Introduction
More than a decade ago, the Institute of Medicine reported a significant patient safety problem in the United States.\(^1\) 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.\(^2\) 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.\(^3\) Similar rates have been reported in a population of Medicare beneficiaries, with tremendous costs born both by the patient and by the system.\(^4\) Indeed, one report estimated that 86 percent of harms may be underreported due to ambiguity over what constitutes reportable harm.\(^5\) In the interim, studies have shown little change in the level of safety in hospitals despite national efforts at improvement.\(^6\) The basic question that begs to be answered is: Why, with all this effort has little or no measureable 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. These large top down improvement efforts although very successful in their own right are dwarfed by the sheer numbers of adverse events now known to occur even in organizations recognized for strength of their safety programs.

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.\(^10\) This paper details an approach designed by the IHI to engage the frontline to identify and correct small defects that have become normalized deviations in the belief that elimination of these safety issues will have a dramatic affect on reducing organizational adverse events. The frontline approach is certainly not new. The Toyota Production System for example is famous for engaging their workers in improving their work with the knowledge that “push” work improvements from the top usually generate tepid frontline enthusiasm but requires a substantial infrastructure. We now outline ideas first envisioned by the Institute for Healthcare Improvement (IHI) in work with Cedars-Sinai Medical Center, combined with a framework designed and tested at Mayo Clinic using a simple, minimal resource, low infrastructure methodology to achieve a new level of safety.
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. The reason for the visit stemmed from a series of serious adverse events. Cedars-Sinai has been a leader in implementing national safety programs and was frustrated with the inability to prevent those future unknown adverse events. A joint IHI Cedars-Sinai team was formed and over three days designed a methodology to surface safety defects previously unrecognized within the system. The working hypothesis was that in order for Cedars-Sinai 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 (normalized deviation). These small defects represent the thousands of randomly occurring “Swiss cheese holes” that, when aligned, can and will contribute to the next adverse event.\(^{12}\)

Six different departments were chosen as a basis for the design of a methodology that would extract and surface these small defects. Each department volunteered 90 minutes in which a cross section of the members engaged in discussions that took place in the department itself. After each department discussion the design team met and reviewed the interaction. The techniques that enhanced engagement the front-line and extracted the most defects were continually tested and improved with each subsequent department visit. Over the following year the methodology was refined further with testing in multiple departments at the Mayo Clinic and a model and framework were designed incorporating the Cedars-Sinai “conversation with the frontline” with a series of action steps moving from the front-line identification of defects to the frontline correction of the defects.

Design of the Model and Framework
Medical residents and a hospitalist unit at Mayo Clinic were selected to participate in the testing needed to design the model and framework. Both of these groups require improvement projects so their was interest in small improvement projects; residents to address ACGME requirements under the core competency of systems-based practice;\(^{13}\) 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.\(^{14}\) 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. The triangle suggests the great number of defects only visible to the front-line with fewer defects visible to leadership represented by the peak of the triangle. 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 designed at Cedars-Sinai to completion projects both at Cedars-Sinai and Mayo Clinic.

The 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 below has now been tested many times and found to be successful 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. The conversation steps, duties and expected outcomes are described in the table below.
## The Unit Visit

<table>
<thead>
<tr>
<th>Conversation Steps</th>
<th>Specific Duties</th>
<th>Desired Outcome</th>
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</thead>
<tbody>
<tr>
<td>1. <strong>Organize the visit to the unit beforehand.</strong></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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<tr>
<td></td>
<td>• Arrange for a location on the unit for the conversation.</td>
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<tr>
<td></td>
<td>• A cross section of staff working on the unit are invited</td>
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<td></td>
<td>• Establish a non-threatening atmosphere.</td>
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<tr>
<td>2. <strong>Have each of the participants describe the job they do.</strong></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 the patients and the organization</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>
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<tr>
<td>3. <strong>Assess the work environment using “anchoring questions.”</strong></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 frequency, type of patient involved, previous attempts to fix, or what might happen with your day if it were resolved.</td>
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<tr>
<td></td>
<td>• Use these questions to learn about both clinical and non clinical situations.</td>
<td>• Keep the discussion to a completely non-threatening, blame-free event to allow for maximal information sharing.</td>
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<tr>
<td></td>
<td>• Center questions around identified defects where actual harm discussions are avoided but the potential of harm is present.</td>
<td>• In a 60-minute conversation, 10-15 defects should be easily surfaced and compiled on a written list.</td>
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<tr>
<td></td>
<td>• Steer discussion away from solutions.</td>
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</table>
4. Debrief

- First, debrief the questioning team.
- Debrief 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.

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. A simple scoping tool is illustrated below:

<table>
<thead>
<tr>
<th>Defect Identified</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this a system or unit level defect?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>If the unit works on this defect could other parts of the organization be negatively affected?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will outside resources be needed?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Can a dyad handle the project?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can the project be finished in 30 days or less?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the project align with unit or organizational goals?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there willing frontline participants?</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Is a coach available for JIT teaching?</td>
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</tbody>
</table>
The second function of this action step is the actual evaluation of the next similar defect that occurs. 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 frontline feedback sought, the frontline is instructed to apply “the 5 whys” to the next similar defect. The analysis of the next similar defect is done as close to the occurrence as practical, because vital causative information is quickly lost if the timeline exceeds even 24 hours. The information gained from the analysis will be used in the subsequent steps of the methodology.

The scoping is undeniably a very important action step. It scores those projects capable of being handled by a dyad with the expectation of a 30 day or less completion. This action forces several key components of our methodology. First the dyad size project limits the scope of the project to what two frontline workers can accomplish while performing their usual jobs. This maximizes the totality of frontline improvement while keeping resource use at the lowest of levels. Our experience with test units has confirmed that the dyad creates the highest level of frontline engagement for the work and uses virtually no resources to finish the project. In addition it drives the 30 day or less expectation because otherwise the frontline rapidly loses interest in those projects lasting longer than a few weeks.

At Mayo Clinic the conversations are planned to occur quarterly on some units. Scoping is used to select 4 projects a quarter. The measured outcome from a unit level is how many of the projects are finished in a year within the 30 day time frame. Projects are not placed in a “parking lot”, but rather each set of projects is based on a new conversation. (This is done to continue to foster the frontline engagement). If at the end of a year the projects have not been completed, it means the scoping has been poorly done and needs tuning and adjustment.

- Validate

The validation step is the baseline measurement of frequency and volume. It makes little sense to initially work on very low volume defects as the frontline will quickly lose interest. 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 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 number of these elderly diabetic patients not versed in their medications and whether the medication reconciliation time was too short. A simple bimodal “yes/no” would give the needed information as to frequency. The measurement is meant to be so easy that the frontline can and are willing to 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” defines the boundary for the specific area of improvement work. The baseline data collection finished in the validation step has measured both frequency of the defect and the frequency where the possible solution would help. Selecting the specific work articulates the boundaries of the improvement work with an aim to create standard work. Using the diabetic example from above, the boundaries would need to include the following:
  
  - Which (who) patients would be included;
  - How much extra time would be given for medication reconciliation;
  - When would the extra work 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 designing the specific strategy, as well as engaging the frontline to articulate these boundaries based on their actual work experience. Simple measurement can also designed for any of the specific attributes of the project.

- **Design and Test Strategy**
  For each of the articulated boundaries, multiple strategies should 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 dyad until a solution is devised. The following small worksheet can be used to design the standard work of the project boundaries.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Clear Description of the Attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who will perform the stated job</td>
<td></td>
</tr>
<tr>
<td>What will be done</td>
<td></td>
</tr>
<tr>
<td>When will it be done</td>
<td></td>
</tr>
<tr>
<td>Where will it be done</td>
<td></td>
</tr>
<tr>
<td>How will it be done</td>
<td></td>
</tr>
<tr>
<td>With what will it be done</td>
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</tbody>
</table>
➢ **Finish the Project**

The end product of the methodology is a defect surfaced from the frontline that shows significant improvement. The 30 day or less timeline allows for leadership to hold the dyad accountable for the work. If the work cannot be accomplished in the allowable timeframe, the scoping was not done properly. This should activate an effort by leadership to evaluate the scoping structure and make changes based on the reasons the project failed to show improvement. The project should have multiple small tests of elements of the attributes discussed above. If frequent small tests were not observed the proper coaching was not provided. A given unit should be able to affect multiple defects a quarter.
Examples and Results

**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 both were defects generated within a deliberate conversation. In both instances leadership was not really aware of the problem nor the potential safety issues associated with the defect. Additionally in both examples the staff involved felt this was just the way their daily work was defined without really appreciating the safety implications. The projects were both completed by a dyad with minimal resource use within a 30 day timeframe.

Discussion

Obviously the focus on energizing the frontline is not new. As noted earlier the Toyota production System has designed an impressive infrastructure to accommodate frontline suggestions. In fact each frontline worker on average has 9 suggestions a year for improvement to the line. Within healthcare itself several excellent examples of a focus on the frontline are to be noted. 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. Kenagy in his book Adaptive Design describes the need to get leadership involved in setting up a frontline empowered improvement strategy. There obviously is overlap in these ideas. The IHI methodology however provides a simple, way forward for those interested in testing the idea on a small scale. The dyad approach encourages the smallest working group which in our early testing activates the frontline to participate to a much larger degree than other groupings and because of the very important scoping function provides the improvement with minimal resource use in a very small time frame.

We believe the dyad represents a disruptive innovation whose time has come. Given the unchanging face of safety in our hospitals in spite of the large national programs, this simple methodology can be a complement to existing programs without endangering a further resource draw. We have seen Cedars-Sinai that the progression from these simple defect improvements to a real culture change on participating units is a likely outcome.

Frequently Asked Questions

Would this methodology apply to a small rural hospital rather than a unit?
Yes, in fact the methodology is highly favorable to these small hospitals. They have fewer resources, have less practical association with large national programs and often
have less practical improvement experience. The simple approach with a small JIT with the dyad is frequently an excellent improvement strategy.

It seems that a 60-90 minute conversation would be very difficult on my unit. It seems we have no time for improvement work.

This is a common and legitimate observation. We have found that when the conversation takes place either at a quarterly meeting or scheduled in off hours these conversations can occur. We have noticed in organizations who have started this work that the investment in this conversation is small compared to the gains in staff satisfaction and patient safety.


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.


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


