				

Quality Improvement Methods [EBM for H C Organizations]

- Betalden and IHI Model of Improvement [Rapid Cycle Improvement]
- 2. Lean Thinking
- 3. Theory of Constraints
- 4. Queuing Theory
- 5. Six Sigma
- 6. ISO 9001
- 7. Baldrige Criteria for Performance Excellence



AIM Skill #1

- •Use the Acronym of "SMART" (to help choose an appropriate "aim")
 - Specific
 - Measurable
 - Attainable
 - Reliable
 - Timely

•Aims should be ambitious – stretch goals

 Make it obvious that the current system is inadequate - a new one is required

Examples of Strong Aim Statements

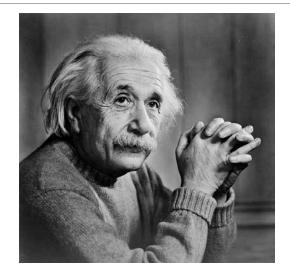
- Improve (i.e. increase) the number of inpatients meeting "continued" stay criteria (these criteria are Governmental criteria that have to be met in order for insurance to pay for that day's stay in the hospital.
- By Jan. '21, the # pts transferred from ER to ward < 1 hour from decision to admit will decrease by 40%
- To reduce the percentage of Observation stays converted to an Admission stay from 48.5% in FY20 to 30% or less by the end of CY21
- To reduce the average length of stay from 5.48 to 5.00 by January 1, 2021

Measurement

[Skill 2]

- •You "can't fix something you don't Measure"
- Remember: Measurement is not the Goal Improvement is the goal
- •You need just enough data to know whether the changes you put in place are leading to improvement
 - Do not wait for a big "Master Plan"
 - Be agile: "What can I do by next Tuesday?"
 - Track and trend your data over time (Run Chart)

Einstein on Data Collection



"Not everything that counts can be counted, and not everything that can be counted counts"

"Six Sigma"

- In statistics, a 'sigma' refers to the standard deviation from the mean of a population
- •Std Dev describes the likelihood of your next data point deviating form the mean of the whole data set

•Six Sigma is all about variance reduction

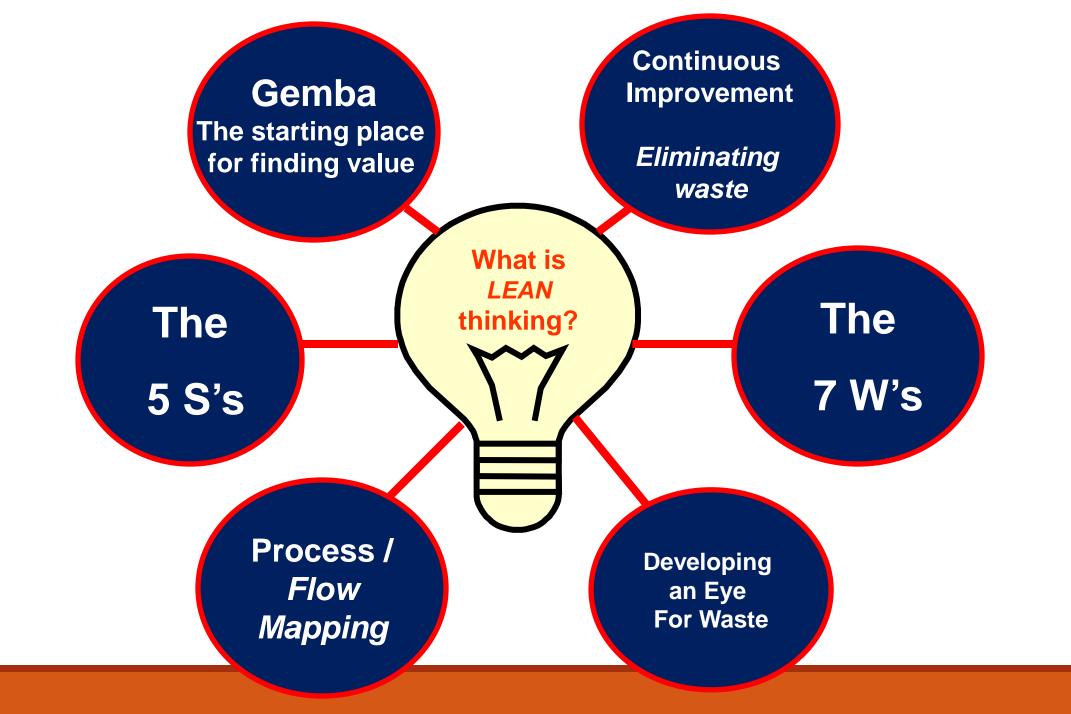
- Variance is a symptom of waste
- High variance means lots of waste (low sigma)
- •Six Sigma is very problem focused- It uses DMAIC to analyze a problem
 - Define, Measure, Analyze, Improve and Control
 - Thus, very similar to PDSA cycles/Rapid Cycle Improvement

Lean Thinking

Lean is an improvement methodology and mindset that centers on:

- Eliminating waste
- The consistent delivery of Value
- The resolution of bottlenecks and constraints that affect the consistent delivery of value by maximizing flow

In Lean, Value is defined by the Patient and family



5 S:

Sort, Set in Order, Shine, Standardize, Systematize

- 5 S: an organized, never ending, effort to
 - Remove all physical waste out of the workplace that is not required for doing work in that area
 - Setting things in order
 - Identify, label, allocate a place to store it so that it can be easily found, retrieved and put away

Lean Six Sigma: 5S

5S is a workplace organization technique composed for five primary phases: Sort, Set In Order, Shine, Standardize, and Systematize.



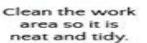


SET IN ORDER

Keep only Arrange items necessary items to promote in the workplace. efficient workflow.



SHINE





STANDARDIZE

Set standards for a consistently organized workplace.



SYSTEMATIZE

Maintain and review standards.



Average Time To Get 8 Drugs = 3:07



"Quality Improvement" - Measurement Tool Kit

•QI Tools: (the most common ones)

- Run Chart [relates data over time; has improvement been secondary to changes?]
- Pareto Chart [helps stratify causes]
- Flow Mapping (Process) Charts [describes a process: current and ideal]
- Cause and Effect diagrams (Fishbone/Ishikawa Charts) [identifies sources of variation]
- [Statistical Process] Control Charts [Shewhart: Is the process "in control"]
- A 3 Diagrams [A structured cycle of improvement that makes problem solving visual by telling a story]

Run Charts

- Measures what we are trying to improve over time
- It helps answer the Q: Are we doing better since implementing the changes we made?

- Does it tell us what us need to do?
 - No!

Run Chart – MRI Backlog



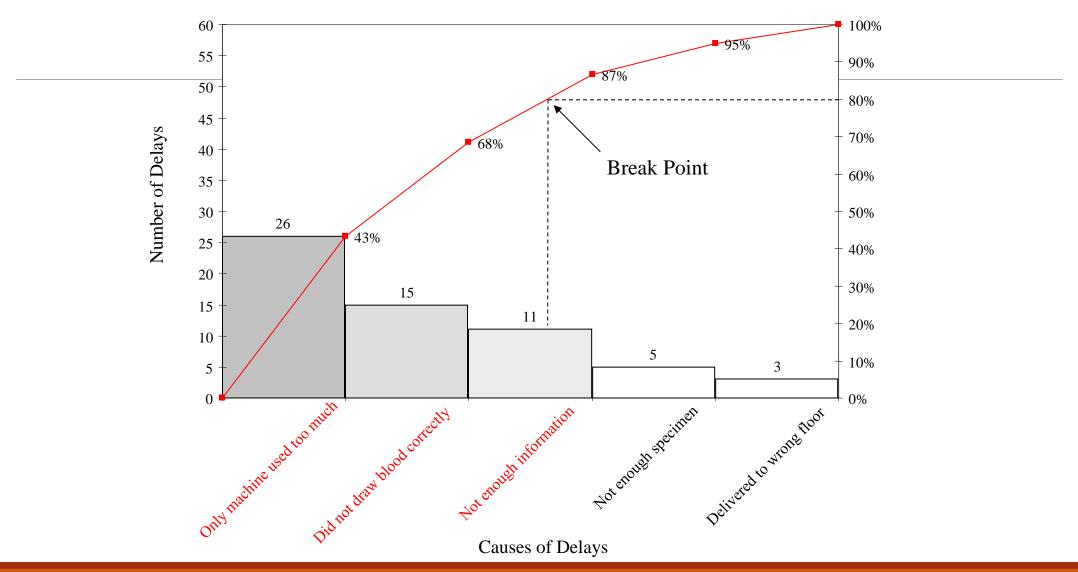
QI Tool – Pareto Chart

•A pareto diagram is a vertical bar chart with the bars arranged from the longest first on the left and moving successively towards the shortest

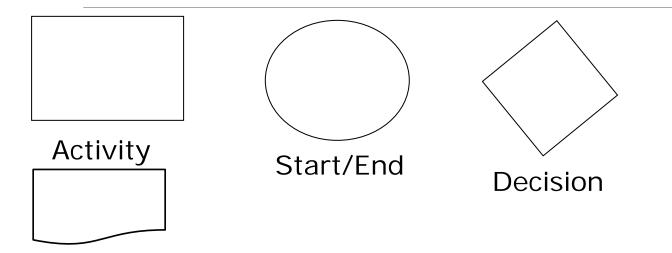
•The arrangement of the vertical bars gives a visual indication of the relative frequency of the contributing causes of the problem with each bar representing one cause

Pareto Chart for Late Lab Work





QI Tools – Process Mapping (Flow) Chart

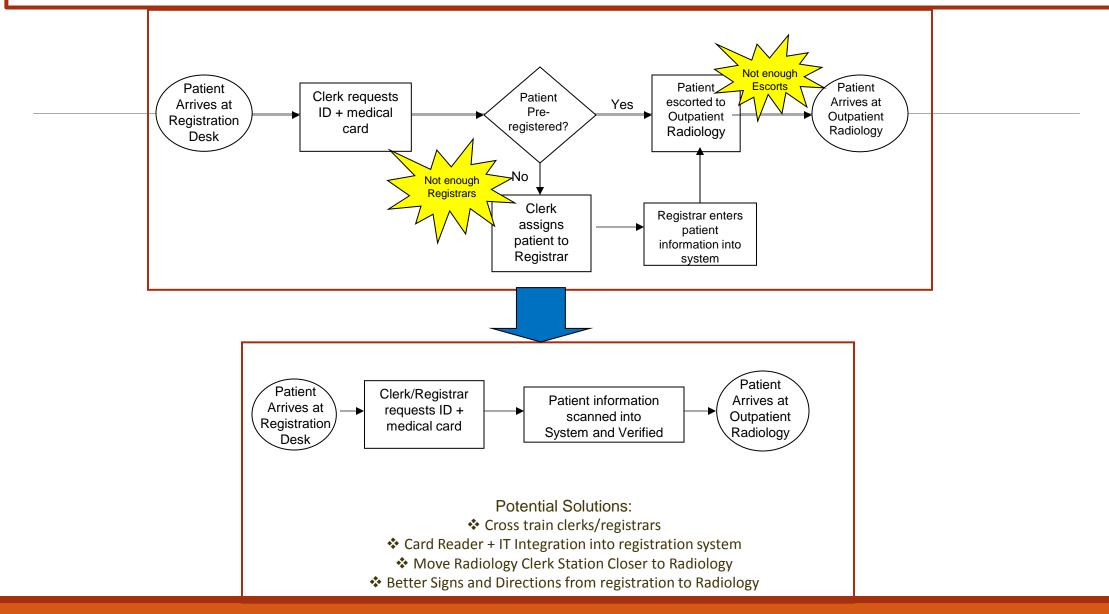


Used to understand the current process and identify opportunities for improvement. It shows the workflow through the process including all activities, decisions, delays, and measurement points

Document

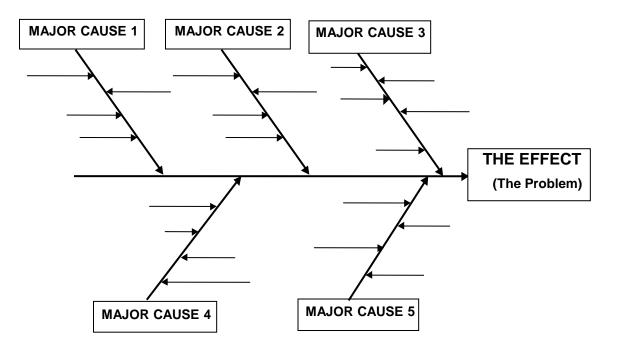
A pictorial representation of how a process works – the sequence of actions that must be carried out to complete a specific task

Process Mapping: Current State to Future State



The Cause-And-Effect Diagram

Used to systematically analyze the *special* causes of a problem. It begins with major causes and works backwards to the root causes. It organizes the results of the *brainstorm*. Also known as the *fish-bone diagram* and the *Ishikawa diagram* (named after its inventor, Dr. Kaoru Ishikawa of Japan)



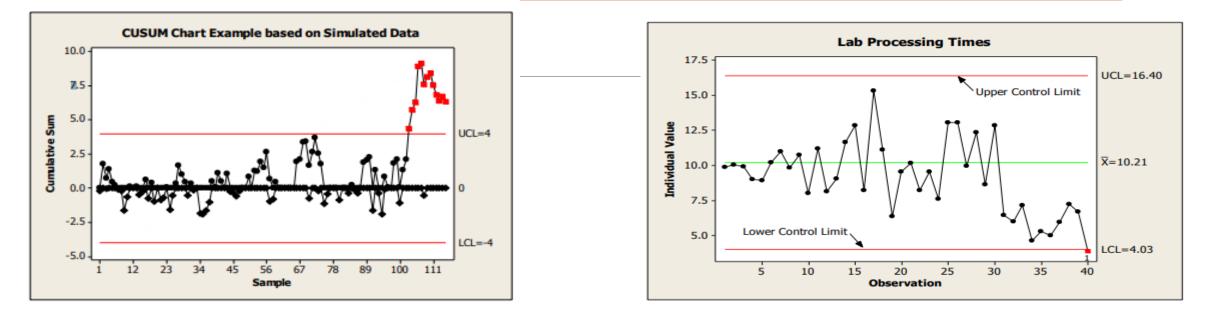
Common Categories of Major Causes (5Ms + E):

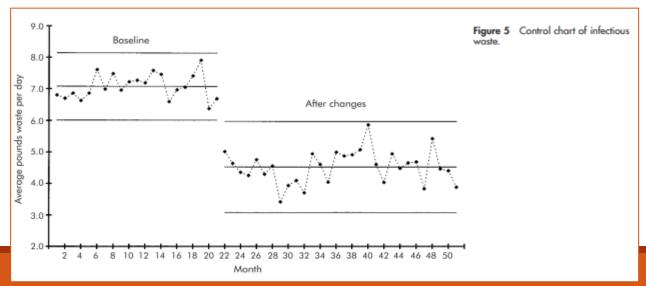
- Man (People)
- Methods (Policies and Procedures)
- Materials (Supplies)
- Machine (Equipment)
- Money
- Environment

Control Chart

- Is a "run chart" that shows the "control" limits of +/- three Standard Deviations
 - It is derived from simple statistics [Many statistical packages will automatically derive these charts]: mean, Std Dev and range
 - It doesn't tell us what to do; It shows if the system 'in' or 'out' of control?
- Two types of "variation"
 - Common cause the object of CQI
 - Variation inherent in the process- usually random in nature
 - Only reduced by improving the underlying system (process)!
 - Special cause the object of QA
 - Externally caused attributable to a specific source non-random

Control Chart



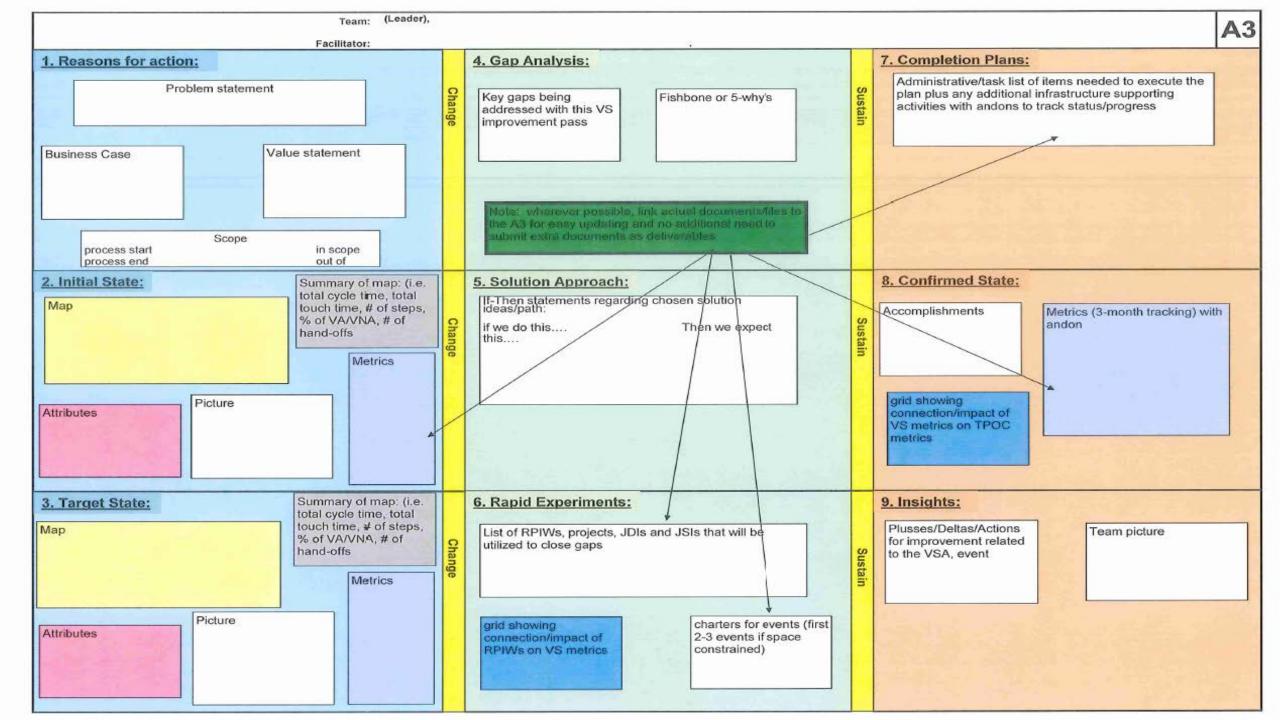


Lean A3 Thinking

- •A standardized approach to problem solving:
 - For Executive Leadership Facility-wide problems/Administrative issues
 - For Front-line clinical staff very helpful in solving unit-based problems
- •A step by step direction to problem solving
 - Continuous Quality Improvement (Patient Care + Admin. Systems)
- •The A3 provides a clear, concise, one-page overview
 - It can consolidate large amounts of information in an understandable format using visual display
- The A3 process should become the "default" way of strategic planning/improvements

LEAN A3

1. Reason for A VISION / Analy Team and AIM	ysis	4. Gap Analysis: Change	7. Completion Plan: Sustain new process Spread
2. Current State Map Process Baseline mea		5. Solution Approach: Change Ideas	8. Confirmed State: Sustain & Spread
3. Target (or Fut Map Ideal/Ta Measure	•	 Rapid Experiments (PDSA Cycles =RCI) Change 	9. Insights: Ideas to help sustain and spread



Business Case for "Quality"

• "Quality" (optimum patient outcomes, safety and service) is a moral imperative

- •The principal source of financial return (providing high Quality care) comes from removing "waste" from your 'system'
 - Process inefficiency
 - Overuse
 - Preventable harm

•Who benefits: Patients, clinicians, staff, your hospital's reputation and "He who pays"

Evaluation of Board's Quality/Pt. Safety Role/Responsibility

1. Do high-quality hospital have better management practices than low-quality hospitals?

2. Is there a relationship between hospital board performance and management performance?

3. Do certain types of board practices correlate with comparable management practices?

Board's Role in Quality What Does The Evidence Tell Us?

•Hospitals with high management attention on Quality are more likely

- To be High-quality hospitals (p < 0.01) [43% vs. 14%]
 - One Std Dev increase in management performance was associated with a 20% increase in being a high-quality hospital
- To have higher Board performance (p < 0.001)

•How:

 Attention to Quality by Board Time spent (~25%) monitoring Quality: tracking effective use of Board approved Metrics

•Result: Effective Board governance improves a hospital's overall performance – not just on Quality!

"Board" Role in PS/QI

- •The Ultimate responsibility for your Hospital delivering High Quality Care (via Patient Safety and Quality Improvement) lies with the Hospital Board of Trustees
- Having a Board level "Patient Safety and Quality Improvement" subcommittee is equally important to having a Board "Finance" subcommittee
- A minimum of 25% of every Board of Trustees' Agenda should be devoted to that hospital's Patient Safety and Quality Improvement program

Caution

•The QI Principles are <u>Tools</u> to mold your local environment.... Not the actual work to make needed change

• Goal: improved Efficiency, Quality and Patient Safety in your facility

•Unless RCI (many PDSA test cycles) take place, you won't get any "change"

• "QI" principles cannot be implemented by Senior Management mandate – instead, it comes from front-line teams

•Different sites using same "QI" principles may lead to different processes in different places (freedom to innovate)

Quality Improvement is a Journey, not a Destination

Some Marvel at the Mountains before them, Others climb them

Institute for Healthcare Improvement

IHI's Open School

<u>http://www.ihi.org/education/</u> ihiopenschool/overview/Pages/default.aspx