Reliability

How to design reliable processes in Healthcare

Moving to 10^{-2}

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Toronto
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"Reliability is failure free operation over time." David Garvin
Harvard Business School

Observation: The reliability of applying known or required processes commonly is 10^{-1} (80%) or worse(When dealing with non-catastrophic processes)

Why should you care?

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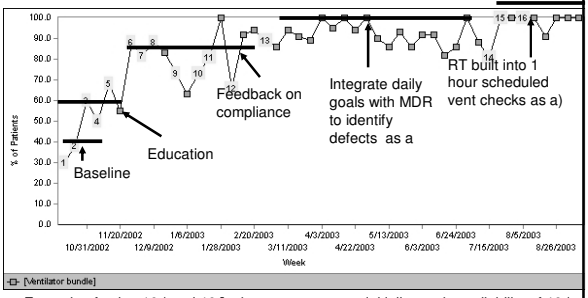
Example of 3 Step Design in Implementing the Ventilator Bundle



Example of using 10^{-1} and 10^{-2} change concepts to initially reach a reliability of 10^{-1} then additionally using a robust 10^{-2} change concept (redundancy) to reach 10^{-2} reliability in the 4 elements of the ventilator bundle (Baptist Memorial, Memphis)

Framework for Reliable Design

- **Process is the action point of all improvement methodologies**
- **Reliability occurs by design not by accident**
- **Segmentation allows the perfection of the design**
- **Design tables augment the planning for the project of which the process is one of several action points**

Starting Labels of Reliability

- Chaotic process: Failure in greater than 20% of opportunities
- 10^{-1}: 80 or 90 percent success. 1 or 2 failures out of 10 opportunities
- 10^{-2}: 5 failures or less out of 100 opportunities
- 10^{-3}: 5 failures or less out of 1000 opportunities
- 10^{-4}: 5 failures or less out of 10,000 opportunities

(These are IHI definitions and are not meant to be the true mathematical equivalent)

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Premises – IHI Innovation Team

For healthcare processes where failure does not cause immediate catastrophic consequences:

- 10^{-1} performance lacks consistent clear understanding of the process (5 front line process users can not easily articulate the process)
- 10^{-2} performance has some variation but 5 front line users can easily articulate the process.
- 10^{-3} performance indicates a well designed system with low variation and cooperative relationships

What does it mean to be 10^{-2}?

Which processes do we want to be 10^{-2} ?

Non Catastrophic Processes

- Definition: Failure of the process does not lead to death or severe injury within hours of the failure
- 10^{-1} performance or worse is most commonly seen in these processes (hand-washing as an example)
- Poor outcomes do not occur with each defect due to either to biologic or system resilience.

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Observation: The reliability of applying known or required processes commonly is 10^{-1} (80%) or worse(When dealing with non-catastrophic processes)

Given all the resources and talent why does this happen?

Reasons for the Reliability Gap In Healthcare

- Current Improvement methods in healthcare are highly dependent on vigilance and hard work
- The focus on benchmarked outcomes tends to exaggerate the reliability within healthcare hence giving both clinicians and leadership a false sense of security
- Permissive clinical autonomy creates and allows wide performance margins
- The use of deliberate designs to achieve articulated reliability goals seldom occurs

Improvement Concepts Associated with 10^{-1} Performance

(Primarily can be described as intent, vigilance, and hard work)

- **Common equipment, standard order sheets, multiple choice protocols, and written policies/procedures**
- **Personal check lists**
- **Feedback of information on compliance**
- **Suggestions of working harder next time**
- **Awareness and training**

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Improvement Concepts Associated with 10^{-2} Performance

(Uses human factors and reliability science to design sophisticated failure prevention, failure identification, and mitigation)

- **Decision aids and reminders built into the system**
- **Desired action the default (based on scientific evidence)**
- **Redundant processes utilized**
- **Scheduling used in design development**
- **Habits and patterns know and taken advantage of in the design**
- **Standardization of process based on clear specification and articulation is the norm**

Key Learning Points

- **Hard work and vigilance although commendable is not a good design principle**
- **If 10^{-2} change concepts do not make up at least 25% of the improvement effort on a given project require the team to rethink the design**

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Biology Protects Us

- **All defects in process do not lead to bad outcomes**
- **Healthcare tends to look at outcomes and not the reliability of the process leading to outcomes (handwashing is an example)**
- **Benchmark to best practice not aggregate averages**

Key Learning Points

- **If you accept benchmark level performance in your organization you compare yourself against mediocrity and foster 10^{-1} performance in non catastrophic processes**
- **Benchmark against the industry best, but also insist on reliable processes**
- **Measure processes against a specific reliability goal (10^{-2})**
- **Measure linked processes using the "all or none" rule**

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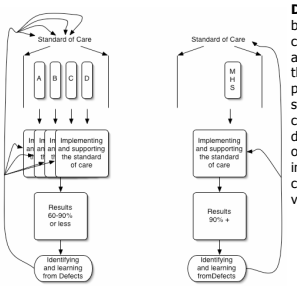
Health Care Processes

Current - Variable, lots of autonomy not owned, poor if any feedback for improvement, constantly altered by individual changes, performance stable at low levels



Desired - variation based on clinical criteria, no individual autonomy to change the process, process owned from start to finish, can learn from defects before harm occurs, constantly improved by collective wisdom - variation

Terry Borman, MD Mayo Health System

René Amalberti: Premises

- "Unconstrained" human performance (guided by personal discretion, only) is worse than 10^{-2}
- Constrained human performance can reach 10^{-2}

Key Learning Point

A single standardized process within the acceptable science is superior to allowing multiple processes while we decide which is the best because it allows testing and training

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The Reliability Design Strategy

- **Prevent initial failure using intent and standardization**
- Identify defects (using redundancy) and mitigate
- Measure and then communicate learning from defects back into the design process

The Three Step Design for Reliability

Design Techniques	Steps
1-Identify the process to standardize 2-Segment the population to test the design for anomalies 3-Use both 10-1 and 10-2 concepts	Prevent initial failure by standardizing the process to achieve 10-1 (step 1)
1-Utilize a robust 10-2 concept to make visible failures from step 1 after step 1 has achieved 10-1 reliability 2-Once the failure is identified, apply an action to mitigate the failure	Identify failures in step 1 and apply an action to achieve 10-1 for these failures (step 2)
1-Identify common failures 2-Develop a method to measure and study failures 3-Utilize knowledge of common failures to redesign either step 1 or step 2	In either step 1 and/or step 2 detect the failures, and use the knowledge from analysis of the failures to redesign (step 3)

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Why not 10^{-2} or better for your patients?

Why not YOU being a leader in the 10^{-2} model?

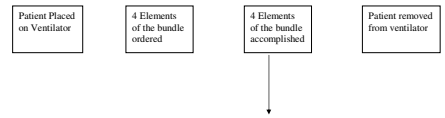
Where to start?

The "Set Up" for Reliability
Exercise #1

- Select a topic whose outcome you want to improve
- Determine a high volume segment for initial design testing
- Build a high level flow chart for that segment
- Determine where the defects occur in the current system
- Determine where your design work will begin with by identifying where the commonest defects occur
- Verbalize the reliability (hint: it is always 10-2)

Topic: Ventilator Bundle

Segment: Medical ICU



Of the 4 elements of the bundle, the head of the bed elevation is most commonly not accomplished

Our aim is to with a reliability of 95% or 10^{-2} achieve keeping the head of the bed elevated.

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Report Out Formula

- Identify the topic area whose processes you have chosen to make more reliable
- Describe the segment on which you will test your design
- Describe your high level flow chart (5 boxes max)
- In which box do most of your defects occur
- State your reliability goal for the segment

The Reliability Design Strategy

- Prevent initial failure using intent and standardization
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Why Standardize?

- Contributes to building an infrastructure (who does what, when, where, how and with what)
- Support training and competency testing to sustain the process
- Achieve front line articulation of key processes by staff
- Allows the appropriate application of Evidence Based Medicine consistently
- Feedback about defects and application of learning to design is possible

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Current Common Standardization Strategies

- Expert meetings design comprehensive protocol using EBM over months of meetings
- The result of the expert meetings is a protocol considered by the team as a finished product
- Changes to the protocol are infrequently tolerated
- Standardized protocols are expected to be stand alone and the end of the design (one size fits all)
- Compliance strategy is Level 1(Vigelance and hard work)
- No expectations form leadership regarding reliability of the standardization process

New Standardization Concepts

- Standardize to provide the appropriate infrastructure (the how, what, where, who and when)
- The “what” we are standardizing is based on medical evidence
- The “how” does not need medical evidence but rather systems knowledge
- Initial standardized protocols are developed with small time investment by experts tested at a very small scale
- Changes to the protocol in the initial stages should be required and encouraged
- Defects are studied and used to redesign the process

Assignment
(Exercise #2)

- Describe the process you will standardize
- Reconfirm the segment where the design will be first tested
- Take at least a part of the process you want to make reliable and describe the who, what, when, where and how
- Describe an initial test you will devise to test your standardization process (or a part of the process)

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Report Out Formula

- Briefly tell us about the details of the process you want to standardize
- Describe how you will test some aspect of the process you want to standardize

Three Tier Design Strategy

- Prevent initial failure using intent and standardization
- **Redundancy/contingency function (identify failure and mitigate)**
- Critical failure mode function (identify critical failures and then redesign)

Why the Step is Needed

- Allows less than perfect design in the standardization step (we do not have to plan for every possible contingency)
- Anticipates and allows failure in the prevent failure (standardization function) step
- Allows a better balance of resource use (no need to spend months coming up with the perfect design)
- Fosters the atmosphere of mitigation and recovery

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Characteristics of "Redundancy Tools"

- Require careful consideration since they do represent a form of "waste"
- Needs to be connected to the process almost all the time (at least 10^{-1})
- Requires a good prevent failure step (standardization function) before implementing a redundancy
-
- Need to be truly independent
- Need to be used or will no longer function as a good filter
- Must follow with a mitigation strategy

What we really mean by the redundancy/contingency step is the use of model 10^{-2} concepts

Model 10^{-2} Concepts

Human Factors and Reliability Science: 10-2 Performance
(Designing sophisticated failure prevention, failure identification and mitigation)

- Decision aids and reminders built into the system
- Desired action the default (based on evidence)
- Redundant processes
- Use fixed current scheduling in design
- Take advantage of habits and patterns
- Standardization of process based on clear specification and articulation

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Assignment
(Exercise #3)

- Design one redundancy that might be tested after your standardization step has been tested and designed
- Design a measurement for the redundancy step (how will you decide how often the redundancy step is used)

Report Out Formula

- Describe how you might use a “redundancy” in the identify failure and mitigate step of the design
- Describe a test of the redundancy you have designed
- How will you measure whether the “redundancy” step has been used?

Three Tier Design Strategy

- Prevent initial failure using intent and standardization
- Redundancy function (identify failure and mitigate)
- **Critical failure mode function (identify critical failures and then redesign)**

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Critical Failure Mode Essentials

- A measurement of critical failure modes needs to be part of the initial design strategy
- Assesses the defects that occur from the current design
- Should be prioritized in terms of overall affect on the reliability of the process change
- Should be used to redesign the process

Assignment

(Exercise #4)

- Describe the method you will be using to review and count the failures
- Describe your method to communicate the failures detected back to the design team

Report Out Formula

- Describe how you will collect the failures in the current process
- Describe how, who and when you will communicate these process failures back into the design

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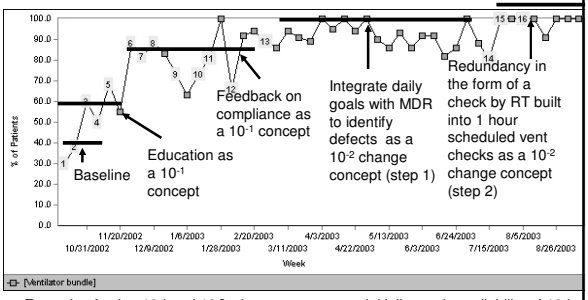
Example of 3 Step Design in Implementing the Ventilator Bundle



Example of using 10^{-1} and 10^{-2} change concepts to initially reach a reliability of 10^{-1} then additionally using a robust 10^{-2} change concept (redundancy) to reach 10^{-2} reliability in the 4 elements of the ventilator bundle (Baptist Memorial, Memphis)

Put it Together

You have a first segment, with an articulated process goal, a clear outcome goal connected to the process with some good medical evidence. In addition you have now set up a theoretical design using the prevent, identify, mitigate and with the knowledge of failures how to redesign

- Now you need to design your first test of change

and

- Determine the tempo of change you will "dance to"

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Tempo of Change

- Dependent on frequency of data collection (one month interval data collection frequency of design change at best monthly)
- Requires rapid testing when new information suggests design changes
- Sets expectations for a timeline

Test of Change

(Exercise #5)

- Build based on the work of one team a test of change with the faculty leading the attendees through a worksheet for a first test of change

Measurement

- Small samples over time should be use to determine if the process is improving
- Data should be collected by the team with strict attention to the agreed upon tempo
- Data should be collected for segments
- Process measurements should be the primary team measures
- Outcome measures are needed but do not need to be collected by the team
- Outcome aims can be set at 0 or 100%, but your process aims should be 10-2

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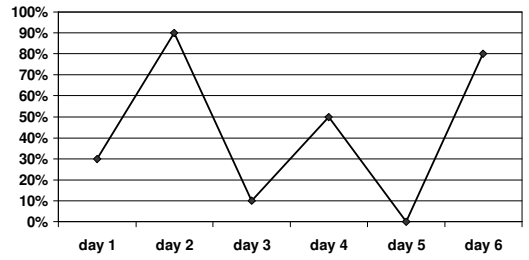
5 charts/day run chart



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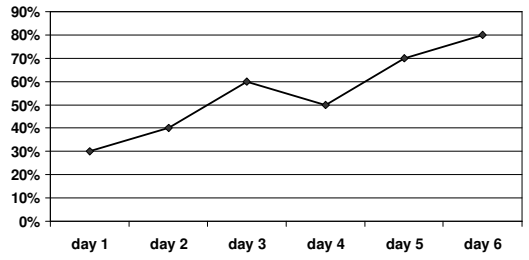

Science and Outcomes

- Process reliability is linked to outcomes by science
- If the process is “reliable” and the outcome is not achieved either the science is wrong or the process really is not being done correctly
- Outcomes are linked to the processes by the confirmation the hypothesis

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Rules of Engagement

- Clearly outlines what is expected of teams and leadership in improvement work
- Allows the realistic setting of goals and timelines
- Permits negotiation for the right “contract”
- Elevates the improvement work to business level relationship

What Teams Should Expect From Leadership

- Clearly describe the organizational outcome goals (VAP, CLI, Mortality etc)
- Understand the relationship between the processes the teams are working on and the outcome goals of the organization
- Set process expectations for the teams(all elements of the ventilator bundle will be done 95% of the time on eligible patients)
- Demand data to show how reliable the process has become
- Setting reasonable timelines
- If outcomes have not improved and process reliability is high provide resources to determine the “correctness of performance” of the processes

What Leaders Should Expect of Teams In Healthcare Reliability

- Initial focus of work should be on “getting the process right” with a known connection to an outcome
- Taking a set of processes to a agreed upon level of reliability within a specified timeline
- Teams will use reliability design principles in improvement work not just hard work and vigilance
- Teams will develop good designs by using rapid cycle small tests of change

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Finding your first segment

- The segment must represent a reasonable volume
- The segment should have clear cut defined boundaries
- The segment should have willing participants so the barrier of agreeing is not a problem
- The segment should allow for key articulated variables or barriers to be neutralized
- The first segment should establish a design theme

Using the Design Table for Reconciliation Planning Using Segments

Segment	Strategy Change/Rule	Structure Change	Process Change
Patients admitted to the medical units	Nurse will be responsible for the verification and clarification. Nurse will call MD with any un-reconciled medications Attending MD responsible for the ultimate decisions regarding reconciliation	A physician champion for reconciliation has been designated and given administrative time to lead the project hospital wide Measurement for ongoing assessment with feedback instituted Standard reconciliation sheet formatted	Nursing standard work set which describes the process for verification, clarification and subsequent reconciliation

Identification of the Other Segments

- The total number of segments for a topic should not exceed 4-5
- Segments should follow some theme in design (route of admission, type of physician, etc)
- Segments should differ by a distinct design feature
- The initial division of segments can be adjusted as the design is developed
- The segments should cover the population involved in the topic

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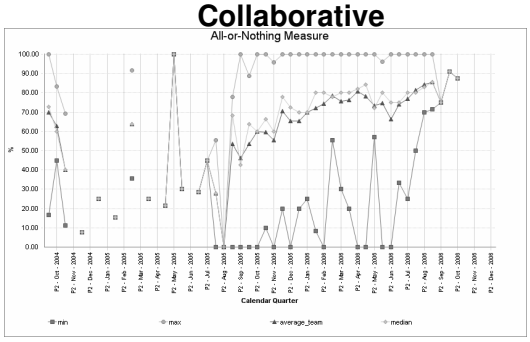
Using the Design Table for Reconciliation Planning Using Segments

Segment	Strategy Change/Rule	Structure Change	Process Change
Patients admitted to the medical unit	See previous slide	See previous slide	See previous slide
Patients admitted to the surgical units	Physicians may opt to have a "medication consult" from the hospitalists	Build a codable "medication consult" for the hospitalists	Develop the process by which the medication consult is to be used with rules and time expectations
Patients seen in outpatient surgery	Only those patients whose medication were touched are to be reconciled	Set up an education program to train new staff for all of the segments	Develop process and rules for the outpatient arena
Patients seen in the ED	Admitted patients not to be reconciled by the ED. Discharged patients only if the medications are touched	Provide a list of discharge medications for patients not reconciled	Develop process and rules for the outpatient arena

Team Results IHI Reliability Collaborative



The Design Table Permits Setting of a Timeline and Tempo

(Mayo Example)

- Design table must be completed within 20 days from the kickoff
- Begin to implement structure change recommendations and test process changes within 30 days
- Improvement to be based on defect analysis of small samples over time
- Data collection, analysis and reporting must be on a 7 day cycle
- 6 cycles of testing, plus set up within a 100 day time frame
- Defects must be measured and used in the redesign

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Go Forth and Succeed
and use the www.ihi.org under communities go to the reliability discussion group

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