Introduction
More than a decade ago, the Institute of Medicine reported a significant patient safety problem in the United States. In the interim, studies have shown little improvement in the level of safety in hospitals despite national efforts at large-scale improvement projects. In fact, a recent study of three hospitals known for strong safety programs, when studied using the IHI Global Trigger Tool, found adverse events ten times more prevalent than commonly thought. The basic question that begs to be answered is: Why, with all the national efforts and within organizations globally known for safety work, has little or no measurable change in safety outcomes been achieved?

We certainly can point to specific areas of safety that have had marked improvements, such as ventilator-associated pneumonia, central line infections, or hypoglycemic episodes. It would appear at first analysis, however, that these examples of improved safety are dwarfed by the sheer numbers of adverse events. Further, it appears that the successes in these areas with large-scale organizational projects, although successful in their own right, will have minimal effect on the total adverse event rate for the organization. Based on the IHI Global Trigger Tool analysis, approximately 4,000 adverse events can be expected for every 10,000 admissions to a hospital. In fact, 33 percent of all admissions to a hospital have at least one adverse event. Similar rates have been reported in a population of Medicare beneficiaries, with tremendous costs born both by the patient and by the system.

Experts posit that the failure to see more improvement relates to the sheer number of frontline defects occurring in the attempt to deliver reliable care to our patients – defects that are neither recognized nor changed. Indeed, one report estimated that 86 percent of harms may be underreported due to ambiguity over what constitutes reportable harm. Such an estimate is likely to be very conservative, considering the low detection rates of most institutional voluntary reporting systems.

This paper outlines ideas first envisioned by the Institute for Healthcare Improvement (IHI) in work with Cedars-Sinai Medical Center, combined with a model and framework designed and tested at Mayo Clinic.

Background
In late 2010, a team from the IHI was invited by Cedars-Sinai Medical Center to evaluate their approach to identifying safety hazards and designing reliable processes. A joint team was formed and over three days the team designed a methodology to surface defects within the system. The team agreed that, in order for the organization to achieve world-class performance in safety, it would need to acquire a new level of
understanding of risk based on the small, continuously occurring defects that have in many cases become part of the daily work in the hospital. These small defects represent the thousands of “Swiss cheese holes” that, when aligned, can and will contribute to the next adverse event.  

Six different departments were used as a basis for the design of a methodology that would extract and surface these small defects. The following table represents the final design of what has evolved into “the conversation with the frontline.”

<table>
<thead>
<tr>
<th>Conversation Steps</th>
<th>Specific Duties</th>
<th>Desired Outcome</th>
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<tbody>
<tr>
<td>1. Organize the visit to the unit beforehand.</td>
<td>• Select a mix of frontline staff (6-8).</td>
<td>• A cross section of staff working on the unit are invited</td>
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<td>• Select a small leadership team.</td>
<td>• Enough time for all staff to have an opportunity to discuss their work</td>
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<td>• Arrange for at least 60 minutes of conversation.</td>
<td>• A location of the conversation where there are minimal interruptions</td>
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<td></td>
<td>• Arrange for a location on the unit for the conversation.</td>
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<td>2. Have each of the participants describe the job they do.</td>
<td>• Establish a non-threatening atmosphere.</td>
<td>• Trust from the frontline staff that this is not about assessing their personal work performance</td>
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<td></td>
<td>• Limit this part of the conversation to the first 10 or 15 minutes.</td>
<td>• Participants who are willing to talk about the work, how they do it, and how they add value to</td>
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<td></td>
<td>• Purpose of this portion of the conversation is to understand the work and the work environment.</td>
<td>the patients and the organization</td>
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<td>3. Assess the work environment using “anchoring questions.”</td>
<td>• Use questions like: Tell me what causes a bad day for you? Tell me about the last time a case was delayed? Tell me about what makes some diabetics more difficult to see?</td>
<td>• Find a specific example of a defect around which you can anchor subsequent questions about</td>
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<td>• Use these questions to learn about both clinical and non clinical situations.</td>
<td>frequency, type of patient involved, previous attempts to fix, or what might happen with your day</td>
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<td>if it were resolved.</td>
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<td></td>
<td>• Keep the discussion to a completely non-threatening, blame-free event to allow for maximal</td>
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<td>information sharing.</td>
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</table>
4. Debrief

- Center questions around identified defects where actual harm discussions are avoided but the potential of harm is present.
- Steer discussion away from solutions.
- In a 60-minute conversation, 10-15 defects should be easily surfaced and compiled on a written list.

- First, debrief the questioning team.
- Follow with a debrief with the frontline team.
- Generate a list of defects that the frontline has surfaced.
- Achieve buy-in from the frontline for possible action.
- Achieve buy-in from the questioning team as to the need for action.

During 2011, colleagues at Cedars-Sinai and Mayo Clinic proceeded with testing the conversation. At Mayo Clinic, a three-stage approach was planned:

1. Design a model and framework based on testing the conversation in multiple settings.
2. Test the model and framework at two sites with the following goals:
   - Staff satisfaction with the process
   - Number of defect-driven projects initiated
   - Number of defect-driven projects completed
   - Outcome measures for individual projects
   - Understand the required infrastructure and resources necessary to achieve the large department or unit goals (stage 3)
3. Implement the model and framework in a large department or unit, with the additional following goals:
   - Show improvement with the institutional culture of safety survey
   - Show improvement with a high level safety measure, ultimately with a reduction of the total number of adverse events
Design of the Model and Framework
Medical residents and a hospitalist unit were selected to participate in the testing needed to design the model and framework. Both of these groups require improvement projects; residents to address ACGME requirements under the core competency of systems-based practice; and hospitalists to reflect the increased emphasis on quality improvement recognized by the ABIM’s new Focused Practice in Hospital Medicine (FPHM), the recertification of which requires twice as many performance points for maintenance of certification as Internal Medicine certification. Conversations were carried out with the intention of training staff in the methodology; identifying frontline defects; and engaging leaders, testers, and frontline staff. The following model was designed:

The model as depicted above shows a large sweeping arrow that represents a bottom-up approach to improvement, structured by a deliberate frontline conversation that looks for both clinical and non-clinical defects in daily work. With defects identified, the frontline continues to participate by collecting simple data, suggesting strategies for improvement, and running small tests of change to achieve project success.

In order to create infrastructure to achieve the practical function of the model, a framework was developed based on the experience of carrying the conversation to completion or near completion with projects.
The Frontline Defect Driven Project Framework describes the timeline, design benefits, specific actions, and design basics.

The following describes in detail each of the action steps (blue boxes) depicted in the framework.

- **Surface Defects**
  Critical to frontline engagement is the methodology used to surface defects. The methodology of the conversation described earlier in the paper has now been tested many times and found to be very useful in generating frontline defects. The process takes 60 to 90 minutes, assuming there was good preparation for the conversation. The anchoring questions will easily surface 10-20 frontline identified defects causing daily difficulties and safety risks in the care of patients. Often they are large system issues where specifics for the unit need to be teased out. For example, a defect regarding the computer crashing is not likely to be fixed at a unit level, but simply asking what’s the unit’s plan for when the computer crashes unearths defects that are amenable to local solutions. Important to this step of the framework is the feedback to the frontline participants. Surfacing defects in the manner described creates both energy for change and an expectation to follow through. The feedback is important in maintaining the frontline engagement regarding defect improvement projects.
➢ **Scope Defects**

This action step has two important functions. The first is to determine the size and nature of the defect with respect to unit, while engaging leadership in the frontline approach to a set of problems. All defects have potential safety and efficiency issues, but not all can be acted upon at the unit level. Some defects require enterprise solutions, while others may not be aligned with department- or system-level strategic goals. The framework charges leadership to gauge the capacity of the frontline to accomplish the improvement work, articulate any possible detrimental effects on other parts of the enterprise, and ensure that the work is in sync with departmental goals. Once the topic area has been found to be workable from the leadership perspective, feedback to the frontline is necessary.

The second function of this action step is the evaluation of the next defect. Unlike major top-down projects, the bottom-up frontline projects require only minimal study for causation. After the defect topic has been properly scoped by leadership and feedback to the frontline accomplished, the frontline is instructed in applying “the 5 whys” to the next defect as close to the occurrence of the defect as practical, because vital causative information is quickly lost if the timeline exceeds even 24 hours. The study of the next defect continues the purposeful engagement of the frontline.

➢ **Validate**

The validation step is the baseline measurement. The measurement is kept as simple as possible by collecting data over several days at most, using “yes/no” criteria. The measurement is necessary to ensure adequate frequency and “prove” the causal hypothesis for the defect, based on the study of the next defect described above. As an example, one of the defects surfaced in an ambulatory medicine clinic was the difficulty in taking care of elderly diabetic patients who were not very versed in their disease or medications in the same time frame as other diabetic patients who understood the disease and medications. The study of the next defect showed the rooming time for medication reconciliation was too short. In this defect, the simple measurement would be the frequency of these patients and whether the medication reconciliation time was too short. The simple bimodal “yes/no” would give the needed information as to frequency. The measurement is meant to be so easy that the frontline can collect the data without spending extra time at the task. The involvement of the frontline in the data collection fosters the frontline engagement for the project when significant frequency is observed and sets the frontline up for willingness to participate in the solution.

➢ **Select Specific Work**

The “next defect study” outlines the specific area of improvement work. The baseline data collection validates both the defect and the frequency. This step articulates the boundaries of the improvement work. With the diabetic example from above, the boundaries would include the following:
- Which (who) patients would be included;
- How much extra time would be given for reconciliation;
- When the work would be done;
- What would be done differently; and
- Where the work would be done.

Articulating these specific actions leads directly to the next action step, as well as engaging the frontline testers. Simple measurement is designed at this step to indicate whether the defect has actually improved safety or efficiency.

- **Design Strategy**

For each of the boundaries, multiple strategies could be tested. The frontline is best suited to design possible strategies. Each of the boundaries (who, what, when, where, and how) will require a decision that may be part of the eventual solution. Each possible strategy will require small tests of change, leading to a solution. These tests of change will primarily be performed by the frontline until a solution is devised.

**Discussion**

Testing the conversation at Mayo Clinic and Cedars-Sinai resulted in the development of the model and framework outlined above. Both organizations have started testing the model and framework on specific units, with the ultimate goal of using the framework at a department level where high-level safety measures show improvement. The following examples illustrate the frontline defects surfaced and how frontline solutions have been utilized.

**Interruptions as a safety issue at Cedars-Sinai:**

One of the tasks of the Unit Secretary on a 30-bed surgical unit is to transpose physician orders from the hand-written order sheet into the computer. Among those orders are therapies, tests, diet, and medications. It is exacting work, and if the wrong order is entered or entered on the wrong patient there is the potential for tragedy.

The Secretary noted that she is besieged by interruptions. We tracked them and found that, on average, they occur 30 times per shift. When we analyzed the nature of the interruptions, most fell into three categories:

- Physicians and others asking for phone numbers;
- Families asking for blankets and water; and
- Physicians looking for patient charts.

In response, we undertook the following solutions:

- The 25 most commonly requested phone numbers were laminated on a reference card and attached to every phone in the area. The Secretary no longer responded to the requests and directed inquiries to the phone lists.
- Staff increased room-to-room rounding and they now ask each patient about blankets and water.
• Staff periodically “round up” charts and return them to the rack.

The result is that interruptions now average three per shift, safety is improved, job satisfaction for all players is improved, and patients’ needs are being met.

Paging as a safety issue at Mayo Clinic:
An alphanumeric paging system constrains effective physician-nurse communication both by the type as well as the amount of information able to be conveyed. Despite inherent limitations, it remains a major means of communicating often vital information which, if not done well, holds significant potential for patient harm.

A mid-level provider on one medicine service covering patients geographically located on two nursing units on one floor felt many pages were unnecessary, leading to “alert fatigue.” Initial testing disproved this, but demonstrated pages were seldom optimally formatted in one of two ways or both:
• Pages did not clearly articulate the urgency of the request; and
• Pages did not include call-back information.

In response, we undertook the following solutions:
• Devising a priority prefix (1-high to 3-low);
• Formatting and including call-back information (5-digit phone*5-digit pager); and
• Equipping all nurses caring for patients with a handheld phone.

Correctly formatted pages improved from a baseline measure of 28 to 87 percent, along with increased satisfaction with improved closed-loop communication.

These examples illustrate the use of frontline defect analysis, but a focus on the microsystem is obviously not new. Pronovost describes a comprehensive unit-based safety program (CUSP) but it remains heavily weighted on a top-down approach to identification of both projects and solutions. In addition to ensuring a connection to department goals, the current framework emphasizes the frontline total control of the improvement work at all levels of the project, ranging from detection of the defect, to simple data collection, strategy design, testing, and implementation. The model and framework built through testing at several organizations provides a clear methodology for simple defect analysis and solutions to safety issues that daily affect the frontline in their attempts to provide safe and efficient care.


3 Classen DC, Resar RK, et al. Global Trigger Tool shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs.* April 2011;30(4):581-589.

4 Classen DC, Resar RK, et al. Global Trigger Tool shows that adverse events in hospitals may be ten times greater than previously measured. *Health Affairs.* April 2011;30(4):581-589.


7 OIG Report: Hospital incident reporting systems do not capture most patient harm. January 2012.


