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Brief Communication

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Lessons learned implementing a complex and innovative patient safety learning laboratory project in a large academic medical center

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ABSTRACT

Objective: The objective of this paper is to share challenges, recommendations, and lessons learned regarding the development and implementation of a Patient Safety Learning Laboratory (PSLL) project, an innovative and complex intervention comprised of a suite of Health Information Technology (HIT) tools integrated with a newly implemented Electronic Health Record (EHR) vendor system in the acute care setting at a large academic center.
Materials and Methods: The PSLL Administrative Core engaged stakeholders and study personnel throughout all phases of the project: problem analysis, design, development, implementation, and evaluation. Implementation challenges and recommendations were derived from direct observations and the collective experience of PSLL study personnel.
Results: The PSLL intervention was implemented on 12 inpatient units during the 18-month study period, potentially impacting 12,628 patient admissions. Challenges to implementation included stakeholder engagement, project scope/complexity, technology/governance, and team structure. Recommendations to address each of these challenges were generated, some enacted during the trial, others as lessons learned for future iterative refinements of the intervention and its implementation.
Conclusion: Designing, implementing, and evaluating a suite of tools integrated within a vendor EHR to improve patient safety has a variety of challenges. Keys to success include continuous stakeholder engagement, involvement of systems and human factors engineers within a multidisciplinary team, an iterative approach to user-centered design, and a willingness to think outside of current workflows and processes to change health system culture around adverse event prevention.

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

INTRODUCTION

Research evaluating health information technology (HIT) often narrowly focuses on its effects on quality, efficiency, and cost.[1] Less well understood are the technical, organizational, human factors, and project management components that are key to its successful implementation.[1] The complex and competing interplays between hospital priorities, provider satisfaction, patient experience, limitations in technical resources, patient safety, and health services research must be balanced for successful uptake of these technologies.[2–4]

Implementation frameworks have been developed to guide user adoption and foster successful integration of evidence-based interventions and technologies into clinical work flow, but there is more work to be done in developing best practices for implementing novel, large scale HIT that integrates well into both vendor electronic health record (EHR) and provider work flows.[5] Because HIT implementation faces obstacles, establishing standards and sharing best practices is critical to understanding the impact of large HIT interventions on care delivery.[1,2] The Patient Safety Learning Laboratory (PSLL) was the first set of HIT tools to be integrated with a newly implemented vendor EHR (Epic, Verona, WI) in our clinical setting, with no established precedent for how to innovate within the newly formed governance and technology support structures.[6]

Using our experiences implementing a complex PSLL study in a large academic medical center, we share challenges, lessons learned, and provide guidance on implementation practices for organizations seeking to improve patient care through large scale patient-centered HIT. This article provides actionable information for healthcare organizations aiming to implement research interventions that complement and interact with vendor EHR systems. While there is no one-size-fits-all implementation approach, our aim is to provide recommendations that can be adapted to other complex healthcare settings.

MATERIALS AND METHODS

Overview of patient safety learning laboratory study and aims

The PSLL project, a 4-year Agency for Healthcare Research and Quality (AHRQ) funded study (2014–2018), was a collaboration between the Brigham and Women's Hospital (BWH) Center for Patient Safety Research and Practice and the Northeastern University Healthcare Systems Engineering Institute (HSyE).[6] The focus was to make acute care more patient-centered and improve patient safety by developing tools and interventions that engage patients along with the care team in mitigating preventable harm during hospitalization. In collaboration with patients and providers, the PSLL team utilized systems engineering approaches to develop a suite of patient- and provider-facing tools to raise patients' awareness of safety issues and prevention strategies, encourage patients to give input into their care, and provide tools for clinicians to monitor patient safety risks in real time.

Patient safety learning laboratory project structure

Governance Structure: A steering committee was created that: 1) guided decisions regarding conduct of the study; and 2) provided multiple methods for gathering stakeholder input. The governance structure is described in Appendix 1, and the PSLL project's division of responsibility is below:

Administrative Core: responsible for the overall leadership, organization and coordination of PSLL activities. Because PSLL was a complex interdisciplinary project spanning multiple hospital units and services, this core focused the project teams on the overarching goals and provided project management 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 HIT development and use of resources across projects.

Systems Engineering (SE) and Human Factors (HF) Core: supported project teams during development, iterative refinement, and implementation of the suite of EHR-integrated HIT tools. The core, a collaboration between BWH and HSyE, drew from a compendium of SE/HF methods during each project phase and encouraged project teams to consider the "systems-of-systems" perspective: how individual tools interact as a single, unified system to identify, assess, and mitigate threats to preventable hospital-acquired harms.[6]

Project Teams: Each project, comprised of a coinvestigator and research assistant, shared a goal of creating an electronic patient-centered tool to improve patient safety. The projects included:

Fall TIPS (Tailoring Interventions for Patient Safety): An evidence-based fall prevention protocol and associated tools to reduce falls by engaging patients and family in identifying fall risks, helping providers create a personalized fall prevention plan and consistently following the plan.[7,8]

MySafeCare (MSC): A reporting tool that enabled patients and caregivers to report safety concerns, which were then displayed on a clinician dashboard to be addressed by providers and unit-based clinical leaders.[9,10] Patients and caregivers could choose to report anonymously or identify themselves.

Patient Safety Dashboard: A real-time safety display for interdisciplinary care team members, complemented by a patient-facing safety portal, which shared information from the safety dashboard with patients/caregivers, and a bedside display with safety and plan information shown on a monitor in the patient room.[11]

PSLL EHR-integrated health information technology tools

The 3 project teams worked together to create a set of tools with overlapping functionality (Figure 1). Many of the tools achieved the goals of more than 1 project and were integrated with our newly implemented vendor EHR (Epic, Verona, WI) using live data services to pull real-time clinical information, manipulate and display it to be maximally useful for clinicians, patients, caregivers, and unit-based clinical leadership. The PSLL team also readied the environment for implementation of the tools in the clinical setting using the Patient SatisfActive model.[2,4,12,13]

Conceptual models and framework

The PSLL utilized the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework to guide the study design.[14] RE-AIM informs implementation and evaluation with guiding questions in each domain, and its focus on external validity makes it well suited for technology innovation projects.[14,15]

The broad research questions from each RE-AIM component were used to guide the study through all phases, providing practical measures of how well the intervention worked in real-world clinical settings.[15,16] Figure 2 describes how the PSLL applied RE-AIM to

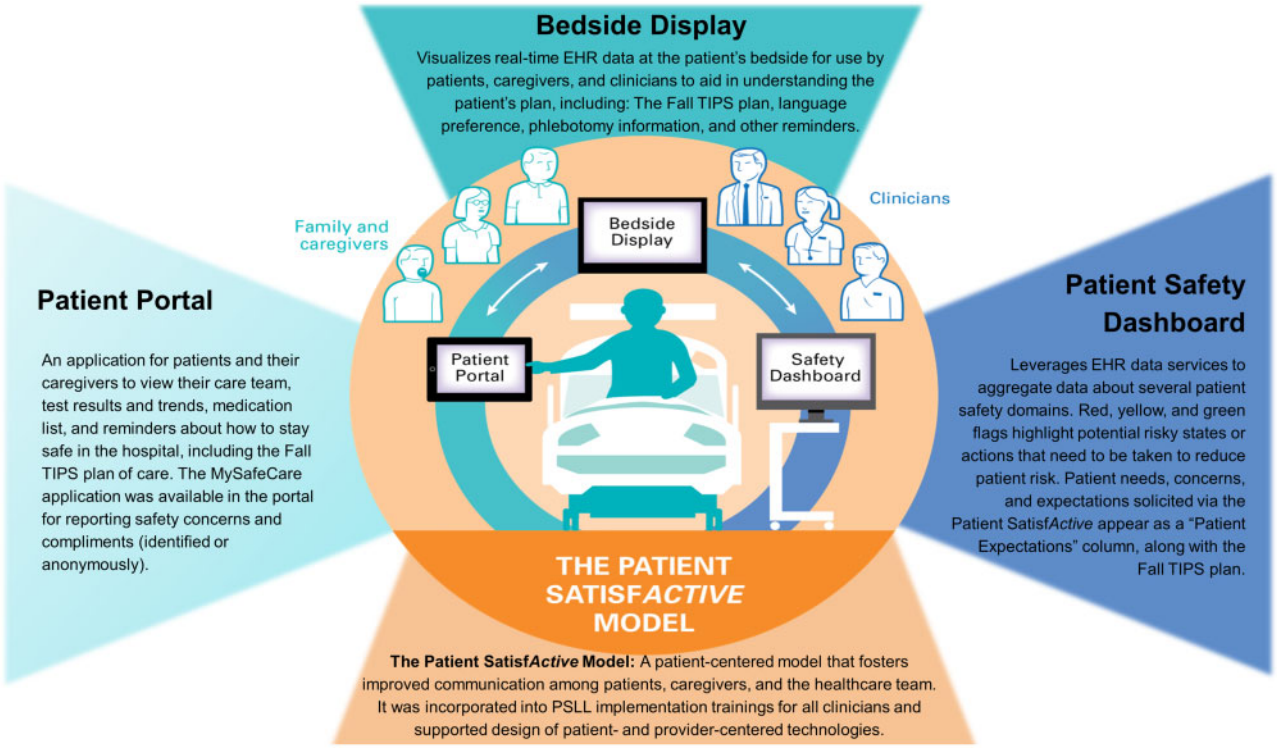

Figure 1. Patient Safety Learning Laboratory (PSLL): EHR-Integrated Health Information Technology Tools. The Patient Safety Learning Laboratory developed tools to help patients become better informed and more involved in their care and provided clinicians with information to facilitate better and faster decisions about patient care. Patients used the interactive patient portal; a bedside display showed patient care plan information on a monitor in the patient room for patients, families and hospital staff; clinicians viewed the patient safety dashboard which contained patient data to alert hospital staff of potential patient risks.[7–11] All of this was built upon the Patient Satisf*Active* model, a communication system that helped clinicians identify, assess, and address patient needs and expectations and helped patients and their caregivers become an active part of their care and decision-making.[2,4,12,13]

our study and how each outcome measure was associated with each RE-AIM component and with the study as a whole.

Project methodology

The PSLL project was phased in accordance with the AHRQ systems engineering project life cycle: 1) problem analysis, 2) design, 3) development, 4) implementation, and 5) evaluation.[17] During implementation planning, we adopted a socio-technical approach to understand the cultural and environmental context.[18]

Our study was approved by the Partners Human Research Committee, the Institutional Review Board of Partners HealthCare.

Throughout each phase, the Administrative Core: 1) engaged with stakeholders at all levels of the organization to establish buy-in, assist with key decisions and strategies, and plan for the implementation; 2) discussed project risks and mitigation plans with project teams; and 3) ensured project teams connected intervention development with overarching design and implementation goals. Table 1 describes the activities and implementation goals during each phase of the PSLL project.

The PSLL research study was designed as a stepped wedge cluster-randomized trial for 12 inpatient units at BWH across 3 services: General Medicine, Oncology, and Neurology (Appendix 2). During the 18-month study period (12/1/2016 through 7/31/17), each unit or group of units (cluster) started in usual care and then moved to the intervention at a prespecified randomized time point. The PSLL tools were implemented on 1 cluster ("step") every 6 weeks. This design allowed us to focus implementation efforts on 1 group of clinicians at a time and allowed each unit to be compared to itself (adjusting for different micro-cultures and patient populations) while adjusting for temporal trends.[19,20]

RESULTS

The PSLL was implemented on 12 inpatient units at BWH. Nurses were trained on the tools via small-group sessions and during unit-based practice council meetings. Physicians and physician assistants were trained via weekly orientation sessions (prior to starting a rotation on 1 of the study units). All clinicians were supported "at the elbow" by PSLL team members and by clinical champions that were identified and trained by the team. The patient safety dashboard and bedside display were available for every patient admitted to the study units during the study period, for a total of 12 628 patient admissions. The patient safety dashboard was opened by 184 nurses (nurses, patient care assistants, and nursing students), 179 prescribers (attending physicians, physician assistants, nurse practitioners, fellows, residents, and medical students), and 19 unit leadership staff (administrators and nurse/medical directors). The patient portal was given to 1761 patients out of 3002 patients approached. The PSLL team's challenges and recommendations implementing the suite of tools is described in Table 2.

Because PSLL was the first large-scale HIT research study to be conducted at our institution after the deployment of a vendor EHR, there were many technical hurdles to overcome (like developing new live data services), and governance issues to be resolved (eg, permis-

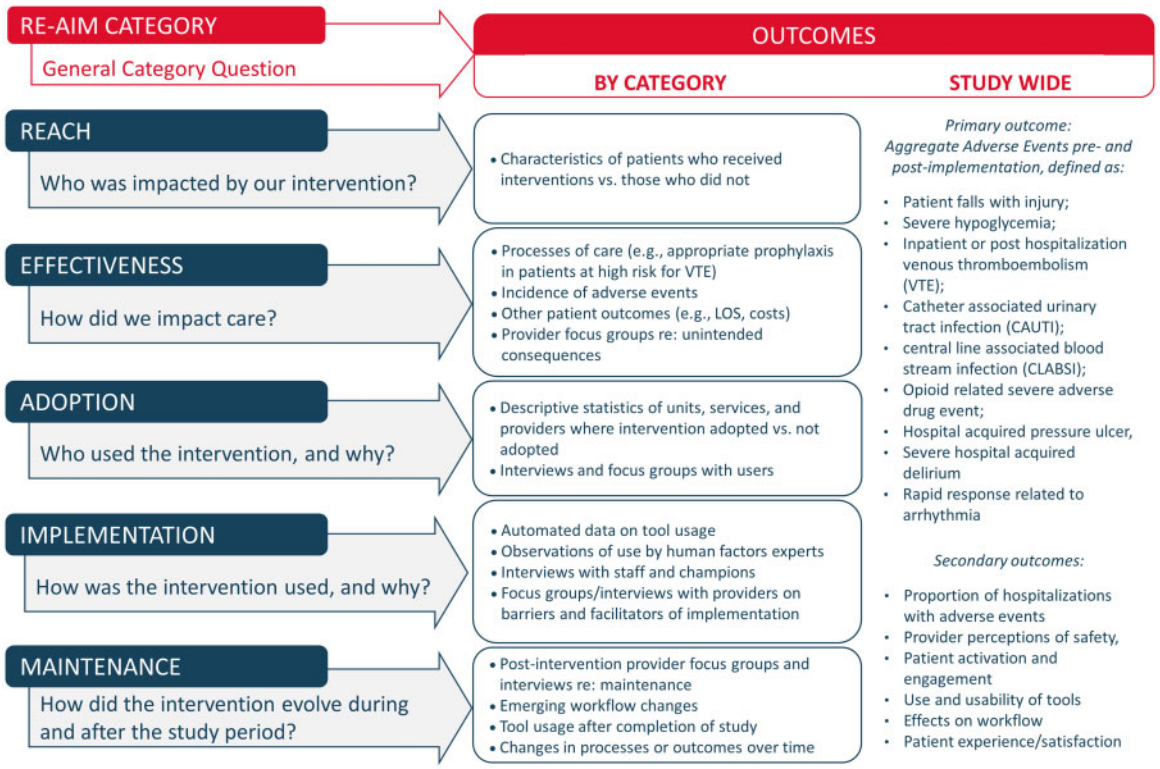

Figure 2. Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework: addressing the barriers to translation of research into practice in the Patient Safety Learning Laboratory (PSLL) study. The PSLL applied the RE-AIM framework to our overall implementation by 1) Formulating research questions from each RE-AIM component to our associated outcome measures, 2) Addressing implementation and dissemination through all phases of the research project lifecycle study-wide; and 3) Providing practical measures of how well the intervention worked in varied clinical settings.[15,16]

Table 1 PSLL project phases, activities, and implementation goals

Project Phase	Activities	Implementation Goals
Problem Analysis	Engage stakeholders to gauge the impact of tools on communication and safety	• Establish relationships and communicate PSLL mission and goals with technology and hospital governance. • Consider the impact of organizational and IT changes on implementation • Complete all vetting and approval required of governance at organization • Submit protocol documents for Internal Review Board/ Human Research Committee approval
Design	Leverage team's expertise to ensure that differing perspectives and prototypes are refined through focus groups with stakeholders using develop-test-revise iterations	• Ensure agreement with technology teams on technical and architectural approach and sustainability • Analyze and define data needed from Epic and define how to display information to providers • Continue stakeholder engagement and buy-in through communication of PSLL goals and mission • Create a website of the PSLL project • Engage users to learn about challenges and concerns • Communicate the benefits of PSLL tools to patient safety and patient care leadership
Development	Collaborate with stakeholders in refinement of tools until a sufficiently mature version is developed that stakeholders agree will both facilitate team communication and engage patients and families	• Pilot PSLL tools on 2 BWH units for proof of concept: to observe the tools in the context of clinical work flows • Utilize predefined RE-AIM metrics to refine PSLL tools • Plan for implementation: create a detailed training and support plan for each unit • Set implementation goals
Implementation	Implement PSLL tools on 12 units on varied services as a stepped wedge cluster-randomized controlled trial design	• Identify and train a core set of clinical champions on each unit • Establish cohesive training plan that considers impacts on work flow • Ensure consistency in messaging of PSLL goals and mission • Refine training tools to accommodate different work flows • Create a poster of our study to display on units

(continued)

Table 1. continued

Project Phase	Activities	Implementation Goals
Evaluation	Evaluate process and outcome measures related to each RE-AIM component	• Continue stakeholder engagement • Encourage usage of tools by demonstrating peer activity to all users • Consistently respond to user requests and feedback

Abbreviations: BWH, Brigham and Women's Hospital; IT, information technology; PSLL, patient safety learning laboratory; RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance framework.

Table 2. Patient safety learning laboratory project: implementation challenges and recommendations by category

Category	Challenge	Recommendation
Stakeholder Engagement	User variety: (MD, PA, RN, Patients, Caregivers, Unit Directors, etc.), 3 clinical services (Oncology, General Medicine, Neurology)	• Create an interdisciplinary leadership and champion team • Leverage areas of common interest across user types • Incorporate a patient-centered communication system (eg, Patient Satisf*Active* model[2,4,12,13])
	Project Complexity	• Develop clear, effective messaging • Maintain consistent communication with stakeholders
	Change fatigue	• Understand demand on users and competing priorities • Align with institutional priorities
	Requirement for Enduring Engagement	• Leverage existing unit meetings • Align with compliance reporting • Reward use with virtual prizes and competition
Project Scope/ Complexity	Multiple products designed for different user groups (clinician vs patient) with different use cases	• Curate and convey the project's united theme • Create a central graphic for "advertising" • Demonstrate willingness to be flexible
	Multiplicity of sites (units) for implementation	• Respond to unit variability with socio-technical approach, limited modification of tools, and work flow flexibility[20] • Leverage human factors/systems engineering
	Varied implementation/ training needs	• Implement via stepped wedge to allow for focused, staggered support • Create printed reference tools for training • Train all staff
Technology/ Governance	Technical bugs	• Respond to user issues quickly (when possible) • Set expectations about resource constraints • Pilot technology multiple times
	Project and scope management	• Leverage administrative core to maintain project scope against institutional pressures • Create development requirements and timeline ("perfection" vs progress) • Establish postimplementation productization scope
	Development of usable, helpful products	• Use iterative user-centered design process • Accommodate all users via human factors engineering
	Data access	• Leverage existing organizational data resources • Align with institutional priorities • Centralize all project data requests
Team Structure	Varied and wide-ranging research assistant (RA) tasks	• Ensure that all RAs are trained uniformly • Establish daily RA "huddles"
	Co-investigator involvement in training and support	• Involve co-investigators with clinical knowledge and experience (RNs, MDs) in end-user training
	Risk mitigation	• Encourage an open dialogue about project challenges • Document and disseminate key learnings amongst team members

Abbreviations: MD, medical doctor; PA, physician assistant; RA, research assistant; RN, registered nurse.

sions to develop new services or provide a link within the EHR environment to launch the PSLL tools). Figure 3 describes the key implementation lessons learned by project phase.

DISCUSSION

The complexity of the PSLL research project involved management of multiple dimensions: research, hospital operations, technology, the newly formed BWH/HSyE collaboration, and engagement with multiple stakeholders (eg, patients, family members, clinicians, and hospital leaders) working amid newly formed governance structures within the organization. The PSLL study was a test case for this hospital, with no established precedent for how to innovate and integrate with a newly implemented vendor EHR system. The RE-AIM provided a framework for the PSLL team to design, implement, and evaluate tools to engage patients in their care and improve patient safety.

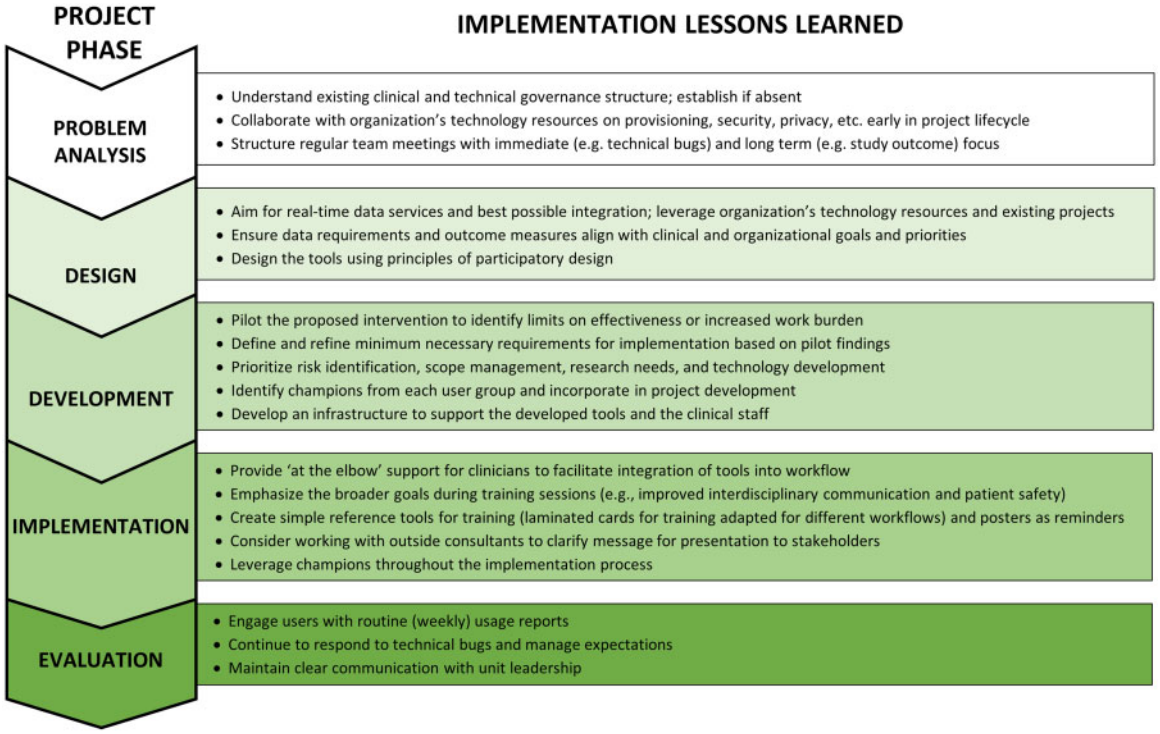

Figure 3. Implementation Lessons Learned by Project Phase. The Patient Safety Learning Laboratory projects followed the Agency for Healthcare Research and Quality Systems Design lifecycle: problem analysis, design, development, implementation, evaluation.[17] During each project phase, the PSLL administrative core prepared for implementation and documented lessons learned.

The success of the PSLL project hinged on building a multidisciplinary team focused on a well-articulated vision, mission, and goals. Establishing buy-in internally about the "why" of our project, then communicating a clear and consistent message to organizational leaders and champions was key to ensure successful adoption of the PSLL technologies into the work flow, and more broadly, into the organization (Figure 3).

The PSLL team benefited from having multiple projects under 1 infrastructure, and implementing multiple tools simultaneously resulted in culture change for a broad group of users across awide array of disciplines. The interventions and tools were synergistic, requiring a common set of data for all projects. The health systems engineering collaboration helped us focus on the whole system and address variability in work flows. The complexity of this study placed high demands on the clinical and administrative infrastructure, and these logistical supports, along with a comprehensive implementation framework, helped ameliorate that demand.

CONCLUSION

A key metric of success for HIT projects of this magnitude is organizational adoption. BWH has committed to adopting the PSLL HIT innovations and is planning to spread the PSLL tools to all clinical units across BWH. This process, which we are calling "productization," has its own set of challenges, but some of the lessons learned regarding implementation during the PSLL study can be applied to this next phase.

Another major highlight of this research is that we successfully extracted data in real-time from the newly implemented vendor EHR and displayed it to providers and patients in novel ways, engaging patients, family members and clinical care teams to improve patient safety and clinical care. We plan to use approaches we developed for future projects, and with the utilization of open application programming interfaces (API) becoming more mainstream, real-time data extraction from vendor systems and the creation of novel applications built "around" a vendor EHR may be possible for many organizations and across multiple vendors.

The evaluation phase of the PSLL study—evaluating outcome measures related to each component of the RE-AIM framework (Figure 2)—is currently underway. Results of the intervention and its impact on clinical care will be forthcoming. Future publications about the BWH/HSyE PSLL will report specifically on our outcome and process measures.

The PSLL vision of health systems collaborating with engineers to engage patients, families, and clinicians in strategies to eliminate harm in acute care hospital settings involves applying new approaches to adverse event prevention. A successful implementation of this magnitude requires a multi-disciplinary team that is willing to think outside of current work flows and processes to change health system culture. Applying user-centered design and systems engineering tools utilized in this PSLL has the potential to redesign the way health systems work.

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AUTHOR CONTRIBUTIONS

All authors have contributed sufficiently and meaningfully to the conception, design, and conduct of the study; data acquisition, analysis, and interpretation; and/or drafting, editing, and revising the manuscript.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

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CONFLICT OF INTEREST STATEMENT.

Dr Jeffrey Schnipper received funding from Mallinckrodt Pharmaceuticals to conduct an investigator-initiated study of opioid-related adverse drug events among hospitalized post-operative patients; and from Portola Pharmaceuticals to conduct an investigator-initiated study of hospitalized patients who decline administration of subcutaneous medications to prevent venous thromboembolism. All other authors report no conflicts of interest.

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