



The Fundamentals of Quality-Improvement: How to do QI ! (Part 1)

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Disclosures / COI

We have no disclosures to report

Who Are You?

Experience you've had with QI & Patient Safety

Dreyfus Level	Description		
None	Vague awareness of general QI terms & relevance.		
Novice	Incomplete understanding, approaches QI mechanistically, needs supervision to complete.		
Advanced Beginner	Working understanding of QI concepts, sees actions as a series of steps, can complete simpler tasks without supervision.		
Competent	Good working and background understanding of QI, sees actions in system context, able to complete QI work independently.		
Proficient	Deep understanding of QI, sees actions holistically, can achieve a high standard routinely.		
Expert	Authoritative/deep holistic understanding of QI, deals with routine matters intuitively, goes beyond existing interpretations, achieves excellence with ease.		



Survey of common over-arching QI methodologies

• IHI Model For Improvement

SMARTIE AIMs

Define types of quality measures

• eg, outcome measures, process measures, balancing measures, qualitative

QI Discovery Tools

• Key Driver Diagram, Fishbone, Pareto charts, Process Mapping, 8 wastes

Strong Interventions/PDSA cycles

Introduce QI data interpretation

• eg, QI vs research data, run charts, control charts, pitfalls

How to lead your QI Team and Sustain Gains

• Engaging stakeholders

	LENGTH	START	TOPIC or ACTIVITY	
	15 m	9:05 am	Basic Concepts & Aims	
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BASIC QI CONCEPTS



Why is Quality improvement important to you? YOU CAN MAKE AN ACADEMIC CAREER OUT OF QI

Diagnostic Errors in Primary Care Pediatrics: Project RedDE

Michael L. Rinke, MD, PhD; Hardeep Singh, MD, MPH; Moonseong Heo, PhD; Jason S. Adelman, MS, MD; Heather C. O'Donnell, MS, MD; Steven J. Choi, MD; Amanda Norton, MSW; Ruth E. K. Stein, MD; Tammy M. Brady, MD, PhD; Christoph U. Lehmann, MD; Steven W. Kairys, MD; Elizabeth Rice-Conboy, MS; Keri Thiessen, MEd; David G. Bundy, MD, MPH

Using web-based technology to improve depression screening in primary care settings

Jessica Jeffrey,¹ Minh-Chau T Do,¹ Nastassia Hajal,¹ Yu-Hsiang Lin,² Rachel Linonis,¹ Mark S Grossman,² Patricia E Lester¹

Improving Care and Outcomes for Pediatric Musculoskeletal Infections

Gabrielle Z. Hester, MD, MS,^a Amanda J. Nickel, MPH,^b David Watson, PhD,^b Gloria Swanson, MD,^c Jennifer C. Laine, MD,^{da} Kelly R. Bergmann, DO, MS¹

A Quality Improvement Initiative to Improve Postdischarge Antimicrobial Adherence

Sheena Gupta, MD, MBA,** Britanny Winckler, MD, MBA,** Michelle A. Lopez, MD, MPH,** Marco Costilla, BSN, RN, CPN,* Jennifer McCarthy, RPh,* Jeffrey Wagner, PharmD, MPH, RPh, BCPS,* Amanda Broderick, MD,* Katherine French, MD,* Brittany Le, BSA,* Huay-ying Lo, MD**

QI/PS: It is scholarly, it is a science



QI Projects can meet Fellowship Scholarly Activity requirements

QI Projects and Publications can meet MOC-4 for Certification

Drivers of Improvement



A Model of Translational Research Stages



Translational – T4

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e.g., Regional/National Policy Research; "How can healthcare systems be motivated to implement effectively?"

QI Methods

Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?





LEAN



Why "The Model for Improvement"?

Overarching strategy

- meant to complement other QI methods, not replace
- designed to accelerate improvement

Simple tool/strategy

- easily shared across a collaborative
- bare-bones scientific method

Proven very effective

- by hundreds of healthcare organizations
- to improve many different processes/outcomes

Also, just a great framework to teach QI Science

The Model for Improvement – Key Ingredients:

The Right Questions

What Aim? What Measure? What test(s) of change?

Plan-Do-Study-Act (PDSA) Cycles

To test/implement changes in real work settings Find optimal balance between ideal and practical

Right People engaged with improvement team

Team leadership, front-line wisdom Senior leadership & stakeholder support Highly variable team structures, very local issues

Model for Improvement

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MODEL FOR IMPROVEMENT



Measures

Ideas

Improvement aims cannot be vague



"Soon is not a time, some is not a number."

– Don Berwick, MD



"What gets measured, gets managed."

- Peter Drucker

A written aim is...

A statement of the accomplishments expected from a team's improvement effort

- A communication tool within a group and between the group & larger system
- A tension-creating reminder to aid in garnering buy in for the project
- Targeted to an Audience (C-suite vs Bedside) and Timeframe (near vs long)

Building your aim statement



Style:

- Succinct: 1-3 sentences (not paragraphs)
- Clearly answers:
 "What are we trying to accomplish?"

Example aim statement

By July 2025, Boston Children's Hospital will have reduced by >30% each of three healthcare associated infections – CLA-BSI, VAP, & CA-UTI – throughout the entire inpatient population. [*high-level, long-term*]

- By December 2024, children <5 years old in our clinic will have improved preventive and developmental services provided. We will achieve this by implementing six core changes for prevention & development, so that:
 - > 75% of parents report receiving age-appropriate guidance & education in a way that meets their informational needs
 - > 75% of young children <5 years have an age-appropriate structured developmental screening

[*implementer-level, near-term*]

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Exercise 1: Aims

Working in pairs (or triads), write a concise Aim Statements:

Challenge 1: Pediatric clinic Underserved urban asthma population

Challenge 2: Pediatric emergency department

If time, each of you write an Aims Statement directed at a Quality/Safety Project of interest to you at your facility.

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SELECTING QI MEASURES



Model for Improvement

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MODEL FOR IMPROVEMENT

Aims



Ideas

Q2: How will we know if a change is an improvement?

"All improvement is change,

but <u>not</u> all change is an improvement"



Good measures are needed to detect and steer improvement

Answering the question: "How will we know that a change is an improvement?" commonly requires a balanced set of 3 to 6 measures

<u>Goal</u>: Create data collection methods that are "just enough" (e.g., small sample sizes, regular collection intervals), not "just in case"





Importance of Measurement

 Measures are an indicator of how the system is working at any given time – important feedback

•It shows whether and how changes are working

•All measures have limitations, but the limitations do not negate their value

•The purpose of measurement in improvement work is for *learning* not judgment

3 Types of QI Measures:

Outcome Measures: patient focused, the harm we are trying to avoid or the quality we are trying to deliver (e.g. CLABSI rate)

Process Measures: measuring the processes that lead to your outcomes (e.g. best practice compliance)

Balancing Measures: unintended consequences of our work (the potential downside)

Anecdotal Measures: can't measure, important to learn (e.g. RCA themes)



"Not everything that counts can be counted, and not everything that can be counted counts." - Albert Einstein

Use of Discrepant Process & Outcome Measures to Stimulate Identification of Erroneous Metrics & Contextual Influencers



A – Common Starting Point

Undesirable performance but informed for improvement

B – Common Goal Point

High performance and informed for emerging defects in process

C – Outcome Discordance

- Low performing and uninformed for improvement; preventable adverse outcomes are the learning events
- Question validity of measures (process overestimated, outcome under-estimated)
- Query presence of contextual factors confounding performance and/or measurement

D – Process Discordance

- High performing and informed for prevention, process simplification, de-bundling, etc.
- Question validity of measures (process underestimated, outcome over-estimated)
- Query presence of contextual factors that
 protect performance or affect measurement

Niedner MF (v2016.05.01)

You've got a good measure when...

- Is related to the aim and linked to key changes
- Is easy to collect
 - Fits into clinical flow (e.g. the billing sheet)
 - Already being collected or electronic
- Is simple
- Shows improvement quickly
- Can be collected regularly (weekly, monthly)

Measures need a <u>specific</u> numerator and denominator

What is the problem with the following measures?

Number of medication errors on our floor per month

- How many medications were given that month?
- 1/5 medications is very different than 1/5,000

% of 2 year-olds up to date on their vaccines

• Is the denominator 2 year-olds seen in your clinic, on your clinic panel, including 2 year-olds who no show, 2 year-olds who just started at your clinic?

EXAMPLE METRICS	TYPE (eg, outcome, process, balancing)	INTERVAL (eg, daily, weekly, monthly, etc)	SOURCE (eg, EHR, form)	DERIVATION if any (numerator / denominator)
Ventilator associated pneumonia (VAP) rate in the PICU	Outcome	Monthly	ICE	VAP Events / 1000 Vent Days
Length of Ventilation in the PICU	Secondary Outcome	Monthly	EHR	Mean
Staff compliance with - prevention bundle - droplet precautions	Process Process	Monthly	ICE Audits	All-or-none % = n compliant / n observations
PICU Costs of oral care kits in VAP prevention bundle	Balancing	Monthly	Admin.	\$ / vent day

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Exercise 2: Measures

Working in pairs, identify 2-3 metrics that would help your QI team keep track of and communicate improvement.

Challenge 1: Pediatric asthma clinic

Challenge 2: Pediatric emergency department

If time allows, identify 2-3 metrics for a problem of interest to you at your facility.

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UNDERSTAND QI METHODS/TACTICS



Model for Improvement

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What change can we make that will result in improvement?



MODEL FOR IMPROVEMENT

Aims

Measures


Understanding the Big Picture

Improvement Initiative



Gemba walk KDD Fishbone diagram Process map Spaghetti diagram Pareto charts Impact/Effort matrix 5 why's 8 wastes FMEA Value stream mapping 5S



Key Driver Diagrams Fishbone Diagrams 5 Whys Process Mapping Pareto Charts 8 Wastes

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Key Driver Diagrams

- •Organizes the Model for Improvement for a specific aim.
- •Key Drivers: all the factors that contribute to desired outcome
- •Identifying key drivers helps focus the selection of changes to be tested.
- •Frequently used in publishing to describe the approach





Key Driver Diagrams **Fishbone Diagrams** 5 Whys Process Mapping Pareto Charts 8 Wastes

Kaoru Ishikawa (1915-1989)



Tally Sheet (Used with the Pareto Chart)

Ishikawa Diagram (a.k.a. Fishbone Diagram)

Ishikawa Diagram

- Structured guide for brainstorming
- •Organizes cause(s) to a problem into categories
- •Helps identify possible causes that may otherwise not be readily noticed
- •Allows for drill down to possible solutions
- •Avoids tendency to believe all cause and effect relationship are simply linear (i.e. 1 dimensional)
- Provides VISUAL context to improvement team
- •Use the 6M's as a start

The FISHBONE Diagram (*see the 6M categories*) AKA: Ishikawa Diagram or Cause and Effect Diagram





Aggregate Qualitative RCAs into Quantitative Pareto Chart Data!



Key Driver Diagrams Fishbone Diagrams **5 Whys** Process Mapping Pareto Charts

8 Wastes

The 5 Whys

•Goal: Determine the <u>root cause</u> of a <u>defect</u> or problem.

•Process: Ask <u>"Why"</u> at least <u>5 times</u>

Defect	Reasons
Why-1: Why did THE DEFECT occur?	
Why-2: Why did THAT occur?	
Why-3: Why did THAT occur?	
Why-4: Why did THAT occur?	
Why-5: Why did THAT occur?	
Why-6: Why did THAT occur?	

The 5 Whys



Key Driver Diagrams Fishbone Diagrams 5 Whys **Process Mapping** Pareto Charts 8 Wastes

Process mapping can help...

- Identify waste
- Identify communication or hand-off issues
- Identify all the people involved in a process
- •Show complexity
- •Explain the whole process to the group
- Identify who should be involved in a project to improve the process



Process mapping can occur at multiple levels

10,000 feet: what is our process for admitting a patient from clinic?

100 feet: what is our process for identifying patients who need to be admitted?

10 feet: what is our process for seeing patients?

1 foot: what is our process for entering a room when a patient is waiting?



What we're trying to avoid...





"The first step in any organization is to draw a flow diagram to show how each component depends on others. Then everyone may understand what his job is. If people do not see the process they cannot improve it." W. Edwards Deming



Swim lane diagram



A Process Map Has At Least 3 Versions



What to do with your map?

- •Eliminate things that aren't used
- •Eliminate multiple entry
- •Minimize handoffs
- •Move steps in the process closer together
- •Do tasks in parallel

- Reduce choice of features
- •Give people access to information
- •Take care of basics
- •Coach customers to use the product or service
- •Reduce setup time

Key Driver Diagrams Fishbone Diagrams 5 Whys Process Mapping Pareto Charts 8 Wastes

Pareto Principle

•80% of a problem is caused by 20% of the causes

- Incorporates 2 tools: Tally Sheet and Pareto chart
- Helps prioritization -- best return on your time & effort
- In a crunch,
 - Strive to focus on the 20% (the vital few) that really matters most
 - Caveat: oft times the hardest (e.g., teamwork, communication)
- We're always in a crunch focus on the things that make a difference!



Pareto Principle is Part of Your Life!

- How much of what you learned in medical school, do you apply to work today?
- How much of what you do today, did you have no formal training for?
- How many pairs of shoes do you own and how many of those do you wear 80% of the time?

Tally Sheet

Example from restaurant industry:

- Primary Reason They Did Not Cumulative Return Number of Responses Total Percent Percent **Overprice** 790 45 45 Small Portions 620 36 81 Wait Time 105 6 87 Food is tasteless 65 91 4 No atmosphere 42 3 94 Not clean 33 2 96 33 Too noisy 2 98 Food is too salty 14 0.8 98.8 **Unfriendly staff** 13 0.7 99.6 Food not fresh 0.3 100 5 Total 1720 100 100
- Brainstorm- categories should be specific, but broad enough to focus on a problem
- Collect data
- Sort data from most common to least common
- Calculate the cumulative percentage for each cause

Pareto Chart plots the total count of various "causes" as a cumulative "percentage" of the total problem

Tally Sheet + Pareto Chart = Pareto Principle

Primary Reason 1 Return	նիey Did Not	Number of Responses	Total Percent	Cumulative Percent
Overprice		790	45	45
Small Portions		620	36	81
Wait Time		105	6	
Food is tasteless	900	100 90.0	.0 D	91
No atmosphere	700 -	- 80.0	- 80.0 - 70.0 - 60.0	94
Not clean	600	- 70.0		96
Too noisy	400	- 50.0) <u> </u>	98
Food is too salty	300	- 30.0 - 20.0	Count Count Count	» 98.8
Unfriendly staff	100	- 10.0	0	99.6
Food not fresh	0 + ions time tless	100		
Total	Overpti por Nait is teste nos	P. Not Croon too and and the food not the		100



What to do next?

Vilfredo Pareto (1848-1923)

•Analyze data to determine the frequency of problems or causes in a process

- •Brainstorm based on your Pareto analysis and develop targeted change concepts to improve your performance
- •Use the 2 tools to then drive your PDSA cycle (navigate the best route to your destination)
- •To repeat analyses over the course of the project to show shifts in key causes over time (do a Pareto of the Pareto...)

Key Driver Diagrams Fishbone Diagrams 5 Whys Process Mapping Pareto Charts 8 Wastes



Taiichi Ohno, TPS, & the "8 Wastes" in Lean methodology

- •<u>Overproduction</u>: making more than is required by the next process.
- •<u>Waiting</u>: any idle time created when waiting.
- •<u>Transportation</u>: any movement of patients, supplies, machines or materials that does not add value to the product or service.
- •<u>Overprocessing</u>: any effort that adds no value to the product or service.

- •<u>Inventory</u>: any supply in excess of a one-piece flow through the manufacturing process.
- •<u>Defects</u>: inspection and repair of materials in inventory.
- •<u>Motion</u>: excess physical movement of people that does not add value to the product or service.
- •<u>Under-utilizing people</u>: the waste of not using people to the best of their unique abilities.

DOWNTIME WASTES WORKSHEET

Туре	Definition	Waste	Causes	Countermeasures
Defects (errors) Ex: Medication errors, missed treatments, wrong tests ordered, unlabeled specimens	Process does not meet quality standards or customer expectations.			
<u>Overproduction</u> Ex: Unnecessary forms, duplicate tests, unused reports, process steps that don't add value	Providing unnecessary products of services, or redundant steps.			
<u>Waiting</u> Ex: Waiting to be admitted/discharged, wait time in clinics, room turnover time, waiting for information or test results	Delays, periods of inactivity, bottlenecks, or patient wait time.			
<u>Non-utilized Potential</u> Ex: Nurses transporting patients, physicians drawing up antipyretics in clinic	Failure to fully utilize human potential (time and talents). Not working to full licensure.			
<u>Travel &</u> Transportation Ex: Staff travel time, moving supplies, multiple sites for testing	Unnecessary movement of supplies, equipment, patients, or staff.			
Inventory/Scrap Ex: Stockpiling supplies, discarding expired supplies, wasting supplies, losing supplies	Excess inventory and supplies that are stored, expired, or discarded.			
<u>Motion</u> (search time) Ex: Searching for equipment, supplies, information or people	Extra steps taken because of inefficient layout.			
<u>Excess Processing</u> Ex: Lack of coordination for discharge, duplicated phone calls, multiple handoffs	Excess activity and processing steps caused by poor process design.			

Reference: Healthcare Performance/page_s%20Wastes%20With%20Healthcare%20Examples. Source URL: http://leanhealthcareperformance/page_s%20Wastes%20With%20Healthcare%20Examples.

Waste Walk

Go to the **GEMBA**

"Go see, ask questions, show respect"

Use a Waste Walk Sheet

Tip: Have a *"Beginner's Mind"* and take advantage of *"Fresh Eyes"*

Complementing Tool: Process Mapping



A few other Discovery Tools:
Visual Workspace: Five-S

Sort & Scrap

• eliminate what is not needed (eg, red tag process)

Straighten (or Set in Order)

- organize what belongs; labeled, ergonomic
- a place for everything, everything in it's place

Scrub / Shine / Sweep

• clean up messes to see/solve problems/disarray

Standardize

- make it easy to maintain by anyone/everyone
- clear role responsibilities in the first 3 S's

Sustain

• self discipline; keep things in order

Visual Workspace / VSM



BEFORE

AFTER

Protocols & Decision-Support Tools

- Steer care down preferred/EBM pathways
- Help mitigate errors of *ignorance*
 - i.e., absence of knowledge



Checklists (distinct from audits)

- Identify minimum set of high-value practices
- Helps mitigate errors of *ineptitude*
 - i.e., failure to apply knowledge



PICU CA-BSI ERADICATION CVL Insertion Bundle Checklist

Purpose: to work as a multidisciplinary team to decrease patient harm from catheter-associated blood stream infections

OBSERVER TO COMPLETE (required)

(for all temporary CVLs, including dialysis lines, PICC insertions, and re-wires)

	CPI	/ Med Re Pat Date of	CVL Insertion was unsuccessful successful (new access) successful (rewire)		
Pr	oced	ure start/	Site of CVL placed:		
Nu	Number of sterile operators:			□ jugular (IJ) □ PICC □ subclavian □ other:	
N	Number of sites attempted:			□ femoral	
NO	YES	Yes, after reminder	Operators' compliance o	bserved / confirmed:	
			Handa washed (immediately before procedure, all operators)		
			Appropriate garb (gloves / gown / ma	ask / cap worn by <u>all operators</u>)	
			CHG Prep (performed correctly: 30-60) sec scrub, 30-60 sec air dry)	
			Avoided iodine prep (both for skin prep and site dressing)		
			Draped maximally (80-100% of patient & bed region covered)		
			All supplies ready (at bedside before procedure; no stock room trips)		
			Biopatch (right size, 1/8 turn, properly	<pre>/ placed at insertion site by RN)</pre>	
			1# Dressing (placed immediately after	r procedure by RN)	
	RN HALTED PROCEDURE due to *possible* contamination being observed If you felt you should have but did not, please comment in the space below.				

"Error-Proofing"

Level 1: Total Prevention

- Defect cannot be made
- e.g., medical gas pin system
- More difficult to identify

Level 2: Reduced Likelihood

- Defect less likely to occur
- e.g., color coding
- Easy to identify







Error Reduction Strategies

More Common but Least Effective Less Common yet Most Effective Education & Info ("Try Harder") **Rules & policies (Set consistent Expectation) Periodic Audits** Simulation Standardization (protocols/pathways) Checklists, double-checks, process measures Simplification ("Lean") Making the easy way the right way Automation & computerization **Forcing functions & constraints**

All can be important and helpful... But are dependent on *effective implementation*

QI Discovery Tools Exercise

Working in pairs : Complete a Fishbone or Key Driver Diagram Related to your Project Aim



https://associationresearch.limequery.com/321978?lang=en

Break





The Fundamentals of Quality-Improvement: How to do QI ! (Part 2)

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MODEL FOR IMPROVEMENT

Aims

Measures

Ideas



Designing, Testing, Implementing



More Efficient Approach:



PSDA Cycle

P – Plan D – Do S – Study A – Act









Act

What changes can now be made?
What's the objective of the next cycle?
3 As: Adapt, adopt, abandon

Plan

State the objective of the test.
Make predictions.
Who will carry out what test? Where?
When?

Study

Data interpretation
Compare data to the prediction
Summarize the learning

Do

•Carry out the test •Document what occurs & observations

Example



Sequential building of knowledge

Include a wide range of conditions in the sequence of tests





Working in Parallel on Multiple Change Ideas or Drivers



Key Points for PDSA Cycles

Do initial cycles on smallest scale possible

- Think baby steps...a "cycle of one" usually best
- "Failed" cycles are good learning opportunities when small (i.e., don't just learn from successes!)

Quantitative results are important, but qualitative results are often more valuable in early PDSA

• PDSA Cycles help teams adapt good ideas to their specific situation

Keep track of dates PDSA cycles were implemented and outcomes

• Will annotate run chart with interventions to demonstrate efficacy

	LENGTH	START	TOPIC or ACTIVITY	
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~100 min	15 m	9:40 am	Exercise 2: Measures	
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	10 m	10:40 am	Break	
	15 m	10:50 am	QI Methods & PDSA	
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Exercise 3:PDSA

Working in pairs (or triads), choose an intervention related to your AIM and create a PDSA cycle

Challenge 1: Pediatric clinic Underserved urban asthma population

Challenge 2: Pediatric emergency department Topic of choice

If time, you can think of a PDSA cycle that you might use to affect your own project metrics and achieve aims.

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INTERPRETING QI DATA





"Trust in God, all others bring data" -Edward Demming

DATA USE	Classic Research	Improvement/Safety Science
Usual Goals	Discovery of new knowledge; providing objective proof; establishing best practice.	Operationalize discoveries or best practice into routine care; ensure/monitor performance.
Intervention or Protocol	Single static protocol; first/last patient in protocol get same management; long timetables.	Flexible/dynamic protocol or multiple serial tests; management adjusted freely based on learning; short and responsive timetables.
Management of Confounders	Identify, eliminate, exclude, and control for biases thru blinding, randomization, cross-over, etc.	Identify and understand biases; stabilize biases during tests or interpret findings in bias context.
Preferred Measures	Hard & unequivocal outcomes ; background data to ensure comparability.	Blend of outcomes measures, relevant process measures, and possible balancing measures.
Power and Scale	Powered to definitively answer question and possibly explore post hoc analyses.	Minimally sufficient data to meet confidence threshold for action or decision; successful tests scale up.
Data Interpretation	Data blinding ; no interim peeking; data safety monitoring boards; classic biostatistics with significance thresholds.	Real-time data; analyze & act on data simultaneously; statistical process control (control charts); data trends influence next steps.



Why Variation Matters

Key in analysis of changes or differences

Must discern kinds of variation to be accurate

- Mistake noise for signal (false positive, or type-I error)
- Mistake signal for noise (false negative, type-II error)

Traditional Statistic Methods

- Accounts for natural variation (SD) by aggregating n (more power)
- Often eliminates or compresses time
 - Data lumped (pre vs post) or ignored (simultaneous limbs)
- Limitations (eg vs traditional time-series)
 - May delay decision making (not real-time)
 - May wash-out short-lived or opposing signals
 - Depends on investigator-defined time periods

Types of Variation

Common Cause Variation (CCV)

- Natural variation, "noise"
- Inherent in all systems

Special Cause Variation (SCV)

- Unnatural variation, "signal"
- May be
 - unplanned (e.g., COVID pandemic)
 - planned (e.g., QI initiative)

Ultimate Goal of QI: Turn good SCV into sustainable CCV!

Pre-Post analysis vs Longitudinal Data Over Time





Rocco et al. BMJ Q&S. 201

Run Charts

Display Data over time

Easy for front line colleagues to understand

X-axis: Days, weeks, months, years....

Y-axis: Your outcome or process measure Median Line



Benefits of Run Charts

At baseline: help formulate aims by depicting how well (or poorly) a process is performing.



Benefits of Run Charts

Help in determining if changes are truly improvements by displaying a pattern of data that you can observe as you make changes.



Benefits of Run Charts

Provide information on if improvements are being maintained



How do you know if you have special cause variation?

Too Few or Too Many Runs (There's a table for that!)

Total number of data points on run chart not falling on median	Lower limit for number of runs (< than this is "too few")	Upper limit for number of runs (> than this is "too many")
10	3	9
11	3	10
12	3	11
13	4	11
14	4	12
15	5	12



Interpretation of a Run Chart: Shift, Trend & Astronomical Data


Annotate your run chart with your PDSA cycles and other significant events to make your data tell a story!

Moderate Temporary Harm

Exercise 4a: Spot the Signals in a Run Chart



Table Reference: For 53 data points, expect 21-34 runs

Run Charts vs. Control Charts

- Readily interpretable (optimizes balance of common vs special cause variation)
- Upper/Lower Control Limits based on $\pm 3 \sigma$

(sigma approximates SD if no special cause variation)



When to use a run chart or a control chart?

Run chart → if you don't have a lot of data, want to rapidly detect signals of improvement, more easily explained to/understood by audience; 12 or fewer data points

Control chart → distinguishes reliably between normal cause/special cause variation; to learn about stability of a system; 20 or more data points

SPC Charts more sensitive than Run Charts (same data *but* need more data points to be powered)



What is a Statistical Process Control Chart?

- •Visual aid allows for graphical presentation of data
- •Allows you to see if a process is working correctly and when it is not (when a process is in control or out of control)
- •Variation is always present (normal vs. special cause)
- Insights into data are often quicker (more real-time), more practical (small samples), more understandable (to decisionmakers)

So, what's the p value on a control chart?

•Equivalent p-value "misses the point"

Technically depends on

- gross variability
- number of "special cause rules" used
- number of points included

•Generally, using 4 rules of SCV, chances of either missing a real signal or seeing a false signal in ~30 points approximately 1 in 50-200

• That would be p ~ 0.02 to 0.005

Proportion of data by SD (σ) in a normal distribution



Standard Deviation

- SPC analog: Sigma (σ)
- avg. distance of data from mean
- how sigma calculated depends on type and distribution of data e.g.

$$\sigma = \sqrt{\frac{\sum\limits_{i=1}^{N} (X_i - \mu)^2}{N}}$$

Control Chart (Shewart Chart)

• Statistical Process Control (SPC)



Control charts are normal distributions with an added time dimension.



Understanding Variation in SPC



There are other numerous other criteria/rules and sources for identifying special cause

Slide c/o Matt Niedner

PICU Phase 1, 2 (N=44) Active since Jul 2008



If we want to apply some "judgment" we can say/assume that all prior data points (not shown) were, on average higher. Therefore, this mean line is probably toward a lowish estimate of steady state, perhaps making us more comfortable with such a short baseline period prior to first special cause.

Slide c/o Matt Niedner

PICU Phase 1, 2 (N=44) Active since Jul 2008



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PICU Phase 1, 2 (N=44) Active since Jul 2008



Slide c/o Matt Niedner

PICU Phase 1, 2 (N=44) Active since Jul 2008



PICU Phase 1, 2 (N=44) Active since Jul 2008



The Power of Annotation (and of Power!)

PICU CLA-BSI Rate (P1+2+3+4)



Month



Two Hardest Things About SPC:

- 1. Picking the right Control Chart! [but once it's done, it's set]
- 2. Deciding If/When to Reset Mean Lines [requires context expertise]

Two Best Things About SPC:

- 1. You don't have to be a statistician to add statistical rigor to your data
- 2. You can collect, interpret, and confidently act on data simultaneously

Out of Control or In Control?



Out of Control or In Control?



Out of Control or In Control?



Special Cause Variation



Special Cause Variation





API Rules for Detecting Special Cause

A single point outside the control limits



Eight or more consecutive points above or below the centerline



Six consecutive points increasing (trend up) or decreasing (trend down)





Healthcare Data Guide

Many sources of Special Cause rules...pick one and cite it.

#	Control Chart Rule	West- gard	Nelson- Juran	AIAG	Mont- gomery	Western Electric	Η

How to Select a Control Chart



Healthcare Data Guide, Chapter 5

Types of Data

•Attribute data \rightarrow classification data or count data

- Qualitative, sometimes including judgement \rightarrow what is an 'error'
- Must be a whole number when collected (discrete data)
- Classification data gets 'classified' as 'yes/no', 'conforming/not-conforming units'
- Count data counts incidents that are undesirable like 'number of mistakes'
- Includes percent or rate data, because when data elements collected, the numbers are a whole number

•Continuous data \rightarrow variable data

- Quantitative data that use some type of measurement scale (lab instrument, clock, survey, financial scale)
- Do not need to be a whole number when collected
- Biologic measures, time, money, perception data (Likert scale), or throughput (productivity)
 - Productivity → # of patients admitted, # of clinic visits (treated as continuous data because of their intent)
 - Still used for data that result in whole numbers (Likert scale, LOS in days)

Control Limits

Continuous data

 Narrowing of limits reflects reduced variation in data used to calculate the limits

Attribute data

- Narrowing of limits DOES NOT reflect reduced variation
- Width of limits is determined by combination of center line and subgroup size
 - Narrower \rightarrow increased sub-group size or change in the center line

How to Select a Control Chart



Just like in classical statistics, different data types use different statistics that are based on assumptions.

Each chart assumes a different distribution.

These assumptions are used to calculate sigma (UCL, LCL)

I-Charts

- •Patient specific clinical measures
- •Monthly accounting data
- •Laboratory test data

X-bar/S Charts

- •Requires data be organized into subgroups
 - •Subgroup = a set of measurements that were obtained under similar conditions or during the same time period (the area of opportunity); this may vary
- •X-bar chart = contains averages of each sub-group
- •S chart = the spread (or standard deviation) between measurements within each subgroup

P-charts, C-charts, & U-charts

Chart Name	Type of Data	Statistic Charted	Subgroup Size
P chart	Classification	% non-conforming units (P)	Constant or may vary
C chart	Count	# of incidents (C)	Constant
U Chart	Count	incidents per unit (U)	Constant or may vary



SPC can help you resist Variation Mind Tricks
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Exercise 4: Control Charts

Working in pairs or triads, identify the type of data for each metric and what type of control chart to use

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Sustaining Gains



Lewin's Model for Change



"Even though change is a constant, this refreezing stage is still important. Without it, employees get caught in a transition trap where they aren't sure how things should be done, so nothing ever gets done to full capacity. In the absence of a new frozen state, it is very difficult to tackle the next change initiative effectively."

Control Plans



Control Plans

					Process	Reaction
Measure	Goal	Documentation	Monitoring	Prevention	Owner	Plan
PHQ9M given to all patients 11 or greater at health supervision visits	90%	 Policy #23, last updated 6/2/2013; OMS for front desk staff family history taking 	Quarterly audits of 5 charts for all physicians by Marie RN	Patient portal sends automatic email to parents before visit	Notify Dr. Thomas if < 90%	Put up data, re- educate front desk staff, audit weekly for 1 month, discuss at staff meeting

CPHQ: Center for Public Health Quality

- 1. We have a Process Owner
- 2. Our Leaders are Involved
- 3. Systems and Processes are Independent of the People Involved
- 4. Tools make it easier for everyone to Follow New Procedures
- 5. Continuously Monitor Results
- 6. Celebrate Successes
- 7. Communicate to our Patients



Project Sustainability Checklist

Developing systems to sustain the gains from your project requires ongoing effort. Maintaining these systems assures that all of your hard work pays off in the long run. Use this checklist to assist you in sustaining your QI project improvements. Under each task, identify ways that you will accomplish the task.

- We have a process owner responsible for reviewing our data to monitor for slippage, designing ongoing improvements or adjustments, and facilitating communication to leaders, staff, and patients about the performance of the process.
 - Who is/will be the QI process owner?
 - What are their specific responsibilities in sustaining the QI project (see Process Owner Handoff Checklist)?
- Our leader(s) are involved in keeping everyone focused on sustaining our improvements. They are knowledgeable about the improvements and communicate about their importance and results of the new process at staff meetings, as well as informally.
 - What information is needed to keep leaders informed about this QI project?
 - How will it be communicated? How often?
 - What will we ask leadership do to keep our practice focused on maintaining the improvements?
- We make sure our systems and processes independent of the people involved by providing relevant ongoing training, making this training part of our new employee orientation, adding relevant roles and responsibilities to job descriptions, considering requirements in the hiring process, and cross-training staff for critical roles related to the OJ project.
 - What training is needed?
 - Who will assist the process owner with ensuring training needs are met?
 - What job descriptions and workplans need to be updated?
 - Who needs to be cross-trained for critical roles?

Teams who hold the gains:

- 1. Use data and continue with run charts
- 2. Continue to report and create accountability and <u>celebrate SUCESSES</u>
- 3. Have leadership's support
- 4. Meet often enough
- 5. Train and orient, make policy
- 6. Assign responsibility for key tasks
- 7. Focus on Mistake Proofing!
- 8. Create Control Plan
- 9. Expect changing conditions and are <u>prepared</u> (new EMRs, new staff hired, etc)



LEADING QI



"What if, and I know this sounds kooky, we communicated with the employees."

Basic QI team structure



ND



Adapted from John Shook, 2006

QI Leadership Pearls

Create multidisciplinary teams and ensure everyone has a voice
Facilitate equality and turn taking

Help set the proper scope/frequency of testing

Usually smaller, more often, more variety of tests

Be a part of the testing

• first hand experience, be wary of over-delegation

Distinguish bad ideas vs poor implementation

Don't let good ideas fail because of poor execution

Allow operations to evolve

Question habits/assumptions, prevent ruts/stagnation

QI Leadership Pearls

Engage higher order improvement strategies

• Think sustainability & reliability (not brute force)

Good leaders don't hoard information

• Create situational awareness for teams/frontline/staff

Be transparent, share data, network

Never ask frontline for info that you don't feed back

Strive engage content experts in the QI processes

• Use "QI coaches" to acquire QI skills, not substitute for

Don't wait until you're "ready"

• Get QI teams meeting regularly, "do" the work



4.4 Make the right thing easy to do

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https://associationresearch.limequery.com/146188?lang=en



Model for Improvement

What are we trying to accomplish?

How will we know that a change is an improvement?

What change can we make that will result in improvement?



MODEL FOR IMPROVEMENT

Aims

Measures

Ideas

Use of Discrepant Process & Outcome Measures to Stimulate Identification of Erroneous Metrics & Contextual Influencers



A – Common Starting Point

Undesirable performance but informed for improvement

B – Common Goal Point

High performance and informed for emerging defects in process

C – Outcome Discordance

- Low performing and uninformed for improvement; preventable adverse outcomes are the learning events
- Question validity of measures (process overestimated, outcome under-estimated)
- Query presence of contextual factors confounding performance and/or measurement

D – Process Discordance

- High performing and informed for prevention, process simplification, de-bundling, etc.
- Question validity of measures (process underestimated, outcome over-estimated)
- Query presence of contextual factors that
 protect performance or affect measurement

Niedner MF (v2016.05.01)

Error Reduction Strategies

More Common but Least Effective Less Common yet Most Effective Education & Info ("Try Harder") **Rules & policies (Set consistent Expectation) Periodic Audits** Simulation Standardization (protocols/pathways) Checklists, double-checks, process measures Simplification ("Lean") Making the easy way the right way Automation & computerization **Forcing functions & constraints**

All can be important and helpful... But are dependent on *effective implementation* Sequential building of knowledge

Include a wide range of conditions in the sequence of tests



Pre-Post analysis vs Longitudinal Data Over Time





Rocco et al. BMJ Q&S. 201

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Control Plans





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