Patient Safety and Quality Improvement 301

GLOBAL HEALTH CONFERENCE
NOVEMBER 2020
Objectives

• To understand the components of an effective patient safety program

• To understand how an “A3” can facilitate both administrative as well as clinical quality improvement projects

• To understand a healthcare Board’s role in Patient Safety and Quality Improvement
What if your hospital has an 80-90% institutional success rate? “Great”? 
- No, from an individual patients’ standpoint, it is unacceptable

For the individual patient, reliability is an “all-or-none” matter

Optimal Patient Safety requires a framework for improving reliability - standardized protocols for care that are evidence-based and widely agreed upon is essential
Patient Safety / Quality Improvement = Culture Change

Culture: “The set of values, norms, mores and behaviors which create formal and informal networks within an organization”

Practical Definition: The way we “do things” around here

Remember, “Culture eats (QI) Change every day”
Cultural Transformation: Business as Usual

Leadership: Powerful few. Make decisions about how work is done

Middle Management: Implement decisions

Front-line workers – many, experts at the work they do: carry out decisions, rarely engaged in deciding HOW work is done
After Culture Transformation – Everybody Contributes!

Font-line Workers: experts at the work they do; decide HOW to do the work

Leadership and middle managers support and filter ideas; and remove barriers for implementation of practices for front-line workers
Common Patient Safety Challenges

• Diagnostic Errors: When a patient is not provided with a timely and correct diagnosis

• Medication Errors: can occur from the time the prescription is written to time of administration (it may or may not result in harm)

• Transition Errors: Change between inpatient and outpatient care (also between hospital units)
Diagnostic Errors (DE)

• A DE is present when there was a missed opportunity to make the correct diagnosis
• The rate of DE is about 10% - most patient will be subject to DE at sometime in their life
• DE are the leading cause of malpractice claims against most MDs
• DE’s are multifactorial in origin with flawed cognitive clinical processes and Systems Issues both contributing
Diagnostic Error Examples

• **Premature Closure**: accepting a Dx and discontinuing the diagnostic process before the data necessary to establish the Dx have been obtained

• **Diagnostic Momentum**: when a Dx is suggested early in the Dx process – and the process continues even if the data do not support it

• **Confirmation Bias**: the predisposition to seek evidence to confirm a suspected Dx without looking for evidence to disprove it

• **Faulty application of knowledge**: the clinician does not possess the underlying knowledge necessary to make the Dx – or does not apply the knowledge properly
Adverse drug event: harm experienced by a Pt as a result of exposure to a medication
- >100,000 hospitalizations per year
- Can be secondary to an accepted risk or the result of a Medication Error

Risk Factors for Medication Errors:
- Polypharmacy
- Advanced Pt Age
- Impaired renal or liver function
- Illegible handwriting
- Use of non-standard abbreviations
- “Look-alike” or “Sound-alike” names
Measures to Reduce Medication Errors

• Computerized physician order entry (CPOE) systems

• Medication reconciliation

• Better Labeling of meds with similar names

• Barcode-Assisted medication administration (BCMA)
“Human Error” = *Modus Operandi* in Current System

• Medicine has traditionally viewed errors as failings for which the individual at fault should be found and blame affixed
• “Train and Blame” methodology
• Nursing Training has emphasized rules
• Physician Training has emphasized knowledge
• Corrective actions have thus historically focused on the individual not the system
The Swiss Cheese Model (Reason, 1991)

Adverse Event – Patient Harm

Triggers
- Lack of Procedures
- Punitive Policies
- Production Pressures
- Mixed Messages
- Zero Fault Tolerance
- Sporadic Training
- Attention Distractions
- Deferred Maintenance
- Clumsy Technology

Defenses
- Policies/Procedures
- Profession
- Team
- Individual
- Environmental
- Equipment

Latent Failures
Defining a Patient Safety Incident

- Patient Safety Incident
  - Hazardous Circumstance
  - Close Call
  - No Harm Event
  - Adverse Event

Did *Not* reach the Patient

Reached the patient
Our Knee-Jerk (unthinking) Reaction?

• Go to the Sharp edge of action:
  • The young staff member; the surgical team; the residents....
  • Don’t follow an unconscious protocol...

• However, a better way is to not automatically blame the caregiver(s)

• Thoroughly investigate the incident
  • Begin a “Root Cause Analysis”
    • A defined process that seeks to explore all of the possible factors associated with an incident by asking what happened, why it happened, and what can be done to prevent it from happening again
Basics of a Root Cause Analysis

• Start with a prompt investigation – complete in a specific time
    • Review the Medical Record
    • Interview those involved
  • Discuss Timeline findings with your multi-disciplinary RCA team
    • Do not settle for an easy answer
    • Ask Why? (the 5 why’s) – Goal: find the root cause of the incident
  • End with a short document: [To be signed by CEO]
    • Issue and Actions to be taken to ensure it doesn’t happen again
      • Who will do the action and Date each action to be completed
Why do Staff not Follow Policies/Procedures?

Because they...

- Don’t know them (knowledge deficit)?
- Can’t find them (P&P not readily available)?
- Staff don’t have the time?
- Can get away with not following them?
- Are careless and/or reckless?
“How can you justly deal with the individual who was involved, while also ensuring that your organization learns as much as it can from the event?” — Sidney Dekker

How will you balance accountability with learning?

Learning: Studying harmful events (or near misses) so as to make improvements that lead to a safer healthcare environment.

If you come down hard on people...

- Staff may be more careful.
- They will certainly be less willing to report instances of harm or even near misses.
- Staff who are in the ‘wrong seat’ may persist.
- Other employees may believe “anything goes.”

However, if you have no sanctions...

- Safety
- Accountability
Basic Pt Safety Structure & Function

• Implementing and Managing an **incident report system**
• Understanding and analyzing **data**
• **Connecting** leadership with front line staff
• Implement **frontline activity** to improve patient safety
• Analyzing **major errors** and sentinel events to prevent reoccurrence
• **Qualifications** and **training** of the **Patient Safety Officer**
• The role of the **patient safety committee**
• **Engaging physicians** in patient safety
• **Board engagement** in patient safety
Patient Safety Measurement

• The ‘basics’ include:
  
  – Data from **voluntary incident report** system
  – Data from **trigger tools** (and results of chart review)
  – **Real time surveillance**: e.g., CLABSI, CAUTI
  – **Key outcome** data: e.g., risk-adjusted mortality
  – Key **process/structural** data: e.g., CPOE use
  – **NQF** serious **reportable** events
  – **Malpractice** claims and payouts
  – **Accreditation/licensing** data from areas of concern
  – Serious **patient complaints**
  – Data from **M & M** conferences
  – Results from **patient experience** surveys
  – Results from **safety culture** surveys
  – Data from **executive walk-rounds**/focus groups

What do I do with data once I have it?

Not very many people really know how to use data.
The Importance of Patient Safety

Approach to patient safety

- Just culture/unsafe acts algorithm
- Normalization of deviance
- Root cause analysis

How does this work?

- On thinking of different approaches:
  - Teamwork and communication
  - Human factors

The vast majority of healthcare harm events are systems issues, not people issues.

Healthcare is safe for the vast majority of people the vast majority of time, but it could and should be safer.

The balance between creating a learning environment and accountability (a "just culture") is difficult to define, create and maintain.

Normalization of deviance is inevitable human behavior, the "path of least resistance."

The process for investigating harm (e.g., RCA) must be well-defined and consistent; if it is, people will be more likely accept the result even if they don’t like it.

By the best methods we know of to measure harm (i.e., trigger tools) not well; the fault of intervention, dissemination, or measurement?

A root cause of about 80% of harm events. Good teamwork and communication cannot be assumed in complex environments.

Physical, cognitive and macro human factors considered by many to be the number one systematic cause of patient harm.
Why “Quality Improvement” not “Quality Assurance” Activities?

“Quality Assurance” will support best outcome within current system design

“Quality Improvement” will transcend current best design specifications
Basis for “Quality Improvement”

• The key element in the “Quality Improvement” is the premise that quality is a system property.

• Therefore, what primarily determines the level of performance is the design of the healthcare system.
Overuse/Overtreatment

• **Definition**: Patients receiving services from which they will not benefit

• **Example**: Giving Antibiotics for “colds”/URI
  
  [>30% of children receive excessive antibiotics for ear infections]

• **Why a Problem**: exposed to the risk of adverse effects of this treatment without the possibility of benefit
Underuse/Undertreatment

• **Definition**: Patients not receiving services from which they would benefit

• **Example**: Heart Failure patients not treated with ACE inhibitors

• **Why a Problem**: desired outcome is reduced because they do not realize the health benefits of these treatments
Misuse

**Definition:** Appropriate health services are provided ineptly [ ~ 7% of hospital patients experience a serious medication error]

**Example:** patients with renal insufficiency who require aminoglycoside antibiotics but receive doses that are not reduced to match their renal function

**Why a Problem:** the probability of a good outcome is diminished by the added risk of avoidable complications
The Basic Sciences of Quality/Pt Safety

Use Evidence-Based Management Principles (HC Delivery) to Improve Healthcare Organizations as “Systems”

Change from the “Why” do this to “How” to do it!
System Attributes

• “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”

• If You Want a New Level of Performance?
Design a New System!

Apply a

“Quality Improvement” Methodology

To Improve (Change) Your HC Delivery System

“The Science of Improving Healthcare Delivery”

[Evidence-Based HC Management]
A Transformed *[Highly Reliable]* Healthcare System
[“A Place where you want to be...”]  A Framework

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<td>[Safety]</td>
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<td>No Needless Pain</td>
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The model has two parts:

I. Three Fundamental Questions:
   1. Setting **Aims**: What are we trying to accomplish?
   2. Establishing **Measures**: How will we know that a change is an improvement?  
   3. Selecting **Change**: What changes can we make that will result in improvement?

II. The Plan-Do-Study-Act (PDSA) cycle to test and implement changes in **real work settings**

Rapid Cycle Improvement (RCI) = multiple small tests (PDSAs) of change
Testing...testing...Aim:
Next Available Appointment < 7 days

Cycle 1: Standardize/reduce # of appointment types

Cycle 2: Reduce backlog

Cycle 3: Hold 50% of schedule for same day care

Cycle 4: Absence plan
Rapid Cycle Improvement (Many PDSA Cycles)

- Standard panel size
- Scheduling protocols
- Appointment types
- Team approach to care
What is Lean Thinking?

“The endless transformation of waste into value from the customer’s perspective”

The **Culture** change in lean thinking is as important as the actual tools or methodologies
How to Determine the **Value** You Provide to Your Patients:

\[ \text{VALUE} = \frac{\text{Outcome}}{\text{Cost}} \]

\[ \text{VALUE} = \text{“A”} \times (\text{Access} + \text{Technical} + \text{Functional} + \text{Satisfac.}) \]

“\text{“A”} = \text{Appropriateness}
If “\text{“A”} = \text{zero}, \text{don’t do process}
If “\text{“A”} = \text{1}, \text{appropriate care}"

“Delight Index”
What is Lean thinking?

The 5 S’s
The starting place for finding value

Continuous Improvement
Eliminating waste

Process Mapping/Flow Mapping

Developing an Eye For Waste

The 7 W’s

Gemba
5 S: an organized, never ending, effort to
• Remove all physical waste out of the work place 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.
5 S Results:

Before 5S

After 5S
Waste "Pre / Post- "5 S"

Unit 1. Basement   (Before) and (After)
Stabilizing Equipment Availability

5-S Techniques:
Sort
Set in order
Standardize
Shine
Sustain

Benefits
Clean equipment = pathogen vector
Saves frustration, searching
Freed up $20K-worth of unused equipment for use elsewhere

BEFORE

AFTER

IV Pumps (4)
Always Plugged In
System Paradox: Does QI mean – Work “Harder”? 

Effort

Improving Time
Working Time

Capability

Actual Performance

Time

Repenning, NP and Sterman, JD: Nobody Ever Gets Credit for Fixing Problems that Never Happened
www.webmit.edu
System Paradox: Work “Smarter”

Repenning, NP and Sterman, JD: Nobody Ever Gets Credit for Fixing Problems that Never Happened
www.webmit.edu
Content: What Skills Do Each Employee Need?

A key operating assumption of building capacity is that different groups of people will have different levels of need for QI knowledge and skill.

Important to make sure that each group receives the knowledge and skill sets they need when they need them and in the appropriate amounts.
Data
Information
Now this is where it gets a little complicated
Why A3 “Protocol”/Thinking?

• A structured cycle of improvement
• A framework for organizing thinking
  • Can be used for any type of problem
  • Individual and teams (and systems) – a living, dynamic document
• Eliminates the waste of debating method
• Reveals the issues, problems and previous ways of thinking
• Makes problem solving visual
• Tells a Story

A Key tool in becoming a High Reliability Organization
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## A3 - Box 1  Reason for Action

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What is the problem statement?

What is the scope of the problem?

What are the boundaries you will set?
What does the organization look like right now?

- Data/Business case for need:
- What are the current/upcoming changes you wish to initiate?
- Have you personally visited the site you want to change?
  - Gemba Walk
- Identify what are the core process?
- Flow Map the core processes
  - Identify (high-level) major issues (Kapowie’s)

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A3 – Box 3  Future (Target) State

What do we want the organization to look like at:
• 1 year
• 3 years
• 5 years from now?

What does a “Good” future look like?

How will we know when we have made an impact?

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Target (Future) State

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### A3 – Box 4 “Gap Analysis”

What are the big differences (gaps to be closed) between the current and future state?

What impact do these gaps have on our ability to be successful or reach our target state?

How much control / influence do we have over these gaps?

What are some of the potential root causes of the gaps?

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## A3- Box 5 Ideas (Solutions) Approach

| What ideas / strategies do we have for closing the gap? |
| Which of the core processes have the most potential to close gaps (attain target)? |
| What have others done to close the gaps? |
| How easy or difficult are the solutions being proposed? |

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A3 – Box 6 Rapid Experiments

Proposed countermeasures to address each root cause

Predicted results for each countermeasure

Do multiple PDSAs

Assessment Q:
- Are there clear countermeasure steps identified?
- Do the countermeasures link to the Root Cause of the problem?
- Who is responsible for what, by when (5 whys)
- Will these action items prevent recurrence of the problem?
Table to document how you will do the different PDSA cycles you do in closing the gaps

- Who  (who leads task)
- What   (task)
- When   (completion date)
- Where

Learn and improve as you go

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A3 – Box 8 “Confirmed State”

Accomplishments

Metrics (data)
- run charts, control charts, etc.
- Document quantified change (% improvement or % no longer happening, etc.)

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A3 – Box 9  “Insights”

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• **Trystorming**

• Rapid Tests of Change (RCI = Multiple PDSA cycles)
SDSA Cycle

- **PDSA**: focuses on experimentation
- **SDSA**: focuses on *Standardization/Sustainability*
- Once you have run many PDSA cycles (RCI) and have achieve a desired level of performance – you want to maintain this gain
  - Adopt new a new **standard** method (till you need to make new improvements)
- **SDSA cycle** is how you *hold the gain*
"Don't be afraid of learning too much; it will never happen!"

Dr Stephen Miles
Healthcare QI Board Responsibilities

- Ensure your HC Board has “Quality & Patient Safety” as part of its agenda – should be ~25% of agenda - Larger facilities: “Q & PS” Board Subcommittee
- Keep your “Board” appraised of “Q and PS” status
- Establish a “Just Culture”
- Select a Quality Improvement (QI) Methodology
- Include QI/PS goals in your CEO’s Performance Evaluation
- Continually communicate QI results to all stakeholders staff (tell “stories”)

Ideal Board Structure

Constituency

HC Board of Trustees

Executive Committee

Finance Committee | Audit Committee | Mission Committee | Quality/Pt. Safety Committee
It began to occur to Bob that the board might be thinking of a change in leadership...
21st Century Health Care System

The Healthcare workplace of the future is:

1. A desirable place to work
2. An efficient place to work
3. Has a Culture of Continuous Systems (Quality) Improvement - “Improving My Work Is My Work”

Every employee has two jobs:

• Their given “job description”
• Daily Improving how they do their “job”
4. Staff work in multi-disciplinary teams:
   • Teams that are peers, empowered and have data about:
     • Cost, Quality, Access
     • Teams have ability to select high priority challenges (those that are important to them) to improve
     • Teams that receive formal QI training
5. Teams have dedicated time to:
   - Do change (PDSA cycles = Rapid Cycle Improvement)
   - Evaluate change

6. Teams choose tasks that are aligned with the organization's values and culture

7. Every Employee has a Safe Forum to raise Questions
Quality Improvement Concepts

1. Serious gaps in quality exist – shared aims are helpful
2. The people of your workforce are good
3. Trying harder is the worst plan
4. All improvement is change
5. Skills for improvement are not common – yet
6. Strong QI Methodology (concepts) are essential
7. Measurement helps learning

8. Local adaptation makes concepts work properly – without it, they won’t

9. “All Teach – All Learn”

10. Improving for an individual staff member:

   “Improving my work is my work”
Caution

• QI Principles are **Tools** to change your local system.... Not the actual work to make needed change
  • Goal: improved Efficiency, Quality and Patient Safety in your facility
  • Unless many PDSA test cycles occur, you won’t get any change / improvement
  • “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 Themes:

• Soon is not a Time!

• Some is not a Number!

• Hope is not a Plan!

• Caring is not Whole Person Care!
  • Compassion without science is well-intentioned kindness; it needs to be combined with evidence-based medicine, evidence-based HC management
  • “This life is full of gracious opportunities, which you can improve in the exercise of your God-given abilities to bless others. YI, Dec. 15, 1886.
What then is Quality?

• Quality is a way of **thinking** about work

• Quality is how you **approach** work every day for yourself personally and for those you serve

• Quality is not about a staff title or using the latest catchy phrase
PS/QI = “The Science of Improvement”

Creating a culture of continuous quality improvement in a “Just Culture”

“Improving my work is my work”

“Remember that what is worth doing at all is worth doing well”

YI, Sept. 29, 1892
Institute for Healthcare Improvement

IHI’s Open School

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