The TRANSFORM Patient Safety Project: A Microsystem Approach to Improving Outcomes on Inpatient Units

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BACKGROUND: Improvements in hospital patient safety have been made, but innovative approaches are needed to accelerate progress. Evidence is emerging that microsystem approaches to quality and safety improvement in hospital care are effective.

OBJECTIVE: We aimed to evaluate the effects of a multifaceted, microsystem-level patient safety program on clinical outcomes and safety culture on inpatient units.

DESIGN: A 1-year prospective interventional study was conducted, followed by a 6-month sustainability phase.

SETTING AND PARTICIPANTS: Four medical and surgical inpatient units within an academic university medical center were included, with registered nurses and residents representing study participants.

INTERVENTIONS: In situ simulation training; debriefing of medical emergencies; monthly patient safety team meetings; patient safety champion role; interdisciplinary patient safety conferences; recognition program for exemplary teamwork.

OUTCOMES: Hospital-acquired severe sepsis/septic shock and acute respiratory failure; unplanned transfers to higher level of care (HLOC); weighted risk-adjusted mortality. Safety culture was measured using a widely accepted, validated survey.

RESULTS: Rates of hospital-acquired severe sepsis/septic shock and acute respiratory failure decreased on study units, from 1.78 to 0.64 (p=0.04) and 2.44 to 0.43 per 1,000 unit discharges (p=0.03), respectively. The mean number of days between cases of severe sepsis/septic shock increased from baseline to the intervention period (p=0.03). Unplanned transfers to HLOC increased from 715 to 764 per 1,000 unit transfers (p=0.08). The weighted risk-adjusted observed-to-expected mortality ratio on all study units decreased from 0.50 to 0.40 (p<0.001). Overall scores of safety culture on study units improved after the 1-year intervention, significantly for nurses (p<0.001), but not for residents (p=0.06). Scores significantly improved in nine of twelve survey dimensions for nurses, compared to in four dimensions for residents.

CONCLUSION: A multifaceted patient safety program suggested an association with improved hospital-acquired complications and weighted, risk-adjusted mortality, and improved nurses' perceptions of safety culture on inpatient study units.

KEY WORDS: patient safety; clinical microsystem; safety culture; teamwork; simulation training.
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INTRODUCTION

Patient safety in hospitals has improved in the past decade, but remains short of national goals.[1–7] Multifaceted strategies are needed to accelerate improvement efforts.

Differences in safety culture between hospital units suggest that culture is a local phenomenon, fueling interest in evaluating clinical microsystem improvement approaches.[8–11] Within a hospital, clinical microsystems represent teams of clinicians working together in local work areas (e.g., a medical ward), providing care for a population of patients.[12] The premise of the microsystem approach is that such teams are empowered to improve quality in their work environment.[13,14]

There is growing evidence that the microsystem approach is a powerful method to advance and sustain quality.[15–20] However, few of these programs have employed in situ simulation training. In situ simulation training fits well with the microsystem approach, because it fosters deliberate practice in the work environment and helps to discover latent safety threats.[21]. Reports of in situ simulation training conducted on inpatient microsystems provide initial evidence that this method can improve team performance and outcomes.[22–24]

We hypothesized that a multifaceted patient safety program, incorporating in situ simulation training, would improve rates of select hospital-acquired complications, unplanned transfers to higher levels of care, and risk-

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adjusted hospital mortality, as well as safety culture, on inpatient units.

METHODS

Study Design and Setting

Project TRANSFORM was a 1-year prospective cohort interventional study aimed at improving inpatient outcomes with a multifaceted, microsystem patient safety program. The study was approved by the Stanford Institutional Review Board and was conducted at Stanford Hospital, a 450-bed, Level I trauma academic medical center.

Our program was supported by hospital leadership. We collaborated with unit leaders [unit-based medical directors (UBMDs), managers, and clinical nurse specialists (CNSs)] of three medical intermediate intensive care units (IICU) and one surgical ward. A Masters-prepared registered nurse coordinated all program interventions. No other hospital quality projects were initiated during the study periods that were aimed at improving our program outcomes.

Participants

Registered nurses and internal medicine and surgery postgraduate year one (PGY-1) residents practicing on these inpatient units participated in program interventions across the study periods.

Planning Period

During the planning period (January–June 2010), unit leaders met with our project team to develop the implementation plan. We sought to improve early detection and treatment for hospital-acquired severe sepsis/septic shock, based on guidelines from the Surviving Sepsis Campaign[25] and hospital-acquired acute respiratory failure. A brief guideline detailing actions for early detection, initial diagnosis and treatment of acute respiratory failure was developed by intensivists and disseminated to participants.

The goal of in situ simulation training was to improve early detection and initial treatment for hospital-acquired complications and advance interdisciplinary teamwork. To learn to effectively conduct simulation exercises and debriefings, UBMDs, CNSs and the project manager completed a simulation instructor training course. We developed and validated simulation scenarios tailored to patient populations of study units. Simulation scenarios were designed to recreate clinical states of complications in the earliest phases, preceding acute clinical deterioration or need for a rapid response team (RRT) call. No scenarios involved emergent resuscitation. Technical and nontechnical competencies for simulation training are specified in Table 1. One month prior to the intervention period, participants participated in an educational session to learn about the patient safety program and teamwork competencies, and to complete baseline survey data.

Table 1. Improvement Strategies Employed in the TRANSFORM Patient Safety Program

IMPROVEMENT STRATEGY	INTERVENTION
Early Detection and Treatment of Hospital Complications	High-fidelity, in situ simulation training - Training facilitated by UBMDs and CNSs using a standardized checklist. Simulation training lasted ~30 min to minimize impact on competing clinical priorities and occurred on both day and night shifts. Training integrated into new-hire orientation for nurses. - Scenarios designed to simulate clinical states preceding acute deterioration to promote early detection and treatment - Training competencies: - Nontechnical: Crisis resource management teamwork behaviors relevant to early detection and treatment - Technical: Assessment, diagnosis, and treatment behaviors as detailed in clinical guidelines - Training rate: - Intervention period: Four exercises per unit per month - Sustainability period: One exercise per unit per month Unit patient safety champion role: Disseminated, promoted and reinforced education on clinical guidelines for select hospital-acquired complications
Identification of Safety Risks	Debriefing of medical urgencies and emergencies - Charge nurses led 5-min debriefing after Rapid Response Team and Code Blue Calls to discover unit/system factors contributing to need for call (e.g., paging issues) - Checklist was used to standardize debriefing process - Manager and unit-based medical director accountable to act on identified issues - Patient safety champion role: Encouraged safety reporting Latent safety threats discovered during simulation training communicated to unit leadership team for discussion/resolution
Quality Improvement of Interdisciplinary Care Issues	Patient safety champion role: - Presented case at monthly safety meeting and disseminated learnings and action plans to frontline clinicians Monthly unit patient safety team meetings - Unit leaders and champions reviewed case involving interdisciplinary care issues; leaders led solution-finding process, implemented defined action plans and monitored unit improvement Quarterly interdisciplinary patient safety conference - Conference held involving nurses, residents and attending physicians; attending physician led case review of interdisciplinary issues and facilitated group discussion to improve care issues
Individual Recognition of Exemplary Teamwork Performance	Monthly award given to recognize a nominated clinician demonstrating exceptional teamwork in clinical practice Award publicized via email to clinicians on units and to hospital executives

Intervention Period

Project TRANSFORM consisted of the following improvement strategies, which are further detailed in Table 1.

1. In Situ, High-Fidelity Simulation Training. Our goal was 90 % participation in at least one simulation exercise during the intervention. We conducted four in situ simulation exercises per study unit per month, on both day and night shifts. Simulation training and debriefings were facilitated by UBMDs and CNSs using a standardized checklist.
2. Debriefing of Medical Emergencies. Charge nurses on study units were responsible for conducting debriefings following RRT and Code Blue calls to discover factors contributing to the call. Our goal was to have 90 % of calls debriefed.
3. Unit Patient Safety Champion Role. At least one registered nurse per shift on each unit functioned as a patient safety champion.
4. Monthly Unit Patient Safety Team Meetings. Unit leaders were responsible to hold a meeting to review a case involving interdisciplinary care issues, as well as to define an action plan and monitor improvement. Our goal was 90 % leader participation in monthly meetings.
5. Quarterly Interdisciplinary Patient Safety Conference. A conference was to be held involving nurses, residents and attending physicians to discuss and improve upon interdisciplinary teamwork or care issues. Our goal was four conferences per year.
6. Individual Performance Recognition. An award was to be given to a nurse or resident nominated for demonstrating exemplary teamwork. Our goal was one award per month.

Sustainability Period

Based on the success of Project TRANSFORM after 1 year of intervention, we sustained the project for an additional 6 months. All study interventions were maintained, though simulation training decreased to one exercise per month.

Outcome Measures and Data Collection

Administrative (ICD-9-CM) codes were used to identify patients who had a study complication not present on hospital admission (Table 2). A chart abstractor retrospectively reviewed records of identified cases to confirm that: (1) the complication developed while the patient was on a study unit, (2) the hospital length of stay (LOS) on the study unit was greater than 12 h, and (3) complications met the clinical case definition (Table 2).

Twenty-five cases of each complication were randomly selected to determine inter-observer agreement. Medical records of selected cases were audited by an author (NS) using the clinical definition for each complication. We found 96 % agreement among cases of severe sepsis/septic shock (kappa coefficient 0.9495, Z 8.50) and 97.3 % for acute respiratory failure (kappa coefficient 0.9657, Z 8.55). A hospitalist with no involvement with the program validated all final identified complications.

Table 2. Definitions of Complications Developing on a Study Unit

A. Severe Sepsis (ICD-9-CD: 995.92 with one of following septicemia codes: 0.38.0–0.38.9)
Clinical Definition: Presence of sepsis and one or more of the following:
- new change in mental status
- capillary refill < 3 s
- increased oxygen need to maintain arterial oxygen saturation of > 90 %
- increase in serum creatinine of 0.3 mg/dl within 48 h
- urine output < 30 ml for more than 6 hours
- serum lactate > 2.0 mmol/L
- absent bowel sounds
- platelet count < 100,000
- total serum bilirubin > 4 mg/dl
- mottled or cool extremities
- systolic blood pressure < 90 mmHg or decrease of 40 mmHg or more from patient's hospital baseline

B. Septic Shock (ICD-9-CM: 785.52)
Clinical Definition: Severe sepsis with hypotension (as defined above) that did not resolve with two liters of intravenous fluid boluses or which reoccurred after administration of two liters.
C. Acute Respiratory Failure [ICD-9-CM: 518.81 with either 96.04 (intubation) or 93.90 (noninvasive ventilation)]
Clinical Definition: One or more of the following:
- arterial oxygen saturation of less than 85 %
- arterial partial pressure of oxygen of less than 60 mmHg
- arterial partial pressure of carbon dioxide of greater than 65 mmHg and, which resulted in either emergent use of bi-level positive airway pressure or intubation on a study unit

Rates of complications on study units were compared to all hospital, non-study inpatient units, which included medical and surgical wards and intermediate intensive care units (ICUs) whose patient populations were stable across the study periods. Complications were identified using administrative codes without medical record validation.

Data of all patients transferred to a higher level of care (HLOC) were obtained from internal administrative data. The abstractor reviewed medical records to determine whether the transfer was unplanned and the medical condition necessitating the transfer. An unplanned transfer was defined as any: (1) transfer to an ICU or an intermediate ICU and was not scheduled for ICU or intermediate Intensive Care Unit (IICU) admission following elective surgery or an elective procedure; or (2) transfer to the operating room (OR) for emergent reasons (excluded elective and planned surgery). We excluded patients who had a "do not resuscitate" (DNR) order at the time of transfer.

All hospital deaths that had at least one stay on a study unit during hospitalization were identified; deaths were excluded if: (1) a DNR order was documented during the first 24 h of admission and (2) the LOS on a study unit was less than 24 h. For a given patient, the total LOS spent on a study unit (s) was determined as a percentage of the total hospital LOS. The Elixhauser Comorbidity Index was used for risk adjustment.[26,27] Both observed and expected mortality were then weighted in proportion to the total LOS on a study unit, and the "weighted" risk-adjusted observed-to-expected (O:E)

Table 3. Safety Issues Discovered through Program Implementation and Actions Taken

Teamwork Issues	Actions
Suboptimal communication of changes in patient status	• 5-min videos demonstrating optimal Situation-Background-Assessment-Recommendation (SBAR) communication by unit clinical leaders was shown to staff during daily huddles • Charge nurses and patient safety champions were trained to "ask for an SBAR" from nurses when hearing of a condition change • A nursing competency on SBAR created requiring 1:1 demonstration and rated by CNSs • SBAR competency was observed during simulation training; if suboptimal, required to repeat performance • Paging guideline was implemented on study units to enhance use of SBAR when communicating patient problems
Inadequate bedside identification of caregiver roles	• Extender placed on name badges identifying role (e.g., nurse, resident, attending physician) • Role identification was observed during simulation training and 1:1 feedback given during debriefing
Staff nurses not reliably informing charge nurses of patient condition changes	• Charge nurses began rounding on patients minimally once a shift to prompt staff nurses to relay clinical changes • Competency of having nurses communicate changes to charge nurses was observed during simulation training and feedback given
Delays in communicating patient condition changes due to mobile nature of staff nurses on unit	• Nurses taught to relay phone number in patient's room when paging resident to ensure a more timely response • Nursing units purchased individual phones for nurses to avoid delays in communicating problems to physicians • Communication behavior observed during simulation training and 1:1 feedback given during debriefing
Early Detection Issues	**Actions**
Failure to compare current status to baseline status	• Nurses taught how to reconfigure electronic medical record to view baseline vital signs and laboratory values for comparison
Delays in diagnosis and treatment by residents due lack of consultation with senior clinician	• Education on need for early consultation was reinforced during simulation training, patient safety conferences and monthly meetings • Consultation competency for nurses and residents observed during simulation training and 1:1 feedback given
Variability in knowledge of diagnosis and treatment of study complications	• Sepsis order set was created in electronic medical record to support optimal ordering of diagnostic tests and treatment • Clinical guidelines for study complications were routinely discussed in depth at quarterly patient safety conferences • Knowledge competencies and ordering behaviors were observed during simulation training and feedback given
Role of "relief nurse" on unit was task-driven	• Role description of relief nurse was revised to emphasize coaching role to help nurses critically think through condition changes and take action
Care Escalation Issues	**Actions**
Least experienced resident being called first for urgent patient situation	• Unit guideline defined new process that intern and senior resident need to be concurrently called for urgent/emergent situations • Guideline disseminated among nurses and supported by UBMDs in monthly unit resident orientation
Suboptimal knowledge of chain of command (COC) and assertion in escalating care	• CNSs reinforced COC to staff nurses during huddles • Patient safety conferences reviewed COC and method for asserting care escalation in face of perceived authority gradients • Patient safety champions empowered staff nurses to elicit COC • COC knowledge and assertion competencies observed during simulation training and feedback given

mortality ratio was determined, based on the premise that clinical deterioration of patients is proportional across inpatient units where they stayed during the LOS. Clinical outcomes were measured at baseline (July 2009–June 2010) and for intervention and sustainability periods.

Safety culture on study units was assessed at baseline and after 1 year, using the Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture (HSOPS).[28] HSOPS data for nurses on non-study, medical-surgical inpatient units were available for baseline and post-intervention periods from an organizational-wide survey. Survey results were analyzed following AHRQ scoring methodology.[28] Participant responses of "agree" and "strongly agree" on the survey's five-point Likert scale constituted the mean percent positive scores (0–100 % measurement range). All survey results are reported as percent positive scores.

Statistical Analysis

Multivariate regression was used to assess the effects of the program on complication rates and mortality over the three time periods, adjusting for patient characteristics. Control variables included patient age, race, payer status, inpatient

Table 4. Rates of Hospital-Acquired Severe Sepsis/Septic Shock and Acute Respiratory Failure on Study Units

	Baseline Period (July 2009–June 2010)	Intervention Period (July 2010–June 2011)	Sustain Period (July–Dec 2011)	Odds Ratio (95 % CI)	p value
Rate of Severe Sepsis/Septic Shock (complications/1000 unit discharges)	1.78	1.21	0.64	0.53 (0.29–0.96)	0.04
Cases of Severe Sepsis/Septic Shock	16	11	3		
Rate of Acute Respiratory Failure (complications/1,000 unit discharges)	2.44	2.10	0.43	0.58 (0.35–0.96)	0.03
Cases of Acute Respiratory Failure	22	19	2		
Unit Discharges	9,000	9,058	4,685		

admission status, and Elixhauser comorbidities.[26,27] Model parameters were estimated using unconditional least squares and goodness-of-fit evaluated by the likelihood ratio test. G charts were used to calculate the number of days between complications.

Linear regression was used to evaluate the effect of the program on the rate of unplanned transfer to HLOC. Pearson's chi-squared tests with Yates' continuity correction and Fisher's Exact test were used to analyze the safety culture data. All statistical analyses were performed in SAS v9.3 (SAS Institute, Inc., Cary NC, USA). A p value of < 0.05 was considered to denote statistical significance for all outcomes.

RESULTS

Program Interventions

After 1 year of intervention, 90 % of nurses (N=247) and 92 % of residents (N=56) on study units had participated in at least one simulation training exercise, with 43 % of nurses and 20 % of residents participating in two or more. Four simulation exercises were conducted each month on each unit during the intervention period and one exercise was conducted each month on each unit during the sustainability period. At the end of the sustainability period, 98 % of nurses (N=269) and 100 % of residents (n=61) had participated in simulation training.

Microsystem leaders led 90 % of monthly patient safety team meetings during intervention and sustainability periods, and each study unit maintained one unit patient safety champion per shift. Patient safety conferences were held each quarter and 90 % of RRT and cardiopulmonary arrest calls were debriefed. Each month during the study, one nurse or resident received teamwork recognition. Of the numerous safety issues discovered by microsystem leaders during the study, the most prevalent issues focused on interdisciplinary teamwork, early detection and care escalation (Table 3).

Outcomes

A total of 13,743 patients were discharged from the study units during the study. The rate of hospital-acquired severe sepsis/septic shock on study units decreased from 1.78 to 0.64 per 1,000 unit discharges across intervention and sustainability periods (odds ratio, 0.53; 95 % CI, 0.29–0.96; p=0.04) (Table 4). The mean number of days between cases of severe sepsis/septic shock statistically increased from 18 at baseline to 34 during the intervention period (p=0.03), with rates decreasing to 25 during the sustainability period (Fig. 1a). No significant change in the mean number of days between cases of acute respiratory failure occurred across study periods (p=0.25) (Fig. 1b). The rate of hospital-acquired acute respiratory failure decreased from 2.44 to 0.43 across the study periods

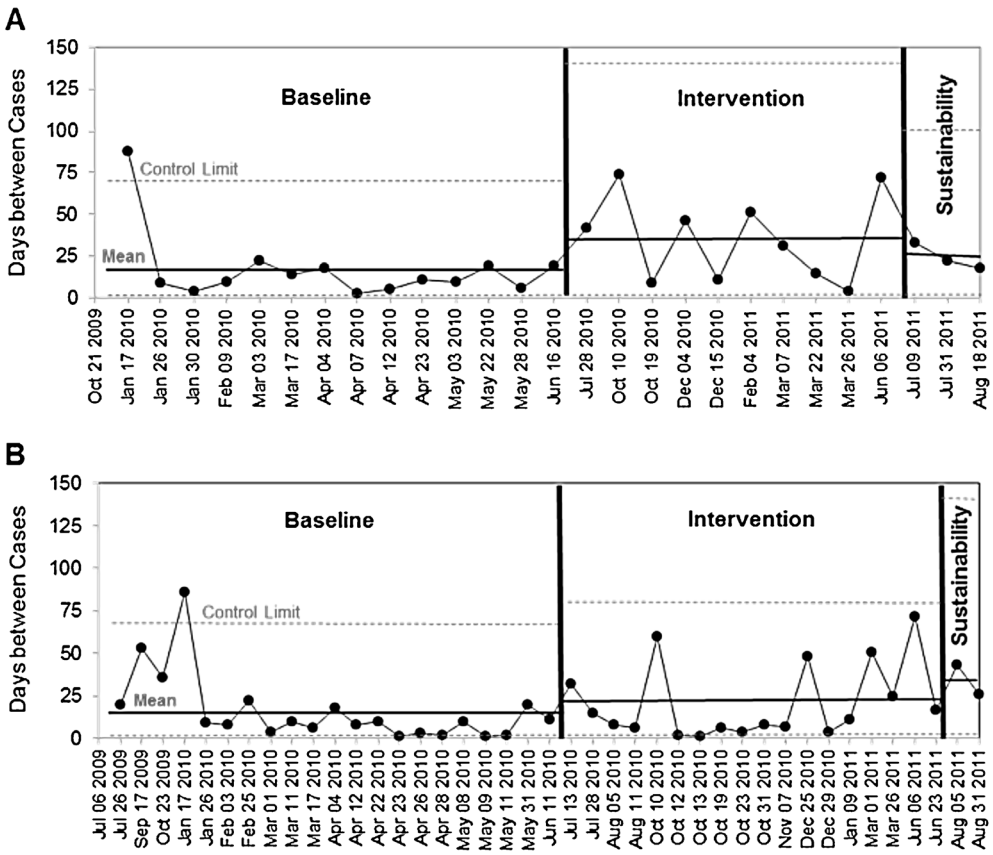

Figure 1. G-Charts showing days between cases on study units of: a severe sepsis/septic shock, and b acute respiratory failure.

(odds ratio, 0.58; 95 % CI, 0.35–0.96; p=0.03) (Table 4). While rates on study units decreased over time, the rates of both complications occurring on non-study inpatient units statistically significantly increased during intervention and sustainability periods (Fig. 2a and b).

The rate of unplanned transfers to HLOC increased from 715 to 764 per 1,000 unit transfers across the study periods (p=0.08) (Table 5a). The medical conditions primarily contributing to the increase in unplanned transfers across the study periods were conditions not related to study complications (Table 5b). The weighted, risk-adjusted observed-to-expected (O:E) mortality ratio on study units was 0.50 at baseline, which decreased to 0.44 during the intervention period, and decreased to 0.40 during the sustainability period (odds ratio, 0.95; 95 % CI, 0.94–0.97; p<0.001).

The response rates of nurses and residents to the safety culture survey were 93.4 and 49.2 %, respectively, after 1 year of intervention. The overall percent positive survey score for nurses practicing on study units significantly increased from 64.9 to 84.7 % after 1 year of intervention (p<0.001), compared to scores for nurses on non-study inpatient units (p=0.70) (Table 6; Fig. 3). Statistically significant improvement in percent positive scores for nurses on study unit occurred in nine of the 12 survey dimensions, including teamwork within and among units (p<0.001). Overall percent positive scores for residents increased from 61.2 to 65.8 % after 1 year of intervention, but results did not reach statistical significance (p=0.06) (Table 6). Residents' scores significantly increased in four of the 12 survey dimensions, but decreased significantly in three. No statistical significant change occurred in residents' scores for teamwork within units or among units.

DISCUSSION

This prospective study evaluated the effects of a multifaceted microsystem-level patient safety program, involving in situ simulation training, on safety culture and clinical outcomes. We found significant improvement in nurses' perception of safety culture, and an association with improved hospital-acquired complications and weighted, risk-adjusted mortality.

Previous reports of unit-based patient safety programs have also shown similar improvement in outcomes. For example,

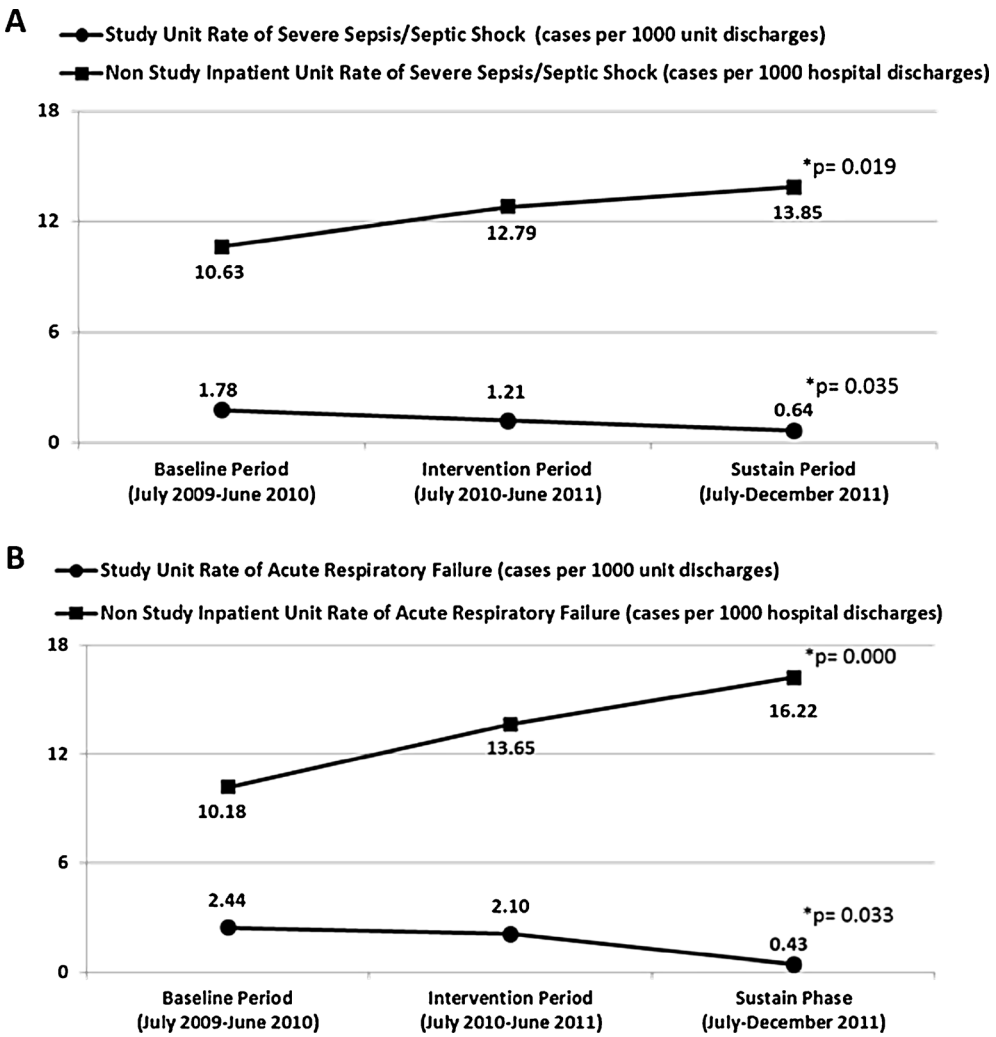

Figure 2. Rates of hospital-acquired complications on study units compared to non-study hospital units (a severe sepsis/septic shock, b acute respiratory failure).

Table 5. Unplanned Transfers to Higher Level of Care (HLOC) on Study Units

A. Effect of Intervention on Rates of Unplanned Transfer to HLOC					
	Baseline Period (July 2009–June 2010)	Intervention Period (July 2010–June 2011)	Sustain Period (July–Dec 2011)	Odds Ratio (95 % CI)	p value
Rate of Unplanned Transfers to HLOC (per 1,000 Transfers to HLOC)	715	763	764	1.27 (0.97–1.66)	0.08
Number of Unplanned Transfers to HLOC	525	583	281		
Total Transfers to HLOC	734	764	368		
B. Medical Conditions Associated with Unplanned Transfers to HLOC					
Medical Conditions	Baseline Period (July 2009–June 2010)		Intervention Period (July 2010–June 2011)		Sustain Period (July–December 2011)	
	N	%	N	%	N	%
Acute Respiratory Failure (met study definition)	22	4.2	19	3.3	2	0.7
All Other Acute Respiratory Failure (not meeting study definition*)	98	18.7	96	16.5	39	13.9
Dysrhythmia	72	13.7	93	15.9	38	13.5
Hemorrhage	34	6.5	43	7.4	18	6.4
Severe Sepsis/Septic Shock (met study definition)	16	3.1	11	1.9	3	1.1
All Other Severe Sepsis/Septic Shock (not meeting study definition*)	33	6.3	32	5.5	28	10.0
Stroke	15	2.9	15	2.6	7	2.5
Other	235	44.8	274	47.0	146	52.0
TOTAL	525	100 %	583	100 %	281	100 %

**Condition present on hospital admission or did not develop on study unit; unit length of stay < 12 h; do-not-resuscitate order documented; no intubation or use of bi-level airway pressure for acute respiratory failure*

the Comprehensive Unit Safety Program (CUSP) studied the effects of safety hazard identification, executive partnership, learning from defects, and a focus on teamwork and communication.[15] Studies employing CUSP have shown significant improvement in safety culture and teamwork climate, hospital length of stay, medication error rate, nurse turnover rates and rates of central-line–associated bloodstream infections.[15–17,29,30] Similarly, the Triad for Optimal Patient Safety Project showed the effects of team training, unit-based safety teams and patient engagement on improvement in safety culture after 1 year.[18] A Dartmouth study found that an ICU intervention model that included team building, uniform system redesign, use of safety measures and enhanced communication resulted in significant improvement in adherence to measures to prevent ICU complications.[31] Other unit-based studies have shown significant reductions in unplanned transfers to ICU and unexpected hospital deaths on a variety of hospital units, from the use of low-fidelity simulation training, track and trigger systems and frequent unit-based huddles aimed at risk management reduction.[20,32] This initial evidence demonstrates that microsystem-based approaches can produce improvements in safety culture and clinical outcomes.

Project TRANSFORM is the first multifaceted patient safety program we are aware of that employed high fidelity, in situ simulation training as an intervention in clinical microsystems. We found this approach to be feasible and effective. This experiential learning afforded clinicians protected time to practice defined competencies and gain insights in how to improve as a team. This training also afforded UBMDs and CNSs the opportunity to evaluate progress on team performance on their clinical microsystem and have teams demonstrate specific competencies again, when needed. We believe that our findings provide strong evidence of the incremental value of in-situ simulation team training.

We attribute improvement in outcomes to all interventions, not only simulation training, since all heightened safety awareness through dynamic activities on study units. The interventions led to the discovery of active and latent safety issues on our clinical microsystems that involved complex, interdisciplinary care practices that directly influenced patient safety (e.g., problematic communication, care escalation) (Table 3). The involvement of microsystem leaders played a major role in improving routine clinical processes.

The rate of unplanned transfers to HLOC increased throughout the intervention and sustainability periods. This finding, in opposition to our hypothesis that earlier detection and treatment of complications would lead to fewer unplanned transfers, may be related to enhanced vigilance and advocacy to seek the appropriate level of care for patients. Additional factors that may have contributed to the rise in unplanned ICU transfers include the emphasis placed on calling for help early, communicating changes in clinical deterioration early, and care escalation during simulation training.

Safety culture is an important determinant of clinical outcomes.[3,33–35] Our program significantly improved nurses' overall percent positive scores on study units, as compared to overall scores for nurses on non-study inpatient units (Fig. 3). We attribute this improvement not only to program interventions, but to actions taken in response to identified teamwork issues on study units (Table 3). Residents' overall

Table 6. Safety Culture Percent Positive Scores of Nurses and Resident Physicians Practicing on Study Units (Mean Percent Positive Scores Determined Using "Agree" and "Strongly Agree" Responses on the Survey's Five-Point Likert Scale)

	Nurses			Residents		
	Baseline (%) June 2010 (*N*=95)	Post-Intervention (%) June 2011 (*N*=256)	p value	Baseline (%) June 2010 (*N*=36)	Post Intervention (%) June 2011 (*N*=30)	p value
UNIT DIMENSIONS						
Teamwork Within Units	95.2	98.8	< 0.001	96.1	94.0	0.53
Manager Expectations	51.7	90.5	< 0.001	50.7	83.6	< 0.001
Organizational Learning	93.9	95.7	0.34	87.0	91.5	0.65
Management Support	72.6	87.5	<0.001	79.7	74.1	0.59
Error Feedback & Communication	92.4	94.0	0.51	74.7	48.7	0.01
Communication Openness	60.5	90.4	<0.001	55.9	77.1	0.03
Non-Punitive Response	49.5	52.9	0.45	41.8	58.5	0.137
Staffing	44.3	71.5	<0.001	41.5	67.1	0.001
HOSPITAL DIMENSIONS						
Teamwork Across Units	56.3	86.2	<0.001	60	67.2	0.44
Handoffs and Transitions	39.9	66.1	<0.001	49.4	16.9	<0.001
SAFETY OUTCOMES						
Overall Perceptions	61.1	80.8	< 0.001	51.0	70.5	0.01
Frequency of Events	83.9	91.6	0.002	56.9	23.1	0.002
Overall Percent Positive Score	64.9	84.7	< 0.001	61.2	65.8	0.06

scores did not significantly improve, although significant improvement was attained in four of the survey dimensions. We attribute the lack of improvement in resident scores and the decrease in scores for three survey dimensions to many contributing sampling and exposure factors. The low survey response rate for both pre-surveys and post-surveys likely introduced bias. Importantly, the cohort of residents completing the baseline and who were exposed to program interventions differed from residents completing the survey after 1 year. Resident rotation to different medical centers during the study periods, along with residents being intermittently present on study units due to co-location issues and consultation, may have prohibited residents' exposure to program interventions and affected their perceptions of safety culture. That nurses' safety culture scores significantly increased compared to residents' scores is consistent with previous research and can be explained by nurses' stable presence on clinical microsystems compared to residents.[18]

This study has several limitations. First, this was not a randomized controlled trial, limiting ability to infer causation between our interventions and improved outcomes. On the other hand, by controlling for patient comorbidities and weighting the outcomes by time on the study unit, and based on the size of differences we found, the findings are still very suggestive of an impact. We, however, are unable to distinguish which of our program's multiple interventions contributed to our results.

Secondly, our ability to identify cases of complications in our study may have been influenced by variability in physician documentation and coding practices.[36,37] Although we sought to control for other factors, our program was associated with a significant decrease in the rate of complications on our study units (Fig. 2).

We excluded hospital deaths in our mortality analysis if a DNR order was written within 24 h of admission, with the justification that treatment for DNR patients would be different. While variability in physician documentation of DNR orders during the study may have potentially affected the analysis, we project that DNR exclusions would have minimal effects on our results.

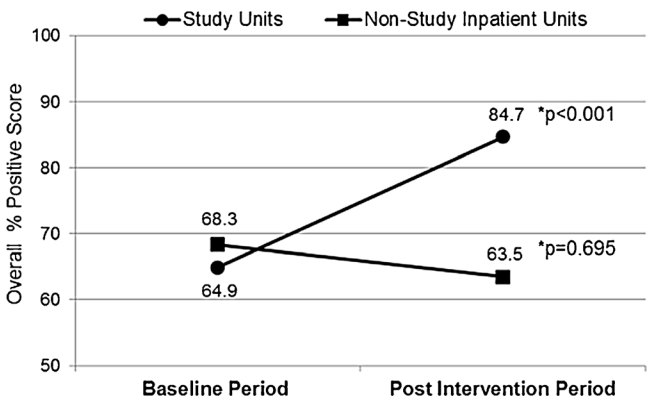

Figure 3. Nurses' perceptions of safety culture on study and non-study inpatient units.

CONCLUSION

Project TRANSFORM adds to the evidence that improvement in safety culture can be attained with a microsystem approach that embraces multiple interventional strategies, and that in situ simulation team training is feasible and substantially augments the microsystem approach. Our findings also suggest an association with improved hospital-acquired complications and weighted, risk-adjusted mortality. Future research is needed to corroborate the program's effect in reducing complication rates using prospective case identification, and to understand if the effectiveness of this bundle of multifaceted improvement strategies is stable across inpatient microsystems possessing different practice elements.

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