The Value of Innovation: Responding to Healthcare Reform with Effective Risk Management
US and Puerto Rico

WHITE PAPER
Over a decade has passed since the US Institute of Medicine’s 1999 semiannual report “To Err is Human: Building a Safer Health System,” when it was noted that patients continue to suffer harm and to die as the result of preventable medical errors. The report concluded that in the United States from 44,000 to 98,000 Americans die each year from preventable harm. In Puerto Rico, these numbers can be alarming as well. Clearly, the need for change was undeniable.

**EXECUTIVE SUMMARY**

There are worldwide efforts to reduce adverse events in healthcare and to move toward an organizational learning culture and away from one that sought individual blame. However, improving the delivery of healthcare and patient outcomes is dependent upon embracing proactive new approaches. Early and frequent identification of problems, extensive current-state analysis and a well-thought-out vision for the future rely on implementation practices that are efficient and effective in achieving goals. Though each health system is different in governance and structure, they are working toward improving patient safety and clinical effectiveness, and inspiring an evolution of adoption of best practices that will ensure meaningful and sustainable change.

This paper is a collaborative effort between The Risk Authority (TRA), Stanford University Medical Network, and Aon Risk Solutions of Puerto Rico, Inc. (Aon), two organizations with a shared goal of enhancing thought leadership around best practice in risk management within healthcare organizations.

We begin with an overview of the current state of US and Puerto Rican health systems in light of health reform measures. This overview examines the ongoing evolution of professional healthcare risk management practice and highlights the opportunities that current best practice offers to healthcare organizations by embracing new approaches to managing and mitigating risk.
Puerto Rico’s Healthcare System is in a state of constant change, with the implementation of a new healthcare model arising from changes in the Medicaid, Medicare and commercial programs. In the case of the Medicaid program, the Puerto Rico Health Insurance Administration (PRHIA or ASES) has recently awarded the healthcare regions to health insurance companies that will assume full risk for services provided to the population under a managed care model. With regards to Medicare, the Medicare Advantage program has penetrated the Puerto Rican healthcare market to be at the 85 percent level of all Medicare beneficiaries on the island, creating access to care issues due to limited health care provider networks. Finally, the commercial health plans are subject to Affordable Care Act (ACA) rules and regulations, whereby all the benefits have been increased in comparison to existing grandfathered health plans. In all, the Puerto Rico Health Insurance system represents over $4 billion in yearly expenditure.

It is best that all of the aforementioned sectors apply innovative approaches to promote patient safety efforts through effective risk management programs. In this manner, the Puerto Rico health system can potentially save millions of dollars in patient management errors at both the ambulatory and hospital levels.

To that effect, Puerto Rico must adopt a stricter risk management culture in order to assure higher quality and cost-effective services.

The experience in the US is similar to the Puerto Rico experience in many ways, considering they are under similar healthcare structures. The coordination of care and complex nature of the US healthcare system has brought the US government to act on multiple occasions to increase quality of care, aiming toward the goal of increasing quality of care and patient safety while simultaneously reducing the growth of healthcare spending.

To understand how US government reform impacts the current healthcare model, it is important to understand how healthcare has changed. Prior to the 1920s, most people had no healthcare coverage. Now, the US is trying to function as one of the few industrialized countries with no national healthcare and develop a way to safely deliver healthcare to the estimated 45.7 million Americans who are uninsured or under-insured. Bringing stakeholders in healthcare together with the government and the private
sector is essential to collectively find the safest and most effective way to deliver healthcare. In the case of Puerto Rico, the implementation of the Healthcare Reform Act in 1994, as established by Public Law 72, as amended, has been the major change, whereby all the uninsured received health insurance under a managed care model. To this day over 1.6 million Puerto Ricans are covered under the Government Health Insurance Plan (GHIP).

**IN THE 1920S, MOST PEOPLE DID NOT HAVE HEALTH**

however, physicians did not charge very much and most people were treated in their homes. As medical knowledge advanced, patients began seeking care in hospitals to take advantage of new medical technology. Costs naturally increased.

By the 1930s, insurance companies were created to help people pay for their hospital bills. As science, medicine and hospitals grew more sophisticated and treatments more successful, more people turned to hospitals and physicians for care. Costs continued to rise (in line with medical advancement and increased demand) and insurance companies started gaining ground as a way for physicians to protect their interests and be paid.

World War II and the labor shortage it created encouraged employers to offer health insurance as an employment package. It soon became the norm to offer health insurance to employees, and, shortly thereafter, the government provided tax incentives. While the insurance industry grew in the US, other countries were moving toward a national health insurance model with the government paying for and regulating healthcare services and financial contributions to these services collected from the population.

Initially, the health insurance system was a nonprofit model charging everyone the same premium. However, this became unsustainable due to differing health conditions. When for-profit insurers entered the market, premiums became based on metrics such as age, gender, health status and pre-existing conditions. These private medical insurers had the best risk management strategy: only insure the healthiest people and avoid the sick. Inevitably, the nonprofit organizations followed.

From 1940 to 1960, more health insurance companies entered the market and the supply of insurance increased, becoming commonplace. The use of healthcare increased as medical technology continued to advance, and the use of health insurance as part of an employee benefits package continued to grow. The 1940’s union negotiations reinforced the employer-based health insurance system and, by 1960, private health insurance in the US was well established. By this time, segments of society began to emerge: the poor, day laborers, workers for small companies, and self-employed and retired people. The common link was they either had insufficient insurance or none at all.
Dramatic change was not inevitable but essential. Currently, the US health system remains an outlier and in flux as a result of reform efforts to control escalating healthcare costs and improve care delivery systems and patient care outcomes. On March 23, 2010, the Patient Protection and Affordable Care Act, also referred to as the Affordable Care Act (ACA) and “Obamacare” was signed into law in the US. The law is designed to increase access to healthcare services, reduce the uninsured population and improve coordination and efficacy of care delivery systems.

Most notably, ACA effected a significant change within the US federal social health insurance payment model, Medicare, which insures upwards of 48 million qualified Americans who are either at least 65 years of age or approved due to disability. The ACA made changes in Medicare payment models that tie provider reimbursement to quality metrics. This represents a paradigm shift from fee-for-service (volume-based) reimbursement to value-based reimbursement. Value-based reimbursement is designed to align incentives for quality, cost and reimbursement. For example, prior to the ACA, providers were reimbursed for each admission and there were no incentives to invest in initiatives targeted at reducing readmissions. Under the ACA, there are now penalties for hospitals with high readmission rates.

Historically, US health system reform impacted the risk management profession by making a necessity of innovation in practice and strategy. Reform changes the risk profile of an organization across all inherent risk domains: financial, operations, human, strategic, regulatory/legal, medical management and technology.

Traditionally, healthcare risk management is an insurance function with a focus on medical malpractice (clinical negligence). The function continues to evolve in response to a medical malpractice crisis and volatility created by mandatory reform initiatives. Sharp increases in insurance premiums plus rapid decline in insurance underwriting for medical malpractice through the ‘70s and ‘80s created a crisis that remains disputed as to its cause but not its response. In addition to further legal and insurance practice reforms, a new focus on the contributing factors of medical malpractice claims and patient safety emerged. The well-supported concept of medical error as a result of systems, instead of one person or physician, evidenced a need for enhancement of traditional risk mitigation approaches.

The evolution of risk management programs from silo insurance functions to enterprise-wide risk management decision-making processes, referred to as enterprise risk management (ERM), has occurred in a variety of global industries since the early 2000s. However, effective ERM implementation has struggled in the US healthcare sector for many reasons. Traditionally, the healthcare risk management profession has had deeply engrained reactive and non-transparent practices, which serve the purpose of loss prevention but don’t optimize improvement efforts across organizational silos, therefore avoiding meaningful change for the organization’s key stakeholders: the patients.
In 2009, the Committee of Sponsoring Organizations of the Treadway Commission (COSO) recommended an ERM model for best risk management practice. Successful application of ERM maximizes value for an organization, benefiting the patient and staff alike, while creating a sustainable care platform for the future. In practice, the International Standards Organization’s 31000:2009 ERM model (structured similarly to the As/NZS 4360:2009 model embraced by the UK’s NHS Foundation Trust) is the most widely adopted model.

**ERM: ENHANCED RISK MANAGEMENT PROFESSIONAL PRACTICE**

The principles of risk management practice necessary to maintain efficacy include:

- The creation of value to the organization and its stakeholders
- Enhancement of decision-making around uncertainty
- Furtherance of transparency and inclusion of stakeholders
- Consideration of human and cultural factors

The ERM framework “provides the foundations and arrangements that will embed the process throughout the organization at all levels” to foster timely information sharing and enhance accountability and decision-making. ERM processes and methodologies may vary, but assessment and mitigation of risk are always iterative and generally summarized in five steps.

Risk identification is the first step in the risk assessment process. Identification may occur in many ways with attention paid to a set of criteria that keep the organization’s resources, values and business objectives at the forefront. One common approach is to survey executives and leadership in each domain to understand their perception of their risk. Risk identification focuses on factors or events that significantly impact finances, operations and objectives. Key to this information gathering effort is that it must be comprehensive and include uncertainties related to any particular risk. The entire resulting data pool is then transitioned into the next step for assessment of priority.

In the next step, information gathered in Step One is assessed and prioritized. In this phase of analysis, the goal is to develop an understanding of the risks. The level of analysis may be qualitative, quantitative or a combination of both, depending on the type of risk. Risk registers, or “heat maps,” influence diagrams. Expert opinions are some examples of tools used to prioritize risk. Key to this step is ensuring clear communication with decision-makers around limiting factors that create uncertainty in the analysis.
The third step of the process, evaluation, is where important decisions are made about the information gleaned from the analysis. Risk evaluation compares the prioritized risks and uncertainties with the established organizational criteria and external criteria, such as regulatory or sociocultural factors. The result is a determination of which risk will be treated (or modified) and the order of the treatment and implementation process.

The fourth step in the process involves selecting options for treating the selected risks. The goal at this step is to choose an optimal mitigation strategy, which can be a combination of options or implementation of individual options. The plan should capture the basis for its need and anticipated benefits of implementation, and identify accountable and authorized decision-making stakeholders, clearly proposed actions and time frames, anticipated and potential resource requirements, established performance measures and reporting requirements.

Finally, and most importantly, the process requires periodic monitoring of performance measures such as dashboards, to identify opportunities to react to data. It is important to clearly identify the monitoring process in writing and whose responsibility it is to react to information that falls outside of the established performance measures. The payoff for a well-organized risk assessment process is this ability to evidence the effectiveness of the risk management program in addressing the needs of the organization(s) it serves, especially in patient safety.

The final section of this paper explores the opportunities for shared risk management strategy toward the betterment of patient care outcomes and services from the US to Puerto Rico.
What is clear, in both Puerto Rico and in the US, is the need for increased transparency to understand the true cost of risk and incidents, enabling management and employees to benefit from the real impact of risk management activity.

A typical risk system uses medical malpractice claims to identify problematic areas and epitomizes a reactionary model. If the system, which includes processes and people, is built on a model that reacts to issues, then harmful events will continue, and it will remain highly unreliable. A proactive approach continually evaluates the current state of the healthcare delivery system and operations, and ensures adherence to standards, best practices and early identification of problems. The combination of system design and monitoring of outcomes produces a more reliable and stable operating system. So what is the first step that must be taken to get ahead of events (reactive) to prevent them from occurring at all (proactive)?

At Stanford, we have successfully transitioned to a proactive, value-based risk management system. Like any high-risk industry, high reliability requires a cultural transformation. Waiting for events to occur or problems to be reported delays an organization’s response to small but significant problems. Keeping a sharp focus on preventing harm is about knowing what and where the problems are. Making small problems visible so that corrective actions can be taken will ultimately prevent serious events from occurring. High reliability in processes of care can bring greater certainty in producing consistent and better outcomes. Better outcomes are less risk tolerant, and lower risk means greater value.
Achieving transparency can be tough, as one must balance the perceived risks and rewards of sharing problems and adverse events. It is important to take the leap of faith; however, it is also important to have thoughtful processes in place. Applying analytic methodologies in quantifying the true potential for patient safety can justify the creation of infrastructure that is focused on cultural transformation and ongoing investigation.

Implementing an ERM system brings the focus on high-risk and high-severity areas, which, in turn, can bring early returns to a program and are the basis for leveraging those lessons to spread successful tactics. Using data and reporting effectively can be the catalyst for driving change. Daily management can sustain and continually improve on the desired impact that those changes can achieve. The use of direct observation of practices and evaluation of systems using a tracer methodology has created greater accountability and demonstrated improvements in care processes.

Early and frequent problem/incident identification relies on an event reporting system that encourages event reporting, provides timely feedback of reported events and encourages future reporting. Aggregated data upon which to make decisions about risk mitigation is highly dependent on high-volume reporting. Use of standard categorization of events to identify causation produces actionable aggregate information, and delayed reporting can result in increased claims and a delay in lessons being learned, leading to more claims. Stanford advocates fewer classification codes to allow for richer content and avoid misinterpretation. Clinicians need to feel safe to report, and a just culture must be reinforced so that feedback is essential. This comprehensive, systematic approach will improve management of events and identify issues before they become problems, or worse, turn into significant events of avoidable harm.
Value-Driven Enterprise Risk Management, or VDERM, is a distinct approach pioneered by The Risk Authority at Stanford for managing enterprise value that builds upon the theories and practices of classic risk management and Enterprise Risk Management, or ERM.

A working definition of VDERM is a framework for making risk management decisions that maximize value protection and creation by managing risk and uncertainty and their connection to total value. The definition was adopted by the Board of Directors of the American Society of Healthcare Risk Management in 2013.

While many definitions of ERM include a capacity toward identifying upside opportunities, predominant tools typically focus on the identification and management of downside risks.

Capability for identifying value-creation opportunities has primarily been seen as the province of the enterprise business development team. In an era where risk management efforts have fallen under sharp criticism for failing to deliver on their promises, it is imperative that risk management programs employ all the tools at their disposal for quantifying and demonstrating the value of their efforts to the organization they serve first by including upside considerations.

For example, whereas a heat map or risk register evaluates the probability and impact of downside risks to an organization, they are not designed to understand potential upside opportunities. While these tools can be augmented to identify sources of value creation, what is really needed is an approach that provides an answer to the following question: what risk intervention investments will deliver the greatest total value to the organization?

VDERM is a distinct approach to ERM employed by Stanford, which brings to bear the tools and processes of decision analysis to the ERM cycle. Decision analysis is an academic and professional discipline developed at Stanford and Harvard universities in the 1960s and 1970s, which, via a suite of specific processes and analytical tools, addresses the issues of making high-quality decisions in the face of uncertainties.
Decision analysis is a “formalization of common sense for decision problems that are too complex for informal use of common sense,” (Keeney, 1982) or, more formally, “a philosophy and a social-technical process to create value for decision makers and stakeholders facing difficult decisions involving multiple stakeholders, multiple (possible conflicting) objectives, complex alternatives, important uncertainties, and significant consequences” (Parnell et al, 2013). One of the strengths of this field is its attention to correcting for the heuristics and biases that plague decision-makers, issues that have been well described by David Kahneman in Thinking Fast & Slow, though they fall outside the scope of this paper. Through the use of value maps, probability trees, tornado diagrams, waterfall diagrams and other tools, decision analysis enables managers of risk to identify, harness and exploit unrealized value-creation opportunities as part of their ERM Process.

For example, in addressing claims resulting from patient handling injuries to patients and healthcare staff some years ago, The Risk Authority looked at potential upside benefits of implementing various risk mitigation programs. Whereas safe patient handling programs are usually justified on the basis of reducing workers compensation (employee claims), loss and restricted workday costs through the course of decision analysis, it was discovered that nursing turnover – a previously unquantified driver of loss under the status quo – was the single biggest driver of upside value that could be realized from the implementation of a comprehensive safe patient handling program.

Using only the “downside” data, the business case analysis predicted that the safe patient handling program would deliver $2 million of upside value to Stanford Health Care. By contrast, a VDERM approach to the problem, which took into account “hard-to-quantify” sources of risk and value using the tools of decision analysis, resulted in funding approval for a safe patient handling program for the new Stanford Hospital that is expected to deliver over $5 million of upside value.
By understanding the major upside and downside drivers of risk and value facing an enterprise, a “total value” driven approach to ERM involves viewing our roles as managers of risk as not only taking care of enterprise-wide downside risks, but also marshaling resources to identify, quantify and realize upside value-creation opportunities. This dual focus not only fosters excellence in safety and quality outcomes for patients, but drives innovation through a continual process of iteration, providing demonstrable results and quantifiable returns on risk investments.

**Communication and Resolution Programs**

Communication and Resolution Programs (CRPs) are a modern approach for addressing unanticipated adverse patient care outcomes. CRPs engage the principles of disclosure and apology and seek to provide patients with the information they need following these events.

In the US, a key driver of malpractice lawsuits is the patient’s perception that an unanticipated adverse event occurred as a result of error for which the provider and organization have not taken responsibility or established steps to ensure the safety of other patients.

Historically, insurance companies and risk management practices fostered within organizations the fear of apologizing due to the perceived negative impact that such transparency could have on litigation costs. However, years of studies have shown that addressing the break in trust and communication within the patient-provider treating relationship is as important to the goal of fair resolution as the overall fact-finding and financial strategy around such incidents. Therefore, a well-structured CRP anticipates the emotional barriers to resolution and incorporates those principles and practices throughout.

The Risk Authority is a pioneer in CRP due to the continued evolution and success of its own CRP, Process for Early Assessment and Resolution of Loss (PEARL), first developed in 2007. PEARL is designed to generate early analysis of a reported unanticipated patient care outcome in order to consider immediate and long-term interventions to meet the needs of the patient, involved providers and the organization.
Independent actuarial studies of PEARL data from 2007 to 2012 show a 31 percent decrease in claim frequency as compared to pre-PEARL implementation and a 38 percent reduction in insurance premiums/contributions paid. In 2012, PEARL expanded access to the program beyond provider reports of events by establishing patient portals for patient self-reporting of outcomes. Additionally, The Risk Authority provides a patient liaison to serve as a point of contact throughout the investigatory process to ensure timely and consistent communication with patients. The PEARL framework and guiding principles are such that they can be adapted and applied in a variety of legal and regulatory landscapes.

Along with a small number of other pioneering health systems across the US, PEARL is routinely studied by health policy experts with the goal of building the evidence base for CRPs and continuing to drive the standards on best practice.

To date, published study results support the benefits of CRPs, including a significant reduction in claim and lawsuit frequency and associated costs while increasing public confidence in the organization’s ability to reach a fair resolution without the emotional and financial trauma of litigation. With such positive findings to date, leading health policy experts in the industry are committed to further study of the impact of CRPs.
CONCLUSION

Communication and engagement with patients and their families can contribute to a poor experience. As has been shown by Stanford and others, taking complete control of mistakes, from incident to claim resolution, may significantly improve the financial outcomes for an organization from expedient learning and reduced claims costs. Patients and clinicians (the second victim) also benefit from a joint, accountable approach that allows for open communication, candor, and timely resolution.

To engage successfully in early resolution, an organization requires the autonomy and the financial independence to be able to agree to a financial settlement, if appropriate.

Fundamental to this joint accountability is an empowered management team that can effectively influence joint? All stages of an incident of avoidable harm. The Stanford risk management team is fully responsible for the end-to-end process from incident investigation to patient compensation. Driven by reputation and financial management to create a powerful, virtuous cycle focused on learning, Stanford’s processes have delivered the community of patients and clinicians a sustainable, safer service.

As Puerto Rican healthcare organizations face significant fiscal pressure and a simultaneous requirement to improve quality and safety under increased public and regulatory scrutiny, it is important to observe other healthcare models that connect/interrogate data to fully understand the total cost of avoidable clinical incidents.

The key messages to be taken from this paper are the benefits of positive management of risk, open engagement with staff and, critically, understanding the full financial impacts of avoidable incidents.

This takes a cultural shift using both patient safety and financial drivers. Most importantly, ultimate control and management of risk requires financial independence.
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