Institute *for* Healthcare Improvement

Innovation Project Final Report:
Next Generation Patient Safety: Risk and Equity
Wave 61 – December 31, 2021

Project Type:

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:

This is the second wave focused on the next generation of IHI's approach to health care safety. This effort concentrated on understanding the relationship between equity and patient safety as well as the role that human factors expertise can play in minimizing risk. Our team relied on traditional research methods and focused primarily on US based hospitals and health systems with key insights from NHS in Scotland. The key findings include:

- Equity – several health systems are beginning a testing effort regarding a system-wide approach to equity. This approach was developed by previous IHI research efforts and is currently being tested. The approach focuses on implement change ideas across the entire system including: will building, strategic guidance, and leadership accountability; improvements to day-to-day operations; and, educational and culture change. The approach is rooted in previous organizational changes to patient safety. And, the measures are embedded in existing patient safety measurement systems.
- Human factors and risk – the role that human factors expertise plays in health care is growing. Yet, health care lags behind other industries focused on quality in utilizing human factors expertise. Currently, human factors experts are most frequently deployed to project-specific improvement efforts and have minimal impact at transforming quality and safety for an organization. However, promising frameworks like the SEIPS model (discussed below) and dedicated leaders across the industry are growing the influence of human factors expertise. This is an area of growing interest for the IHI research team and a worthwhile space for further exploration.

Team:
John Whittington
Frank Federico
Alex Anderson

Intent & Aim:
This is the second wave of work on the next generation of IHI's approach to health care safety. We concentrated on two ideas:

1. **Equity** – to better understand the interdependence of equity and safety work while identifying promising approaches to improvements in safety that lead from a focus on equity. This builds on Wave 53's *Health Inequity is a Patient Safety Emergency*.
2. **Human Factors and Risk** – In this wave we explored human factors and risk.

Background:
In wave 60, we discussed an approach to safety focused on four ideas:
1. System transformation (involving the board, engaging executive leadership, involving the front line to lead, and implementing a robust learning system)
2. Safety is one – eliminating the separation between workforce safety and patient safety. Organizational alignment includes sharing data between human resources and patient safety teams.
3. No safety without equity – the specific harm of inequity needs to be seen and managed.
4. Situational risk awareness, hazard identification, and human factors needs a greater role in health care safety.

To be sure, the above does not negate the great past work on health care safety. We see this current work as building on top of the culture of safety paradigm of the last 20 years.

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:

Terry Fairbanks, MD MS Vice President and Chief Quality and Safety Officer, MedStar Health System	**Pascale Carayon, PhD (retired)** Former Director of Wisconsin Institute for Health Care Systems Engineering, University of Wisconsin
Tam Duong, MSPH Director of Quality, Safety, and Equity, American Medical Association	**Jeff Brady, MD MPH** Director, Center for Quality Improvement and Patient Safety, AHRQ
Karthik Sivashanker, MD MPH Vice President of Equitable Health Systems and Innovation, American Medical Association	**Paul Bowie, PhD** Director and Owner, PSL Safety and Human Factors Ltd
James Won, PhD Human Factors Program Manager for the Center for Healthcare Quality and Analytics at CHOP	**Erin Lawler, MS** Human Factors Engineer, Office of Quality and Patient Safety, The Joint Commission
Raji Thomas, PhD Director of Safety, The Joint Commission	**Derek Mazique, MD** Associate Chief Quality Officer, New York-Presbyterian Hospital

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Ed Pollak, MD FASA CPPS Chief Quality Officer and Associate Chief Medical Officer, Henry Ford Hospital	**Bruce Spurlock, MD** President and CEO, Cynosure Health
Blan Godfrey, PhD Former IHI Board Member	**Gregg Meyer, MD MSc** President of the Community Division and Executive Vice President of Mass General Brigham's Hospitals (Newton-Wellesley and Salem Hospital)
Kevin Weiss. MD MPH Chief Sponsoring Institutions and Clinical Learning Environment Officer, ACGME	**Suzanne Gavigan, MSN** Patient Safety Specialist, The Joint Commission
Bonnie Mason, MD Vice President, Diversity and Inclusion, ACGME	**Joy Rivera, PhD** Senior Human Factors Systems Engineer, Children's Hospital of Wisconsin

Additionally, several sessions at the 2021 IHI National Forum were helpful contributions to this work and are referenced in the footnotes.

Results:

In wave 60, we identified three issues for further development:
- unifying patient safety and workforce safety
- equity issues within safety
- situational risk awareness at all levels of the organization.

Additional research is needed to unify patient and workforce safety. And, we elected to focus on two topics for this research cycle: equity and situational awareness.

Equity and Safety

In 2019, an IHI research team (Karthick Sivashanker MD, Brigham and Women's; Tam Doung MPH and Dorian Burks MPH, IHI) spent a year focused on equity and safety. They developed a framework and set of changes which were foundational for Wave 60's innovation report.[1] The following change ideas are well-aligned with our current patient safety work:

- Systematically embed equity into an organization's quality/safety/risk conceptual model
- Systematically incorporate equity into reviews (RCA, RCA2, FMEA, etc.), standardize, and spread use (Discuss any bias or structural inequities that contributed to this case.)
- Include reports and analysis of physical and non-physical harm from disrespect (ie. individual forms of bias, bigotry, and discrimination)

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[1] Health Inequity is a Patient Safety Emergency Wave 53 December 2019 IHI Innovation Series

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- Incorporate equity into quality/safety education, including coaching, feedback, and use of cases
- Use tools and strategies (e.g. Powerful Conversations Guide)
- Measure impact through a validated tool / instrument
- Set up central Quality/Safety/Risk registry
- Stratify all data using reliable REAL, SOGI, SDOH data
- Develop and vet equity improvement goals, operationalize, and track progress
- Create, monitor, and support equity culture, including addressing institutional factors that support structural racism
- Board involvement in leadership accountability
- Transparency (institutional history and data)
- Diverse and inclusive patient and community engagement in organization
- Develop and use equity-specific quality/safety measures for regulatory bodies

Karthik and team also developed a four-level measurement framework for equity and health systems some of which is applicable to patient safety.

1. **Access** refers to whether patients can even gain entry into the health care institution. One way to measure access is to calculate the difference between the percent of Medicaid patients treated by a health care institution and the total percent of Medicaid recipients in service geography for the health system.

2. **Transitions** refers to whether patients will be offered the services they need to fully thrive as they transit the health care system.

3. **Quality of Care** refers to the clinical outcomes and associated process measures of care delivery. Most institutions focus primarily on this level without addressing other two lower-level measures, which addresses more structural discrimination and inequities.

4. **Socioeconomic/environmental impact** refers to the vitality and broad socioeconomic and environmental conditions in the neighborhoods and communities served by the institution. This includes the organization's responsibility to impact: 1) the neighborhood's economy, which can be measured as the percent of supplies or services a health care organization obtains from minority-owned businesses in the local community; 2) social conditions, which can be measured by pay/wage of employees from neighborhood and/or the percent of employees sent to collections; and 3) the environmental impact of the intuition, as measured by reduction in greenhouse gas emission.

NYC Health + Hospitals is another organization focused on equity and patient safety.[2] They recommend "a proactive approach to continuously investigate, catalogue, and monitor for bias as a contributing factor at: the interpersonal level (i.e. explicit bias), the human behavioral level (i.e. implicit bias), the institutional level (i.e. policies and practices), the structural level (i.e.

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[2] From Theory to Impact: Ingraining Health Equity Into Quality/ Safety at NYC Health and Hospitals. IHI forum A03 presentation. Komal Bajaj, MD, MS-HPEd, Linelle Campbell MD, MS, Louis H. Hart III, MD, Eric K. Wei, MD, MBA
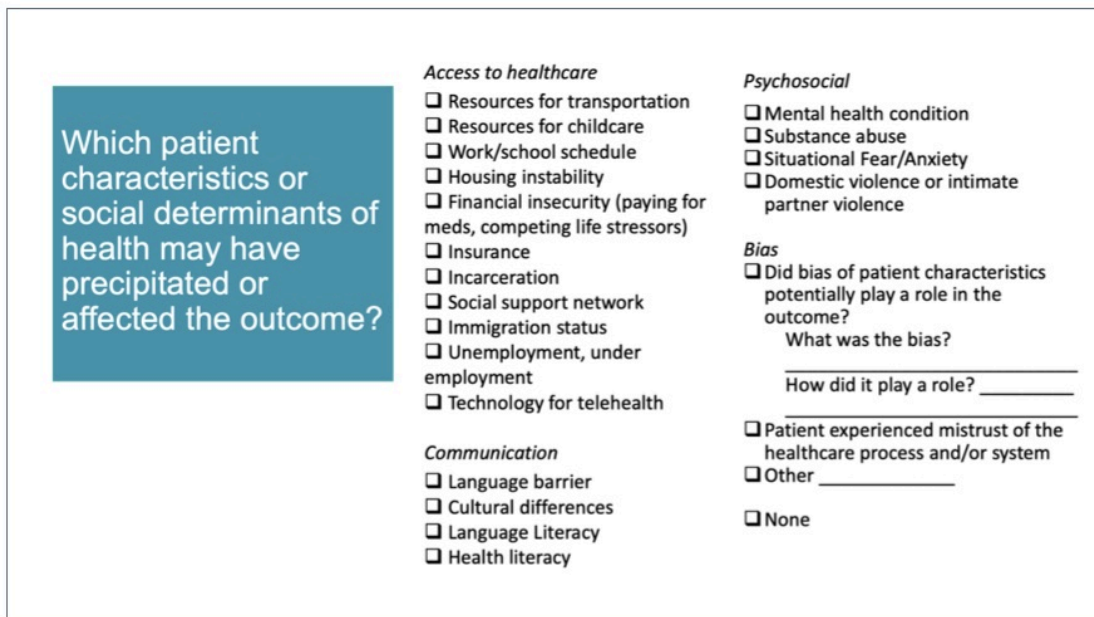
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social & political determinants of health)" Another important safety issue that NYC Health and Hospitals is working to eliminate, is race based medicine for kidney function and vaginal birth after cesarean (VBAC). Historically, race related factors have influenced the calculation of renal function and VBAC along with other algorithms. NYCHH currently sponsors a coalition to end racism in clinical algorithms across New York City.

Additionally, NYC Health + Hospitals incorporated bias/inequity prompts for incident reporting. They ask: "Were there potential sources for bias and/or structural inequities that may have contributed to this event (e.g. medical mistrust, discrimination, language or cultural barriers, implicit bias, prejudice, disrespect, delays in access to care)."

Similarly, Yale OBGYN department explicitly identifies what role social determinants of health play for their morbidity and mortality outcomes (see Figure 1).

Yale OBGYN Department: M&M TEMPLATE

Apparent Cause Analysis Checklist

Which patient characteristics or social determinants of health may have precipitated or affected the outcome?

Access to healthcare
- Resources for transportation
- Resources for childcare
- Work/school schedule
- Housing instability
- Financial insecurity (paying for meds, competing life stressors)
- Insurance
- Incarceration
- Social support network
- Immigration status
- Unemployment, under employment
- Technology for telehealth

Communication
- Language barrier
- Cultural differences
- Language Literacy
- Health literacy

Psychosocial
- Mental health condition
- Substance abuse
- Situational Fear/Anxiety
- Domestic violence or intimate partner violence

Bias
- Did bias of patient characteristics potentially play a role in the outcome?
   What was the bias? _____
   How did it play a role? _____
- Patient experienced mistrust of the healthcare process and/or system
- Other _____
- None

Figure 1

These examples show equity-focused changes that can be implemented to improve health care safety and equity issues.

Human Factors and Situational Risk/Hazards

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While focusing on situational awareness, human factor expertise emerged as a key area of interest. We interviewed several human factor experts which influenced our thinking below.

Health care lags other industries in applying human factors expertise to operations and safety. For example, EUROCONTROL (air traffic control) has ~7500 employees including 40 human factor experts. The NHS of the UK with more than a million employees has fewer than 10 human factor experts.

When IHI began patient safety work, there was a broad base of safety experts that were involved with the initial thoughts on safety. Over time, the main faculty for IHI's work were clinicians with safety expertise. These clinicians had practical experience; they were eager learners and avid readers. And, none had degrees in safety science. They certainly were aware of human factors and applied some of the tools human factors experts would use. Yet, deep human factors expertise was missing.

Based on our interviews, IHI's experience here is comparable to many health care organizations. Safety experts are still clinicians. Healthcare is insular. It tends to prefer expertise to be grown from within and sees the need to use clinicians. This is rooted in thinking that experts without healthcare experience will have a demanding time understanding the unique challenges of healthcare. Additionally, there are a limited number of trained human factor experts. To address this gap, organizations like the University of Wisconsin have developed courses for health care leaders to learn human factors.

Because of these efforts, the field of human factors in health care, pioneered by Dr. Pascal Carayon, is growing. The following figures and descriptions come from the work of Professor Paul Bowie.[3] [4]

> Human factors is designing for people to make things easier and safer.

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[3] Presentation by Paul Bowie New Frontiers in Healthcare: The Need for Human Factors Integration

[4] SH14 IHI Forum 2021 Designing for Work as Done : Applying Human Centered Design to enhance Patient Safety and Workforce Wellbeing Gill Smith, BA (Hons), CPPS, IHI Fellow & Faculty Paul Bowie, PhD MSc
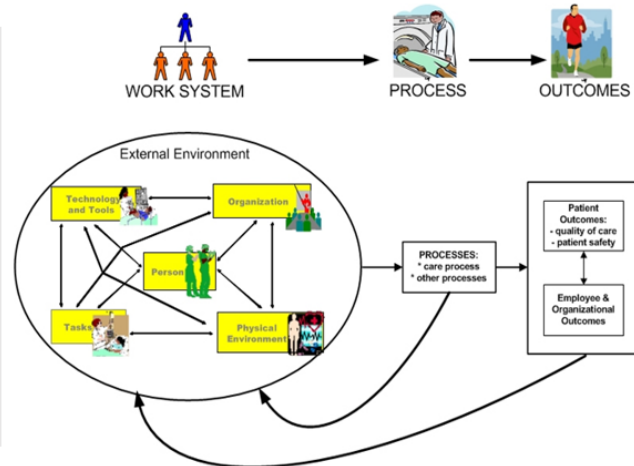
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Figure 2

The Human Factors discipline promotes a fundamental rejection of the notion that humans are primarily at fault when making "errors" in the use of a complex sociotechnical system.

As part of this system thinking Professor Bowie points out that there are 12 human-factors ideas to think about particularly when doing incident analysis:

1. No blame, we look at problems as being systemic.
2. Avoid counterfactual reasoning. We project on people what they could/should have done but that is an alternative universe because it does not exist. Why did the system or person not act as expected? That is where the learning lies.
3. Consideration of local rationality. Whatever was done at the time of the event made sense in the moment. We need to understand *why.*
4. Reconciling work as imagined and work as done.
5. Accepting that there is no singular root cause in complex systems.
6. Accepting multiple interacting contributing factors.
7. Seek multiple perspectives.
8. Explore context and situation.
9. Explore performance variability.
10. Aim recommendations at the system level.
11. Prioritize the needs of everyone involved in incidents.
12. It's up and out, not down and in. Drilling down on a single incident will only teach us a limited amount about the system. We need to look broadly across the

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system and ask people what has happened previously when something similar has occurred.

One of the main tools that all human factors experts shared with us was the Safety Engineering Initiative for Patient Safety (SEIPS) developed by Pascal Carayon. SEIPS is the Safety Engineering Initiative for Patient Safety. It is based on a Human Factors systems approach to understanding care systems, processes, and outcomes to inform better design and improvement.
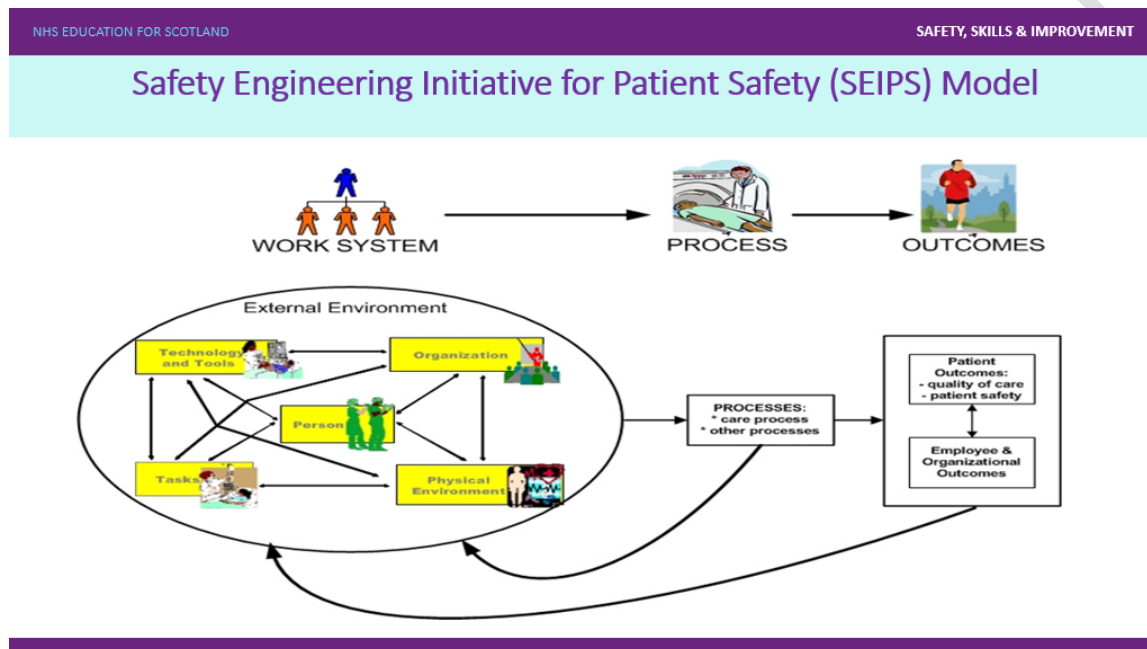

Figure 3

The work system is composed of 6 parts:
- **Tools & Technology** – design interaction and usability issues; positioning; availability; access; mobility; operational/calibrated; device usability; various IT design issues; electronic records, barcoding.
- **Person Factors** – Physical and psychological capabilities (including limitations and impacts from frustration, stress, fatigue, burnout, musculoskeletal, satisfaction, enjoyment, experiences, job control); personality/social issues; cognition and competence: skills, knowledge, attitudes; risk perception; training issues; personal needs and preferences; psychological safety; performance variability; personal goals; adaptation to work conditions; care team make-up (eg. roles, support, communication, collaboration, supervision, management, leadership); patient/client engagement (e.g. complexity of clinical condition, physical, social, psychological, relationship factors); Others individual stakeholders (e.g. families and carers and other health and social services colleagues).

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- **Task Factors** – level of task complexity; time taken; hazardous nature; capacity and demand match/mismatch; distractions; interruptions; variety of tasks; job content, challenge and utilization of skills; autonomy, job control and participation; job demands (e.g. workload, time pressure, cognitive load, need for attention).
- **Physical Environment –** Layout; Noise; Lighting; temperature; humidity and air quality; design of immediate workspace or physical environment layout; location; size; clutter; standardization, aesthetics; crowding.
- **External Influences** – Societal, government, cultural, accreditation and regulatory influences (e.g. funding, national policies and targets, professional bodies, regulatory demands, legislation and legal influences, other risks and influences).
- **Organization of Work Factors –** Coordination, collaboration and communication; organizational culture and safety climate; work schedules and rota design; social relationships; teamwork; supervisory, management and leadership style; performance evaluation, rewards and incentives; organizational strategy, work priorities/targets; conflicting goals; structure and hierarchies; staffing levels; rewards and incentives; risk assessment; education, training and development environments e.g. supervision, competence, protected time, professional development, physical and social learning environment

The work system will give rise to both wanted and unwanted outcomes. Those outcomes should be categorized into two groups:
- **System Performance –** Safety; productivity; resilience; efficiency; effectiveness; care quality
  Human Wellbeing – Health and safety; patient satisfaction and experience; enjoyment; staff turnover; staff welfare; job satisfaction

SEIPS can be utilized in any organization with the appropriate human factors experts as a general systems analysis and problem-solving tool for incident investigation, hazard identification, incident reporting & data collection, simulation design, protocol and checklist development, research design, and data analysis.

Here are two examples of guidance based on human factors that were developed for the UK.
- [Guidance to help design effective and usable work procedures for health and social care teams](#)
- [Capturing Lessons from Covid 19 and Beyond](#)

Most of what we have included above comes from the work of Professor Paul Bowie. In the previous cycle of research, we drew the conclusion that we should be more focused on situational risk at all levels of an organization. We recognize that organizations do this to various degrees with various mechanisms. Daily huddles are an opportunity to identify unit-based risk. And organizations that develop nested huddles can use this to escalate problems to top level leadership. In our observation, risk is not always identified and organizations need help thinking about situational risk. Even when huddles are done well, risk is not static. New risks will develop during the day after the huddles are over. We need to see them and have mechanisms in place to communicate them.

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Risk is not always clear. The book *How Risky is it Really?: Why Our Fears Don't Always Match the Facts*[5] informs several observations for our work. First, defining risk as the understanding or perception of being in a situation where something could go working and have a negative consequence for someone. Applying this to risk in health care, as in everyday life, is relative. Several considerations come to mind to inform health care's understanding of risk in real time:

- How many patients receive health care and nothing bad happens?

- How many providers use workarounds and nothing bad happens? (Amalberti's work)

- When is something risky?

- How do healthcare providers assess risk?

- Is how HC providers see risk in health care related to how they see risk in everyday life? (might someone how has been in a high risk industry have a different view than s someone who has not been in any high risk situations?)

- Are we spending too much time dealing with low or moderate risk and not enough on serious risk (page 198 of book)?

- Do we focus on the hot topics and ignore others?

- Are we focusing on public opinion or on what we know are the real issues?

- What risk contributes to the greatest harm and mortality? Should we be focusing on those areas only? How is it managed in other high risk industries?

During this wave, we focused on developments and change ideas for equity and patient safety as well as risk and human factors. The above analysis informs our conclusions, recommendations, and challenges discussed below.

Conclusions, Recommendations and Challenges:
We spent the last year discussing and thinking about the state of health care safety. For the last 6 months we have intensified that work through IHI's research team. We need to move to results focused work on health care safety at IHI.

Our recommendations are the following:

First, we believe this work could be used for a 'coaching and consulting' model for large systems/hospitals that desire assessments and support on this transformational journey.

Second, we also think the following could be developed and used:

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[5] How Risky Is It, Really?: Why Our Fears Don't Always Match the Facts David Ropelk

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1. Attract a set of organizations to work on health care safety with IHI in a long-term learning network. (Short term collaboratives, seminars and other tools may have been helpful in the past, but they will not lead to the deep transformative changes that are needed). It would be good to have a diverse group of health care organizations to form this group.

2. This work is about transformation and requires Board and Leadership support and commitment. We will have specific learning opportunities for leadership in this network.

3. During the last 6 months, we identified possible faculty who could lead this work. During the last three months we have been looking specifically for faculty with equity or human factors expertise. Possible faculty with human factors knowledge are: Terry Fairbanks, Paul Bowie, and James Won. Faculty with equity experience in safety are Ron Wyatt, Komal Bajaj, Louis Hart, and Linelle Campbell. It may be wise to use a format of three co-chairs for this work, Ron Wyatt and Paul Bowie are good choices and a nurse with workforce safety experience should be included.

4. We should start the work of the participating organizations using an assessment tool. We can use previous IHI tools, but they will need some modification given our current thinking.

5. Organizations can start testing the change ideas that we have mentioned in this paper.

6. A learning network will need continued innovation help to work on new topics and to help investigate older topics in more depth.

We have a set of internal and external challenges at IHI that we want to discuss along with some further comments for reflection.

1. Identify the funding for this work. It would be helpful to have the organizations who participate fund part of the cost of the network, and it would also be good to have some outside support. If the funding solely relies on organizations, smaller and poorer organizations will have difficulty participating.

2. 20 years ago, safety work was new and different and there was regulatory pressure for health systems to work on patient safety. Right now, there is no new regulation pushing for greater safety or equity within health care. A challenge will be to attract health systems to work with us in a learning network.

3. Within IHI leadership, there are differing opinions on what direction safety should take. Those need to be resolved for this work to move forward.

4. Health care organizations are really stressed at this time. As of the time of this writing we are seeing another wave of Covid across much of the US with an expected crippling wave coming from a new strain of Covid. Fatigue has set in among the remaining

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workforce and many have left the field causing even more strain. In addition, health care organizations are still trying to catch up with work that was delayed because of earlier waves of Covid. This provides an opportunity to align our existing work in patient safety and IHI's strategic focus on resilience.

5. Human Factors: What is different about our approach? Discussion of the application of human factors is not new. It is part of original PSO design. And, it is part of many recommendations from the origin of the program including James Reason, Rene Amalberti, J. Rasmussen, and R. I. Cook. Our focus is on situational awareness. This also is not new as it is part of HRO language. For example, huddles are intended to identify and mitigate risks. However, in healthcare: we have not employed human factors experts as part of system redesign efforts. Few health systems include Human Factors experts in any work. Huddles are in place in many places but are not effectively applied. It seems to be the shiny new intervention and like other interventions taken from other industries it was not well adapted and adopted. Risk is dynamic because health care is a dynamic event. Risk is not resolved with huddles at set times of the day, the situation is fluid and there is a need to monitor for risk on a constant basis.

6. To be clear, we still see culture as an important driver of patient safety. Transformation of any large system that has ingrained processes and culture will take time. One can begin to change culture locally but not change it for all at one time. Culture change has its own set of changes. The challenge is sustainability, leadership at the board and executive level, and patience. There is no simple tool box. Tool boxes turn into tick box exercises. Each leader must examine their own style of leadership, not all can be Gary Kaplan or Paul Oneil.

7. Further thoughts about unifying patient safety and workforce safety: safety as one. Emphasis on workforce safety is necessary. If the workforce feels safe, then the chances are that they will be in a better position to ensure patient safety. However, this is not a linear relationship. There are many other factors that contribute to patient harm. For some workforce safety may be seen as an interruption to productivity and flow. Cannot stop the line for conditions that may negatively impact workforce safety. Patient safety is dependent on a series of activities that the workforce must accomplish. Some require rapid action while others can be completed at a slower pace. So, what is the connection? Workforce safety must also include well-being and properly designed systems and processes. Preventing needle sticks and back injuries is important but will not solve the bigger issue contributing to patient safety. We will need to study hospitals that have decreased workforce harm to determine if there is a reduction in patient harm. And, is it that harm for both has decreased because one has addressed workforce harm, or is it that these organizations have a detailed approach to safety that when applied to workforce also decreases harm? Or, that the approach decreases harm for both? We

know that more research needs to be done on this topic.

8. Equity and safety is new and seems to have some traction. However, we must consider what we mean by equity and what is in the scope of influence of those providing care. Is it holding back of services? Is it the application of treatments which is influenced by implicit bias? We need to have a clear picture of what it is that we can and should do. The same principles that have been applied to make care safer should have a parallel set of change ideas that will address inequities, and some should be the same so that they can be easily implemented.[6]

9. Partnering with "big data". There is and will be more and more data available. Use of technology will continue to grow. IHI's approach has been agnostic to both. As a result, big data companies have stepped in and provide both data repositories and analysis and associated consulting services. Artificial Intelligence will have a major influence in how care is delivered. Precision medicine may produce faster and better outcomes but we do not know the implications to safety and can assume the rise in inequities. To compete, we must partner with several big data companies in order to take advantage of the information that can be produced by the data and then offer the services to drive change.

Open Questions and Future work

1. Safety is one. No separation between workforce safety and patient safety. They need organizational alignment. Some of the information on workforce safety will be housed with human resource and so getting their cooperation may be challenging. Building a central data structure that includes HR and safety data is needed but will be challenging.

2. Input measures into safety may be important and we would like to explore those more. Some examples of inputs are traditional such as staffing ratios, training and bed availability. And there is some similarity to Charles Vincent's work on measurement of Safety in the Future. That is, what has to be in place to be safe in the future. In Charles' work he uses the term "case studies" to examine others in similar areas that have spent many years developing safe systems (oil platforms) and determine if you have made the same 'inputs' to ensure that you have designed and applied safety principles. In some way, it is also Safety II- Learn from what works well (Hollnagel).

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[6] Achieving Zero Inequity: Lessons Learned from Patient Safety NEJM Catalyst Tejal Gandhi May 27, 2021

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