

SECTION I

Recognizing and Supporting the Value of Proaction in Healthcare

CHAPTER 1

The Need for Reliability Tools in Healthcare

Background Information

A general comment about healthcare should be stated up front:

“Based on our experiences with people who work in the healthcare field, they are one of the most committed groups to their profession that we have had the privilege to work with”.

This statement is made up front, because many of the observations and candid conclusions that will be delineated in the pages that follow may give the reader the impression the statement is not true. However, the comparisons presented between the industrial culture decades ago and healthcare today are meant to help the two communities come together in the interest of learning for the betterment of the entire healthcare industry and especially all of us as patients. The impediments will be explored that are imposed on the healthcare community by their unique form of communication.

In industry there is a well-known field of engineering called Reliability Engineering (RE). This field of engineering was pioneered in the heavy manufacturing industry by Charles J. Latino who was the founder and Director of The Reliability Center for Allied Chemical Corporation (Now Honeywell) in 1972. RE is a field that focuses on equipment, process and human reliability. Several methods and tools were modified for

industry by this group including Root Cause Analysis (RCA), Failure Mode and Effects Analysis (FMEA) and, a hybrid called Opportunity Analysis (OA). These three (3) methods are singled-out to be discussed in detail in later chapters, because they represent requirements under The Joint Commission (TJC) guidelines.

The perspectives and tools presented in this text have been field proven in the manufacturing industries for over 35 years. What this book hopes to accomplish is to convince the reader that Reliability tools such as RCA, FMEA and OA are NOT unique to any specific industry. Such Reliability tools provide invaluable skills for the human beings tasked with determining risk, opportunities and why things go wrong.

The specific approach for the application of RCA, FMEA and OA is referred to in the text as PROACT^{®1}. While many approaches exist in the market, our tool of choice is PROACT[®] thus making it simply a brand name for our approach to identifying and solving problems.

The PROACT[®] Approach is used at such Fortune 500 companies as Lyondell-Citgo (oil refining), Weyerhaeuser (paper), Eastman Chemical (chemicals), Southern Companies (power), the U.S. Navy (defense) and many more industrial companies. In addition, healthcare systems such as MedStarHealth (Maryland), PeaceHealth (Oregon) and Loyola (Illinois) also use PROACT[®]. The intent here is to demonstrate the range of applications. Whether it is problems making candy bars or problems aboard naval ships, the thought processes used to solve the issues are common to the analysts themselves.

¹ PROACT is a registered trademark of Reliability Center, Inc.

Solving problems in healthcare is no different. Humans are still tasked with figuring out what went wrong and need tools to accomplish the task.

The Signals Were Stacking Up in Healthcare

In 1998, it became apparent that the healthcare industry was on the verge of a new frontier, that of Patient Safety. Several studies would be released to the press about the delivery of healthcare that would not be endearing to the medical community. It was also apparent that pending legislation would follow that would insist on efforts to reduce medical errors (or medical harm as many would prefer to call it).

In short, the writing was on the wall; the healthcare industry would soon be “under the microscope” for deaths resulting from excessive medical errors. This tension in the industry climaxed with the release of the Institute of Medicine (IOM) report in 1999 indicating that between 44,000 – 98,000 people are killed a year by medical error². This would surely create a public uproar and it did, and now a worldwide epidemic of medical error would be exposed.

As “outsiders” to this healthcare industry, such numbers are astounding. Deaths by medical error are the eighth leading cause of death for all Americans³. What is even more frustrating is finding out that the IOM report only considered “errors of

² Kohn, Linda T.; Corrigan, Janet M. & Donaldson, Molla S., [Editors]. (2001). *To Err is Human: Building a Safer Health System*. Washington D.C.: Institute of Medicine.

³ Centers for Disease Control and Prevention (National Center for Health Statistics). *Deaths: Final Data for 1977. National Vital Statistics Reports*. 47(19):27, 1999.

commission”. Errors of commission are when someone takes an inappropriate action in handling a patient’s care and the patient ends up worse than they were before as a result of the error.

The point here is that “errors of omission” were not in the report. Errors of omission are where someone *should have* taken action and did not. For instance, a patient comes into the Emergency Department (ED) with some symptoms that are not diagnosed properly by triage. As a result, they wait in the ED for an extended period of time and suffer a heart attack, a seizure, or any other adverse consequence due to not being seen in a timely manner. The number of people killed by errors of omission would likely be a significant multiple of those killed by acts of commission. Very few in the healthcare profession have openly contradicted the validity of the IOM report and most believe the statistics are grossly understated. What the IOM report did accomplish was a challenge to the idyllic belief that errors occurred rarely and therefore brought the fact that mistakes happen in healthcare to the forefront and gave the industry the opportunity to respond to the challenge.

The Paradigm of Patient Safety

When looking at healthcare from an outsider’s perspective, it is like going behind the curtain minutes before the opening of a Broadway play. The audience’s perspective sees chaos that they would have never expected to see. This is where the traditional view of the hospital being a safe haven, turns to the view of “avoiding getting sick or hurt at all costs so we do not have to run the risk of being admitted to the hospital”.

Most Americans feel this way. They see going to the hospital as a place where they can place their health and welfare in the competent professional's hands and the risk of a poor outcome is infrequent. Even many healthcare professionals anonymously admit they have reservations about leaving their loved ones in a hospital. Even healthcare professionals indicate patients must watch and question everything regarding a loved one's care. It is clear that education is necessary for both perspectives in order to gain a deserved respect for the other's position.

In a 2005 study conducted by VitalSmarts⁴, the following conclusions were published:

1. 53% of nurses and other clinical care providers expressed concerns about the competence of the peer's they worked with.
2. 81% of physicians expressed concerns about a nurse's or others clinical-care provider's competence.
3. 75% of nurses and other clinical care providers expressed concerns about a peer's poor teamwork.

These few conclusions support our previous discussion where most patients would not expect this type of discord "behind the curtain" of their hospitals.

⁴ Maxfield, David; Grenny, Joseph; McMillan, Ron; Patterson, Kerry and Switzler, Al. *Silence Kills: The Seven Crucial Conversations for Healthcare*, VitalSmarts Study, 2005, 7-8.

Having attended many healthcare conferences, it was not rocket science to figure out the buzzword in the healthcare industry was “Patient Safety” and its impact on patient outcomes and public opinion. Many very dedicated, talented and esteemed speakers tell of their efforts to implement a culture of patient safety their respective hospitals.

From the outsider’s perspective, all we think about while listening to this is, “If Patient Safety is only becoming the focus now, what was it before?” From the patient’s perspective, we would have thought Patient Safety was always the primary focus of healthcare!

Reflecting on experience from industry, “What parallels could be drawn?” In industry, most every facility will have a safety department. It may be called something else like Environmental, Health and Safety (EH&S), but nonetheless they are charged with ensuring compliance with governmental safety regulations (i.e. – EPA, OSHA, etc.) and making the workplace as safe as possible. However, while this group exists for their chartered purpose, very few who work in the facility believe their safety is totally in the hands of this Safety Department. It is well known in industry that YOU are the one most responsible for your own safety!!

This is certainly the way healthcare workers would prefer it. However, the public believes their safety is the responsibility of those individuals providing their healthcare. Oftentimes people perceive this as rude, inappropriate or condescending (especially in the very hospitable South) if they ask questions about what is going on with their care. One

thing that should be understood is that patients should speak up and take control of their own care. After all it is their lives that are at stake.

The Role of the Risk Manager: Industry Compared to Healthcare

Understanding Patient Safety is everyone's responsibility, it must be accepted that individuals are obligated to be responsible in the organization for carrying out the programs that will assist in achieving patient safety goals and ensure compliance with regulatory agencies. In healthcare, this role is primarily assumed by the title of Risk Manager (RM). While roles and responsibilities vary from hospital to hospital and system to system, the remainder of this topic will assume the title of RM assumes the responsibility of patient safety from the corporate standpoint. Such positions as TJC Compliance Manager, Patient Safety Officer, Quality Manager, Performance Improvement Manager and Continuous Improvement Manager are all titles that may share this role as well.

Having visited hospitals and attended conferences around the USA, it became apparent that a new vocabulary would have to be learned (as is the case with exploring any new working environment). Part of the frustrating task of this endeavor is not as much learning new words and acronyms, as it is re-defining current words in our respective internal dictionaries.

One of the key terms that had to be redefined was with the title of Risk Manager (RM). Having met, talked with and interviewed hundreds of RM's, a consistent description of

roles and responsibilities could not be determined. The role and function of the healthcare RM depends upon the following: Size of the organization (single hospital vs. large healthcare system), scope of services and activities, available resources, location of the organization to be served (rural vs. community), type of facility or organization (acute care, LTC) and the complexity of the organization (academic medical center).

The Office of Managing Risk and Public Safety (An Office of the Department of the Interior)⁵ defines Risk Management as (www.mrps.doi.gov):

“Simply put, Risk Management is a set of mitigation measures, including policies, and the associated decision making processes that reduce or eliminate risks. A risk is the likelihood of occurrence and severity of an adverse consequence of a hazard. Hazards are events, activities, and conditions that have the potential to cause harm.”

However, as these wonderful people described their positions, we had to impose our definition of what a Risk Manager was as compared to their roles in healthcare. Why is this significant?

In an effort to try and explain the differences between the role of the RM in healthcare and the role of the equivalent position in industry, some job postings for each were researched. The purpose was to compare the “average” job descriptions and explore the differences. It must be noted the equivalent position of RM in healthcare to that of

⁵ The Office of Managing Risk and Public Safety. (2004). What is Risk Management?. [Online]. Available: <http://www.mrps.doi.gov>

industry typically falls under the department of Environment Health and Safety or EH&S. Titles such as Quality Manager, Reliability Manager and Maintenance Manager may also include such roles as Risk.

Here is the healthcare Risk Manager job posting found (all the references to a specific system have been removed):

Manager, Risk Management

The Risk Manager is responsible for the development, implementation, and management of the hospital's corporate risk management program which includes coordinating the placement of all insurance coverage, risk financing, managing claims against the facility, interfacing with defense legal counsel, medical staff, insurers, and brokers. The Risk Manager administers the risk management program on a day-to-day basis, serves as the Patient Safety Officer, managing and analyzing data, conducting educational programs, and complying with the governmental regulations and TJC standards. A Bachelor's Degree and a minimum of five years experience in Risk Management, Safety, Insurance Management, Loss Prevention or related discipline required. Previous experience in clinical or hospital setting is preferred.

Here is the manufacturing equivalent of a similar job opening:

Certified Quality Engineer (Reagent Manufacturing) - 5+ Years' Exp, Degree, Pharmaceutical

Certified Quality Engineer - Reagent Manufacturing Job Duties:

- 25% - Implement cost of quality concepts, including quality cost categories, data collection, reporting etc. for reagents and reagent manufacturing.
- 25% - Implement a systematic program for planning, controlling and assuring product and process quality for reagents and reagent manufacturing.
 - Processes for planning product and service development

- Material characterization
- Acceptance activities
- Measurement systems
- Product and process validation
- 25% - Implement a systematic program for reliability and risk management for reagents and reagent manufacturing
 - Reliability life cycle characteristics
 - Design for reliability
 - Reliability and maintainability of reagents
 - Reliability failure analysis and reporting
- 25% - Implement a systematic program for quality problem solving and continuous improvement in reagents and reagent manufacturing.
 - Quality improvement models such as Kaizen, plan-do-study-act, TQM, etc.
 - Corrective and preventive action
 - Barriers to quality improvement

Minimum Job Requirements: (Skills, Knowledge, Education, Experience, Certificates)

- Minimum of five years' experience in the pharmaceutical industry.
- Minimum of five years' experience as a certified quality engineer.
- Bachelors or Master's Degree in a life science or chemistry discipline or equivalent.
- ASQ Quality Engineering Certified for at least five years
- Thorough understanding of quality philosophies, principles, systems, methods, tools, standards, organizational and team dynamics customer expectations and satisfaction, supplier relations and performance, leadership, training, interpersonal relationships, improvement systems, and professional ethics.
- Thorough understanding of a quality system and its development, documentation and implementation with respect to domestic and international standards and requirements.

- Thorough understanding of the audit process, including types of audits, planning, preparation, execution, reporting results and follow-up.
- Able to develop and implement quality programs, including tracking, analyzing, reporting and problem solving.
- Able to plan, control and assure product and process quality in accordance with quality principles which include software validation, product and process validation, planning processes, material control, acceptance sampling, and measurement systems
- Thorough knowledge of statistical analysis, reliability, maintainability and risk management, including key terms and definitions, modeling, systems design, assessment tools and reporting
- Thorough understanding of problem solving and quality improvement tools and techniques, including management and planning tools, preventive and corrective actions, and how to overcome barriers to quality improvements
- Able to acquire and analyze data using appropriate standard quantitative and statistical methods across a spectrum of business environments to facilitate process analysis and improvements.

Knowledge, Skills and Abilities:

- Specific knowledge of quality systems and design control for reagents and biological systems
- Excellent oral and written communication skills.
- High degree of initiative with the ability to work independently
- Good use of process and business judgment
- Ability to plan and organize work while remaining flexible
- High degree of accuracy and quality
- Ability to work with all levels of employees
- Knowledge of word processing and spreadsheets

While these two (2) descriptions are not manufactured, they suggest an unfair comparison because of the contrast in level of detail. Much of this can be attributed to what people perceive about engineers and their tendencies towards “paralysis by analysis”.

What can be seen as the key differences in these two roles? In healthcare, in many instances the role of the Risk Manager is geared towards compensating for bad outcomes when they occur, or Risk Compensation. Hence their responsibilities are geared towards ensuring the proper insurance levels are maintained, dealing with claims brought forth and implementing systems to prevent recurrence. Another noted contrast between these two (2) positions is that the RM more often than the engineer would place a lower weight on compensation in their decision to take a position. This clearly shows they are not in it solely for money but for more humane reasons that aspire to patient safety.

Contrast this to the manufacturing industry where their Risk Management roles focus on identifying and quantifying the risks that exist in their environment (or Risk Reduction), and then using technologies available to minimize the risk. In short, their job is to make sure the incident does not occur, as opposed to compensating for them when they do occur. This is quite a divide and is quite in-line with the healthcare culture.

This gets back to the basic paradigms associated with a culture. Responding to events only after they occur is a reactive approach that is typically very costly. Taking measures to eliminate or considerably reduce the potential of such events is a proactive approach

and is much more economical in the big picture. This is a key fundamental principle of Reliability, the distinction between proaction and reaction.

Over the past 30 years, a growing majority of manufacturers have adopted proactive approaches in their operations, which include the development and support of, Environmental Health & Safety (EH&S) departments, Reliability Departments, and Quality Departments. Within these departments they have systems set-up for preventive (time-based) approaches, predictive (condition-based) approaches and proactive approaches. Proactive approaches include tools such as RCA, FMEA, Risk Assessment, Lean Six Sigma, Reliability Centered Maintenance (RCM) and much more. Industry has proven beyond a shadow of a doubt that such proactive activities increase productivity, decrease the need for maintenance, decrease injuries and improve the quality of the product.

In 1997 a benchmark survey, Top Quartile Paper Mills claimed an average Return-On-Investment (ROI) of 19:1, while Chemical Processing came in at 16:1, and Steel production came in 18:1 for their Maintenance and Reliability initiatives.⁶

In healthcare there is still much skepticism as to the value of the business case for Reliability or for proactive activities, which are geared towards Patient Safety and Care. Building the business case for Patient Safety should not be too difficult a task when we consider what is at stake – patient lives!

⁶ Shultz. (2004). The Business Case for Reliability. [Online] Available: http://reliabilityweb.com/art04/buisness_case.htm

Error Rates and Technology

When reviewing the IOM report and the reported underestimation of deaths attributed to medical error, the question must be asked “What makes the healthcare field more prone to such high errors than any other industry?”

Again, reflecting on the history of industry over the past century, we found ourselves in the Industrial Age. This was a time where machines were evolving to help man accomplish work of various types. However, much of the work was still based on the brawn and physical stature of the man. The term “man” is used because at the time, there were few women in the industrial workplace because of the physical requirements required. At this time, industry was very labor intensive and required much man-to-man interfacing. Error rates for industry during this time period could not be found since the primary recorder of such information, OSHA, was not created until 1971.

Moving more towards the information age, where the equipment became very sophisticated (i.e. – robotics), it took less and less muscle and more and more brainpower to be multiple times more productive. This era saw the influx of women into the workplace.

Given this evolution, there is a heavy “person-machine” interface in industry today. As compared with the industrial revolution era, today in industry, three times more output is

achieved with one third the manpower. As robotics become more sophisticated, the human will serve in a support role to the technology.

Now revert back to healthcare and curiosity about why error rates would be so high in such an industry? Again, another paradigm about healthcare from an outsider's perspective is the technology used is of "star wars" caliber in healthcare. This has proven to be a half-truth. High technology in healthcare is employed on the sharp-end or the medical diagnostics end, but NOT in the administrative end. Remember, this is using generalities, but this is what an industry outsider's observation has been.

The administrative infrastructure of a hospital today is reminiscent of that of industry 15 to 20 years ago. Experience shows that when the Reliability Approach⁷ was introduced into industry 35+ years ago, the same resistance then in industry can be seen today in healthcare. The information infrastructure in healthcare is archaic compared to the technologies that are available on the market today. Why?

Here a very labor-intensive industry like healthcare where success depends and relies on responsible handoffs and good communication between caregivers, and they are expected to deliver care in an environment of archaic information systems.

Anytime there is a very labor-intensive industry that requires massive "human-to-human interfacing", the risk of human error is significantly increased. The risk of human error is

⁷ Latino, Charles J. (1980), *Strive for Excellence..The Reliability Approach*. Allied Chemical Corporation.

reduced in industries where man primarily interfaces with machines and Reliability is highest when machines talk to machines. Remember we are human, and with that comes human fallacy!

Regulatory Compliance Versus Patient Safety – Are They the Same?

In the previous chapter it was established that error rates in healthcare are expected to be higher because of the dependency on “person-person” communications. This means that conditions are ripe for a breeding ground of human error.

Knowing this, accreditation agencies such as TJC and patient safety organization such as IHI, implement various guidelines to assist in ensuring that such risk of human error in decision-making is minimized. These are often well-intentioned acts that are designed to be in the best interest of patient safety. However, how can this good intent be misconstrued and abused to the point it is counterproductive to patient safety?

It is very common practice that when TJC either schedules an audit or arrives for a surprise audit, the tension in the facility quantumly elevates. Stress abounds and everyone is trying to get their “ducks-in-a-row”. People scatter to get documentation in place; everyone is put on notice of the visit to ensure proper practices and housekeeping measures are in place and utilized. What is most important to notice here is whatever the priorities were that the facility was working on before the audit, have now been dropped and placed on a back burner for the time being.

There is little doubt the primary objective of such an audit, from the facility's perspective, is that they pass the audit with flying colors and maintain their accreditation status. This keeps the necessary federal funds flowing in order to keep the hospital running. From TJC's standpoint, auditors arrive with the greatest of intentions, a multitude of questions and checklists. Depending on the auditor, if they are satisfied the facility has met or exceeded their expectations, they recommend their accreditation status remain intact.

To complicate this matter even further, the General Accounting Office (GAO) released a report⁸ outlining their findings regarding an audit done on TJC's performance. The highlights of this audit are summarized below:

“In a sample of 500 TJC-accredited hospitals, state agency validation surveys conducted in fiscal years 2000 through 2002 identified 31 percent (157 hospitals) with deficiencies in Medicare requirements. Of these 157 hospitals, TJC did not identify 78 percent (123 hospitals) as having deficiencies in Medicare requirements. For the same validation survey sample, TJC also did not identify the majority, about 69 percent, of deficiencies in Medicare requirements found by state agencies.”

Now the auditing agency has been audited and it has been found to be significantly deficient in identifying whether hospitals are in actual compliance with Federal Medicare requirements or not.

⁸ GAO Report. [2004]. MEDICARE - CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals (GAO-04-850). Washington D.C.

What appears to have been lost in the translation is Patient Safety.

1. How does a successful audit directly correlate to actual patient safety numbers?
2. How is it actually measured that a patient is any safer in a facility that has passed an audit, versus one that has not?
3. Are such audits correlated to actual patient safety or more a “snapshot in time” that a facility passed an inspection?
4. Who is measuring actual patient safety - when a patient leaves in better condition than when they arrived at the hospital?
5. Can a facility pass an audit without demonstrating an effective patient safety program?

The intent here is to demonstrate a disconnect between measurement and actual performance. Does this actually happen?

Here are some examples:

1. One facility’s surveyor asked to review an RCA, while another facility’s auditor does not.
2. A Surveyor reviews an RCA for 3 minutes and determines it looks like all is order. However, it is not identified that all of the hypotheses in the analysis are validated with only hearsay, no hard evidence.

3. One Surveyor accepts an RCA using a Fishbone Diagram, while another does not for the same event.
4. A Surveyor may request an RCA on a near miss rather than a sentinel event while another auditor only expresses an interest in an RCA associated with a sentinel event.

The point trying to be made here is there can be a lack of continuity in how such surveys are done, as well as difference in the objectives. The GAO report confirms this. This is not saying this happens everywhere with every surveyor, but it does happen more often than it should.

When such disconnects occur the patient loses out. This is because the patient may do well-intentioned research on a facility's record in the past, and see that they are accredited. However, that accreditation may be misleading because the actual patient safety performance measurement is poor. How would the patient know? The patient is relying on the information by the regulatory agency to be accurate, so they can make informed decisions. As will be discussed in this text, when efforts are made to measure the effectiveness of Root Cause Analysis not by their ability to be compliant but their actual impact on patient safety, then reporting accreditation status will reflect a more accurate picture of a hospital true performance in the arena of Patient Safety.

In a recent presentation made to a group of hospital CEO's, such concerns were raised. The sums of the responses were equivalent to; "We do not put much stock in TJC

compliance. We feel if we focus on Patient Safety, then such compliance should be a by-product. If we have made our patient's much safer and we are not in compliance, then there is something wrong with the compliance process.”

Notice the difference in perspective from the CEO to the Risk Manager (RM). The CEO's do not put much stock in the compliance efforts; however the compliance effort consumes the RM at the sharp-end.

This divide must be brought together with a common purpose and vision of absolute Patient Safety.