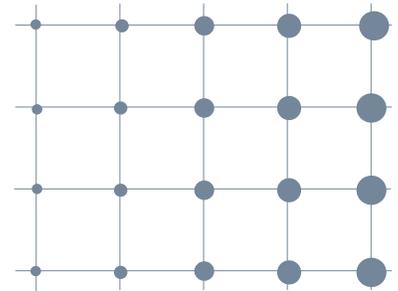


Innovation Series 2004



Improving the Reliability of Health Care

We have developed IHI's Innovation Series white papers to further our mission of improving the quality and value of health care. The ideas and findings in these white papers represent innovative work by organizations affiliated with IHI. Our white papers are designed to share with readers the problems IHI is working to address; the ideas, changes, and methods we are developing and testing to help organizations make breakthrough improvements; and early results where they exist.

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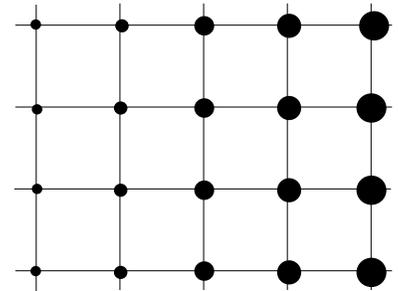
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Innovation Series 2004



Improving the Reliability of Health Care

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Executive Summary

Reliability principles are used successfully in industries such as manufacturing and air travel to help evaluate, calculate, and improve the overall reliability of complex systems. Reliability principles, used to design systems that compensate for the limits of human ability, can improve safety and the rate at which a system consistently produces desired outcomes.

Reliability is measured as the inverse of the system's failure rate. Thus, a system that has a defect rate of one in ten, or 10 percent, performs at a level of 10^{-1} . Studies suggest that most US health care organizations currently perform at a 10^{-1} level of reliability.

The Institute for Healthcare Improvement (IHI) uses a three-step model for applying principles of reliability to health care systems:

- 1. Prevent** failure (a breakdown in operations or functions).
- 2. Identify and Mitigate** failure: Identify failure when it occurs and intercede before harm is caused, or mitigate the harm caused by failures that are not detected and intercepted.
- 3. Redesign** the process based on the critical failures identified.

Within each step of this model, specific reliability principles and change concepts can be applied to reduce ambiguities and opportunities for error, and improve the reliability of the processes used to support care.

Using the **Prevent, Identify-and-Mitigate, Redesign** approach, IHI has created a template for increasing reliability of care for heart failure (HF) patients. Since a number of quality assessment and accreditation organizations are using quality measures for heart failure care, as well as promising or considering financial reward for those who achieve top performance, a template for improving reliability of heart failure care is an important tool.

IHI urges hospitals to increase their efforts to improve the reliability of care by adopting or adapting the principles of the heart failure care template presented in this paper. The template presented is not meant to be the only or the best way to improve the reliability of heart failure care, but gives an example of how the principles can be employed.

Introduction

It is a widely held view that the American health care system does not perform nearly as well as it should or could. Recent studies show widespread inconsistency in the delivery of high-quality care. In particular, two studies by RAND Health found that Americans with common health problems receive only about 50 percent of recommended care.^{1,2}

These studies confirm an earlier assessment of the state of US medical care by the Institute of Medicine (IOM). In 2001, the IOM published an influential report designed to guide efforts to improve the system. *Crossing the Quality Chasm: A New Health System for the 21st Century* calls for fundamental change, organized around six aims for improvement. The IOM says health care should be:³

Safe: Patients should not be harmed by the care that is intended to help them.

Effective: Care should be based on scientific knowledge and offered to all who could benefit, and not to those not likely to benefit.

Patient-Centered: Care should be respectful of and responsive to individual patient preferences, needs, and values.

Timely: Waits and sometimes-harmful delays in care should be reduced both for those who receive care and those who give care.

Efficient: Care should be given without wasting equipment, supplies, ideas, and energy.

Equitable: Care should not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.

Many health care organizations have embraced the challenges set forth by the IOM, and are making progress in these six areas. However, the progress still falls far short of the goal. For example, for treatment of community-acquired pneumonia, improvements that increase the compliance with evidence-based practice from 60 percent of cases to 85 percent are typical. While the relative improvement is impressive, the fact remains that a minimum of 15 percent of patients receive substandard care; the true figure is probably much higher.

Reliability principles—methods of evaluating, calculating, and improving the overall reliability of a complex system—have been used effectively in industries such as manufacturing to improve both safety and the rate at which a system consistently produces appropriate outcomes.

Can reliability principles be applied effectively to improve the consistent delivery of high-quality health care? The Institute for Healthcare Improvement (IHI) believes that applying reliability principles to health care has the potential to help reduce “defects” in care or care processes, increase the consistency with which appropriate care is delivered, and improve patient outcomes.

Background

IHI is working with a number of hospitals to apply reliability principles to care processes. This work currently focuses on improving the outcomes of five diagnoses: community-acquired pneumonia; heart failure; acute myocardial infarction; hip and knee replacement; and coronary artery bypass graft surgery.

These five diagnoses are of particular importance because they are the focus of a three-year quality improvement demonstration project sponsored by the Centers for Medicare & Medicaid Services (CMS), which oversees care in the US for elderly and poor, and Premier, Inc., an alliance of hospitals and health systems. The five diagnoses are also the source of core quality indicators used by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the National Quality Forum, and the Leapfrog Group, a Washington, D.C.-based consortium of private and public health care purchasers focused on recognizing and rewarding quality.

Although the care processes for the five diagnoses are varied, they share a reliance on multiple steps or processes, each one of which can affect the ultimate outcome.

Reliability in Health Care

Reliability is defined as failure-free operation over time. In health care, this definition connects to several of the IOM's aims for the health care system, particularly effectiveness (where failure can result from not applying evidence), timeliness (where failure results from not taking action in the required time), and patient-centeredness (where failure results from not complying with patients' values and preferences).

Reliability is measured this way:

Reliability = Number of actions that achieve the intended result ÷ Total number of actions taken

It is convenient to use failure rate (calculated as 1 minus Reliability), or "unreliability," as an index, expressed as an order of magnitude. Thus, 10^{-1} means one defect per 10 attempts, 10^{-2} is one defect per 100 attempts, and so on. Put in terms of health care, a process measuring 10^{-1} fails to be effectively applied for one out of every 10 patients. For example, if 90 percent of surgery patients get their prophylactic antibiotic within an hour of surgical incision, the reliability of that process as measured by defect rate is 10^{-1} .

These levels are measures of reliability (or unreliability), but they also serve as useful labels for design characteristics of systems. The characteristics of systems that perform at 10^{-1} , for instance, are different from those that perform at 10^{-3} , which represents one defect in 1,000 attempts. It is those design characteristics that organizations must integrate into their systems in order to improve reliability.

To help describe what these levels look like in an organization, IHI offers the following framework:

10¹ performance on process measures indicates no articulated common process, and an emphasis on training and reminders. A range of international studies of adverse events in hospitalized patients shows a convergence around an error rate of 10 percent (plus or minus 2), suggesting that this is the level at which most health care organizations currently perform.^{4,5,6,7} (Since this error rate represents an average, clearly for some tasks and processes the rate is lower, but for some, it is higher.)

10² performance on process measures indicates processes intentionally designed with tools and concepts based on the principles of human factors engineering.

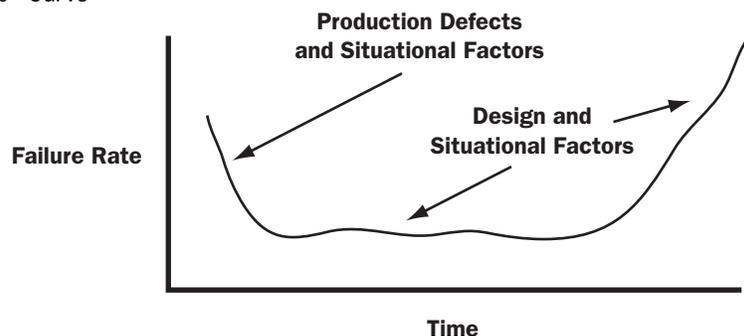
10³ or better performance on process measures indicates a well-designed system with attention to processes, structure, and their relationship to outcomes.

To understand these performance levels in a broader context, consider that aviation passenger safety is measured at 10⁻⁶. Nuclear power plants must demonstrate a design capable of operating at 10⁻⁶ before they can be built.⁸

It is important, however, to note that an essential aspect of reliability is the level of performance over time. Thinking about health care reliability simply in terms of overall defects doesn't differentiate reliability from the definitions of quality that are typically used in health care. While efforts to examine defects over time in a hospital, for example, often look across patients in time, these data represent the aggregate experiences of different patients flowing through the system. Our definition of reliability—failure-free operation over time—also refers to an *individual* patient's experience over time. This is a crucial distinction, and an aspect of health care reliability that connects effectiveness with patient-centeredness.

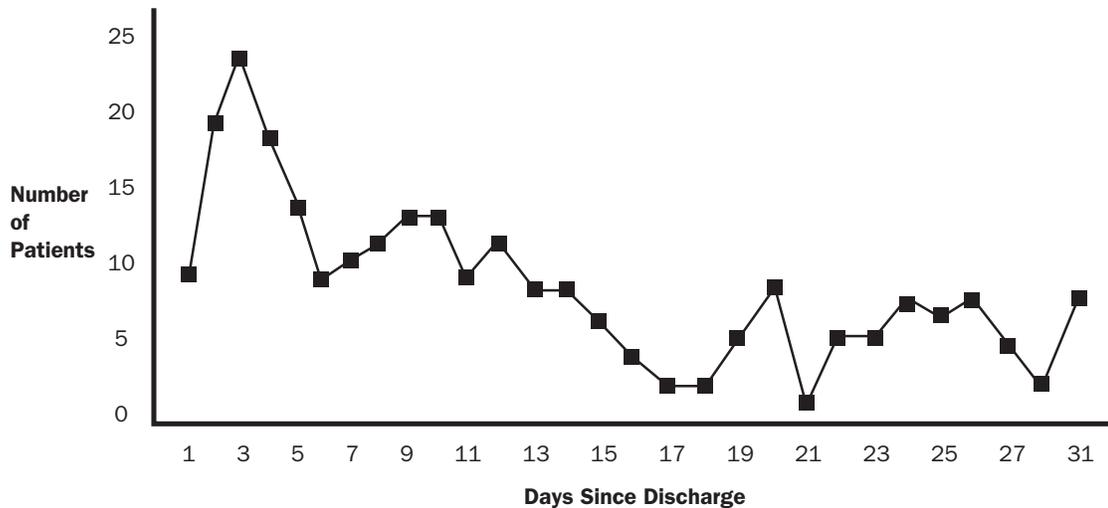
The measure of operation over time is depicted in the “bathtub” curve shown in Figure 1. Whether measuring the performance of a computer or the human body, there is typically an initial failure rate due to production defects and situational factors. That failure rate generally decreases and flattens out during the “useful life” of the item, and continues at a flat rate until the “wear-out” phase, when the failure rate increases again, this time due to design and situational factors.

Figure 1. The “Bathtub” Curve



This bathtub curve also applies to care processes. An example showing readmissions to a community hospital is shown in Figure 2, in which the measure looks quite similar to the beginning and middle of the bathtub curve in Figure 1. This could be due to production defects (e.g., the patient doesn't understand how to take his or her new medication) or situational factors (e.g., there is not adequate support at home).

Figure 2. Readmissions



Designing care processes for increased reliability involves paying attention to production issues—reducing defects—and increasing patient-centeredness by understanding and addressing, for each individual patient, situational factors that affect outcomes.

Providing reliably good care over time also requires understanding and addressing the reasons that patients are re-admitted after the initial failure phase, during the “useful life” or flat part of the curve (such as an inappropriate change in medication), and during the “wear-out” phase, when disease progression is more likely.

Designing Systems of Care for Reliability

Some researchers estimate that most people under work and time pressures make errors at the rate of 10^{-2} even when doing their best work. To be highly reliable, systems must be designed to compensate for the limits of human ability.

IHI uses a three-tiered strategy for designing reliable care systems, with processes and procedures in place intended to:

1. **Prevent** failure (a breakdown in operations or functions).
2. **Identify and Mitigate** failure: Identify failure when it occurs and intercede before harm is caused, or mitigate the harm caused by failures that are not detected and intercepted.
3. **Redesign** the process based on the critical failures identified.

1. Prevent: Most improvement efforts begin with a declaration of the intent to follow a uniform process or guideline. The emphasis is then placed on determining whether individual doctors or nurses adhere to the specified process or guideline. This typically results in 10^{-1} performance.

The focus of 10^{-1} performance is the creation and use of a standardized approach to care for eligible patients. Standard tools and techniques used at the 10^{-1} performance level include:

- Basic standardization, such as the use of common equipment brands or standard order sheets and guidelines
- Memory aids such as checklists
- Feedback mechanisms regarding compliance with standards
- Awareness-raising and training

These tools are effective for the first phase of improvement. But taking the system to a higher level of reliability requires more sophisticated strategies.

2. Identify and Mitigate: While 10^{-1} strategies are designed to ensure that patients receive the standardized process of care, strategies in the second tier reflect a focus on “catching” or identifying instances when the standardized approach is not used.

Some useful concepts at this level are those that seek to reduce the opportunities for humans to make mistakes. These design concepts are often referred to as “error-proofing,” and seek to eliminate ambiguities in the way tasks are performed, reducing the need for “workaround” solutions.

Four common methods for error-proofing systems are:⁹

Reminders: Examples include calling patients the day before their appointments to reduce no-shows and late arrivals, and using checklists or alarms to prompt specific actions.

Differentiation: To reduce confusion when actions, parts, or numbers are similar, patterns are broken by color coding, sizing parts differently, numbering items in easily distinguishable ways, or separating similar items.

Constraints: Constraints restrict or limit the performance of certain actions. For example, computers that signal an alarm when two medications prescribed for the same person should not be taken together serve as a constraint.

Affordances: An affordance provides clear visual or other sensory clues that lead the user to use a product or tool correctly, or perform the correct action. An outward-swinging door with a push-plate but no handle is an example.

In addition, in working with health care organizations to design more reliable processes, IHI has made use of other useful design concepts, including:

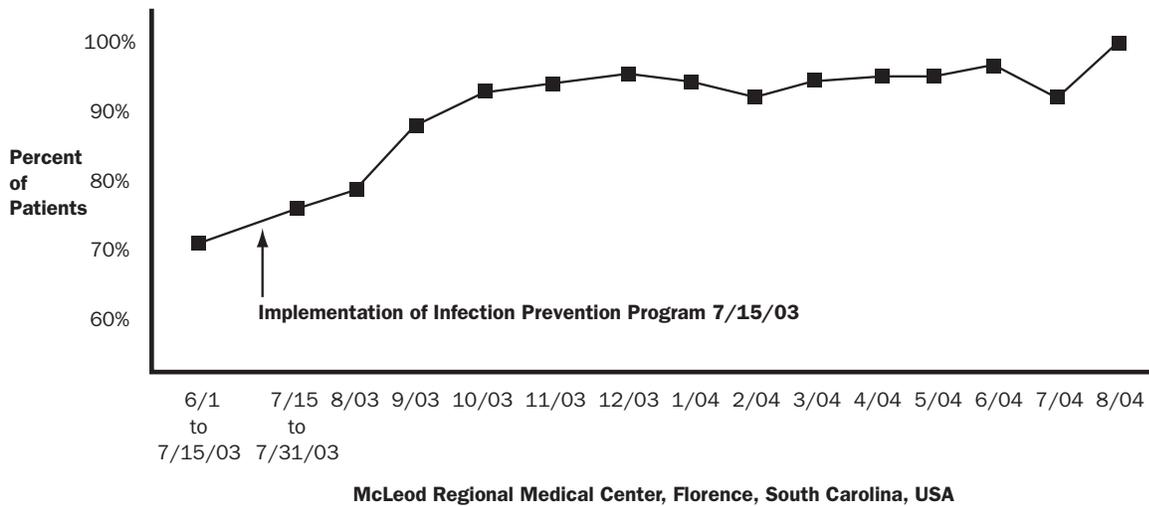
- Building decision aids and reminders into the system
- Making the desired action the default (based on evidence)
- Creating intentional redundancy
- Scheduling key tasks such as discharges
- Taking advantage of existing habits and patterns
- Agreement among doctors and nurses to follow and learn from standard processes

Strategies such as these, effectively employed, can boost the reliability of a process to or toward 10^{-2} .

Following are two examples of these design concepts in use.

Taking Advantage of Habits and Patterns: At McLeod Regional Medical Center in Florence, South Carolina, USA, part of the Premier/CMS Hospital Quality Incentive project, staff sought to apply 10^{-2} strategies to the administration of prophylactic antibiotic within an hour prior to surgery. Noting that all patients are placed in a holding room before surgery, the improvement team gathered data on the length of time from when patients leave the holding room to the first incision. Since the data showed that in the vast majority of cases the elapsed time was 30 to 60 minutes, a protocol was created that calls for the antibiotic to be started as the patient is transferred to the OR. The compliance rate increased from 70 percent to 100 percent (Figure 3). In addition, this change, in combination with other interventions, reduced the rate of surgical infection by half.

Figure 3. Prophylactic Antibiotic Received Within 1 Hour Prior to Surgical Incision (CABG, Colon, Hip/Knee, Hysterectomy, Vascular)



Making the Desired Action the Default: At McLeod, staff who were working to implement smoking cessation counseling as part of a protocol for treating patients with acute myocardial infarction (AMI) recognized that such counseling would be appropriate for all patients who smoke. They created a program whereby all inpatients who smoke receive counseling.

3. Redesign: Performance at 10^{-3} and beyond involves identifying the failure modes of the standardized process. In other words, even with the first two levels of strategies in place, what weaknesses in the design of the standardized processes are leading to or might lead to failure?

This requires a focus not only on processes, but also on the structure in which the processes operate. Structure in health care includes such things as the linkages between different locations of care, information transfer, the roles of different caregivers, and the degree to which physician autonomy trumps the evidence or the needs of the system.

Failure Modes and Effects Analysis (FMEA) is an important and powerful tool at each level, but especially at 10^{-3} . FMEA is a method for evaluating the structures of systems and predicting their performance. Although developed outside of health care, FMEA has been adapted by IHI and others to health care systems.

FMEA is a systematic way to evaluate a process in order to identify where and how it might fail and to assess the relative impact of different failures. This is useful in identifying the parts of the process that are most in need of change. FMEA calls for a careful review of the following:

Steps in the process:

Failure modes (What could go wrong?)

Failure causes (Why would the failure happen?)

Failure effects (What would be the consequences of each failure?)

Failure modes that happen frequently can be addressed by some of the process design concepts. Failure modes that happen infrequently but have serious consequences can be addressed by the **Prevent, Identify-and-Mitigate, Redesign** approach.

The following is an example of an FMEA process used to evaluate and improve the reliability of chemotherapy administration. Figure 5 shows the analysis of one organization’s chemotherapy administration process as of March 1, 2003; at the time, the “risk priority number” (RPN) of the process was 647. Figure 6 shows the analysis of the same process as of May 1, 2003, at which time the RPN of the process dropped to 246. Figure 4 graphs the change in RPN over time.

Additional examples, as well as detailed step-by-step instructions on conducting FMEA, can be found on IHI’s website, IHI.org, at www.ihl.org/ihl/workspace/tools/fmea/.

Figure 4. East Alabama Medical Center Chemotherapy. Risk Priority Number from FMEA

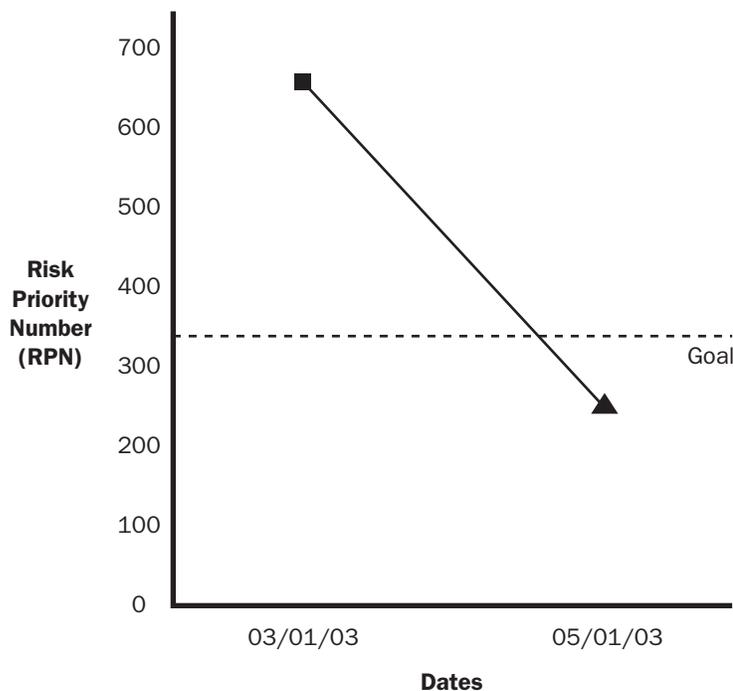


Figure 5. East Alabama Medical Center Chemotherapy. Risk Priority Number from FMEA: Original Process Data (3/1/03)

Step 1: MD Order							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	Actions
Wrong drug	MD has mental lapse; pharmacist failed to intervene	Serious ADR or death	1	6	10	60	
Wrong dose or dose inappropriate for patient	MD has mental lapse; pharmacist failed to intervene	Serious ADR or death	1	2	10	20	
Wrong patient	Wrong patient chart selected	Serious ADR or death	1	1	10	10	
Unclear number of doses or duration of therapy	Illegible handwriting or directions unclear	Serious ADR or death	1	2	10	20	
Proper labs not ordered for outpatient prior to administration of chemo	MD failed to order labs, patient arrived and forced to wait	Dose is held; patient is inconvenienced, if outpatient	7	5	1	35	
Labs not ordered; dose given that should have been held	MD failed to order labs; EAMC did not intervene	Potential ADR	2	3	5	30	
MD failed to order proper preparatory orders (ie., hydration, anti-emetic)	MD had mental lapse; EAMC did not intervene	Potential ADR	1	3	8	24	
Miscommunication as to agent and/or dose	Nurse/pharmacist misunderstood MD intent for drug/dose	Serious ADR or death	2	5	10	100	
Agent(s) abbreviated or multiple drug regimen abbreviated	Nurse/pharmacist misunderstood MD abbreviation for drug or multiple drug(s)	Serious ADR or death	2	2	10	40	
Step 2: Pharmacy Order Entry							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	Actions
Order misread and wrong drug or wrong dose entered into the computer	Illegible handwriting, calculation mistake or pharmacist has mental lapse	Serious ADR or death	2	2	10	40	
Wrong patient selected from computer census	Error in patient selection from file	Serious ADR or death	2	1	10	20	
Step 3: Pharmacy Preparation							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	Actions
Error in dose prepared	Technician or pharmacist mental lapse	Serious ADR or death	2	2	10	40	
Error in final concentration of prepared product	Improper preparation of product	Serious ADR or death	2	2	10	40	
Error in product prepared	Selection of wrong product for preparation	Serious ADR or death	2	2	10	40	
Step 4: Administration							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	Actions
Administered to wrong patient	Improper ID of patient	Serious ADR or death	1	1	8	8	
Wrong drug administered	Nurse failed to verify drug to be administered	Serious ADR or death	2	2	10	40	
Patient not properly prepped by nurse (hydration, anti-emetic, etc.)	Nurse failed to follow MD's preparatory orders	ADR ranging from minor to serious	2	2	6	24	
Extravasation occurs	Not checking blood flow or administration line every 5 minutes or giving a vesicant through a peripheral line	ADR	3	2	4	24	
Administered at excessive rate or improper route	Pump error or failure of RN to properly monitor patient	ADR ranging from minor to serious	2	2	8	32	
Calculated Totals: Total Risk Priority Number for the process						647	

Occ: Likelihood of Occurrence (1-10) • Det: Likelihood of Detection (1-10) • Note: 1=Very likely it WILL be detected, 10=Very likely it WILL NOT be detected • Sev: Severity (1-10) • RPN: Risk Priority Number (Occ x Det x Sev)

Figure 6. East Alabama Medical Center Chemotherapy. Risk Priority Number from FMEA: Most Recent Process Data (5/1/03)

Step 1: MD Order							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	Actions
Wrong drug	MD has mental lapse; pharmacist failed to intervene	Serious ADR or death	1	2	10	20	
Wrong dose or dose inappropriate for patient	MD has mental lapse; pharmacist failed to intervene	Serious ADR or death	1	2	10	10	
Wrong patient	Wrong patient chart selected	Serious ADR or death	1	2	10	10	
Unclear number of doses or duration of therapy	Illegible handwriting or directions unclear	Serious ADR or death	1	2	10	20	
Proper labs not ordered for outpatient prior to administration of chemo	MD failed to order labs, patient arrived and forced to wait	Dose is held; patient is inconvenienced, if outpatient	7	5	1	35	
Labs not ordered; dose given that should have been held	MD failed to order labs; EAMC did not intervene	Potential ADR	1	1	5	5	
MD failed to order proper preparatory orders (ie., hydration, anti-emetic)	MD had mental lapse; EAMC did not intervene	Potential ADR	1	1	8	8	
Step 2: Pharmacy Order Entry							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	
Order misread and wrong drug or wrong dose entered into the computer	Illegible handwriting, calculation mistake or pharmacist has mental lapse	Serious ADR or death	1	1	10	10	
Wrong patient selected from computer census	Error in patient selection from file	Serious ADR or death	1	1	10	10	
Step 3: Pharmacy Preparation							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	
Error in dose prepared	Technician or pharmacist mental lapse	Serious ADR or death	1	1	10	10	
Error in final concentration of prepared product	Improper preparation of product	Serious ADR or death	1	1	10	10	
Error in product prepared	Selection of wrong product for preparation	Serious ADR or death	1	1	10	10	
Step 4: Administration							
Failure Mode	Causes	Effects	Occ	Det	Sev	RPN	
Administered to wrong patient	Improper ID of patient	Serious ADR or death	1	1	8	8	
Wrong drug administered	Nurse failed to verify drug to be administered	Serious ADR or death	1	1	10	10	
Patient not properly prepped by nurse (hydration, anti-emetic, etc.)	Nurse failed to follow MD's preparatory orders	ADR ranging from minor to serious	2	2	6	24	
Extravasation occurs	Not checking blood flow or administration line every 5 minutes or giving a vesicant through a peripheral line	ADR	3	2	4	24	
Administered at excessive rate or improper route	Pump error or failure of RN to properly monitor patient	ADR ranging from minor to serious	2	2	8	32	
Calculated Totals: Total Risk Priority Number for the process						246	

Annotation: Change: Develop internal mechanism to track/double check/verify order entry, preparation, reconciliation between pharmacy and nursing and final administration (removing two failure modes from Step 1).

Occ: Likelihood of Occurrence (1-10) • Det: Likelihood of Detection (1-10) • Note: 1=Very likely it WILL be detected, 10=Very likely it WILL NOT be detected • Sev: Severity (1-10) • RPN: Risk Priority Number (Occ x Det x Sev)

IHI's Challenge for Hospitals: Increase the Reliability of Care for Heart Failure

Through our work with hospitals, IHI has created a template for increasing reliability of care for heart failure (HF) patients based on the **Prevent, Identify-and-Mitigate, Redesign** approach. Since a number of quality assessment and accreditation organizations are using quality measures for heart failure care, as well as promising or considering financial reward for those who achieve top performance, a template for improving reliability of heart failure care is an important tool.

Step 1: Create a Standardized Approach for HF Care

Many hospitals already have a standardized approach to care for heart failure, such as a set of guidelines or an order set. Based on common quality measures of heart failure care, the standardized approach should include:

- Left ventricular function (LVF) assessment
- Detailed discharge instructions
- ACE inhibitor for left ventricular systolic dysfunction (LVSD)
- Smoking cessation advice/counseling

An understanding of the appropriate use of standardization must be applied here. A simple, standardized approach has the advantage of being minimally controversial. Most clinicians generally accept the four elements of the HF care protocol; however, there are exceptions based on the uniqueness of patients. The demand for customized care highlights the difference between the production of widgets and the care of patients.

The HF care template should be understood to be standardized to care for 80 to 90 percent of patients. There will be patients with unique characteristics such as allergy to ACE inhibitors, or ones for whom another medication might be more appropriate. In these situations, the easiest approach is to employ the concept of the “opt-out” rule. A clinician can opt out of any of the four simple elements of care for HF patients listed above, as long as reasons for the departure are documented in the chart.

In the design of the measurement system, an “opt-out” with a medical reason should be considered adherence to the guideline. If measures are ignored or no reason is given for a change from the standardized approach, this should be measured as non-adherence.

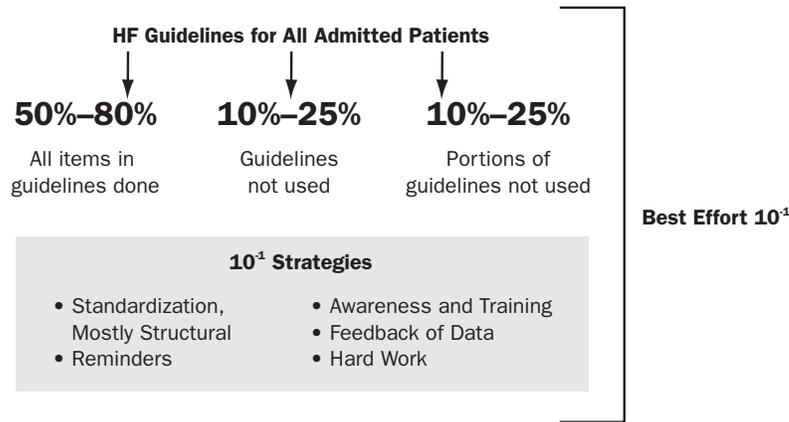
If your hospital doesn't have a standardized approach to HF care, you can create one that reflects the four care elements listed above. Additional items can be added, but they must be added judiciously. The longer the list, the more challenging compliance becomes. Seek input from local experts, and develop a mechanism for placing the guidelines on the chart of every patient who is admitted with HF.

You should also design and implement mechanisms that seek to ensure their use, especially in the emergency department (ED), the most common entry point for HF patients.

Step 2: Evaluate Adherence to Your Standardized Approach to HF Care

To evaluate how much of the time your standard approach is implemented, pull a random sample of 20 to 25 charts with a diagnosis of HF, and look for documentation that the standard approach was initiated. What percentage of HF patients had the standard approach initiated? If it is less than 90 percent, the reliability of your process for caring for heart failure patients is 10^{-1} . Figure 7 shows what this might look like schematically.

Figure 7. Heart Failure Template for Reliability – Standard Approach: 10^{-1} Strategies



Moving your HF care process from 10^{-1} to 10^{-3} performance will depend on the implementation of strategies that reflect reliability principles.

Step 3: Move from 10^{-1} toward 10^{-2}

Moving toward 10^{-2} performance will depend on the use of 10^{-2} strategies. The use of 10^{-1} strategies—standard order sheets, personal check lists, awareness, and training—will not be sufficient to move the performance level to 10^{-2} or beyond. For this, you must implement strategies such as building decision aids into the system; creating redundancy; and piggybacking protocol steps on established habits and patterns.

When you achieve an adherence rate of 80 to 90 percent—that is, the guidelines are fully followed for 80 to 90 percent of HF patients—you are ready to move to the next step.

Step 4: Move to 10²

Now that a standardized process is in place, you must create strategies that will identify failure to use the process. This might be the result of a failure to initiate the guidelines in the ED, or because patients were admitted through another portal.

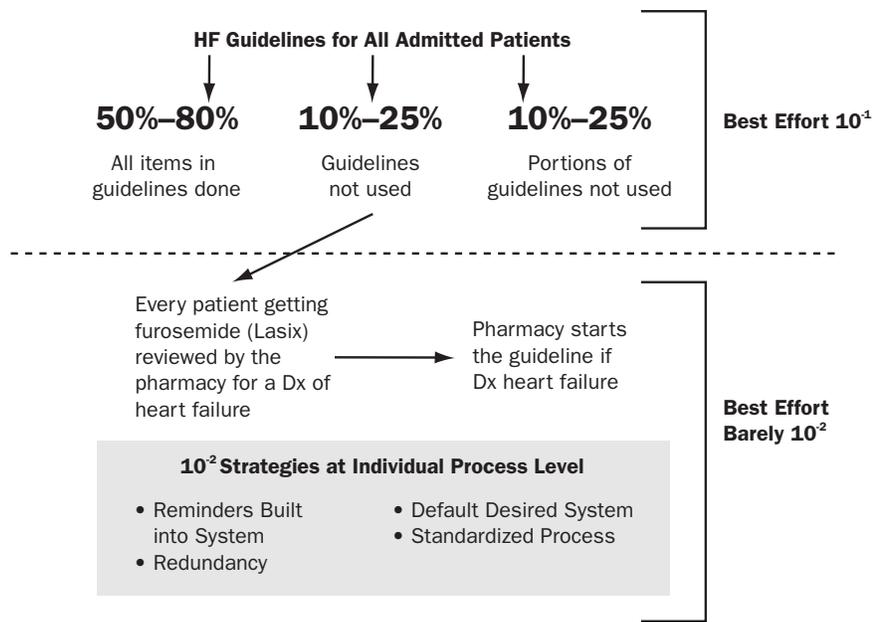
This step requires an “identification trigger” to identify those HF patients who have not been placed on the guidelines. Triggers should be items that every HF patient has ordered or uses during hospital admission. Examples include:

- Furosemide (Lasix) or equivalent diuretic
- HF-specific lab test results
- Radiology result

This might mean, for instance, generating a daily list of all patients with orders for furosemide (Lasix) or equivalent diuretics. A pharmacist could check to see that each patient on the list with an HF diagnosis has the guidelines applied (identification). If an HF patient is not on the guidelines, the pharmacist would contact the physician and request their use (mitigation). (Feedback and data should be collected from physicians who choose not to use the guidelines; this will help identify barriers to use of the standard process.)

Notice how these triggers are added to the process schematic in Figure 8. Putting steps in place to help identify and mitigate failure will help move the reliability of the HF care process to 10².

Figure 8. Heart Failure Template for Reliability – Moving Toward 10²



Step 5: Move toward 10^{-3}

Despite a well-designed system with 10^{-2} reliability strategies in place, critical elements of the HF guidelines sometimes still may not be used. Examples of why might include:

- The guidelines are initiated in the ED, but are not fully followed. Critical items of the guidelines are not used, including any one of the four items central to quality measures.
- Patients are started on the guidelines elsewhere in the hospital, and critical elements of the guidelines are not used.

Now the process should be tested to determine its weaknesses or most frequent failure modes. Some weaknesses in the design may be obvious, and solutions clear.

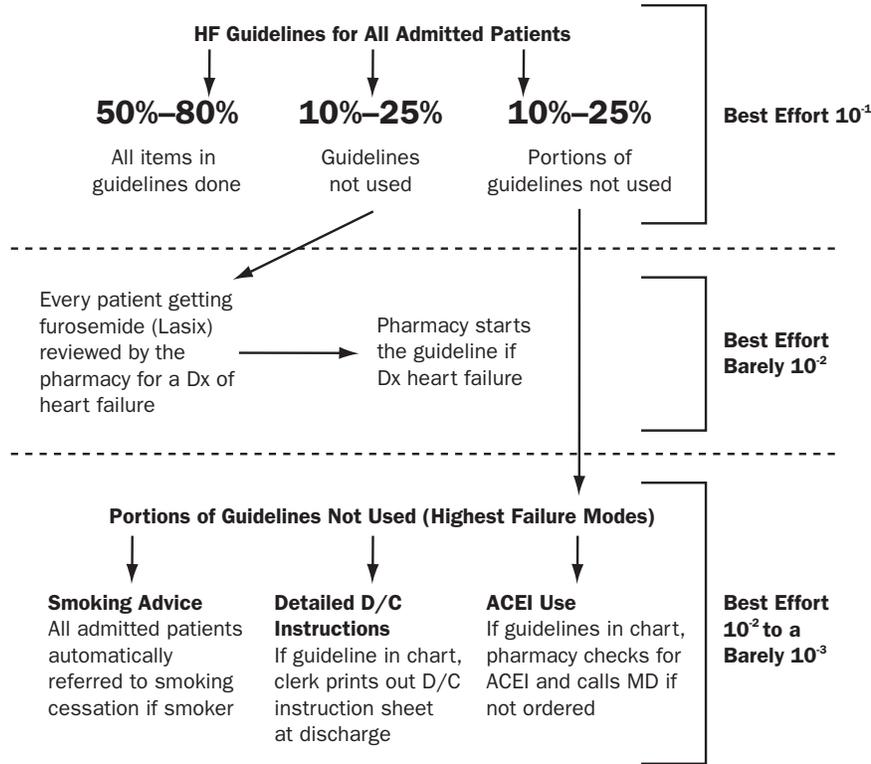
The challenge at this step is to understand the failure modes within the guidelines where individual elements are not carried out, and improve the guidelines by remodeling them to achieve the best results.

The items related to the four HF quality measures can be divided into two categories: those that lend themselves to a global, or system-wide, strategy, and those that do not. For example, smoking cessation counseling could (and should) be provided to all admitted patients who smoke, regardless of diagnosis. Once a global strategy is in place, that element can be removed from the diagnosis-specific protocol.

For those items that do not lend themselves to a global strategy—detailed discharge instructions, ACE inhibitor use, LV function assessment—structural change concepts should be employed. Each item may require a distinct strategy. For example, the detailed discharge instructions might depend on a reminder in the system that generates specific instructions to be added to the discharge packet.

Figure 9 shows how these changes can bring the reliability of HF care up to the 10^{-3} level.

Figure 9. Heart Failure Template for Reliability – Getting Ready for 10^{-3}



Conclusion

This paper offers ideas for using reliability principles to reduce production defects in health care, one aspect of improving reliability. Reliability principles provide a way to examine a complex system and its processes, calculate its overall reliability, and develop mechanisms to increase the likelihood that the system will perform its intended functions reliably. Applying the lessons from reliability engineering to a health care setting requires strong leadership and commitment, but holds the promise of moving our health care system to new levels of consistency and quality.

(In a subsequent white paper, IHI will address the second aspect of reliability: improving reliability of care for individual patients over time.)

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