Institute for Healthcare Improvement

INSTITUTE FOR HEALTHCARE IMPROVEMENT
SUMMARY REPORT: 90-DAY PROJECT
Comprehensive System of Patient Safety
September 2016

I. Research and Development Team:
John Whittington

II. Intent:
The purpose of this work is to understand the evolution of patient safety and to think about the future direction of safety improvement in healthcare. The goal is to develop a system of safety that fits with the many competing priorities of health care.

III. Background:

In a 2008 IHI R and D report, Roger Resar said, "An IHI consensus group in 2001 defined a set of strategies that described a rudimentary system of safety for hospitals, which over the years has demonstrated measured success in decreasing adverse events and improving the safety culture. The strategy emphasized projects whose aim was to decrease events such as those related to known high-risk drugs or nosocomial infections for example, but also incorporated other strategies to change the culture such as team training. Even though hospitals have been able to achieve many of the recommended project goals, few if any would say safety has reached the desired goal in any hospital. Nor can a conclusion be made that a comprehensive system of safety currently exists in any healthcare organization."[1]

He further went on to say "The quest for a comprehensive system of safety for healthcare is driven by a shared belief held by both experts and implementers of safety efforts that the current project oriented approach will not achieve the level of safety desired."

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

[1] IHI Wave 6 R and D Report "System for Safety Consideration" Roger Resar

pervasive—than initially appreciated."[2]. There has been progress in patient safety in the last 15 years, but it has not been as fast as we might have expected or hoped.

The NPSF Panel went on to say, "Advancement in patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach to safety" They provided the following 8 recommendations:

1. Ensure that leaders establish and sustain a safety culture.
2. Create centralized and coordinated oversight of patient safety.
3. Create a common set of safety metrics that reflect meaningful outcomes.
4. Increase funding for research in patient safety and implementation science.
5. Address safety across the entire care continuum.
6. Support the health care workforce.
7. Partner with patients and families for the safest care.
8. Ensure that technology is safe and optimized to improve patient safety.

IHI and the NPSF are both saying the same thing. We need a comprehensive system of safety for healthcare. In this paper we will briefly outline such a system.

IV. Description of Work to Date:

During this cycle of activity we reviewed past IHI R and D waves of work on safety: 3,4,5(2),6 (2), 7,13, 35 and 36. Most of this work did not move forward. There is the possibility that some could be used or incorporated into new work.

We conducted interviews within IHI and externally. A set of key articles and books were reviewed for this work.

V. Results of the 90-Day scan:

The challenges to improving health care safety.

IHI and others have been thinking about a comprehensive system of safety for many years.

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[2] Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human
Report of an Expert Panel Convened by The National Patient Safety Foundation

The question is why haven't we achieved it. There are number of issues to consider. As the NPSF wrote, an underestimation of the complexity of healthcare is probably part of the problem. 15 years ago safety was a hot topic. Today it is just one of many topics. . The focus now is on new payment models, the Triple Aim, health equity, new approaches for health care on quality improvement, etc. These have all competed for strategic time with patient safety. Safety is more of a "state of being" than simply working on projects or doing quality improvement.

Our approach to the implementation of patient safety in the US was probably wrong on several fronts. First, and maybe most importantly, we seemed to approach safety as a set of projects to be accomplished. We thought if we can only decrease medication adverse events, serious events, falls, infections, etc then we will be safe. If we can get enough people to understand a just culture then we can be safe. If we just train everyone on team resource management than we will be safe. If we can just find best practices and share them, that will improve safety. All of those initiatives are good, but they were often layered one on top of another without an overall redesign of the system. A practical example today is that nurses are inundated with various safety check lists, each important, but no one thinking about what it means to do the entire collection of check lists.

We looked for new models of safety outside of health care and tried to apply them to healthcare. This is a noble idea with merit, but perhaps we didn't know how to apply them and where to apply them as well as we should. For example, we used information from the nuclear power industry and tried to incorporate that into health care safety. Probably the strongest part of nuclear industry safety deals with the idea of defense in depth, i.e. multiple layers of engineering design to build in multiple layers of safety. There are 67 nuclear facilities in the US that contain about 99 reactors. A new nuclear power plant costs $9 billion dollars to build today. A new hospital cost $1.5 million per bed to build. So a 200-bed hospital costs $300 million. Although this is speculation, if we built hospitals to nuclear power specifications, we might increase the cost of building a hospital 10 fold. Healthcare is already 10% of the workforce and 17.5 of the GDP.
Another favorite has been the nuclear aircraft carriers and the work on high reliability. There are 11 US nuclear aircraft carriers in the world. There are 5000 hospitals in the US. Now we certainly should take ideas from those 11 carriers or from those 67 nuclear power facilities, but we must recognize something about the scope and scale issues that we will face when we try to introduce and spread those ideas in healthcare.

Safety reporting and route cause analysis 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. Have we determined that this is the best use of organization time?

We should talk about the complexity of health care. A typical hospital has many different departments within it. There is a great deal of difference between what happens on a medical ward versus labor and delivery versus elective surgery versus the emergency department, etc. Key safety principles can be applied in these various units, such as work on improving communication and teamwork, but we need to recognize the difference in context between the units. Also we need to think about other sites of care such as ambulatory facilities, specialty care offices, primary care, home health and skilled nursing facilities, etc and the complexity associated with this. The handoffs between facilities create more complexity. If that is not enough complexity, consider the variability among patients in physiology ,culture , behavior and socioeconomic status. Healthcare is complex, patients are complex, the knowledge management for all of the above is complex. In short, this is a very complex system.

YOU NEED a SYSTEM OF SAFETY

Comprehensive System of safety.

Work at IHI has been evolving over time in regards to patient safety. In 2001 IHI ran a collaborative on patient safety called Quantum Leaps. Their goal was to decrease medication adverse events by a factor of 10. The collaborative learning community involved over 50 organizations. The learning community used a trigger tool to measure adverse medication events. There were 4 big change ideas: safety culture, medication reconciliation, failure mode and effects analysis applied to the dispensing of medication and a focus on high-risk medication.

At present IHI teaches a model of safety that includes the following items. This model has evolved over time through a joint partnership between IHI and Safe and Reliable Healthcare. A white paper is being developed by IHI in which they will share this model in more depth. Here is a condensed version of it.

Culture

Leadership - Facilitating and mentoring teamwork, improvement, respect and psychological safety.

Psychological safety- Creating an environment where people feel comfortable and have opportunities to raise concerns or ask questions.

Accountability- Being held to act in a safe and respectful manner given the training and support to do so.

Teamwork and communication- Developing a shared understanding, anticipation of needs and problems, agreed methods to manage these as well as conflict situations

Negotiation - Gaining genuine agreement on matters of importance to team members, patients and families

Learning System

Transparency - Openly sharing data and other information concerning safe, respectful and reliable care with staff and partners and families.

Reliability - Applying best evidence and minimizing non-patient specific variation with the goal of failure free operation over time.

Improvement and Measurement - Improving work processes and patient outcomes using standard improvement tools including measurements over time.

Continuous Learning - Regularly collecting and learning from defects and successes.

There is also an acknowledgement in this model that patients and families are critical to the work.

There are other models of patient safety that could be considered.

The fine work of Eric Hollnagel et al on safety 1 and safety 2[3] is another example of a comprehensive system of safety.

[3] From Safety 1 to Safety 2- A white paper 2015 September 2013 – European Organisation for the Safety of Air Navigation

	Safety-I	Safety-II
Definition of safety	That as few things as possible go wrong.	That as many things as possible go right.
Safety management principle	Reactive, respond when something happens or is categorised as an unacceptable risk.	Proactive, continuously trying to anticipate developments and events.
View of the human factor in safety management	Humans are predominantly seen as a liability or hazard.	Humans are seen as a resource necessary for system flexibility and resilience.
Accident investigation	Accidents are caused by failures and malfunctions. The purpose of an investigation is to identify the causes.	Things basically happen in the same way, regardless of the outcome. The purpose of an investigation is to understand how things usually go right as a basis for explaining how things occasionally go wrong.
Risk assessment	Accidents are caused by failures and malfunctions. The purpose of an investigation is to identify causes and contributory factors.	To understand the conditions where performance variability can become difficult or impossible to monitor and control.

Before we introduce any more models we should probably stop and think about what we are really trying to accomplish. Charles Vincent, in the paper *The measurement and monitoring of safety*,[4] asks the following 4 questions: has patient care been safe in the past, are clinical systems and processes reliable, is care safe today and will care be safe in the future? He suggests measuring and monitoring these 5 processes:

1. Past harm: this encompasses both psychological and physical measures
2. Reliability: this encompasses measures of behavior and systems
3. Sensitivity to operations: the information and capacity to monitor safety on an hourly or daily basis

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[4] *The measurement and monitoring of safety* the Health Foundation, http://patientsafety.health.org.uk/sites/default/files/resources/the_measurement_and_monitoring_of_safety.pdf

4. Anticipation and preparedness: the ability to anticipate, and be prepared for, problems
5. Integration and learning: the ability to respond to, and improve from, safety information

Charles Vincent and René Amalberti have described a model that incorporates many if not most of the above ideas and adds a few others in their recent book, Safer Healthcare Strategies for the Real World. Figure 1 outlines five important strategies from their work that is perhaps the best approach to a comprehensive system of safety.

Figure 1. Five Safety strategies[5]

1.Safety as best practice: aspire to standards – Reducing specific harms and improving clinical processes

2.Improving healthcare processes and system (system design) – Intervening to support individuals and teams, improve working conditions and organisational practices

3.Risk control – Placing restrictions on performance, demand or working conditions

4.Improving capacity for monitoring, adaptation and response. (Resilience)

5.Mitigation – Planning for potential harm and recovery.

This approach could act as a foundation for a system of safety coupled with a measurement set that would attempt to measure past, present and future harm. We are suggesting at this point in time that this approach is the one that IHI should use.

VII. Conclusions and Recommendations:

1. We have to stop thinking of safety as layered on to an organization, but rather built into the fabric of ongoing work. This means issues around population management, quality, access, safety and equity all have to be part of the overall design.
2. We need a chair for patient safety. An example might be Charles Vincent.
3. IHI should work closely with organizations to test and learn from the Charles Vincent comprehensive safety system including measures

[5] Charles Vincent, René Amalberti Safer Healthcare Strategies for the Real World ISBN: 978-3-319-25557-6 Springer Open

4. We need to create space for discussion, reflection and learning at IHI regarding safety.
5. We need to increase effectiveness of R and D and the safety team to take ideas and translate them into action and programs.

VI. Open Questions:

1. What would the responsibilities be for a chair in patient safety?
2. How long a term should they have as a chair? It might be good to bring in someone new every two years.
3. We have lost talented people in the past because we did not listen to them. What structure will we create to support them?
4. What is the outcome that we expect?