



Designing Reliability Into Healthcare Processes
Based on the work of the Institute for Healthcare
Improvement Innovation Team
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Introduction

Although much of American health care is effective, the landscape of health care improvement is blighted by systems that over promise and under-deliver. Understanding why this occurs and how to use this knowledge to design reliable processes is the focus of this paper. The rationale and methodology has been developed over the last several years by the Institute for Health care Improvement (IHI) Innovation Team and presented as a series of seminars. This companion paper can be used to enhance the teaching and application of reliable design.

The ability to perform a given key process reliably has been thrust into improvement work by issues of mandatory public reporting, CMS measures, Joint Commission standards, and pay-for-performance initiatives. It is becoming no longer acceptable to be at “benchmark” with 60 to 80 percent performance level. Since this change in levels of acceptable performance, new concepts and tools are needed to understand how to accomplish higher levels of performance in key health care processes.

Reliability Basic Definitions and Understanding

Defining reliability is more difficult than it appears. Simply counting up the total number of “defects” could be used to indicate reliability, but the element of time usually needs to be added. David Garvin at the Harvard Business School defines it as “failure free operation over time”. The *Handbook of Reliability Engineering* (Igor Ushakov, editor) defines reliability as the “measurable capability of an object to perform its intended function in the required time under specified conditions.” Many of the key processes in health care lack good definable time components but nevertheless are being tied to reliability concepts. It would appear that most efforts being called reliability *work* in health care are actually quality control; regardless, quality control still can benefit from knowledge and skills to reliably design processes.

A definition of reliability in health care might be: *The measurable ability of a health-related process, procedure, or service to perform its intended function in the required time under commonly occurring conditions. Reliability equals the number of actions that achieve the intended result, divided by the total number of actions taken. From the patient perspective, this is an all or none measure. That is, patients receive all of the elements of care associated with a process in order to be considered reliable.*

“Unreliability” would then be seen as 1 minus “reliability.” It is then convenient to use “Unreliability” as an index expressed as an order of magnitude (e.g., 10^{-2} means that 1 time in 100 the action fails to achieve the intended result). The IHI Innovation Team has taken some liberties with the strict mathematical definitions and has been using the following definitions in applying reliability to health care processes:

- Chaotic process: Failure in greater than 20% of opportunities (This means if you perform a process with a success rate of 75% or less, the process is considered “chaotic.”)
- 10^{-1} : 80% or 90% success. 1 or 2 failures out of 10 opportunities (The key to this level of performance is the understanding no articulated process exists. If 5 frontline individuals are asked to describe the process, less than 5 will be able to do so.)
- 10^{-2} : 5 or fewer failures out of 100 opportunities (Although the mathematical definition of 10^{-2} would be 1 failure out of 100 opportunities, the IHI Innovation Team has taken liberties with the

mathematical definition.). Based on experience, 5 frontline individuals will commonly be able to describe the process at this level of reliability.

At the 10^{-1} performance level, no articulated, shared process exists; in contrast, while processes vary substantially at a 10^{-2} level of performance, an articulated common process is present.

Based on these definitions, the IHI Innovation Team has developed the following thinking regarding failures in non-catastrophic processes. (Non-catastrophic processes generally do not lead to death or severe injury within hours of the failure.) Hand hygiene is considered a “non-catastrophic process” because the failure to wash hands prior to contact with a patient does not automatically lead to a nosocomial infection (although multiple failures to wash hands will lead to increased numbers of nosocomial infections, as evidenced by the literature). The direct observable relationship between defect and bad outcome would fall into the “catastrophic process” category. An example might be failure to identify the correct surgery site leading to the wrong leg being amputated.

Why Does the Reliability Gap Exist?

The track record of clinicians in delivering care for which solid research evidence exists, whether in acute, chronic, or preventive situations, is commonly less than 80 percent. This low level of reliability at the basic process level means that health care’s work to improve reliability starts from a much lower baseline than in most commercial endeavors, and therefore may require a different approach.

In their book, *Managing the Unexpected*, Weick and Sutcliffe have described the “hallmarks” of high-reliability organizations. These hallmarks include the idea of “collective mindfulness,” and the need to apply concepts such as preoccupation with failure to achieve high process reliability. Not clearly stated but implied in their work is the concept that in high-reliability organizations *processes* are already considerably more reliable than those in health care. It’s one thing to be preoccupied with failure and analyze defects in an industry where key basic processes operate correctly 98% of the time. It’s quite another in health care: how practical would it be to investigate defects if the processes were defective 50% of the time?

The critical question is why, with all the good intentions and talent available in medicine, are clinical processes backed by solid medical evidence carried out at such low levels of reliability? Certainly, few people come to work with the intention of performing poorly. The politically correct answer is to shift the responsibility entirely to a defective system; although the system may be defective, this answer may not be particularly helpful in detailing how to improve the clinical processes. IHI has been involved in learning about reliability from the experience of 40 organizations working on reliability design principles. The faculty informally reviewed the improvement efforts of these organizations prior to their involvement with IHI, specifically the efforts involving the CMS pay-for-performance conditions. The following four common themes, which we offer as partial explanations for the reliability gap, were observed:

1. Current improvement methods in health care are excessively dependent on vigilance and hard work;
2. The current practice of benchmarking to mediocre outcomes in health care tends to give clinicians and leaders a false sense of process reliability;
3. A permissive attitude toward clinical autonomy creates and allows for wide, and unjustifiable, performance variation; and
4. Processes are rarely designed to meet specific, articulated reliability goals.

The practical applications of reliability principles require knowledge about initial project design. The failure to “set up projects” properly will at worst doom the project from the start and at the least delay meaningful change by months. All improvement methodologies (Lean, TPS, Six Sigma) eventually require process improvement. The “set up” described below assumes organization or team has completed preliminary work. The following steps are recommended to properly set up a new design for a non-catastrophic process

Step 1: Identify a segment of the process you wish to redesign.

Segmentation of the process is critical to testing the design. By the process of appropriate segmentation the team can spend most of the initial resources on testing the actual design rather than dealing with

barriers. For practical purposes if a team cannot design a reliable process in the context of controlling key variables (barriers) for a segment there is little chance of designing a reliable process for the whole. Based on work with segmentation the following characteristics should be followed:

- The segment must have a high enough volume to permit rapid-cycle tests when the testing stage is reached; low-volume segments force the team into infrequent testing, and learning is therefore stunted.
- The choice of segment should take into account various anticipated barriers and should attempt to minimize some barriers or variables.
- The segment should be suitable for testing the design and represent basic learning about the design required. If the design does not work in a chosen "best group," its chances of working in the entire population are minimal.

Step 2: Create a high-level flow map for the process being improved with application to the segment of population chosen.

Understanding the key steps for the process is essential. However, the intent in developing this flow map is not to be too detailed. The flow map should include no more than 5 or 6 steps and be able to describe the process from start to finish.

Step 3: Prioritize steps with highest number of defects

Consider actual or hypothesized failures in the flowed out process and identify the step with the highest number of defects. (With all-or-none measurement, it makes more sense to start with the part of the process with the most defects.)

Step 4: Testing design

Start the design testing on the part of the process which manifests the greatest number of defects. In reality, teams will need to work on multiple aspects of the process at the same time.

Step 5: Articulate clearly the goal of the process.

For our design purposes the 10^{-2} reliability performance is the goal.

Step 6: State the hypothesis

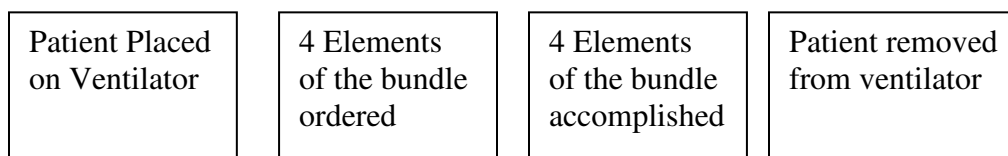
State the hypothesis which relates the segment chosen and the process being designed to either science or commonly held beliefs. Hypothesis Example: If our Intensive Care Unit accomplishes all elements of the ventilator bundle where applicable, and reaches 10-2 reliability, ventilator associated pneumonias will decrease. The literature generally supports this conclusion.

EXAMPLE of a Reliability “Set-Up” For the Ventilator Bundle consisting of 4 components

- Elevation of the head of the bed
- Daily sedation vacation
- DVT Prophylaxis (Deep Vein Thrombosis)
- PUD Prophylaxis (Peptic Ulcer Disease)

Segment for Design: The team chose to initially design the process for patients admitted by one group of intensivists who are particularly interested in quality improvement. The team determined that it was easy to identify these patients on admission.

High-level flowchart of the existing process:



The team determined the ability of the unit to keep the head of the bed elevated throughout the day was accomplished less than 50% of the time. Since this was the most common defect the specific process to be redesigned was a process to keep the head of the bed elevated at least 95% of the time.

The IHI design methodology incorporates a 3 step design. The first step is prevention of initial failure the second step is the identification of failure of the first step, and then mitigate the failure. The third step is to use knowledge of failure to redesign the evolving process.

First Design Step (Design Intent and Initial Prevention of Failure)

In the First Design step, the design work primarily involves use of standardization. The knowledge needed to standardize processes is usually taken for granted, and standardization is seldom done well in health care. The goal for the First Design step is to achieve a level of defect prevention in the 80 to 90 percent range (10^{-1}). Teams will use the both vigilance and hard work strategies complemented by human factors design.

Reliable design of health care processes requires understanding and implementing standardized processes. No level of reliability in health care processes can be achieved without stabilization of process, (a level of one or two defects per 10 opportunities). Once a process has been stabilized, the work of improving reliability can occur. If a process has not been stabilized, there is no realistic expectation of attaining minimal defects in a process.

Most clinical processes have a range of possible ways of to accomplish a given clinical task and still be within the scope of acceptable medical practice. For years, clinicians have agreed that if there is a single standard based on good medical science standardization is warranted. However, very few of these clinical opportunities exist. The difficulty with allowing any acceptable process within the scope of practice is a pragmatic one, and is related to the lack of infrastructure to support multiple competing processes. For example, multiple approaches will work for the standardization of potassium administration in the ICU. The ability of the ICU to train all nurses and pharmacists in multiple approaches is difficult. It involves training new employees in all of the approaches, follow-up on skills for current staff, coordinating which physicians desire which approaches, and follow-up of the efficacy of any one. One of the major benefits in standardizing care is it helps to create a learning environment. The multiple methods approach makes the recognition of system defects difficult and the correction of defects in a particular protocol even more difficult.

A single standardized care process allows the institutional expectation of training all the staff in the single protocol and follow-up of the efficacy of a single protocol. More importantly, it allows the detection of defects from the standardized care process and tracing the defect back to cause. Each defect then becomes an opportunity to learn and improve the process. With multiple approaches, all of which are consistent with scope of acceptable practice, the ability to learn from individual defects of a given care process are extremely limited, and would be resource intensive.

Local providers of service should be limited to a single care process. Any variation should be the result of customer desire. Commonly, industry will standardize, but also have available customized products available to those special customers.

Method of Standardization (both within and across organizations)

No standardization can be expected to be successful if isolated experts try to develop the perfect protocol without actual testing in the clinical environment by the front line. In most organizations, a protocol or care process is written by a group of experts in a non-experiential setting, making an attempt to compromise and account for all possible objections and contingencies. The protocol or care process that results is at worst completely unworkable, or at best used by only a portion of the clinical staff and never spreads to others and has little ability to be sustained over time. With this type of experience, most clinicians and

improvement staff have concluded that standardization of clinical processes is almost impossible. The fault lies in the methodology of development and implementation, however, not in the fundamental concept of standardization. Successful implementation both demands and expects local customization of standards and protocols. This means that a given standard or protocol is essentially never 'finished', but is always in a state of adjustment as we find better ways to provide care.

Steps to Standardization

Step 1: Define the current and future targets

By observation, identification of problems, and drilling down for root causes of process failure, understand how the current process works. Describe the ideal process for management of the condition, using evidence from the literature, knowledge of the local environment, and any available local data.

Step 2: Define and implement a practical measurement strategy

The measurement should be practical both for short term testing and longer term outcomes.

Step 3: Write the protocol.

The first draft of the protocol or care process should be written by several of the pertinent experts, taking a minimum of time and utilizing out-of-organization examples of the protocols if necessary just to get a start. The initial protocol or care process should be reflective of the few experts who will be willing to try the first version of the protocol on several patients within the next day or so. The protocol should be written in such a way that changes to the protocol or care process can be made within minutes. The goal for most organizations should be to include as few items as possible combined with good evidence. Only the most mature should attempt to write complex if/then type statements.

Step 4: Send out an early draft

Stakeholders should be encouraged to comment with short turnaround time limits to begin the buy-in process and improve the safety and robustness of the protocol.

Step 5: Test an early draft of the protocol.

The early draft of the protocol should be tested with a few patients. Immediately after these patients have been tested, the authors of the protocol should huddle with nurses and other staff who will be using the protocol to discuss what worked well and what needs to be changed. The information should immediately be incorporated into the protocol for the next series of tests.

Step 6: Seek additional input from other interested participants.

The initially tested and modified protocol should now be re-communicated with all other clinicians and staff who will eventually use the protocol and further input requested. The input should then be used to remodel the protocol. The remodeled protocol should be tested and continually re-modified as needed.

Step 7: Set expectations on use of the protocol

Expect either that the protocol will actually be used, or that the reason for opting out is communicated to the development team whenever a clinician decides not to use the protocol. This feedback information is crucial for remodeling and improving the protocol as necessary.

Step 8: Assign a process or protocol owner.

The ability to sustain a protocol is dependent on an owner. The owner of a protocol has several responsibilities including being aware of any new literature that would impact the protocol, having basic data regarding the reasons why the protocol is not being used, and having available the compliance data regarding the use of the protocol. No changes can be made to the protocol without consent and delegation of those changes from the process owner.

Step 9: Remodel the protocol

Changes should be made to the protocol based on knowledge from non-use of the protocol and defects detected in the use of the protocol.

The information provided to the team and the protocol owner by those clinicians who elect not to use the protocol, as well as when defects are detected, is used to remodel and change the protocol as appropriate. Modifications and improvements of the protocol should be an ongoing and continuous process. In essence, no protocol should ever be finished. The protocol will actually always be in the design mode.

Leadership Responsibilities

The leadership responsibilities in the standardization of processes must consist of the following attributes, but are certainly not limited to these:

- Develop a culture that expects and insists on standardization.
- Build standardization into processes as part of overall reliability design and insist on at least 10^{-2} level reliability.
- Require clinicians who do not use the protocol to communicate why they do not use it. Develop the concept that opting out of protocol use is acceptable for the certain conditions that the protocol does not cover, but that a requirement for opting out requires communicating the reason(s) why the action was taken.
- Assign resources to measure the outcomes and reasons for non protocol use.
- Insist on every protocol having an owner who is responsible to maintain the standardization.
- All standardization must use human factors knowledge in the development and implementation of protocols.
- Patients and customers of a service, rather than individual providers, should drive any variation in protocols.

Initial standardization of a care process need not be perfect and the design should allow some failures. If an attempt is made in the initial design to deal with any and all probabilities that engage the clinical process, the initial protocol will become far too complicated. A complicated design is much more difficult to understand by the front line staff who needs to implement the protocol. The goal for the first step of reliable design is 10^{-1} . The method of standardization is more important than the standard itself. When the process is inclusive and everyone has input, then acceptance and utilization increase. The process of testing, measuring, and improving the protocol also creates agreement between clinicians and certainty that the protocol is an improvement. Deming noted in his book, *Out of the Crisis*, that if we do not use standardization (voluntarily), we end up with regulations (required by regulating agencies).

Second Step (Defect Identification and Mitigation)

The first design step focused on standardization, with the intent to prevent initial defects from occurring. The design principles were used to get to a 10^{-1} level of performance. Once that level of performance is reached, the second tier of the design can be used. The second step sets up a methodology to identify defects from the first step and the subsequent mitigation of the defect. The step is needed in the design for several reasons. First, it allows and even anticipates failure in the standardization step because the defect will be identified and mitigated in the second step. Second, it allows a better balance of resource use. If a design has to be perfect from the beginning, commonly more resources are needed up front since every opportunity will need to be placed under the same high level of scrutiny. Third, the step truly fosters the atmosphere of mitigation and recovery. Most importantly, however, it allows less than a perfect design in the standardization step so we do not have to plan for every possible contingency in the first tier.

The second step is really all about using human factors in a design to identify the defect. A frequent approach is to use redundancy. Redundancies need to be carefully considered since they do represent a form of “waste” and should not be a complete re-audit. In general, they need to be independent of the original process used in the first step to prevent the defect. Experience in setting up deliberate second step redundancies is they should not be used before a solid 10^{-1} level of reliability has been reached in the first step, because poor standardization designs propped up by expensive audit level redundancy interventions are difficult to maintain over the long run.

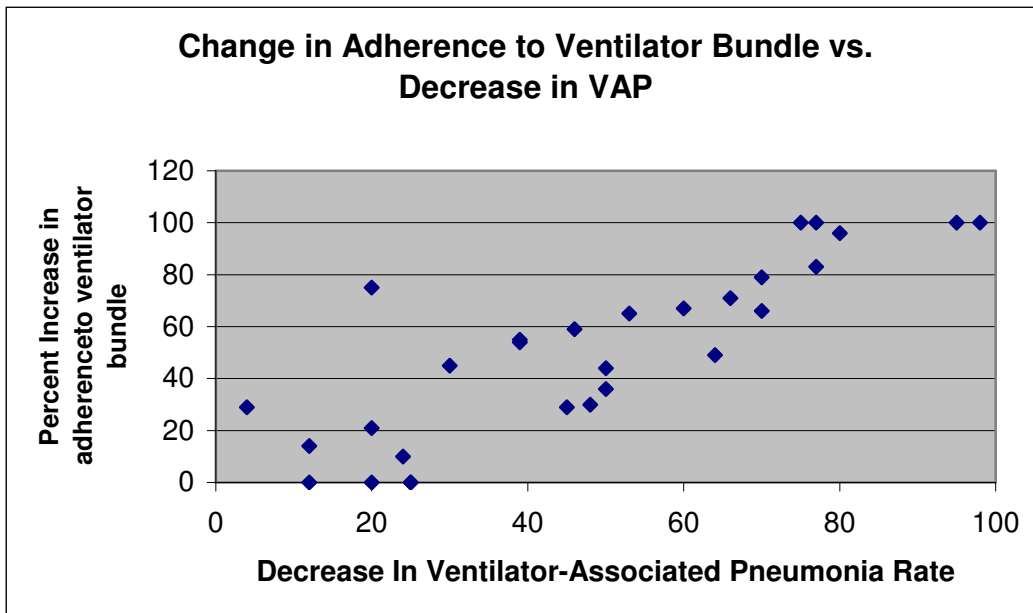
The use of redundancy techniques basically follows the principles of human factors science. The design strategies include, but are not limited to, decision aids and reminders built into the system, desired action becomes a default, use of scheduling, and taking advantage of habits and patterns.

The second design step actually has two components. The first is the design of a sensible redundancy to detect failure from the first tier, and the second is designing into the process the ability to mitigate the defect. Mitigation can include primary or retrospective correction of the defect. The second component of the redundancy step is to set up a measurement tool to determine the frequency of use of the redundancy. A redundancy rarely used will erode over time and not be dependable. A redundancy used too frequently suggests a poorly designed first-tier standardization step and warrants some basic redesign.

Here is how applying the first two steps successfully will achieve a 10^{-2} level of reliability. Assume 100 opportunities where the first step achieves a 10^{-1} level of reliability [80% (or 80) of the opportunities were achieved]. Twenty opportunities failed and moved to the second step. In the second step, the design was built to also achieve a 10^{-1} level of reliability. Of the 20 opportunities, 80% were achieved. The remainder (4 opportunities) were not achieved and remained as defects. Out of the 100 opportunities, 96 were achieved and 4 were not. A 10^{-2} level of performance was achieved.

Some designs, however, might call for a higher level of performance than 10^{-2} . When a sustained level of 10^{-2} has been achieved, an organization might deliberately move forward to a 10^{-3} level of performance. The design for this level of performance will by necessity be more sophisticated. A deliberate decision would need to be made for the added expense by having a clear understanding of the relationship of process reliability to the outcome desired. For much of the work in non-catastrophic processes, 10^{-2} appears to be adequate for very good outcomes.

As an example, a recently published paper on the ventilator bundle has shown process improvement to the 10^{-2} level of reliability and the relationship to decreased episodes of ventilator-associated pneumonia. The ventilator bundle consists of four processes in the care of patients on respirators: prophylaxis against deep vein thrombosis, prophylaxis against peptic ulceration, elevation of the head of the bed, and sedation vacation. When all four of these processes are improved simultaneously to a level of 10^{-2} reliability in ventilated patients, rates of ventilator-associated pneumonia decrease.



Intensive care units that successfully reduced ventilator-associated pneumonia used 10^{-2} model change concepts with obvious 3-step design. For example, head-of-bed elevation was standardized, with defaults involving family and respiratory therapy was step 1. Step 2 involved the ward clerk checking the room on

an hourly basis to see if the head of the bed was elevated and, if not elevated, mitigated by a predetermined process. Defects requiring mitigation were studied and the process redesigned as needed. The standardization of process, identification of initial failure, and using the knowledge of the failure to redesign clearly were employed. The result was reliability of process and marked reduction in ventilator associated pneumonia.

Third Design Step (Identification of Critical Failures and Subsequent Redesign)

Understanding why the initial designs fail, and using the information about failures to redesign, is an essential part of reliability work. The effort in the third design step consists of two components. The first is the deliberate measurement of defects; the second is the deliberate creation of a direct link from the defects identified to the redesign process. All designs need a measurement of defects. These defects provide the learning necessary to take the design to the desired articulated level of reliability. The causes for the defects need to be prioritized, and then the highest-priority defects used for redesigning either the first or second tier. In order for this to occur, both components of the third tier need to be in place. The feedback loop to the design should be deliberate and swift to ensure rapid design.

Generic 3- Step Design Model

First Design Step	Considerations
Prevent initial failure at 10^{-1} level by achieving standardization.	Use the reliability “set-up.” Specify the segment for the initial design . Initially design to attain 10^{-1} . Use defects to redesign as necessary to achieve 10^{-1} .
Second Design Step	
Identify failures from tier 1 and mitigate with the intent of achieving 10^{-1} .	Utilize human factors designs Measure failure rates from design step 1. Use second step changes unless design step 1 is at least 10^{-1} .
Third Design Step	
Prioritize defects and redesign design step 1 and design step 2 until the articulated goal of 10^{-2} is reached.	Redesign only if articulated goal not reached and sustained. Tackle 1 defect type at a time based on prioritization.

The following example illustrates the 3 step design applied to the use of the ventilator bundle.

Designing the First Test of Change and Beyond

Reliability design methodology is intimately linked with rapid-cycle tests of change. The initiation of rapid-cycle tests is dependent on getting the first test of change started and then continually building on the knowledge gained. The worksheet for testing change has been a powerful tool in designing those first tests of change. The worksheet forces the team to be explicit in terms of the individual responsibilities in the design of the test, the tasks needed to be done before the test is carried out, and the measures to be used to decide if the test was successful. The worksheet below is an example of a well-planned test of change.

Worksheet for Testing Change

Aim: (Overall goal you would like to reach)

For all four components of the ventilator bundle we will achieve 10^{-2} “all-or-none” performance on the four measures by Jan 2006.

Every goal will require multiple smaller tests of change.

Describe your first (or next) test of change.	Person Responsible	When to be done	Where to be done
Test the ability of the ICU team to keep the head of the bed elevated in ventilated patients by using the RT hourly rounds on 1 patient for 1 day	Penny	Oct 15	SICU

Plan

List the tasks needed to set up this test of change.	Person Responsible	When to be done	Where to be done
1-Train the RT	Carol	Oct 14	Office
2-Select a patient\	JoAnn	Oct 14	SICU\
3-Educate the ICU staff	JoAnn	Oct 15	SICU
4-Write protocol for keep HOB elevated	Jim	Oct 14	Office
5-Arrange for a huddle at the end of Oct 15 to review.	Penny	Oct 14	SICU

Predict what will happen when the test is carried out.	Measures to determine if prediction succeeds
1-Protocol will be used. 2-Protocol will need refinements. 3-HOB will be maintained. .	1-Observation yes or no 2-Debrief with nurse and RT 3-Yes or No

After the first test of change is finished, the rest of the worksheet is filled out to assess what went right, what went wrong, and what you will change during the next cycle of testing. The tempo with which the repeating tests of change occurs will determine the speed with which the actual process becomes more reliable. Testing every day or every other day results in a key process improvement every couple of weeks. Testing once a week results in key process improvement every 3 to 4 months. The speed of testing is the key to speed of implementation and spread. The rest of the worksheet is completed in the following manner:

Do Describe what actually happened when you ran the test.

The nurse was unsure of the use of the protocol. He failed to cover all the items needed for the complete instruction set.

Study Describe the measured results and how they compared to the predictions.

Protocol was not used correctly. Some of the confusion was related to how the protocol was laid out. The nurse gave some suggestions for improvement. The nurse felt that the process would not take any longer especially if the form is modified.

Act Describe what modifications to the plan will be made for the next cycle from what you learned.

The form will be modified by Jim, and we will set up another test tomorrow on 3 North.

Conclusion

The introduction of reliability into health care design will be required if we are to achieve the higher levels of performance demanded not only by regulatory agencies, but also to fulfill our own need to provide the totality of safe, high-quality care to our patients. The 3 step design strategy will give organizations the tools to accomplish the task of making promises and the ability to keep the promises we make to our patients.