Title: Making Acute Care More Patient Centered, Patient Safety Learning Laboratory (PSLL)

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~~Patient Safety Learning Laboratory (PSLL) Administrative Core~~

ABSTRACT

Purpose: We assembled a core team with expertise in project management, implementation science, data analysis, and research methodology.

Scope: Our goal was to design, implement, and evaluate a suite of tools integrated within a vendor Electronic Health Record to improve patient safety. The administrative core focused on the lessons learned and challenges and recommended solutions throughout the project lifecycle.

Methods: The Administrative Core provided leadership, organization, and coordination of PSLL activities. This core focused the teams on the overarching goals and provided oversight of the following activities: 1) collaboration and communication between team members, collaborators, and stakeholders; 2) selection of strategies for utilizing HIT to facilitate patient activation in reducing harm in hospital settings; 3) scientific support for study design and analyses; 4) adherence to allotted time frames and budgets; and 5) coordination of Health Information Technology (HIT) development and use of resources across projects.

Results: The administrative core oversaw the multidisciplinary approach to the design, development, and implementation of the intervention, considering the complex organizational environment, research needs, and technology governance. The PSLL intervention was implemented on 12 inpatient units during the 18-month study period, potentially impacting 12,628 patient admissions. The administrative core contributed to the design and development activities, defining key implementation goals and lessons learned at each project phase, and ensured that the project teams utilized the RE-AIM framework (reach, effectiveness, adoption, implementation, maintenance) to guide the study design and focus on external validity.

Key Words: Patient safety, health information technology, quality improvement, consumer health informatics, patient-centered care

Systems Engineering, Usability, and Integration (SEUI) Core

ABSTRACT

Purpose: We assembled a core team with expertise in systems engineering and human factors (SE/HF) as part of an AHRQ-funded patient safety learning laboratory.

Scope: Our goal was to optimize a suite of novel health IT tools integrated with our electronic health record to identify, assess, and mitigate threats to patient safety in real time.

Methods: We employed a variety of SE/HF methods to analyze problems, design and develop improvements to intervention components, support implementation, and evaluate this system-of-systems as an integrated whole. To assess the utility of SE/HF supporting this work, we surveyed and conducted focus groups of project team participants to assess their experience using these methods.

Results: We identified seven key themes using a group consensus approach. Our experiences can help guide other organizations in using SE/HF to improve patient safety in the hospital.

Key Words: Systems engineering, human factors, patient safety

PURPOSE

We established a core team with SE/HF expertise to support individual project teams in introducing a suite of health IT tools integrated with the electronic health record (EHR) from analysis of problems, design and development of intervention components, and implementation and evaluation. Our objectives were:

- To assemble an interdisciplinary team with expertise in systems engineering (SE), human factors (HF) and usability, and data analytics as part of a large, AHRQ-funded Patient Safety Learning Laboratory (PSLL)
- To facilitate the planning, design, development, implementation, and evaluation of a suite of novel health IT tools (patient portal, bedside display, safety dashboard) that serve to reliably identify threats to safety as a unified "system-of-system," integrated with our EHR

SCOPE

The safety failings of healthcare systems are attributed to difficulty introducing new initiatives in complex settings. To maximize success of hospital safety and quality improvement initiatives, implementation teams must define problems, understand workflows, analyze user requirements, identify potential barriers, predict failures, and continuously improve. Applying SE/HF methods to a broad range of processes should help create practical, reliable, and generalizable health IT-enabled interventions that serve to engage patients and clinicians in

identifying, assessing, and mitigating threats to safety, thereby decreasing adverse events related to hospital-acquired conditions.

METHODS

We created a core team (physician with expertise in hospital medicine and clinical informatics, a professor of health systems engineering, 1-2 rotating graduate SE students, an HF expert, and a research assistant) tasked with supporting the three project teams in introducing a suite of EHR-integrated health IT tools to identify, assess, and mitigate threats to patient safety in real time as a unified intervention. We frequently interacted with hospital quality and safety leaders; hospital-based clinicians; clinical unit leaders; patients and patient advocates; and institutional stakeholders. Our team was tasked with providing methodological assistance to each project team using a subset of SE/HF methods following the systems engineering lifecycle.

RESULTS

Our experience employing SE/HF methods are summarized as follows:

- Interviews, focus groups, usability testing, and workflow observations were used most often; these were employed directly by individual project teams familiar with these methods because of their quality improvement and informatics backgrounds.
- SPC, FMEA, and RCA were least often used; these were most often employed by the core team, not individual project team members.
- Usability testing, interviews, and cognitive analyses generated a high level of insight, regardless of how frequently they were used.
- Cognitive load and task analysis were conducted on a specific intervention sub-component (safety dashboard's "opioid management" domain), in which a clinician was asked to complete a complex task via the EHR and the safety dashboard.
- Use and compliance reporting comprised an instrumental, data-driven approach for generating buy-in from clinicians and unit leadership and to promote end-user adoption during implementation.
- Simulation modeling did not generate much insight per survey respondents; we attribute this to challenges in obtaining timely access to institutional data and our use of Monte Carlo simulation largely to support post-intervention analysis during the current evaluation phase, not to inform design and development during earlier phases.

Regarding lessons learned, the overall structure of the PSLL may have contributed to a disconnect between core and individual project teams. There was consensus that each project team worked toward individual deliverables independent of methods assistance from the core team. At the beginning, we struggled with a lack of clarity of roles and responsibilities, variable degrees of experience of participants, insufficient resources, competing project priorities and development schedules, team-forming dynamics, and balancing rigorous academic vs. practical user experience research ("R" vs. "r"). In latter phases, more SE/HF methods were applied across projects (FMEA, use and compliance reporting, cognitive load and task analysis), which encouraged more cross-project participation and cohesiveness between the different components. Although there was clear intent from the onset for the individual tools to function as a unified intervention, their design early on did not fully consider their role within the larger systems-of-systems.

In summary, we employed a SE/HF approach to support introduction of novel, EHR-integrated health IT tools as a systems-of-systems to mitigate preventable harm to hospitalized patients. Our recommendations (**Table 1**) should be useful to other institutions considering this type of collaboration.

Table 1. Key Challenges and Recommendations for Using Systems Engineering and Human Factors Methods

Category	Key Challenges	Recommendations
Methods	• Ensuring consistency and standardization across projects • Contemplating trade-offs at individual project vs. system-of-system level	• Set expectations to ensure consistent and standard use of methods at the beginning • Develop standardized templates and test plans that could be used across projects

	• Navigating appropriate rigor for academic vs. practical use: "r" vs. "R" research • Dealing with varying degrees of project team member understanding of methods	• Conduct learning sessions by SE/HF experts to facilitate project member understanding of methods and appropriate level of rigor • Engage project teams in systems-level thinking
Team Logistics	• Navigating a decentralized project team structure with competing interests • Synchronizing phases across sub-projects	• Underscore centralized SE/HF expertise and leadership from the outset • Encourage project management to engage with core experts to ensure synchronization
	• Frequent research team transitions • Arduous on-boarding process for rotating, cross-institutional team members	• Centralize project management within core to ensure more seamless transition • Assign appropriate roles and expectations for active and passive participants
Data Needs	• Managing conflicting requirements for operational priorities vs. research purposes	• Develop quarterly reports that demonstrate alignment in tool use with hospital-reported safety process measures to drive adoption
	• Navigating data ownership (i.e., nursing vs. physician sensitive data)	• Engage stakeholders early during project to identify data sources and seek administrative approvals for access

Project 1- Fall Prevention

ABSTRACT

Purpose: The study aim was to engage patients and their family caregivers in the design of a fall prevention toolkit; to implement and iteratively refine the toolkit for use during an acute hospitalization; and to evaluate the effects of the intervention on patients' perceptions of fall risk communication, care plan concordance by patients and care team members, and the incidence of patient falls and fall-related injuries.

Methods: Iterative participatory design methods were used to involve patients, families, and clinicians in design, development, and testing of a patient-centered Fall TIPS Toolkit. The toolkit was implemented within the existing institutional framework at two large academic medical centers in the Northeast. After a pilot in which we evaluated usability of the toolkit in the context of acute care workflows, we used a 21-month pre/post study to evaluate the long-term effectiveness of the toolkit on reducing falls and falls with injury at three large academic medical centers with ethnically diverse patients.

Results: After the successful development of both low and high-tech modalities of the Fall TIPS Toolkit, the outcomes of this project are the intervention's impact on patient activation and patient falls/injurious fall trends. The Fall TIPS Toolkit has been widely disseminated to prevent falls in hospitalized patients.

Key Words: innovation science, patient safety, quality, clinical decision support, fall risk assessment, fall prevention, information technology

Scope (Background, Context, Settings, Participants, Incidence, Prevalence).

Since 2007, our team has studied the problem of falls in hospitalized adults.[1-9] Our team learned that patient falls are a consequence of suboptimal communication and that fall prevention is a three-step process: 1) assessing fall risk, 2) developing a personalized prevention plan, and 3) executing the plan consistently, along with universal fall precautions (e.g., clear path to bathroom, wiping up spills, patient call bell in reach, etc.). Providing bedside tools to communicate patient-specific fall risk status and a tailored plan can ensure that all care team members have the information they need to routinely engage in the fall prevention process.[2]

Based on these findings, a web-based fall prevention toolkit, Fall TIPS (Tailoring Interventions for Patient Safety), was developed and tested in four academic medical centers within a large healthcare system in the Northeast United States. Nurses would complete an online fall risk assessment, triggering the automatic selection of multifactorial fall prevention plan tailored to each patient's specific risk factors. The nurse could then further tailor the plan based on their clinical judgment and knowledge of the patient. Three output tools---a bedside poster, plan of care, and a patient education handout---were then printed to communicate fall risks/interventions via icons depicting fall risk factors (e.g., unsteady walk, medication side effects) and fall prevention interventions (e.g., assist to bathroom, walking aid). These icons were validated with professionals and nursing assistants.[10] Fall

TIPS print-outs replaced the generic "high risk for falls" signs typically used in hospitals. In a randomized control trial involving over 10,000 patients, Fall TIPS reduced patient falls by 25% and was most effective with patients over age 64.[1]

A follow-up case-control study[3, 11] was performed to determine why some patients on intervention units fell, despite having access to the toolkit and found that the most frequent root cause was patient nonadherence to the fall prevention plan. For example, despite the toolkit recommendation for planned assistance, incident reports indicated that patients were frequently alone at the time of the fall. Other studies have also identified suboptimal patient adherence with fall prevention interventions. Bedside interviews with patients who had fallen in the hospital revealed that patients, particularly those who were younger and more independent at home, did not believe their risks for falling.[12]

The aim of this study was to partner with patients and families to develop and evaluate the bedside tools, strategies, and techniques that are needed to engage patients and family caregivers in the three-step fall prevention process. Another intention was to increase accessibility to Fall TIPS by hospitals that did not have the funds or the informatics expertise to implement a sophisticated electronic solution. We hypothesized that a suite of both low- and high-tech tools with varying levels of automation would enhance adherence to the fall prevention plan and further reduce fall rates.

Several pilot studies and a long-term pre/post analysis of the Fall TIPS Toolkit were conducted on adult medical, surgical, oncology, and neurology units in three academic medical centers: Brigham and Women's Hospital (BWH; Boston, MA), Montefiore Medical Center (MMC; Bronx, NY), and New York-Presbyterian/ Columbia University Medical Center (NYP; New York, NY).

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

Problem Analysis. Individual and group interviews and workflow analyses were used to learn about the needs and preferences of patients and providers and other sociotechnical factors that relate to fall prevention. This information informed the design and development of the toolkit. Basic content analysis methods[39] were used to interpret descriptive data obtained from interviews. Workflow analysis was completed to validate interview findings and to explore opportunities for use of electronic tools to improve communication and fall prevention practices on patient care units. Using methods applied in our previous work,[13-16] patient and care team interactions related to the three-step fall prevention process were observed. A series of direct observations of patients and providers during this Problem Analysis was used to 1) identify current workflow patterns and 2) consider how they might be impacted by the intervention. This information informed the configuration of the intervention and was used to anticipate needs for training.

Design & Development. Common themes of interviews and workflow analyses were prioritized, mapped to the three-step fall prevention process, and used to inform the toolkit prototypes. Initial mockups were developed, refined, and iteratively tested and evaluated with patients, families, and other stakeholders. This included icon content validity index (CVI) testing to ensure patient comprehension. Here, 88 patients and 60 nurses from oncology and medical units at BWH and MMC rated the degree to which six fall risk icons and 10 fall prevention intervention icons represented the concept (e.g., walking with assist) on a 4-point Likert scale (icon validation process/results published previously).[17, 18] Software simulation was used throughout the development process to explore the potential impact of the toolkit on workflow. There was a need for standardization, interoperability, and integration of the toolkit with other patient safety tools being developed simultaneously through the larger AHRQ-funded study (published previously).[19] Through collaboration with the system engineers at Northeastern University's Healthcare Systems Engineering Institute and usability experts, the design process was informed by end user needs and usability considerations. Each component of the toolkit's requirements (e.g., legibility of icons from the bedside, efficacy of color mapping in linking patient's individual risk factors to corresponding interventions, adequacy of decision support incorporated into the design, fit within existing workflow, re-use of existing EHR data to populate tools) was assessed. Using develop-test-revise iterations, prototypes were refined and usability testing was conducted until a sufficiently mature version of the toolkit was developed that stakeholders agreed would support patient and family engagement in the three-step fall prevention process without significant usability problems.[17, 18]

Implementation. *Laminated paper poster pilot testing:* The Fall TIPS laminated paper poster was pilot tested (published previously)[3] on seven medical units within BWH and one medical unit at MMC.[20] The majority of patients on the MMC unit were Spanish speaking, which allowed us to test the efficacy of Fall TIPS in a diverse patient population. The research team created a training competency and recruited unit "Champions," or super-users, to facilitate trainings on the evidence-based fall prevention toolkit via in-service

education, meetings with staff, practice councils, and clinical leadership. Champions collected baseline and post-implementation data on patients' perceived abilities to identify their risk factors for falls and the components of their personalized fall prevention plan. A Mann-Whitney U test was used to compare patient knowledge pre and post intervention. During go-live, 11"X17" laminated paper posters were hung at the patients' bedsides, and units Champions continued to provide training, support, and peer feedback to the staff nurses. Compliance audits were performed on a weekly basis to collect information on whether the posters were completed with the correct information, indicating adherence to the protocol. Audits consisted of three questions: 1) is the Fall TIPS Toolkit completed correctly and displayed at the bedside, 2) is the patient/ family familiar with their fall risk factors, and 3) does the patient/family understand their fall prevention plan? Fall and fall with injury rates for participating units were collected in the pre and post implementation periods.[3]

Paperless bedside display (screensaver/mobile device) pilot testing: The Fall TIPS paperless bedside display was implemented as single component of a larger integrated suite of clinical dashboard tools (Patient-centered Fall Prevention Toolkit, Patient Safety Checklist Tool, and MySafeCare patient reporting system) on two oncology units at BWH.[19, 21] This modality was integrated with the EHR accessed through an existing electronic bedside communication center, allowing for observation of the effect of Fall TIPS itself and in the context of the larger integrated suite of tools. The pilot implementation provided an opportunity to enhance the software and to correct any "bugs" that could lead to "workarounds" and impede adoption. A human factors evaluation of the toolkit by patients and clinicians was performed to reveal 1) the facilitators and barriers to effective use of the toolkit by patients and/or family members and 2) how communication and collaboration related to the fall prevention process changed from the pre- to post-intervention period. The pilot provided an opportunity to test the integrated system and identify any sociotechnical factors or unintended consequences that could limit effectiveness or create excessive work burden on care team members.[19, 21] After the toolkit was refined and the most effective training techniques for patients and providers were identified, the paperless bedside display was rolled out to three neurology units at BWH.

Modality Efficacy Comparison: The relative effectiveness of the Fall TIPS EHR-integrated, laminated paper poster, and paperless bedside display modalities in engaging patients and families in the three-step fall prevention process was evaluated on medical and neurology units at BWH, MMC, and NYP (published previously).[22] Effectiveness was defined by the patient/family's ability to express their personalized fall risk factors and prevention plan. Presence of the personalized prevention plan at the bedside indicated adherence to the protocol.

Long-Term Efficacy: After substantial testing and refinement, 14 patient care units within three academic medical centers in two geographic regions with diverse patient populations implemented either the EHR-based or the laminated paper poster Fall TIPS Toolkit between September 2015 and November 2016. The purpose was to rigorously evaluate the toolkit's efficacy over a 21-month pre- and post-intervention period. Each hospital was able to choose to implement the modality that best fit into their existing workflows. MMC and NYP implemented the EHR version, and BWH implemented the laminated paper poster. We used a Peer Champion model for education and training, as previously described.[13]

Evaluation. *Long-Term Efficacy:* The research team tracked outcome measures related to each component of the RE-AIM framework. In addition to the quantitative measures, focus group-style interviews using methods described in the Problem Analysis were conducted to identify patient and care team perceptions of the facilitators and barriers to use of the patient-centered toolkit and recommendations for improvement. Throughout the evaluation we sought to answer whether use of a patient-centered Fall TIPS Toolkit by patients and family 1) improves patient activation in the three-step fall prevention process and 2) leads to fewer falls and injurious falls.

In the long-term pre/post analysis at BWH, MMC, and NYP, patient falls and falls with injury were obtained from each hospital's event reporting system. Use of the toolkit components was tracked via unannounced site visits and compliance audits. The effect of the intervention on patient falls (dichotomized as fall/no fall) and falls with injury (dichotomized as falls with injury/no injury) was analyzed using logistic regression estimated via generalized estimating equations (GEE) to account for clustering within unit. The global concordance with fall prevention plan score was dichotomized (0 to 5 vs. 6 to 12). Logistic regression via GEE to account for clustering within unit was used for the latter two outcomes. The main predictor was the patient centered Fall TIPS Toolkit effect, tested by comparing the intervention to no intervention (usual care).

Patient Activation: The effect of Fall TIPS on patient activation, or the level of knowledge, skill, and confidence one has in managing their health, was measured using an adaptation of the 13-question Patient Activation Measure (PAM)[23-25] survey (to be reported elsewhere). The survey was administered to patients at six units at BWH and one unit at MMC and NYP over a period of 15 months prior to the implementation of Fall TIPS and 15 months post implementation. A robust t-test was used to compare pre- to post-implementation patient activation.

This implementation science study is not without limitations. Due to the nature of this work, the problem analysis, design, development, implementation and evaluation were not chronological, but iterative. Development of each Fall TIPS modality arose from barriers identified through continuous feedback provided during all stages of the project. There is a possibility that, by changing processes (e.g., working with clinical groups, engaging in participatory design), we impacted practice and outcomes.

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications).

Problem Analysis. Initial workflow observations revealed much variation in practice related to the three-step fall prevention process between hospitals in the study. MMC was not using any tailored fall prevention tool at the beginning of this project. BWH had access to a simple Fall TIPS laminated paper poster prototype that was based on findings from the team's previous research[1, 2, 12] and a fall prevention program observed during a visit to Cathay Hospital in Taiwan. At this time, BWH did not have electronic clinical documentation; however, it was scheduled for implementation during this project. MMC had electronic clinical documentation and was changing EHR vendors during this study. It was hospital policy for nurses to perform the fall risk assessment once per shift at both BWH and MMC. Because MMC did not have a paper tool, nurses would document fall risk factors on prevention plans in the EHR.[18] Workflow observations exposed that BWH nurses seldom used the Fall TIPS poster for educational purposes and regularly recorded fall risk assessments on the patients' paper flowsheets. Risk factors and tailored fall prevention plans were infrequently communicated to patients at both study sites.

Interviews confirmed that patients and their families were overwhelmingly unaware of their fall risk factors and/or that a fall prevention plan was in place. Many patients reported that their nurse communicated they were at risk for falls; however, they could not identify specific risk factors nor strategies for mitigating these risks. Interviews also revealed that many patients, particularly those who were younger or independent at home, did not believe they were at risk for inpatient falls. Patients expressed an interest in understanding and being involved in their fall risk assessment and prevention plan. Interviews with nurses provided insight into the aspects of a fall prevention toolkit that they found most valuable, such as integration with the EHR, and provision of clinical decision support. A set of user requirements for a toolkit to support patient and family engagement in the three-step fall prevention process emerged from the Problem Analysis.

Design & Development. The original electronic version of Fall TIPS, with updated icons, was integrated into the EHR as BWH, MMC, and NYP went live with their Epic EHR systems. This is a high-tech option whereby clinical decision support is integrated into the tool.

The low-tech Fall TIPS modality with no automation is an 11"X17" laminated paper poster hung at the patient's bedside. Color-coded clinical decision support links risk factors to evidence-based interventions. The poster is updated with a dry-erase marker and is completed at the patient's bedside. Clinicians' feedback on the Fall TIPS laminated paper poster revealed that it provided standardized communication of risk status to both the care team as well as patients and families with varying levels of healthcare literacy.[3, 22] Usability testing of the paper poster via the System Usability Scale[26] (published previously[18]) revealed that the iteratively developed laminated paper poster was popular with staff and made it easy to engage patients in the three-step fall prevention process.[18]

The high-tech Fall TIPS modality with a high level of automation is the paperless bedside display version, available in the form of a screensaver or downloadable app on a mobile device.[19, 21] This modality reuses clinical documentation in the EHR to drive the display and overcomes workflow barriers, such as issues related to printing or filling out the poster. The high-tech modality automatically populates the bedside display monitor/app with the patients' tailored fall prevention plan based on clinical documentation in the EHR.

Implementation. *Laminated paper poster pilot testing:* A 6-month pre/post pilot of the Fall TIPS laminated paper poster (published previously[3]) revealed that, after Fall TIPS was implemented, patients on study units showed increased confidence in identifying their fall risk factors prevention strategies. This increase in knowledge was statistically significant at MMC but not at BWH. A reduction in falls with injury from the pre period to the post period was observed at both sites.[3]

Paperless bedside display (screensaver/mobile device) pilot testing: Although the value of communicating patient-specific risk factors and prevention plans was embraced on care units, barriers to adoption and spread throughout the pilot included both technical and workflow challenges (e.g., patients thinking the display was only meant for the nurse to view, the display screen being turned away from the patient's bedside, missing icons on the fall prevention plan due to inaccurate or incomplete EHR documentation, lack of buy-in from nurses and/or families, screensavers turned off at night---meaning the prevention plan was not displayed). These were addressed through increased education on use of the toolkit and on necessary EHR documentation practices.[19]

Modality Efficacy Comparison: All study units reached at least 80% adherence and effective patient engagement by the end of the pilot study. There was no significant difference between patient engagement in each Fall TIPS modality: laminated paper poster, EHR-integrated version, paperless bedside display tools. The analysis revealed that all Fall TIPS modalities effectively facilitate patient engagement in the three-step fall prevention process, suggesting each can be used to integrate evidence-based fall prevention practices into diverse existing clinical workflows.[22]

Long-Term Efficacy: Based on continuous feedback from unit Champions, barriers to adoption and spread (details will be published separately) were addressed.[3] Vital techniques for successful Fall TIPS implementation and sustainability were identified and will be reported elsewhere.

Evaluation.

Long-Term Efficacy: The research team is currently performing a statistical analysis to see the effect of Fall TIPS on fall inpatient acute care fall rates and will publish the results of the evaluation elsewhere. Patient activation was measured all three academic medical centers (results pending publication).

Project 2: Patient Safety Dashboard

1. Abstract

Purpose: The study aim was to develop, iteratively refine, implement, and rigorously evaluate a Patient Safety Dashboard integrated with a vendor electronic health record (EHR) to identify and mitigate potential threats to patient safety in real time on medicine, neurology, and oncology services of an academic medical center.

Scope: As currently designed, vendor EHRs can lead to information overload and siloed information by data type and provider type. A patient safety dashboard, if thoughtfully designed, has the potential to increase interdisciplinary communication and provider awareness of patient safety issues, providing just enough information to inform management.

Methods: This study was conducted as part of the larger Patient Safety Learning Lab Study (PSLL). The dashboard was designed using live data services from the hospital's EHR and with the input of a multi-stakeholder team. Use of the dashboard was tracked during the implementation period and analyzed in-depth for two 1-week periods. Providers' perceptions of tool usability were measured using the Health Information Technology Usability Evaluation Scale. Research assistants conducted field observations to provide insight into tool adoption. Impact of the entire PSLL intervention on processes of care was assessed using time-series methodology as part of the stepped wedge cluster-randomized trial. An on-treatment analyses correlated processes of care with intensity of weekly dashboard use on the unit where patient was hospitalized.

Results: The dashboard was used 70% of days the tool was available, with use varying by role, service, and time of day. Satisfaction with the tool was highest for Perceived Ease of Use, with attendings giving the highest rating (4.23). The overall lowest rating was for Quality of Work Life, with nurses rating the tool lowest (2.88). Results of the intervention on processes of care was mixed, with some processes showing improvement after implementation but other processes showing no effect or a negative effect. On-treatment analyses with intensity of dashboard use was also mixed. The study provides many important lessons on how best to design and implement these types of tools. A new version of the dashboard is currently being refined and implemented in response to these lessons.

Key Words: Patient Safety, Clinical Decision Support Systems, Electronic Dashboards, Electronic Health Records

2. Purpose

Specific Aims:

1. To engage healthcare providers and patients in the design and development of a Patient Safety Checklist Tool for use by healthcare providers and patients/families.

2. To partner with an interdisciplinary group of healthcare providers and patients to implement and iteratively refine a Patient Safety Checklist Tool.
3. To evaluate the effect of the Patient Safety Checklist Tool on length of stay, team communication, and patient outcomes.

3. Scope

Inpatient adverse events (AEs) are patient injuries due to medical management that prolong hospitalization, produce a disability at time of discharge, or both. Patient safety experts have increasingly leveraged health information technology (HIT) as one way to reduce the incidence of AEs. The potential of HIT to provide generalizable solutions has been aided by the recent proliferation of electronic health records (EHRs) in the inpatient setting, with 96% of all US hospitals having implemented a certified EHR technology as of 2015 and 92% using one of the top six EHR vendors.

One benefit of EHRs is that they can collect data on routine clinical care processes for innovation and improvement purposes. However, current EHR systems have also created cognitive overload for clinicians as the amount of information they hold has drastically increased. To further complicate matters, data within a single EHR may be "siloed" by data type (e.g., test results, medication information, vital signs) and provider type (e.g., nursing vs. physician view of the same patient). These structural limitations inhibit interdisciplinary communication, reduce user performance, and potentially negatively impact patient safety.

Data automatically abstracted from an EHR can form the basis of clinical decision support systems (CDSS). Such tools built "around" an EHR (i.e., using live EHR data, accessible from the EHR environment and yet still proprietary software) can be iteratively refined more quickly than the vendor EHR itself, may provide added value over an EHR's current offerings, and can be spread to other institutions that use the same EHR platform. CDSS tools in the form of a dashboard, which queries multiple datasets onto one visual display, may improve patient safety by addressing concerns related to siloed data. Studies implementing dashboards have reported improved compliance with evidence-based care and reduced patient safety events.

The goals of this study were to leverage the expertise of systems engineers, human factors experts, HIT developers, clinicians, patient safety leaders, and other stakeholders to build a patient safety dashboard around a common vendor EHR; implement it on several inpatient services as part of a full suite of patient- and provider-facing interventions; and evaluate its use, perceived usability, and impact on processes and outcomes of care.

4. Methods

Setting

This IRB-approved study was performed at an academic, acute care hospital. The tool was implemented in a cluster-randomized, stepped-wedge trial on 12 units in neurology, oncology, and general medicine services beginning December 1, 2016, and ending May 31, 2018.

Intervention

We developed the Patient Safety Dashboard in a 16-month period after the hospital adopted the Epic Systems EHR in May 2015. Our team used a participatory design approach that relied on iterative refinement and continuous collaboration with stakeholders.[20] Focus groups composed of attending physicians helped us gather initial requirements of the tool and goals of implementation. Throughout development, we sought feedback from physician and nursing leadership dyads, other quality-directed researchers, and frontline providers regarding visualization, content, functionality, and work flow integration of the tool. Thus, the design prototypes, content, and alerting logic were iteratively refined to meet user and health system needs.

One key lesson learned during the initial design period was that clinicians were concerned about the dashboard requiring any additional documentation on their part (unlike an earlier checklist developed for the ICU, in which the patient census is much lower but the acuity and patient risks are higher). Clinicians agreed that a dashboard could repurpose already documented information.

Preliminary content was chosen based on alignment with institutional priorities and initiatives within the Department of Medicine and the hospital's Department of Quality and Safety. Additional safety domains were suggested by clinician stakeholders and clinical leadership. To identify which data would populate each domain in the dashboard, we solicited feedback from 50 providers regarding the information they would need to make clinical decisions. We adjusted alerting thresholds so that the dashboard would alert for some but all patients in each domain.

Accessing data from the vendor EHR was difficult throughout development. For preliminary proof of concept, we collected a daily report on study unit patients that was generated from the EHR data repository system (Clarity)

to yield a snapshot of the state of the unit from midnight the night before. To access corresponding data in real time such that the tool would be maximally usable, we then supported the BWH reporting team in the development of multiple new web services, including ones that would deliver data about medication administration, test results, procedure orders, flow sheets (e.g., vital signs), and placement of lines, drains, and airways. Once a working prototype was built, it was iteratively refined, including the logic of the alerts, visual display, features, and functions.

By the beginning of the trial, the Patient Safety Dashboard was built around 13 safety domains: Code Status, Glucose Control, Nutrition, Bowel Regimen, Venous Thromboembolism (VTE) Prophylaxis, Opioid Management, Antibiotic Management, Pressure Ulcer Prevention and Management, Delirium Management, Fall Risk, Vascular Access, Urinary Catheter Management, and Telemetry. Two additional domains, Discharge Planning and Patient Expectations, were added to the dashboard later in the study. The dashboard used a color grading system to indicate when inpatients were at risk for potential harm (yellow) or were at high risk for harm that warranted a specific action to be taken (red). The text of the color-coded alert boxes ("flags") consolidated information of several different data types around each domain to support providers in making clinical decisions. The dashboard also flagged when the patient was not at risk (green) or when the safety domain was not applicable (gray). The decision support was available by clicking directly on flags from the unit-level view or by accessing the patient-level view, which displayed patient-specific decision support for all flags. Users could also acknowledge an alert by clicking on a check-box next to the text.

Implementation

As units moved from usual care to the intervention as part of the stepped-wedge study design, researchers systematically trained most of the unit-based nurses (>80%) and engaged with physicians during weekly meetings. Study staff continued to provide "at-the-elbow" support and visited the units weekly to answer questions and promote user buy-in. Feedback from providers was collected early in the study to determine barriers to tool adoption and to develop approaches to increase use. Suggestions from users informed iterative refinements to the dashboard, including changes to the user interface and to the logic that prompted alerts.

Measurement of Dashboard Use

Usage by unit and provider type was automatically tracked throughout the implementation period to determine the number of times the tool was accessed by providers, including prescribers (physicians or physician assistants [PAs]), nurses, and unit-level clinical leadership. Two representative 1-week periods of the study were analyzed for detailed insight on typical use by unit and provider role.

Measurement of Perceived Usability

Provider perceptions of usability of the tool were measured using the Health Information Technology Usability Evaluation Scale (Health-ITUES). The customizable questionnaire is composed of four sub-components: quality of work life, perceived usefulness, perceived ease of use, and user control, each rated on a 5-point Likert scale (higher is better). The Health-ITUES survey was administered to providers on study units through the REDCap platform 4-14 weeks after the intervention period ended.

Research Assistant Observations:

RAs observed provider use of the dashboard throughout the duration of the study. Following completion of the intervention, a question guide was sent to former and current RAs involved in the study, and responses were provided verbally or on paper. Field observations were collected on provider use of the dashboard, provider use of additional electronic tools in conjunction with the dashboard, and overall RA impressions of implementation.

Analysis

Data on use of the dashboard are presented descriptively. Health-ITUES responses were analyzed for mean scores and standard deviation for each survey item. Qualitative data gathered from PSLL RAs was descriptively coded into major themes and sub-themes around tool usage by three research team members (PG, TF, KB). Two team members independently coded the RAs' feedback and identified common themes and sub-themes, with final consensus made by the team's human factors expert (PG). Finally, representative quotes for each sub-theme were identified.

Effect on Processes of Care

To determine the effect of the entire PSLL suite of tools on processes of care related to each of the safety domains, we collected retrospective data from the EHR corresponding to each safety domain. Results were analyzed using multivariable regression using a mixed linear model (GLIMMIX Procedure in SAS), adjusted for patient comorbidity score, sex, race, insurance status, and service of admission. We used time series methodology

to adjust for the study month, then measuring a "step" or value change following implementation of the PSLL intervention as well as a "slope" change in temporal trends (i.e., greater improvement over time compared with pre-implementation trends). Analyses were clustered by study unit. We used logistic regression models for binary outcomes and Poisson regression for most other measures, including fraction of patient-days in which a given quality measure was met (of all applicable patient-days).

To look more closely at the effect of the dashboard itself, we also performed "on-treatment" analyses, comparing the same processes of care in patients on units where the dashboard was not used that week to patients on units where the dashboard was used 1-5, 6-10, 11-15, and 16 or more times that week.

5. **Results**

Dashboard Use

The Patient Safety Dashboard was accessed by at least one provider on 70% of intervention days (382 of 547 days), for a total of 8302 logins by 413 individual providers. Providers included 184 nursing staff, 179 prescribers, and 19 unit leadership staff. All users who open the dashboard default to the unit-level view. The total numbers of individual flags and patient detail views opened were measured and analyzed by service, with patient detail views (as opposed to flag views) accounting for 24% of additional views on medicine, 87% of views on neurology, and 68% of views on oncology.

The number of providers that logged in each hour was captured throughout the implementation period. There was a high concentration of logins between 5AM and 8AM, a large increase in logins during morning rounds (8:30AM-11:30AM), and a decrease in logins each subsequent hour.

Use of the dashboard was also measured by the number of logins per week, with a fairly steady increase throughout the implementation period. Several notable points of uptake in use were associated with implementation on additional study units ("steps"), enhancements made to the tool, or the distribution of basic and competitive user reports to track and incentivize use on each unit.

Further analyses ("deep dives") were conducted on two separate weeks of the study. During the week of January 14-20, 2018, most logins were by nurses on medicine units viewing red and yellow flags, followed by patient detail views. It is notable that medicine providers only opened the dashboard on morning rounds three times during that week (i.e., while rounding with nurses), whereas medicine nurses opened it 31 times during those same hours, most likely when not rounding with the team. In contrast, on neurology, the dashboard was rarely opened by nurses but was opened by a single prescriber (PA) on 3 separate days during the 30-minute interdisciplinary rounding sessions. The dashboard was never opened on oncology units during this week. Similar results were noted during the second deep dive, the week of April 1-7, 2018.

Assessment of Usability

There were 53 respondents of 180 providers who were emailed the Health-ITUES (response rate 29%). The overall ratings for the four measures were quality of work life (3.19 ± 1.09), perceived usefulness (3.27 ± 0.85), perceived ease of use (3.61 ± 0.95), and user control (3.40 ± 0.72), with variability by provider role and service. Attendings rated each measure highest out of the four groups, and nurses provided the lowest ratings for the tool.

Research Assistant Observations

Seven RAs who worked on the PSLL project responded to the question guide (response rate of 100%). Themes that emerged from qualitative responses centered around v*ariation and inconsistency in how the dashboard was accessed and used, social and cultural barriers influencing user retention and adoption, usability and technical issues,* and *overall impressions and suggestions*. Most RAs reported on variations in use across different roles and services. Overall impressions were that nurses on general medicine typically pulled up the dashboard periodically throughout their shift to check on their patients. PAs on both general medicine and neurology were strong proponents of the tool. Providers who frequently used the dashboard had identified specific domains in which they found value and fit it into their workflow where they found it appropriate.

RAs also provided opinions on what impeded use by providers, citing barriers such as uncertainty on who should take responsibility for flagged items. There was also difficulty with providers buying into the tool at the beginning of the study due to issues with accessing the tool within the EHR, bugs, and slow loading times. Although many of these issues were addressed throughout the study, RAs observed that many providers were discouraged by their initial impressions. There was also agreement that future efforts should focus on stronger implementation planning and increased engagement of stakeholders.

Effects on Processes of Care

In the intention-to-treat analysis corresponding to the stepped-wedge study design, the impact of the PSLL intervention as a whole was mixed, at least based on preliminary analyses to date. For some domains, such as Nutrition, the effect was unequivocally positive (e.g., a decrease in the proportion of patient-days when a patient was not eating [NPO, "nothing by mouth"] but still receiving scheduled nutritional insulin, which can place the patient at risk for hypoglycemia). There was also an increase in the proportion of patient-days when patients with diabetes were ordered an appropriate consistent-carbohydrate diet. In other cases, the results were mixed. For example, for glycemic control, there was an improvement (reduction) in hypoglycemia rates, but it came at the cost of a mild increase in patient-day-weighted mean glucose. Similarly, for urinary catheter management, there was an improvement (reduction) in proportion of patient-days with urinary catheters in place but a decrease in urinary catheters placed that had an active order. For VTE prophylaxis and central line use, effects were neutral or negative. For all other metrics, there were no significant differences associated with implementation.

On-treatment analyses of the Patient Safety Dashboard also demonstrated mixed results. Several metrics demonstrated improved processes of care when the dashboard was used more often on that patient's unit, such as code status documentation, glucose readings within range, patient-days with hyperglycemia, use of sedatives in patients at high fall risk, and patient-days with central lines. For other measures, such as patient-days with hypoglycemia and patient-day-weighted mean glucose, results were positive or negative depending on the degree of dashboard use on that unit. For use of scheduled nutritional and basal insulin in patients with diabetes, consulting physical therapy in patients with unsteady gait, and patient-days with urinary catheter in place, results were neutral or negative. For most other measures, there was no association between intensity of dashboard use on the unit that week and process measures for the patients on that unit.

Discussion

This study demonstrates that a Patient Safety Dashboard can be built "around" a vendor EHR using live web-based services, implemented on multiple inpatient units in a busy academic medical center, and rigorously evaluated. The potential for it to improve patient care has not yet been fully realized.

We identified considerable variation in use by role, provider type, time of day, and individual. Despite a rigorous user-centered design process and implementation plan, we identified several barriers to use, mostly involving the previously well-described interactions between technical issues, the work environment, the organization, the people involved, and the tasks required.

Not surprisingly given the data on use, the impact of the intervention on processes of care were mixed. Though there were certainly hints that the dashboard had an impact on certain domains, the results were not strong or consistent.

We are currently working with a "productization" team to further enhance the dashboard and implement it throughout the hospital and an affiliated community hospital. During this process, we are taking into consideration all the findings from this study regarding both the design and implementation of the dashboard.

Project 3, MySafeCare: Patient Preferences for Automated and Mobile Reporting of Safety Concerns

Abstract

Purpose: The study aim was to develop, test, and evaluate the MySafeCare web-based application implemented on six acute care units over 18 months as part of a patient-centered health information technology tools to promote engagement and safety in the acute care setting.

Scope: Hospitalized patients and their care partners have valuable and unique perspectives of the medical care they receive. Direct and real-time patient reporting of safety concerns could provide opportunities to improve patient care.

Methods:

The MySafeCare allowed hospitalized patients to submit safety concerns in real time. We describe characteristics of patient submissions including their categorizations and evaluated rates of submissions to MySafeCare and compared them to rates of submissions to the Patient Family Relations (PFR) department at the hospital. Additionally, we performed thematic analysis of narrative concerns submitted to the application.

Results: We received 46 submissions to MySafeCare, and 33% of concerns received were anonymous. The overall rate of submissions was 0.6 submissions per 1000 patient-days and was considerably lower than the rate of submissions to the PFR during the same period (4.1 per 1000 patient-days). Identified themes of narrative concerns included unmet care needs and preferences, inadequate communication, and lack of trust. Though the

submission rate to the application was low, MySafeCare captured important content directly from hospitalized patients or their care partners. A web-based patient safety reporting tool for patients should be studied further to understand patient and care partner use and willingness to engage as well as potential effects on patient safety outcomes.

Key Words: Patient safety, safety reporting, patient participation, hospital incident reporting

2. Purpose

Specific Aims:

Aim 1: Rapid iterative development and pilot trial of patient preferences for MySafeCare

Aim2: MySafeCare integration with Brigham and Women's Hospital (BWH) inpatient clinical and reporting systems

Aim 3: Evaluation of impact of MySafeCare on patient safety and fostering a learning health system

3. Scope

Research has shown that patients are a valuable source of information and can correctly identify medical errors and adverse events when prompted. Patients and their care partners have unique perspectives of the medical care they receive, and these may include concerns about the safety of their care. Research focused on capturing patients' safety concerns is limited, with only a few interventions piloted. We developed and implemented MySafeCare, a web-based application for hospitalized patients to electronically submit and categorize safety concerns in real time. MySafeCare was developed using participatory user-centered designed to supplement existing safety and incident reporting systems in the hospital, to proactively mitigate safety risks before incidents occur, and directly capture patients' perspectives about the safety of their care. In this study, we evaluated the rate of patients' safety concerns submitted via MySafeCare and explored patient perspectives on safety during hospitalization.

4. Methods

Study Setting and Design: MySafeCare was designed and implemented as part of the PSLL patient portal, which provided real-time care information through tablet computers and smart phones during a patient's hospitalization. MySafeCare was also available separately as a standalone web-application.

The PSLL patient portal intervention followed a randomized stepped-wedge implementation from December 2016 to May 2018. A 3-month pre-intervention period occurred from September to December 2016; every 1 to 2 months during the intervention period, the PSLL patient portal was introduced on a new study unit. A total of six units participated, including general medicine, neurology, and oncology units.

The research team approached patients and care partners daily on study units to enroll them to use the patient portal using a study-provided tablet computer (iPad, Apple Inc, Cupertino, CA) or their own device during their hospital stay. Users provided an e-mail address and created a password to access the portal. A mobile application of the patient portal was also made available, which included MySafeCare. Research staff provided an overview to the patient after enrollment, including a brief explanation of MySafeCare.

Intervention: MySafeCare: Using MySafeCare, patients and care partners could submit safety concerns by choosing from one of nine categories, and all included a free-text narrative option. Concern categories included My Care Plan, My Medication, My Room, My Communication, My Hygiene, My Privacy, My Pain, My Waiting Time, and Other. Users could also choose subcategories, rank their concerns by severity, specify how recently the concern occurred, indicate if they had shared the concern with a member of their care team, or submit a compliment. Additionally, they had the option to self-identify with their name and room number or remain anonymous. They could also submit optional demographic information. When patients and care partners submitted an entry, an automated email was sent to the unit leadership along with the research team, notifying them of the submission and providing a link to the MySafeCare clinical dashboard. Nurse Directors were the primary responsible unit leaders for reviewing and following up on submissions. Submissions were viewable on this secure dashboard, and it included designated areas for follow-up notes from clinical staff or the research team. All staff identifiers and patient names were removed from submissions using a text identifier in the application before entries appeared on the dashboard.

Outcome Measures: We analyzed use of MySafeCare and performed quantitative analyses of submission rates and the optional demographic data reported by MySafeCare users. Submission rates were calculated as submissions per 1000 patient-days and reported with 95% confidence intervals (CIs). Submission characteristics, frequency of submission instances to each category, and visits to the MySafeCare module in the patient portal are provided. Rates of submissions to Patient Family Relations (PFR) prior to MySafeCare implementation were compared with

the total sum of the rates of submissions to PFR at the hospital and the rates of submissions to MySafeCare during the implementation period to observe trends in overall reporting. The rates of submissions to PFR during the 3-month pre- and 18-month post-intervention periods were also compared. The PFR provides patients and families to report their concerns and complaints via telephone, walk-in, or email, but they currently do not provide any online form to submit concerns. Rates were compared using Poisson regression, and the total rates of submissions were adjusted to account for unit variations. Finally, we conducted thematic analysis of the free-text narrative of concerns submitted to MySafeCare. The concern was reviewed by the research team, and common themes were identified and analyzed iteratively until reaching consensus. Patient safety risks relevant to the submission were also extracted. All study activities were approved by the Partners Healthcare Institutional Review Board.

5. Results

Principal Findings: We received 46 submissions to MySafeCare over 18 months. Of those, 57% of users completed the optional demographic questions (Table 1). Most individuals who self-reported demographic information were white (85%), were non-Hispanic (81%), and spoke English (92%). Approximately 73% were women, 81% were younger than 65 years old, 65% had completed at least some college, and 65% had a moderate or high health literacy level.

Over the intervention period, 1755 patients were enrolled in the study. There were 2845 visits to the MySafeCare, and this includes visits to the application by research staff for demonstrations of the application to patients, which are estimated at 1.6 times per hospitalization. MySafeCare was the sixth most used module of the patient portal out of 14 modules, with a total of 2845 clicks on the MySafeCare tab out of 53,325 total clicks within the portal. All users had the ability to submit more than one concern or compliment per submission; therefore, there were 62 unique submission instances (Table 1). The overall rate of submissions to the application was 0.7 submissions per 1000 patient-days.

Table 1. Use of MySafeCare

Unit	Beds on unit	Days live	Unique submissions*	Unique submissions per week	Unique anonymous submissions	Documented follow up		Submissions per 1000 patient-days (95% CI)
						Nurse director	Other	
Neurology	46	547	20	0.26	7	0	20	0.9 (0.6-1.4)
Medicine A	30	499	11	0.15	6	6	5	0.8 (0.4-1.4)
Oncology A	20	457	5	0.08	2	1	4	0.5 (0.2-1.3)
Medicine B	30	403	5	0.9	1	0	5	0.4 (0.2-1.1)
Oncology B	10	361	2	0.04	0	0	2	0.6 (0.2-2.4)
Medicine C	30	319	3	0.07	0	2	1	0.3 (0.1-1.0)
Total								0.7 (0.5-0.9)

*More than one concern or compliment can be entered per submission (instance to submission = many to one). Total of 62 submission instances and 46 submissions.

There was considerable variation in submission rates to both PFR and MySafeCare across the units (Table 2). In particular, the submission rate to PFR pre-intervention on the Medicine C unit was very high, at 21.9 submissions per 1000 patient-days. After adjustment for variation between units, the overall PFR submission rates during the pre-intervention period were 6.1 submissions per 1000 patient-days, and the rates during the post-intervention period were 4.1 submissions per 1000 patient-days (P=0.14). The reduction of PFR submissions in the post-intervention period was not statistically significant. The adjusted rate of submissions to MySafeCare in the post-intervention period was 0.6 submissions per 1000 patient-days. The total combined adjusted rate of submissions to MySafeCare and PFR in the post-intervention period was 4.7 submissions per 1000 patient days. Though there were significant differences in some units, overall after adjustment there was not a significant difference between the rates of submission to PFR pre-intervention and the rate of total submissions post-intervention (P=0.32).

Table 2. Rates of submissions to MySafeCare (MSC) compared with Patient Family Relations (PFR)						
	Rate of submissions per 1000 patient-days (95% CI)					
	Group A	Group B	Group C	Group D	Group A vs B	Group A vs D
	PFR submissions (Pre)	PFR submissions (Post)	MSC submissions (Post)	Total: MSC + PFR submissions (Post)	*p*-value*	*p*-value**
Neurology	3.2 (2.0-5.3)	5.7 (4.8-6.8)	0.9 (0.6-1.4)	6.6 (5.6-7.8)	0.03	0.01
Medicine A	3.3 (1.9-5.8)	4.5 (3.6-5.8)	0.8 (0.4-1.4)	5.3 (4.2-6.7)	0.30	0.18
Oncology A	1.5 (0.6-4.1)	1.4 (0.8-2.5)	0.6 (0.2-1.3)	2.0 (1.3-3.1)	0.90	0.64
Medicine B	5.1 (3.3-8.0)	4.7 (3.6-6.1)	0.4 (0.2-1.1)	5.1 (4.0-6.6)	0.76	0.98
Oncology B	3.9 (1.6-9.3)	5.2 (3.2-8.3)	0.6 (0.2-2.4)	5.8 (3.7-9.1)	0.57	0.42
Medicine C	21.9 (17.7-27.1)	5.0 (3.7-6.6)	0.3 (0.1-1.0)	5.3 (4.0-7.0)	<.0001	<.0001
Total	7.0 (5.9-8.2)	4.6 (4.2-5.2)	0.7 (0.5-0.9)	5.3 (4.8-5.9)	<.0001	0.01
Adjusted Total	6.1 (3.9-9.6)	4.1 (3.0-5.7)	0.6 (0.3-1.3)	4.7 (3.5-6.4)	0.14	0.32

* Comparing PFR submissions (pre-intervention) vs. PFR submissions (post-intervention)

**Comparing PFR submissions (pre-intervention) vs. total: MSC+PFR submissions (post-intervention)

There were 46 submissions and 62 submission instances, which resulted in 23 (37%) concerns and 39 (63%) compliments. Among all submissions, 33% (n=15/46) were submitted anonymously. Approximately 30% (n=7/23) of concerns and 23% (n=9/39) of compliments were anonymous. Forty-three percent (n=3/7) of users who submitted concerns anonymously also indicated that they shared their concern with their care team. More submissions were submitted directly by patients (70%, n=32/46) than by care partners (30%, n=14/46). Most frequently, concerns were submitted to the categories Plan (8%, n=5/62), Other (8%, n=5/62), or no category selected (8%, n=5/62). The remaining categories included Medication (5%, n=3/62), Room (5%, n=3/62), Communication (2%, n=1/62), and Pain (2%, n=1/62). No concerns were submitted to Hygiene, Privacy, or Waiting Time. Submissions to the other category was related to the following themes: nutrition and diet, plan of care, facilities, communication, clinical protocols, and care needs and preferences.

After reviewing all concern free-text narratives, the main themes identified were 1) unmet care needs and preferences, 2) inadequate communication, 3) clinical protocols, 4) facilities, 5) dietary and nutrition, and 6) security. Many free-text concerns submitted described multiple concerns, and many themes were overlapping in domains of quality, safety, and experience. Safety risks specified by patients and care partners in the submissions and extracted by the research team included risk of fall, risk of medication overdose, risk of medication side effects, risk of infection, and risk of malnourishment. In other cases, patient safety risks were not identified; however, the concerns were related to quality of care or patient satisfaction.

Discussion: Although we did receive concerns with useful and important content, as well as compliments, the overall submission rate was low. Many patients chose *Other* when categorizing their concerns and themes of narrative concerns centered around safety risks, quality of care, and patient experience.

The overall submission rate during this study (0.6 submissions per 1000 patient-days) was much lower than the 4.8 submissions per 1000 patient-days the application received in our standalone trial. We expected the rate to be approximately the same or higher because of the expansion of the application to additional units; however, this was not the case. Additionally, the rate was lower than the submission rates of complaints and concerns received by PFR from the same units (4.1 submissions per 1000 patient-days). There was variation in the rates of

submissions across the units, although it is difficult to draw any conclusions on this variation because of the small submission numbers.

A smaller percentage of concerns (30%) was submitted anonymously in this study compared with that submitted in the standalone trial, in which 55% of concerns were reported anonymously. Although direct follow-up with patients is not possible for concerns submitted anonymously, our data still confirm that it is important to provide this option. Despite efforts to engage patients and promote a culture of safety, patients are often hesitant to speak up when they have concerns about their care. The anonymous data provided through the application is valuable on both unit and hospital levels to learn from patient experiences and provide feedback to staff. Narrative responses from free-text areas provide further insight into what is important to patients and their care partners. This type of patient-reported data is likely not captured elsewhere, emphasizing the importance of tools such as MySafeCare.

There are a few potential explanations to our findings that differ from our standalone data. Patients may have preferred to use the existing reporting options already known to them or their care team. They may not have been aware that the application was available, may not fully understood its intended use, or may have had other concerns about using the application. Patients may have had reservations that submissions that were initiated from the patient portal – which required a username and password - were not truly anonymous. Such reservations may have resulted from inadequate communication between the research staff and patients regarding MySafeCare, as the main method of engagement during this trial was in conjunction with the patient portal. The complexity of the patient portal and factors affecting use of the patient portal may have also affected use of MySafeCare. Additionally, the application was implemented on a different set of units than in the standalone trial. In this trial, MySafeCare was implemented on units where the other PSLL interventions were simultaneously implemented. Given the extent and scope of the multifaceted PSLL intervention on the clinical units, it is possible that the PSLL interventions, which emphasized safety and patient-centeredness, promoted an enhanced culture of safety on these units, so patient-reported concerns via the application were reduced.

We found many of the narrative submissions to have the same themes as identified previously in the standalone trial, although details of the concerns differed. The consistent themes identified included lack of trust, inadequate communication, clinical protocols, unmet care needs and preferences, facilities, and security. In this study, we identified the additional theme of diet and nutrition in some concerns. Many users self-categorized their concerns as *Other* or did not select a category at all. Similarly, in the standalone trial, the *Other* category received the most submissions and a few categories did not receive any submissions, including the privacy category, which we also saw in this trial.

Conclusion: Although the submission rate to the application was low, MySafeCare captured important and unique content directly from hospitalized patients or their care partners. Web-based reporting tools for patients should be studied more to understand patient and care partner use and willingness to engage as well as effects on patient safety outcomes. Future work should emphasize accurate categorization of concerns and focus on strategies for implementation within the hospital setting.

List of PSLL Manuscripts

Project 1: Fall TIPS

Manuscripts

a) Dykes PC, Bogaisky M, Carroll DL, Carter E, Duckworth M, Hurley AC, Jackson E, Khasnabish S, Kurian S, Lindros ME, Lipsitz S, Scanlan M, Yu SP, Bates DW, Adelman J, Adkison L,. Development and Validation of a Fall Prevention Knowledge Test. Journal of the American Geriatrics Society. In press.
b) Dykes PC, Adelman J, Adkison L, Bogaisky M, Carroll DL, Carter E, Duckworth M, Herlihy L, Hurley AC, Khasnabish S, Kurian S, Lindros ME, Marsh K, McNinney T, Ryan V, Scanlan M, Spivack L, Shelley A, Yu SP. Preventing falls in hospitalized patients. September 2018, 13(9), pps. 8-13.
c) Dykes PC, Adelman J, Alfieri L, Bogaisky M, Carroll DL, Carter E, Duckworth M, Erickson JI, Flaherty LM, Hurley AC, Jackson E, Khasnabish S, Lindros ME, Manzano W, Scanlan M, Spivack L. The Fall TIPS (Tailoring Interventions for Patient Safety) Program: A Collaboration to End the Persistent Problem of Patient Falls. Nurse Leader. In press.
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Across Modalities of an Evidence-Based Fall Prevention Toolkit for Engaging Patients and Family in the Three-Step Fall Prevention Process. Journal of Medical Internet Research. In press.

e) Dykes PC, Duckworth M, Cunningham S et al. Pilot Testing Fall TIPS (Tailoring Interventions for Patient Safety): a Patient-Centered Fall Prevention Toolkit. *Jt Comm J Qual Patient Saf*. 2017. 43(8): 403-413
f) Dykes PC, Duckworth M. Pilot Testing Fall TIPS (Tailoring Interventions for Patient Safety): A Patient-centered Fall Prevention Toolkit. Joint Commission Journal on Quality and Safety. In press.
g) Leung WY, Adelman J, Dykes PC, Hurley A. Validating Fall Prevention Icons to Support Patient-Centered Education. Journal of Patient Safety. 2017.
h) Duckworth M, Dykes PC. Nurse, Patient and Care Partner Perceptions of a Personalized Safety Plan Screensaver. Journal of Gerontological Nursing. 2016.
i) Katsulis Z, Ergai A, Leung WY, Schenkel L, Rai A, Adelman J, Benneyan J, Bates DW, Dykes PC. Iterative user centered design for development of a patient-centered fall prevention toolkit. Appl Ergon. 2016 Sep; 56:117-26. PMID: 27184319.
j) Dykes PC, Leung WY, Vacca V. Falling Through the Crack (in the Bedrails). AHRQ Web Morbidity and Mortality Cases and Commentaries. 2016.
k) Christiansen TL, Lipsitz SR, Scanlan M, Yu SP, Lindros ME, Leung WY, Adelman JS, Bates DW, Dykes PC. Patient Activation Related to Fall Prevention: A Multi-Site Study. Jt Commission Journal of Patient Safety. 2019;

- **Conferences and Presentations-** 24 webinars
- **Regional-** 28 regional presentations in the US
- **International-** 10 International Seminars and Teaching presentation on FALL TIPs in Mexico, Finland, China

Project 2: Patient Safety Dashboard

- **Manuscripts**
  a) Mlaver M., Schnipper J., Boxer R., Breuer D., Gorbovitsky G., Harry E., Gershanik E., Wolf L., Dykes P., Benneyan J., Bates D., Lehmann L. "Design and Development of a General Medical Inpatient Safety Dashboard to Improve Quality and Efficacy of Hospital Care." Society of Hospital Medicine. [accepted January 2017]
  b) Bersani, K., Fuller, T. E., Garabedian, P., Espares, J., Mlaver, E., Businger, A., Chang, F., Boxer, R., Schnock, K. O., Rozenblum, R., Dykes, P. C., Dalal, A. K., Benneyan, J., Lehmann, L., Gershanik, E., Bates, D. W., Schnipper, J. L. Use, Perceived Usability, and Barriers to Implementation of a Patient Safety Dashboard Integrated within a Vendor EHR. Appl Clin Inform. 2019; In press.
- **Posters and Presentations:** 10

Project 3: MySafe Care:

- **Manuscripts**
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