Reliable Design

Designing Reliable Systems of Care

Patient Safety Executive Program

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These presenters have nothing to disclose.
Reliable Design

Objectives

• Identify the reasons for poor reliability in current improvement efforts
• Articulate the design requirements for reliable process design
• Utilize the 3 step design methodology on a practical example

Framework for Reliable Design

• Reliability occurs by design not by accident
• Process is the action point of all improvement methodologies
• Segmentation allows the perfection of the design
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Starting Labels of Reliability

- Chaotic process: Failure in greater than 20% of opportunities
- 80 to 90%: 1 or 2 failures out of 10 opportunities
- 95% or better: 5 failures or less out of 100 opportunities

Reasons for the Reliability Gap in Health Care

- Current improvement methods in health care are highly dependent on vigilance and hard work
- The focus on benchmarked outcomes tends to exaggerate the reliability within health care 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
The Reliability Design Strategy

• “Set-up” for success

• Use the following three step method:
  – 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 “Set Up” for Reliability

• 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 95% or better)
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Why Segmentation is Helpful

- Allows for the control of some variables
- Defines the boundaries around which sequential expectations for success can be found
- More likely to test the validity of the design rather than deal with barriers
- Fosters a deeper understanding of the design complexity required for the project
- Forces understanding of the differences between segments as design strategies
- Allows the formation of more predictable timelines

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
Segment for the Ventilator Care Bundle

- Patients in ICU-9
- Dr. Smith’s patients
- Patients on the South side of the ICU
- Medical ICU with two willing doctors

Example: Ventilator Care Bundle “Set Up”
Segment: Medical ICU With 2 Willing Doctors

- Patient placed on ventilator
- Elements of the bundle ordered
- Elements of the bundle accomplished
- Patient removed from ventilator

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

Our aim achieve a 95% or better reliability at keeping the head of the bed elevated
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Exercise

- Select a topic
  - Pneumovax administration
  - Ensuring that patients are receiving preventative screening (e.g., colon cancer screening)
- Select a segment
- Draw a high level flow diagram

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
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The Reliability Design Strategy

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

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
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 (Vigilance 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
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Example: Ventilator Care Bundle – Head of Bed Elevation

- Who: Nurse caring for the patient
- What: Measure the head of the bed elevation
- With What: Tool at side of bed
- When: Every two hours when checking VS
- Where: At the bedside
- How: Read degree elevation at bedside monitor and adjust if needed

Your Turn – Using the Process You Selected Earlier:

- 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, (with what), when, where and how
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Exercise

- Who:
- What:
- With What:
- When:
- Where:
- How:

Three Tier Design Strategy

- Prevent initial failure using intent and standardization

- **Identify and mitigate** *(Redundancy/contingency function)*

- Critical failure mode function (identify critical failures and then redesign)
## Reliable Design

### 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

### Characteristics of “Redundancy Tools”

- Redundancy: back-up plan, failsafe etc.
- Require careful consideration since they do represent a form of “waste”
- 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
Human Factor Concepts

Human Factors and Reliability Science:
(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

Example: Ventilator Care Bundle – Head of Bed Elevation: Redundancy

- Elevation is checked by unit secretary every two hours. If not elevated contact nurse.
- Elevation is checked by respiratory technician at each visit to patient. If not elevated contact nurse.
- Measure: how many times does this task find that the HOB is not elevated?
- Who should be info?
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Your Turn – Using the Process You Selected Earlier

- Design a redundancy (who, what, when, where and how) 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)

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)**
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

Measurement

- Small samples over time should be used 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 95% or better
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5 Charts/Day Run Chart

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Example: Head of Bed Elevation: Critical Failure Mode Evaluation

- Number of times that the head of the bed is not elevated and what time of day.  
  —Identified by nurse
- Number of times that the head of the bed is not elevated and what time of day.  
  —Identified by redundancy/contingency

Your Turn – Using the Process You Selected Earlier

- Describe the process (who, what, when, where and how) you will be using to review defects

- Describe your process (who, what, when where and how) to communicate the failures detected back to the design team
Example of a Run Chart Showing Implementing the VAP Bundle

Integrate daily goals with MDR to identify defects as a 10^2 change concept (step 1)

Redundancy in the form of a check by RT built into 1 hour scheduled vent checks as a 10^2 change concept (step 2)

(Baptist Memorial, Memphis)

Tempo of Change

- Dependent on frequency of data collection (one month interval data collection frequency of design change at best monthly)

- Dependent on rapid testing when new information suggests design changes

- Dependent on the timeline
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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

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 VAP 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 Health Care 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
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 clinician, 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

Key Questions To Analyze
Testing and Implementation

<table>
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<tr>
<th>Key Question</th>
<th>Your Evaluation</th>
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<tr>
<td>Is the connection between goals and process clear?</td>
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<td>Is the design strategy primarily vigilance and hard work?</td>
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<td>Has some degree of segmentation been used to test the design?</td>
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<td>Is standard work with testing been part of the design?</td>
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<td>Is a design methodology being used?</td>
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<tr>
<td>Are small tests of change being used in a rapid cycle?</td>
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<tr>
<td>Is data collection rapid enough?</td>
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### Key Questions To Analyze Spread

<table>
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<th>Key Question</th>
<th>Your Evaluation</th>
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<tr>
<td>Have you repeated the small test cycles as you spread from the initial site?</td>
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<tr>
<td>Is the process of spread dependent on one person?</td>
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<tr>
<td>Has some degree of segmentation been used to spread?</td>
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<td>Has customization been allowed or encouraged?</td>
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<td>Is the same team who developed the pilot now responsible for spread?</td>
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<tr>
<td>Have you shifted your focus from process reliability to outcomes too early?</td>
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Take a moment to reflect on the action plans you are creating.
What will you incorporate from this session into your action plan?