Institute *for* Healthcare Improvement

**Innovation Project Final Report:**
**Patient Safety – Next Generation**
**Wave 60 I July – September 2021**

**Project Type:**

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| ***90-day Innovation Project:*** **A full wave to scan, test, and document recommendations in a formal deliverable** | *30-day Innovation Project:* A short project to scan, provide research assistance, or design an expert meeting | *Content Development:* A full wave of research support with the potential for continued support |

**Executive Summary:** Health care safety is not making the progress that we think is possible. The intent of this project is to explore advancements in safety.

We have identified a set of ideas that will be discussed in this paper that are influencing our recommendations:

Definitions of safety
Thinking of safety in isolation
Moving away from a narrow focus on projects
Understanding the complexity of health care
Simplistic reliance on ideas from other industry

The following are four recommendations that will be discussed further in this paper.

Safety is not just a series of projects, it requires a systems transformation approach.
Patient and staff safety need to be seen as part of the same system of work.
No safety without equity - the specific harm of inequity needs to be seen and managed.
Situational risk awareness is a key driver of safety. Lack of awareness is the cause of increased risk.

**Team:**
John Whittington, Lead
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Institute for Healthcare Improvement

## Intent & Aim

Health care safety is not making the progress that we think is possible. The intent of this project is to explore advancements in safety:

By harvesting a set of ideas and principles from safety experts outside of health care.

By exploring how existing IHI safety content is being applied and identifying advancements and challenges in patient safety within health care.

The aim of this project is to explore what concepts and practices are currently improving safety outcomes for organizations. The research team will prioritize advancements outside of health care with the goal of translating other industry best practices into the health care environment. The research team expects more than one innovation wave to allow this wave to focus on vetting safety ideas and then a subsequent wave to focus on validating applicability in health care settings.

## Background:

Much progress has been achieved in patient safety, but we still have significant opportunity to make improvements. For example, in 2015 the National Patient Safety Foundation (NPSF) convened an expert panel to look at improvements and opportunities in patient safety since the initial report by the Institute of Medicine (IOM), To Err Is Human: Building a Safer Health System. The panel said, "the expectation at the time was that expanded data sharing and implementing interventions to solve specific concerns would result in substantial, permanent improvement. In the intervening decade and a half, it has become increasingly clear that safety issues are far more complex—and pervasive—than initially appreciated."[1] In a recent book, Still Not Safe by Robert Wears and Kathleen Sutcliff, they assert that what we did learn from outside expertise was too shallow. For example, we talked about systems of safety, but when you analyze the interventions, they are basically at the individual level instead of true system thinking. And when you look at the individual level, you see that healthcare thinks about errors that humans make instead of errors within the system.

Just because we have not achieved all that we want, we cannot abandon all that we have. The opportunity is to repurpose and reinforce the need for a strong foundation on which to build.

## Description of the Work

During this innovation cycle the team relied on traditional research methods including literature review and expert interviews. The following experts were interviewed during this wave:

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|---|---|
| Jennifer P. Stevens | Director, Center for Healthcare Delivery Science<br>Beth Israel Deaconess Medical Center |
| Gökçe Sargut | Associate Professor<br>Governors State University |
| Skip Grieser | FAA |
| Jim Bagian | NASA |
| Steve Spear | Lean Principles |
| Sandip Godambe | Vice President of Patient Safety and Quality, King's Daughter Children's Hospital |
| Terry Fairbanks* | Vice President and Chief Quality and Safety Officer, Medstar |
| Gregg Meyer , | Member, Lucian Leape Institute |
| Ron Wyatt | Vice President and Patient Safety Officer, MCIC Vermont |
| Cynthia Barginere | Chief Operating Officer, IHI |
| Bruce Spurlock | President and Chief Executive Officer, Cynosure Health |
| Kaveh Shojania | Scientist, Evaluative Clinical Sciences, Veterans Research Program, Sunnybrook Research Institute |
| Komal Bajaj | Chief Quality Officer, NYC Health and Hospitals/ Jacoby |
| Christopher Derienzo | WakeMed and Airline Safety |
| Bob Wachter | Member, Lucian Leape Institute |
| Charles Vincent | Experimental Psychology, University of Oxford |
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*Experts contacted during this wave and expected to interview during following wave.

**Discussion and Recommendations:**

*Discussion*

There are a few interrelated ideas that we want to discuss initially before we make our recommendations for advancing patient safety:

Discuss definitions of safety

Thinking of safety in isolation

Moving away from a narrow focus on projects

Understanding the complexity of the health care

Simplistic reliance on ideas from other industry

First, how do we define safety? The answer to this question will influence an organization approach. Safety is often framed as the absence of harm, but another approach is "to increase the number of acceptable outcomes."[2] One frames it negatively and the other positively. To say it another way: are they designing care from the beginning to produce the best possible outcome or are they trying to prevent harm? And along this same line, what is their goal? Health systems often describe the goal of achieving "zero harm" – an aspirational aim that all health systems can strive for yet none can achieve. The nature of providing care accepts that some harm will always exist. In the short term perhaps the most effective way to achieve zero harm is for health systems to close their doors and not provide any care. But no sensible system would do this. Working towards zero harm is reasonable and we must recognize it is impossible to achieve in all situations every time. What we are really trying to achieve is both the best feasible outcome in all situations.

A duality of thinking of safety as both the absence of harm and the best feasible outcome helps us to see that safety needs to be coupled to quality. And as we stratify our data by various demographic indicators, we recognize that there are differential outcomes for various groups. There is no comprehensive quality without equity. Therefore, any health system that wants to transform safety cannot do it in isolation. A coordinated effort is needed between quality, safety and equity staff in any organization.

Organizations are looking for a set of straightforward projects that would make health care outcomes safer. And for many years, that was often what we provided: do this training, do this project and your system will be safer. Both training and projects can help, but it is doubtful that they will be transformative. "Disguising complex problems as simple problems by offering apparently "simple" solutions does not really make the problems any simpler. It only makes it more likely that the solutions will not work."[3] Healthcare organizations are complex organizations dealing with humans who are

complex beings. In the past we have tried to manage both the organization and the person as if they were just a complicated engineering problem.

For example, anesthesia has made some of the most important progress on patient safety in health care.[4] Advocates for patient safety could have simply pursued better anesthetic machines (an engineering solution) to address avoidable harm when using anesthesia. Instead, anesthesia specialists devised a set of simple rules to guide their improvement:[5]

1. Train, educate, and supervise.
2. Use appropriate monitoring instrumentation and vigilance.
3. Recognize the limitations influencing individual performance.
4. Establish and follow preparation and inspection protocols.
5. Assure equipment performance.
6. Design and organize workspace.
7. Act on incident reports--eliminate the pitfalls.

The above rules are just for illustration purposes. They move us away from the notion of just working on projects to working on design principles that are better for complex adaptive system management and lead to  better health outcomes. The ideas behind complexity theory expand on this notion:

> [Previous] efforts assumed that complicated phenomena could be understood by analyzing their constituent parts, when in fact the sum of the whole was greater, and more complex than the sum of the individual parts. Consequently, reforms modified one or two elements in a system apart from related elements, assuming that these actions would produce the intended outcome through a linear, cause-and-effect relationship... Complexity theory draws attention to the evolving interrelationships among system elements at various levels of the system. It offers a means to analyze emerging patterns and trends to illuminate how the disparate system parts are, or are not, working together[6]

Others often say that health care should learn from outside industries. We believe this is true and there are limitations to what can be learned and applied. Airline safety is used as an example – let us compare for the moment. The airlines ground planes because of weather, fatigue, IT problems, etc. and so do other businesses. Airlines only deal with a few different aircraft. (There are about 7000 in commercial use but just 10 aircraft make up about 60% of the total.) Hospitals, on the other hand, maintain operations through

natural disasters (i.e., Hurricane Ida in New Orleans, Louisiana) and rely on a tired and understaffed workforce overflowing with thousands of unique complex human beings.

Health care is so different from everything else that the way forward requires unique solutions. With all that said, we are not going to offer this organization just a set of projects to work on. **What will we offer? That is simple: the best feasible outcomes for all patients.** From the article, *Managing Risk in Hazardous Conditions: Improvisation is not enough:*

> "...We must in a sense, give up hope of waiting for things 'return to normal'. We can of course continue to innovate and improve the system. However, we must face the fact of unsafe practice and ask how risk can be minimized in essentially dangerous conditions."[7]

Focusing on best possible outcomes in the face of ever-present risk is necessary for health care delivery. This insight feels truer than ever in the context of the last 18 months of the global COVID-19 pandemic. It is especially insightful given its publication before the pandemic in 2019.

*Recommendations*

In this section we will discuss these four items which form the core ideas on how to move patient safety forward:

1. Safety is not just a series of projects, it requires a systems transformation approach
2. Patient and staff safety need to be seen as part of the same system of work
3. No safety without equity - the specific harm of inequity needs to be seen and managed
4. Situational risk awareness is a key driver of safety. Lack of awareness is the cause of increased risk.

*1. Safety is not just a series of projects;* it requires a systems transformation approach. To start this work there are a set of **prerequisites** that are needed: board engagement, leadership alignment, front line involvement and a learning system.

Many health care organizations start on this journey only to have a CEO transition resulting in the journey's end. Organizations that are serious about this work must commit for the long haul. This requires strategic direction and planning from the board

with their current executive team *and* consistency for all future executive teams. Without the board commitment to the work and succession planning, this journey is made in vain. Boards steady long term strategic direction for organizations and typically focus on vitality, reputation, and outcomes. Many boards make meaningful commitments to safety, quality, and equity. Truly committing to a forever journey on safety requires boards to recognize the interdependence of safety, quality, and equity.

Building the will for a forever journey on safety is a human centered, adaptive challenge. Elevating safety beyond a project-based priority and to a long-term organizational principle requires behavior change and must address the culture of an organization. Boards can ensure this focus stays consistent across leadership transitions within health systems. IHI has a comprehensive assessment tool that any board can use to help work on a safety, equity, and quality journey along with an accompanying white paper. Also, there are a series of short videos that accompany the white paper that can be used for teaching purposes with the board.

If bringing the board along is a key prerequisite, equally as important is the executive team. We do not think it is possible to focus on safety by itself. The executive team needs to see health care quality and equity as strategic too. When you go back to the possible definition of safety, we are not just trying to minimize harm, we are also trying to achieve optimal outcomes. To get optimal outcomes, we are going to need stabilized processes. Just as safety can be wrongly looked at as a series of processes, quality is too often considered a set of tools. Steve spear explains:

> Lean Production, as an approach to managing complex operations was introduced more than 30 years ago. Yet, despite decades of Lean thinking and practice, the utter dominance of its industry by Toyota (the inspiration for lean), and the well-documented gains by those enterprises that have practiced lean in a high fidelity fashion, Lean is often viewed as a shop-floor skilled trade, to be assigned to subject matter experts in staff (not line) roles; and conducted through programs and initiatives rather than as fundamental to the means and methods of the firm.
>
> A key reason is that Lean in particular, and other methods of achieving outstanding operations more generally, are primarily taught as the practice of tools and techniques—and not as a complete, coherent system of thinking that addresses the strategic concerns of senior leadership.[1]

The failure of the application of Lean in many industries is the result of the adherence to tools without considering the enabling environment to ensure success (ie. psychological

[1] Steve Spear Why Doesn't Lean Have a Seat at the Table? https://www.lean.org/LeanPost/Posting.cfm?LeanPostId=1085 accessed on September 9th

safety, team building, trust, communication). IHI is certainly not the first organization to recognize this and others have been working on solutions to this problem. IHI has developed a comprehensive approach for executives which we think is helpful. We call this approach Whole System Quality A Unified Approach to Building Responsive, Resilient Health Care Systems.

A third prerequisite is the engagement of frontline clinicians and staff. The classic example of frontline work is the example we discussed earlier about the work of anesthesiologists to dramatically improve their field. In the IHI white paper, Engaging Physicians in a Shared Quality Agenda, there are six main ideas: discover common purpose, reframe values and beliefs, segment the engagement plan, use engaging improvement methods, show courage as a leader and adopt an engaging style. This white paper should be part of the plan if we are going to make quality, equity and safety strategic. But even a well written document like this is not the only way to engage clinicians and staff. The key is to decide that to move forward you need to engage all frontline personnel where it makes sense. If the problem is primarily one of pharmacy, then engage pharmacists, or a nursing problem, engage nursing or the same for physicians. If the problem crosses boundaries, then engage all that are needed. But don't avoid one group because they are hard to work with. We have seen too much working around physicians in the past. To be safe we need to engage the entire organization.

The final prerequisite is a learning system. Any transformation to full system change requires a robust learning system There are seven items to consider for a learning system:

1. System level measures. Effective measures for safety need to address past, present, and future safety. Most measures of safety or quality look to the past, (e.g. how many adverse events during the past month, how many musculoskeletal injuries did employees have). Measures of the current situation should focus on day-to-day operations. Consider the ICU scenario discussed under risk. That is an example of day-to-day operations. Every unit in the health system could do an assessment like that to understand risk/operation. This could be aggregated for the whole facility to get an overall level of risk for the system. Hospital level measures of acuity and staffing have existed for a long time. Could they be used in a new way to assess the current safety risk? The final measure is probably hardest of all – how safe we will be in the future? And, how should we consider the short-term future and long-term future? In the short-term, how safe will a ward be on the next shift (using some of the operational measures

discussed above). For the long-term, measures like training requirements, financial allocation, succession planning for safety leadership etc. will be useful.

One area of measurement that we want to discuss is safety reporting/incident report and root cause analysis. These were adopted from other industries, but the number of safety problems and reports can become overwhelming. The burden of reporting safety events and the analysis of those events creates a significant burden on the personnel in the healthcare system. Additionally, hospital incident reporting systems do not capture most patient harm.[2] We haven't determined that this is the best use of organization time. We suggest that we revaluate both of these standard practices in safety as we work on transformation.

2. Segmentation of the population when it comes to safety issues. What this will look like practically is data stratification of your system level measures. Stratifying the population is necessary to understand the burden of harm experienced by different people in the same system. Stratification allows health systems to understand the ways in which their care delivery works – or doesn't – for people of different race and ethnicities, genders, ability status, insurance status and other demographic factors that matter for access, treatment, and outcomes in health care.
3. Have an explicit theory or rationale for system changes related to safety.
4. If you have an explicit theory or rational for change, you can then learn by testing changes sequentially. You can use some form of plan, do, study, act cycles to build knowledge progressively.
5. As you gain confidence in your changes, you will probably want to take them to scale which then requires further learning. For some problems, you might consider 5x scale up. You start with 5 people and test your ideas. Next increase to 25, then 125 etc. Each jump of 5x may require a slightly different strategy until you reach your goal. The idea is that instead of planning for full scale without insight you can learn from each 5x scale up.
6. In regard to explicit theory or rationale you may need to come up with some new ideas on how to approach the problem. One idea is to use informative cases: "Act with the individual, learn for the population." Often when solving a problem for one person you can discover ideas that can be used for the whole population.

[2] Hospital Incident Reporting Systems Do Not Capture Most Patient Harm, Department of Health and Human services

Another important resource are patient and family councils. Hearing the inputs from this structure needs to be incorporated into the learning system.

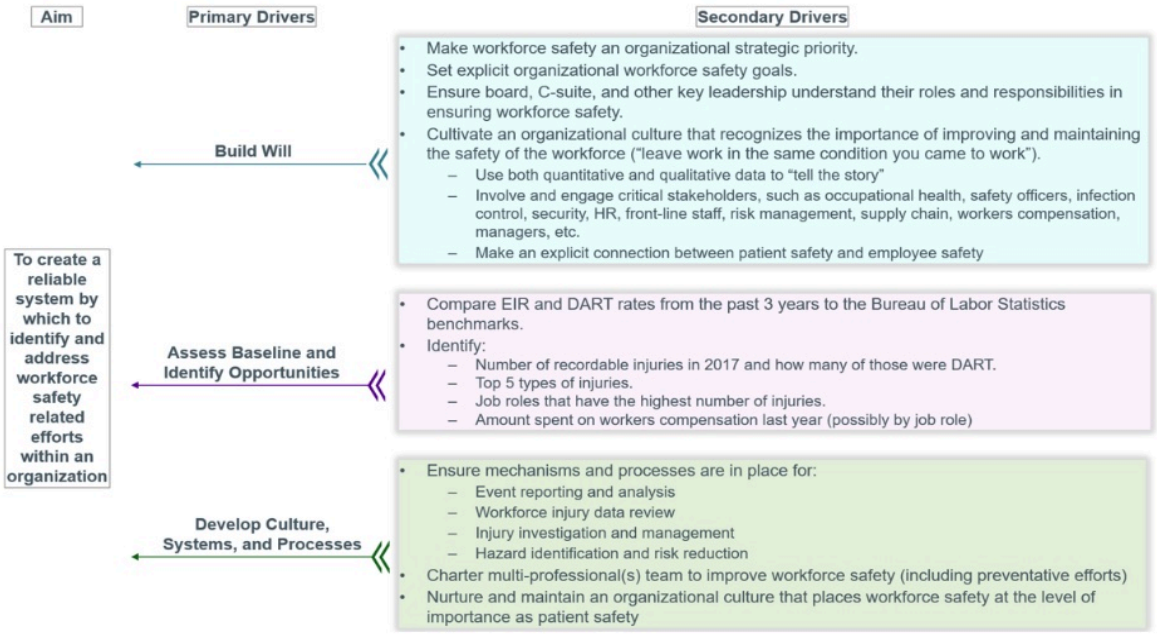
7. The learning system needs to have periodic review of all of the above. This could be done weekly, monthly or quarterly. The organization needs to provide accountability for all of this work and part of that is accomplished through periodic review.

Now that we have discussed these prerequisites what else should we consider for system transformation. Healthcare tends to put too much burden on individuals when it comes to patient safety. We often say we are doing a systems approach but when you evaluate the design it is still based on a set of policies that need to be executed perfectly by individuals to prevent harm.

It is not easy to develop a robust system approach in healthcare but it can be done or at least we can move further away from a person-centered approach. For example, one of the authors is a primary care physician who for all of his time in practice managed all his patients who were on coumadin. Since then, two things have occurred one is much safer anticoagulants that don't require management and for those who can't afford these new drugs there are coumadin clinics that are managed with set protocols. In both examples there is still a significant human element involved but they each involve a systems approach. You might say, weren't those changes just projects. And the answer is certainly a coumadin clinic is a project but for it to be successful you need leadership support for resources and to get all the clinicians involved so that they use the clinic or prescribe the new anticoagulants.

**2.** We can no longer afford to differentiate and compartmentalize patient safety and employee safety. They are all linked together. When Paul O'Neill was CEO of Alcoa, he focused on workforce safety to transform the entire business. MemorialCare In California is explicit about this in their COVID Command Center Principle #1 – *Keep our staff and physicians safe, so that we can take safe care of the patients we serve*. The ideas that can keep employees safe are also ones that help patients. Safer Together, the National Action Plan to Advance Patient Safety, identified workforce safety as one of the 4 key elements. For several years, the Leadership Alliance within IHI has been working on workforce safety. They have shared data and developed a framework that they used to improve workforce safety.

Figure 1: Year 6 Workforce Safety Workgroup: Working Theory of Change and Foundational System Pillars




Reviewing these primary drivers around will, opportunities, and culture for workforce safety makes it clear that each driver also could apply to patient safety. Once you dig into the specific opportunities, there will be some that work for both and some that are unique for each group. Patients and employees need the same support from the board and the executive team.

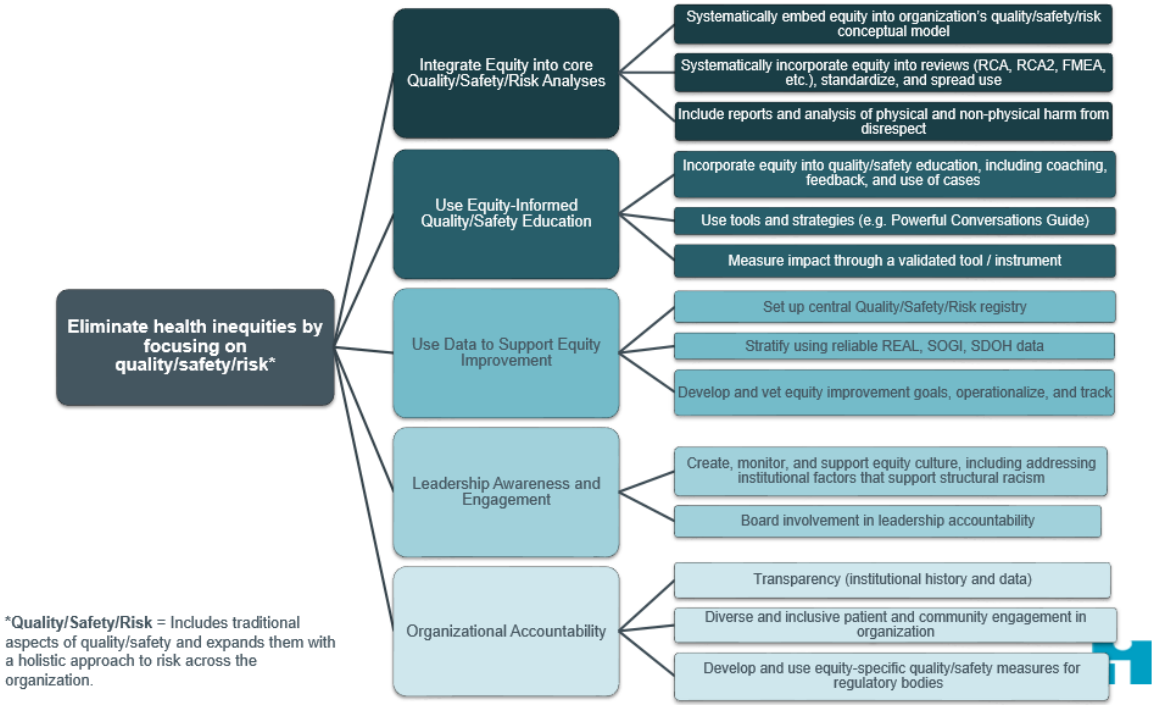
**3.** There is and has been a lack of equity focus on safety. Health care organizations at large are more seriously focusing on equity as core to their work. In 2016, IHI published Achieving Health Equity: A Guide for Health Care Organizations. This paper focused on 5 ideas: make equity strategic, develop structure and process to support the work, work on the multiple determinants of health, decrease institutional racism and discrimination and develop partnerships with community. Since its publication, many health systems have embraced this framework. It is a good starting place for safety work, but it needs more to help it. Therefore, IHI had a research team spend a year thinking through health care safety and equity.

That team had specific safety recommendations.

- Incorporate equity into reviews such as RCA$^2$ or FMEA
- Use Equity-Informed Quality/Safety Education
- Use Data to Support Equity Improvement
- Leadership Awareness and Engagement

- Organizational Accountability

Figure 2 Driver Diagram for equity in patient safety




4.Situation risk awareness is important to provide a safe environment within the health system. For example, imagine an ICU physician. First, the physician needs to understand how sick each patient under their care is. To do this, many providers rely on algorithms that calculate a sickness/risk score for each patient. Secondly, you need to understand the risk for the unit. Right now, with ICU's overflowing with very sick COVID-19 patients, unit-based risk is at a higher sustained level than before the pandemic. ICU nurses are taking care of 6 patients compared to their normal one-to-one care ratio. Finally, risk for the whole hospital must be accounted for. Patients crowding emergency departments in hospital systems that do not have capacity in the appropriate units to admit additional patients creates patient safety risks. Achieving Hospital-Wide Patient Flow makes it clear that delivering the right care, in the right place, at the right time, and with the right team is necessary for safe, quality, and equitable care. Understanding the various levels of risk – at the individual patient level, the ward level, the system level, and the community at large level – is necessary to effectively produce the best possible outcomes in care delivery. Safety is a state of being that can change minute by minute based on variation in relative risk within the system.

As noted, many interventions from other industries have been adopted in health care. One such intervention is the use of tiered huddles to identify risk issues. IHI has advocated the use of huddles starting with our work to improve medication safety. However, over the many years that this intervention has been available, it is only lately, with the focus on HRO, has there been an uptake. Observations about the effectiveness of the huddles either through direct observation or as part of an assessment process reveals that they are not used as intended. The capability and capacity for effective huddles has not been fully implemented. However, we believe this tool provides a unique opportunity for health care if implemented effectively. But no single tool can do it all. For example, there is dynamic risk that occurs at different time during the day that will not be captured by the scheduled huddle process as is now employed. This dynamic risk is often not considered because it is either not known or staff are not trained or equipped to think in ways that surfaces risk awareness.

Unlike other industries, health care does not have the luxury of shutting down as contextual risk changes unexpectedly (ie. due to natural disaster, crisis events, etc.). It must manage risk as it moves forward. The COVID-19 pandemic highlights how individual and community risk factors influence the severity of symptoms, likelihood of hospitalization, degree of treatment received, and mortality in the hospital.[3] Hospitals that serve populations with heighten risk factors experience greater demand and strain on their health systems.[4] To be clear, the ICUs are not always as dire as the above picture paints, but there are everyday risks that always need to be considered about the patients, staff, unit, and organization that could impact the health of both staff and patients.
Rene Amalberti and Charles Vincent describe an approach to managing risk in hazardous conditions in a BMJ Quality and Safety viewpoint piece:

- First, we must in a sense, give up hope of waiting for things 'return to normal'. We can of course continue to innovate and improve the system. However, we must face the fact of unsafe practice and ask how risk can be minimised in essentially dangerous conditions.
- Second, we must accept that we can never eliminate all risks and hazards. There is nothing wrong with eliminating risks where this is feasible we need to balance these preventative actions with a wider

[3] Individual and community-level risk for COVID-19 mortality in the United States, Nature Medicine, December 2020

[4] Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Delivery: Results of a National Pulse Survey February 2021, US Department of Health and Human Services

portfolio of safety strategies that are explicitly aimed at managing dynamic threats and pressures.

- Third, although most of the literature on adaptation focuses on the management of surprises and unexpected problems, we believe the principal focus should be on expected problems and hazards. Pressures of beds, staffing, equipment and sick patients are unexpected in that it is hard to know when they will happen but entirely familiar. These situations are quite different from sudden, unexpected and unusual crises that are the focus of much of the literature.
- Finally, we must acknowledge from the start that the management of risk when an entire unit or organisation is stressed necessarily requires engagement and action at all managerial levels. Negotiating new priorities, comprehensive training and strategies in a stressed organisation requires coordinated action between executives, middle management and frontline staff."[5]

One comment, it is true that many health systems have a risk department. However, these departments are almost all focused on financial risk from malpractice/harm claims. This focus is inadequate to create a system that addresses risk in service of achieving the best possible outcomes.

Finally, the authors note that there are larger system changes needed such as policies that address issues in the community, legal and accreditation requirements that may drive activities in certain areas, financial pressures that impact resourcing, and the impact of new technologies and how care is delivered. The recommendations outlined are applicable in all settings. Some of the influencers are outside the scope of this work. Others may influence policy indirectly such as ability to greatly reduce specific hospital acquired conditions which resulted in altered reimbursement from CMS and other insurers.

**Next Steps**

The innovation team plans to take the learning from Wave 60 – which focused on big picture, high level thinking about the current state of patient safety – and drill down to more specific patient safety approaches in Wave 61. Currently, the research team believes several key areas stand out for improvement in the patient safety field:

[5] Amalberti R, Vincent C. BMJ Qual Saf 2019;0:1–4 Managing risk in hazardous conditions: improvisation is not enough

increasing the focus on human factors, more effectively addressing risk, and increasing the ability of health care teams to problem solve up stream.

Additionally, the research team is interested in understanding where this content can go for patient safety. Currently, health care leaders often take a piecemeal approach to capability building. For example, a mid-level manager on a leadership track may attend a professional development program on patient safety and not spend similar amount of development time on quality, equity, flow, etc. An opportunity may exist for IHI to create a curriculum-based program for health care professionals on the leadership track. This program could tie together the best thinking in safety, quality, equity, and other content areas for an “executive health care leadership” style credential.

**Open Questions:**

- Are we differentiating this approach enough from HRO and other LEAN approaches that makes this work standout?
- Who are the experts that need to be brought in to HC to guide organizations in this different approach?
- Are there both small-scale and large-scale initiatives/offerings that will draw different audiences to IHI?