Healthcare Threat Safety Science: The Future

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ABSTRACT

Healthcare organizations are dealing with an expanding threat spectrum. Our threat assessment and risk management activities to date have naturally evolved with tactical focus around specific and typically visible hazards. We need strategic focus and tactical excellence across ever growing threat diversity and velocity. A threat matrix of all serious threats, recognizing dependencies and causal relationships, will drive rapid response before harm happens – the “boom”. The rapid evolution and intensity of visible and invisible threats demand that we move Left of Boom and practice the 4 P’s. We must move beyond Protection at the time of an event, and move upstream not only to Preparedness, but to Prevention. Prevention includes both primary prevention to make sure certain things never happen, AND secondary prevention– making sure damage is minimized, the disruption is shortened, and the recovery is most complete. Lastly, the discipline of Performance Improvement pioneered in patient safety and aviation can be applied to the former three P’s. Our approach must be unified, integrated, and embedded in our work. We need multidisciplinary, cross functional teams working across silos to develop new integrated strategies to fortify three vital systems. Leadership systems that build trust and drive success through our people, best practice systems that help us perform optimally during a crisis, and new technology systems that enable the former two. By leveraging teams of teams and networks of networks, we can be rapid responders, use “big data”, and become safer. This is the future of Healthcare Threat Safety Science.

INTRODUCTION

Healthcare is an industry sector uniquely different than other industries and therefore requires very unique solutions.

The relationships between those who serve and those they serve are very different than the seller-customer transactional relationships of other industries. The life and death and personal nature of the issues and care service creates what some say is a “sacred trust” or bond between them. This dynamic makes it very difficult to apply generic solutions from other fields. The fate of the people, property, and prominence or reputational currency of healthcare institutions will lie in how their leaders get “left of boom” or ahead of bad events. How they move upstream and develop innovations of prevention and preparedness. How they learn protection when the bad event occurs, and how they learn performance improvement after the “boom” or bad event occurs.

By charting the past, present, and future of our healthcare threat spectrum and risks, we seek to establish a case for Research and Development in a field of Healthcare Threat Safety Science.

In medical science we have been legitimately criticized for “admiring the problems” through thoughtful academic studies, yet failing to innovate new solutions. We have often appeared to

have the misguided belief that merely the process the documentation of our woes will somehow mysteriously enable us to solve our problems. The purpose of this article is to drive innovation.

We believe an idealized design approach to a future where healthcare institutions take the best care possible of those we serve and those who serve will define a “shining city on a hill” that will inspire future leaders and caregivers to develop breakthrough innovations in the science of healthcare threat safety.

THE PAST

Most U.S. hospitals and healthcare systems evolved from being non-profit community resources that were passively administrated by relatively untrained leaders and governed by voluntary untrained representatives from the general business community. "Hospitals and health systems are incredibly complex organizations and they are largely governed by well-meaning amateurs," according to James E. Orlikoff, a healthcare governance expert.[1]

In the past, risks to people and property were not managed, but reactively addressed by insurance payments after a bad event occurred. In the absence of the internet, the prominence or reputation of the organizations revolved around word of mouth and local support. National ranking systems did not exist and consumers relied on their contacts in the community for advice.

FRAGMENTED STRUCTURES AND SYSTEMS

- **Constant and Stable Forces:** Up until the Reagan era prior to the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), few financial pressures challenged hospitals. The establishment of the prospective payment system for inpatient hospital care using the Diagnosis-related group (DRG) Coding system forced hospitals to work within a capped payment for the first time. Previously healthcare payers paid whatever was charged and insurance companies’ topline and bottom-line growth was linked to the continuous annual natural increase in costs. Before TEFRA, everyone was happy. Revenue for everyone increased every year until this shocking and sobering development of capped payment for conditions.[2] Finally the soaring healthcare costs began to break the bank.

- **Command and Control Pyramid:** Most corporate organizations historically have been patterned on the old Prussian military model and hospitals were modeled on the Prussian military hospitals model. Physicians had a firm hand on the leadership controls and hospital leaders were called “administrators” and lived up this passive moniker. They “administrated” services for physicians and patients, providing clean well-staffed facilities for them to do their life saving work. Trustees were community representatives and spent an enormous amount of time on philanthropy to support those facilities.[3]

- **Tactical Service Silos and “Silo Saviors”:** The services of hospitals were typically organized around unintegrated tactical and hierarchical functional service centers or silos. Clinical and administrative leaders stayed in their swim lanes and sought the gold medal for their own business lines. They understood little about interdependencies, causation, or correlation of threats and risks outside of their areas of focus. As local competition became intense, competing hospitals entered the medical arms race to have the best doctors and best technical equipment to deliver the best care in those silos. Very talented specialty doctors were recruited to be “silo saviors” who generated enormous revenue and margin contribution to the bottom line. With no cap on revenue, volume was king…and made kings. There appeared to be no end of financial success in sight until TEFRA and payment for performance shocked the system.

- **Risk Management = Malpractice Case Management:** Historically, and even now when the term “risk management” is used in reference to a healthcare organization, those inside know what it means. It really means “malpractice case management” and the group who are responsible for working with the lawyers to protect the financial assets of the organization from malpractice awards. Unanticipated harm to people and property was handled by insurance coverage and risk management behaviors were largely reactive. If risk managers existed other than those handling malpractice cases, few staff were aware of them.

SLOW THREAT VELOCITY AND NARROW THREAT SPECTRUM

- **Inside versus Outside Threats:** In the past, internal threats were limited in scope, not well understood, and the rate of evolution was very slow. Because hospitals were fairly self-contained and evolved very late to digital platforms compared to other industry sectors, inside threats were few. Outside threats were visible and narrow.

- **Nature versus Manmade Threats:** Threats from nature have not changed and were limited to storms and natural disasters. The manmade threats were limited to malpractice for the most obvious and egregious errors of commission such as wrong site surgery, wrongful death, and medication errors.

- **Systems Threats:** Prior to the 1990's very little systems theory was applied to healthcare. The understanding of systems failures was rudimentary other than from then nascent work that now has become mainstream.

    - **Leadership Systems Threats:** Command and control leadership systems with little cross communication between tactical silos were the norm. Although the evolution of business theory recognizing performance improvement methods and the impact of good leadership was documented Peters in *In Search of Excellence in 1982* and Collins in *Built to Last in 1994* and *Good to Great and 2001**,*** we were very far behind and evolved slowly. [4] [5] Even when Collins described the stages of death an organization can go through with suboptimal leadership in his *How the Mighty Fall and Why Some Companies Never Give In* published in 2009, few healthcare leaders took heed.[6] We had a collective case of mural dyslexia – we could not read the writing on the wall. Collins was also talking about us.

    - **Practices Systems Threats:** Best practices development, benchmarking, and performance improvement science was in its infancy in the 1990s and well even after 2000. Early pioneers were organizations such as the Institute for Healthcare Improvement (IHI) that began their Idealized Design work in the mid-90's.[7] Their work led to innovations which now are part of the patient safety fabric such as Medication Reconciliation, use of Failure Modes and Effects Analysis (FMEA), and bundled checklists for common infections and surgical procedures.

    - **Technology Systems Threats:** Prior to broad scale use of the internet, technology systems were limited to clinical technology systems delivering supporting physician care processes. The CT Scanner was a real breakthrough which earned the inventors a Nobel Prize in 1979, however images that were generated had limited transmission over the internet until the mid-90's.[8] Technology breaches were unheard of and inside threats were due to failures of the technologies or human error in the use of them. Electronic health records and integrated medical records used by multiple doctors were a dream and not in use other than at leading organizations such as the Mayo Clinic where the integrated practice model developed by Henry Plummer has allowed physicians to thrive as collaborators in their patients care.[9]

DRIVING THROUGH REAR VIEW MIRROR

In the past, the threat velocity was very slow and threat spectrum was very narrow. For years, leaders could keep the car creeping forward on the road by driving looking through the rear-view mirror and not looking at the road ahead. Even the biggest threat, which was malpractice, was viewed through past performance. Malpractice insurance companies set rates based on loss run history, not based on other probabilities or adjusted risk factors. There was no such thing as an all hazard cross-functional team, the enterprise patient safety team, or probabilistic risk assessment. Security personal did not practice de-escalation methods or getting "left of boom". Left of boom was a concept popularized during the Iraq war when the military explained to congress why they needed to get funding to move upstream and stop production of improvised explosive devices (IEDs) by terrorists after funding for protection from armor was found not to be enough to prevent harm.[10]

THE PRESENT

EVOLVING STRUCTURES AND SYSTEMS

- **Expanding Service Networks:** Enormous consolidation of the healthcare sector is happening with hospitals combining into massive systems over vast geographical areas. Simultaneously, they are vertically integrating with the acquisition of physician practices. The leadership structures and systems are having a hard time keeping up with these massive complex and multi-tiered businesses.

- **From Physician-centered Leadership to Professional Administrators:** The high-income doctors and those controlling the market have moved from inpatient care to outpatient care. With this transition, there are fewer hospital based physicians and those who remain there are service based care providers who do not control the flow of new patients and thus the market. Over the last 30 years, the

private practitioners who used to help lead the hospitals lead their own businesses and left a leadership vacuum that had to be filled by the professional administrators who had little clinical experience.

- **A Slow Transition – From "Command and Control" to Care Teams:** Although the transition has been very slow, many progressive organizations began to see the value in developing team based care and have had great success. For instance, the Geisinger Health System developed ProvenCare, a program for self-funded employers) It was a model of all-inclusive professional services, hospital services, and a preoperative through 90 days postoperative "warranty." The 90-day care warranty balanced all these considerations and made this process acceptable to everyone. By working as a team on common vital processes, they reduced readmission rates, eliminated a number of perverse incentives and improved their margin while reducing the cost to payers.[11] Geisinger was a standout and the majority of healthcare organizations clung to maximizing silo revenue at all costs.

ACCELERATING THREAT VELOCITY, INCREASED THREAT INTENSITY, AND EXPANDING THREAT SPECTRUM

The financial market forces, internet, and disrupted personal accountability drove new threats, made invisible threats visible, and began overwhelming healthcare leaders.

- **New Evolving Forces:** The enormous financial transaction flow in healthcare now exceeding $3.2 trillion dollars per year is causing enormous pressure on all actors. This combined with the unprecedented open-access to valuable data and disrupted personal accountability linkages has created a perfect storm of risk. A highly connected world has great benefits yet has created entirely new opportunities for bad actors to weapon-ize the internet, to commit fraud, commit drug diversion, expand workforce violence to cyber-bullying, and magnify professional misbehavior.

- **"No Margin – No Mission" and Serving One Master:** The prospective payment programs such as TEFRA described above spawned a whole new consulting sector populated of business types who often said their role was to help "hospitals run like a real business". Over the years many of them were hired into the finance and operations divisions of hospitals and brought the "no margin – no mission" mantra to hospitals. Hospital staff know they can only serve one master and interpreted the message from these business disciplinarians to mean "margin **IS** the mission". As philanthropy started to wane and a confluence of financial pressures began to mount, the market got increasingly competitive with the medical arms race intensifying.

- **No Outcome – No Income Tsunami:** The "no outcome – no income tsunami" was first used in 2004 to describe the Pay 4 Performance phenomenon and the impact it would have. Thereafter, the metaphor was used in other articles and a Discovery Channel documentary to describe how payment reform with payment tied to outcomes or process performance would overwhelm an industry addicted their own revenue with little thought of how the collective behavior would bankrupt the country. [12] [13] As this phenomenon developed, it had a terrific impact on our industry; the world's largest by dollar volume. When penalties for high hospital readmission rates were invoked and hospitals had to pay for their own complications such as giving patient infections, the tsunami hit in full force. And as we describe below, historical profit centers became cost centers overnight with one stroke of the pen upon execution of risk sharing payer agreements.

- **Well Known Patient Safety Crisis – Above the Waterline:** In 1999, the Institute of Medicine report *To Err is Human: Building a Safer Health System* made headlines when it estimated patient safety deaths to be as many as 98,000.[14] Since then report after report has shown that these numbers were just a fraction of the problem, with the most recent estimates to be more than 400,000 by James and the third leading cause of death as described by Makary of Johns Hopkins.[15] [16] In 2002 more than 4 out of 10 American consumers and 1 out of 3 physicians reported that they themselves or a member of their family had experienced a medical error. In the case of the physicians, almost 1 in 5 of those events caused death, disability, or severe pain. In the case of the consumers, almost 1 out of 4 of the medical errors resulted in death, disability, or severe pain.[17] [18] Also in 2002, the Centers for Disease Control estimated an additional number of Healthcare Associated Infections (HAIs) to be 1.7 million with estimated associated deaths to be 98,987, often rounded to 100,000.[19] These are infections we gave patients and were not included in the original patient safety numbers. Then in 2010 an Office of Inspector General (OIG) Report found "An estimated 1.5 percent of Medicare beneficiaries experienced an event that contributed to their deaths, which projects to 15,000 patients in a single month." This is the equivalent of 180,000 deaths per year.[20] This is the

view of those over 65 years of age who are Medicare beneficiaries. In 2014, results of a project known as the HAI Prevalence Survey were published. The CDC updated the burden of HAIs in U.S. hospitals and reported that, in 2011, there were an estimated 722,000 HAIs in U.S. acute care hospitals. Additionally, about 75,000 patients with HAIs died during their hospitalizations.[21] More than half of all HAIs occurred outside of the intensive care unit.[22] In their NEJM 2014 article, Magill et. al indicated that on any given day approximately 1 of every 25 inpatients in U.S. acute care hospitals has at least one health care–associated infection we give them.[23]

- **Unknown Patient Safety Crisis – Under the Waterline:** We are finding that the well-known patient safety issues are just the tip of the iceberg. These estimates do not even include errors or harm due to omission such as missed diagnoses described in the National Academies of Sciences 2015 report *Improving Diagnosis In Health Care*.[24] This report made the conservative estimate that five percent of U.S. adults who seek outpatient care each year experience a diagnostic error. Postmortem examination research spanning decades has shown that diagnostic errors contribute to approximately 10 percent of patient deaths. Medical record reviews suggest that diagnostic errors account for 6 to 17 percent of hospital adverse events. Another view of the same issue was addressed in a Mayo Clinic study published April 4, 2017, showing in 21% of cases Mayo Clinic doctors gave a completely different diagnosis than the original diagnosis made before coming to Mayo. The diagnosis was refined or extended in 66 percent of cases.[25] The findings of the Mayo Clinic mortality reviews described later in this paper addressed Mayo's own opportunities for improvement in issues of omission related to preventable death and improvement of a patient's quality of life before death.[26] These new issues under the waterline may not be as visible as wrong site surgery or medication errors, but they are enormous in number and represent significant threats to healthcare institutions in the near future as payers and malpractice attorneys begin to appreciate them.

- **Hospital to Outpatient Care to the Home Transitions:** Care processes and systems will only get more complex and expansive as our aging population must deal with an aging population, living longer, and having more outpatient needs. As the care responsibility of healthcare networks expands, so do the threats, risk, and real harm that can occur. Predatory malpractice forces will try to take advantage of those organizations who have not anticipated their new risks.

- **Home Family Caregivers:** More than 90 million Americans are caregivers of someone else. They are undertaking a tremendous number of clinical tasks such as wound care, medication management, nutrition support and tasks well trained clinical caregivers will do in hospitals. The unappreciated risks to healthcare leaders is the threat to risk shared contracts and the consequences of readmissions to hospitals that generate penalties when things don't go well at home. Often because of ineffective discharge instructions given by caregivers stressed to get patients out of the hospital.[27]

- **A Conspiracy of Incentives and Disrupted Accountability:** Many of the new and invisible threats along the healthcare threat spectrum have to do with people and their behavior whether inside or outside the organization. Why good people do bad things and bad people do more new bad things needs thoughtful attention. The confluence of personal incentive forces and simultaneous disrupted or absent counterbalancing forces of accountability are predictive. Behavioral economics is the study of the effects of psychological, social, cognitive, and emotional factors on the decisions of individuals and institutions and the consequences of those decisions. The combination of a market in payment disruption, fierce consolidation, and enormous downward market pressure in the face of little legal or public and personal accountability has created a minefield of potential threats to people, property, and prominence or reputational currency. Whether intentional or unintentional, as we describe below, the frequency of clinical, administrative, and research misbehavior is at epidemic proportions. Much is due to the short-term desire to acquire. Acquire or preserve power, profit, or prominence.

- **Cybercrime in the Connected World - SoMoCoGo:** The world of social networks, mobile portability, Cloud-based repositories, and global connectivity is exciting and creating enormous new opportunities. However, in healthcare it has created many new access points for information to be used in improper ways for actors who do not have accountability for their actions. The explosion of risk for medical identity breach, theft, and contamination is enormous. Less appreciated are the risks to the professional identities of caregivers and researchers and the risk of fraud. Many of these are completely invisible to those who have practiced traditional threat and risk management in healthcare.

PRESENT THREAT PROFILE

- **Inside versus Outside Threats:** The disruption of payment mechanisms, consolidation of the market, and enormous impact of the internet have created an amazing new set of inside threats. The dramatic increase in terrorism and violent intruder events although small in real numbers demands a new focus on outside threats. As hospital systems acquire outpatient clinics, they have acquired the history of risk and now a number of new responsibilities they have to bring up to the same level of care as hospitals. This is a big surprise when they are sued or are ensnared in accreditation audits.

- **Nature versus Manmade Threats:** Some may argue that there has been climate change and weather is changing, however the impact of natural threats whether consistent or not has become much greater due to the growth in size and complexity of healthcare institutions covering broad outpatient services over wide geographic areas.

    - **Weapon-izing the Internet:** The combination of internet connections of the enterprise and connectedness of patients and caregivers has opened a floodgate of opportunity for bad actors. Be it targeting people, property, or prominence of reputation; the risk is exploding.[28]

    - **CBRNE Terrorism Unique to Healthcare:** Not only have those with malicious intent identified the bountiful opportunity for mischief in healthcare with enormous access to harmful agents and the geographic concentration of potential victims, but even a clandestine group of undercover bureaucratic investigators from the Government Accountability Office has found out how easy it was to access nuclear material for terrorism intent in a real-life simulation they conducted. Formed in April 2014 in North Dakota, Texas and Michigan — “they discovered that getting a license and then ordering enough materials to make a dirty bomb was strikingly simple in one of their three tries. Sellers were preparing shipments that together were enough to poison a city center when the operation was shut down.” This was the second time they ran the same sting in 9 years, illustrating the glaring gaps in our protective mechanisms. Their report to Congress was entitled *Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effective.*[29] [30]

    - **CBRNE Terrorism becomes CBRNET:** After the experience of the devastating impact of the transportation related terrorism events in Nice and other cities in Europe, we realize we have very unique risks to those who serve during shift changes at hospital when many caregivers are vulnerable to vehicular incidents. However, unlike government buildings, we have not established protective defenses and surprisingly, few caregivers are trained for acute trauma in programs such as the Stop-the-Bleed program developed by the American College of Surgeons which would enable them to deliver bystander care onsite during a vehicular terrorism event.[31] [32] [33] In April 2017, a Transportation Safety Administration security alert was released to law enforcement leaders regarding the use of stolen trucks and the current new threat landscape.[34]

    - **Nation-state Espionage:** A large number of foreign students, researchers, scientists, and professionals come to the United States and work with foreign governments to contact and recruit individuals with the hopes to acquire advanced technology without research costs. The threat can come from current or former employees, business partners, consultants, contractors, temporary hires, foreign agents, suppliers, or even vendors who have access to proprietary information. For instance, China has programs focused on access to research and expertise for cutting edge technology. Such an approach provides benefit from years of scientific research conducted in the United States supported by US Government grants and private funding.[35] Security leaders of our top research centers are very aware of the constant threat of intellectual property theft; however have to balance this with the need for collaborative dialog to move science forward. This is a daunting challenge that needs our best minds to help develop solutions.

    - **Tightly Coupled Supply Chain Risks:** Like many of our urban centers, our hospitals are slaves to “just in time delivery” of the vital lifeblood of their supplies. With a disruption in service, both the people they serve and the people who serve are at enormous risk. A surge in medical needs with an epidemic or disruption in service at a major medical center has enormous threat potential. We are not prepared, especially

where there is a geographic concentration of competitive hospitals who are not communicating. For instance, many emergency preparedness plans of such competitors' factor the same resource availability such as ambulances for evacuation presuming that no other hospital in the area will compete for the same resources during a larger scale event…but, they will.

- **Leadership Systems Threats:** The present and emerging threat to and through leadership systems are exploding and without addressing those below, there is little hope to stem the tide of harm which may engulf healthcare institutions in the future.

  - **Emerging Professional Identity Threats:** The threats to organizations originate both from the inside and outside due to fraudulent behavior of employees, business partners, potential employees and consultants. Administrative and human resources misbehavior relative to the "second victims" of healthcare accidents has dramatically eroded trust of caregivers in their leadership. Again, this is a leadership as well as a process systems issue.[36]

  - **Enormous Fear of Retaliation in the Work Place:** The elephant in the board room is the enormous problem of trust among the ranks in hospitals and healthcare institutions. The fear of retaliation by mid-level managers and senior leaders has been documented across the industry. Studies in 2012 and 2016 by the Agency for Healthcare Research and Quality revealed very similar results. The 2012 study included than 1,100 hospitals (20% of all U.S. hospitals) and 1,128 hospitals and 567,703 hospital staff respondents. The 2016 study included than 326 hospitals and 447,584 hospital staff respondents. Both studies showed that 50% of staff believes that errors are held against them and that at least one third believes their mistakes are written up in the personnel file.[37] [38] The 2016 study found two thirds are afraid to speak up when "something does not seem right". There should be no surprise why we have a patient safety crisis.

  - **Sham H.R. Review and Administrative Misbehavior:** Although difficult to document by large studies, sham employee reviews can be used to protect the financial assets of an organization after a medical error, terminate an employee for reasons other than their performance, and to pave the way for professional advancement of other staff. Well documented in the academic sector, the processes are the same. Alain Zucker in 1996 set out a number of distinctive variations of employee targeting and mobbing: (1) mobbing by employees against a colleague, (2) by employees against a subordinate, and (3) by employees against a superior.[39] The behavior involved may include "social conflicts such as defaming a person, isolating them, instigating rumors that progress into major conflicts e.g. preventing employment, lack of promotion and even threats of physical violence. It may be deliberately coordinated, or may develop through the influence of a copycat atmosphere in the workplace." Ramage goes on to say that, "Therefore it is often insidious, difficult to detect and harder to prevent once discovered and potentially incurable."[40] Speaking of the impact upon the unfortunate victim, Ruth Swartz et al who wrote "As a result, the individual experiences increasing distress, illness, and social misery...Resignation, termination, or early retirement—the negotiated voluntary or involuntary expulsion from the workplace—follows." [41] (Mobbing: Emotional Abuse in the American Workplace [2004]) "For the victim, death—through illness or suicide—may be the final chapter in the mobbing story." (Mobbing: Emotional Abuse in the American Workplace [2004]).[42] An organized approach at discrediting a healthcare employee is a major fear and is not surprising in light of the AHRQ studies cited above. Our team has firsthand knowledge of suicide resulting from the release of human resources records of a caregiver after a medical error.

  - **Bad Apple Tactic Protects the Barrel:** As in the words of one of the committee members co-authoring the National Academy of Sciences report, entitled *Fostering Integrity in Research*, we've been fond of the 'bad apple' narrative and were talking about switching to the barrels and barrel makers'. The report documented the dramatic growth in misbehavior of researchers including fabrication, falsification, and plagiarism and addressed a problem across the academic system, not just among a few researchers.[43] Unfortunately, the "bad apple" approach often guided by legal advisors, is undertaken with opposition research and even fabrication and falsification of human resources files to make an employee appear to be a bad apple. The same is done by defense legal teams to discredit plaintiffs and their families in order to negotiate reductions in settlements of malpractice suits before a trial.

  - **The Sandusky Trap:** The recent conviction of the President of Penn State for his role in allowing the

physical abuse of children to continue is a warning horn for governance boards and leadership teams who do not act on known risks or insulate themselves from being aware of threats and risks.[44] Once CEOs and senior leaders find themselves in orange jumpsuits for mishandling risks to the public by placing profit over principles, behaviors will change to avoid the Sandusky Trap. The fear of retaliation for speaking truth to power over patient safety issues illustrated by the AHRQ studies cited above describes an ecosystem ripe for public accountability that led to the conviction of the Penn State President and the demotion of Baylor University President for the university's reported handling of sex assault cases of alleged misbehavior of football players."[45] When healthcare legal advisors try to shelter top administrative leaders and trustees from the handling of the details of the very risks that threaten their patients and their staff to give them plausible deniability, they are setting them up for a fall. To quote Abraham Lincoln, "To sin by silence when they should protest makes cowards of men"[46] and Edmund Burke "The only thing necessary for the triumph of evil is for good men to do nothing.[47]

- **Sham Medical Peer Review:** Sham peer review is a premeditated process by a group typically comprised of healthcare administrators and physicians. A leading expert who has documented the process and tactics, U.S. neurologist Dr. Lawrence R. Huntoon defines it as "an official corrective action done in bad faith, disguised to look like legitimate peer review". Hospitals use it to rid themselves of physicians who advocate too often or too vociferously for quality patient care and patient safety, and economic competitors frequently use it to eliminate unwanted competition[48] [49] [50] [51] An emerging threat, this is correlated and causes damage to the professional identity of caregivers, researchers, and academic personnel. Medical mobbing describes similar behaviors that may be an informal or formal campaign to discredit a competitive colleague.

- **Healthcare R&D Fraud and Intentional Misbehavior:** A frightening and not well known or understood phenomenon is the enormous frequency and systemic nature of fraud in medical research. The 2017 National Academy of Sciences report *Fostering Research Integrity* cited above documented this growing problem in its report to the public and congress.[52] [53] "One recent analysis cited in the report that focused on articles contained in the PubMed database found that more than two-thirds of retractions were due to misconduct defined as falsification, fabrication, and plagiarism"[54] (Fang et al., 2012). Another analysis that examined retractions of articles in a variety of databases that collectively covered all disciplines between 1980 and 2011 found that 17 percent of the 3,631 retractions in which a cause was identified were due to data fabrication or falsification, and 22 percent were due to plagiarism (Grieneisen and Zhang, 2012).[55] Further, adding up all the grants that contributed in any way to papers retracted due to misconduct over those 20 years, which the authors point out may overstate the costs of misconduct, totals $1.67 billion in actual funds and $2.32 billion in 2012 dollars. This analysis only looked at cases where an investigation has been completed and findings of misconduct have been made.[56]

- **Widespread Academic Misbehavior in Publications:** The majority of retractions of medical and biomedical articles is due to outright fraud. A 2012 National Academy of Sciences detailed study of all the 2,047 biomedical and life-science articles indexed by PubMed revealed only 21.3% were due to error. Fully 67.4% were due to misconduct with the majority due to fraud by falsification or fabrication. Only 9.8% were due to plagiarism. The frequency of fraud is up 10 times since 1975.[57] As described in the article entitled The Problem of Publication-Pollution Denialism Caplan describes the dishonesty across the continuum from authors to the scientific journals. He states "publication pollution is corroding the reliability of science and medicine and yet neither the leadership nor those who rely on the truth of science and medicine are sounding the alarm loudly or moving to fix the problem with appropriate energy. The currency of science is fragile, and allowing counterfeiters, fraudsters, bunko artists, scammers, and cheats to continue to operate with abandon in the publishing realm is unacceptable". His example of how Harvard researcher Mark Shrime created a bogus nonsensical article Harvard researcher recently entitled "Cuckoo for Cocoa Puffs?".[58] *The Surgical and Neoplastic Role of Cacao Extract in Breakfast Cereals*." With fake authors named Pinkerton A. LeBrain and Orson Welles. Shrime submitted this fake article to 37 journals. At the time of the Mayo article, 17 had accepted the obviously phony and nonsensical paper.[59] The risk to our leading healthcare academic and research centers is enormous. One such scandal can ruin the careers and reputations of innocent caregivers and scientists and permanently harm the future of the institution. Few

organizations have any type of formalized program to deal with this threat.

- **Intentional Clinical Misbehavior:** The intentional clinical misbehavior leading to harm of patients is thought to be exceedingly rare, however such stories are ideal for the increasingly scandal hungry press desperate for ratings. Stories such as that of Donald Harvey, known as the "Angel of Death", who pleaded guilty in 1987 to killing 37 people mostly while he worked as a nurse's aide at hospitals in Cincinnati and London, Kentucky.[60] The threat and number of deaths due to impaired caregivers unintentional behaviors and unintentional process failures dwarfs this risk; however, healthcare leaders need to be aware that this can happen.

- **Practices Systems Threats:**

  - **The Chains of Habit - Overuse, Underuse, and Misuse:** To quote business guru, Warren Buffett, "Chains of habit are too light to be felt until they are too heavy to be broken".[61] A substantial fraction of overuse, underuse, and misuse of care processes and practices are merely due to habit and not intentional fraud. In her 2003 *New England Journal of Medicine* paper Elizabeth McGlynn is widely cited for recognizing the low adoption rate of evidence based medicine by frontline clinicians when on average she found that just over half of U.S. patients received the care defined by the accepted evidence based guidelines.[62] Not typically described as a threat in threat and risk management circles, however now that pay for performance is increasing, many organizations are paying a financial price with their customers and although tort reform has crippled the malpractice industry; the lack of delivering standard of care can be a contributor to the harm of an organization's reputation at the very least.

  - **Errors of Omission and Opportunities for Improvement:** The recent discovery of errors of omission described above in the Unknown Patient Safety Crisis – Under the Waterline section and Mayo Clinic Mortality Review work described in detail below must be recognized as an enormous threat and opportunity for improvement of practice systems.

  - **Physical Violence in the Healthcare Workplace:** The National Institute for Occupational Safety and Health defines workplace violence as "violent acts (including physical assaults and threats of assaults) directed towards persons at work or on duty."[63] The March 2016 *GAO Workplace Safety and Health Report* to Congress sub-titled *Additional Efforts Needed to Help Protect Health Care Workers from Workplace Violence* found "private-sector health care workers in in-patient facilities, such as hospitals, experienced workplace violence-related injuries requiring days off from work at an estimated rate at least five times higher than the rate for private-sector workers overall, according to data from the Department of Labor (DOL)". It found *"The most common types of reported assaults were hitting, kicking, and beating. The full extent of the problem and associated costs is unknown, however, because according to related studies GAO reviewed, health care workers may not always report such incidents, and there is limited research on the issue".*[64] The 2015 OSHA *Guidelines for Preventing Workplace Violence for Healthcare and Social Service Workers* found that "while under 20% of all workplace injuries happen to healthcare workers…healthcare workers suffer 50% of all assaults".[65] In a Journal of the American Medical Association (JAMA) article in fall of 2016 entitled *Workplace Violence in Health Care A Critical Issue With a Promising Solution*[66] the authors cite an OSHA report of 24 000 workplace assaults occurring in health care settings between 2010 and 2013, resulting in major and minor physical injury, psychological harm, temporary or permanent physical disability, and death.[67] They go on to recommend that a leadership commitment must be made by healthcare institutions to establish a violence prevention program, encourage reporting of violent and behavioral safety events, reassure employees that appropriate actions will be taken, engage personnel and patients in safety plans, and measure performance of violence prevention programs. Few healthcare organizations are dealing with this threat aggressively. The emergency department personnel are at especially high risk.

- **Healthcare Workplace Bullying:** Not only has physical violence in the healthcare workplace become a major problem, but bullying is at crisis proportions. So much so that the major accreditation organization of hospitals, the Joint Commission has addressed it in their work. In their 2016 Quick Safety Issue: Bullying Has No Place in Healthcare, they define it to include lateral or horizontal violence and cite OSHA above: "while 21 percent of registered nurses and nursing students reported being physically assaulted, over 50 percent were verbally abused (a category that included bullying) in a 12-month period. In addition, 12 percent of emergency nurses experienced physical violence, and 59 percent experienced verbal abuse during a seven-day period."[68] [69] It is not surprising that some anonymous hotline call in services for the public and all industries report that 60% of the calls from nurses and caregivers.

- **Technology Systems Threats:**

  - **Healthcare Cybercrime and Harm:** The frequency, severity, cost, and difficulty to deal with cybercrime and harm is growing with no end in sight. Breach, theft, and harm to institutions are considerable.[70] Breaches in 2016 hit a new high soaring to 1,093 up from 780 in 2015,[71] [72] however the number of records exposed dropped. The medical and healthcare breaches reported in 2016 were 377 (34.5% of reported breaches), while the education sector had 98 breaches (9.0%) and the government and military had 72 (6.6%) according to the Identity Theft Resource Center. [73] We know there is reluctance to report and the numbers for healthcare and all sectors is likely higher. Businesses understand the erosion of trust can damage their financial success. As described below, as of May 2017 a global cyberattack impacted hospitals around the world with many impacted in the United Kingdom.[74] [75]

  - **Emerging Medical Identity Threats:** The harm to the medical records and medical identity for individual patients is enormous and is not only a technology and cybercrime issue, but one embedded in overuse, underuse, and misuse of care processes as well as errors. The "medical identity" of an individual includes their medical and health records as well as demographic information and financial information including all medical insurance numbers and identifiers. Thus a cyber-attack or unauthorized access to an individual or healthcare organization's medical information systems using computers, communication systems, or the internet without known or apparent use of the data is a Medical Identity Breach cybercrime. The former White House CIO reported that it was expected that one in three Americans would have their medical identity breached in 2016. One in five of those medical records breached will be contaminated by fraudsters who use the records to get drugs, make false claims to insurers to receive funds directly, or use the information to submit false federal tax returns. Of those who have their medical identity and records falsified by such fraudsters, one in three will lose their healthcare insurance. According to the Ponemon Institute in their 2016 report, for those who can restore their medical identity, victims spend on average $13,453 to restore them and others report the number as high or higher than $20,000:[76] [77]

  - **Failure to Restore Medical Records**: Despite the risks to patients who have had their records lost or stolen, only 19 percent of healthcare systems responding to the Ponemon study have a process in place to correct errors in victims' medical records.

  - **Ransomware and Disrupted Service:** A growing threat to healthcare institutions is the breach and seizure of electronic medical records that are held for ransom.[78] [79] As much as we want to take a stance of not negotiating with blackmailers and terrorists, there is life and death risk for every minute without medical record access. At the time of this writing a global cyberattack was unfolding with more than 150 countries impacted by ransomware with the perpetrators demanding payment through Bitcoin encrypted currency systems on the dark web where terrorists and criminals conduct untrackable business. It has been reported that hospitals in the UK had significant disruption in service including outpatient services and cancelled services.[80] [81]

  - **H.I.T. Systems Flaws:** Failure of basic functions of health information technology (H.I.T.) systems continues to be a major source of potential harm. The 2017 ECRI Report of Patient Safety Concerns reflects H.I.T threats to patients.[82] Early in 2017, the Pennsylvania Patient Safety Authority published a report regarding a total of 889 medication-error reports that listed HIT as a factor contributing to the event.[83] This was for the period between January 1 and June 30, 2016. Authority analysts found that HIT-related errors occurred during every step of the medication use process and further, a majority of errors reached the patient. High-alert medications (i.e., medications that bear a heightened risk of patient harm if used in error) such as opioids, insulin, and anticoagulants,

comprised three of the top five drug categories involved in most events.[84]

FLYING FASTER AND FLYING BLIND

The metaphor of aviation and flying an airplane is much more fitting to describe the present time than the automobile metaphor we used to describe the past. The complexity, speed of change, exploding scope of risk, and massive consolidation has made successful and safe passage orders of magnitude more difficult. The threat velocity is so high and magnified by the size of the organizations, that most pilots would say that we are behind the airplane – meaning we are in reaction mode and are very likely to have accidents because we are not anticipating when we need to act and when we are acting, we are distracted from keeping control of the situation. We are flying very fast in a storm with more complex systems and no instruments for certain threats and ineffective ones for others.

We are making decisions from data that is old, incomplete, and using surrogates for outcomes with real lives and families at stake.

THE FUTURE

To succeed in the future, institutions and their leaders who truly want to take the best care of those they serve and those who serve will have to deal with the ever-accelerating threat velocity, exploding scope of an ever-expanding threat spectrum, and the challenges of financial disruption that has besieged the healthcare sector. They have two choices: they can take a passive reactive approach and scramble to respond to harm as it happens or they can actively and aggressively “get left of boom”.

In doing so, they need to create a vision of an organization that is the proverbial “shining city on a hill”. Such an organization will have ethical behavior consistently witnessed from the boardroom to the bedside. It will be a place where the care of the caregivers and staff (those who serve) is as important the care of patients and their families (those who are served). Such an organization will be role model of extraordinary leadership that is a beacon of inspiration to the industry**.** Presidents Reagan, Kennedy, and others from both US political parties have often used the image of a shining city on a hill to challenge the electorate to reach for the stars to make for a better future.[85]

Below, we describe the idealized design and function of what leading healthcare organizations should aspire to become. This establishes the rationale for what threat safety science research and development must achieve in order to make this a reality. We believe the leaders of great organizations will use their core values as their compass to chart the course to that ultimate destination where they can put the care back into healthcare and the trust back into the public trust.

IDEALIZED DESIGN, VISION, MISSION, AND VALUES GENETICS

If one considers the vision of an organization as the ultimate destination of the institution and the mission to be the strategy and tactical objectives that bring us to that destination, then we must define both in the context of reality and empowered by our aspirations. Henry Adams who was an American historian and descendant of two U.S. Presidents was known for the quote: “The American President resembles the commander of a ship at sea. He must have a helm to grasp, a course to steer, a port to seek.”[86] Applying this visual framework to the notion of aspiring to make our destination the shining city on the hill, we must use the best design tools available to plan our journey. They include idealized design methods, development of our values DNA, and focus on both those we serve and those who serve.

- **Idealized Design:** The concept of idealized design was originally employed at Bell Labs in the 1950's with the intent of redesigning the telephone. They were looking at making incremental improvements in the standard telephone features - the dial, coaxial cabling and multiplexing. However, by looking at the ideal scenario, they ultimately developed revolutionary items such as touch-tone phones, call waiting, call forwarding, conference calls, voice mail, and what was then the beginning of the mobile phone. Later applications ranged from the redesign of Paris of the future and the launch of the OnStar system by General Motors.[87] Simply put, it is clarifying the optimal outcome and working back from it, rather than forward from where we are today. We describe it to mean design the optimal outcome if you had unlimited time, talent and treasure – “Triple T”, then modify the design with best achievable performance given the time, talent, and treasure you have.

- **The Ideal Vision:** If we were to apply the idealized design methodology to the healthcare organization of the future, we would have to start with the core values of the institution and identify how our vision synchronized with that future. Such an organization will consider the “conspiracy of

incentives" and lack of accountability disincentives that put their leaders and staff at risk. Many are surprised to find the amazing predictability of behavioral based interviewing and how core values factored into the great successes of companies like Southwest Airlines and JetBlue who employed this scientific approach through the leadership of Ann Rhoades, author of *Built on Values: Creating an Enviable Culture that Outperforms the Competition.*[88] Rhoades, the former head of HR for Southwest and co-founder of JetBlue is known for saying: "Leaders drive values, values drive behaviors, behaviors drive performance, and the collective behaviors of your organization are its culture". Safety is one of the core values of JetBlue and the safety of those we serve and those who serve must be at the top of the list and leaders must do what Rhoades is known to say: "They must live their values".

- **Values Genetics Concept:** The values genetics model was developed and published to help scientific and clinical leaders such as physicians understand the performance psychology and behavioral economics methods employed by leading non-medical businesses.[89] Human resources and psychology of performance has largely been held in low regard by clinicians and researchers who thrive on evidence based medicine and data.

In this ''values genetics model" that was developed by learning from Rhoades, one can consider the intrinsic core values of human beings as their values genetic code or genes that are expressed through behaviors. That is nature. The environment where they work and deliver care is how nurture factors can come into play. The core values of an organization can be considered its genetic code or corporate genotype expressed through the collective behavior of its people or phenotype. The translator or mediator between values and behavior is ''choice''. Values are about choices we make that are expressed through our behavior. In some cases, we choose to behave one way or another; however, this is not a simple issue of conscious preference. We, as individuals and as organizations, make conscious and unconscious choices every day. We are blind to many of the unconscious choices that are embedded in the systems of which we are a part. Also, certain instincts, such as self-preservation and survival instincts, can trump conscious choices. We believe future healthcare threat and risk managers will need to have to understand the written and unwritten values of their organizations to fully plumb the depth of their threats, risks, and opportunities for improvement.

- **Loved Ones Caring for Loved Ones:** In healthcare we have always prioritized the patient and their families – those we serve, however we have been slow to recognize the critical importance of our people who serve them. In his best seller, *Everybody Matters: The Extraordinary Power of Caring for Your People Like Family*, Bob Chapman, entrepreneur and inspirational leader of a multi-billion-dollar empire has focused their attention on their people.[90] His company Barry-Whemiller, is a $2.4 billion global supplier of manufacturing technology and solutions serving a diverse platform of industries--packaging, paper converting, sheeting, corrugating, engineering and IT consulting. They have grown to 11,000 team members strong in 100 global locations. They say that every single one of their employees is inspired by a culture of what they call *Truly Human Leadership* which is a culture of care, compassion and human connection. The stellar financial performance of their company and history of 100 successful acquisitions and no failures is a testimony to investing in their employees. They say "we measure our success by the way we touch the lives of others and that comes through in everything we do". We believe that tomorrow's great healthcare organizations are going to learn from leaders like Chapman and unlock their treasure in their people. Future healthcare institutions that extend their threat and risk reduction innovations to their own employees and their families will see the kind of success Chapman has experienced. When interviewed for the 2012 Discovery Channel documentary Surfing the Healthcare Tsunami, Chapman states of healthcare that leaders should consider their people as "loved ones caring for loved ones"[91].

A values grounded idealized design approach that prioritizes both our staff and the patients and families we serve is worth the effort in that we can deal with so many of the causative issues of inside threats and our response to those from the outside.

THREAT SAFETY MISSION:

- **Mission:** So if we consider our idealized designed vision, we must take great care in the design of our strategies and the mechanism by which we reach our objectives along the way. We must break our journey and the construction of the passage into proper objective segments while keeping the ultimate destination in mind. We must recognize we must construct guardrails to prevent perverse incentives from drawing our people off of the right path and for some real valleys of death to our patients and our reputations we may have to build new bridges and still for others we may have to develop new strands of leadership, practices, and technologies to weave together safety nets when we befall certain threats we cannot stop.

- **Moving "Left of Boom":** The concept of "left of boom" came from military leaders who had to communicate critical needs in Iraq to prevent harm from Improvised Explosive Devices (I.E.D.s) to the US Congress for funding. It refers to the timeline before a harmful explosion. When the explosion happens (the boom). Left of boom refers to preparedness and full prevention of the bad event. We believe to move left of boom or upstream from bad events, that our most successful organizations will practice prevention, preparedness, protection, and performance improvement – what we call the 4 P's which we describe below.[92]

THREAT MATRIX TACTICAL OBJECTIVES

A successful healthcare organization of the future will have to integrate their leaders around a common continuously updated threat matrix across the organization and realize that winning against threats is through teams of teams and networks of networks learning and working together.

- **Enterprise Threat Spectrum Approach:** Only looking at the entire spectrum of threats and risk including visible, invisible, and emerging threats with an eye toward dependencies, causation, and correlation can an organization allocate the right resources at the right time for the right impact.

- **Integrate Threat and Risk Management, Quality, Patient Safety, and Security:** It will take many years for structural integration of silos within healthcare organizations if it ever happens. However, the divisions and units within healthcare organizations will have to integrate their views of threats and risks. They will have to move beyond their present swim lanes and participate in collaborative and integrated Enterprise Threat and Risk Management.

- **Multi-disciplinary Cross Functional Teams:** The requirements to prevent harm in the future will take knowledge and skills that no one department or individual can possibly possess. Therefore, coupled to an accurate enterprise-wide threat matrix, future institutions will have to have players working together from multiple departments. To quote Upton in Harvard Business Review, **"**Managing insider cybersecurity threats is akin to managing quality and safety. All were once the responsibility of one specialty department. But organizations can no longer anticipate every risk, because the technology environment is so complex and ever changing. Thus the leaders of enterprises large and small need everyone in the organization to be involved."[93]

- **'All Cause Harm" Teams and Committees:** Leading organizations are developing groups who regularly meet on threats and risks across one enterprise and some are even groups representing hospitals that might even be competitors co-located in the same geography. Terrorism and natural events demand that they work together even if they are fierce competitors.

- **Join Communities of Practice:** Learning communities are now acquiring and testing new concepts, tools, and resources much faster than the academic system can authenticate them. Also, with the increasing distrust of the academic leaders and greater access to larger bodies of data, learning communities or communities of practice are much faster at innovating and testing new interventions for performance improvement.[94] [95]

- **Emerging Threat Focus:** Medical identity threats through cybercrime and professional identity threats through misbehavior of individuals are both emerging rapidly and catching many organizations off guard. Organizations in the future will have to be better and better at identifying such new emerging threats to be able to get ahead of the harm and fortify the security of the most valuable assets to patients and their caregivers.

- **In the Moment Information:** Our amazingly and increasingly connected world is offering new opportunities to couple new sources of data from very disparate sources to apply machine learning methods that can bring context and real time threat insights to scenarios as they are developing. Future organizations need to leverage this power of speed when lifesaving actions are measured in minutes.

STAYING AHEAD OF THE AIRPLANE – REAL-TIME DASHBOARD

In a perfect world, leaders will have a continuous near real-time dashboard and an integrated picture of their threat matrix very much like aviators now have a "glass cockpit" with an integrated moving map that overlays the weather over the intended route.

HEALTHCARE THREAT SAFETY SCIENCE

Our review of the past, present, and an idealized designed future provides the foundation for our concept of establishing a research and development framework for threat safety science and innovation. As mentioned above, the term "risk management" has been used for decades to mean "the malpractice claim department", therefore we chose our words carefully to address this new approach.

DEFINING HEALTHCARE THREAT SAFETY SCIENCE:

Our approach to defining Healthcare Threat Safety Science is to apply scientific method, stand on the shoulders of great work by those who have been working and writing about threats and risk, and address the uniqueness of the healthcare threat continuum.

- **Threat Safety Science:** There are a number of definitions for the word “science”. We propose to define healthcare threat safety science for our purposes as “the pursuit and application of knowledge and understanding of the natural and manmade threats to healthcare institutions, the people they serve, the people who serve, and the systems that support them using an evidence based approach through observation and experimentation in order to develop innovations that reduce harm’. This is an amalgam of concepts commonly found in the definition of science and medicine.[96]

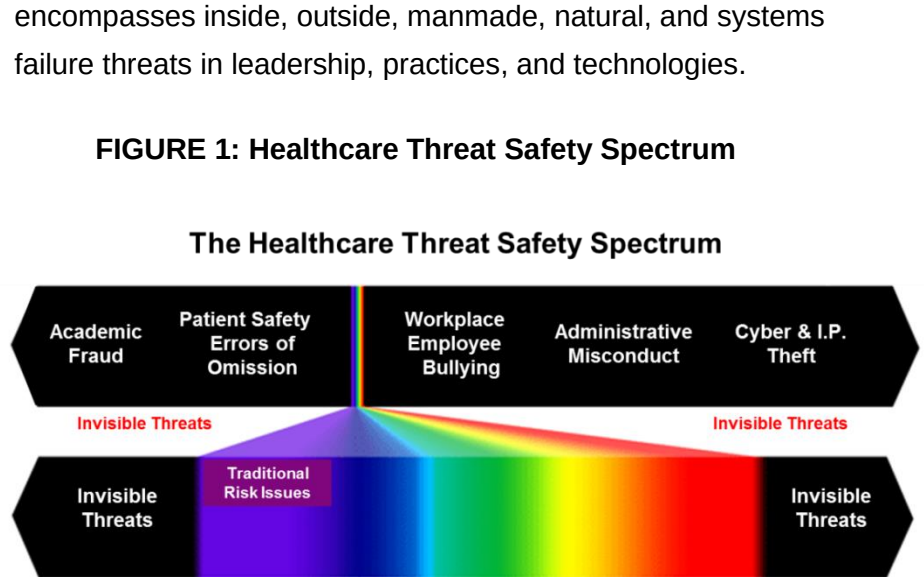
- **Threat and Risk Articles:** Risk, hazards, and threats have been defined by great work over the last 50 years. We who are not academicians in threat and risk domains must stand on the shoulders of this work and apply it to the very unique challenges of healthcare. As Borum has stated in his 2015 article *Assessing Risk for Terrorism Involvement* “in the past 25 years, risk has been defined and discussed alternatively as a hazard, a probability, a consequence, or a combination of probability and severity of consequence (National Research Council, 2007). From a security perspective, the U.S. Department of Homeland Security’s Risk Lexicon defines risk as *“potential for an adverse outcome assessed as a function of threats, vulnerabilities, and consequences associated with an incident, event, or occurrence”.* Borum goes on to describe how risk can be viewed functionally, not just an opinion to be rendered, but a problem to be solved.[97]

In the International Handbook of Threat Assessment, edited by Meloy and Hoffman, threat is described as the perceived possibility of harm. “The key feature of a threat, risk, or hazard is that it is uncertain. We are unsure of exactly what will happen (its nature), how bad the consequences will be (severity), when it will happen (imminence), how often it will happen (frequency), how long it will last (duration), or the probability it will happen (likelihood). A threat is inherently dynamic, changing over time, and contextual, changing in response to the environment.[98] These definitions are very helpful to us as we apply them to the healthcare sector.

- **Scientific Method:** The systematic observation, measurement, and experimentation, and the formulation, testing, and modification of hypotheses describe scientific method. The Oxford Dictionaries define the scientific method as "a method or procedure that has characterized natural science since the 17th century, consisting in systematic observation, measurement, and experiment, and the formulation, testing, and modification of hypotheses".[99] We propose to apply the discipline of scientific method to the R&D in healthcare threat safety.

- **Threat Spectrum:** While in search of the best way to describe the enormous expansion of types of threats, both visible and now invisible that are barraging healthcare organizations; we came upon a very effective visual framework. We have adapted the commonly used visual images of the electromagnetic spectrum to communicate the range of threats and that the threat matrix for a healthcare organization goes far beyond the traditional visible threats and risks we have dealt with in the past. As described below, the R&D work will be organized using a threat matrix approach that encompasses inside, outside, manmade, natural, and systems failure threats in leadership, practices, and technologies.

FIGURE 1: Healthcare Threat Safety Spectrum



- **Threat Velocity and Threat Intensity:** Not only has the threat diversity expanded, but the frequency of threat challenges and the intensity of the forces in both power to harm and duration has increased. This again supports a more aggressive proactive approach than the passive reactive approaches we have taken in the past. These operational terms of “threat velocity, threat intensity, and threat diversity” will be used to characterize issues of research and development of innovations.

- **Defining Healthcare Specific Threats and Risks:** When senior administrative, clinical, and governance leaders are briefed on threats and risks, it is important to minimize the use of jargon and complex technological terms. The threat spectrum and threat matrix framework defined below will be comprehensive reconciling frameworks to be used for research. Threats will also be described by their dominant centricity to help non-technical and non-clinical leaders understand relative threats and risks.

- **People Centric Threats:** MD Anderson Cancer Center uses the phrase “Those we serve and those who serve” to emphasize the importance of the people they care for and all of the people employed or working through the center to deliver its services. We have adopted it to make sure our threat and risk work always considers all of the souls who make up the ecosystem of a given healthcare institution. So many of the major threats and risks to healthcare organizations revolve around people-centric issues, be they inside or outside threats or systems failures. The rapid decay of ethics and impact of perverse incentives demand we focus on the people-centric issues.

- **Property Centric Threats:** The property held by healthcare institutions typically consists of real estate, structures, and intellectual property. The risks associated with the first two are covered by various insurance policies but a significant residual exposure is a loss that does not reach the deductible limit for a particular insurance policy on a per occurrence basis. For example, recent research within The University of Texas Health Science Center at Houston (an institution within the Texas Medical Center which is the world’s largest concentration of hospitals) revealed that water leaks, property theft, and electrical power interruption accounted for the vast preponderance of the losses experienced by the institutions. By focusing on mitigating these threats, annual retained losses have been reduced eight-fold and the preventive controls that have been put in place also provide a level of resilience when much more significant and widespread disaster events occur.[100]

- **Prominence – Reputational Currency Threats:** As described in the Past section above, with the explosive and uncontrolled messaging broadcasted over the internet, the media threats to an organization have exploded. Whether legitimate stories are generated or not, it has become an echo chamber for scandal. Reinforced by 24 hour cable news channels who must, as they say “feed the beast”, the opportunities for harm have no limits. Consider the financial impact of the stories regarding the Ebola cases treated at Texas Health Resources (THR) in Dallas Texas. Revenue declined by a quarter and emergency room visits dropped by half over the first 20 days of October 2014.[101] Millions of dollars were lost as well as the damage to the public’s trust. THR survived because it is a large system with a broad revenue base, however a solo hospital may not have.

  Another issue is the standard practice for legal advisors to aggressively seek “opposition research” on families of plaintiffs who have been harmed by medical error to assist in negotiations and take away the leverage in a future trial. The same has occurred with employees who seek fairness from their employers over HR issues. After a medical error, the approach has also been used to make healthcare employees a “bad apple” to lay the blame for a medical error in order to minimize awards and publicity regarding the hospital where a medical error occurred.[102] In the short term, such behaviors may save money; however in the long term it destroys the culture of the organization.

- **Healthcare Threat and Risk Measures:** The uniqueness of healthcare lies in its complexity. Threats, risk, performance decay, and performance improvement must be viewed from three dimensions - clinical, operational, and financial. All three are interdependent and tightly coupled. The harm to an organization must be measured along these three dimensions simultaneously. The clinical, operational, and financial measure types are as follows:

  - **Outcomes:** Measures such as death and disability are clinical outcomes. An operational measure might be total patients cared for and financial outcomes might be profit or loss for a year or fully loaded profit or loss per specified patient. Harm might be measured in death, permanent disability, temporary disability, or harm requiring unanticipated care.

  - **Process:** Because pure outcome measures are rare, we often have to use surrogates that are frequently process measures. For instance, we know an unanticipated readmission after surgery is not an outcome measure, but it rarely means a positive clinical, operational, or financial outcome for the patient or the hospital.

  - **Structure:** Structural measures refer to the existence of a structural element such as the presence of a patient safety officer or the existence of an All Cause Harm and Threat Committee.

  - **Experience Measures:** Such measures are both for those who are served including patients and their families as well as those who serve who are the

caregivers and non-clinical staff. Although more qualitative than the other measures above, they are increasingly important to insurers who pay the bills.

We propose to define the impact of threats and the probability of harm specific to scenarios of vulnerability using the above metrics in order to study solutions using the discipline of scientific method as we do in healthcare to develop pharmaceutical, device, or service innovations.

HEALTHCARE THREAT SAFETY SCIENCE RESEARCH & DEVELOPMENT:

As General Stanley McChrystal discovered when he took command of the Joint Special Operations Task Force in the Middle East, the Al Qaeda threat in Iraq was a decentralized network that struck quickly and ruthlessly without warning. The hierarchical disciplined approach was failing, and they had to adjust to a "team of teams" approach to become flatter, faster, and more flexible, as McChrystal describes in his book of the same name.[103] We in healthcare now face the same challenge with a broadening threat spectrum of visible and invisible threats of increasing intensity and velocity. We need new concepts, tools, and resources to deal with the decentralized threats coming from all directions.

- **Healthcare Threat Safety Classification:** In order to build the knowledge base in healthcare threats and risk, a classification is being developed to incorporate the most frequent, severe, measurable, and preventable harmful events that can befall the people (those we serve and those who serve), property, and prominence or reputational currency of healthcare institutions. The classification is organized using the Threat Spectrum metaphor and includes inside, outside, and mixed inside-outside threats and risk. It includes natural, manmade, and mixed natural-manmade threats as well. Manmade threats are subdivided into intentional and unintentional by individuals or organizations. The classification includes systems related issues and failures of leadership, practices, and technologies. The classification will continue to grow through the research we will undertake in threat safety scenarios. A risk adjustment component will be added to the classification that addresses specific vulnerabilities of targets within each scenario. For instance, a threat will impact two hospitals very differently depending on their vulnerability profile. The nuances of such vulnerabilities will be addressed and documented to enable development optimal and replicable solutions for the scenarios.

- **Threat Safety Real Life Scenarios:** Our team has developed a "real life scenario design framework" from real life events that illustrates the impact of threats, the measures of harm, and vulnerabilities of the targets. We are developing multimedia training resources for each scenario to be used to reduce vulnerability to threats, enhance recovery, and develop strategies for prevention of harm, preparedness if the threat is experienced, protection when events cannot be prevented, and performance improvement after an event to reduce the potential for harm in the future.

- **Real Life Scenarios Library:** We have assembled a library of real life scenarios as described above. A major focus of Healthcare Threat Safety Science will be to build this library from a growing network of experts and hospitals who are present collaborators. This network will also grow through healthcare institutions and leaders who will join our *Threat Safety Innovations Community of Practice* described below. Launched virtually through an existing global webinar series and through physical meetings in late 2016 and early 2017; the group of collaborators are already sharing stories of threats and risk which will be recorded as resources and also developed into composite scenarios that provide enormous value to certain market segments.[104]

- **Red Cover Reports:** The Red Cover Report is the brainchild of John Nance, a global expert in aviation and patient safety and frequent commentator on the ABC network and Good Morning America. He believes healthcare needs a program similar to that provided by the National Transportation Safety Board (NTSB). He coined the term and described it in a medical article *An NTSB for Health Care - Learning From Innovation* and defined it as an analog to the "blue cover reports" which are accident investigations and reports generated for the aviation industry to learn to prevent similar events. By using the NTSB investigative process and blinding the references to sites and names of people, such reports of real events and constructed composite events can have the same impact the "blue cover reports" have in aviation. Pilots and aviation businesses seize them as soon as they are released to make sure they minimize their likelihood for experiencing similar harm. Such Red Cover Reports and investigative approaches to real events should be a part of a state of the art healthcare threat safety R&D program.[105]

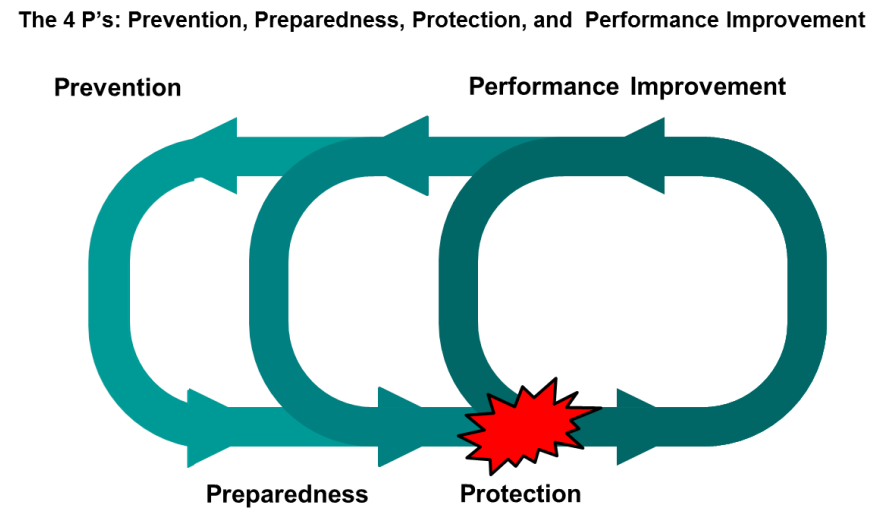
- **Healthcare Safety Innovation Model - Map-Gap-Plug-Play:** A disciplined evidence based approach to threat and risk issues will be undertaken using a market tested system used in healthcare and other industries. A rapid cycle development model beginning with mapping the clinical, operational, and financial processes that lead to harm from a threat allows development of the performance gap. The measures described above are used to define the performance gap to help define a simulation model. Proposed solutions are then plugged into the model to render a probabilistic result. If successful, the solution is “played” back out to the frontline people who experience the threat. Running solutions through multiple cycles can lead to viable solutions or provide an evidence based rationale for rejecting them.

- **Simulated Hospital - Standardized Healthcare Service Unit:** Our development team has found great homogeneity in many of the market segments. The concept that “once you have seen one hospital, you have seen one hospital” and you cannot standardize an approach is a myth. The team has national experience in standardizing certain approaches and adjusting to the local scenarios. By creating simulation models representative of common market segments, solutions can be tested rapidly and then adjusted to the differences of certain affinity groups and geographic idiosyncrasies.

- **Unified, Integrated, and Embedded Approach:** Research has to be undertaken to find the best ways to help healthcare organizations migrate from separate silos of risk management (mostly malpractice claim management), emergency preparedness, security, patient safety, quality, and compliance to a unified and integrated approach where best practices are embedded in how they do their work. Good research questions include: How do you start an “All Cause Harm/Hazard Team”? How can threat’s and risks be communicated in a comparative way to help governance boards and professional administrators make good decisions about resource allocations? What outside collaborative communities can be tapped to help develop the best approach to reducing harm? Who needs to tackle the new threats that keep showing up every month? What kind of “early warning system” do we need?

- **4 P’s - Prevention, Preparedness, Protection, and Performance Improvement:** Research and innovation development is critical in each of the 4 P areas. Using a robust threat safety classification energized by real life scenarios, both primary prevention (preventing a threat from causing harm) and secondary prevention (preventing damage from an event when it happens) research must be undertaken. Preparedness is a condition of “readiness” when an event happens. Research and development here will reduce harm, increase resilience, and accelerate recovery thus reducing disruption of service. Performance improvement tools used in aviation and patient safety are very robust and can be taken across all threat areas and silo service areas. Innovations can be developed using the map-gap-plug-play method described above.

FIGURE 2: 4 P’s: Prevention, Preparedness, Protection, and Performance Improvement



- **Threat Safety Performance Envelope:** The concept of the performance envelope has been pioneered in aviation and refers to a safe operational status with the boundaries measured by altitude, speed, performance limits, and other factors that can be measured by instruments used by the pilot. Research of the safety envelope of an organization using integrated instrumentation measuring the threat matrix as near to real time as possible will provide decision support to leaders. Multi-disciplinary teams need guidance concepts, tools, and resources to enable them to undertake assessment of threats and move to action effectively. For instance, “hot spots” of workforce violence in certain units can help security professionals’ de-escalation methods to areas before physical violence occurs. Research in these areas that integrate threats and risks with interdependent with causal relationships will have enormous impact.

- **From A Prosecutorial Model to Enterprise Health:** The security and law enforcement professionals on our team have pioneered de-escalation techniques that effectively take them left of boom and are preventing events of harm

on a regular basis through their threat management unit at the MD Anderson Cancer Center. This represents an enormous opportunity for impact in light of the staggering frequency of healthcare workplace violence and decay of integrity.

- **In the Moment Information:** The internet can be used as a real-time neurosensory system to provide data about individuals, groups of individuals, and track flow through geographic spaces. Now with real time machine learning methods, security and threat response leaders can manager incidents and practice. For instance, the integration of license plate recognition, social media inputs, and geographic fencing techniques may allow security teams move left of boom. When a terrorism or epidemic occurs which creates a “medical surge” and stresses care resources, such in the moment information will become very important.

- **Communities of Practice 5 C’s:** There is so much to be learned by collaboration with other organizations. We use a model successfully employed with Google and other global organizations for our *Threat Safety Innovations Community of Practice* launched in late 2016. We convene the great organizations, connect them so that they can collaborate, co-create new knowledge and solutions, and finally create change. This approach is energized by a common cause.

- **The Healthcare Institution as an Organism:** Healthcare professionals, be they clinical, non-clinical, or support services personnel resonate with the notion that the institutions where they work are like the human body with organ systems that work together to get their work done. They also agree that fear, corruption, and despair at work is not unlike cancer. The problem may be localized, regional, or widespread and systemic. The treatments must be mapped to the extent of disease where some combination of surgery (most local), radiation therapy (loco-regional), and chemotherapy and immunotherapy are systemic. The perverse incentives for financial and professional gain and protection of losses are the driving force for insider threats. As mentioned earlier, the widespread fear of staff of retaliation of leaders and enormous incidence of workplace violence and medical error demands focused research in behavioral economics and development of solutions. Corruption and fear can metastasize, however if caught early, these threats can be stopped. The healthcare institution organ system model will be used to strategize and develop innovations.

THREAT MATRIX – REAL-TIME DASHBOARD

In order to develop a continuous near real-time picture of an institution’s threat status, research and development of concepts tools and resources must be undertaken. The goal is to ultimately provide a technology enabled “glass cockpit” such as pilots now enjoy with an integrated moving map showing progress and threats and risk along an intended route. The work required to develop such a threat matrix lies in a number of areas to include, but not be limited to the following:

- **The Threat Spectrum:** Threat Diversity, threat Intensity, and threat velocity need to be well understood. They need to be quantified and be able to be visually communicated. The site-specific vulnerabilities need to be identified to enable risk adjusted probabilities of harm, and again these need to be understood and tested using solid scientific method described earlier. The threats, risk, and relative risks for inside, outside, manmade, natural, and systems failures of leadership, practices, and technologies must be studied in order to develop a workable institution specific threat matrix.

- **Multi-disciplinary Team Guidance Tools:** According to Ray Gerwitz, Director of Risk Strategy and Operational Excellence at the UT-Police-Houston, “when establishing or nurturing multi-disciplinary teams in large organizations it becomes necessary to promote a common value narrative using tools or scripts capable of guiding the team to success.” Gerwitz has found story boards; strategy maps and visualization tools can be used to define a common goal or shared purpose and unify the team in pursuit of their goals. Over time tools can be used to recalibrate or reimagine a team’s goals and better adapt to the emerging or shifting needs of the collective organization.[106]

- **Leadership Systems Research:** Governance leaders of hospitals need to understand the dangers along the threat spectrum for healthcare institution. Few understand that their duties extend to credentialing of caregivers and responsibility for quality.[107] [108] Professional administrative misbehavior is at an all-time high as discussed earlier. Development of scenarios that can educate staff regarding the inside threats of institutionalized misbehavior are critically needed.

    - **Misbehavior of Administrative, Clinical, and Research Professionals:** Academic and clinical misbehavior such as sham peer review, falsification and fabrication of research results, and high threat behaviors regarding conflict of interest desperately need research work to help provide guidelines to young faculty members and clinicians who will want to avoid damage to their reputations and careers.

- **Employee Misbehavior:** The frequency of drug diversion, employee theft, fraud regarding human resources claims, and job injury claims continues to grow. Again, the behavioral economics are predictive regarding the dynamic balance between core values, personal incentive, and accountability disincentives. One area of work is in the area of employee integrity testing designed to assess whether certain employees exhibit personality traits relevant to predicting "insider threat behaviors" and the potential response to environmental and other triggers need further development. Similarly, personality mapping tools using psycholinguistic analysis to identify personality traits that may predispose an employee to commit destructive acts may be effective and need further study.[109]

- **Professional Identity Security Special Focus:** As described earlier, the emerging threat to the vital lifeblood of healthcare institutions is professional identity harm both from within and from outside. As with medical identity documentation, this area is of critical importance for special attention, especially in light of the enormous fear healthcare workers have regarding retaliation from their leaders. This is at the intersection of sham H.R. review, sham peer review, and research fraud.

  Research regarding how leaders can become unified in their approaches to an integrated threat focus so that harm reduction behaviors become embedded in their leadership systems has to be undertaken to equip them for the ongoing battle against corruption of their institutions aspirational core values.

- **Practice Systems Research:** Clinical, operational, and financial practices are woefully behind the curve compared to the threats that are challenging healthcare. The opportunities for practice are too numerous to mention here, so we provide a couple of examples below. As described in the Med Tac Certificate program and the Mayo Clinic Mortality Reviews examples, there is ample evidence for accelerated improvement in care processes that can dramatically reduce the threat and risk impact through the process of care.

  - **Deliberative Practice through Immersive Simulation of Real Life Scenarios:** The military often quote Archilochos, the a Greek lyric poet: "We don't rise to the level of our expectations, we fall to the level of our training."[110] This is very true in healthcare where crisis blinds what we know and we fall back to mental muscle memory. As described below in the Med Tac example, our R&D efforts are focused on maintaining competency very much like aviation. We believe this triad of repetitive deliberate practice while immersing learners into real life scenarios will help healthcare staff optimally and consistently in threat situations.

- **Technology Systems Research:** It is easy to fall into a "magical thinking" mode and believe technology will solve all our problems. We believe that the best leadership and practice systems must be in place and then enabled by technology. Otherwise an organization might just make its mistakes faster or on a broader scale using the wrong technology.

  - **Technology Innovations:** Machine learning, use of big data, and leveraging social, mobile, cloud-based, and global solutions that enable best practices are where we believe the research and development must live. Accurate probabilistic risk assessment for certain threats on a real-time basis could take us to a whole new level of harm reduction at healthcare organizations.

  - **Healthcare Cybercrime and Harm:** As addressed in detail earlier, the severity and intensity of cybercrime in healthcare cannot be understated. A research agenda must include those threats from the outside, inside, and mixed threats with outsiders and insiders working together. Continuous vigilance and collaboration by creating a network of networks to learn from will be the only way to move from passive defense to offense in these cyber wars.

  - **Medical Identity Security Special Focus:** The magnitude and the far-reaching costs of insidious damage to patient records will catch up to healthcare institutions only when it is too late. As addressed in the Emerging Medical Identity Threats section above, this is an exploding problem that needs special R&D attention immediately.

    Two examples of current threat safety R&D projects are the Med Tac Certificate Program and the Mayo Clinic Mortality Review collaborative described below.

MEDICAL FUSION AND MED TAC CERTIFICATE PROGRAM EXAMPLE

The Med Tac Certificate Program has been developed to

address the leading causes of death for children, youth, college age adults, and those in their workforce years. Med Tac is an abbreviation for “medical tactical”. The team has coined the term Medical Fusion for the integration of the best practices of medical, law enforcement, and bystander care to address the processes of working together to address the threats, risks, and hazards encountered that are the most common causes of death to healthy children and adults. The Med Tac and Medical Fusion concepts provide examples of how a unified, integrated, and embedded approach to common threats from “time zero” when bystander care can begin through pre-hospital care by professional first responders, through emergency care at hospitals can save lives. We authors comprise part of the multigenerational team who are developing the Med Tac Program.

- **Med Tac Story:** A review of active shooter events in hospitals and schools included interviews of leading expert investigators who have analyzed both the celebrated events and many that have not been extensively covered revealed a surprising list of preventable health hazards and conditions that may lead to loss of life.[111] Further, most were not being addressed by an integrated program tackling them together. Despite their frequency, severity, preventability and measurability, most of them were not being tracked by federal or state agencies.

- **7 High Impact Care Hazards:** The input from Michael Dorn, a global expert on threats in schools led the Med Tac team to identify seven conditions that are frequent, severe, preventable, and measurable. They are the leading causes of death that strike children, youth, and those in their workforce years. They include sudden cardiac arrest, choking and drowning, life threatening allergies, major trauma, opioids and poisons, common accidents, non-traffic vehicular accidents, and bullying.[112]

- **Lifeline Behaviors:** The skills and competencies that bystanders can learn that will save lives in the few precious minutes before the professional first responders arrive are called “lifeline behaviors”. Such behaviors can be learned by children, adults, and entire families. Training is being developed for children, adults, law enforcement, educators, and caregivers.

- **Bystander Care Training:** Immediate care of victims of injuries or those suffering a health crisis is a critical need in all communities. The preventable deaths we see in the news are the tip of the iceberg. The Med Tac program has been called a Good Samaritan support system to help everyone move to life saving actions that will save lives and fulfills a need identified by two 2016 National Academy of Sciences reports including the *A national trauma care system: Integrating military and civilian trauma systems to achieve zero preventable deaths after injury* and *Exploring Strategies to Improve Cardiac Arrest Survival.*[113] [114]

- **Competency Currency:** The program is delivered through CareUniversity, a platform of programs and simple mobile training solutions to help families, home caregivers, law enforcement, and professional caregivers deal with the most common causes of preventable harm to children and adults. Focused on knowledge transfer, skill building, competency testing, and establishing competency currency, it delivers the Med Tac Certificate Program. Leveraging best practices from aviation, it uses immersive simulation and deliberate practice to train non-clinical and clinical individuals to help save lives. Competency currency is the concept of certified learners being regularly tested for their competency. For instance, an Instrument rated pilot may not be legal until their competency is verified by a certified flight instructor. This program uses the same approach. One may be certified, however to be “current” they must have their knowledge and lifeline competencies regularly retested.

- **Impact Opportunity:** Predictive analytics applied the evidence-based studies for frequency, severity, measurability, and preventability were used to calculate the impact of the lifeline behaviors for each high impact health hazards. We have calculated the lifesaving potential of Med Tac training of the public for the United States, California, and Texas. We believe this is an untapped potential. For the United States, the preventable deaths the Med Tac programs target are between 153,643 and 236,534 per year**.** For Texas and California where we have programs being piloted, the combined target is between 42,239 and 61,141. Clearly, due to many circumstances, all of these deaths are not preventable; however this provides the scope of the opportunity.

- **Sudden Cardiac Arrest Example:** One of the high impact health hazards targeted by Med Tac are sudden cardiac arrest in otherwise normally healthy children, youth, and adults. The impact on saving lives of children and youth, especially who have SCA at sporting events is remarkable.

    - **National Lifesaving Opportunity for SCA:** The frequency of Sudden Cardiac Arrest in children and youth For the United States, if the proper 911 calls, bystander CPR and AED use was immediate there are 78,288-152,227 lives that

could be saved. For Texas, the potential is of 10,977-18,011 saved, and for California, the potential is 15,644-25,666 lives saved. [115] Since one quarter of SCA's in children and youth occur at sporting events, the combined lives that could be saved in Texas and California with CPR/AED and proper 911 response would be 77-154 deaths this year. This is in otherwise normal children and youth, just at sporting events.

- **Bystander Efforts and 1 Year Outcomes in Out of Hospital SCA:** Many people who have out-of-hospital cardiac arrest suffer brain damage from a lack of oxygen, and may require constant care at home or in nursing homes. With the increasing frequency of bystander CPR and defibrillation and to improvements in post-resuscitation care, there has been increasing survival after out-of-hospital cardiac arrest, however little had been known about long term functional outcomes beyond survival until a Danish study was reported in the New England Journal of Medicine in May of 2017.[116] Investigators used data from Investigators used data from the Danish Cardiac Arrest Registry from 2001-2012 and found that of 34,459 eligible persons with out-of-hospital cardiac arrest for whom resuscitation was attempted. As compared with no bystander resuscitation, bystander CPR and defibrillation were both associated with a significantly lower risk of anoxic brain injury or nursing home admission. The authors conclude that bystander interventions were associated with significantly lower risks of brain damage or nursing home admission and of all-cause mortality than no bystander resuscitation. This large scale study provides significant evidence that not only lives can be saved, but the quality of life of those who survive is significantly better and the costs associated with their care is likely much less.

- **Learning CPR in Schools & WHO Endorsement:** We now have clear evidence that CPR can be taught to youth and in schools successfully and that by training children, lives will be saved. The World Health Organization has endorsed the *Kids Save Lives* program. A six-year longitudinal study of school children revealed that pupils who were trained by non-clinical teachers performed better in knowledge tests and even after 6 years their knowledge was very good. Even following a 3 year interval with no training, pupils were able to retain knowledge of the theories.[117]

- **Story Power – The Secret Weapon:** The power of using stories to inspire new behaviors is incorporated into Med Tac because the development team has seen firsthand what stories can do to inspire action. The Josie King story of the loss of life of an 18-month old at Johns Hopkins and the plea to caregivers to make their care safer was captured through a 10-minute grainy videotape. It is now being used in more than 2000 hospitals and watched in 3 languages. It has raised more than $250,000 for the Josie King Patient Safety initiatives. It is being studied as a new weapon in the war on medical harm. The producers conservatively estimate the impact of the video costs $60 per life saved. Put another way a Return on Philanthropy (ROP), is one life saved for every $60 invested.[118]

MAYO CLINIC MORTALITY REVIEW EXAMPLE

Death is an ideal outcome. It is irrefutably measurable and especially for inpatients is typically well documented with a finite end point. The Mayo Clinic research and development work from study of more than 12,500 sequential deaths led by Dr. Jeanne Huddleston has created an actionable treasure-trove of opportunities to improve. They are clear threats to life and threats to having the best death. "Better death" at first glance would appear to be an oxymoron. Physical mortality on this planet may be absolute; however there definitely are better deaths.

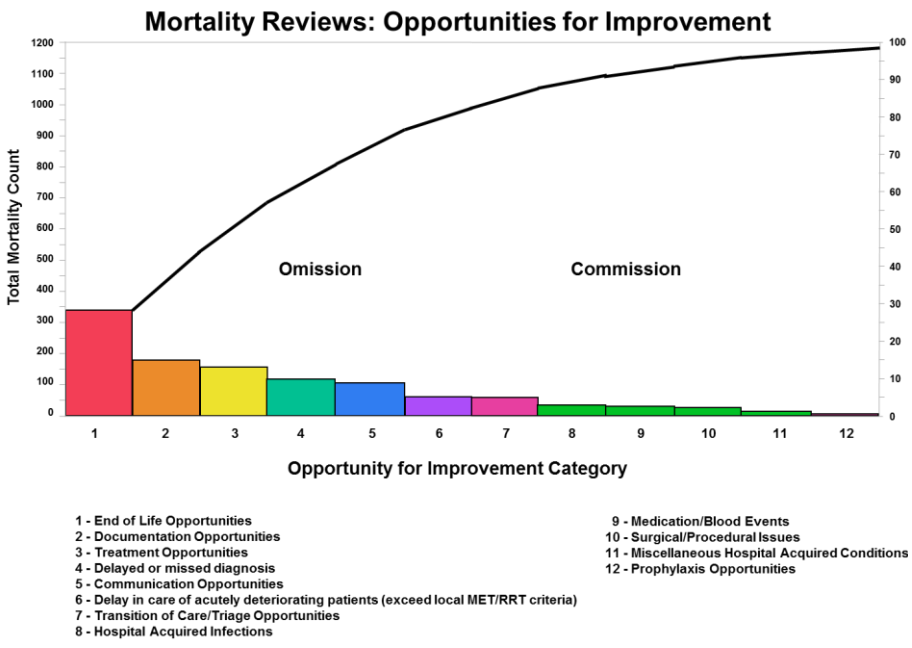
- **Mayo Clinic Mortality Review Story:** Jeanne M. Huddleston, MD, FACP, FHM, is a hospitalist and founder of Hospital Medicine and program Director of the Hospital Medicine Fellowship at Mayo Clinic, Rochester, MN. She chairs the Mayo Clinic's Mortality Review Subcommittee, a multi-disciplinary group of providers that review every death in search of where the health care delivery system may have failed the providers and/or the patient. In 2003 she embarked on a challenging journey that ultimately led to the formal review of 12,500 sequential deaths at the Mayo Clinic Health System. Using this method, they have seen significant reduction in mortality and improved quality of life at the end of life. This work is now inspiring the next generation of patient safety innovation around the world.[119] She has partnered with Mayo to establish a collaborative learning network of hospitals that has begun to include hospitals from multiple countries.

- **Stories, Data, and Opportunities for Improvement (OPI's):** In the beginning, the findings of the mortality reviews by clinicians produced compelling stories; however senior leaders sought

supportive “data” and substantive measures. Dr. Huddleston then pursued Masters' Degrees in both Clinical Research and Industrial Engineering in order to develop the supportive evidence from mortality reviews to improve.[120] The combination of stories, data, and characterizing shortfalls as “opportunities for improvement” rather than adverse events has been the winning combination not only for Mayo, but for the hospitals that have joined their collaborative.

- **Opportunities of Omission versus Opportunities of Commission:** After more than 12,500 sequential mortality reviews, it is clear that there will be a continuous flow of new threats healthcare organizations can tackle and reduce preventable harm. Mayo has brought down their raw mortality, improved recognition of the deteriorating patient, improved recognition and treatment of sepsis, improved triage of emergencies, and improved pain management.121 They have not had an opioid related death in undiagnosed cases of sleep apnea. Today’s R&D surprises will be tomorrow’s mainstream threats. As depicted in Figure 3, their most recent preliminary analysis of 1,123 patients revealed 1,350 Opportunities for Improvement (OPI) with an average of 1.2 OPI’s per patient.[122]

FIGURE 3: Mortality Reviews: Opportunities for Improvement



This graph is provided with the written permission of Dr. Jeanne Huddleston of the Mayo Clinic.

- **What is a better death?** Only clinicians and the public who have experienced a “bad death” really understand what this is. Fully 40% of cancer patients die with intractable pain. Many in the last hours of their life when they would want to leave good memories behind and say goodbye to their loved ones are suffering from preventable discomfort. Mayo has learned from mortality reviews that although death may be inevitable that a patient and their family can have a much better experience with attention to certain opportunities for improvement such as pain control.[123]

- **Community of Practice:** The global community of practice launched by Dr. Huddleston and Mayo is now practicing the “5 C’s” described above. Hospitals are learning from their own mortality reviews, those of collaborators, and finding new opportunities to improve tackling threats to their patients that they could not do on the own.

We are honored to be collaborating with Dr. Huddleston and for the mentorship of our community of practice in threat safety science.

BUILD THE SHINING CITY ON THE HILL

Healthcare threat and risk managers are at a defining moment. We can play defense, remain reactive, stay in our comfort zone with traditional programs dealing with visible and historical threats or we can become proactive and develop programs to tackle the exploding threat spectrum of new visible and invisible threats. Leaders can set out to build the proverbial shining city on a hill where their leadership, practice, and technology systems are ever improving by being built on the solid rock of great core values rather than the passive shifting sand of fear.

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