

Delivering Reliability in the Healthcare System

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Introduction

The alarming truth for patients in US hospitals is their likelihood of dying highly correlates with their choice of hospital. This fact is cause for hospitals to reflect and continuously evaluate all methods to eliminate preventable deaths. Hospital mortality rates can be systematically reduced through reliable implementation of proven interventions. This is a statement [1] from the Institute for Health Improvement (IHI), a not-for-profit organization, widely recognized in healthcare. This organization, has taken the initiative to apply industry methods of system reliability to healthcare systems.

IHI defines Reliability as failure-free performance over time [2]. This is simple enough to be understood by anyone. The aim is to have no failures over extended period time in spite of variability in patient environment. This is in line with the technical definition of reliability as the probability of successful performance of intended functions for a specified length of time under specified user (patient) environment. In a system where the severity of consequence is high, such as in hospitals, the goal is to achieve reliability as close to 100% as possible. This is called failure-free performance. Some hospitals have achieved this goal for specific medical procedures for several quarters. Can they extend this performance over years instead of quarters? That depends on many factors such as management culture, changes in the process, and teamwork, etc.

The failures of the U.S. healthcare system are enormous considering the severity of failures. As much as 100,000 patients die each year from hospital mistakes. Another 2.1 are harmed from nosocomial infections (infections acquired during hospital stay). The cost is in the billions of dollars (USD). My personal discussions with doctors show that there is reluctance to apply reliability principles to healthcare systems because the variability in healthcare is enormous compared to aviation and other industrial fields. Each customer (patient) is different and each illness is unique in its own way. Then there are interconnecting systems, such as cardiology, gynecology, gastroenterology, emergency medicine, oncology, and patient data from various doctors, pagers, computers, vendor software, and intensive care, which operate independently most of the time.

In healthcare, each critical process can have its own reliability goal. For example, if a protocol requires that a patient coming to the ED (emergency department) must get attention within ten minutes of arrival, then the performance can be defined as “patient must be registered with the triage nurse within 10 minutes”. A failure can be defined as “patient waiting longer than 10 minutes”. A woman in a New York hospital died while waiting for an hour in the emergency department. Her blood clot in the leg traveled all the way to her brain. In another New York hospital, a woman waited about 24 hours before collapsing on the floor. All 24 hours were recorded on the hospital video.

The time dimension for reliability can be defined in terms of calendar time every three months (quarterly) or every 1000 patients. Then the reliability can be measured as a percentage of patients receiving service within 10 minutes during the quarter or per 1000 patients. IHI is taking a similar approach for patients needing anti-biotic within an hour after surgical incision. In this case, reliability is measured as the ratio of number of patients receiving the antibiotic within an hour and the number of patients requiring this treatment.

This paper is about what reliability principles we can apply to healthcare based on my experience of over 25 years as a consultant to the aviation and medical device industry. More comprehensive knowledge can be found in the references at the end of this paper.

System Reliability Theory

Before we define system reliability, we need to define a medical system. It is a composite, at any level of complexity, of medical equipment, caregivers, medical procedures, lab work, environment, communications, and patients with a specified system mission. Medical equipment includes CRT, MRI, ventilators, artificial heart, and dialysis machines. People include physicians, residents, interns, attendings, nursing staff, med techs, support associates, administrative personnel, patients, visitors. Medical procedures include diagnosis, surgery, intensive care, intermediate care, lab procedures, intubations, intra-venous fluid infusions, patient visits, admittance, discharge, emergency patient processing, and trauma support. Communications include patient handoffs, verbal communications, communication among pharmacists, doctors, nurses, residents, patients, pagers, telephones, computer screens.

The mission obviously is safe and positive experience for patients. Therefore system reliability is the function of the integrated performance of all these. This model is pictorially shown in Figure 1 and is called a series system. Any block in the system fails, the whole mission fails.

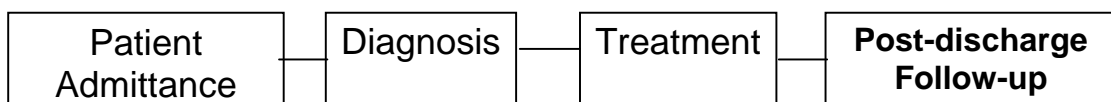


Figure 1. The chain shows that any subsystem fails, the mission fails.

We can write the reliability model as:

$$\text{System Reliability} = R(\text{Patient admittance}) \times R(\text{Diagnosis}) \times R(\text{Treatment}) \times R(\text{Post-discharge follow-up})$$

In this equation R stands for reliability. A hospital may modify the model if this model is not comprehensive. This model assumes that each of these for processes is independent of each other and each task must be performed right. If not, the laws of conditional probability apply. Reference [3] covers calculation of conditional probability. Numerically, the system reliability the above model will then be

System Reliability = (Percent patients admitted without harm or inconvenience)X(percent patients receiving right diagnosis the first time)X(percent patients receiving the satisfactory treatment)X(percent patients follow the treatment regimen after discharge)

If the reliability of each of these four subsystems is 90 percent, the system reliability (chance that all of these will perform as intended) would be

$$.90 \times .90 \times .90 \times .90 = .656 \text{ or } 65.6 \text{ percent}$$

To my knowledge no hospital is measuring reliability at system level. Most of them are applying to a component of a system. The IHI is applying reliability measurements to components such as diagnoses, community acquired pneumonia, heart failure, acute myocardial infraction, hip/knee replacements, and bypass graft surgery. The reliability for each is simply the ratio of patients receiving the right care and the number of patients requiring the care. It may be noted that the system reliability model can be applied at component level also as long as the components are functions of equipment, people, procedures, environments, and communications. The mission is still the same, safe and positive patient experience.

How to Design the System for Reliability?

Reliability begins with the design. The design is constantly improved through verifications and validations. As a minimum, the following design process is followed:

1. Assess the current reliability using the above model and past data
2. Identify weak links and allocate higher reliability goals to them
3. Perform Healthcare FMEA (Failure Mode and Effects Analysis) on weak links to predict potential failures of healthcare and determine strategies to achieve the desired reliability goals
4. Use Fault Tree Analysis when the causes of failure in the FMEA are too complex
5. Redesign the healthcare system using reliability improvement techniques
6. Verify that the work done on the FMEA and the design improvements was done using divergent brainstorming and convergent solutions
7. Understand the “bath tub” shape of the failure rate behavior over time and take proactive actions to minimize failures
8. Validate that the new design is achieving the reliability goals

A brief description of each is in order. Hospitals should adopt what fits into their culture and should use innovation as much as possible. Continuous improvement is often insufficient because teams tend to make marginal improvements that yield very low return on investment.

Assessing the current system reliability

Whether one is dealing at system level or component level, the expected reliability (percent patients receiving the treatment as intended) needs to be established from the current data.

Since reliability is a measure of the proportion of successes, we must define what a failure is. If a physician fails to sanitize hands before touching a patient, is it a failure? Also, no one generally documents such failures. In aviation, there are four categories of failures measured by the amount of harm which is documented. Category I for deaths, category II for major harm such as amputation of the wrong body organ, category III for minor harm such as patient falling out of bed but recovering from pain within a day, and category IV for negligible harm such as a diabetic patient given a glass of grape juice with the breakfast and then given high dose of insulin to lower his blood sugar. Hospitals should decide which categories constitute a failure before assessing reliability.

If the data is not documented, an estimate can be made by a cross-functional team, to be verified as data accumulates. This process of estimating reliability is called Reliability Prediction. The purpose of this step is to see if the expected performance is acceptable. If not, then there is a need to redesign the process for higher reliability.

Identifying weak links

In healthcare, reliability depends on sequential chain of tasks done correctly. If any link in the chain fails, the whole performance fails. The weak link theory says that the chain is only as strong as the weakest link. Each critical task must be performed as intended. Any of these tasks done incorrectly can result in a patient mishap. Knowing the weakest link sets priority for reliability planning. We have to strengthen the weak links first. In the system level chain at the beginning of this paper, there are four links in the chain: the patient admittance process, the diagnosis process, the treatment process, and the post-discharge care. If the treatment process has the lowest reliability number, we need to fix this process first. The reliability of the entire chain cannot be higher than this number no matter how much improvement we make on other links. A fraction multiplied by another fraction cannot be higher than the lowest fraction. This is not say that we must work on weakest link only but the priority should be fixing the weakest, then fixing the next weakest, and all the way to other links, till the reliability goals are achieved.

Performing Healthcare FMEA

The purpose of FMEA is to identify all the possible things can go wrong by having a divergent brainstorming. The composition of the team is very important. As a minimum, there should a doctor associated with the procedure, nurses, a person from the patient safety office, and a quality assurance representative.

The team constructs a process flow chart of work and documents the following in a standard FMEA table (reference 2 shows the portion of the FMEA conducted at the East Alabama Medical Center):

- Description of each step in the process
- What can go wrong in each step (failure mode)
- Why would it go wrong (cause)
- What are the consequences (effects)
- How frequently this event is likely (occurrence)
- If anything is going wrong, how early it is going to be detected (detection)
- How severe the harm can be (severity)
- How would you mitigate harm (action)

There will be hundreds of potential things going wrong. It is a time consuming process. It can take one to three days, but the return on investment is very high. Most hospitals do this in blocks of few hours at time. If we prevent 50 or so mishaps such as infections or wrong medications or medication at wrong time, the savings can be in millions. As an example, Dr. Peter Pronovost introduced a simple checklist to decrease catheter-related bloodstream infections in the surgical intensive care unit at Johns Hopkins Hospital, it brought down the infection rate to zero most of the time. Then 103 ICUs in Michigan started to use this mitigation strategy, the infection rate went down from 7.7 per 1000 catheter-days to 1.4 over a 16 to 18 month follow-up period⁴. This is a very significant improvement in reliability resulting in millions in savings. The cost of implanting the checklist is practically nothing.

In the aviation system only occurrence (frequency) and severity are estimated to assess the risk. In the industrial systems such as the one used by East Alabama Medical Center the occurrence, detection and severity are estimated on a scale of 1 to 10. They are multiplied to calculate the relative risks. This multiplication is called the risk priority number or RPN. Reference 3 has such guidelines. As an example, the following is one of the many items in the East Alabama Medical Center FMEA:

Step in the process: Order medication
Failure Mode: Miscommunication about the dose
Causes: Illegible writing, calculation mistake or pharmacist has mental lapse
Effects: Potential for death
Occurrence: 2 (on a scale of 10)
Detection: 5 (scale of 1 to 10)
Severity: 10 (scale of 1 to 10)
RPN: 100
Mitigation Action: The report did not contain a list of actions

Using fault trees

As mentioned earlier, fault trees are to be used when the causes are unknown or not understood. They are the best root cause analysis technique. It was developed by Boeing on the Minuteman Missile Program to avoid any mishap. It is a standard practice for over 40 years in aviation, nuclear power and in industry. It is covered in reference [3]. It systematically forces the team to think of all the possibilities of hidden hazards, errors,

and unusual events. The users use the aviation guide for mitigation, in the order of following precedence (I have tailored to application in healthcare):

- Change the design to avoid or eliminate hazards
- Design for failsafe exit (If the procedure fails, there should be no harm to the patient)
- Provide early warning of things going wrong (If the physician does not sanitize hands before touching a patient, it is a warning of more things to go wrong)
- Provide special training with frequent validation that it works all the time.

Redesign the system using reliability improvement techniques

Some of the reliability improvement techniques are:

- **Fault Tolerance:** Mitigate the effect of error by providing redundancy such as the nurse checking the doctor's actions. You can add one more redundancy: the head of the unit periodically confirming that the doctors welcome the reminder by the nurses and provide rewards for good work.

We have three choices:

- A: only the physician is controlling the infection
- B: the physician is controlling and the nurse is cross-checking (dual redundancy)
- C: the physician is controlling, nurse is cross checking, medical director validating periodically (triple redundancy)

If the reliability of each of the three persons performing right is 0.90, the reliability is 90 percent for scenario A, 99 percent for scenario B, and 99.9 percent for scenario C. Method of computation can found in reference [3].

- Derating (Put fewer loads than the capability. Allow some spare time for doctors and nurses, minimize interruptions, not assign to too many patients)
- Minimize the number of components (example: minimize the number of steps in the checklists, the less the steps the easier to remember)
- Perform root cause analysis to eliminate as many root causes as possible)

Understand the bath tub shape of the failure rate behavior

This understanding is especially critical on any new procedure or using a new medical device. The failure rate is very high in the beginning because of learning curve problems and until training gets validated. This time period has decreasing failure rate over time because the care providers are learning from mistakes and latent hazards are being addressed.

The second behavior of constant failure rates over time is called random failure region. You know that unexpected failures can occur such as someone inadvertently disconnecting the power or someone cannot find the replacement battery. It is like you know some day a rock can hit the wind shield of your car while driving but you don't know when.

The third region is called the wear out region. Medical devices such as artificial heart valve, pacemakers and defibrillators, wear over time and eventually they fail. People can wear out too in their attention to details when they use the same procedure for years, especially when no one is cross-checking. This period is called the region of increasing failure rate over time. So there are three regions over time: decreasing failure rates, constant low failure rates, and increasing failure rates. They regions occur sequentially and the three together look like a bathtub (see Figure 2). Knowing this nature of failures, we need to have a mitigation strategy for each region.

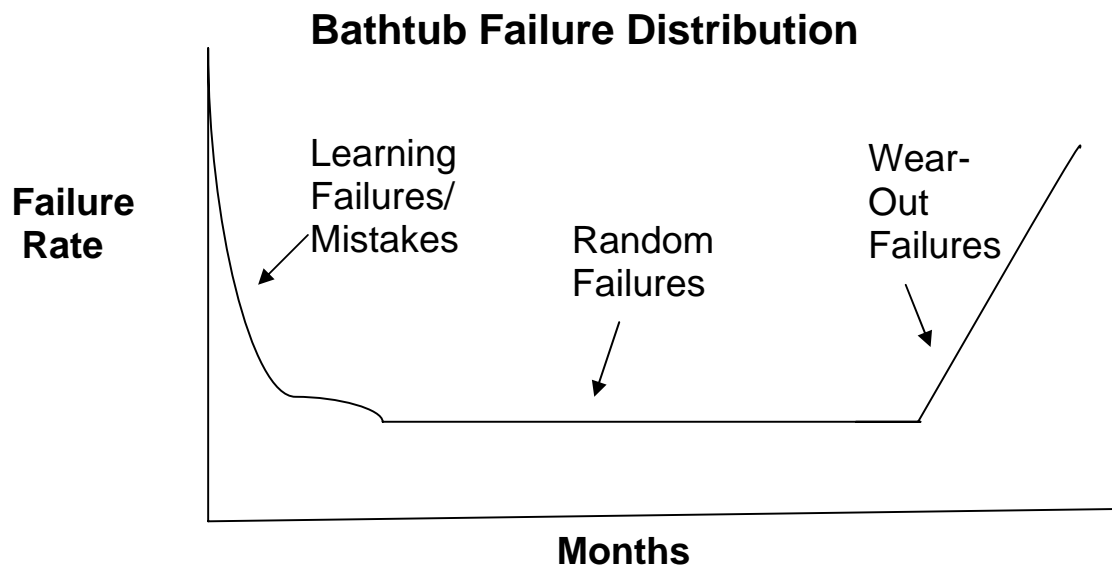


Figure 2. The failure rate behavior of a typical system over time

Validating the design for reliability

After defining what constitutes a failure and what not, the data collection effort needs to be planned to measure reliability (percent successes over time). One must review trends of failure rates. They tell that our mitigation actions are providing high value or not. If the progress is too slow or negative, we need to review if the FMEA was done correctly. Go back to the drawing board and redesign the process and procedures. We need not wait until there is a mishap!

Readers are welcome to contribute articles on reliability in healthcare. Please send comments and opinions to Dev Raheja at raheja@PatientSystemSafety.com

References:

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