Internal Medicine Grand Rounds

University of Texas Southwestern Medical Center

The Role of High Reliability in Patient Safety

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The Role of High Reliability in Patient Safety

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Purpose and Overview: The purpose of this Grand Rounds is to provide information on the current state of health care quality in the U.S. and describe the role of high reliability theory in quality improvement and patient safety. This will be accomplished with a discussion of quality metrics and outcomes of the U.S. health care system. The role of high reliability will be discussed in a review of current theories of high reliability and how some organizations have used the principles of high reliability in building safer health care delivery systems.

Educational Objectives: At the conclusion of this lecture, the listener should be able to

1. Describe the state of the U.S. health care system in terms of quality and safety,
2. Describe the components of an effective health care quality system,
3. Discuss two theories of high reliability, and
4. Describe several principles that any health care provider can use to provide more reliable and safe care for their patients.

The Role of High Reliability in Patient Safety

Case: X is an academic health care system with multiple hospitals and multispecialty clinics affiliated with a prominent university medical school. While the quality of care measured by multiple outcome metrics ranks X as one of the top healthcare systems in the country, its risk-adjusted sepsis mortality is below the median for U.S. academic medical centers. The clinical leaders of X want to decrease sepsis mortality in their hospitals and set an institutional aim of reaching the best decile in sepsis mortality among academic medical centers in the U.S. within two years. What would be the best methodology to accomplish this goal?

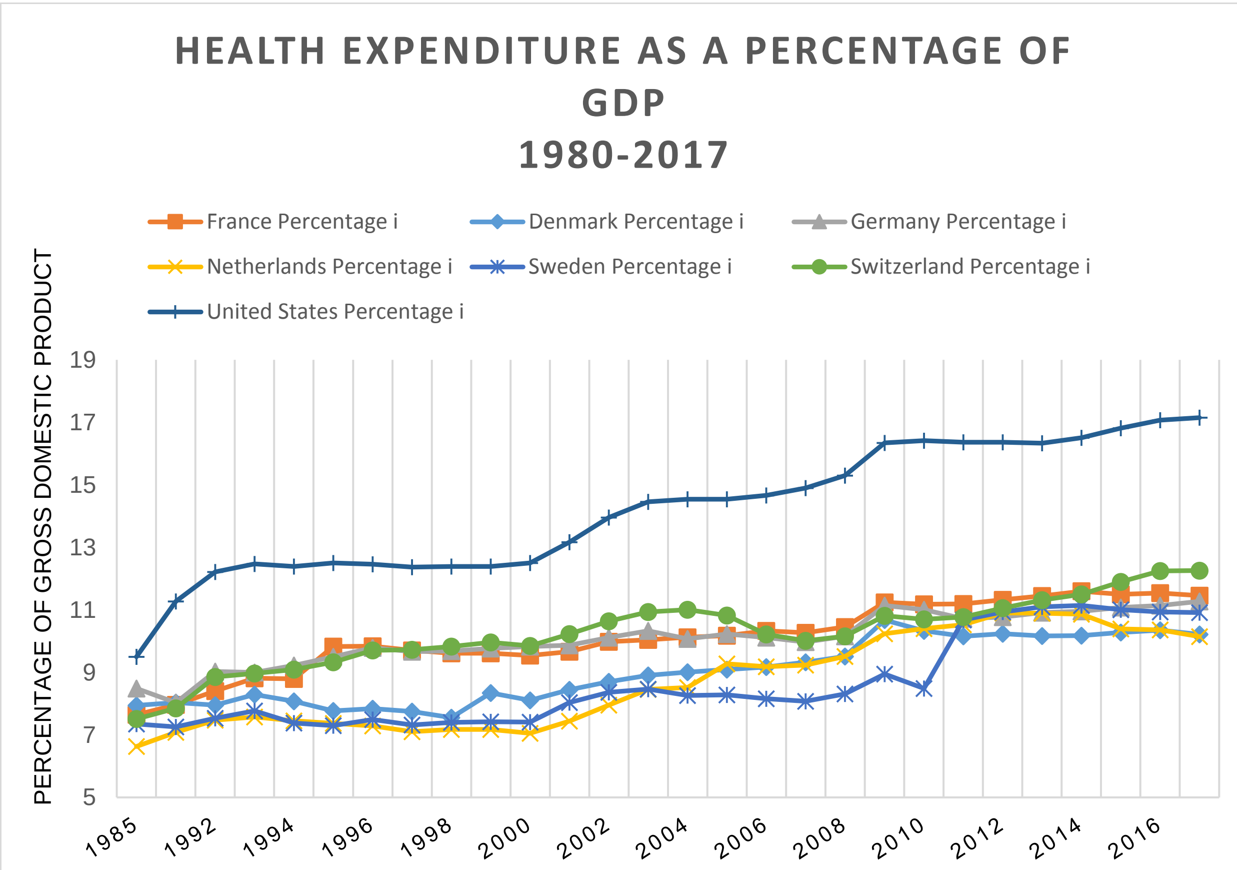
The above case represents a frequent problem encountered in medical practice and health care administration, i.e., how to address a specific, system-wide patient care concern in a system that otherwise appears to deliver excellent care. Most people who enter a health care profession do so with a passion to help others in need. When the system in which they operate is not performing well, those professionals frequently want to correct the problem and correct it immediately. This rush to "do something" often leads to the implementation of inefficient and often incorrect solutions that result in no improvement or worse outcomes. This presentation will address some of the concepts of total quality management in health care delivery systems and how those concepts should drive a strategy of quality improvement and patient safety in an organization. Specifically, the role of high reliability in quality improvement and patient safety will be examined. Finally, a few recommendations to achieve reliable and safe care in any practice, hospital, or health system will be presented.

What is the state of health care quality in the United States (U.S.) in 2019?

The quality and safety of health care in the United State (U.S.) has been a frequent topic of discussion and debate since *To Err is Human: Building a Safer Health System*[1] was released in 1999 by the Institute of Medicine (now the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine). This treatise examined the quality and safety of health care in the U.S. in response to a growing public and academic sentiment that the system was broken and needed serious reform. Two of the many conclusions of that publication were that health care in the U.S. was expensive and not as safe as it should be. The response of the public to this news was as expected. Some in the lay press declared a national patient safety emergency,[2] and most medical professionals agreed that something should be done to correct the situation.

The cost of health care in the U.S. is enormous when compared to any other country in the world. The U.S. spent $3.5 trillion or $10,739 per person on health care in 2017[3] which ranks number one in the world by far. These expenditures accounted for 17.9% of the Gross Domestic Product (GDP) in 2017, again number one in the world. A comparison of the percent of GDP spent by numerous developed countries is illustrated in Figure 1.[4]

Figure 1. Health Care Spending as a Percentage of GDP, 1985-2017



Retrieved Mar. 7, 2019 Organization for Economic Cooperation and Development
https://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT#

The reasons for the high cost of healthcare in the U.S. are numerous and widely debated. They include a historical fee-for-service reimbursement system which rewards high utilization, underspending, compared to other countries, on programs that affect social determinants of health, and the high cost of pharmaceuticals and procedures. Analysis of recent data indicates that the primary drivers of the differential costs of U.S. health care when compared to other countries are labor (including provider reimbursement) and goods (including pharmaceutics and administration).[5] Health care utilization metrics reveal a mixed picture in the U.S. when compared to other developed countries. Discharges per 100,000 population and length of stay per capita in the U.S. are about the same as when compared to other countries while the number of surgical procedures per 100,000 population is higher in the U.S for many procedures such as coronary artery bypass grafting (CABG), coronary angioplasty and lower extremity amputations.

Early studies on the occurrence of medical errors were quite shocking to the medical community as the estimated deaths from medical error were higher than anyone thought possible. Data from two widely quoted studies examining the prevalence of medical errors are shown in Table 1.

Table 1. Estimated deaths in U.S. due to medical error

	Utah/Colorado Study[6]	Harvard Practice Plan[7]
Hospitalizations studied	15,000	30,000
%Hospitalizations with adverse event (AE)	2.9	3.7
% AE resulting in death	6.6	13.6

These landmark studies defined an adverse event (AE) as an injury to a patient that was caused by the treatment of a condition rather than the condition itself. The authors of *To Err Is Human* used the above data to estimate the number of deaths in U.S. hospitals in 1997 that were due to preventable adverse events (medical error) by extrapolating the percentages in each study to the total number of patients admitted to U.S. hospitals in 1997 (approximately 33.6M). By this method, the widely quoted numbers of patients who die each year from medical errors (44,000 – 98,000) were calculated. These numbers made medical errors the 7th leading cause of death in the U.S. in 1997. In later studies, Makary and Daniel[8] and James[9] estimated the number of deaths to be as high as 250,000 to 440,000 per year, respectively, making medical errors the third leading cause of death in the U.S.

The above estimates are subject to considerable bias as are many estimates of the rates of medical error for several reasons. Cases are identified using administrative or coding data which are collected for patient billing purposes, not to detect medical errors. This bias was acknowledged by the authors from Johns-Hopkins.[8] In addition, the detection of medical errors by retrospective chart review is subject to considerable error.[10] However, most agree that the number of patients suffering harm from medical error is too high, even if the estimates are off by several orders of magnitude.

Some medical providers question the medical error estimates because most practitioners do not observe a similar number of medical errors in their practice or hospital. There is also a certain amount of denial due to the fact that many providers were trained during a time when making a medical error was considered evidence of incompetence or negligence.

Most likely, these numbers do not seem correct because of a general misunderstanding of the nature of errors among the medical community and the general population. Many think of medical errors as a single event that has a direct and identifiable negative effect on a patient or health care worker. This concept is probably not true for many errors as will be discussed in detail later in this review. In complex situations such as health care, minor and frequently imperceptible slips or mistakes trigger a cascading series of events that result in a bad outcome for a patient. In many situations, the triggering event may not be discoverable or known by anyone. A medical analogy is the coagulation cascade which amplifies and controls the effect of blood coagulation after an injury where each step alone would not produce the end effect.

Why has there not been more dramatic improvement in the quality of U.S. health care over the past two decades?

Following the publication of *To Err is Human,* the medical community launched a sincere effort to improve the quality of care delivered in the U.S. by focusing on medical errors and preventable adverse events of hospitalization. The results have been disappointing overall. Costs have not decreased; and despite some improvements in some hospitalization complication rates, readmission rates, and mortality in certain conditions,[11,12,13] quality of care and medical errors remain a problem and initial improvements in many quality measures have not been sustained. In summary, many feel the quality of U.S. health care overall has not improved significantly since 2000 despite pockets of improvement.

One might ask why efforts to improvement medical quality not been as successful as we hoped they would? First, reimbursement for medical care has traditionally been determined by a fee-for-service model which results in an incentive for increased utilization. This model is changing as quality and value of care is taking a larger role in many reimbursement structures such as that used by Medicare. Second, health care workers, especially physicians and nurses, have a long history of dealing with mistakes or error as individual failure and not as human error occurring the context of systems that can increase or decrease the likelihood of making an error. This has led to a "culture of blame" that views errors as an indication of incompetence usually requiring retraining or punishment. Third, there has been a perception that some accidents are unavoidable in medicine and are part of the risk of medical intervention. This has led to many medical errors being referred to as "complications" instead of a more proper term. Fourth, there is a common misperception that improving quality always increases costs. This perception results from the assumptions that 1) medicine is already functioning at optimal quality as far as cost is concerned and/or 2) non-conformance, or poor quality, does not contribute to the total cost of quality. In addition, many quality improvement (QI) initiatives have failed due to lack of rigor in the use of established QI methodology and the use of these methodologies as a "quick fix" without sustainable changes in organizational culture.

Many early efforts to improve health care quality emphasized quality improvement methodology to improve care delivery processes. These methodologies were taken primarily from the engineering and manufacturing world and included programs such as Six Sigma (DMAIC), Lean, and improvement tools and ideas resulting from the initial works of Water Shewhart[14] and Edwards Deming[15] in the early 20th century (PDCA and PDSA). Doing quality improvement projects using classic PDSA or DMAIC methodology produced significant short term improvements in care but the improvements were frequently not sustained and were not enough to transform the quality and safety of health care in an organization as a whole. This was nicely illustrated by Kathleen Goonan as she described the journey successful health care organizations took in developing the kind of quality program recognized by the Baldrige Award,[16] She noted that organizations that focused only on improvement methodology without leadership and organizational alignment that resulted in a healthy quality culture were unable to sustain improvements made by the quality improvement projects over time.

The reasons that dramatic improvements have not been realized with medicine's trial of rapid cycle improvement methodologies have been debated, and several plausible hypotheses have been presented. First, the quality improvement tools and methodology that have been used in many projects were treated as a "quick fix" to quality problems and not part of a broader program of systems improvement that is required of complex organizations.[17] Another reason for the failure is that process improvement methodologies require just as rigorous adherence to established tools and methods as research, and many improvement projects do not adhere to rigorous methodology.[18] Third, many improvement projects reach an established aim or goal, but the success decays over time due to lack of an effective sustainability and monitoring plan. Also, we have a tendency to want to "do something" without a rigorous approach to find the root causes of problems in medicine. This frequently leads to a "solution in search of a problem" mentality which inhibits the thoughtful development of tailored solutions to specific problems as recommended by Deming in *Out of the Crisis.*[15] Finally, it is possible that medicine needs to modify its current model of quality improvement.

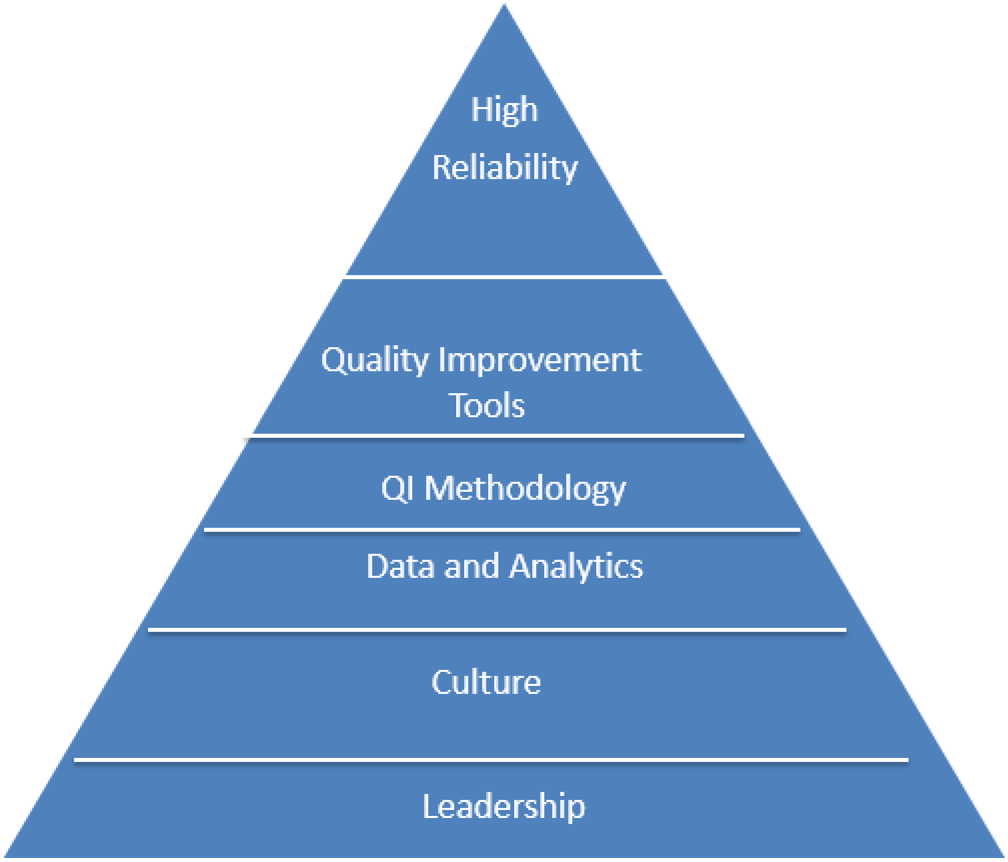
A more scientific approach to health system improvement should follow establish guiding principles such as the following adapted from Hagood[19] that emphasize a systems approach to quality improvement rather than the random use of quality improvement tools to realize sustainable gains:

1. Organizational focus on a strategy that emphasizes quality and patient safety values at all times to which improvement activities of the organization are aligned. The emphasis here is on organizational values and not short-term priorities, goals or rankings.
2. Deployment of the strategy at all levels of the organization with outcome metrics
3. Education of all employees in the use of basic quality improvement tools.
4. Support of quality improvement activities at all levels by organizational leadership.
5. Consistent communication with organization that supports constant improvement.
6. Focus on sustainability of improvements and process reliability.

Certain components of a highly functional quality system seem to always be present in successful organizations. These components include 1) effective leadership, 2) a supportive culture, 3) appropriate data and analytics, 4) knowledge of quality improvement (performance) improvement methodology at all levels of the organization, 5) use of quality improvement tools, and 6) use of high reliability concepts in day to day operations.

However, the presence of these individual components will not result in a successful quality program if each functions independently of the others. They must act as a complex, interdependent <u>system</u> where each is highly interactive with and depends on the other functions

Figure 2. Components of a high quality, reliable health care system



As suggested in this figure, the individual functions should not be developed randomly. Each builds upon the successful completion of the milestones before it. For example, a common mistake for organizations that want to build a functional quality improvement program is to begin by teaching quality improvement methodology and tools. While these components are critical to the program as a whole, they cannot provide the foundation of long term success unless they are built on previous successful implementation of 1) leadership principles that foster values of patient (customer) service, 2) a commitment to continuous improvement of all critical operations of the organization, and 3) a commitment to a culture of performance excellence. Part of culture development is a recognition by leaders and staff that effective change must be driven by data and analytics. Leaders must be committed to provide the process and outcome data and analytics necessary for front-line workers to improve basic organizational processes that support organizational priorities. Only then will the education of front-line workers and providers in the methodology and use of tools of quality improvement be successful.

In summary, early efforts to improve quality and patient safety in the U.S. focused on methodology, QI tools, leadership and culture. While the use of these concepts have resulted in some improvement, the results overall have been disappointing. This leads to the question whether there are other components of a QI program that are necessary for success; and if so, is high reliability that component.

What is the role of high reliability in an effective quality improvement and patient safety program?

Early descriptions of PDCA and PDSA methodology referred to reliability as the ability of a process to produce a predictable outcome. While this concept was a critical component of process improvement, it failed to emphasize how the outcomes of complex organizations depend on the output and interactions of many interrelated processes. In this model, Deming and others emphasized the concepts of optimization and sub-optimization.[13] Optimization occurs when improvement methodology in a single process improves the outcome of all of the processes in an organization or system. Sub-optimization is when improvement in a single process results in worsening of the outcomes of another process or the organization/system as a whole.

Since the 1980s, high reliability has taken a related but different meaning, i.e., the ability of some organizations to avoid catastrophic failure in situations where failure was expected in the past. In this context, two theories have emerged to explain what can be done to prevent failure of processes in certain types of organizations where this failure can result in catastrophic outcomes such as medicine. Much of the literature regarding reliability of processes in healthcare delivery has focused on areas termed High Reliability Organizations (HRO). A generally accepted use of this term is to describe an organization that has succeeded in avoiding catastrophes in an environment where normal accidents can be expected due to risk factors and complexity (Wikipedia). Examples include flight deck operations on aircraft carriers, the nuclear power industry, the air travel industry, and wild-land firefighters with the focus on how teams have transformed very dangerous working conditions into much safer environments. This review will focus on the history and development of the concepts of HRO, specifically with the contributions of two lines of thinking that may have relevance to medicine:

1. Normal Accident Theory (NAT) – illustrated by the works of Charles Perrow and Scott Sagan
2. High Reliability Theory (HRT) – illustrated by the works of Karlene Roberts, Carolyn Libuser, Karl Weick, and Kathleen Sutcliffe.

NAT and HRT are frequently compared and contrasted in the literature as if they were two competing theories trying to explain why serious accidents occur in some complex situations and what can be done to mitigate those accidents. This distinction may not be valid because each provides complementary explanations depending on the perspective of an outside view of the organization in study. This review will illustrate the similarities and differences in the two points of view and provide a summary of defined steps a health system or work unit can implement to take advantages of what these theories offer.

Charles Perrow, a sociologist, is given much of the credit for starting the discussion of HROs with his book *Normal Accidents*[20] published in 1984 in which he discussed the risks associated with the advanced technology developed in the nuclear power and weapons industry. He argued that catastrophic accidents were inevitable in certain high technology situations including the nuclear industry. These situations consist of humans working in systems that possess 1) interactive complexity and 2) tight coupling.

Interactive complexity describes a system in which multiple, interdependent processes are working simultaneously, and an outcome of one process can affect another. Perrow argued that errors in one of the processes in this type of system unpredictably interact with or cause an error in another process. Also, the interaction between these individual errors may be unpredictable and perhaps even undetectable because they are so small. However, the result of these interactions may create risks of a poor outcome that multiply exponentially and ultimately a catastrophic accident.

This interactive complexity is certainly evident in health care delivery, especially in the hospital setting where technology (EMR, medication delivery systems, alarm systems, results reporting, etc.) interacts with multiple processes (physician, nursing, pharmacy, materials management, transport, etc.) containing hundreds of different people interacting tens of thousands times daily. The problem develops when a small error in one process interacts with a small error in another process which then interacts with an error in a third process. The effect of the interactions multiply exponentially as the number of interactive errors increases.

Tight coupling refers to the lack of tolerance for delay in response to new information in some systems and processes. In a tightly coupled system, actions or responses to new information from other people or processes are expected to occur quickly. In medicine, we have developed many processes that depend on tight coupling to many other processes. A good example of tight coupling is the way we have developed the use of the electronic medical record (EMR). In an effort to increase the speed of communication and processes, we communicate through the EMR for nursing and medication orders or for important information to and from consultants. This system fails when there is a low tolerance for delay in a system with variable communication capability or when variability in human response time is added. This tight coupling of processes due to the EMR has been found to be the root cause of many catastrophic failures in patient care, e.g., failure to implement orders in a time frame expected by the person writing the electronic order.

Another way to think about tight coupling is to consider how interdependent processes exist and interact in some systems.[21] In a completely linear system, the consequences of a human or process error are usually predictable and recognized so interventions to mitigate the risk can occur in time to prevent a catastrophic failure or loss of function. This type of process error is and mitigation strategy is implied by the “Swiss Cheese Model” as described by James Reason. When multiple processes influence or are dependent on other processes, this interactivity produces a situation such that a seemly small error can multiply exponentially producing failure in multiple processes that result in a catastrophic failure of the entire system instead of only one of the processes. Mitigation strategies in this situation are much more difficult to conceptualize and, the interdependence of processes implies that errors that occur in one process may increase the severity of an error in another process making them more likely to occur than would be expected by a chance alone.

The interdependence also has implications as we develop safety policies, procedures and warning system technology. One can legitimately ask if these safety and warning systems can be completely independent of other processes, which is preferable in redundant warning systems.

The multiple interactive processes required to deliver medical care certainly qualifies as a system characterized by interactive complexity and tight coupling. Multiple processes involving nursing, physicians, pharmacists, transport, technology, etc., are working in concert to deliver care to a given patient. These processes and their respective functions are vitally dependent on each other explaining, for example, why a seemly small error such as a small delay in the notification of a mild tachycardia in a patient can cascade into a series of seemly unrelated events that result in the death of a patient from sepsis in a short period of time. In retrospect, these events frequently expose interactions that involve multiple small failures that no one could have anticipated or even recognized when they occur. For example, retrospective analysis of poor outcomes in medical care frequently cannot identify one dominant error to explain the final result. Consequently, no change in system process is recommended. Even more disturbing is that changes that are recommended may have little effect in the future in similar situations where the nonlinear, unanticipated interactions of these seemly small and independent process errors will overwhelm most safety procedures even if they exist. Perrow has suggested that the only system interventions that will prevent these catastrophic results are those that decrease tight coupling and interactive complexity (see section on recommendations below for examples).

The Concepts put forth in Normal Accident Theory differ in some aspects from the traditional Swiss Cheese Model of human error put forth by James Reason. In this model a single error is allowed to reach its logical conclusion (patient outcome) as it passes without detection through several people, processes, or systems before reaching the patient. This “chain of errors” is important in Reason’s model because any one person or system along the line can stop the error and prevent it from reaching its natural conclusion. This model seems to be logical for well-defined, obvious major errors in a linear system that have a predictable bad outcome if it reaches the patient.

However, according to Normal Accident Theory, many inciting errors are small and do not propagate on their own most of the time. This leads providers to not expect a bad outcome every time the error occurs resulting in the assumption that the error is minor and of no consequence. It is when this initial error is unexpectedly or unpredictably combined with another, seemingly unrelated error that the amplification occurs. The more downstream errors that are combined with the first, the worse the eventual outcome of the process is. This amplification of the original error explains the unexpected and occasionally catastrophic outcome that results. This phenomenon explains why retrospective review of most bad and unexpected outcomes in hospitals do not reveal an egregious error at its root as would be expected with the Swiss Cheese Model.

Finally, another factor may explain our inability to predict and prevent these catastrophic outcomes in some patients is the contribution that central tendency theory has on these outcomes. If this is hypothesis is correct, some poor outcomes may not even involve the minor errors described above. That poor outcome may result from random variation in the outputs of multiple processes, each within the acceptable range but on the upper side of risk for the patient. If we consider the overall risk of a poor outcome in a patient as the result of the inputs from multiple independent processes, we depend on the fact that the risk added by an independent contributor to the overall risk will fall on the lower or average risk of the central tendency. If one is randomly on the higher risk side, we hope for another process outcome downstream to randomly fall on the lower risk side of risk to counteract it.[22] In a given patient, consider the risk contributed by the variables if all of the outcomes of processes randomly fell on the higher risk side of the central tendency even though each process output was within the acceptable range for its respective process. Could this result in the unpredictable, poor outcome in some patients?

Complicating the central tendency theorem explanation is Perrow's concept that high risk situations include interactive complexity which results in many process outcomes not being completely independent from others meaning a poor result of one process may increase the likelihood of a poor result in another process. In summary, the central tendency theorem suggests that the only way to decrease the probability of a catastrophic outcome is to decrease the variation in the output of individual processes.

Other authors writing about High Reliability Theory have described the characteristics of organizations that have successfully reduce the number of catastrophic accidents instead of the causes of the failures. Karlene Roberts has contributed significantly to our understanding of HROs through the study of effective military operations such as flight deck operations of aircraft carriers. Her observations illustrate several characteristics of HROs:

1. They continually reinvent themselves.[23,24,25] When these organizations discover structural or operational weaknesses, they immediately change them, even if major reorganization is required. They also frequently deploy existing operations group to different tasks or functions during an emergency. In summary, they are not resistant to change if it is necessary for safe operations
2. Decision-making is delegated to the lowest level consistent with implementation.[26] This includes challenging higher level decisions if safe operations are in jeopardy. This does not imply anarchy or top levels not making important decisions. In these organizations, the top levels of authority make decisions in routine situations. The delegation to a lower level on the power hierarchy occurs during emergency situations or during any implementation where lower level personnel have a better idea or local situations that upper level personnel do. Also upper level leaders set the overall priorities for the organization, even during emergencies.
3. All parts of the organization share risk assessments and risk mitigating responses[27].

A colleague of Roberts, Carolyn Libuser was responsible for the description of a high reliability leadership model.[28] This model has been successfully implemented in health care settings such as the Back Bay Children's Hospital in the pediatric intensive care unit.[29]

The model consists of the following essential elements:[28]

1. Process auditing by regular checks to identify safety problems. Follow up of problems identified by these audits is critical.
2. Reward systems that promote safety oriented behaviors.
3. Avoiding quality degradation by constantly comparing outcomes to industry standards
4. Risk perception. This has two parts:
    a. Knowledge that risk exists
    b. Taking appropriate steps to acknowledge and mitigate risk
5. Command and Control consists of five elements:
    a. Decision responsibility delegated to the person with the most expertise regardless of where that person is on the power hierarchy

b. Redundancy of safety backup systems. This does not mean duplication of backup systems
c. Situational awareness among senior managers who see the big picture. They should oversee the entire operation but not micromanage the operation.
d. Formal rules and procedures. This does not mean bureaucracy in the negative sense but means a formal structure of rules and procedures.
e. Training in safety procedures and risk mitigating procedures.

The most popular and quoted framework for high reliability has been the work of Karl Weick and Kathleen Sutcliffe from the University of Michigan. They have argued that accidents are not inevitable in complex organizations and can be prevented. Their most popular work, *Managing the Unexpected*[30], identified 5 characteristics of HROs using their background in organizational behavior and psychology. In their book, those 5 characteristics were grouped according to their usefulness in 1) preventing errors or 2) recovering from errors.

Preventing Errors/Anticipate failures

<u>Sensitivity to operation</u>. According to Weick and Sutcliffe, an HRO is sensitive to operations when "they are responsive to the messy reality inside most systems".[30] In order words, leaders and managers maintain a big picture perspective of operations and respect front-line worker's opinions regarding system operations. They do this because front-line workers have the most accurate assessment of how effective and safe the work of the system is accomplished and whether the work is being done according to plan and intentions. Much of the knowledge front line workers have about operations is qualitative which effective leaders understand and respect. The astute leader instructs front line workers to notice and report small deviations in operations so corrective actions can be established. In other words, they treat "near misses" as opportunities for learning and improvement and not a reason to celebrate a disaster averted.

<u>Preoccupation with failure.</u> Organizations that have achieved high reliability realize they have embrace failure[27] to avoid it. These groups have constant vigilance to pick up "soft signals" or small errors and events which can be the catalyst for the cascading error propagation that results in catastrophic failure discussed in the section on Normal Accident Theory. They also develop plans to contain errors that are anticipated but have never happened. They are constantly vigilant for these soft signals. This approach is much different than that utilized by most hospital and medical group administrations who do detailed analysis only after a severe or "sentinel" event occurs. This soft signal, proactive approach to error and systems failure results in a workforce that is better prepared to respond to a serious event when it occurs and is more likely to recognize and contain a small error before it escalates. The practice that comes with constantly thinking about ways things can go wrong results in an increased ability to anticipate and detect actual small errors when they do occur.

An efficient reporting system for large and small events is critical to the effective use of this principle. This has resulted in medical event reporting systems that are present in every hospital system now. However, the effectiveness of these systems in improving patient safety is critically dependent on the response to event reporting, not on the event reporting itself. In this area medicine is severely lacking. Most hospitals do not produce detailed reports of soft signals or near-misses that are communicated with every hospital worker, and consequently, those workers are not constantly watching for and reporting these signals. Furthermore, many workers hold the opinion that reporting these soft signals or near misses will negatively impact their work performance evaluations as evidenced by the Culture of Safety Survey System used by AHRQ to survey U.S. hospital and health system employees. These surveys have consistently shown that less than half of U.S. health system employees feel they can report patient safety issues to their supervisors without retaliation. In the 2018 AHRQ Hospital Survey on Patient Safety Culture, 53% of respondents indicated that event reports are held against them and that mistakes are kept in their personnel file.[31]

Also, supervisors frequently feel that a decrease in reporting of “near misses” means that they are occurring less frequently and is, therefore, a good thing. This is rarely the case and usually indicates that staff are reporting less because management wants to see lower numbers. Health systems that use event reporting effectively in improving safety encourage and even reward staff for reporting individual errors, analyze these errors looking for soft signals, and use the data to encourage more reporting and develop solutions for the small problems in the safety system before they escalate into large or catastrophic events.

Event reporting systems also require robust communication of results to be effective. The communication should include reports on error prone tasks or areas, changes in policies or procedures in response to error reporting, and individual communications on the systems response to an individual report. Without these communications, many of the advantages of event reporting are lost.

<u>Reluctance to simplify.</u> It is our natural tendency to simplify explanations. The problem is that simple explanations of failure tend to obscure the complicated nature of cascading events in catastrophic outcomes. When a Root Cause Analysis (RCA) of these accidents is done, a picture of multiple errors and missteps emerges which defy a simplistic explanation. Ignoring this fact inhibits the chance of developing effective preventive measures for multiple components of the overall accident. For this reason, HROs resists simplistic answers.

Another way we over-simplify explanations is with the use of categories. We tend to lump things together to organize our thinking. However, categorization of problems frequently results in a superficial explanation of a complicate scenario. An example is the use of the category of “lack of supervision” to describe a cause for an event without examination of the details. This label obscures many possible, specific reasons for a bad outcome when each one has very different preventive strategies for similar situations in the future. Many times a “lack of supervision” category obscures the real problems of lack of knowledge or procedural skill, poor call schedule, excess fatigue, poor culture, etc.

In summary, the reluctance to simplify means that we must retain the ability of collect, analyze and prioritize all warning signs and avoid making assumptions regarding the cause of failure until all of the facts are known and all of the possible causes have been considered. Finally, we must always resist the simplistic tendency to blame the individual involved.

Containment of unexpected events/Recovering from Errors

No process, equipment, computer program or human is perfect. Errors are inevitable, and any program that relies on perfection, especially human perfection, is flawed. Unfortunately, many leaders and managers in health care insist on human perfection as their primary patient safety strategy. HROs do not make this mistake. These organizations realize that zero defects, while being a lofty aspiration, is not possible. Weick and Sutcliffe described two characteristics of HROs that deal with the inevitable errors when they do occur. These strategies have the goal of mitigating the effects of errors on process outcomes.

Commitment to Resilience. Resilience is the ability of people and processes to maintain function when internal errors or outside influences present unexpected challenges to the ability to maintain adequate function. HROs realize that a decrease in function is preferable to a total loss of function when these inevitable external challenges or internal errors occur so they plan for and practice their responses to these events before they occur. They realize that policies and procedures do not always work in an emergency and learn to use available resources to mitigate the effect of the unexpected event and, in retrospect, document what they needed to accomplish the recovery. HRO leaders also realize that, in emergency situations, policies and procedures do not always work and are sometimes inaccurate or inappropriate for the emergency situation. An important capability of these organizations is the ability learn from these events so that they can develop prevention strategies for the future and improve their ability to detect and respond to similar events in the future. They see these events as learning and training experiences rather than putting out fires that are quickly forgotten.

Deference to Expertise. HROs typically have an interesting method of decision making in emergency situations. During routine operations, decision making is hierarchical as in most organizations using normal organizational structure. However, this changes during emergencies when decision making flows to the person with the most local expertise, no matter their position in the organizational power structure. Usually this requires decision making to flow downward to someone with direct knowledge of the emergency situation. This poses an obvious challenge for organizations with a rigid, hierarchical power and decision making structure, especially when the person with the most knowledge about the situation is not obvious. It takes practice and confidence in your organizational resilience for leaders to relinquish hierarchical power to a subordinate who has more direct knowledge of a situation in an emergency. However, this ability is critical if the goal is containment of an error before the error results in a catastrophic failure.

The role of mindfulness and mindful leadership in HROs

Weick and Sutcliffe also stressed the importance of organizational mindfulness in organizations that have achieved HRO status. Organizational mindfulness means there is a general sense of what is going on, or strengths and vulnerabilities, in an organization. Mindfulness also involves expectations and how we deal with expectations. For example, a healthcare provider may engage in some reckless behavior such as not performing adequate hand hygiene before seeing a patient or not documenting a phone conversation with a patient. When there is no consequence to these behaviors because nothing serious happens, the provider may develop the expectation that nothing serious will happen to the patient every time they have that behavior, even though they know that the likelihood of a serious adverse event in these situations is a relatively rare event. A provider in a high reliability healthcare system is always questioning his/her assumptions and expectations by considering the worst case scenario for any situation or decision.

Mindfulness in a healthcare organization can be improved by several means. Bottom up reporting of events or bad news by engagement with frontline staff gives leaders a more comprehensive picture of organizational vulnerabilities and capabilities when under stress. Other methods used to gain organizational mindfulness are 1) proactively looking for system problems with internal audits to detect weaknesses and process vulnerabilities that may not be obvious to the casual observer, and 2) analysis of "near misses" in event reports to detect trends in "soft signals."

Criticisms of the application of High Reliability Theory to the delivery of medical care do exist. Much of the research thus far has been qualitative, and there are limited data on the effect of high reliability concepts on clinical outcomes. In addition, studies have yet to be done in medicine to examine which HRT components work, and if so, why do they work. Finally, there is little information on the effect of high reliability applications on health care employees, i.e., the wellness effect of reporting errors in the medical culture.

Ten evidenced-based recommendations leaders can implement tomorrow that will make their work unit a high reliability team

1. Communicate to your organization, work unit or team that patient safety is the number one priority of the group and the personal responsibility of every member of the group or organization. The leader should acknowledge the tension between productivity and safety and what they are doing to reduce that tension. Members of the team should understand that given the choice between productivity and safety, safety always takes priority and that they will not be punished for making safety the priority in an emergency.
2. Establish a robust event reporting system that includes real time monitoring of severe events and periodic review of all categories of events, including near misses. Reward staff who report these events and encourage a culture of reporting all events, no matter how small. Do not allow managers to punish or discourage reporting of events. Communicate summary data from event reporting to all staff of your organization. Define unacceptable and reckless behavior for your organization and consider a no-fault reporting program for reporting near misses and errors that do not result from reckless or unacceptable behavior.
3. Develop a reward system for staff who identify vulnerable or risk prone processes in your organization, no matter how small the vulnerability or risk. Perform a Failure Mode Effect Analysis (FEMA) on all of the identified processes. Do not ignore small warning signs of potential process failure such as frequent similar near misses.
4. Establish periodic mandatory debriefings (each shift or daily) that involve all members of your team or work unit. They can be brief but should completely discuss what did not go smoothly and perceived vulnerabilities that were noticed during the time period being debriefed. Participants should be expected to report things that happened that were not expected or errors that they made. Participants should also be expected to discuss things that went well, especially those that went better than expected. No person should be criticized during a debriefing but they should be expected to admit any errors that were made. Discussions of errors in the debriefing should include system factors that were involved and how to prevent similar errors in the future.

5. Debrief all major events or emergencies soon after they occur and with all members of the team involved.
6. Implement regular *in situ* simulations of effective communication strategies and emergency events for all staff.
7. Train staff in and utilize QI methodology (especially Lean and PDSA) to be used to effectively reduce production pressure and time stress while maintaining efficiency.
8. Establish a process that considers the effect of any cost cutting measure on patient and employee safety.
9. Measure Critical to Quality safety metrics for your work unit and post them publically.
10. Train members of our team how to make decisions that affect patient safety quickly, even if the decision required is not routine; then give them permission to make those decisions without fear of retribution in an emergency.

Back to our case. The health system started an improvement project of care of patients with suspected sepsis. That team, after extensive evaluation of the care processes involved, discovered that the system had slow responses to soft signals of sepsis and this resulted in slow response processes such as time to antibiotics. The team made several changes to those processes that involved many of the concepts presented in this review. The steps included in the evaluation and intervention included, but were not limited to, the following:

- *a detailed review of all sepsis deaths in the hospital (organizational mindfulness, preoccupation with failure, reluctance to simplify),*
- *a review of all care processes involved in sepsis diagnosis and treatment (reluctance to simplify, sensitivity to operations),*
- *development of a protocol by which nurses could enter patients into a diagnostic workup before being seen by a physician in the Emergency Department (loosening of tight coupling, deference to expertise),*
- *development of visual cues to alert nurses of times for antibiotic infusion (loosening of tight coupling, sensitivity to operations),*
- *focus on communication at all levels during transfers of care (preoccupation with failure, sensitivity of operations, deference to expertise),*
- *engagement of staff in sepsis campaign (deference to expertise, mindfulness), and*
- *development of order sets to standardize and reduce variation in decisions and practice regarding treatment of possible sepsis (reducing the effects of interactive complexity of processes and tight coupling)*

The results were dramatic, and over a relatively short period of time, the absolute mortality rate for sepsis dropped from 16% (2017 CY) to near 8.6% (2018 CY) and the observed to expected mortality ratio decreased from 1.5 (2017) to 0.75 (2018) which placed the health system in the top decile (<0.95) of sepsis mortality for U.S. academic medical centers for 2018.

Summary

- Traditional leadership principles and improvement methodologies alone are not enough to transform a health care system into a high reliability organization (HRO).
- Catastrophic failures in health care frequently occur as a result a small error or variation in practice in the context of a system that magnifies the error or variation in practice.
- Systems that contain interactive processes that are tightly coupled are more likely to result in catastrophic failure when compared to simpler, linear systems.
- High reliability principles can be effectively applied to any health care organization or team to improve patient care outcomes and reduce the number of or avoid catastrophic failures.

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