TRANSFORMING PATIENT SAFETY
A SECTOR-WIDE SYSTEMS APPROACH

Report of the WISH Patient Safety Forum 2015

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World Innovation Summit for Health

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FOREWORD

During the early 1900's, the medical profession began to exhibit awareness of the increasingly complex nature of providing safe and effective care to the ill, injured, or aged.[1] Since that time, despite a century of evolving practice, technology, and business models – and trillions of dollars in investment – the storyline is the same: heartbreaking stories caused by preventable harm.

For too long in healthcare, the mindset has been that patient harms are inevitable, that silos are natural, and that heroism rather than thoughtful design keeps patients safe. These beliefs persist today, and they are significant reasons for the perpetuation of harm. Thousands of patients continue to die and many more are injured as a result of preventable medical errors – errors that occurred despite the caregiver's best intentions. In many cases, these errors could have been avoided if the right mindset and mechanisms were in place.

Other industries, faced with similar safety crises, reacted in effective ways to manage and mitigate errors and reduce customer, employee, or societal harm. The methodical approaches were (and continue to be) broad, extending across cultural, technological, and procedural elements. They followed a clear and dedicated plan over many years to drive out potential contributors of error. Generally, safety improved – sometimes dramatically.

Healthcare, on the other hand, has taken a local, more heroic, and less systematic, regulatory and sector-wide approach; and the problem of patient safety persists. Despite notable examples of well-intentioned safety initiatives, healthcare researchers tend to consciously and narrowly focus on safety problems in isolation, rather than consider the problem as many interdependent systems at work. Efforts to date have been simplistic and myopic. Healthcare has taken some safety concepts from other industries but applied them superficially and independently of a comprehensive approach to creating high reliability.

If healthcare is to significantly reduce patient harm, a holistic perspective is necessary to capture the requirements and needs related to the culture, workflow, and technology associated with caring for patients. In this paper, we relate the problem to other industries and how these industries have addressed safety. We identify the current gaps in today's healthcare approach and describe the actions that can be taken, and the change in mental models that must be made by the global healthcare community, to continuously improve patient safety.

The time for action is now. Together we can – and must – eliminate preventable harm in healthcare.

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EXECUTIVE SUMMARY

Historical perspective

Patient safety has long been recognized as an area for improvement. Reduction in harm and waste are goals of us all – patients, providers, policymakers, and payers. Yet harm and waste endure, seemingly unabated. Each of these stakeholders has made tremendous efforts to remedy the problem, yet the efforts have largely been superficial and siloed, and the inferences regarding improvement often exceed the robustness of the results. What is missing is a systematic, sector-wide approach, underpinned by sound principles in safety science. How do we build on these initiatives, re-energize and co-ordinate the various stakeholders, and re-focus our collective efforts to realize patient safety?

Today's healthcare system

The healthcare system of today generally operates according to three patient safety premises:

- Harms are inevitable, meaning healthcare feels helpless.
- Data silos and superficial and segmented improvement efforts are natural; therefore, healthcare does not fully understand the benefit of systems that are well co-ordinated.
- Heroism is the norm, meaning healthcare has grown accustomed to a care system that is wholly dependent on save-the-day actions.

These premises inadvertently provide excuses for not addressing patient safety comprehensively, and their persistence perpetuates patient harm today. Because these premises are taken for granted, **they can be overcome with the right approach.**

Systems approach

The goals of patient safety – *to partner with patients, their loved ones, and all interested parties, to end preventable harm, continuously improve patient outcomes and experience, and eliminate waste in healthcare delivery* – must be clearly articulated, designed throughout the healthcare sector, and woven into healthcare system operations. The end state needed to realize these goals must be envisioned, using the tools of a systems engineer.

Other industries such as defense, automobile, mining, and nuclear power have holistically embraced safety and have leveraged the system integrator role to improve safety and productivity. If healthcare is to accomplish something similar, it needs to recognize that other safety-conscious industries operate in comparably complex

and dynamic environments, and that tools and processes that brought about safety in those arenas can be applied to achieve similar results in healthcare. Though it has learned from other industries, healthcare has generally selected tools or technologies, such as error reporting or crew resource management, in isolation, failing to recognize that these tools are part of a comprehensive system to ensure safety. Isolated tools have limited impact.

Starting with the end in mind

Drawing on comparisons with other industries, analysis of representative case studies, and the opinions of the World Innovation Summit for Health (WISH) Patient Safety forum members, we postulate that each of the following themes must be addressed to realize patient safety in healthcare:

- Policy and regulation help rather than hinder safety improvements and ensure that minimum patient safety standards are maintained.
- Patient safety is a core value of the culture.
- Leadership influences patient safety at all levels of healthcare.
- Education leads to informed decision-making and system resilience.
- Transparency and open disclosure are professional expectations.
- Metrics are used to evaluate progress and success.
- Technology facilitates healthcare without constraining it.
- Patient safety is sustainable.
- Patients and their families are engaged partners in patient safety.
- Patient safety research is transdisciplinary.

These themes are enablers to move healthcare from its current state into one where preventable harm is eliminated. They are interdependent and must be approached in an integrated fashion. They also include other topics that need to be addressed, such as stakeholder incentives and financial impacts on the overall system.

Gaps in today's patient safety approaches

During our analysis, we identified five system-level gaps that need to be addressed:

1. **Holistic sector-wide approach:** Patient safety interventions must evolve to health system safety; must be designed using a systems approach; implemented using proven methods for large-scale organizational change; tailored to local cultures and resources; and aligned from strategic, operational, and execution perspectives.

2. **System integrators:** Healthcare must fully embrace a disciplined approach to patient safety that other industries have used. System integrators are required for each element of patient safety, such as legal, regulatory and technical systems. In turn, these integrators must work together to create an overall integrated system of safety.
3. **Risk assessment and performance reporting:** Patient safety reporting systems require comprehensive and methodical analyses coupled with industry-wide learning and improvement, similar to programs implemented in the aviation and transportation industries. Healthcare should adopt risk management processes and tools as other industries have. These industries have learned that safety must be systematic (in 'burning down' risk) and uniformly applied (across the total process).
4. **Patient safety regulation:** Patient safety requires a regulatory body at the national/regional level empowered by law with strong enforcement mechanisms and associated standards of performance, robust data collection, and methodical analysis.
5. **Transdisciplinary science for safety:** Research laboratories for healthcare that couple basic and applied research and development involving diverse fields of expertise must be created. Open business models for broad dissemination must also be supported.

Next steps

To bring about widespread changes in patient safety, the global healthcare community needs to acknowledge the gaps and develop a plan (within a systems context) to address each issue. We propose four initial steps to position and prepare the healthcare community to move forward:

1. Develop a patient safety declaration and have nations pledge commitment and resources.
2. Convene a panel of transdisciplinary subject matter experts to classify and quantify the appropriate definitions and metrics for preventable patient harms, to ensure consistency in tracking and reporting throughout the global healthcare system.
3. Engage the systems engineering community to help describe the various constructs for the multiple system integrators (and their associated responsibilities) that are needed in the healthcare system.
4. Identify candidate nations and local organizations, representing varying levels of industrial and socio-economic development. Work with relevant stakeholders in those systems to create concepts of operation (CONOPS) and requirements for holistic patient safety solutions that are tailored to their specific culture and available resources.

In parallel, each nation might consider its plans for policy and regulation, and other means to incentivize the desired outcomes and behaviors of the various stakeholders.

Each of these efforts requires strong collaboration and partnerships. Collaborative tools and techniques need to solicit input from many relevant stakeholder vantage points to formulate a roadmap for planning and execution. A recurring meeting, perhaps as part of future WISH events, could be planned to provide an update on the various patient safety projects and initiatives.

INTRODUCTION

Patient safety has historically been recognized as a significant area for improvement by healthcare professionals, patients, and other stakeholders in the system. As far back as 1917, the medical profession began to exhibit awareness of the increasingly complex nature of providing safe and effective care:

> "Until a few years ago, hospital services were relatively small, diagnostic methods were simple, the staffs small, and the turnover slow. Consequently the details were simple, comparatively few, and readily kept in mind. The treatment of the individual was, in general, conscientious and satisfactory. With the large service of the present day, however, the complicated methods of diagnosis, the large staffs and the rapid turnover, systemization has become essential. By means of it, the time and the energy of the staff are conserved; moreover, other things being equal, thoroughness in the study and treatment of each case is better insured, and oversights and mistakes are less in proportion to the degree of systemization."[2]

Despite decades of evolving practice, technology, and business models – and trillions of dollars in investment – the storyline is the same: heartbreaking stories caused by preventable harm. Stories abound in which an error, incorrect interpretation, or accident has led to unrelated harms, treatment complications, and in too many cases, death.[3,4] Each incident is devastating – not only to the patient and loved ones, but also to the impassioned healthcare professionals who had intended to help.

Worse still, the effects compound with each incident and have led to a healthcare system that too often harms rather than helps. It is well known that harms dramatically lead to longer patient stays, additional treatments and surgeries, and more downstream complications including long-term psychological and physical pain. These events tax the already burdened and limited resources of the healthcare system. All of these factors (along with the resulting lawsuits and associated resource costs to defend these cases) contribute to waste in the system and sky-rocketing healthcare costs.[5]

Reduction in harm and waste are goals of us all – patients, providers, policymakers, and payers; yet harm and waste endure, seemingly unabated. It is estimated that as much as one-third of all US healthcare spending was consumed by waste in 2011.[6] Despite tremendous efforts to remedy the problem, initiatives have largely been superficial and narrow, and the inferences regarding improvement (and what caused the improvement) often exceed the robustness of the results. Inflated claims without the support of rigorous science (and in some countries, regulatory oversight) tend to be the norm.

How do we respect what has already been achieved, but also re-energize and coordinate the various stakeholders and re-focus our collective efforts to realize patient safety?

This paper answers the call and takes the reader through a methodical process to describe the current state of patient safety, articulate the desired goals and end state for the healthcare system, identify good practices demonstrated by other safety conscious industries, document gaps in the current healthcare approach, and provide recommendations and next steps for improving patient safety from a holistic sector-wide perspective. The intent is to describe common gaps in patient safety across the healthcare spectrum today, and to establish a framework for delving into local solutions in the future.

Patient safety premises

The healthcare system of today generally operates according to three patient safety premises:[7, 8, 9, 10]

- Harms are inevitable.
- Data silos are natural.
- Heroism is the norm.

Unfortunately, these premises have inadvertently provided excuses for not addressing patient safety comprehensively. Realistically, some harms and mistakes will occur; however, the number and severity of harm can be continuously reduced with the right approaches and sound risk mitigation strategies in place.[11, 12] The belief that data silos are acceptable in healthcare settings is an irresponsible view regarding the role of data; it lacks an understanding of the current operational setting. Healthcare is a complex, multidisciplinary environment that requires collaboration and sharing of data across an integrated stakeholder community. The idea that saving patients' lives demands heroism is also a harmful misconception about health and medicine seen in popular culture. In the real-world, the true heroes are not just rescuing patients, they are voicing their concerns and taking proactive measures to reduce the risks, before a patient is potentially put in harm's way.[13]

Hope and humility

Our goal can be stated simply:

> **To partner with patients, their loved ones, and all interested parties, to end preventable harm, continuously improve patient outcomes and experience, and eliminate waste in healthcare delivery.**

Though our goal is simple, how it can be achieved is not.

We have already seen many valiant efforts among organizations at global, national, and local levels;[14, 15] and within highly-resourced and under-resourced areas.

For example:

- National policies have attempted to influence behaviors and incentivize goals. A national policy to promote open disclosure of patient information has been developed in Ireland, supporting timely and consistent communication with service users and their families when things go wrong in healthcare.[16] The National Health Service (NHS) in England has introduced nationally mandated requirements (with associated financial incentives) designed to increase venous thromboembolism (VTE) risk assessments.[17]
- Local approaches such as problem decomposition, training in root cause analysis, and the development of the Incident Decision Tree have also been employed.[18] Intensive care units in Michigan (US) introduced a checklist approach to identify underlying causes of central line associated bloodstream infection (CLABSI). The intervention raised awareness of CLABSI and led to significant improvements in safety culture.[19] Operations research was employed to improve process workflows to preserve patient heart muscle by responding to heart attacks more quickly.[20]
- Programs in under-resourced areas have demonstrated how incremental development within a holistic systems context and a learning system can lead to a continuously improving care setting.[21] The current Ebola outbreak revealed how the disposal of waste and protection of healthcare workers might be accomplished in under-resourced regions.
- Organizations at various levels have demonstrated improved patient safety and patient experience as a result of leadership directives, changes in employee behaviors, and education and teamwork. At the national level, an initiative to reduce MRSA in England was led by the NHS. Through its efforts, MRSA was reduced by 90 percent.[22] At the local level, some organizations have identified patient safety as a strategic objective, and they have chartered teams with leadership endorsement to influence cultural changes and implement proven customer service practices.[23] Other local organizations have emphasized the importance of education, simulation, and teamwork to develop very focused goals, shared accountability, and resilience.[24, 25]

While the above references are positive, there are many areas for improvement. It is too often the case that patient safety studies address one harm at a time, and that the design and evaluation of these studies are poor.[26, 27] This leads to claims that interventions were successful, when there is not rigorous science (or even the right science) to support those claims, and a general lack of context to scope boundaries of applicability.[28] Even more importantly, statements about safety and quality in healthcare lack regulatory oversight and seem largely focused on marketing.[29]

Perhaps most concerning, healthcare has not fully embraced safety as a science. This is an enduring problem. Despite a mature literature on safety in sociology, management and organizational theory, psychology, engineering, anthropology and political science, healthcare has only superficially drawn on this evidence.

CURRENT STATE OF PATIENT SAFETY

The following points summarize patient safety initiatives to date:

- **Policymakers have taken action to improve safety, but impact has been limited.** Some of these policies are beneficial and create much needed focus on safety. Policymakers and regulators in the US and UK, such as The Joint Commission, have clear safety goals around infections and medication efforts. Yet many of these policies are implemented without deep understanding of the context of care delivery, how they will impact care, or the potential consequences. As a result of the persistence of preventable harm, policymakers accelerate their efforts, providers respond, and patients continue to be harmed. In addition, there are too few regulations requiring that technologies used in healthcare meet defined specifications and integrate with other technologies.
- **Patient safety culture is widely recognized as important for safety, though healthcare's understanding of culture remains superficial – something to 'fix' rather than evolve.** Many health systems talk about the importance of creating a 'safe culture' and attempt to measure culture and cultural improvements. However, the changes are largely superficial, seeking quick fixes often without the deeper qualitative understanding of staff concerns or the desired behavior changes. Culture in healthcare can appear punitive, focusing on judging rather than learning and improving the system. Staff members frequently suffer abusive behavior, feel demoralized, and have high rates of burnout.[30]
- **Healthcare has applied improvement tools, though often dogmatically and without understanding of how the tool fits into a safety system.** Healthcare applies tools to improve safety such as lean; six sigma; and plan, do, study, act (PDSA). Though these tools have a place, the evidence supporting their impact is limited, and healthcare has too often seen them as a salvation. Healthcare has yet to deeply embrace the cultural, leadership, technological, work systems design, and workflow processes needed to realize high reliability.
- **Healthcare recognizes that teamwork is important and has developed training programs on teamwork; however, this training is not routinely implemented or sustained.**[31, 32] Healthcare has borrowed teamwork training concepts, largely from aviation, yet this training is not yet widely implemented or required. Much of the training has been dogmatic, such as communicating using the situation, background, assessment, and recommendation (SBAR) model, and often lacks understanding of the underlying theory. Furthermore, accreditation boards do not evaluate teamwork skills, and teamwork competencies are not used to hire and evaluate clinicians. The science for how to measure and improve teamwork has received limited funding.
- **Leadership is increasingly engaged in patient safety, though leaders' understanding of safety and the effectiveness of management are underdeveloped.** Leadership attention is critical to signal the importance of safety and to shape organizational culture. Healthcare boards and senior executives now routinely discuss patient safety and highlight its importance.[33] Yet the quality of over-

sight for safety is still underdeveloped. Few boards have valid metrics of safety or training to interpret safety measures.[34] The presentations about safety are often limited to stories, rather than disciplined reports of risks that would mirror financial reports, and the accountability for performance on safety is underdeveloped. Healthcare lacks line-of-sight (or cascading) accountability, whereby individuals at each level of an organization are accountable for safety. It also lacks methods at each level to ensure staff members have sufficient resources, skills, and time to improve, as well as methods for holding local leaders accountable. Management practices in healthcare are underdeveloped and contribute to significant harm.

- **Education in patient safety and quality has advanced, though it still remains superficial.**[35] Medical, nursing, public, and allied health schools now teach patient safety as a matter of course. Some schools use patients as teachers. Accreditation boards routinely include safety and quality requirements in residency, and healthcare professionals often require ongoing work in quality improvement to maintain their certification or license. Yet the training lacks long-term internalization and applicability, and few academic medical centers draw on other disciplines that have mature safety sciences. Safety training is often limited to an hour lecture and is frequently taught by clinicians rather than faculty with formal training in safety sciences. Students, residents, and faculty generally emerge without sufficient skills or understanding in quality and safety.

- **Transparency has increased, though not nearly enough, and the validity of the data is largely unknown.** Transparency in healthcare has grown. Physicians are now required to disclose to patients when they are harmed from medical efforts and ever-increasing amounts of data are made public. Yet, in some countries, there are no standards about what healthcare provider organizations can say about healthcare quality,[36] and many use their transparency as marketing. The number of measures that are meaningful to patients and clinicians and their accuracy are woefully deficient, with most measures focusing on the process of care rather than outcomes.[37] The format of the data is often not intuitive or useful to consumers. There is too little investment in how to make performance data meaningful to patients.

- **Metrics have increased, though their validity is still largely unknown.** Healthcare now has measures at the local health system, national and regional levels, and global level. Yet the validity of most of these measures is unknown or low. Healthcare lacks an entity like the Securities and Exchange Commission, which works with the private sector to create rules such as generally accepted accounting principles (GAAP). Healthcare can mature its methods for developing and reporting measures, while recognizing that it must constantly evolve with the science.[38]

- **Technology for improving safety has expanded, though the usability and usefulness remains poor.** Healthcare providers have implemented web-based systems to report adverse events and errors. They have greatly accelerated their use of electronic medical records (EMRs) and new innovations to improve safety and quality have greatly increased. Yet the benefits from these technologies are far from evident. The usability of EMRs is poor and generally viewed as clunky and

clumsy; the analytics and decision support tools are underdeveloped. Because these systems are closed, it is very difficult to get data out of them and to create tools that predict who is at risk of harm, recommend therapies to get patients well, monitor if they received them, and learn how the patient did and what worked.

Intensive care units, operating rooms, emergency rooms and clinics are packed with an ever increasing number of devices that do not talk to each other. Caregivers are fatigued by frequent alerts, many of which are false alarms, from instrumentation and bedside systems that lack the most basic of safety features.[39, 40] For example, infusion pumps can deliver potentially lethal medication, yet healthcare still relies on manual double checks to see if the dose is accurate rather than electronic double checks. Checklists have helped improve use of evidence-based practices, yet they have focused on a single harm, and patients are at risk of a dozen harms. Every harm has a checklist, every checklist 5–10 items, and every item might need to happen three times per day, resulting in over 100 interventions required to prevent all harms. No current IT system lists these or even gives a visual display if patients are receiving the recommended therapies. It is no wonder that despite investing heavily in health IT, healthcare has had negative productivity since 1990.[41]

- **Patients and families have become increasingly engaged, though not nearly enough.** Healthcare providers and patients increasingly understand that outcomes are better, costs lower, and workers more joyful when patients are actively engaged in their care. Progress has been made to engage patients and their families.[42] More healthcare provider organizations are involving patients in their governance. Many have created patient and family advisory councils to infuse the patient voice into policies and practices, and clinicians are working to ensure they meet patients' needs.

  Patient experience is now viewed as a measure of quality that is valid in its own right, and is publically reported and included in pay-for-quality programs in the US. Clinicians too often send signals to patients and families that they do not want to be questioned and that they have the answers, rather than co-creating the way forward. At the global level, the World Health Organization initiated the Patients for Patient Safety program, which is a network of over 300 patient safety champions. They are not career advocates, but volunteers committed to being collaborative partners and co-producers of safe care.[43]

SYSTEMS APPROACH

Intuitively, we know what a system is. A system is the realization of a capability that cannot be achieved by any of its sub-parts alone. Systems are generally developed for specific applications to solve one or more problems, with certain operational characteristics in mind. In the case of healthcare, many systems are brought together with the intent of adding incremental value to the assessment and care of patients, without introducing any harm.

The system (which may be created via several paths, ie, equifinality) must not only achieve the goals intended to solve its specific problem, but must also conform and co-operate with other elements within the context of the larger system to which it belongs. The context ensures that the system is operationally viable and that it does not introduce inadvertent effects.

The operational setting is critically important because healthcare is a system-of-systems. **Perturbing one element of the system without considering its impact on the other elements of the system may result in a breakdown.**

For example, an infusion pump delivering narcotics to a patient typically does not communicate with a heart-rate monitor. If a patient's heart rate drops to dangerous levels because he or she is getting too much of the narcotic, the pump does not automatically reduce the amount of the drug delivered. Instead, the system is dependent on a nurse who must recognize the heart-rate monitor alarm, against the background noise of other beeping devices, and stop the infusion. Clinicians may take pride in making those saves, but they know that it should not be that difficult.

Rather than relying exclusively on heroes, healthcare needs safer system designs so that all of the technologies communicate and make it easier for clinicians to do what they do best – heal and comfort patients. Systems engineering has helped fields such as aviation to integrate technologies so that they work together for greater safety, more reliability, and efficiency. Think of a jetliner. Many modern planes can be programmed to fly and land themselves more safely than humans can, thanks to multiple instruments and components working in concert. There are no comparable systems in healthcare.

An important issue to resolve is the characterization of specific processes and how much automation should be incorporated for each. Technology can be a wonderful enabler and facilitator; however, there is a danger of too much automation. The airline industry has witnessed failures and crashes when the technology was not understood and appropriately integrated with the pilots in the system.[44, 45]

Just like aviation, healthcare is also dependent on the orchestration of people, processes and technology, within the contexts of policy and regulation, the specific operational environment, payments and incentives, education, and other legal and safety elements – each of which can be described itself as a system. All of these various parts and their interdependencies, along with any transitions of care, must be considered to enable seamless continuity in patient safety.[46, 47]

There are fundamental development issues that need to be solved at the interface between systems. One system must be able to establish a connection with the other and communicate information in a way that the second system can interpret, translate, and act on. If it requires communication in both directions, then that must be accounted for as well.

At an interface, a set of standards is needed to define the required interactions, as well as a way to map or interpret what is being communicated. This process must be performed at each proposed interface to ensure seamless communication. For healthcare, the number of systems is very large and the interactions between systems can track exponentially with these numbers. It is easy to see why healthcare is complex and the problems are hard.

The good news is that the problems – including patient safety – can be better addressed by viewing healthcare as a system-of-systems problem. **Systems engineering practices** can be applied to consider the various interdependencies and constraints that each system imposes on other systems, to understand the context of patient safety and how each system contributes. It is important to note that a system is not just a technology, but also comprises people, processes and so on.

Once the context is understood, methodical practices will be followed to **envision the end state and proceed through the steps in a systems engineering lifecycle.** Intermediate capabilities for iterative development will be determined. The system will be decomposed into its constituent parts, requirements defined, alternatives considered, and a solution designed and developed. Next, the proposed solution will be tested and exercised in an operational environment that simulates the planned use setting, to ensure that it functions as expected. The system will then be deployed for actual use in an applicable care setting, and the next cycle will begin. Finally, in some future iteration, the system or some of its components may be retired or replaced with upgraded versions.

Users provide feedback regarding the performance of the first iteration, and suggestions for improvement are rolled into development concepts for future iterations. This method enables capabilities to be realized early, and subsequent capabilities expanded based on a roadmap. The roadmap then informs the various stakeholders of expectations regarding planned capability development and associated timelines.

At this point, the challenge of pursuing a systems approach is daunting. Some have even said impossible. They argue that healthcare is unlike any other system in the world. It is very complicated, dynamic, unpredictable and must account for a plethora of devices and personalities, as well as variations in workflow processes and organizational behaviors. Furthermore, the healthcare system today generally consists of disjointed interactions of culture, organization, workflow, technology, environment, learning, and accountability.

Although this depiction of healthcare is accurate, it is not unlike other industries. In fact, healthcare needs to recognize that comparably complex and dynamic environments exist in other safety-conscious industries. Like those industries, healthcare needs to acknowledge the need for system integrators to comprehensively address its safety problem under harsh financial pressure.

SYSTEM INTEGRATORS

A system integrator is a person or group of people who are responsible for bringing the components or subsystems of a system together and ensuring that the combined system functions properly. The use of a system integrator is common in the information technology (IT), defense, aerospace, telecommunications, and highway vehicle industries.

So why have system integrators emerged in other industries and not in healthcare?

Defense system integrator

The role of the system integrator can be traced to the early 1940's, as the US military sought to develop and employ complex combat systems. A classic example is the development of the proximity fuse, which is often considered one of the most important technological innovations of World War II. Prior to the proximity fuse, if a naval ship wanted to protect itself from enemy aircraft, the gun round would have to either physically hit the aircraft, or a timer would have to be set so that the gun round detonated in close proximity of the aircraft. The probability of success for either of these methods was very small. Consequently, sailors requested munitions that would explode within a specified distance of enemy aircraft.

With this goal in mind, researchers and engineers set off to solve the problem. After intensive investigation and concentrated experimentation, a new technology was developed and employed in an operational setting amidst high expectations. It performed dismally. Why? It turned out that the newly developed technology was not adequate to address the objective alone. Its deployment involved very labor-intensive tasks that introduced significant time delays in the process, making it infeasible for the operational context.

Disappointed by the performance but fueled by the mission criticality, the scientists and engineers returned to the problem and took a more comprehensive view – a systems view. As a result, the problem was restated. Instead of narrowly focusing on a single technological solution, the team took a more holistic view of the overall mission requirements. The initial technology became a necessary, but not sufficient, contributor in solving the problem. Its effective application required a broader operational context, and integration with other systems, to realize the goal.

The integrated system was tested, manufactured, disseminated at scale, and maintained by trained personnel. Tactics, techniques, and procedures for using this new equipment were developed. A holistic, end-to-end, full-life-cycle infrastructure, test, operation, support, and sustainment capability was implemented to successfully deploy this system.

In the end, this war-time capability was enabled by the co-ordination of a diverse group of people, technologies, and processes that were orchestrated by the system integrator. This role changed the tide of the war and demonstrated that the development of sub-system technology is crucial; but the integration of the system components is required to achieve the desired mission results. The case further demonstrated how system engineers can purposefully design and deploy a system that meets critical operational requirements, and tailor the system to meet the urgent needs of end users in a dynamic and chaotic environment.

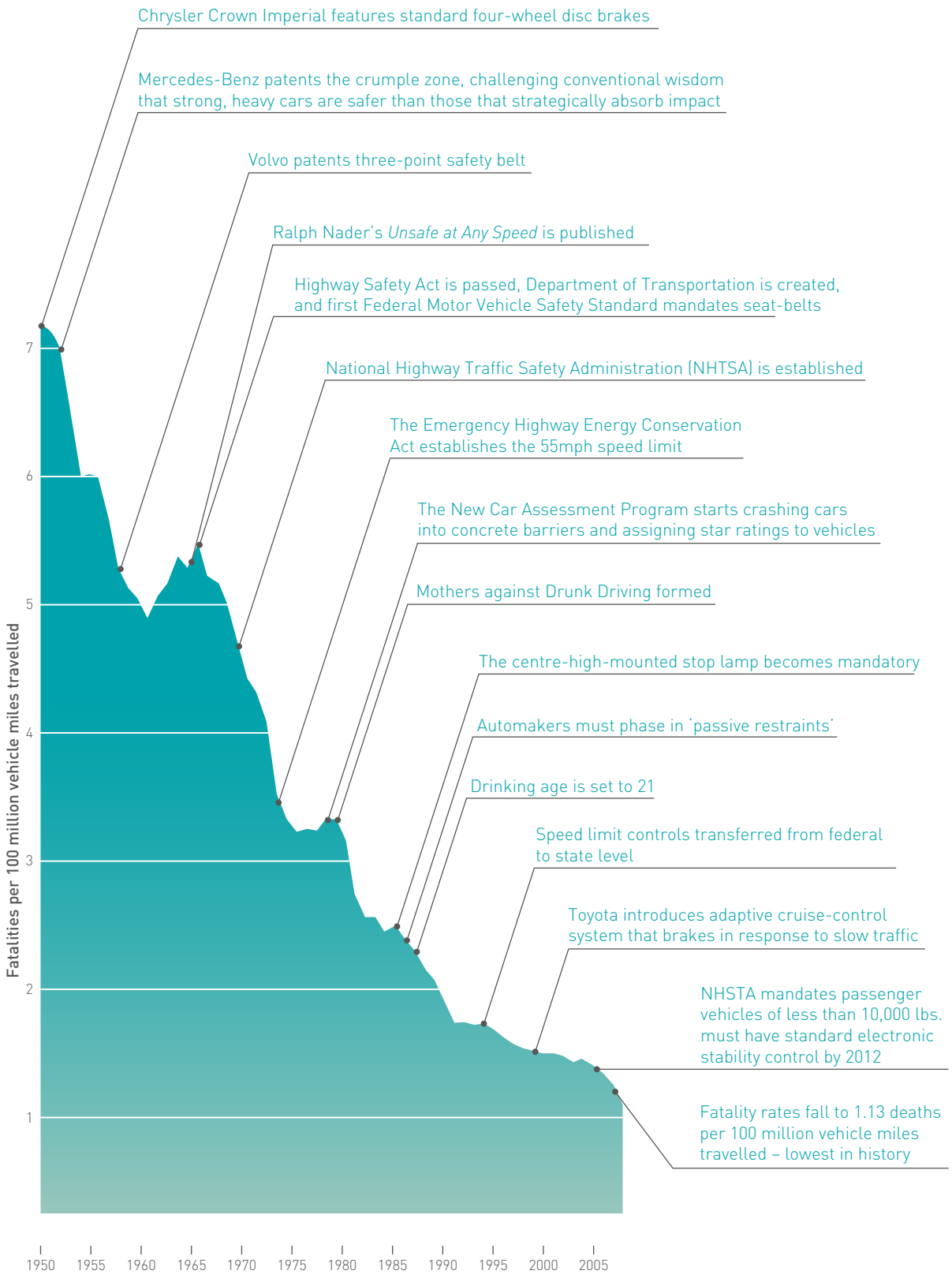
Highway vehicle system integrators

In the highway vehicle industry, an obvious system integrator is the automobile manufacturer. The manufacturer builds a system – an automobile – with design features that appeal to its consumers in terms of design, functionality, economy, and safety. The manufacturer develops its automobile within the constraints set forth by national (and in some cases local) regulatory bodies, as well as industry standards and industry associations. Those constraints include a combination of environmental and safety boundaries required to sell products to the consumer. But this is not a complete capture of the requirements. The manufacturer must also ensure that the automobile design is compatible with a broad range of transportation systems that are not controlled, developed, or maintained by the manufacturer. The system integrator must address how its system co-ordinates with other systems within the operational context.

These additional systems also require a system integrator – national and/or regional governments. These systems include highway infrastructure such as road surfaces (for example, asphalt and dirt) and geometry (such as banking and inclines), fueling infrastructure, road signage and toll infrastructure, in addition to the individual automobiles discussed previously. The regional and national government system integrators have also developed safe interoperable interfaces with other transportation systems – for example, the rail industry. Consider the implementation of track-crossing gates to prevent collisions between trains and vehicles.

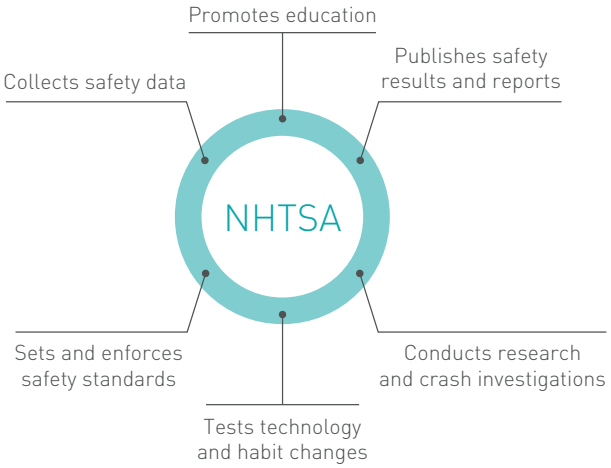
But safety has not always been associated with highway vehicles. Figure 1 illustrates the introduction of safety interventions, regulations, and other activities dating back decades. Turning the clock back to the 1960's, the automobile industry was in much the same position as patient safety is today. There were a disturbing number of safety and environmental issues. Ralph Nader's book, *Unsafe at Any Speed: The Designed-in Dangers of the American Automobile,* highlighted the issues, just as the Institute of Medicine's report, *To Err is Human: Building a Safer Health System*, has highlighted the issues in patient safety. The US response to Nader's book was the establishment of the National Highway Traffic Safety Administration (NHTSA) as a part of the Highway Safety Act of 1970. This Act demonstrated leadership endorsement and established a regulatory body that was needed to create change in automobile safety.

Figure 1: Highway vehicle safety in the United States[48]



Today, the NHTSA can be considered another system integrator, comprehensively co-ordinating system interactions to achieve the highest standards of excellence in motor vehicle and highway safety. Figure 2 shows many of the elements that it integrates. Specifically, the NHTSA focuses on preventing crashes and their attendant costs, both human and financial. It has accomplished this by setting and enforcing safety and performance standards and by providing grants to state and local governments to conduct effective local highway safety programs. There is recognition that total safety will never be achieved; however, the system is equipped to address safety issues as they arise and to continuously strive for improvement.

Figure 2: NHTSA safety activities



For example, when the Toyota unintended acceleration issue resulted in 14 deaths, the highway vehicle industry took action. The various stakeholders, ranging from the NHTSA, the Los Angeles Times, and Toyota consumers, applied the necessary pressures within the system framework to bring about a recall and subsequent fixes to address the problem. In the end, Toyota complied, thereby improving safety in its cars.

The NHTSA has a strong educational component, promoting safe practices such as use of safety belts, child safety seats, and air bags. It helps state and local governments conduct safety campaigns such as reducing drunk driving and it provides consumers with information on motor vehicle safety topics.

With a focus on learning, the NHTSA investigates vehicle crashes and safety defects, and conducts research on driver behavior and traffic safety. The NHTSA Vehicle Safety program provides the scientific strength needed to support the agency's motor vehicle and traffic safety goals.

As a regulatory agency, the NHTSA has the authority to issue vehicle safety standards and to require manufacturers to recall vehicles that have safety-related defects or do not meet Federal safety standards. Manufacturers voluntarily initiate many of these recalls, while others are either influenced by NHTSA investigations or ordered by

NHTSA via the courts. Since 1970, more than 390 million cars, trucks, buses, recreational vehicles, motorcycles, and mopeds, as well as 46 million tires, 66 million pieces of motor vehicle equipment, and 42 million child safety seats have been recalled to correct safety defects.[49]

NHTSA works to ensure that complete, accurate, and timely traffic safety data are collected, analyzed, and made available for decision-making at the national, state, and local levels. Analyzing reliable and accurate traffic records data is central to identifying traffic safety problems and designing effective countermeasures to reduce injuries and deaths caused by crashes. NHTSA promotes a comprehensive, systematic approach to assessing the performance of traffic records systems, and it works with several partners in the public and private sectors, including national non-profit organizations, to achieve this vision and mission.

Federal Motor Vehicle Safety Standards ensure that automotive safety is sustainable. They set minimum performance requirements for those parts of the vehicle that most affect its safe operation (for example, brakes, tires, lighting) or that protect drivers and passengers from death or serious injury in the event of a crash (such as air bags, safety belts, child restraints, energy absorbing steering columns and motorcycle helmets). These Federal Standards are applicable to all vehicles and vehicle-related equipment manufactured or imported for sale in the US and certified for use on public roads and highways.

The Government Performance and Results Act of 1993 established goals for transportation safety. The motor vehicle fatality rate has dropped each year since the establishment of these goals. In 2012, there were almost 212 million drivers and 3 trillion miles driven, over 5.6 million crashes, but only 33,500 lives lost on US highways.[50]

With this comprehensive systems approach, it is not surprising that the highway vehicle industry is often cited as a model for safety. Patient safety can achieve similar levels of success using a similar method.

It is important to note that healthcare may choose to adopt a multi-level system integration approach. As described, the system integrators in the automobile industry have a clear definition of the system for which they are responsible. Highway safety rules are also well defined (and evolving as technology advances and driver habits change over time) and, just as importantly, safety in the automobile industry is highly controlled and regulated by empowered and enduring entities. These regulatory bodies define standard safety features, safety performance requirements, standard performance tests, and a robust analysis and reporting system for both performance test results and real-world safety performance – all of which are accessible to consumers.

An important, subtle point highlighted by the automobile industry is that it has been able to produce remarkable safety improvements with multiple system integrators competing in the market – think about how many various models appear throughout our transportation system. Some are safer than others but across the board, this industry has proven that a single system integrator is not required to achieve high levels of safety.

FUTURE STATE – STARTING WITH THE END IN MIND

To realize patient safety, the goals described earlier must be clearly articulated and woven into healthcare system operations. This statement seems straightforward, but how does one assess when the system is successful? The answer is to describe the end state, and specifically the attributes of an improved healthcare system. One that can improve patient outcomes and experience; continually reduce preventable harms; and eliminate waste from the system.

Based on the industry comparisons discussed previously, analysis of representative case studies, and the opinions of the WISH Patient Safety forum members, we postulate that each of the following themes must be addressed to realize patient safety in the healthcare system:

- **Policy and regulation ensure that minimum patient safety standards are maintained.** Ideally, each national healthcare system is organized to ensure that policy and regulatory criteria are established, operational incentives are aligned with goals, and daily execution is appropriately tailored to meet the requirements of each unique care setting. When more stringent policy and regulation are needed at a particular level (for example, within a hospital unit), then that entity enacts the specific policy and regulation needed to achieve its desired goals.
- **Patient safety is a core value of the culture.** The ideal culture is focused on a patient's wellbeing; is founded on principles of trust, open disclosure, learning, and accountability; is communicated and championed by leadership; and is wholly adopted and institutionalized by the stakeholders who comprise it. There is a 'collective mindfulness' towards patient safety and the culture nurtures positive and proactive behaviors.
- **Leadership influences patient safety at all levels of healthcare.** Patient safety must be unequivocally endorsed by leadership at all levels of individual organizations, and the message and incentives appropriately disseminated for execution. Leaders must inspire and align every healthcare employee so that they understand their role in improving patient safety. Leaders must also provide clarity and direction regarding organizational vision and transitions. They must empower and hold managers accountable to oversee execution, and must further ensure core values are instilled in employees. These should perpetuate even beyond the leader's tenure. Leaders' intentions will become apparent on review of how they allocate resources for creating safety management and reporting systems, provide training and development, and evaluate and report on staff perceptions of safety climate.
- **Education leads to informed decision-making and system resilience.** In the healthcare system of the future, the community is educated and providers are highly skilled and exquisitely trained for resilience and agility when faced with uncertainty and adversity. Education is accomplished in a supportive learning environment via a collaborative learning process. Furthermore, education

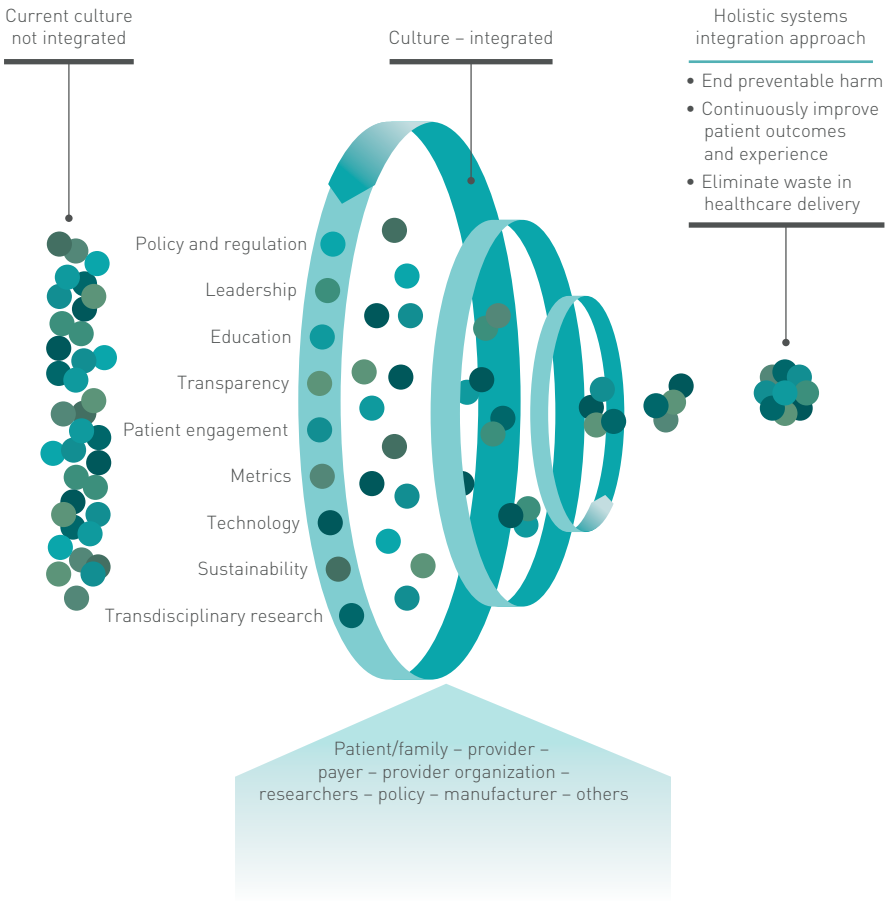
provides a critical mechanism to foster a continuous-learning healthcare system that disseminates lessons learned and best practices across organizational boundaries.

- **Transparency and open disclosure are professional expectations.** The healthcare system will seek out failures – rather than hiding them – to identify opportunities to improve safety. Transparency and open disclosure will solidify the partnership among the patient, practitioners, and other stakeholders, and will provide the basis for a healthcare system focused on continual improvement of patient outcomes and experience.
- **Metrics are used to evaluate progress and success.** Metrics must be tied to specific patient safety goals. An approach, founded in sound scientific practices, must be developed to collect the necessary data for patient safety assessment related to outcomes, experience, and waste. Metrics must also be well-defined and consistent across organizations for roll-up and comparative purposes. Data must be collected to determine functional gaps and improvement opportunities, and must be complemented by powerful narratives that provide a human connection and context to the specific goals.
- **Technology facilitates healthcare without constraining it.** Technology is a component of the larger system and therefore must be developed to interact with the other system elements to prevent patient harms, promote patient safety, and meet system reliability goals. Interoperability of systems and components is needed to enable high-performance systems that make the right information available, prevent duplication of tasks or data entry, and facilitate decision support and workflow capabilities. Furthermore, technologies do not use a proprietary infrastructure that might create a barrier for other vendors to interoperate with the device.
- **Patient safety is sustainable.** The patient safety system must be developed in an iterative manner, appropriately resourced, and continuously measured to make patient safety an enduring component of healthcare delivery. To maintain relevance, the system is adaptive and flexible to change, and enables continuous improvement. High priority items are addressed and developed first, followed by subsequent iterations so that healthcare professionals continually have better resources to address patient safety issues.
- **Patients and their families are engaged partners in patient safety.** Patients and families are educated on treatments, medications, and other risks of harm, and they are empowered to voice concerns about issues that could result in harm or diminish their experience. They are treated with dignity and respect and must be considered as valued collaborators in the healthcare system. Patients are also valuable partners at all levels of healthcare: shaping and supporting policy, raising public awareness about patient safety issues, participating as patient safety advocates, and educating the future generation of medical professionals.
- **Patient safety research is transdisciplinary.** Academic health systems need to create transdisciplinary research teams that include experts in the fields of medicine, health services, organizational and management theory, sociology, psychology, engineering, political science, and informatics. Essentially, patient

safety requires collaborative technical teams that combine applied and basic research principles to solve the toughest problems in safety.

These 10 themes are represented in Figure 3, as enablers to move healthcare from the current state of today into the envisioned system of tomorrow. Note that the themes are interdependent and consequently must be approached in an integrated fashion.

Figure 3: Systems approach and themes to realize patient safety



All or most of the preceding themes are prominent in the other industries that have significantly improved safety standards. For example, the aviation industry is a complex and dynamic system-of-systems that is focused on the safe transport of passengers. Furthermore, it is complicated, sometimes unpredictable, and must account for many different devices and personalities, as well as deviations in workflow processes and organizational behaviors. Despite these attributes, aviation has been able to achieve significant improvements in passenger safety.[51] Part of the success in aviation safety can be attributed to the following initiatives:

- Safety is a fundamental objective that has leadership endorsement and is regulated by an overarching International Civil Aviation Organization,[52] and national entities such as the National Transportation Safety Board and Federal Aviation Administration in the US.

- The re-engineered cockpit is designed to be a decision support tool for pilots.
- Checklists are routinely used.
- Crew resource management is widely practiced.
- Education and training includes simulated environments to create an agile and resilient team in the face of adversity.
- Education of passengers and transparency in the event of an emergency is standard.
- Customer service focuses on safe and comfortable transportation.
- Technology facilitates and supports goals (for example, sensors to track planes) of aviation.
- Metrics are maintained regarding leading indicators of potential adverse events, for example distances between airplanes.
- Black box devices are used to conduct post-incident analysis and extract best practices and lessons learned, to feed back into the system.
- An overarching system integrator of airplanes ensures that all subassemblies and components are integrated and work as intended for all planned operational scenarios.
- Vendors furnish components that meet the interface specifications of the system integrators.
- An integrated system-of–systems continues to evolve.

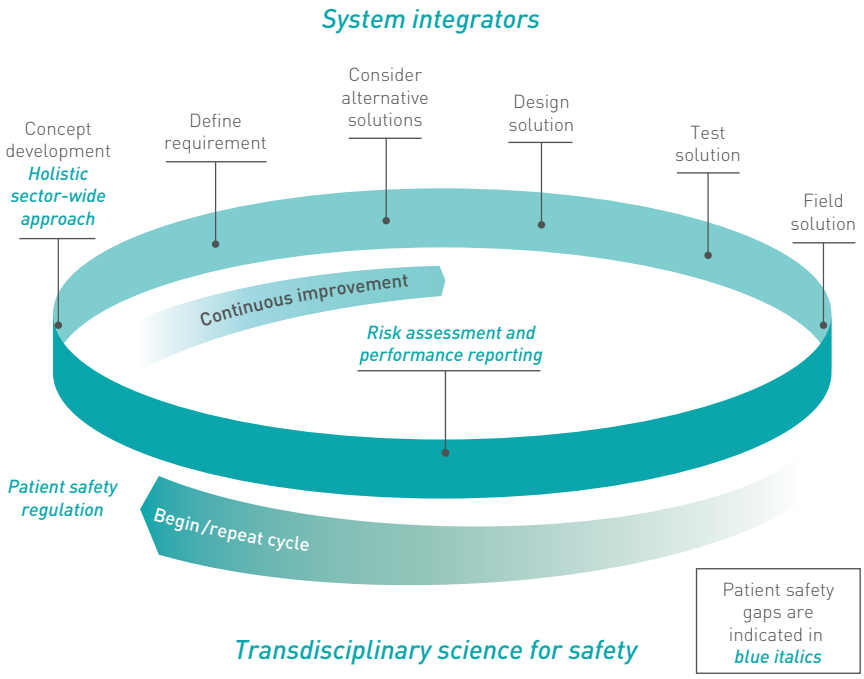
Collectively, these initiatives are interdependent and represent all of the themes identified to bring about the desired end state in healthcare. Furthermore, they offer some insights into the patient safety gaps in today's healthcare system.

GAPS IN TODAY'S PATIENT SAFETY APPROACHES

This section focuses on gaps between current patient safety programs and safety programs implemented in other industries, discovered through research and in conversations with WISH Patient Safety forum members. Associated with each gap are recommended actions that patient safety stakeholders can implement to address the issue and approach the desired future state.

Figure 4 illustrates the high-level process steps to achieve the desired state. Note the gaps appear in blue italics.

Figure 4: Systems engineering process steps and patient safety gaps



Gap 1: Holistic sector-wide approach

Recommendation 1: Patient safety interventions must be designed using a systems approach, implemented using proven methods for large-scale organizational change, tailored to local cultures and resources, and aligned from strategic, operational, and execution perspectives.

Lessons from other industries illustrate the importance of the simultaneous integration of many factors to bring about large-scale, sector-wide improvements in safety. There is no one single action, program, technology, or other change agent that can instantly solve the challenges associated with patient safety universally in all care

settings. As discussed in the 'Systems Approach' section, each initiative to address patient safety – regardless of whether at a local or global level – should be designed using a systems engineering approach, starting with the end in mind, defining the requirements, considering alternatives, developing the solution, and testing it in the operational context.

Once the initiatives are designed and developed, they need to be introduced using the principles of large-scale organizational change. The work will be hard and will require continual iteration, but it can be done.

The construction industry is an example of efforts to improve safety through broad holistic means. In 2004, six construction bodies, including the European Construction Industry Federation, signed the Bilbao Declaration. The bodies that signed the declaration, which included representatives from trade associations, technical groups, and government, committed themselves to industry-specific measures to improve the sector's safety and health standards. These measures included the following:

- Commitment to addressing safety issues throughout the entire construction project lifecycle including procurement, design, construction, maintenance, and demolition.[53]
- Enforcement to improve safety measure compliance.
- Guidelines to share compliance best practices.
- Designing for safe and healthy construction work.
- Improving safety and health performance through the use of robust process improvement tools, social dialogue regarding safety issues, programs, and change agents.

These actions by the construction industry reflect the importance of wide-ranging activities, engagements, and policies necessary to bring about renewed focus on safety across an entire industrial sector.[54, 55, 56, 57]

Each of the following attributes is necessary to realize large-scale, sector-wide, holistic organizational change:

- Leadership commitment (not just at the start but consistent focus and commitment throughout the process).
- Clear goals and definitions of success.
- Data to prove that change was needed and to measure progress/improvement.
- Incentives for meaningful participation and success.
- Shared accountability and openness (systemic problem not individual mistake; learning rather than blame).
- Well-defined process for change (often including patient safety alerting system).
- Education about goals and process for change.

- Multidisciplinary (not just caregiver) teams, with a focus on front-line staff and patients.
- Focus on communication and collaboration.
- Sustainability plans.

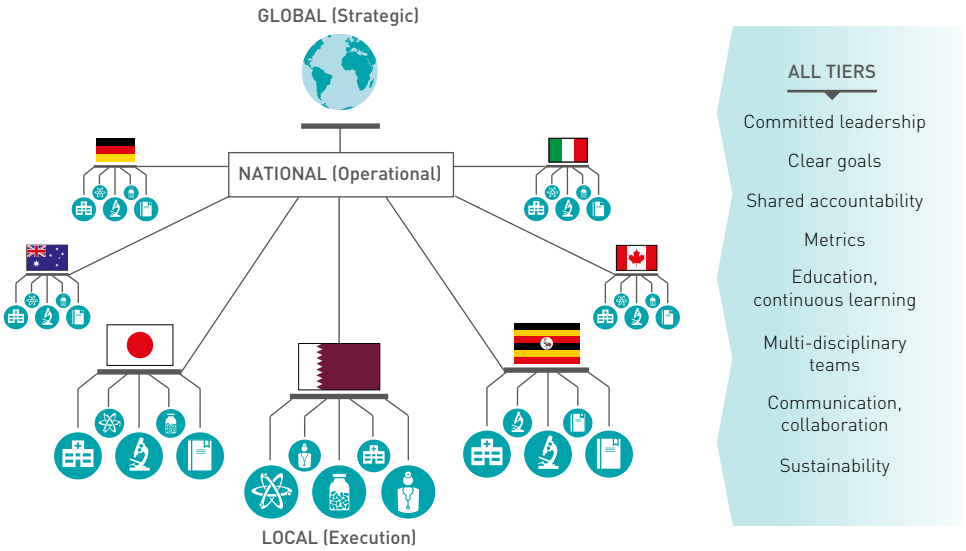
Examples of patient safety programs that strongly displayed these attributes also achieved the desired level of improvement.[58, 59, 60] Initiatives lacking any one (or a subset of) these attributes were less likely to realize the desired improvement.

To date, healthcare has largely focused improvement efforts on a local scale, hoping it can then transition the local solutions to other peer organizations. That approach has largely been ineffective and inefficient. A systems approach would function more like a fractal, balancing independence and interdependence of safety programs at the global, national/regional, and local levels.[61] Healthcare would benefit from focused efforts at the global and national levels.

As illustrated in Figure 5, each level (global, national/regional, and local) would play a different role in improving safety, though all would be interconnected. The global and national levels could focus on strategy (macro level), the national or regional level could focus on operations (meso), and the local level could focus on executions (micro).

In healthcare, a global effort could ensure that medical technologies have open application program interfaces that use specific standards. The national level could ensure all technologies sold in their country satisfy these criteria and perform as expected, not only individually, but also in a co-ordinated manner with other elements in the system. At the local level, clinicians can incorporate them into workflow processes, education and training programs, and other ways to continuously improve safety.

Figure 5: Notional healthcare system hierarchy



The elements of successful change translate to recommendations at the Global, National/Regional, and Local tiers as:

- *Global:* a global **patient safety declaration** is a unifying commitment that serves as a beacon for all those who have a role in patient safety. Further, **global standards for medical device interoperability and a library of valid safety measures** would provide a means to consistently measure progress.
- *National/Regional:* drawing on existing well-regarded patient safety reporting systems, implement enhanced reporting systems that meet the defined global standards; establish a patient safety consortium, similar to the aviation industry's Commercial Aviation Safety Team (CAST), to systematically analyze patient safety data, define interventions, and measure the implementation success of these interventions on a continual basis; invest in advancing the science of patient safety; invest in systems engineering and learning laboratories to continually improve productivity and safety.
- *Local:* tailor patient safety implementations to local-level culture; continuously collect and monitor patient safety metrics; employ systems engineering best practices (for example, using actual end users); and ensure new systems are tested in the specific operational setting in which they will be deployed.

To achieve success at these tiers, Global, National/Regional, and Local initiatives must be mutually supportive of one another.

Gap 2: System integrators

Recommendation 2: Healthcare must fully embrace the disciplined approach to patient safety that other industries have used. System integrators are required for each element of patient safety such as legal, regulatory and technical systems. In turn, these integrators must work together to create an overall integrated system of safety.

Lessons from industries such as aviation, defense, and automobile transportation provide instructive guidance to healthcare and patient safety, particularly regarding the role of system integrators in developing and maintaining complex integrated systems involving social, technical, and economic dynamics.

When most people hear 'system integrator' they tend to think of technical system integration – the interconnection of two or more technical items. But as described earlier in the case of the proximity fuse, the gun round was only one aspect of a system-of-systems that needed to be integrated to meet requirements. The system integrator had to develop and integrate many non-technical elements to make the proximity fuse successful.

In the automobile industry, manufacturers serve as platform integrators producing various models targeting a range of driver populations. Regional highway depart-

ments integrate a system of transportation routes ranging from super highways to local surface roads. They oversee integrated safety programs that include signage, guard rails, road markings, and even road topology, such as banks, to better ensure safe travel among a wide variety of vehicles at designated speeds. There is a legal and regulatory system that tests driver proficiency and knowledge of safe driving practices, issues licenses to those who demonstrate adequate skill and who fill minimum requirements, and can revoke driving privileges for egregious unsafe actions. In this manner, three integrators – the manufacturer, the highway department, and the legal and regulatory authorities – each function as integrators. Collectively they integrate their subsystems into an automobile transportation system – truly a system-of-systems. These systems are not flawless in terms of safety, and neither is the collective system-of-systems; but, over many years the automobile industry has systematically addressed safety issues, incrementally showing improvement.

Similarly, healthcare and patient safety could benefit from multiple system integrators that further integrate collectively into a system-of-systems. Doing so would eventually eliminate the silos that exist today. Manufacturers could design and implement a technical architecture in which safety interventions are built into the system from the start. These manufacturers would integrate rather than merely interconnecting; consider, for example, an infusion pump and a ventilator. With end-user involvement, they would follow systems engineering best practices to develop integration across all technologies as well as procedures for use, support, sustainment, and training associated with the technology.

To complement the manufacturer's technical system integration role, a clinical practice's system integrator could implement a system of clinical integration. The American Hospital Association describes clinical integration as "the means to facilitate the co-ordination of patient care across conditions, providers, settings, and time in order to achieve care that is safe, timely, effective, efficient, equitable, and patient-focused."[62] Integrated technology can be a tool to help achieve this clinical integration; however, today's many silos between technologies, providers, and organizations lack meaningful connections and information exchange across healthcare entities.

For example, many office-based physicians practice alone or in small groups. A patient may see a number of office-based physicians but there is limited ability to share information between these care providers in a timely, complete, and robust manner. If information is shared across providers, it often happens because the patient hand-carries or verbally communicates this information from provider-to-provider. Without seamless co-ordination, patients are likely to receive duplicative diagnostic tests, have adverse prescription drug interactions, and get conflicting care plans.[63] This example highlights the need for a holistic system concept with integration across multiple dimensions spanning clinical practices and technology integration as well as factoring in social and business model dynamics.

The role of the system integrator cannot be discussed without the importance of test and evaluation. For complex systems such as healthcare, in which numerous systems are integrated, each system integrator must be responsible for integration of their constituent system, and collectively the systems must be tested together. Such testing is important because introduction of new capabilities is rarely done in isola-

tion – a change in one area may have known or unknown impacts in other areas. Only through holistic test and evaluation can these effects surface.

Front-line care providers can relate stories in which a new patient safety program ('system') that was supposed to improve the effectiveness or efficiency of care, was introduced into their care setting and actually made the situation worse. The details of the stories vary, but they often have a common theme: the new system was added without testing by actual end users in the specific operational setting for which it was developed.[64] This is a lesson other high-risk industries such as the US Department of Defense, the automobile industry, and others learned decades ago. The final stage of testing, before a system is introduced, is called 'operational acceptance testing'. It represents the opportunity for end users to exercise the system in the actual operational environment or a high-fidelity representation of the intended environment to ensure the system meets requirements.

The automobile industry is an excellent example of how this can be executed. This industry's regulatory bodies apply minimum safety standards before allowing vehicles to be marketed to consumers. Associated with these standards, vehicles are tested in standardized and controlled settings to test the limits of safety performance. Similarly, the aviation industry must qualify its aircraft before putting them into service.

Each of these examples speaks to the importance and value of testing and certifying new technology, processes, procedures and policies before introducing the new system. This testing is performed over an evolution of steps from controlled settings to, eventually, the actual intended operational setting. The end users are also involved in the testing and certification process throughout. This type of operational test and evaluation is holistic in nature in that it involves assessment across, for example, technology, training and procedures.

Rethinking healthcare as a safe and integrated system-of-systems requires drawing on the lessons learned from decades of safety progress in other industries including defense systems, automobile, aviation, and nuclear power. This is a daunting challenge for healthcare; however, history shows the barriers to overcome start with:[65]

- A clear definition of the healthcare 'system'.
- Clear integration and interoperability expectations or goals.
- Entities responsible for integrated safety aspects related to technical, legal and regulatory, business model, and other dynamics that form the healthcare system-of-systems.

A top-down holistic view of the envisioned future state of healthcare and patient safety is needed at the start, followed by prioritization of the initial tasks to tackle, and then a disciplined, methodical, and evolutionary progression from the current state to the desired state of safe healthcare. Similar to other industries, setbacks will arise; however, a committed group of system integrators, continually focused on the vision, can continually make progress toward the goal.

Gap 3: Risk assessment and performance reporting

Recommendation 3: Patient safety performance and risk reporting system require comprehensive and methodical analyses coupled with industry-wide learning and improvement similar to programs implemented in aviation and transportation industries.

While we know that patient safety is a critical issue, we do not have reliable data to tell us just how large the problem is. We do not know where the biggest problems are – either organizationally or in terms of specific safety issues – nor do we know where to focus attention. Finally, we do not have reliable data to tell us if our interventions are actually improving patient safety.

The need for a patient safety reporting system is not new; a number of healthcare reporting and learning systems have been implemented, such as the UK's confidential National Reporting and Learning System (NRLS). So, why is it that we still do not have reliable data to improve patient safety?

- There are no standards for what data to collect and how to collect it.
- There are too many individual reporting systems that do not share information.
- The focus tends to be on individual and organizational accountability (blame) rather than learning.
- There is a lack of analytic methodologies for making effective use of the data that does exist.

The automobile industry has a very effective safety reporting system. NHTSA data systems are the single source of real-world crash data for conducting basic research; identifying problem areas; developing effective countermeasures; identifying program and rulemaking needs; developing and evaluating programs, rules, and standards; evaluating new technologies; and providing information to accurately assess and allocate grants for reducing crashes.

It is important to note that NHTSA's data systems date back to the late 1970's. They have been developed and modified over the years to improve them and make them more efficient. The safety improvements that are a direct result of this data are too numerous to list. However, this tremendous success does not come free. As documented in a 2010 report to Congress, the NHTSA spends about $30–40 million annually to provide these data.

The Aviation Safety Reporting System is another good example. Reporting is voluntary, confidential, and focused on system improvements rather than individual blame (there is an 'immunity' policy that further encourages participation).[66] The entire aviation

industry, such as the airlines, air traffic controllers, manufacturers, and airport authorities, has access to the analyzed safety information.

The Aviation Safety Information Analysis and Sharing (ASIAS) Program has access to 185 different data sources including the Aviation Safety Reporting Systems. Each of the data sources provides information from different parts of the National Airspace System.

The Commercial Aviation Safety Team (CAST) uses the information provided by the ASIAS program to monitor known risks, evaluate the effectiveness of deployed mitigations, and detect emerging threats. CAST is a public–private partnership made up of three core teams: a joint safety analysis team, a joint safety implementation team, and a joint implementation measurement data analysis team. Operators, manufacturers, labor organizations, and the government appoint members to support these teams. The strength of CAST lies in its extensive membership, its proactive commitment to safety, and its ability to design and broadly implement strong system changes. CAST reports that by implementing the most promising safety enhancements, the fatality rate of commercial air travel in the United States was reduced by 83 percent between 1998 and 2008.[67]

Patient safety root cause analysis approaches are helpful to a degree; however, CAST has refined the process of conducting disciplined and methodical analyses, coupled with industry-wide learning and improvement to a degree much more comprehensive than what we generally see in patient safety.

Healthcare should consider the use of these risk management processes and tools as other industries have adopted them. Industries outside of healthcare have learned that safety must be systematic (in 'burning down' risk) and uniformly applied (across the total process). This process implies that the following takes place:

- Risk factors are identified and tracked (through subject matter expert analysis and data collection).
- Risks are tracked on a risk register (plotting probability of occurrence versus consequence).
- Best practices for eliminating risk are delineated and agreed to by the community, and are learned through the success of the local units.
- Data are collected (sometimes experimentally) and analyzed continuously.
- Policies and processes are then adopted or adapted across the community with an agreed-on compliance assurance mechanism that is more than a coalition of the willing.
- Impact is measured through global data collection.
- Failures are noted and analyzed to be ruthlessly eliminated (using failure review boards).
- Improvements are identified and the policies and processes are modified accordingly.

There is a catch. All of this requires transparency into local data and a perceived loss of autonomy. It does, however, provide a framework for continual assessment of the current factors that have an impact on patient safety, and leads to consumer trust in the system when patients are able to view these reports.

Gap 4: Patient safety regulation

Recommendation 4: Patient safety requires a regulatory body at the national/regional level empowered by law and strong enforcement mechanisms and associated standards of performance, robust data collection, and methodical analysis.

A regulatory agency is a public authority or government agency responsible for overseeing a particular activity. It is independent from the activity it is overseeing. Regulatory agencies are set up to implement and enforce standards, rules, or laws. Some are authorized to fine the relevant parties or order certain measures. One of their primary purposes is to reduce risk and ensure the safety of the population.

Various forms of regulation exist in the healthcare industry. Regulatory bodies ensure the safety and efficacy of devices and pharmaceuticals. Accreditation bodies license clinicians and care facilities. There are few examples of regulatory bodies that independently oversee patient safety implementations.

Examining the history, responsibilities, and enforcement methods of the NHTSA reveals many similarities between the issues of highway safety and patient safety. The NHTSA might provide valuable elements of a model to apply to patient safety.

The National Traffic and Motor Vehicle Safety Act gives the NHTSA the authority to issue vehicle safety standards and to require manufacturers to recall vehicles that have safety-related defects or do not meet Federal safety standards. Since 1970, more than 390 million cars, trucks, buses, recreational vehicles, motorcycles, and mopeds, as well as 46 million tires, 66 million pieces of motor vehicle equipment, and 42 million child safety seats have been recalled to correct safety defects.

Manufacturers voluntarily initiate many of these recalls, while others are either influenced by NHTSA investigations or ordered by NHTSA via the courts. If a safety defect is discovered, the manufacturer must notify NHTSA, as well as vehicle or equipment owners, dealers, and distributors. The manufacturer is then required to remedy the problem at no charge to the owner. NHTSA is responsible for monitoring the manufacturer's corrective action to ensure successful completion of the recall campaign.

What are the valuable aspects of the automotive regulatory example that could be applied to patient safety?

- Single regulatory body, established and empowered by law.
- Clear, measurable safety standards.

- Robust data collection and analysis capability.
- Strong enforcement mechanisms.

These factors can provide healthcare with the means to drive and positively influence patient safety by establishing expectations for stakeholders in the system. Specifically, the organizations and initiatives can impact attitudes, behaviors, respect, interpersonal relationships, communication styles, individual responsibility, and accountability – all of which can lead to increased patient safety and its awareness.

Gap 5: Transdisciplinary science for safety

Recommendation 5: Support the creation of research labs for healthcare that couple basic and applied research and development involving diverse fields of expertise. Support open business models for broad dissemination.

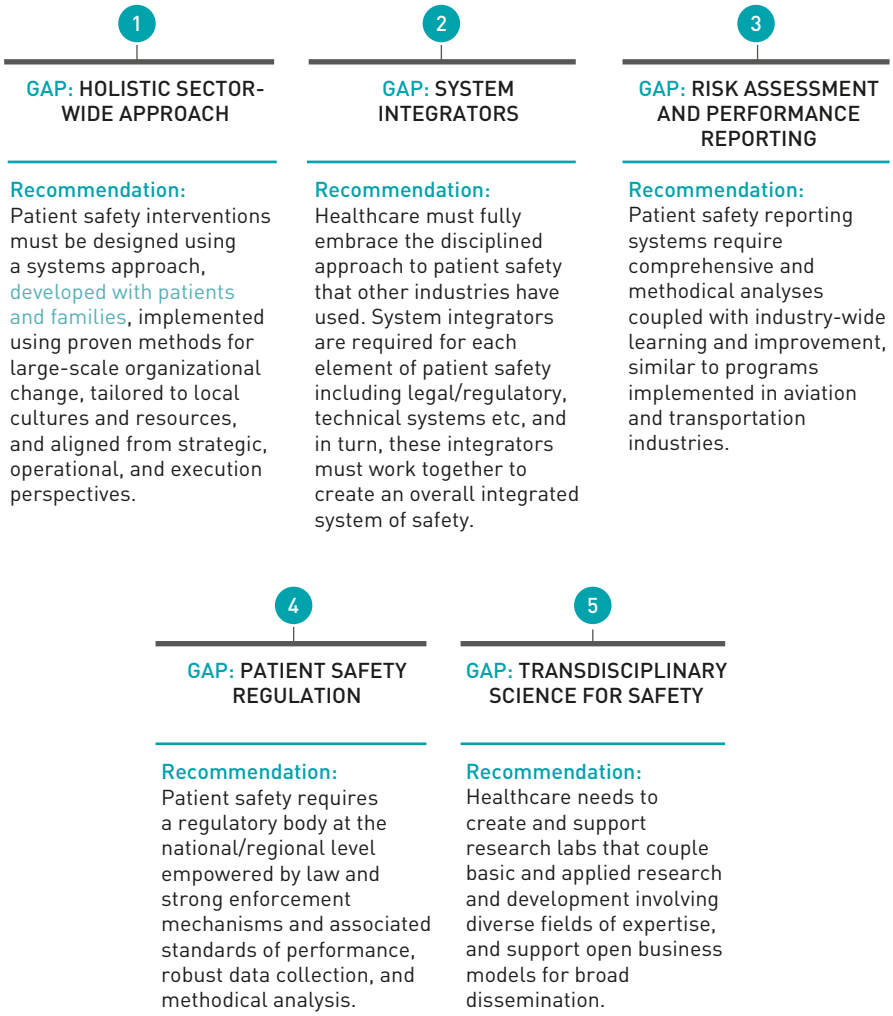
Patient safety requires the creation of laboratories for healthcare that couple basic and applied research and development, charged with solving tough problems. These laboratories must focus on solving problems yet also advance basic research through collaboration across diverse, transdisciplinary teams.

Too often healthcare research focuses on only one discipline and too often it assumes a linear approach from basic to clinical research.[68] Yet large breakthroughs emerge by combining applied researchers with basic researchers to solve tough problems from conceptualization through prototyping to realization. Such laboratories are possible in healthcare, but approaches require financial support to hold the groups together. These research laboratories should collaborate with system integrators (similar to industries outside of healthcare) to create a pathway from basic research to applied engineering, and should support open business models for broad dissemination.

NEXT STEPS

To bring about the widespread changes required in patient safety, the global healthcare community will need to acknowledge the gaps in Figure 6 and develop a plan (within a systems context) to address each issue. The plan can, and should, leverage ideas from other safety-conscious industries to bring about the desired end results. Because this paper is focused on a holistic system solution, and not specific individual solutions directly, the following next steps are proposed as mechanisms to: (a) address patient safety concerns at the global and national level, and (b) develop a framework that can be tailored for implementation at the various local levels, in consideration of influencing factors such as resources and culture. Note that these proposed actions are meant to provoke thought and are not meant to be detailed action plans.

Figure 6: Summary of system level healthcare gaps



We propose four initial steps to position and prepare the healthcare community to move forward:

1. Develop a patient safety declaration and have nations pledge commitment and resources.
2. Convene a panel of transdisciplinary subject-matter experts to classify and quantify the appropriate definitions and metrics for preventable patient harms, to ensure consistency in tracking and reporting throughout the global healthcare system.
3. Engage the systems engineering community to help describe the various constructs for the multiple system integrators (and their associated responsibilities) that are needed in the healthcare system.
4. Identify candidate nations and local organizations, representing varying levels of industrial and socio-economic development. Work with relevant stakeholders in those systems to create concepts of operation (CONOPS) and requirements for holistic patient safety solutions that are tailored to their specific culture and available resources.

In parallel, each nation might consider its plans for policy and regulation, and other means to incentivize the desired outcomes and behaviors of the various stakeholders.

Each of these efforts requires strong collaboration and partnerships to accomplish the immediate goal, and position healthcare for the road ahead. Collaborative tools and techniques need to solicit input from many relevant stakeholder vantage points, analyze and aggregate the perspectives into coherent themes (within a systems context), and formulate a roadmap for the healthcare system being explored. The roadmap can then be used to identify projects and participants who can help affect the changes, guide the implementation, and assess the system performance and utility with respect to the relevant metrics. A recurring meeting, perhaps as part of future WISH events, could be planned to provide an update on the various patient safety projects and initiatives.

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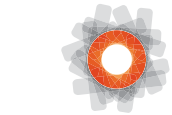

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