

# Gordon and Betty Moore Foundation ICU Redesign Portfolio Evaluation

*Stanford School of Medicine*

*Evaluation Sciences Unit*

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## Authors

Elizabeth Malcolm, MD MSHS

Laura Holdsworth, PhD

Marcy Winget, PhD

Nadia Safaeinili, MPH

Mary Lough, PhD RN

Karl Lorenz, MD MSHS

Richard Mularski, MD

Steven Asch, MD MPH

## Knowledge Advisors

Richard Mularski, MD (*Advisory Group Chair*)

Adam Wilcox, PhD

Derek Angus, MD

Mary Sue Collier, MSN, RN, FABC

Shannon Carson, MD

## Stanford University Evaluation Sciences Unit

Our mission is to be the evaluation partner of choice in developing, evaluating, and implementing healthcare delivery innovations towards optimizing healthcare for patients, families, providers and payers. We aim to inform the delivery of high quality, coordinated, patient/family-centered care through embedded health care delivery research.

## Executive Summary

The Gordon and Betty Moore Foundation contracted with Stanford University School of Medicine's Evaluation Sciences Unit to conduct an external evaluation of the Patient Care Program's Intensive Care Unit (ICU) Redesign Portfolio. The evaluation aims were to 1) evaluate the portfolio's achievements to date, 2) assess the design and implementation of the portfolio, and 3) assess the potential for scale and spread of the portfolio's contributions both inside and outside of the ICU setting.

Our team conducted a mixed-methods evaluation between May and October 2016. The evaluation included review of key ICU Redesign Portfolio documents, analysis of secondary data submitted by the sites, two-day rapid appraisal site visits at each of the four sites involving more than 75 grantees and stakeholders, phone interviews with five key stakeholders, and a three-hour web-ex meeting with a panel of nationally recognized knowledge advisors. We received input and guidance from the foundation's Learning and Evaluation officer, Patient Care Program staff, and our knowledge advisor chair throughout the evaluation process.

### History and background of the ICU Redesign Portfolio

In 2012, the Gordon and Betty Moore Foundation launched the new Patient Care Program putting forth the theory of change that ***"preventable harms and unnecessary health care costs can be eliminated by meaningfully engaging patients and families within a redesigned, supportive health care system"***. The establishment of the program indicated that the foundation intended to make a long-term commitment to philanthropy in the area of patient care. The foundation's board approved the ICU as an initial area of focus for the work.

From 2012-2016 the foundation funded \$29.3 million in the ICU Redesign Portfolio, including: 1) grants to four academic medical center demonstration sites to measurably improve patient and family engagement, reduce adverse hospital-acquired events, and reduce costs through application of the theory of change; 2) Path to Scale grants as a mechanism to spread the technology developed in the demonstration projects; and 3) an ICU Consortium to foster collaboration among demonstration sites. The portfolio grants were considered an "investigation". The results were intended to assist the program team and the foundation's board in determining whether to approve an "initiative" committing a time-bound discrete amount of funding to ICU redesign. The first grant in the portfolio, to Johns Hopkins Medicine, was announced the same day the new program was publicly launched at a National Health Club event. On initiation of the portfolio projects the program team defined measures of success as: achieving a measureable reduction in more than one adverse hospital-acquired event (multiple patient harms); improvement in measures of patient and family engagement, including dignity

and respect, and care concordance with goals; evidence that the work is scaling to other ICUs; and evidence that the innovations can be applied to non-ICU settings

A few significant events shaped the portfolio. The Path to Scale, introduced to grantees in 2013, put forth a plan to develop an open middleware platform to scale each site's technology innovations. The strategy was poorly received by some grantees, and was changed in early 2014 to reflect individual grantee preferences for the platform. In addition, staff turnover in the Moore Foundation and Patient Care program leadership in late 2013/early 2014 resulted in grantee uncertainty about the future of funding in the area.

At the time of writing of this report, two of the sites have completed their grant periods and submitted final data. The other two sites are still in the implementation phase, and have not submitted final data. The assessments presented below represent the work that has been completed to date.

### **Aim 1: Evaluation of demonstration project achievements to date**

**We found insufficient evidence that the overall portfolio of grants reduced preventable harms, improved patient and family engagement including respect and dignity, care concordance with goals, or costs. There were positive findings in a few areas and particularly at Brigham and Women's Hospital (BWH), but a lack of shared metrics across the sites, variation in site-level evaluation design, and incomplete implementation prevented a full comparative test of the theory of change. The complex environments and many concurrent initiatives made it difficult to attribute most measured changes to any specific program component.**

Since launched, the four demonstration sites of Johns Hopkins Medicine (JHM), Beth Israel Deaconess Medical Center (BIDMC), Brigham and Women's Hospital (BWH), and the University of California, San Francisco (UCSF) have begun implementation of 23 interventions in 13 intensive care units (ICUs). Each site implemented an electronic patient communication portal, care team information technology (IT) tools to create situational awareness and prevent hospital-acquired adverse events (harms), and one or more culture change or process change strategies.

<i>Innovations, by type, implemented at each site</i>			
Grantee Site	Patient & Family Engagement IT Tools	Care Team IT Tools	Culture Change and Care Process Interventions
<a href="#">BWH</a>	<b>Patient-Centered Toolkit (PCTK) – Patient Portal</b>	<b>PCTK – Provider Portal Microblog</b>	<b>Patient SatisfActive</b>
<a href="#">BIDMC</a>	<b>MyICU</b>	<b>Risky States</b> <b>Patient-Specific Checklist</b>	<b>Rounds Redesign</b> <b>Standardizing Room Entry</b> <b>Access to Policies &amp; Procedures</b> <b>Consult Quality</b>
<a href="#">JHM</a>	<b>Emerge Patient Family Portal</b>	<b>Emerge Care Team Portal</b> <b>Emerge Administrator Portal</b>	<b>Comprehensive Unit Safety Program (CUSP)</b> <b>Concept of Operations (CONOPS)</b>
<a href="#">UCSF</a>	<b>Emerge Patient Family Portal</b> <b>Critical Care Innovations Group (CCIG) Website</b>	<b>Emerge Care Team Portal</b> <b>Critical Care Innovations Group (CCIG) Website</b>	<b>Comprehensive Unit Safety Program (CUSP)</b>

Key:

**Black bold:** intervention and data collection complete at time of site visit

**Green:** intervention in progress, data collection not complete

**Red:** intervention in development

**Grey:** intervention considered a core element of demonstration, but was in place prior to grant project

We gathered data through document review and site visits to discern whether projects were implemented and adopted as planned, and in a manner that would achieve the intended results. Below we summarize the implementation findings as context for interpreting the quantitative outcomes.

#### *Demonstration project implementation*

The success of the projects' implementation, particularly their fidelity and reach, varied widely across sites and program characteristics. On the whole, interventions less reliant on technology were more completely adopted. Areas of implementation reflecting the cultural or research strengths of the sites were also more successful. In some cases, short developmental time frames imposed by grant deadlines and other external factors resulted in premature deployment, inhibiting uptake of the innovations.

- **Integration of innovations into clinical workflows was an important determinant of adoption. There was wide variation in the degrees of integration and adoption across the sites.**
  - Culture and process change interventions such as Patient SatisfActive at BWH, Rounds Redesign at BIDMC, and the Comprehensive Unit Based Safety Program (CUSP) at UCSF reached the most patients, were most highly adopted by providers in daily practice, and have shown the greatest potential for maintenance. They were also the least reliant on technology.
  - Higher uptake of provider tools was seen when they were integrated directly into the provider workspace and where there was a high degree of fit with previous workflows. The BWH team obtained high adoption of provider tools in the ICU by these means.
  - The Emerge provider platform has been difficult to integrate into provider and nursing workflow due to initial conceptualization at JHM as a proof of concept/prototype and limited early focus on “production” or implementation in the ICU environment. This was an interesting feature of the collaboration with the Applied Physics Lab (APL), where projects are normally first completed and tested in a simulation environment.
- **Patient portals have had modest to low adoption across the intensive care sites to date, (approximately 12% to 24%) and hence there has been no test of their true effectiveness.** Burdensome institutional review board and consent processes hampered uptake, as most sites chose a research regulatory framework for their evaluations.
- **Communication and IT tools requiring adoption of new workflow practices were easier to test within “closed” unit environments.** It was more difficult for providers to adopt new workflows that they were not using on other care units.
- **Implementation was more successful when innovation development was done as a separate phase from implementation.**
  - Deep engagement of end-users and frontline clinicians to ensure workflow fit prior to deployment was widely viewed as a successful strategy for improved uptake of interventions. This included involvement of ICU-specific Patient and Family Advisory Councils (PFACs).
  - Projects were delayed when plans did not allot time to establish the productive stakeholder relationships needed in large healthcare re-design efforts.

#### *Demonstration Site Outcomes*

The sites reported a number of outcomes targeted to the Moore Foundation goals including several adverse hospital-acquired events, patient satisfaction with care, family satisfaction with care, goal concordance (i.e. the extent to which patient goals matched the goals of the care

team), and costs. Improving “dignity and respect” was a desired outcome set forth in the foundation’s theory of change, but there was not a suitable measure for non-palliative care ICU patients when the program was launched. To remedy this issue, the Berman Institute at JHM was funded to develop a measurement instrument for dignity and respect.

The sites employed a range of measurement techniques ranging from simple quality improvement pre/post- design to mixed methods pre/post- quasi experimental design. BWH had the most rigorously planned and executed evaluation. The results reported here reflect primarily two sites (BWH and JHU) where data collection was complete at the time of our evaluation. All sites had very low baseline rates of some harms (central line-associated blood stream infections [CLABSI], ventilator-associated events [VAE]), limiting the ability to detect changes.

We summarize the observed changes below:

#### Reduction in physical harms

- BWH demonstrated a clinically meaningful reduction in aggregate harms in the ICU, but not the oncology unit. The ICU changes were driven by a reduction in catheter-associated urinary tract infections (CAUTI) and reduced incidence of pressure ulcers. The study was not powered to detect differences in individual, physical adverse events. We observed strong uptake of the provider tools on the ICU, but not on oncology, supporting the reductions seen in the physical harm outcomes. The patient portal, which BWH also designed to address physical harm, had low uptake (18% of all admitted patients or proxies) in ICU and modest uptake (33% of all admitted patients or proxies) in oncology. We cannot confidently attribute changes in outcomes to the intervention because there were concurrent quality improvement initiatives in the ICU.
- Only the physical therapy/RN mobility team at JHM fully adopted the Emerge provider platform as intended. JHM observed an increase in mobility process and decreased ICU delirium, but the analysis was not able to account for patient acuity. No other measures improved, though two measured harms had perfect baselines thus precluding any measureable improvement.
- There is insufficient data to draw conclusions about harm reduction, or other outcomes, in the two sites where the interventions are still in process.

#### Patient engagement/Dignity and respect

Sites used the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) which measures domains such as physician communication, nurse communication, and staff responsiveness to report changes in patient dignity and respect. Centers for Medicare & Medicaid Services (CMS) regulations limited data collection to the post-hospitalization period, making it difficult to attribute patient satisfaction to the care received in the ICU, though one site was able to have the rule waived for the ICU patients in the study. In addition, high baseline satisfaction scores produced a ceiling effect on any measured change.



- BWH observed significant improvement in patient and family satisfaction in the ICU, but not oncology. The improvement is likely due, at least in part, to the implementation of the strongly adopted Patient SatisfActive Model. The satisfaction scores were higher at baseline on the oncology unit.
- JHM was unable to collect enough data to meaningfully assess changes in patient satisfaction and did not measure family satisfaction. They observed low uptake of the patient portal, JHM's primary intervention to impact engagement and satisfaction.

#### Goal concordant care

Each site measured goal concordant care differently, reflecting divergent opinions for how patient goals should be addressed. Sites perceived the available measures to be inadequate.

- BWH reported a statistically significant improvement in goal concordance on the oncology unit. The improvement has face validity, despite the small sample size, because of high uptake of the Patient SatisfActive Model and modest patient portal uptake on oncology. There was no difference in goal concordance in the intensive care unit, where uptake of the portal was lower. Portal users had higher goal concordance than non-users.
- JHM intended to measure goal concordant care through use of the patient portal, however due to low uptake of the portal there is no meaningful data available to assess this outcome.
- There is no data available at the time of this writing to assess goal concordant care at the other sites.

#### Costs

Although costs were a stated outcome in the theory of change, there was no explicit framework or perspective put forth for how to assess for costs in the portfolio. For example, was the cost reduction goal for the portfolio to reduce broader health care costs or simply to demonstrate that savings would accrue to hospitals through lowering costs associated with patient care? There was not routine measurement of implementation cost across the sites, limiting the ability to perform cost-benefit analyses.

- BWH demonstrated no change in utilization measures (ICU, oncology unit length of stay, 30-day hospital readmissions) or total hospital costs after the innovations were implemented.
- JHM calculated per-patient variable hospital-related costs (not including labor), and there was no difference after implementation.
- JHM produced a financial model that compared the program costs and predicted savings against projected hospital revenue. The predicted savings were based on assumptions regarding expected changes (rather than the actual results) in cost and hospital utilization after full implementation of the program. They found that program-related expenses would outweigh any projected increase in hospital profitability, making the cost-benefit ratio unfavorable for the hospital over a five-year time horizon.

### *Achievements of the Libretto Consortium*

The foundation launched a consortium of the four demonstration sites, named Libretto, in October 2013 to unify the portfolio of work. The consortium was effective in creating a network and sense of community among the sites, despite early distrust and differing visions for change. Grantees stated that the opportunity to collaborate was the strongest and most rewarding aspect of the Libretto strategy. Some other lessons learned from the consortium work included:

- Integration groups (in which sites worked together on common challenges) were felt to be a positive and productive experience and produced outputs perceived to be highly impactful, especially the cross-institutional work on acute care patient portals.
- It was difficult to use other sites' successes or failures to accelerate the work because sites were developing slightly different interventions on roughly the same schedule. The consortium served the role of peer support for challenges, as opposed to an accelerator role.
- Grantees felt there was insufficient focus on culture and behavior change mechanisms for creating a zero harm environment until later in the consortium timeline.

Early in the history of the consortium, the foundation initiated a vision for scaling technology applications called "Path to Scale" through creation of an open middleware platform on which the emerging technology applications would operate. There was disagreement among the demonstration sites as to whether the platform was needed in the proof of concept stages of the interventions. The Path to Scale strategy was adjusted and the idea of concurrent platform development was dropped. JHM and UCSF continued to use the middleware in the Emerge development and implementation.

### *Impacts on the field*

It is premature to make conclusions regarding impact on the field. To date, however, projects have had a high profile among hospitals doing patient safety work and in professional societies, such as the Society of Critical Care Medicine (SCCM). Sites have produced a number of publications. At the time of this writing:

- 15 original research articles have been published in peer-review journals and an additional 37 other types of journal articles have been published, including descriptions of frameworks and conference proceedings.
- Nine articles had more than ten citations on Google Scholar and these articles reflected almost every domain of the work.

## Aim 2: Assessment of the portfolio design and implementation

**Interviewees felt the strategy of re-engineering the ICU to create a zero harm environment was highly aligned with the fields of critical care and patient safety. Strengths of the portfolio included the emphasis on patient and family engagement, and the collaborative grant-making style of Moore staff. Limitations included the lack of a detailed, predefined evaluation strategy that could be applied across the portfolio, leading to inconclusive findings for many areas of interest to the foundation. Also, the time frames for achieving outcomes in these projects was exceedingly ambitious as grantees were expected to invent, test, and implement technology in a complex clinical environment at a large enough scale to achieve outcomes, within two years.**

Other key themes identified by grantees, stakeholders, and knowledge advisors are listed below.

### *Strengths:*

- Grantees perceived that the foundation filled a funding gap by supporting high-risk, applied projects directed at creating meaningful change.
- Funding of transdisciplinary partnerships, as well as the emphasis of interprofessional engagement in care re-design were strengths of the grant making strategy.

### *Areas for improvement:*

- Turnover in program leadership and staff led to uncertainties and perceived delays that had repercussions on project timelines and staffing.
- The grantees perceived site visits from Moore staff early in the projects as burdensome, taking precious time away from project work.
- The strategy of investment in technology, including in the middleware and Path to Scale, could have benefitted from engaging formal expert external assessment of market conditions, and input from experts for funding high-risk technology projects in the health care sector, earlier in the investigation. As an adjunct to this, peer review of grant proposals could have yielded risk mitigation strategies early in the development of the investigation.
- The sites varied in how patient and family engagement was operationalized in pursuit of safer care. A robust conceptual framework for patient and family engagement put forth by the foundation at the outset may have strengthened the approaches that were taken in this aspect of the portfolio.

### *Topaz and the Path to Scale*

The Moore program team created the Path to Scale strategy to as a means to spread the technology under development at demonstration sites to other hospitals. The idea was that the

sites would work together in a shared governance model to develop software apps (such as the patient portals, provider tools). A middleware (Topaz) was to be developed to integrate data from multiple sources (e.g. different EHRs, sensors, etc.) allowing for easier spread of products developed at the sites, and was to be open source, enhancing the opportunities for future innovation. Development was launched with an initial \$2.3 million grant to JHM in May 2013 who subcontracted with a company called dataFascia to build a commercial grade, scalable platform that could be deployed across all sites by May 2014 (JHM Grant 3186.01 Grant Summary Document). Some sites disagreed with the strategy. An external consulting group was tasked in late 2013 to evaluate the Topaz strategy. The group recommended against continuing the Topaz platform integration with Emerge at UCSF, to refine and test Emerge without an integration layer middleware, and to use the learnings from testing to define requirements for the middleware after the proof of concept phase. Perhaps because work was already underway, Emerge software was nonetheless deployed at both UCSF and JHM using the Topaz middleware. An alpha version of the Topaz platform was installed and is not ready for commercial scale.

### Aim 3: Potential for sustainability, scale, and spread of demonstration project interventions

**Taken individually, the culture and process change interventions such as the Comprehensive Safety Unit Program (UCSF and JHM), and the Patient SatisfActive Model (BWH) have been the most strongly tested and maintained, so currently offer the greatest potential for spread. Although there has been evidence of spread of some interventions beyond pilot units, the short-term possibilities for spread to other institutions for many of the technology-based interventions is limited, at best, for now. Many are still under development and testing. The interventions were not tested in such a way that allowed us to determine whether the “package” of culture change and technology tools was more impactful than each individual intervention; therefore, it is not possible to recommend an ideal unit of spread.**

#### *Sustainability of interventions*

We define sustainability or maintenance of the interventions as continuation of programs and practices after the funding ends. Our observations include the following:

- Transition in the electronic health record (EHR) systems disrupted the maintenance of interventions at both BWH and JHM. BWH has re-implemented a version of the provider IT tools in the ICU that is likely to be maintained.
- Emerge is at risk for being sustained at UCSF because the technology will not be optimized to seamlessly fit into workflow when grant funding ends, limiting the potential for robust, ongoing use in day-to-day clinical practice. Strategic planning and comparative business modeling for maintenance and ongoing interoperability requirements were not performed at the outset, limiting ability to move beyond the demonstration scope without additional funding.

- Emerge has not been maintained at JHM and will require investment to re-implement in the new EHR.
- Although we were not able to observe maintenance at UCSF and BIDMC because they are still in their funding cycles, we were able to see indications that primary culture and process interventions were likely to be maintained, including CUSP and the Patient and Family Advisory Committee at UCSF, and Rounds Re-design and Access to Policies and Procedures at BIDMC.

### *Potential for Scale and Spread of Interventions*

The terms “scale-up” and “spread” are often used interchangeably to refer to efforts to increase the impact of successfully tested innovations to benefit more people. Both BIDMC and BWH have begun to spread innovations to other units in the hospital. Although spread and scale is a complex process, we based our determination on evidence of the innovation’s effectiveness and whether it has been adequately defined in a manner that can be replicated in a different location. We list our primary findings, including our observations of work that has been spread to date, below:

- The culture and process change interventions developed at BIDMC have been spread beyond pilot units to all eight intensive care units. The common governance structure for ICU care and engaged hospital leadership may have facilitated this achievement, unique among the demonstration sites. BIDMC has also considered spreading innovations to affiliated community hospitals.
- With the assistance of grants from The Agency for Healthcare Research and Quality (AHRQ), the Patient-Centered Toolkit interventions are already being adapted to spread to other intensive care units and the medical-surgical wards at BWH.
- The Patient SatisfActive Model has been tested previously, and there is face value for its effectiveness and adoptability at BWH. It has been clearly defined and a toolkit for spread is under development. Once the work demonstrating its efficacy has been published, the intervention will be ready for additional spread beyond BWH.
- The Berman Institute at Johns Hopkins has completed several tools for measuring dignity and respect in ICU patients. The measures have undergone preliminary validation and are ready for further testing.
- No proof of concept yet exists for acute care patient portals developed through this work and they will need further refinement before being considered for wide-spread adoption.

- The PROSPECT provider tools developed at BWH for the ICU may be easily transferable to community hospitals within the Partners in Health network, though they will need further testing of effectiveness and transferability to a community setting.
- Emerge will need further modification and testing of effectiveness prior to spread. It is not clear that Topaz would be needed for sustainability or spread, though additional investment would be needed to re-implement the software on top of other middleware products widely in use within healthcare systems.

### Recommendations:

The demonstration sites have laid considerable ground work in the areas of patient and family engagement, team care, situational awareness, and using applied systems engineering to re-design care. The two completed projects (BWH and JHM) have received significant follow-on funding. Although there are positive results in some parts of the portfolio, we are unable to conclude that the theory of change as implemented across the portfolio reduced multiple harms, improved patient and family engagement goal including dignity and respect, and increased goal concordant care. We reflected on lessons for program design and monitoring arising from our evaluation findings and interviews with grantees, stakeholders, and knowledge advisors:

- We strongly recommend future funding efforts incorporate a robust monitoring and evaluation strategy at the outset of large investments such as the ICU Redesign Portfolio. Formative and process evaluation techniques in which mixed methods are applied throughout the development and implementation process may be particularly helpful. Consider peer review as a mechanism to inform robust measurement and evaluation at individual sites.
- The simultaneous emphasis on invention, implementation, obtaining clinically meaningful results, and scaling interventions beyond the pilot sites paradoxically led to slowdowns in implementation and, in some cases, inconclusive findings. Match the developmental stage of the work to the grant making structures. For example, if focusing on innovation, smaller funding cycles with scrutiny at each stage of development for continued viability might weed out infeasible ideas earlier and produce a smaller group of high quality projects.
- Carefully elucidate root causes and measurement gaps when defining the scope of a problem. For example, the foundation hypothesized that dignity and respect was a problem in ICUs and that situational awareness and communication through information technology tools could eliminate that problem. However, adequate measurement instruments were not available to define the scope of the problem or the baseline in demonstration site ICUs. Also, information technology was supported as the

primary tool for addressing dignity and respect and goal concordant care; however, it is likely only one of many strategies needed to improve patient and family engagement in care.

- Consider expert consultation and rigorous market analysis prior to funding new health care IT. In addition, consider deploying mechanisms to de-risk up front such as requiring health system cost-sharing at the time of project start up, co-funding with an experienced health care industry partner, or small grants with rigorous requirements for progression to the next phase.

# Main Report

## 1 Introduction

The Gordon and Betty Moore Foundation's Patient Care Program launched the ICU Care Redesign investigation portfolio in 2012 with a goal of reducing preventable harms (including physical harms, loss of dignity and respect, and failure to provide care consistent with goals and preferences) and unnecessary costs through the meaningful engagement of patients and families in a redesigned health system.

The foundation has funded \$29.3 million in the ICU Redesign Project, which includes three strategies:

1. Grants to four demonstration sites to develop care innovations designed to improve patient and family engagement, reduce harm, and create strategies for spreading success.
2. Grants enabling scale of successful care innovations.
3. Funding an ICU Consortium to increase grantee collaboration, as a mechanism to increase the impact of the innovations, through a) knowledge sharing for design and implementation, and b) as a means to increase public awareness of the work through joint presentations and publications.

While many of the grants in the portfolio have been completed, others are still in progress. At this juncture, the foundation has commissioned an evaluation to address the following goals:

- assess the results of the care innovations at the four demonstration sites,
- capture lessons and perspectives from the implementation of the portfolio, and
- provide evidence base from which the foundation can make decisions about its future patient care investments.

The results of the evaluation serve to assess the impact of the portfolio to date and will inform the field about lessons learned in implementing an integrated strategy to improve patient safety.

## 2 Evaluation aims, design, and methods

### Aims

The aims of the evaluation were to:

- 1) evaluate the portfolio's achievements to date, including demonstration projects' success in improving patient and family engagement and safety over time, the Libretto Consortium's accomplishments, and an assessment of impacts of the portfolio on the field;
- 2) assess the design and implementation of the portfolio including structures, processes, alignment with the field, and changes in the portfolio over time; and
- 3) assess the potential for scale and spread of the portfolio's contributions both inside and outside of the ICU setting.

### Design

This evaluation used a mixed methods approach along with close involvement by Moore partners and a group of subject matter knowledge advisors, who oversaw the team's efforts towards the evaluation goals and provided context for our final recommendations to the foundation. A mixed methods



approach is appropriate for addressing our evaluation questions, which seek to simultaneously quantify effectiveness and explore the implementation process and contextual detail important to understanding the effect of the innovations.<sup>1</sup>

## Data collection methods

### *Quantitative methods*

Quantitative data from each site were obtained through the Moore Foundation in the form of quarterly reports and end of study reports. Some sites also shared relevant published abstracts or publications. BWH had outcome estimates and p-values from methodologically-sound, adjusted regression models in their final report, so data from the final report were directly abstracted. Outcome measures were categorized into the following four categories: Physical Harms; Patient/Family Engagement; Goal Concordance; and Costs. Patient/Family Engagement was further categorized into Patient Satisfaction and Family Satisfaction/Dignity/Respect, based on the measurement tools used.

Pre/post analyses for Physical Harms were conducted independently for each physical harm measure. Only measures for which there was baseline data available were included; thus, some measures included in sites' quarterly reports are not presented herein. The pre/post periods were defined based on information obtained during the site visits. Each site identified the dates the interventions began and the end dates when their respective interventions had been fully implemented. With the exception of BWH, the pre/post analyses were simple unadjusted z-tests or non-parametric tests (in the case of small sample sizes or very low rates). The BWH results were adopted directly from the final report because we found their methods to be adequate upon review.

### *Qualitative methods*

The qualitative portion of the evaluation utilized a rapid appraisal approach during two-day site visits. The approach was chosen for its suitability to streamlining the data collection, analysis, and interpretation processes.<sup>1</sup> Rapid assessment techniques produce a contextually defined picture of what is happening within a setting from the point of view of those doing the work and who are best positioned to explain what works or not. Multiple data collection methods were used including: interviews, observations, field survey, and document review. We relied heavily on a well-developed field guide.<sup>2</sup> The field guide contained all data collection instrumentation needed for the visit and was developed using: site documents submitted previously to the foundation, the theory of change logic model, and implementation frameworks including RE-AIM<sup>3</sup> and the Consolidated Framework for Implementation Research (CFIR)<sup>4</sup>. The researchers who attended each site visit were trained in the method and process by the project's qualitative expert, prior to the site visits, and the same three researchers carried out each visit. We worked closely with a collaborator at each site to prepare for the visit and relied on their expertise as inside informants to ensure that all necessary data was collected. In keeping with the participatory approach of rapid appraisal, at the end of each visit, one researcher presented the synthesized findings from the visit to one or more members of the site team for confirmation and clarification of our findings, as a validation check. As an additional validation check, the written case summary was sent to each site to confirm the accuracy of our findings. Further description of the qualitative methods is provided in Appendix 5.

In addition to the rapid appraisal site visits, interviews were carried out with key informants and documents were reviewed regarding the history of the portfolio, Libretto Consortium, and portfolio design and implementation. Data were handled in the same way as above.

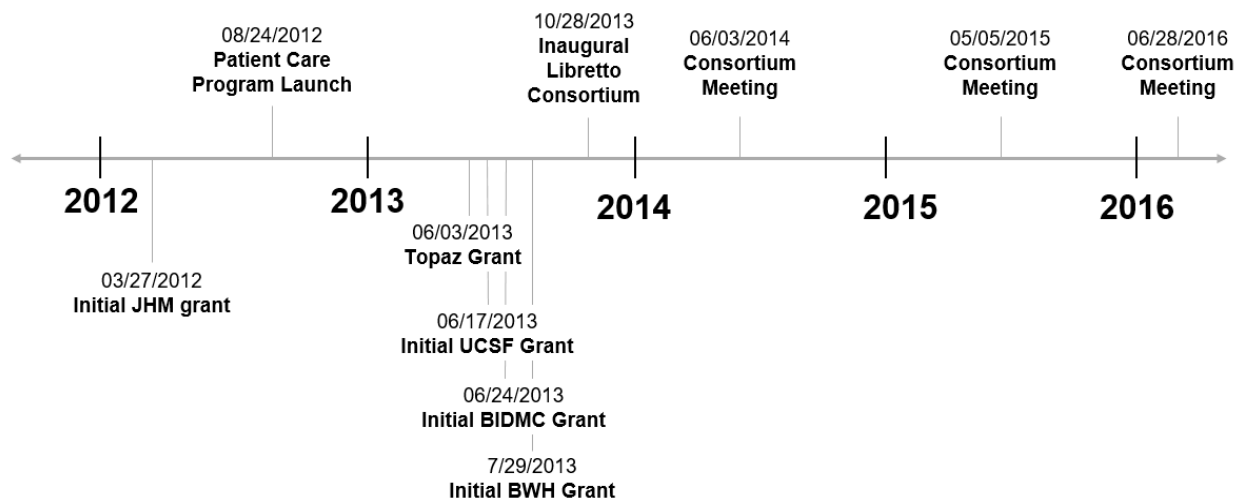
## Analysis and method integration

We utilized the mixed methods approach at various stages of the evaluation. For example, we explored findings in the quantitative data to develop interview questions during site visits, and interpreted quantitative findings by looking for evidence in our interviews and observational data to explain why certain effects from the innovations were observed or not. This approach to mixing methods can be likened to “following a thread” in that we moved back and forth between datasets to corroborate findings on particular issues.<sup>5</sup> This approach ensures that our findings reflect “the sum of the whole”, rather than presenting independent findings from different methods.

## 3 History of the portfolio

The history of the portfolio has been compiled following interviews with five key informants and by reviewing project documentation. The timeline for the portfolio history is presented in Figure 1.

Figure 1. Timeline of the ICU Redesign Portfolio

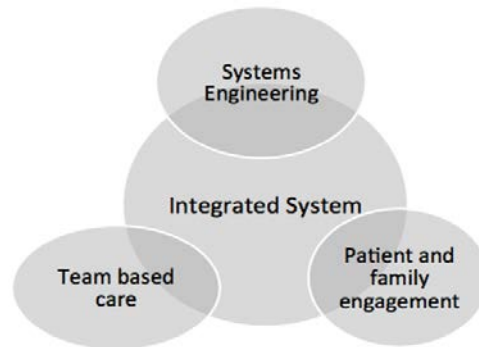


In February of 2012, the Gordon and Betty Moore Foundation board of trustees endorsed the new Patient Care Program. The program has its roots in the Betty Irene Moore Nursing Initiative, which had successfully targeted patient safety outcomes in Bay Area hospitals through a focus on nurse-implemented evidence-based care. It was decided that the new program would widen the focus from nursing, have a national rather than regional focus, and build on the foundation of patient safety work from the Nursing Initiative. The National Press Club launch of the new program in August 2012 indicated that the Moore Foundation was committed to spending \$500 million in the program over the coming 10 years.

The theory of change for the Patient Care Program asserted that *preventable harms and unnecessary health care costs can be eliminated by meaningfully engaging patients and families within a redesigned, supportive health care system*.<sup>6</sup> There was a more specific set of mechanisms hypothesized to underlie the broad theory of change, which included creating a “system of systems”

incorporating patient engagement, team based care, and systems engineering components (represented in Figure 2).<sup>7</sup>

*Figure 2. Mechanisms underlying theory of change*



The Intensive Care Unit (ICU) Redesign portfolio was launched as a first investigation into the new program. The ICU was chosen as the setting because patient acuity and complexity of care results in a higher risk of preventable hospital-acquired adverse events (preventable harms) and high per-patient costs of care.<sup>6</sup> There was an hypothesis that the potentially higher preventable harm rates might enable the foundation to see measureable improvement over a shorter time frame, i.e. in three to five years. The initial aims of the portfolio were inspired by work of Peter Pronovost and colleagues at Johns Hopkins Medicine. The Pronovost team proposed using applied systems engineering and information technology to create an ICU which achieved zero preventable harm.<sup>8</sup> In collaboration with an advisory board and grantees, the foundation expanded the definition of harms to include not only errors in care resulting in physical harm to the patient, but also patient loss of dignity and respect, and failure to provide care consistent with patient goals. The focus on patient engagement was central to the program theory of change, but there was a noted tension that it would be difficult to engage many seriously ill patients in the ICU and therefore the focus was expanded to include families. The program evolved over time to encompass three strategies:

- 1) grants to four academic medical center demonstration sites to develop innovations to engage patients and families, reduce harms, and spread success;
- 2) a Path to Scale to spread innovations to other ICUs and sites of care across the country; and
- 3) an ICU consortium (the Libretto Consortium) to enhance collaboration and increase impact.<sup>9</sup>

The ICU Redesign work was labeled as an ‘investigation’ with the expectation that within two years after the launch, the foundation board would decide whether to commit funds to a board-approved initiative, allocating a larger amount of funding over a longer period. Initiative status would be based on demonstration of the effectiveness of the theory of change through meeting the following measurable outcomes within the first two years of the project:

- 1) Achievement of a substantial reduction in a set of targeted preventable harms, including typical hospital-acquired adverse events such as central line-associated bloodstream infection (CLABSI), as well as improvement in patient dignity and respect, and care concordance with goals. Where harm reduction could not be demonstrated, there was interest in demonstrating improvement in process measures.

## 2) Reduction in costs.

Within five years, there was an expectation that the projects would scale to other ICUs and have potential for generalizability to other care settings.

There were several unique features of the strategy:

- The foundation expanded the *definition of harm* beyond preventable physical harms, first to include *loss of dignity and respect*, and later to include *failure to provide care consistent with patient goals and preferences*.
- There was a desire to address multiple harms at once as opposed to tackling harms one-by-one.
- Funding was primarily allocated to create demonstration projects at four prominent academic medical centers: Johns Hopkins Medicine (JHM), University of California, San Francisco (UCSF), Beth Israel Deaconess Medical Center (BIDMC), and Brigham and Women's Hospital (BWH).
- The funding included support for novel transdisciplinary partnerships including work with the Applied Physics Laboratory (APL), Massachusetts Institute of Technology (MIT), human factor psychologists, and the Berman Bioethics Institute.
- There was an expectation that interprofessional teams would work together to bring about change.

The keystone grant was given to Johns Hopkins Medicine (JHM) in September 2012, just after the launch of the Patient Care Program at the National Press Club in Washington DC. JHM had already been developing a systems engineering approach with the Applied Physics Laboratory (APL) for about 18 months. Through collaboration with the foundation, JHM expanded the focus of their aims from one or two harms to five physical harms. The foundation's emphasis on patient and family engagement was not previously an explicit goal of the JHM's redesign project, but the addition was viewed positively and the foundation is credited with shaping the project. Moore was also interested in the potential for spread, and so at the outset JHM had to consider replication in one of their community hospital sites and at a Bay Area site. Hence, UCSF was chosen as a spread site.

In 2013, the foundation sought to expand the number of demonstration site grantees and gave additional grants to Beth Israel Deaconess Medical Center (BIDMC) (June 2013) and Brigham and Women's (BWH) (July 2013). These high performing academic sites were chosen because it was felt that the program aims would be more likely to be achieved in a high-performing academic setting than in a community hospital setting. BWH was chosen because of their expertise in informatics research and innovation. BIDMC was selected because their 'zero harms' aim aligned with the foundation's goals and because of their reputation for engaging patients and families in care.

The original goal for the portfolio was that all hospitals would collaborate on the system of systems approach, similar to JHM, resulting in a scalable suite of interventions all working under a common operating system. As a consequence, a middleware product (Topaz) was proposed that would serve as an open source platform for enhancing data interoperability, and allow for scale past the demonstration projects by acting as a bridge between data and applications. The foundation named this strategy the Path to Scale and an initial grant was given to JHM, who contracted with a group of engineers with

connections to the foundation, in June 2013. There was an expectation that Topaz would be commercial grade within six to eight months.

When funded, BIDMC and BWH were in the midst of developing their own, different approaches through streams of work that were broadly aligned with the Foundation's aims. The foundation was therefore unable to get agreement from these additional sites to unify around the JHM vision for the Emerge portfolio of work.

The Libretto Consortium was launched in October 2013 as a means to unify the portfolio. The Path to Scale was introduced to the grantees along with a vision to create a common governance structure, measures, measurement strategies, and a data warehouse at the consortium launch. The sites did not all agree on the unified approach or the need for the Topaz platform. By February 2014, the foundation adjusted the strategy to reflect a more independent demonstration project approach from each of the sites. Topaz remained contracted to support the JHM and UCSF implementations. The rocky start to the Libretto Consortium left the sites feeling confused as to the aims of the group, even after the unified approach was abandoned. However, the consortium was ultimately viewed positively, especially the task force work groups that formed around common issues at each site (see section on ['Achievements and future of the Libretto Consortium'](#) for discussion).

Just after the Libretto Consortium was established in the fall of 2013, the Foundation underwent a change in leadership with both the president and chief program officer for the Patient Care Program departing. This change created some uncertainty at the sites regarding foundation priorities and the availability of future funding. The initial commitment expressed at the National Press Club for the systems engineering approach to redesigning the ICU seemed to wane in the run up to this transition period as grants were given out to other sites, but did not follow the typical initiative structure which would have indicated a more sustainable, long-term future.

At the time of writing this report (October 2016), each of the projects were at different stages of completion:

- BWH was the only site that had completed development, implementation, and evaluation of their innovations, and had begun working on a follow-on project with new funding which would further develop some of the innovations.
- BIDMC had implemented some interventions, but others were in final stages of development.
- JHM had completed implementation of a prototype version of their projects, and completed basic research on dignity and respect and a behavioral marker system related to teamwork in the ICU. JHM had finished their final report and were looking to further develop their innovations.
- UCSF had only recently gone live with all of their innovations and had not yet completed follow-up data collection.

## 4 Aim 1. Demonstration project overview and effectiveness to date

In this section we will summarize the effectiveness of the demonstration site interventions. Detailed case summaries, which underlie these summaries, can be found in [part two of the report](#):

## 4.1 The innovations

Each site developed a set of innovations that were implemented over a two to three-year period; Table 1 shows the innovations implemented at each site. The demonstration projects were extremely complex interventions being implemented in complex environments. The types of interventions fall roughly into the following categories:

1. **Patient and Family Engagement IT Tools (patient portals):**

Each site developed an electronic patient portal with a range of features, which varied by site. The use of the tools ranged from a platform for communication about specific care plans or test results, to an informational tool to orient a patient and family to the intensive care unit. Sites had different conceptualizations about whether and how patient goals for care should be incorporated. All were initially deployed on hospital-owned iPads kept within the units, though BIDMC has now re-implemented the tool on patient and family owned devices. Thus far, the adoption of the tools by patients and families has been low-to-modest (ranging from about 12%-24%), though two of the four implementations or evaluations are still ongoing.

2. **Care Team IT Tools:**

Each site developed, or is developing, an electronic care team tool that creates “situational awareness” for key clinical care processes to prevent patient harm, including harm from loss of dignity and respect and lack of goal concordant care. The IT tools are a “checklist of checklists” designed to aggregate and display the status of key preventative measures. For example, in ensuring patients have adequate pain control, an electronic checklist might display a patient’s reported pain level, the target pain level, medications that were ordered and what time they were given. The checklists were generally interactive with the patient/family IT tools—for example, at BWH the goals of care chosen by the patient would populate on the provider checklist. Tools also varied in terms of what degree human factors were designed into the interface, to what extent providers could visualize a state of care over time, and whether results were displayed as progress towards a goal. Several other provider tools were developed, or are being developed, in conjunction with the checklists. BWH developed a nurse care plan tool (needed to operationalize sharing a care plan with the patient) and a [microblog](#)—a social media-inspired messaging platform for providers and patients. BIDMC is developing a “[Risky States](#)” predictive model to be used to understand the unit-level state of risk for patient harm. For example, does the unit have more complex patients than usual, are there nurses on duty who aren’t familiar with the unit, etc.?

3. **Culture change and care process interventions:** This group of interventions is designed to change provider behavior, culture, workflow, and in the case of JHM, an overarching approach to re-designing care. The focus of these varied considerably, from eliciting and addressing patient expectations, concerns, and needs (BWH Patient SatisfActive Model), to addressing interprofessional care and culture of safety (Comprehensive Unit Safety Program [CUSP] at JHM and UCSF, Rounds Redesign at BIDMC). The outlier to this was the “concept of operations” (CONOPS) model at JHM, which was the fundamental organizing principle behind the applied systems engineering approach to re-designing ICU care. In some cases, the care team IT tools were engineered to integrate with the other strategies. For example, at BWH the care team

portal included a section on whether the patient had unmet needs, expectations, or concerns, elicited from the Patient SatisfActive Model, on the checklist.

The table below lists the interventions for each site, and the color of the text reflects the status of the project at the time of our evaluation. [For further details about the implementation for each project please click on the hyperlink attached to the site name.]

<b>Table 1. Innovations by type implemented at each site</b>			
<b>Grantee Site</b>	<b>Patient &amp; Family Engagement IT Tools</b>	<b>Care Team IT Tools</b>	<b>Culture change and care process interventions</b>
<a href="#"><u>BWH</u></a>	<b>Patient-centered toolkit (PCTK) – Patient Portal</b>	<b>PCTK – Provider Portal Microblog</b>	<b>Patient SatisfActive</b>
<a href="#"><u>BIDMC</u></a>	MyICU	Risky States Patient-Specific Checklist (PSC)	Rounds Redesign Standardizing Room Entry Access to Policies & Procedures Consult Quality
<a href="#"><u>JHM</u></a>	<b>Emerge Patient Family Portal</b>	<b>Emerge Care Team Portal Emerge Administrator Portal</b>	Comprehensive Unit Safety Program (CUSP) Concept of operations (CONOPS)
<a href="#"><u>UCSF</u></a>	Emerge Patient Family Portal Critical Care Innovations Group (CCIG) Website	Emerge Care Team Portal Critical Care Innovations Group (CCIG) Website	<b>Comprehensive Unit Safety Program (CUSP)</b>

Key: **Black bold:** intervention and data collection complete at time of site visit

**Green:** intervention in progress, data collection not complete

**Red:** intervention in development

**Grey:** intervention considered a core element of demonstration, but was in place prior to grant project

The table below describes the interventions at each site:

<b>Table 2. Summary of innovations implemented at each site</b>		
<b>Grantee</b>	<b>Innovation</b>	<b>Description</b>
<b>BWH</b>	PCTK – Patient Portal	Electronic patient portal designed to engage patient and all care team members in the plan of care.
	PCTK – Provider Portal	Electronic provider portal designed to implement a safety checklist and facilitate shared information and communication through the patient portal.
	Patient SatisfActive	Structured communication intervention designed to incorporate patient-centered care into clinicians’ daily routine and enhance patient and family experience in real-time.
<b>BIDMC</b>	MyICU	A patient and provider facing electronic portal that will give patients and families a personalized system for enhanced communication about and comprehension of the events that occur during an ICU admission.
	Risky States	A predictive model that will identify when a unit has a set of conditions that may increase the risk of patient harm
	Patient-Specific Checklist	Electronic patient safety checklist that will provide patient-specific information to providers, allowing them to make the right preventative care decisions at the right time with the least cognitive burden.
	Rounds Redesign	A process to improve the quality of rounds in the ICU and to ensure that bedside nurses are able to fully participate in rounds.
	Standardizing Room Entry	A uniform process for any type of room entry which will improve patient and family satisfaction, create a physical environment that drives correct workflow and ensures best practices around hand hygiene and infection control practices.
	Access to Policies & Procedures	Standardization of the structure and content of BIDMC’s existing Critical Care Practice Manual, including 80 policies and procedures, to align practice with current best-evidence, and improve formatting, readability, and electronic search functionality.
	Consult Quality	A project to design a reliable tool to measure inpatient consultation quality



Grantee	Innovation	Description
<b>JHM</b>	Emerge Patient/Family Portal	Electronic patient portal, accessible by iPad, with information specific for the patient/family.
	Emerge Care Team Portal	Electronic care team portal that displays an interactive “harms monitor” for each patient by integrating data from EHR and other data sources
	Emerge Administrator Portal	Electronic portal that allows hospital administrators to manage user accounts, deliver surveys, and export data.
	Comprehensive Unit Safety Program (CUSP)	Standardized program in which environmental, team, or work process defects are identified and supported by management processes to rectify to improve patient safety.
	Concept of Operations (CONOPS)	Process intervention in which desired outcomes are first stipulated and then the steps to achieve the outcomes are worked out in reverse at a systems level.
<b>UCSF</b>	Emerge Patient/Family Portal	Electronic patient portal, accessible by iPad, with information specific for the patient/family.
	Emerge Care Team Portal	Electronic care team portal that displays an interactive “harms monitor” for each patient by integrating data from EHR and other data sources
	Comprehensive Unit Safety Program (CUSP)	Standardized program in which environmental, team, or work process defects are identified and supported by management processes to rectify to improve patient safety.
	Patient and Family Advisory Council (PFAC)	ICU specific PFAC, first PFAC for adult inpatient care at UCSF.
	Critical Care Innovations Group (CCIG) website	Publicly accessible website with information about critical care for patients and families (about arrival at ICU, ICU care, discharge), and for providers (e.g. preventing harms in the ICU).

## 4.2 Clinical effectiveness across sites

We formulated our conclusions about clinical effectiveness by triangulating the site-reported quantitative and the qualitative data from site visits and documents. We sought to understand the relationship between the planned interventions and the expected outcomes. We also gathered information on intervention timing, context (to identify co-occurring initiatives that may have influenced the results), reach (how many patients/families received the intervention), the extent to which the intervention was delivered as planned and adoption (the extent to which providers and patients used the innovations as intended).

The complexity of the interventions and their deployment in the real-world clinical environments made it difficult to determine the impact of the innovations. There is significant heterogeneity not only in the thrust of the interventions, but in the pilot ICU characteristics, the reach, and level of adoption across the sites. Of the four sites, only BWH had adequate statistical methods applied to control for differences between the patient populations pre/post intervention. The other sites either have not collected the data to make this adjustment or have not yet reported the data because the projects are still ongoing. The case summaries, available in part 2 of this document, provide the rich detail needed to understand the results of the interventions in context.

### 4.2.1 *Summary of findings*

Table 3 summarizes the sites and corresponding units in which implementations occurred and their results. Only statistically significant changes between pre and post measures are highlighted for reduction in physical harms, patient and family engagement/dignity and respect, and goal concordant care. This summary is then discussed in detail in the following three sections. Detailed results for each site can be found in the case summaries in the second part of this report.

**Table 3. Across site results for reduction in physical harms, patient and family engagement/dignity & respect, and goal concordant care (All reported changes are statistically significant)**

Site	Unit	Context	Implementation <sup>c</sup>	Physical harms	Patient & Family Engagement	Goal concordant care	Interpretation of changes
BWH	Medical ICU	20 beds, average LOS = 5 days	PCTK provider checklist +++ Microblog ++ PCTK patient portal + Patient SatisfActive Model +++	Reduction in aggregate harms (CAUTI, CLABSI, VAE, Falls, Med Errors, Pressure Ulcers) <sup>a</sup>  Reduction in CAUTI <sup>a</sup>  Reduction in Pressure Ulcers <sup>a</sup>  No difference, but study not powered to detect individual harms-- in CLABSI, VAE, falls, medication errors.	Improvement in patient (HCAHPS) and family (FS-ICU 24) satisfaction <sup>a</sup>	No change (Haberle) <sup>a</sup>	Study not powered to detect differences in individual harms. Cannot confidently attribute improvement in aggregate physical harms to innovations due to concurrent external interventions. Improvement in patient and family satisfaction in ICU likely due to robustly implemented and adopted Patient SatisfActive Model.
BWH	Oncology	18 bed unit, average LOS = 14 days	PCTK provider checklist 0 Microblog + (part of provider PCTK) PCTK patient portal ++ Patient SatisfActive Model +++	No reduction in aggregate harms.  Reduction in CLABSI <sup>a</sup>  No difference, but study not powered to detect individual harms-- CLABSI, VAE, falls, CAUTI, medication errors, pressure ulcers.	No change in patient satisfaction (HCAHPS) <sup>a</sup>  Family satisfaction not measured	Improvement (Haberle) <sup>a</sup>	Checklist most likely to impact CLABSI, but cannot attribute reduction to checklist because it was not adopted. Improvement in goal concordance, in spite of small sample sizes, has face value due to modest uptake of patient portal and high uptake of Patient SatisfActive Model.

Site	Unit	Context	Implementation <sup>c</sup>	Physical harms	Patient & Family Engagement	Goal concordant care	Interpretation of changes
BIDMC	All 8 ICUs – medical (2), coronary care, surgical, neuro, trauma/surgical, cardiovascular, Finard medical/surgical	Unit sizes and length of stay (LOS) varies	Rounds Redesign +++ Standardized Room Entry ++ MyICU patient portal v1 + MyICU patient portal v2 in process Policies and Procedures ++ (Patient Specific Checklist, Risky States, Consult Quality not yet implemented)	Reduction in VAE <sup>b</sup>  Reduction in Delirium <sup>b</sup>  There was no statistically significant change for CLABSI.	Not able to assess patient satisfaction (HCAHPS): interventions in process  No change in family satisfaction (FS-ICU 24) <sup>b</sup>	Not able to assess: interventions in process	The primary interventions have not yet been implemented, or are in early stages of implementation so changes to date cannot be attributed to specific interventions.
JHM	Surgical ICU	12 bed unit, average LOS = 2 days	Emerge provider portal ++ Emerge patient portal + CUSP +++	Increase in mobility process measure <sup>b</sup>  Reduction in delirium <sup>b</sup>  No difference, but study not powered to detect individual harms-- CLABSI, VAE, DVT/PE.	Not able to assess patient satisfaction (HCAHPS): small sample sizes <sup>b</sup>  Not able to assess family dignity and respect (ICU-RESPECT): no 'pre' data	Not able to assess: no 'pre' data and small sample sizes in 'post' <sup>b</sup>	High uptake of the provider portal by the Mobility Team (93%) and use of CONOPS may have positively impacted delirium and mobility. Not adjusted for patient acuity so results inconclusive. Baseline values for CLABSI and VAE were 0.

Site	Unit	Context	Implementation <sup>c</sup>	Physical harms	Patient & Family Engagement	Goal concordant care	Interpretation of changes
UCSF	Mixed medical/surgical ICU	32 bed unit, average LOS = 4	Emerge provider portal + Emerge patient portal + CUSP +++ CCIG website ++	Not able to assess: no 'post' data yet	Not able to assess (HCAHPS, FS-ICU 24): no 'post' data yet	Not able to assess (CollaboRATE): no 'post' data yet	No results yet to draw conclusion.

<sup>a</sup> Adjusted comparison

<sup>b</sup> Unadjusted comparison

<sup>c</sup> For implementation, adoption ratings for each innovation: 0 = not adopted, + = limited adoption, ++ = moderate adoption, +++ = good adoption

<sup>d</sup> **Black results** indicate statistically significant positive or negative findings; **Grey results** indicate unable to determine.

<sup>e</sup> Physical harms abbreviations: CAUTI: catheter-associated urinary tract infections, CLABSI: central line-associated blood stream infections, VAE: ventilator-associated events

<sup>f</sup> Innovation abbreviations: PCTK: patient-centered toolkit, CUSP: comprehensive unit safety program, CCIG: Critical Care Innovations Group

<sup>g</sup> Patient and family engagement tool abbreviations: HCAHPS: Hospital Consumer Assessment of Healthcare Providers and Systems, FS-ICU 24: Family Satisfaction in the Intensive Care Unit

### Reduction in physical harms

**Measurement of physical harms:** The sites attempted, through the Libretto Consortium Measurement and Evaluation Integration Group, to agree on common outcome measures across the sites. However, differences in existing measurement infrastructure at each site led to different sets of measures reported for each site. The only outcomes common to all sites were CLABSI and ventilator-associated events (VAE), which tended to be already very low at baseline. Sites chose outcomes that were relevant for their harm reduction strategies and for which they had measurement infrastructure in place. CLABSI, CAUTI, and VAE were measured using existing standard methods, whereas other measures that do not have standard measurement protocols were reported in different ways across sites. Delirium was assessed in a consistent way using the Confusion Assessment Method for the ICU (CAM-ICU), however, one site reported percentage of delirium-free days (BIDMC), whereas others reported percentage of patients with a positive delirium screen (JHM, UCSF).

**Baseline rates:** The baseline rate for some physical harms, especially CLABSI, was low making it difficult to demonstrate effects of the interventions.

**Impact of interventions:** Overall it is difficult to draw conclusions as to the impact of individual interventions because sites simultaneously implemented multiple interventions, and because we were unable to adjust for acuity at JHM and BIDMC. All sites had ongoing concurrent patient safety interventions that were external to the project. The observed BWH reductions are most robust because comparisons were adjusted using appropriate statistical techniques. We used the triangulation of our quantitative and qualitative data to make educated guesses about the extent to which reduction in harms were related to the interventions.

### Patient and Family Engagement/Dignity and Respect

**Measurement of patient and family engagement/dignity and respect:** The foundation had a strong interest in improving and measuring patient dignity and respect, but it was acknowledged that there was not a good ICU-specific measure for the constructs. The sites agreed upon the use of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. Though HCAHPS survey was not designed to measure patient level dignity and respect, it measures some likely correlates: communication with doctors and nurses, responsiveness of hospital staff, and pain management. There are challenges in using HCAHPS. First, when sites have high patient satisfaction at baseline there is a ceiling effect that makes it difficult to detect further improvement. The Center for Medicare and Medicaid Services (CMS) requires survey implementation 48 hours to 6 weeks after hospital discharge, making it temporally difficult for patients to separate their experience about ICU care from the rest of the hospital stay. The Berman Institute at Johns Hopkins University was funded through the initial grant to JHM to develop an ICU-specific measure of respect and dignity, which in future could be used as to address these issues.

The 24-item Family Satisfaction with Care in the ICU (FS-ICU 24) was used to measure family dignity and respect at BWH, BIDMC, and UCSF, but not JHM. Similar to HCAHPS, the survey does not specifically measure the construct of dignity and respect; however, sites felt the composite scores were likely to be correlated with respect and dignity. The composite scores include an overall score, one score specific to care (14 questions related to: treatment of patient and family, symptom management, nursing and physician skill, atmosphere of ICU, and satisfaction with the amount of care received), and one score

specific to decision-making (10 questions related to: access to information to support decision-making and the process of decision-making about patient care).

**Impact of interventions:** The patient portals were expected to have the greatest impact on patient and family engagement and dignity and respect. At BWH, the Patient SatisfActive Model also was directed at these outcomes. It is perhaps surprising that, at BWH, the Patient SatisfActive Model was implemented almost equally across the ICU and oncology unit, yet there was no change in oncology unit HCAHPS scores while there was improvement in the ICU. There was less room for improvement in oncology. Post-intervention data were not available at BIDMC or UCSF to draw any conclusions on the impact of their interventions.

### Goal Concordant Care

**Measurement of goal concordance:** Each site used different metrics to determine whether the care received was concordant with patient and family goals, largely because strong measures do not exist for measuring goal concordance. BWH used the Haberle goal concordance method, which uses a list of seven items from which the patient selects his/her goal for the hospitalization. Concordance is measured by whether the provider's goal matches the patient's goal from the seven-item list. Perfect agreement is required for concordance. BIDMC developed a question with a five-point scale asking patients if they had received care consistent with their goals. This was administered at the time of discharge from the ICU. The intended measure for JHM was the match of the care goal the patient/family entered in the patient portal to that of the intensivist or attending, similar conceptually to the Haberle. Due to very low uptake of the patient portal by patients/families at JHM, however, there was not enough data to assess concordance. UCSF used CollaboRATE, a three-question survey with a zero to nine scale that asks patients/families the degree to which their care team made an effort to help them understand their health issue, listen to things that matter most to them, and include them in choosing what to do next. Most sites expressed some frustration/discomfort in the lack of availability of a widely accepted tool.

**Impact of interventions:** The oncology unit at BWH was the only site that achieved statistically significant improvement in goal concordance. We suggest that this is due to modest uptake of the patient portal and high uptake of the Patient SatisfActive Model on the unit. The MICU also had similar uptake of the patient portal and model, and although the results were not statistically significant, there was a trend towards improved goal concordant care.

### Conclusions

Consistent and complete measurement of physical harms, family engagement/dignity and respect, and goal concordance was a challenge at each of the sites, limiting our ability to draw comparisons across interventions. The attribution of the effect of complex interventions in complex environments is difficult. However, our mixed-methods study enabled us to identify situations in which incomplete adoption or concurrent initiatives may have impacted the results and thus improve interpretation. We discuss implementation lessons in a following section. Data were not available to make adequate comparisons across BIDMC and JHM, resulting in an inability to draw conclusions. We strongly recommend that sites ensure that the infrastructure for data collection, reporting, and statistical analysis needed for adequate pre/post comparisons are in place prior to funding in the future.

### 4.3 National comparators

This section is for reference purposes only and cannot be compared directly to any of the measures reported by the sites. This is because the absolute rates in the table below are calculated using a standardized national reference population whereas the rates in the case summary tables are based on the ICU-specific populations at each site.

Several organizations have developed standardized outcome measures for hospitals and ICUs, with detailed protocols for collecting and reporting them. Some of these include the Joint Commission<sup>10</sup>, the AHRQ<sup>11</sup>, and CMS<sup>12</sup>. Publicly-reported national comparators for the ICU, however, are limited to annual reports from the National Healthcare Safety Network (NHSN), a division of the Center for Disease Control (CDC). The only ICU-specific measures included in the reports are for CLABSI and CAUTI. National comparators for other physical harms were not available. Table 4 shows the standardized incidence rates for CAUTI and CLABSI in each of 2013 and 2014, the most recent NHSN report. Rates of both decreased significantly, although the absolute change is very small in each. Assuming these data are generalizable across more recent years, one could infer that rates of these harms are improving by small amounts annually due to national and local initiatives.

<b>Table 4. National standardized incidence rates for CAUTI and CLABSI in ICU<sup>13</sup></b>					
	2013 SIR*	2014 SIR*	Percent Change	Direction of Change	p-value
CLABSI, ICU	0.497	0.450	9%	Decrease	0.0000
CAUTI, ICU	1.171	1.155	1%	Decrease	0.0139

\*Standardized Infection Ratio: a statistic used to track healthcare associated infections (HAIs) over time, at a national, state, or facility level. The SIR compares the actual number of HAIs at each hospital, to the predicted number of infections based on a standard reference population.

### 4.4 Implementation lessons across sites

The culture and care process interventions were more highly adopted and had broader reach than the technology interventions. The demonstration site teams strongly believed that the IT tool innovations meant to support the culture could not stand alone. Although none of the projects were designed to test this presumption, the provider and patient IT tools were built with specific elements to reinforce the culture and care process interventions. As a result, the impacts of the IT tools cannot be separated from the culture change interventions. For example, BWH integrated patient responses from the Patient SatisfActive Model into the checklist portion of the provider tools, and reinforced patient engagement by sharing a real-time care plan with patients through the patient portal. Not surprisingly, the implementation process closely reflected the culture and experience at each site. For example, the UCSF team drew on a strong interprofessional culture, involving nurses and pharmacists in the development and implementation of the Emerge technology; BWH has longstanding experience developing and implementing in informatics and this was reflected in meticulous attention to clinician workflow prior to launch of the PROSPECT tools; and BIDMC has a collaborative culture and co-created their workflow innovations with front line clinicians across all eight ICUs.

The key themes we uncovered across the sites are described here. More detail on each site's implementation can be found in the case summaries.



**Integration of technologic innovations into clinical workflows:** As noted above, the checklist function of the care provider IT tools was meant to create situational awareness for care processes that should be implemented to prevent adverse hospital-acquired events. Their utility depended on the degree to which they fit into workflow and how they were used. These tools were adopted primarily as part of the physician-led rounding process. Where the tools were imbedded into the medical record workspace and easily accessible as a tab on the workspace platform (BWH), there was relatively robust adoption for use during preparation for and during rounds. Where they were harder to access, for example available only on iPads and not on provider work stations (JHM), or required providers to open a separate window (UCSF), they were not as well adopted. We found that nurses used the safety checklist/situational tools much less than physicians, likely because of inability to access and document care changes directly onto the application and have them reflected in the medical record.

*Emerge right now does not replace anything, so they still do their documentation in another system, there's still other things. The idea is that it's a two-way thing so in Emmerge when you do something it makes documentation easier, you're there, you just click on it and push information in. When that happens I think there's gonna be a lot more nurse buy-in because it helps them do their work (Presentation Site A 03)*

Finally, it should be pointed out that the Emmerge technology (at UCSF and JHM) was intended to be used not just on rounds, but continuously with clinical care during the day. The clock-face interface was designed to allow clinicians or patients to visualize the status of the harm preventative measures continuously. This feature would potentially change how clinicians interact with patient safety processes from current methods of checking each shift when charting or rounding. However, issues with the software interoperability and hardware have not allowed for this aspect of the technology to be tested.

**Unit staffing structure:** It was much harder to test an innovation if staffing on units was in flux. If clinicians worked across multiple units, it was almost impossible to have them adopt a technology, communication practice, or workflow that would only apply to one unit. For example, UCSF has an open unit structure, allowing hospitalists to follow their patients and care for them in the ICU. To date, Emmerge technology has only been adopted by the unit-dedicated critical care consult team (fellow, pharmacist, nurse practitioner). Another example was the high adoption of the provider tools from the Patient-Centered Toolkit in the MICU at BWH, compared to the low adoption on oncology. The MICU had dedicated critical care providers who would relatively frequently rotate through the unit learning to use both the checklist tools and the microblog communication tools. The oncology providers followed patients on multiple units (not just the pilot unit), and some had only two weeks' exposure to the new system. One potential advantage of the microblog tool was to engage clinicians and patients in asynchronous communication about patient issues; however, it was inefficient for providers to communicate one way on non-pilot units and another way on the pilot unit.

*The microblog- the patient-centered communication platform that we implemented, the vision of that was always to engage these outside providers and get their input. Now it's hard to do that [...] because they're like I get like 20 emails a day, 50 emails a day, I have other ways of doing things on the rest of my patients, you just want me to respond to that one message there? [...] There was a lot of pushback. (Interview Site C 05)*

On the other hand, if the tools were to be widely accepted and implemented within the hospital, it is these types of open unit staffing models where they might be hypothesized to have the greatest impact. For example, the microblog communication tool is likely to be more useful for providers that are not always present in the unit to communicate about patient care -- asynchronous communication. Emerge is another example where providers coming in and out of the unit could see the instantaneous status of the harm preventative measures, potentially increasing the adherence to the care practices needed among the diverse providers and complex care process.

**Regulatory burdens for research and use of personal health information:** Because ICU patients are typically very ill, their families were often the primary audience for the patient portals. The adoption for these portals has been low to modest to date because they were implemented on hospital-owned iPads to meet regulatory issues related to personal health information (PHI). This limited their utility for family members, who expressed greater need for access to a portal communication tool when not present in the hospital with their loved one. BIDMC is piloting a second version of the acute care patient portal which is stripped of PHI, allowing patients and families to self-register and log in on their personal devices. Other institutions may follow suit. By far the biggest barrier to portal adoption was the onerous process of consenting the patients or family members to participate in research as a pre-requisite to using the tablets.

*One of the barriers for us [...] (was) our approach to IRB [...] this consent process they approved was so onerous, I mean I've done actual invasive research that was less onerous than the consent process that they were making us put patients through.*  
(Interview Site A 01)

This limited the degree to which unit-based clinicians could autonomously encourage enrollment and registration for portal use. A lengthy consent document had to be reviewed for each patient, in most cases requiring research staff to enroll eligible patients during paid hours on the units. The low patient portal adoption limited the test of how effective they were in promoting engagement, safety, or goal concordant care.

**Innovation development as separate phase to implementation:** Because the innovations were being implemented into clinical care, there was importance in having reliable clinical data in real time fostering clinician "trust" in the tools and technology to create efficiency, rather than additional technologic burden. When sites implemented versions of the technology that had been tested and refined with end users (including front line staff and patients) in a closed environment to fit workflows before adding into practice, there seemed to be higher success with adoption. BWH was especially strong in this area given the team's expertise in informatics.

*We were continuously doing the development with [the nurses] [...] We were trying to understand first the workflow, so we were doing workflow observations. [...] We did it early so we had enough time to then meet their requirements, revise and get that development in, which was key* (Interview Site C 01)

JHM, and to some extent UCSF, were in a position where having to go live with a prototype that was not optimal for efficiency and clinical flow may have resulted in lower use, and in the case of JHM lessened interest in the app once it was more highly reliable.

## 4.5 Achievements of the Libretto Consortium

The aim of this section is to describe the degree to which the consortium achieved the desired outcomes of 1) accelerating the speed of innovation and quality of implementation at the demonstration sites through facilitation of knowledge transfer among sites; and 2) increasing public awareness of the work in the portfolio as a path to adoption and scale of the demonstration projects. An analysis of the implementation and adoption of the Topaz platform will be included in this aim.

### 4.5.1 History of the consortium

The Libretto Consortium was launched in October 2013. The initial vision for the consortium, as described in the history section, was to unify the portfolio of work under one umbrella.

*The sites are intended to function as an ongoing laboratory of testing of approaches and creating innovations to eliminate harms in the ICU (Presentation: ICU Consortium Design Background Materials 2013)*

Two visions were put forth in this initial meeting:

1. **The Path to Scale** was a vision for scaling the technology applications developed at each site. The idea was that the sites would develop “essential apps” similar to Microsoft Word, and there would be simultaneous development and deployment of an open platform middleware to integrate clinical data and ease spread of the software developed to other healthcare sites. Scale would happen when new institutions adopted the apps developed at the demonstration sites, and in so doing would also adopt the middleware platform (Topaz). Topaz would allow hospitals and companies to more easily build other new applications and spread them using various types of integrated clinical data to improve quality/reduce harms.
2. **The foundation proposed creating consensus** within approaches including standard measures, definitions, evaluation approaches, and a data warehouse. This involved a strategy of forming integration groups, which would allow members from different sites to work together on specific problems.

There were nearly universal positive reviews for the first meeting of the consortium (Doc: Libretto ICU Consortium Survey Results, 2013). However, some participants did not embrace the proposed Path to Scale, which included a description of the middleware platform and a common governance structure, Topaz. To a certain extent this reflected how far along the sites were in their own projects, and the commercial strategy being described was a poor fit with academic culture. There was also disagreement about whether a scalable platform (Topaz) was necessary at the proof of concept phase of the projects.

This led to a refined focus and Path to Scale in that the idea of concurrent platform development across the consortium was essentially dropped, and the Libretto Consortium focus shifted to cross-institutional collaboration (Doc: Board Presentation and Document Jan 2014). JHM and UCSF were the only sites to include Topaz in their implementation strategies.

### 4.5.2 Participant views on the consortium

Interviewees at site visits were asked how their involvement with the Libretto Consortium impacted their projects/interventions and follow up questions were asked to understand the extent to which the consortium accelerated the speed and quality of innovation, what felt particularly transformative, and

what could have made the consortium more impactful. The following themes emerged and were fairly consistent across the sites:

**Cross institutional network was highly valued.** There was strong consensus that cross institutional collaboration was the most valued aspect of the consortium. The grantees made informal and formal connections that were felt to contribute to personal and professional development. Participants described a lack of trust among the institutions at the beginning that developed into robust relationships over time. The yearly consortium meetings created positive energy and enthusiasm for the projects. It was felt that the foundation did a great job of fostering a sense of network and community among the sites.

*Interviewer: Do you feel you have the network now?*

*Yes, I could pick up the phone now and call [X] at Site B and the people I've gotten to know over the last 3 years and could say 'Hey we're stuck here and don't know what to do' – we never would have had that before (Notes from Interview Site D 02)*

**Integration groups were largely a positive and productive experience.** Five task force groups were created to integrate the streams of work across the sites: governance, patient and family engagement, IT, clinical workflow, and measurement and evaluation. The grantees were also able to apply for small amounts of funding from the consortium to do collaborative work. Grantees were very satisfied with this strategy and perceived some outputs to be highly impactful, particularly a jointly produced paper on the definition of patient and family engagement in the intensive care unit<sup>14</sup>, and the acute care patient portal conference, supported by the foundation. The participants valued the ability to generate ideas and attain funding for small projects through the consortium. In addition, there was agreement that the opportunity to deepen thinking in certain areas of discovery, such as how to measure delirium and over-sedation, spurred innovation and academic discovery.

*I would say that the collaborative projects were pretty useful and several of those will have produced a number of useful outputs. Like the stuff on acute care portals is going to be the best stuff that has been done around that [...] it was very helpful for the foundation to make available some support to do things together. (Interview Site C 08)*

On the other hand, integration group work created a heavy workload and competed with time needed to get the site-level project development and implementation work done.

**The learning cycle not was not synced with projects timelines.** In answer to our questions about whether the consortium helped to accelerate the speed and quality of innovation at the sites, we heard that it was difficult to learn from other projects' successes or failures because of project timing. Although there were a few areas where sites benefitted from sharing knowledge together, or from experiences at another site (for example harm measurement and how to handle iPads in the ICU), in most cases the work was happening simultaneously. As a result, the consortium interactions provided affirmation that sites had struggled with the same issues, rather than facilitating a space to solve problems.

*Interviewee 1: We all have lessons learned, like they bring up management of iPads and we're like "oh wait yeah we found out the same time" and Site D's like "oh we*

*have Wi-Fi issues” and then we were like “yeah we did too” but they were all happening around the same time, they weren't that far apart, because everyone went live between the last- less than year or two.*

*Interviewer: So it really just didn't allow you to benefit from learning from each other.*

*Interviewee 2: Yeah (Interview Site B 05)*

Also, the timing of the collaborative, having started a few months to a year after the sites began working on their projects, meant that project plans were fairly well rooted before the consortium launched and hit its stride. BIDMC, perhaps, benefitted the most in terms of learning from other sites for some aspects of the patient specific checklist and the patient portal, simply because their innovations were less developed when they entered the project.

**The focus on IT was too narrow.** Grantees felt the culture and behavior change aspects of the projects were underemphasized until the later stages of the consortium.

*When you look across the Libretto sites, we were probably the only ones that had in our grants some of these [culture-based] kinds of things. So that there was always an emphasis that the kind of connection- the sharing [within the Libretto Consortium] was around the things that were very IT-related. And that probably came out of the very beginning [...] there was always an emphasis on IT. (Interview Site D 07)*

This is in marked contrast to the fact that the culture change interventions were by far the most highly adopted, “sticky”, and had the most evidence for impact at each site.

**Sites had different approaches for improving care.** Each site had its own vision for the development and deployment of the innovations. Whereas JHM and UCSF were focusing on Emerge, BIDMC and BWH had their own conceptual models and strategies for bringing together the components of the integrated system. There was a healthy sense of competition among the sites, and there was a feeling that sites learned from the different approaches.

*[the foundation] kinda wanted us to think about doing everything exactly the same way, I think that was not really a reasonable expectation. I think, you know, when you're trying to solve a hard problem like this it's very reasonable to let several groups go at it in somewhat different ways, see what you find, take the things that you learned at the end, and then see where you go. (Interview Site C 08)*

On the other hand, the lack of alignment of visions also seemed to limit learning across the sites.

#### **4.5.3 Recommendations for future of the consortium**

There was no consensus from the sites about the future of the Libretto Consortium. All interviewees highly valued the networking and collaboration, but did not see these as justification for continuation. On the whole they expressed that continued formal collaboration would be valuable only if its work was relevant to ongoing work at the sites. It was also suggested that the consortium would likely be more successful if members provided the leadership and could make decisions about the scope of work.

Some suggestions for the future of the consortium included:

- 1) **Patient portals:** This work is felt to be ripe for continued collaboration because it the concept is still relatively young. It was felt that the grantees' collective experience could be valuable to the developing field. Toolkit development, mentored implementation, and workshops with potential strategic partners (industry, EHR vendors, health systems) were mentioned as areas of interest.
- 2) **Trials group:** It was suggested that the sites organize as a group to carry out multicenter investigations or incubate ideas and new innovations for testing.

In sum, Libretto did not appear to spread innovation development across the sites as we did not see any examples of sites adopting innovations from one another (except for the "bring your own device concept for patient portals). Rather they were interested to see the outcomes of the evaluations before making adoption decisions. However, the consortium may have had intangible benefits in allowing the innovators to interact with one another.

#### 4.6 Impacts on the field

Most of the sites' work is either very recently completed or still being implemented, so it is too early to determine its impact on the field. We assessed the dissemination activities from the demonstration sites and the consortium to date. Table 5 includes citations from portfolio work in the public domain that were submitted to the foundation or to the evaluation team. See Appendix 4 for the full list of dissemination activities.

<b>Table 5. Dissemination activities by site; only includes items which can be found online</b>								
Site	Journal items				Book/ chapter	Report	Media <sup>e</sup>	Total
	Original Research <sup>a</sup>	Other Peer Review article <sup>b</sup>	Thought piece or Editorial <sup>c</sup>	Presentation - abstract <sup>d</sup>				
BIDMC	2	1	1	8	-	1	10	<b>23</b>
BWH	4	5	-	-	1	-	3	<b>13</b>
JHM	10	7	3	-	1	1	2	<b>24</b>
UCSF	-	-	-	5	-	-	2	<b>7</b>
Collaborative <sup>f</sup>	2	1	3	2	-	-	9	<b>17</b>
<b>TOTAL</b>	<b>18</b>	<b>14</b>	<b>7</b>	<b>15</b>	<b>2</b>	<b>2</b>	<b>26</b>	<b>84</b>

<sup>a</sup> Original research (project results) and systematic reviews.

<sup>b</sup> Descriptions of practice, conceptual papers, papers from presentations published in full.

<sup>c</sup> Editorials, viewpoints, brief communications.

<sup>d</sup> Abstracts published in a journal following presentation at a national, peer-reviewed conference.

<sup>e</sup> Original news piece. Press releases that were picked up nationally were only counted once.

<sup>f</sup> Papers were classed as collaborative if more than one consortium site were included as authors or if media coverage mentioned more than one site.

Table 6 shows the number of journal items that have been cited 10 or more times by other papers.

<i>Table 6. Published journal articles with 10 or more citations<sup>a</sup> as of October 2016</i>					
<b>Citations</b>	<b>Paper title</b>	<b>Journal</b>	<b>Paper type</b>	<b>Year</b>	<b>Site</b>
<b>52</b>	Preventing patient harms through systems of care	Journal of the American Medical Association	Thought piece	2012	JHM
<b>34</b>	Care partners and online patient portals	Journal of the American Medical Association	Thought piece	2014	Collaborative
<b>27</b>	Developing predictive models using electronic medical records: challenges and pitfalls	AMIA Annual Symposium Proceedings	Presentation	2013	JHM
<b>19</b>	From heroism to safe design: leveraging technology	Anesthesiology	Thought piece	2014	JHM
<b>18</b>	A systematic review of teamwork in the ICU: what do we know about teamwork, team tasks, and improvement strategies?	Journal of Critical Care	Research	2014	JHM
<b>14</b>	Participatory design and development of a patient-centered toolkit to engage hospitalized patients and care partners in their plan of care	AMIA Annual Symposium Proceedings	Presentation	2014	BWH
<b>12</b>	A systematic review of behavioural marker systems in healthcare: what do we know about their attributes, validity and application?	BMJ Quality and Safety	Research	2014	JHM
<b>11</b>	Enhancing the quality of care in the ICU: a systems engineering approach	Critical Care Clinics	Journal article	2013	JHM
<b>11</b>	Defining patient and family engagement in the intensive care unit	American Journal of Respiratory and Critical Care Medicine	Thought piece	2015	Collaborative

<sup>a</sup> Citations identified using Google scholar on October 5<sup>th</sup>, 2016.



We expect the list of primary research papers to grow as sites complete their projects and find publication venues. To date, the only demonstration project results that have been published are from the implementation of the BWH microblog, but there are several papers that are just reaching completion or that have been submitted across all the sites. JHM's research paper output has been heavily driven by the work of the Berman Institute on respect and dignity in the ICU, though this publication is fairly recent and has not yet been widely cited. BIDMC's work has attracted a lot of media attention, primarily around issues of emotional harm in the ICU. Most papers have been published in American journals.

Of interest is the article on 'Care partners and online patient portals' which was produced by the collaborative. This paper has received a high number of citations considering it was published relatively recently in 2014. This may indicate that the work of patient portals in the ICU environment is novel or at least of interest to the wider critical care community. Interoperability through systems of care also seems to be of interest to the academic journal audience.

Most of the sites have not yet published their full research findings, and based our findings regarding consortium members being cautious to adopt innovations without being confident of their effectiveness, it seems likely that the innovations developed and tested as part of the portfolio will not have maximal impact through wide adoption until their effectiveness is known.

## 5 Aim 2. Assessment of portfolio design and implementation

We identified a number of strengths of the grant making. The foundation's leadership around eliminating adverse hospital-acquired events was highly aligned with the field. Grantees felt that enlisting patient and family engagement in as a means to achieve a safer environment was forward thinking and spurred reconsideration of assumptions about the role of patients and families in care. The foundation's encouragement in enlisting patient and family advisory councils enhanced the quality of the innovations and led UCSF to establish the first PFAC in their system.

Other key findings regarding portfolio strengths are listed below.

- **Filling a funding gap:** It was widely viewed that the foundation filled a funding gap by supporting applied, high-risk projects directed at creating meaningful change in health outcomes.

*I think [the foundation's] vision of doing transformative, hard problems - and what Gordon Moore did - is unique from a philanthropist, it's what we started with this but I think it got narrowed, but I would plead that they keep that in health care because nobody else is doing this. [...] This is hard work but if you can get 30% productivity gains, if you can get 10% productivity gains we've solved America's healthcare [cost] problem (Interview Site A 02)*

- **Collaborative grant making style:** Moore staff engagement, partnership, and flexibility were identified as fundamentally different from experiences with other funders and a strength of the grant making approach.



- **Transdisciplinary partnerships.** Partnerships across diverse fields such as between the Applied Physics Lab (APL) and JHU, or between BIDMC and MIT were felt to be highly advantageous and unlikely to have happened without the foundation's support.
- **Making dignity and respect an issue for all patients:** It was felt that moving the concept of dignity and respect out of palliative care and into the mainstream of ICU care was innovative and could potentially have wide impact in care delivery for seriously ill patients
- **Deep interprofessional engagement in change efforts:** Perhaps because of the history of the foundation in funding the Betty Irene Moore Nursing initiative, there was support and encouragement for an interprofessional composition of the innovation teams. As a result, demonstration sites were able to cultivate and develop a range of different types of professionals who are expected to continue to contribute their newly learned skills to the organization.

*Something that I'm personally extremely proud of is the transprofessional nature of it [...] the ability to get some of these people [...] these are remarkable people who, although I have worked with them every day, I worked with them in a narrow range of skill sets. This project allowed them to be really equal partners in something[...] it actually created a transprofessional environment that was different [...] because I think the contributions were really equally valued. (Interview Site B 05)*

We uncovered the following areas for improvement:

- **Innovation development and implementation in health services takes longer than two years:** There was a feeling that trying to "build the plane while flying it", while an exciting concept, was difficult to do in practice, especially in the case of technology because of the known difficulties with technology implementation and workflow integration. Though there was initially an acknowledgement and expectation that their demonstration would be achieved through "prototypes", rather than full-scale implementation, it was not clear how a non-full scale prototype could bring about the clinical change needed to drive outcome improvement. The Applied Physics Lab team called this the difference between "prototype and production" and noted that they normally have a commercial partner focused on optimizing technology for the end users. Having to implement a product within a short timescale meant that in certain cases non-optimal products were implemented, hindering adoption.

*By launching so early they [Site A team] didn't make a good impression. They had a lot of clinicians that were engaged and excited to be involved – but they didn't get that 'wow' feature they wanted with the clinicians. (Presentation Site A 04 notes)*

- **Lack of a fully resourced, pre-defined evaluation and monitoring strategy that could be applied across the portfolio led to inconclusive findings in some areas of interest to the foundation.** Specifying the evaluation strategy up front might have set the demonstration sites up for success in 1) appropriately scoping outcomes to a two-year proof of concept demonstration; 2) choosing feasible and mutable shared outcomes (i.e. baseline is not already zero); 3) ensuring sites had the infrastructure and guidance to apply statistical techniques to adjust pre/post data;

and 4) identifying areas where metrics have not yet been developed to establish baselines and adapting the strategy for those areas (e.g. dignity and respect).

- **Turnover in Patient Care Leadership and staffing led to perceived delays and uncertainty about whether there would be continued funding.** At several sites key project staff left because of need to be certain about their source of funding for the coming year. This particular situation is more acute when funding an academic team that works primarily on soft money, and is an issue to consider when funding higher risk projects.
- **Oversight from the foundation in the first years of the projects, though expected, was at times felt to be burdensome.** Preparation for site visits from the foundation was time intensive and took grantees away from project work. Visits became less frequent over time, and this was perceived favorably by the sites.
- **Lack of external health care expert assessment of market conditions prior to funding technology development may have unnecessarily slowed development.** A review from an outside consulting company, after funds had been granted to develop the middleware (discussed in more detail below), revealed a weakness in the strategy. There was strong rationale for the more efficient approach of integrating technology with existing enterprise software, similar to what was done at BWH and BIDMC, for the proof of concept phase.

### 5.3 Topaz and the Path to Scale

Development of the Topaz platform was launched with an initial \$2.3 million grant to JHM in May 2013 who then subcontracted with a dataFascia to build a commercial grade, scalable platform that could be deployed across all sites by May 2014 (JHM Grant 3186.01 Grant Summary Document). In late 2013 an external consulting group evaluated the strategy and found significant shortcomings. The strategy of achieving commercial grade software within the defined timeline was felt to be infeasible and associated with significant risk for accomplishing the Emerge proof of concept. The consultant additionally raised viable concerns about the long term viability of the platform. The recommendation was to remove the platform from the Emerge replication critical path and replace, if necessary, with commercial off the shelf products available in the market. This was perhaps a missed opportunity to “de-innovate” as Emerge software was ultimately deployed using the Topaz middleware. At the time of the evaluation an alpha version of the Topaz platform was deployed at UCSF and is not ready for commercial scale. At present, the utility of Topaz beyond JHM and UCSF is unclear.

## 6 Aim 3. Potential for sustainability, scale, and spread

The original vision for the ICU Redesign Portfolio was to create a “system of systems” that would be engineered to produce zero patient harm. The foundation’s theory of change required each site to implement two or more complex interventions within high-risk clinical settings. None of the interventions were tested in such a way that there could be determination of whether one innovation had more impact than another and should be spread on its own, or should be spread as package of work which includes technology, workflow changes, and culture.

It should further be noted that many of the innovations are either still under development, or are being reworked into a beta version for additional study, which limits the short-term potential for spread (though perhaps strengthens the potential for long-term effectiveness). Costs associated with implementation and maintenance were not collected, which may limit the assessment of cost/benefit for adopting organizations. In addition, since the sites that have reached completion of the demonstration projects are no longer submitting data, it is not possible to tell whether any changes observed are being maintained.

## 6.1 Sustainability of interventions

We define sustainability as continuation of the programs preservation of any outcomes achieved after the funding ends.<sup>15</sup> Because this evaluation is being conducted while some work is still in progress, it was not possible to observe maintenance for all sites. In addition, the EHR transition that occurred at both of the completed demonstration sites significantly interfered with maintenance.

However, we found substantial evidence of programs being maintained or adapted. More can be found in the attached case summaries. Some standout examples include:

- BIDMC implemented the Rounds Redesign intervention across all eight ICUs, and our observations confirmed that the intervention is still in place and has changed how nurses interact with the daily physician-led rounding process. The common governance structure for ICU care may have facilitated this process.
- BWH re-implemented a version of the provider IT tools for the Patient-Centered Toolkit in Epic and these are being used on the pilot units, and are being spread to other units. They received grants from AHRQ to implement a modified version of the both the patient and provider tools across additional units, including general medical units, to further study their impact. This work is in progress and was very evident during our site visit. The Patient SatisfActive model and the microblog are also being rolled out across the units covered by the AHRQ grant.
- The CUSP program was implemented at UCSF in November 2014 and has been robustly sustained. There are plans to expand the PFAC, widely viewed as a success, to include all five ICUs
- JHM has not sustained the Emerge technology since the transition to Epic. However, they have received grant funding to create a simulation lab for the zero harm ICU at the Applied Physics Lab.
- The Emerge technology is the most at risk for being maintained. Although UCSF has made a lot of progress in refinement and implementation of the Emerge provider technology, more work will be needed to seamlessly integrate the platform into the current provider workflow. The software and hardware will also have ongoing maintenance costs. At JHM, work is needed to re-launch the Emerge technology within the new EHR. It is also important to consider the fate of Topaz, since the Emerge technology uses Topaz at both sites. This is a difficult issue since Topaz only exists for these two implementations and some engineers have been working on the Topaz project without drawing salary for some time now. Also, there are existing IT solutions in the marketplace and future adopting health systems may have their own components that can function as middleware. The absence of Topaz as a continuing partner could place the maintenance of the project further at risk, depending on the resources available at the sites.

## 6.2 Potential for Spread of Care Innovations to other hospitals

The terms “scale” and “spread” refer to efforts to increase the impact of successfully tested innovations to benefit more people.<sup>16</sup> Although spread of innovation is a complex process, we base our determination here on evidence of the innovation’s effectiveness and the extent to which it has been adequately defined in a manner that would allow it to be replicated in a new environment.

*The cultural interventions, such as Rounds Redesign, the Comprehensive Safety Unit Program (CUSP), and the Patient SatisfActive Model, offer the greatest potential for scale and spread.* These interventions were the least complex, were well adopted, and there is evidence that they have had an impact on outcomes. These interventions were also felt to be relevant (“generalizable”) outside of the ICU; for example, the Patient SatisfActive model is not ICU-specific and has previously been tested in other hospitals. CUSP, developed at JHM, has been widely spread. As has been noted, there was general consensus that spreading these cultural components was essential to achieving the maximum benefit from the technological innovations.

*No proof of concept yet exists for the acute care patient portals.* The portals will need further refinement and testing before being considered for wide-scale adoption. The patient portals varied in the type of data that they used, their functionality, and therefore their security requirements. Those that drew on EHR and PHI had more onerous institutional review board (IRB) consenting processes that interfered with adoption. The MyICU portal at BIDMC, which is currently being tested, may represent a more real-world application and evaluation of a patient portal.

Other considerations for spread of the patient portal work are the wide range of functionalities and the importance of co-occurring culture or behavior change interventions. For example, the current MyICU portal at BIDMC is directed toward empowering patients and families by orienting them to the ICU, whereas the BWH portal was designed to give patients and families more transparent and specific information and communication about their care (e.g. medications, lab results, care plan, and microblog). If portals are determined to be useful and effective in the ICU setting, potential spread sites will likely need to make adaptations to fit their setting.

*You can't just take a new innovation and plop it anywhere [...] If the goal would be to spread some of these innovations in different places, there is probably a little bit of refinement and adaptation that needs to be done before you can, sort of, turn it on. And so, supporting that I think would be very useful. (Interview Site C 04)*

*The BWH ICU provider tools appear to be scalable to other ICUs, but not to settings without a culture reinforcing the tool.* The impact of checklists is related to how the checklists are used and whether they re-inforce or improve safety culture.<sup>17</sup> The BWH Patient-Centered Toolkit provider tools are transferable, but the site does not think they will be as impactful without co-implementation of the Patient SatisfActive model. There are other elements of the BWH culture that would likely need to accompany the IT tools, such as how and when the tools are used for patient care. For this reason, the sites have discussed “mentored implementation” as a potential model for transferring the tools to other environments. The tools will need further testing of effectiveness if spread to a community setting.

*Tools that are designed for only one EHR, especially if the EHR is unique or uncommon, will require modification to spread.* For example, Risky States logic, should it prove sound, could work elsewhere, but it would need to be developed for different EHRs and would likely take some time to spread.

## 7 Recommendations

The demonstration sites have laid considerable ground work in the areas of patient and family engagement, team care, situational awareness, and using applied systems engineering to re-design care. Taken as a whole, we are unable to conclude that the theory of change, as implemented in the ICU Redesign Portfolio succeeded in simultaneously reducing preventable harms, improving patient and family engagement including dignity and respect, and improving goal concordant care (to date).

There is still work ongoing -- we do not have final results for two of the four sites. However, the fact that the two sites (BWH and JHM) that have completed work have received significant follow-on funding speaks to continued interest in and relevancy of the work.

We reflected on lessons for program design and monitoring arising from our evaluation findings and interviews with grantees, stakeholders, and our meeting with the knowledge advisors.

- We strongly recommend incorporating a robust monitoring and evaluation strategy upon the initiation of large investments. For this portfolio, formative evaluation in which mixed methods are applied throughout the development and implementation process may have led to earlier insight into areas where grantees were experiencing challenges. Consider peer review as a mechanism for elucidating risks, examining the adequacy of measurement strategies, and the suitability of proposed methods of analysis.
- The simultaneous emphasis on invention, implementation, obtaining clinically meaningful results, and scaling interventions beyond the pilot sites paradoxically led to slowdowns in implementation at some sites, and inconclusive findings. Inventors need different supports and structures for success than implementers, and this holds for spreading proven interventions. The project might have benefitted by differentiating the development phases of the work and matching strategy and structures to the phase. For example, at the innovation stage the structures could look more like incubators with smaller funding cycles and scrutiny at each stage of development in order to produce high quality projects and determine if ideas continue to be viable. If emphasis is on implementation, then supports and structures should be in place to facilitate successful fit with workflow and maximal adoption. When knowledge gaps exist, the structures should be more exploratory and hypothesis generating. The work in this portfolio spanned these developmental phases and so might have benefitted from a differentiated strategy from the beginning.
- Carefully elucidate root causes and measurement gaps when defining the scope of a problem. For example, the foundation hypothesized that was a problem in ICUs and that situational awareness and communication through information technology tools could eliminate that problem. However, there were not adequate measurement instruments to define the scope of the problem or the baseline in ICUs. In addition, information technology may be considered only one strategy to improve communication. Some communication interventions may have been more efficiently tested by piloting on paper.
- In the future, consider external consultation and careful market analysis prior to funding new health care IT. In addition, consider deploying structures to de-risk up front such as requiring

that health systems share costs at the time of project start up, co-funding with an experienced health care industry partner, or small grants with rigorous requirements for progression to the next phase.

The next section of the report is a series of detailed case summaries illustrating the successes and challenges encountered by the demonstration sites.

## Case Summaries: Findings of effectiveness and implementation of the projects

This section of the report presents case summaries for each of the four demonstration sites which includes the clinical effectiveness as reported in documents provided by each site and the qualitative data collected as part of the site visits. Each summary evaluates the achievements to date for the demonstration projects and analyzes the implementation of the interventions including barriers and facilitators, lessons learned, and sustainability. These summaries form the basis of our conclusions given in the main report. The summaries contain the following information:

- Data sources
- A summary of the site project and innovations
- Context in which the project took place
- Experience of implementation including facilitators and barriers
- Clinical effectiveness and costs (if reported)
- Maintenance and sustainability potential and issues
- Lessons learned from the sites
- Conclusions

Appendix 2 provides a profile of each hospital site and the units in which interventions were implemented.

## Brigham and Women's Hospital (BWH)

### Data sources and limitations

The data for the evaluation of Brigham and Women's Hospital (BWH) includes the following:

- 10 interviews: Eight conducted in person during the site visit and two by telephone, following the visit. Interviews were conducted with research team members, clinical directors, an executive level officer, and PFAC member.
- Two observations: One planned observational session was carried out by one researcher in each of the two intervention units (MICU and oncology). The two other researchers were given a tour of MICU separately and notes from this visit were included as an appendix to the observations. Observations usually included informal conversations with frontline staff.
- 13 documents: Documents submitted to the Moore Foundation and received directly from the site were analyzed for their content, and quantitative data was extracted for the assessment of effectiveness.
- Three presentations: Notes taken during presentations were used to help clarify points raised in project documentation.
- One demonstration: Use of the dashboard, developed as part of the Patient Safety Learning Lab, was demonstrated during the site visit.

The site visit took place during July 2016, which was just over a year after the project had been completed. Therefore, due to recall bias, interviewees may only have recalled the most salient elements of the project or implementation process. We have tried to balance the limits of this perspective with the project documentation that was produced in step with the project. With regards to issues around sustainability, we have aimed to reflect more of what was said and observed during the site visit, as this was felt to be a better indication of what project elements have been maintained over time.

### Summary of site project and innovations

The project at BWH was called PROSPECT, which stands for Promoting Respect and Ongoing Safety through Patient-centeredness, Engagement, Communication, and Technology. PROSPECT had the following three aims:

1. Optimize the overall experience of patients with regards to dignity/respect, engagement, care plan concordance, and satisfaction.
2. Minimize preventable harms.
3. Reduce unnecessary healthcare resource utilization and associated costs. (Doc BWH 02).

The two interventions introduced to meet these aims included the Patient SatisfActive Model and an electronic patient-centered toolkit (PCTK) which included both patient and provider communication and documentation tools (Table 7). The PCTK built on the infrastructure from an electronic bedside communication center already developed at BWH.



**Table 7. Description of BWH innovations including current status and implementation period**

<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (July 2016)</b>
Patient SatisfActive Model	<p>Structured communication intervention designed to incorporate patient-centered care into clinicians' daily routine and enhance patient and family experience in real-time.</p> <p>The model is made up of steps that enhance interpersonal communication between clinicians and patients/families, incorporate clinicians' efforts to ascertain, address and document patients' needs, concerns, expectations and perceptions through hospitalization, and include elements that empower and engage patients in their care. Model has been tested in two prospective, cluster-randomized, controlled trials. In both studies the model substantially improved patient experience.<sup>18</sup></p>	June 6, 2014 to May 29, 2015	<p>Structured, paper-based tool no longer in use for auditing due to changeover to Epic therefore we were unable to observe retention of behavior change. However, nurses we observed are still doing parts of the intervention. Training suspended for now. Intervention will be incorporated into Patient Safety Learning Lab project and documentation into Epic.</p>
Patient - Centered Toolkit (PCTK) - patient portal	<p>Electronic patient portal designed to engage patient and all care team members in the plan of care. Portal was accessible by patients/families using bedside iPads. Features include:</p> <ul style="list-style-type: none"> <li>- a patient-centered 'microblog' messaging system for communication between patients/families and care team members, displayed in a single 'patient' thread;</li> <li>- daily plan of care (allowed patient to enter problems/goals and to view problems and goals entered by care team in EHR;</li> <li>- educational tools with links to MedlinePlus;</li> <li>- My Care Team with names, roles, pictures of providers assigned to the care team</li> <li>- health condition monitoring tools (medication list, test results, discharge checklist), food and diet information, and tailored patient care needs/safety action plans (including preventing patient falls).</li> </ul>	July 1, 2014 to May 30, 2015	No longer in use due to changeover to Epic. Elements will be incorporated into Patient Safety Learning Lab project.
<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (July 2016)</b>

	<p>These tailored interventions were integrated with patient safety checklist tool and nursing plan of care form (depending on patient conditions, icon illustrations were auto populated and patients/family could access tailored intervention plans and learn about patient risks to avoid adverse events.</p> <p>The patient portal, including all features, was developed by the PROSPECT team. The patient-provider messaging tools were developed in collaboration with an external vendor, Care Thread, Inc.</p>		
Patient - Centered Toolkit (PCTK) - provider portal	<p>The provider tools were designed to maximize shared information and communication through patient portal and to implement a safety checklist. There were four key components:</p> <ol style="list-style-type: none"> <li>1. Care plan summary page</li> <li>2. Nursing plan of care tools (supported the checklist and RN plan of care summary)</li> <li>3. Safety checklist tool<sup>i</sup></li> <li>4. Patient-centered 'microblog' messaging tools: social media inspired messaging platform that synchronizes with the electronic health record to identify care team members and allows providers to communicate about plan of care in a single 'provider' thread; also allow communication with patient through the patient portal via a 'patient' thread.</li> </ol> <p>Some provider tools were not a part of the original grant proposal (care plan summary page, nursing plan of care worksheet, Patient Safety Checklist tool), but were added after workflow observations and focus groups demonstrated the need for these tools to maximize patient engagement through the patient portal.</p>	July 1, 2014 to May 30, 2015	No longer in use as implemented in the project due to changeover to Epic. However, the safety checklist has been re-designed using provider input, incorporated into Epic, and implemented in the ICU. The messaging tools will be implemented as part of a new grant to improve discharge communication.
<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (July 2016)</b>

<sup>i</sup> Tool includes checklist for following care processes related to patient safety areas: ventilator bundle, DVT prophylaxis, GI prophylaxis, vascular access, Foley catheter, restraints, nutrition, glucose control, physical therapy and early mobility, patient expressed unmet needs/concerns/expectations, need for family meeting, outpatient clinicians notified of admission/updates, need for SW, code status, and disposition along with planned care for the shift.

	<p>The care plan summary page, safety checklist, nursing plan of care were developed by the PROSPECT team.</p> <p>The patient-centered ‘microblog’ messaging platform was a customized configuration of secure messaging tools developed in collaboration with an external vendor, Care Thread, Inc.</p>		
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The BWH ICU-specific Patient and Family Advisory Council (PFAC) provided input into the design of the interventions. The PFAC was asked for feedback on prototypes and functionality of the PCTK and the Patient SatisfActive Model at monthly meetings. The PFAC’s input was felt to be particularly important because the perspectives of the researchers and patients/families were not always aligned. The PFAC helped to bring the innovations closer to the end users’ needs.

Two grants (#3914 and #4609) were awarded to BWH to carry out the work described above and for participation in the Libretto Consortium. The PROSPECT grant award total was \$1,985,875 over 29 months, and the Libretto grant was for \$342,500 over 29 months.

## Context

Brigham and Women’s Hospital is a 793-bed non-profit, academic teaching hospital. It is part of the Partners Healthcare health care system, which includes Massachusetts General and seven additional community and specialty hospitals. BWH has seven ICUs. The project was implemented in a 20-bed medical intensive care unit (MICU) and an 18-bed oncology unit. Approximately 95 nurses in MICU, and approximately 63 nurses in oncology, were exposed to the intervention. The average length of stay for MICU patients was about 5 days, and the average length of stay for oncology patients was 14 days.<sup>19,20</sup> BWH, and David Bates’ team, is a world leader in using health information technology to improve patient safety, particularly in the area of medication safety.<sup>21</sup>

## Experience of implementation

A major contextual issue, which provides the backdrop for this project, was the planned transition to Epic in July 2015. This impending change, which would require the developed electronic tools to be switched off, was known to the team prior to the start of PROSPECT. Rather than being a barrier to project success, the impending transition motivated the team to complete the project prior to the transition.

*We knew we were going to Epic way before and we knew when it was going to come way before we were even approached by the Moore Foundation and they knew it too. So it was a known that we needed to get this done before Epic (Interview BWH 05)*

Additionally, the unexpected end of a major contract with the oncology physician assistants (PAs) was detrimental to the project because it was planned that the PAs would have responsibility for implementing the Patient Safety Checklist on the oncology unit.

The next sections describe the reach and adoption of the individual innovations and the overall process of implementation.

### Patient SatisfActive Model

***Overall the adoption and implementation of the Patient SatisfActive model was robust. There were high adoption rates in both units and the intervention was implemented with good fidelity, except at discharge where there was a mismatch with workflow and hesitancy on the part of RNs to reach out to families and patients, especially after death.***<sup>20</sup>

Implementation was assessed through BWH reports of completion rates of the structured documentation in nursing packets, reports of peer champions on nurses' use of the models, and audits of the MICU patient/family communication note. 84% of the 1,825 model nursing documentation packets were at least partially completed, representing robust uptake and strong alignment with nursing workflow at admission and intermediate time periods in the patients' stays.<sup>20</sup> Discharge communication was only documented 50% of the time.

The Patient SatisfActive model was intended to reach all patients on both MICU and oncology units. While theoretically the Patient SatisfActive model could be utilized by any clinician, the workflows of the units meant that it was mainly used by nurses to elicit information about and respond to the patient needs and expectations. This information was then fed back to doctors during rounds. Because it became a part of nurses' workflows, all patients potentially received the model of care. The nurses felt that the model was not a major shift in what nurses were already doing (except upon patient discharge), but rather provided structure to asking about and trying to address patients' concerns and expectations. Training for frontline nurses in the model involved approximately a one-hour session (split between the Patient SatisfActive model and the rest of the PCTK) in which they were taught the model and how to use the documentation. Nurse leaders and managers were given more training and were involved in weekly, or every other week, meetings to maintain their engagement and to support frontline nurses in the use of the model. Physicians, PAs and social workers also received a short educational session about the Model and their role.

We heard that some nurses in both units were initially hesitant to adopt the Model because there was fear about what patient expectations would be and whether the nursing team would be able to meet them; essentially they were concerned about patient expectations being too high:

*I think there was a lot of fear around what the expectations were going to be, and so they went into it thinking that these patients were going to have these outlandish expectations that they were never going to be able to meet (Interview BWH 02)*

These concerns appeared to be unfounded, however, and ultimately nurses reported more positive than negative experiences. There was also pushback in adopting the model because nurses did not like the idea of being "scripted" in having to ask questions a certain way. To support adoption, the units utilized a system of peer coaching in which nurse "super-users" mentored other nurses in the use of the model. The sustained efforts to train staff and support use meant that the model was well used. In oncology, to achieve sustained adoption of the model, the nursing director reminded nurses daily, for up to three to four months, to complete the forms to reinforce the practice change.

While it was felt the nurses were good at carrying out the Model at admission and during the patient's stay, it was recognized that asking about patient expectations and perceptions at discharge was inconsistently performed. In oncology, this seemed to be the result of a simple administrative quirk in which the Patient SatisfActive papers were separate to the rest of the discharge paperwork, which meant that nurses simply forgot to complete it. Conversely, at admission the Patient SatisfActive paperwork was placed on the top of the admission paperwork, which meant it was reliably completed.

#### Patient-Centered Tool Kit (PCTK) – patient portal

***Uptake of the patient portal was low in the MICU and modest in oncology, reflecting the acuity of the ICU patients' illnesses and the inability of caregivers to access the portal remotely.***

The BWH team reported that 24% (427) of patients or proxies registered and used the portal on the iPad provided by the hospital. More oncology patients or proxies used the portal than those in the MICU (33% vs. 18%, respectively).<sup>22</sup> 65% of users logged on to the portal at least one other time after enrollment and 21% entered five or more days during the hospitalization. 66% of users entered a goal for care and about 66% sent messages directly to physicians using the microblog.<sup>22</sup>

<b>Table 8: Uptake of the Portal/PCTK by Oncology and MICU Patients/Proxies<sup>20</sup></b>				
	<b># Admitted</b>	<b># (%) Eligible</b>	<b># (%) of all admitted patients/proxies who used portal</b>	<b>(%) of eligible patients/proxies who used portal</b>
<b>MICU</b>	1075	838 (78%)	194 (18%)	23%
<b>Oncology</b>	701	641 (91%)	233 (33%)	36%
<b>Total</b>	1776	1479 (83%)	427 (24%)	29%

Note: Eligible users are defined as patients able to access the portal themselves, or those who were not able to but had a healthcare proxy.

It was never expected that the patient portal would reach all patients and family in the MICU, largely because testing of the portal under onerous institutional review board (IRB) processes. As a result, patients who lacked capacity, had no identified health proxy, did not speak English, or were unable to consent for any reason were excluded from participating, though people in these categories would be unlikely to use the portal anyway. Consistent with the issue of incapacitation in the ICU environment, approximately three times more caregivers in the MICU enrolled than in oncology. Adoption of the patient portal was driven by the research team who enrolled patients in the portal (clinical staff were not responsible). The 10-page IRB consent process, however, deterred some patients and families who were otherwise interested in using the portal. It was felt that more patients and caregivers would have adopted the portal if the IRB consent process had not been so burdensome and if they had been allowed to use their own devices, particularly if caregivers could log in remotely.

*I think a whole lot more would have done it if they could have used their own device  
[...] It's just easier. They're used to it. (Interview BWH 02)*

Another barrier to adoption, for some patients, was the existence of the enterprise electronic patient portal, through which patients could already view laboratory and study results in outpatient settings. Integrating with this portal, however, was not in the scope of the project.

The overall assessment of implementing innovations targeted at patient engagement and communication in an ICU setting was that such an environment presents unique challenges for testing

these innovations. High patient acuity can make patient engagement in goal-setting difficult, and for most patients using an electronic tool is not feasible unless a care partner is available. In addition, the ICU is a highly networked setting where there is a higher nursing ratio and, in this hospital, dedicated teams of physicians, making an electronic communication tool possibly redundant—at least when family is present. However, such tools could potentially improve communication with primary care providers (PCPs), sub-specialty consultants and other non-localized care team members who are not always readily available to talk to on the unit. It was felt that communication tools would be more important for remote family members and on the medical and surgical wards, rather than for patients in the ICU. However, some improvements were achieved in MICU that were not seen in oncology, which is perhaps counterintuitive to this overall experience.

#### Patient-Centered Tool Kit (PCTK) – provider tools

***The Patient Safety Checklist was well-adopted in the ICU, but not adopted on oncology. The electronic nursing care plan worksheet was adopted by all nurses on both units. The microblog was modestly adopted by physicians in the MICU, but not routinely adopted by oncology providers.***

The microblog messaging tool was studied most extensively during the second half of the implementation period. Over the six-month time period, 180 providers sent 961 messages regarding 35% of 497 patients admitted to the MICU.<sup>23</sup>

Reach and adoption of the electronic provider tools varied by innovation and unit. Among the innovations, some were influenced by the clinical staffing arrangements, which were different in MICU and oncology. The microblog system was thought to be better adopted by physicians in the MICU because it is a closed unit, meaning there is a provider team assigned to the unit that takes care of patients only on that unit and not elsewhere in the hospital, and only 50 dedicated MICU physicians needed to be trained. In oncology, the providers rotated in from the Dana Farber Cancer Institute, sometimes every other week, and cared for patients on many different hospital units. It was, therefore, difficult to engage and train over 300 oncologists in a communication system which had to be learned for such a short period of time and could only be used for a small portion of their patients in the acute care setting. A post-deployment survey, conducted by the BWH team of ICU physicians, suggested that the biggest barrier to future adoption was likely to be ensuring everyone used the same communication platform.<sup>23</sup> In practice, identifying the whole care team was the first hurdle in using the messaging system and was a key challenge when care involved providers from multiple specialties.

Adoption of the Patient Safety Checklist also varied between MICU and oncology settings. The reason behind this difference is related to the cultural working practices – safety checklists are not widely used outside of intensive care units. In the MICU, the Patient Safety Checklist was adopted as a rounding tool and was led by residents.

*Checklist and dashboard are being used by resident from last team- he is responsible for presenting to the group; each time checklist is presented there is at least one issue that is addressed which affects the plan of care for the day- nurse is engaged with questions during each of these and adds to-dos to her list; one intern who is typing notes pulls up dashboard and clicks into overview for note writing. (Observation BWH*

*01)*

The nursing tools, which in addition to the messaging system included the nursing plan of care, were developed over a period of nine months and involved observations of workflows and involvement of nurse leaders through a leadership council. The extensive work done during the pre-implementation period meant that the tools were well-adapted to nursing workflow before they were implemented and did not need to be modified once introduced. The nurses were initially resistant to adopting the electronic plan of care because of a previous experience in which there had been a lot of planning for implementing a new system, but then the plans were not executed. This seemed to set a tone of skepticism towards whether planned changes would materialize, but did not actually appear to slow adoption. The nurses seemed to perceive a relative advantage in the new tools because the tools reduced the gap between what had been ordered by the physician and what had been completed by the care team, which increased adoption and use. The high adoption of the plan of care among nurses could also be a result of the switch to the electronic version, which meant there were no other ways to document care.

*It was nursing driven because part of it was a plan of care that was electronic so we took their paper plan of care away; they had to document their plan of care into this portal. So we kind of forced them into it because nobody likes change so we would've just continuously met resistance (Interview BWH 02)*

The above discussion highlights a number of facilitators and barriers in the implementation process, which are summarized here.

### *Facilitators*

**Strong clinical leadership:** In each of the units, the strong medical and nursing leadership gave frontline staff a clear message regarding the need to implement the interventions. The nursing director was very engaged with frontline nurses, encouraging them on a daily basis to use the Patient SatisfActive Model and nursing tools, which likely helped to embed them in practice. Early on in the process the research team also engaged nurse practice councils, made up of frontline nurse leaders, who then became champions of the project and improved receptivity on the units.

**Integration into existing workflows:** There was extensive work done prior to implementation to observe workflows and interview front line providers within each of the units. These observations allowed the PROSPECT team to adapt the tools and plan implementation based on how the innovations could be woven into practice, rather than radically re-engineering work practices which likely would have met with greater resistance to change.

*We were continuously doing the development with [the nurses] [...] We were trying to understand first the workflow, so we were doing workflow observations. [...] We did it early so we had enough time to then meet their requirements, revise and get that development in, which was key (Interview BWH 01)*

**Checklist culture:** Workflow observations indicated that the MICU had an established culture of using checklists during rounds, which was not apparent in oncology. This existing culture of practice facilitated the adoption of the Patient Safety Checklist into the MICU because of its compatibility with this culture.

**Experience in IT Innovation and implementation:** It was apparent that the research team and clinical leadership at BWH have extensive experience in IT innovation and implementation.



*Our implementation was pretty smooth. I think part of it is that we have implemented so many informatics projects that- we use project management; we use the champion model. (Interview BWH 04)*

They used a sociotechnical approach<sup>24</sup> to implementation which was felt to have helped facilitate the implementation success. This previous experience also meant that clinical leaders were ready and willing to engage in making such improvements.

**R&D separate to implementation:** Some minimal testing had been done for a previous prototype version of the patient portal, called the electronic bedside communication center, though this was not implemented in a hospital. Some prototyping of the microblog was also done before the grant was awarded. The team spent the pre-implementation period observing workflow, working with stakeholders to adapt the prototyped tools to the units where they would be deployed, and developing the new PCTK provider tools. This resulted in few modifications needing to be made after implementation. The clear demarcation between development and implementation, along with significant investment in adapting the innovations to unit workflow appeared to make implementation go more smoothly.

*We had a pretty substantial foundation [...] We had to do an awful lot of development, to actually build the [patient portal] application was not trivial so we didn't have a working application, but had we not had a lot of the foundation in place, we never could have done it in this time frame or with this level of support. (Interview BWH 08)*

**Capitalizing on established relationships:** The research team had established relationships with the organization's enterprise IT developers making it easier to call on their expertise during development and iteration of the innovations. It also meant that there was greater willingness to make the innovations work once the changeover to Epic began.

*On the IT development side, we hired people, who, you know A) are real stars at development, and then B), both knew the old system inside and out and had contacts with the right people in the system so that's actually kind of important [...] and some people were willing to do stuff for us 'cause they knew 'Frank', so it's like, so Frank is asking you know so you say 'yes' and if it's someone else you say 'no'. (Interview BWH 08)*

## *Barriers*

**Lack of compatibility with workflows and existing culture:** In oncology, the culture of practice did not include using checklists and there was no evidence for their effectiveness in such an environment. The Patient Safety Checklist, therefore, was not compatible with workflows.

**Multiple sources and methods of communication:** Providers use multiple sources and methods of communication in current workflows, making it less efficient to adopt microblogging unless all colleagues collaborating in patient care also adopt microblogging. This was particularly impactful in oncology, where providers tended to have patients in multiple locations.



**Static devices:** It was suggested that allowing users to use their own hardware (i.e. bring your own device) would be more attractive to patients and families and would increase utilization of the portal.

**Redundancy with existing patient portal:** The existence of the well-adopted enterprise patient portal, used primarily in the ambulatory setting, appeared to make the PCTK patient portal redundant to some patients and their families. It was concluded that any such inpatient portal should build on an existing portal infrastructure to increase functionality, rather than create an entirely new system.

**Open unit configuration:** The open nature of the oncology unit, in which patients on the units were seen by a revolving rotation of physicians with patients across all units, meant it was difficult to engage providers in the electronic provider facing tools because the effort to train and sustain use was not practical.

*the microblog- the patient-centered communication platform that we implemented, the vision of that was always to engage these outside providers and get their input. Now it's hard to do that [...] because they're like I get like 20 emails a day, 50 emails a day, I have other ways of doing things on the rest of my patients, you just want me to respond to that one message there? [...] There was a lot of pushback. (Interview BWH 05)*

Likewise, MICU microblog users found it difficult to engage with specialist or primary care providers.

**Unstable workforce:** In oncology, the loss of all PAs due to contractual issues created chaos and was disruptive to the workforce in the unit. This made it more difficult to implement the interventions, especially the Patient Safety Checklist.

**Patient acuity and complex IRB processes:** The extreme poor health of patients in the MICU was perceived to be a barrier to patient and family adoption of the patient portal because some patients and family members were put off by the onerous IRB consent process when already faced with a stressful situation. Adoption was more successful in oncology where patients were more stable and had longer stays. As a result, the patient or a proxy could be approached more easily for participation in testing the patient portal.

*Unfortunately, in the ICU if somebody didn't have, if somebody was not healthy enough, as many ICU patients are not, and they didn't have a care partner or healthcare proxy then, yeah, then you can't use [the patient portal] (Interview BWH 01)*

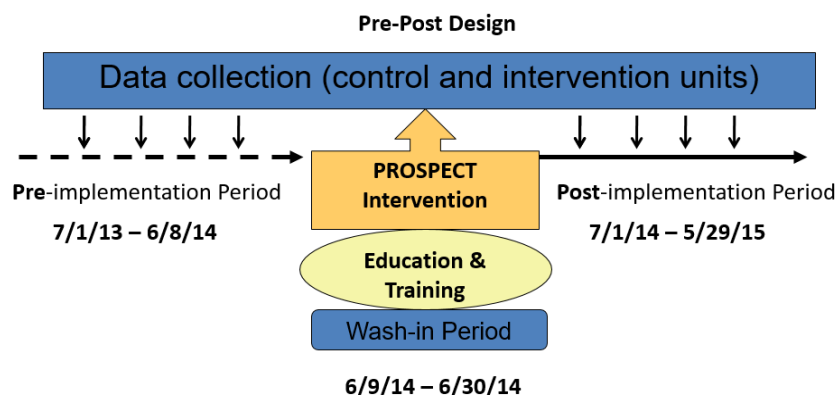
## Clinical effectiveness

***In the medical ICU, there was a significant decrease in the aggregate measure of physical harms. This was driven by decreases in pressure ulcers and CAUTI, improvement in HCAHPs global scores, statistically significant improvement in six of the seven HCAHPS composite scores and the FS-ICU 24 global and Care composite scores. In oncology, there was only a significant reduction in CLABSI and improvement in global care plan concordance. Utilization was used as an indicator of cost and was unchanged in both units.***

The effectiveness of the innovations was studied through a pre/post mixed-methods design (Figure 3). The pre-intervention period (baseline) was approximately 11 months, from July 1, 2013 to June 8, 2014,

and the post-intervention period was also approximately 11 months, from July 1, 2014 to May 28, 2015 (Document: BWH Presentation, Libretto Consortium Meeting June 2016). As noted above, the study was conducted on two 10-bed MICUs and two 10-bed oncology units.

Figure 3. Pre/post design of the PROSPECT project<sup>20</sup>



A more detailed assessment of each of the outcome categories is presented in the subsections below. The results are described and shown below in Tables 9 and 10 for MICU and oncology, respectively, and were taken directly from the BWH final report to the foundation; we did not reanalyze their results.

<b>Table 9. Results: BWH MICU<sup>25</sup></b>				
	<b>Pre-implementation (Jul 2013-Jun 2014)</b>	<b>Post-implementation (Jul 2014-May 2015)</b>	<b>Absolute Change</b>	<b>P-value</b>
<b>Physical Harms</b>				
Aggregate (per 1000 event days)	65.2	47.3	18.6	<0.001
CAUTI (per 1000 catheter days)	3.75	1.24	2.5	0.02
CLABSI (per 1000 line days)	1.71	1.05	0.7	0.4
VAE (per 1000 ventilator days)	10.96	10.64	0.3	0.9
Falls (per 1000 patient days)	0.19	0.34	+0.15	0.6
Med Errors (per 1000 patient days)	6.47	4.06	2.4	0.2
Pressure Ulcers (per 1000 patient days)	42.13	30.01	12.1	<0.01
<b>Patient Satisfaction</b>				
HCAHPS Overall Hospital Rating	71.8% (n=56)	93.3% (n=58)	21.5%	<0.001
<b>Family Satisfaction</b>				
FS-ICU 24 Total Satisfaction Score	84.3% (n=106)	90.0% (n=156)	5.7%	<0.001
<b>Goal Concordance</b>				
Haberle	28.3% (n=133)	34.0% (n=74)	5.7%	0.4
<b>Costs</b>				
Median Hospital Cost, MICU	\$36,366	\$35,779	\$587	0.81

Note: table replicated from BWH presentation to Libretto

<b>Table 10. Results: BWH Oncology<sup>25</sup></b>
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	Pre-implementation (Jul 2013-Jun 2014)	Post-implementation (Jul 2014-May 2015)	Absolute Change	P-value
<b>Physical Harms</b>				
Aggregate (per 1000 event days)	17.3	16.3	1.4	0.6
CAUTI (per 1000 catheter days)	0	0	0	N/A
CLABSI (per 1000 line days)	2.37	0.21	2.2	0.02
VAE (per 1000 ventilator days)	N/A	N/A	N/A	0.1
Falls (per 1000 patient days)	1.14	1.9	+0.8	0.96
Med Errors (per 1000 patient days)	10.15	6.43	3.7	0.12
Pressure Ulcers (per 1000 patient days)	2.86	4.81	+2.0	0.15
<b>Patient Satisfaction</b>				
HCAHPS Overall Hospital Rating	83.8% (n=46)	84.4% (n=81)	0.6%	0.9
<b>Family Satisfaction</b>	N/A	N/A	N/A	N/A
<b>Goal Concordance</b>				
Haberle	31.2% (n=101)	57.8% (n=59)	26.6%	0.005
<b>Costs</b>				
Median Hospital Cost, Oncology	\$18,605	\$19,780	\$1175	0.5

### Physical Harms

#### Outcomes reported and methods:

The primary outcome for physical harms was an aggregate of the following measured hospital-acquired harms: catheter associated urinary tract infection (CAUTI), central line-associated bloodstream infection (CLABSI), ventilator-associated events, falls, medication errors, and pressure ulcers (see Definitions of Harms following the report for definitions) occurring during unit stay. Differences were analyzed using Poisson regression to compare pre/post rates. The regression was adjusted for patient age, sex, race, insurance, Charlson score, median income by zip code, and care unit length of stay.

#### Results:

There was a significant reduction in hospital-acquired physical harms of about 19 harms per 1000 patient days in the MICU. There was no significant change in oncology, with the exception of a significant decrease in CLABSI rates.

- The MICU results were driven primarily by reductions in pressure ulcer rates and CAUTI, which accounted for approximately 14.5 of the 19 harms decreased
- Although the aggregate harms measure did not significantly decrease in oncology, the individual measure of CLABSI did.

#### Conclusions and limitations:

The aggregate decrease in harm in the MICU was driven by significant decreases in rates of CAUTI and pressure ulcers. These changes may reflect the tailored interventions incorporated in the patient portal which showed educational information to patients and families who were at risk for physical harms, such as guidance to help families reduce CAUTI through proper Foley catheter care. However, uptake of the portal in the MICU was low (18%), with 65% of those patients logging in more than once, and we do not know the ways in which the portal was used. We interpret the impacts of the PROSPECT interventions on these harms with caution because there were two concurrent initiatives which may

have influenced the outcomes. First, there was a skin care initiative ongoing in the MICU which may have influenced the observed reduction in pressure ulcer rates. Second, there was a hospital-wide “Just Culture” initiative ongoing, which aimed to create a system of shared accountability to reduce adverse events and improve safety expectations.<sup>26</sup> Skin care was not an element of the Patient Safety Checklist, but mobility was included which could have led to improvements in pressure ulcers. Another possible limitation was that the baseline starting point for some of the harms was already quite low in oncology and higher in MICU, which meant there was little improvement to be observed for some harms.

### *Patient/Family Engagement*

#### **Outcomes reported and methods:**

The BWH team measured patient engagement, dignity and respect using a subset of questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, plus additional questions developed by the BWH team related to dignity and respect. Patients were called at least six weeks after discharge based on a limited list of patients that had not responded to the Press Ganey administered HCAHPS survey. All patients on the list who had been admitted for at least 24 hours were called. The number of patients responding to HCAHPS surveys in the pre and post period were 59 and 61 respectively in MICU, and 50 and 84 in oncology. This represents about 6% and 12% of MICU and oncology patients, respectively. The pre/post analysis was propensity adjusted, by the BWH team, for patient age, gender, education, self-reported health status and race.

Family experience and satisfaction (including engagement and dignity and respect) were measured using the Family Satisfaction with Care in the ICU (FS-ICU 24)<sup>ii</sup> survey, additional questions developed by the BWH team related to dignity and respect, and other items related to family experience. Using convenience sampling, surveys were administered in person to family members of patients who had been admitted to the ICU for at least 24 hours and some surveys were also administered after patient discharge via phone. Family members were not surveyed after patient death. Surveys were only collected from family members of ICU patients because there is a validated, ICU-specific tool (FS-ICU 24); a validated tool does not exist for families of oncology patients. The pre/post analysis was propensity adjusted, by the BWH team, for family member age, gender, relationship to patient, education and race.

30 semi-structured interviews were also conducted in the post period by the Patient SatisfActive team in the MICU (n=14) and oncology (n=16) units and included patients only (n=22), family members only (n=6) and both (n=2) to assess issues around dignity and respect, and clinician activities related to the Patient SatisfActive Model.

#### **Results:**

*Patients:* Overall HCAHPS global top box scores improved significantly in the ICU in the category of overall hospital rating (rated hospital 9 or 10 on a 10-point scale). Additionally, significant improvement was seen across six areas of care as measured by improvement in the composite scores for:

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<sup>ii</sup> The FS-ICU 24 stands for Family Satisfaction with Care in the ICU; it is the most commonly used, validated 24-question survey specific for ICU families. Each question is scored on a 0-100 scale. There are three standard measures from the survey: 1) FS-Total which averages the responses to all 24 questions; 2) FS-Care which combines 14 of the questions related to the care delivery experience; and 3) FS-DM which includes 10 questions related to family satisfaction on decision-making around care the score for the questions related to.

communication, responsiveness of staff, pain management, communication about medicines, and discharge information. There was no significant improvement seen in oncology in global scores or composite scores, although four areas improved and were significant prior to adjusting. These included the composite scores for communication with nurses, pain management, communication about medicines, and care transitions.

*Families:* There was significant improvement in all three FS-ICU composite scores in the MICU. Baseline mean scores for each composite were about 84 which increased to about 90, post-implementation.

#### **Conclusion and limitations:**

Satisfaction improved for patients in the MICU, but there was no statistically significant improvement in oncology even though the Patient SatisfActive Model was well implemented in both settings. There was less room for improvement in oncology. Family satisfaction improved in the MICU and was not measured in oncology. We do not know whether users of the patient portal were more or less likely to complete the HCAHPS survey. As with physical harms, there was less room for improvement in oncology as scores were already quite high for overall hospital satisfaction. These findings, however, are also limited by the small sample which may not be representative of the patient and family population, especially as families were not surveyed if the patient died. Also, family engagement and satisfaction was only measured in the ICU because the FS-ICU 24 is an ICU-specific tool; there was no commensurate tool available for use in the oncology setting. There is a gap in measurement tools to assess family engagement in the oncology setting.

#### *Goal Concordance*<sup>20</sup>

##### **Outcomes reported and methods:**

The BWH team measured goal concordance using the Haberle method.<sup>iii</sup> Patients who did and did not use the toolkit were randomly sampled. Pre/post scores were compared using generalized estimating equations to account for multiple ratings on the same patient and adjusted for age, sex, race, insurance, Charlson score, median income by zip code, and care unit length of stay.

##### **Results:**

After adjusting for important demographic and clinical patient characteristics, goal concordance improved significantly in oncology, and there was a trend toward improvement on the MICU.

Additionally, in both the MICU and oncology units, the patients that used the PCTK had higher goal concordance than non-users suggesting that the PCTK facilitates patient-provider communication around care goals. Although the numbers of patients in the sub-analysis were rather small, the finding has face value as one of the components of the PCTK specifically invites patients to enter their goals, thus providing a natural venue for written and further verbal communication between patients/families and providers.

##### **Conclusions and limitations:**

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<sup>iii</sup> The Haberle goal concordance method uses a list of seven items from which the patient selects his or her goal for the hospitalization. Concordance is measured by whether the provider's goal matches the patient's from the seven item list. Perfect agreement is required for them to be considered concordant.

Overall the sample size is small, but there does seem to be face value in the significant increase in goal concordance in oncology and the trend toward an increase in the MICU. This may be related to the fact that there were more portal users in oncology, and the oncology setting is more conducive to setting care goals than the MICU setting where patients' conditions may be changing rapidly. There also may have been some interaction between the Patient SatisfActive Model and the goal-related section of the patient portal in the sense that prompting patients to consider their needs as part of the Patient SatisfActive Model may have influenced their consideration of their goals of care in the patient portal. Therefore, we cannot be sure whether one of the interventions, or their combined effect, impacted goal concordance.

## Costs

### Outcomes reported and methods:

Cost<sup>20</sup> was evaluated using median hospital cost in the ICU and oncology units, respectively. The analysis used a pre/post design adjusted for age, sex, race, insurance, Charlson comorbidity score, median income by zip code, and care unit length of stay.

### Results:

There were no meaningful changes or statistical differences in median hospital cost in the MICU or oncology units.

### Conclusions and limitations:

The interventions did not appear to impact utilization either positively or negatively. The cost of implementation was not reported.

## Maintenance and sustainability

Since the site did not report data past the end of the implementation period, we do not know if the impacts from the innovations have been sustained.

The transition of the enterprise EHR to Epic significantly disrupted maintenance of the innovations themselves. The culture change created through the Patient SatisfActive Model is still in effect to a certain extent, but the fundamental processes are no longer in place (paper documentation, formal training). These are planned to be re-instituted in the next few months as part of the Patient Safety Learning Lab project. The patient portal and microblog are not currently “turned on”, though there are plans to refine the product and implement it again in the coming months as part of new grant funded projects. The MICU checklist has been re-implemented and refined in the Epic workspace and is consistently used on all MICU patients daily. There are plans to develop and spread a second version of most of the interventions to other hospital units as part of two different research projects.

## Patient SatisfActive

Although the Patient SatisfActive Model had robust adoption and is likely related to a significant boost in patient and family experience in the MICU, it was significantly disrupted by the Epic implementation. The core components of the Model have not been maintained in recognizable form in the transition to the new EHR, following the end of the project period. While nurses on oncology and the MICU continue to document patient concerns and expectations at admission and throughout the patient stay, the

orange paperwork is no longer present on the floor. and they do not have a structured way to document the elicitation of needs, expectations, and satisfaction with care that are fundamental to the model.

*No orange signs anywhere in patient room, outside, or in the family waiting room.  
(Observation BWH 02)*

New nurses coming onto the unit since the end of the implementation do not receive training specific to the model. However, there has been a pull through of knowledge via nurses who were on the units during the pilot in which new hires (not floaters) were trained on the importance of addressing patient concerns and expectations, especially at admission. Patient facing materials used during the pilot are no longer distributed. It is important to mention that, as part of the AHRQ Patient Safety Learning Lab grant (described below), the team is optimizing the Model to fit into post-Epic workflow for re-implementation.

### Patient-Centered Toolkit

#### *Patient tools—portal and microblog*

The implementation of Epic also disrupted the use of the patient portal, which was stopped after the trial. However, the study team has received a \$4 million grant from AHRQ for a Patient Safety Learning Laboratory which will support the refinement and testing of new elements for the portal. It will also include building an application that patients and caregivers can download on their own devices. Partners Health System has a long-term plan of integrating the acute care functionality for the portal into the enterprise wide patient portal.

#### *Provider tools*

The Patient Safety Checklist has been very resilient in the ICU, but not on oncology where it was never adopted. Since the conversion to Epic and the end of the implementation period, the MICU teams continue to use the checklist at the end of each patient's presentation on rounds, and seem to continue to review the checklist on each patient, each day.

Though the microblog tools are currently not being used, version 2 of the application has been built on top of Epic and is ready to deploy for both patients and providers. This work is part of a new grant evaluating the tools' efficacy with respect to discharge preparation, care coordination, and post-discharge communication.

#### *Threats to maintenance*

**EHR implementation:** As would be expected, the implementation of the electronic health record significantly disrupted maintenance of all three interventions. Despite this, the team was able to re-implement a next version of the Patient Safety Checklist and maintained some aspects of the Patient SatisfActive Model.

**Need to refine original interventions:** The Patient SatisfActive Model has already been tested in a number of hospitals and does not need to be refined further to be sustained and maintained at BWH. The other interventions all need some degree of refinement to gain maximal adoption and impact. For example, the patient portal is planned to be deployed on patient and caregiver devices, rather than hospital iPads, to stimulate ease of use and higher adoption. There are also discussions about folding it into the enterprise patient portal.



**Need for data to monitor and maintain impact:** ICU clinicians typically do not have access to data regarding patients' experiences in the ICU, specifically. The grant offered clinicians an important glimpse into experience and satisfaction, specifically with respect to the ICU stay. Without sustained measurement it may be hard to maintain the performance achieved in the grant.

**Sustaining provider behavior change to major cultural interventions:** The Patient SatisfActive Model requires clinician (especially nurses') sustained behavior change over time. While compatibility with nurses' roles and values was clear in the intervention, maintaining performance over time would require sustained institutional focus for measurement, training, recognition, and competency. The structured documentation is an important tool for maintaining fidelity to the model, as is the structured training curriculum (train-the-trainer guide) for clinicians. Re-implementation is planned as part of the Patient Safety Learning Labs grant.

### *Supporting maintenance*

**Compatibility with workflows and existing culture:** Reasons for robust maintenance of the Patient Safety Checklist in the MICU echo the reasons for robust adoption –namely that the intervention is highly aligned with existing checklist culture and team workflow.

**Grant funding:** Funding from AHRQ was a significant enabler for the teams to continue to refine and adapt the innovations, especially those that need significant refinement to maximize impact and adoption.

### *Lessons learned*

There were a number of takeaway messages from the experience of implementing the Patient SatisfActive Model and the PCTK patient and provider tools, which are summarized below.

**Bring Your Own Device (BYOD):** With regards to the hardware for accessing the patient portal, having a static device which could only be used while in the unit was a barrier to adoption. Learning from this experience suggested that uptake of the portal would be increased if patients and their families could access the portal from their own mobile devices.

**Add inpatient portal to enterprise wide portal:** Another barrier to using the patient portal was the existence of the enterprise EHR portal. It was decided that any future developments of the portal should be made on the back of the existing platform so that patients only have to use one system and can access it seamlessly, regardless of whether they are an inpatient or at home.

**Identifying the whole care team is a challenge in its own right:** Implementation of the provider messaging system showed that the first challenge was simply in identifying those providers who should be included in the discussion. External and specialist providers do not routinely identify themselves as part of the care team in the EHR, but are essential in ensuring coordinated delivery of care. This is a first hurdle which must be addressed in any system which requires participation by all providers involved in complex patient care.

**ICU was not ideal environment for all interventions:** The high acuity of patients in the MICU and subsequent low adoption of the patient facing interventions, as compared to the oncology setting, suggests that the ICU is a less than ideal environment for patient engagement supported by technology.



However, these types of interventions may be more suitable for family engagement and may have higher adoption on general medical units.

**Onerous IRB consent processes:** The IRB consenting process required as part of testing the patient portal as research was a major barrier to adoption for patients and families, particularly in the ICU. Such a process would not be required in a real-world setting or if a BYOD solution were used. This was a suggested next step for testing a patient portal as it would likely increase patient and family uptake.

**Improvements are difficult to sustain without continued monitoring:** The MICU showed significant improvements in HCAHPS scores. This improvement was insightful and useful for the unit which normally does not receive such feedback from patients because they are rarely discharged home directly from ICU. However, it is difficult for the unit to sustain these improvements without continued performance monitoring now that the project is over.

### Comparison of implementation in MICU and oncology settings

Comparison of the implementation and impact of the interventions in MICU and oncology settings offers important information about generalizability of the innovations.

**Patient SatisfActive Model:** The model appears highly generalizable as it was well adopted in both settings. Though nurses on both units were initially concerned about eliciting patient concerns, in both settings patient expectations were found to be reasonable and straightforward to address.

**Patient portal:** This intervention was felt to be most feasible for patients who are able to engage in their care during the hospital stay, such as patients on the medical or oncology wards. Goal setting, in particular, may be difficult for patients and families in the fluid, rapidly changing ICU environment. Additionally, family members who are present at the bedside in the ICU may not need the portal. The next iteration will make the portal more available for use by family members who are not present in the MICU which may enhance adoption.

**Microblog:** The microblog aspect of the PCTK was easier to adopt in a closed unit where providers tend to do most of their patient care, and harder on open units where providers only have one or two patients. However, it is in these more diffuse networks where the microblog might be most useful as an asynchronous means of patient-focused communication. The team plans to study the microblog as a means of enhancing discharge, next.

**Patient Safety Checklist:** As mentioned above, the Patient Safety Checklist is currently not generalizable outside of the ICU because there is not a common practice or culture of using safety checklists on general medical wards. This has prompted the team to adapt the checklist into a safety dashboard that can be more easily incorporated into workflows.

### Conclusions from BWH

A major key to the successful delivery of the PROSPECT project at BWH was that a significant amount of development work on the innovations (patient portal prototype and Patient SatisfActive) preceded the implementation period allowing the team to focus on adapting the interventions to clinical workflow. Implementing a fully developed product also meant that the site was able to collect straightforward pre/post data for the evaluation, which was another strength of the PROSPECT project. This approach to development, implementation, and evaluation likely reflects the strong informatics research expertise at this site. The changeover to Epic as the new EHR was highly disruptive to the maintenance of the

innovations, yet the site is already engaged in looking at implementing and evaluating the next iteration of the innovations through new grants. The experience of implementing the Patient Portal into the ICU was found to be challenging because of the high acuity of the patient population, whereas the Patient Satisf*Active* Model was robustly adopted. Of the interventions coming out of the site, the Patient Satisf*Active* Model is readiest for scale and spread, followed by the new version of the Patient Safety Checklist deployed in Epic. The team is busy refining the other interventions, and generalizing their use onto the general medical units in the hospital, potentially increasing their readiness for future spread.

## Beth Israel Deaconess Medical Center (BIDMC)

### Data sources and limitations

The data for the evaluation of Beth Israel Deaconess Medical Center (BIDMC) includes the following:

- Two one-to-one interviews and five group interviews conducted in person, during the site visit.
- Three observations: One of the use of MyICU within the TSICU, one in the MICU for standardized room entry and rounds redesign, and one of a bed meeting.
- 42 documents: Documents submitted to the Moore Foundation and received directly from the site were analyzed for their content and quantitative data was extracted for the assessment of effectiveness.
- Two presentations: Notes taken during the presentation were used to help clarify points raised in project documentation.
- One demonstration of the Patient Specific Checklist.

The site visit was carried out in August 2016. At the time of the visit, some of the interventions had already been implemented for some time and so we were able to speak to implementers and observe their use. For the patient portal, MyICU, a second version had just been launched weeks before our visit, so we were unable to get a good sense of its adoption and use. Other innovations were still in development.

### Summary of site project and innovations

The project at BIDMC entitled 'Optimizing ICU Safety through Patient Engagement, System Science and Information Technology' was organized around three work streams:

1. Managing Risky States to Prevent Harm
2. Engineering Care to Prevent Harm
3. Partnering with Patients and Families

The seven innovations developed and implemented as part of the project include (Table 11): Risky States, Patient-Specific Checklists, Rounds Redesign, Standardized Room Entry, Consult Quality, Access to Policies and Procedures, and MyICU, which was the electronic patient portal.

<b>Table 11. Description of BIDMC innovations including current status and implementation period</b>			
<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (August 2016)</b>
<i>Managing Risky States to Prevent Harm</i>			
Risky States	The goal of the project is to develop a predictive model that identifies when a unit has a set of conditions that may increase the risk of patient harm (e.g. high acuity patients, more "floater" nurses, high admissions, etc.). Clinicians will interact with the model through an application which displays the output from the "risky states" model for each ICU	In development – preliminary data collection completed June 2016. Pilot to begin fall 2016.	In development. The logic for the model is being validated against retrospective data and event occurrence, and calibrated against

Intervention	Description	Implementation Period	Status at the time of Site Visit (August 2016)
	as a visual alert for when a unit is tipping into a high risk state and should trigger an intervention for action.		nurse expectations.
Patient-Specific Checklist (PSC)	Electronic patient safety checklist that will provide patient-specific information to providers, allowing them to make the right preventative care decisions at the right time, with the least cognitive burden.	Roll out late fall 2016.	In development.
<i>Engineering Care to Prevent Harm</i>			
Rounds Redesign	Goal is to improve the overall quality of rounds in the ICU. Key changes include creating a daily order for rounding on patients to ensure nurses can participate in care, a hard stop for nurse input, and feedback of the plan of action to the entire team at the end of each round.	Implemented from Jan 2015. Baseline data from Apr-Jul 2014 (survey and observation). Post-implementation data: March-June 2015 (observation), July 2015 (survey)	Live.
Standardizing Room Entry	Create a uniform process for any type of room entry which will improve patient and family satisfaction, create a physical environment that drives correct workflow and ensures best practices around hand hygiene and infection control practices. Changes include installation of a cart inside the room for staff to perform hand hygiene and don personal protective equipment, as needed. Staff are asked to introduce themselves to patients and state what they are doing in the room.	Piloted in the SICU Aug 2014-Nov 2015. New carts rolled out to all units Dec 2015.	Live.
Access to Policies & Procedures	The structure and content of BIDMC's existing Critical Care Practice Manual, including 80 policies and procedures, were standardized to align practice with current best-evidence, and improve formatting, readability, and electronic search functionality. A format for leveling evidence was adopted to better inform rationale for practice. Moore Nurse Consultants (frontline ICU nurses with grant-funded protected time) coached members of the Critical Care Practice Committee to utilize the	Completed implementation 2014.	Live. Policies and procedures to be updated every 2 years.

Intervention	Description	Implementation Period	Status at the time of Site Visit (August 2016)
	standardized template when creating and revising policies and procedures. They developed an instruction manual to guide clinicians with future policy revisions. Policies and procedures were made available to all community hospital affiliates.		
Consult Quality	The purpose of this project was to design a reliable tool to measure inpatient consultation quality by identifying: 1) consultations of high quality in the ICU through detailed, electronic surveys of the stakeholders of consultations; 2) markers of high or low consult value, available through chart review; and 3) potential outcomes associated with high and low quality consultations in the ICU, as measured by the chart review tool.	Jul-Dec 2015: Identified seven markers for defining a 'good' vs 'bad' consult through surveys with MICU physicians. Completed data collection: 488 surveys on 200 consults. Response rate was 80% among ICU physicians & ICU nurses, 57% among consultants, and 32% among families. Lack of agreement in what constitutes quality, more work to be done.	Project complete. Next steps being done as part of new, additional funding.
<i>Partnering with Patients and Families</i>			
MyICU	A patient and provider facing electronic portal that will give patients and families a personalized system for enhanced communication about and comprehension of the events that occur during an ICU admission. Developed following a comprehensive national online survey, in-person survey at BIDMC ICUs, and focus groups. Not connected to the EHR.	Version 1 piloted Oct 2015 – Jan 2016 in the MICU & SICU. Version 2 in all BIDMC ICUs July 11, 2016.	Live. Currently starting data collection for post-period for pre/post evaluation.

Four grants (#3906, 3906.01, 4607, and 5079) were awarded to BIDMC to carry out the work described above, and for participation in the Libretto Consortium, for a total of almost \$7.4 million. This included a seven-month planning grant for \$323,000, main project grant for 30 months for \$5,381,260, a modification to the main project grant to add \$1,340,623 for the remainder of the project period (which was extended for an additional six months as part of this modification), and participation in Libretto

Consortium and task force groups for 15 months for \$342,500. A final grant of \$90,000 was awarded over a 12-month period to support a convening of experts to develop a research agenda for further study in the realm of patient dignity and respect.

## Context

Beth Israel Deaconess Medical Center (BIDMC) is a 672-bed not-for-profit, academic teaching hospital with 49,865 discharges per year. BIDMC is the flagship academic medical center for an integrated system including three community hospitals and a large physician practice group. The health system has a growing network of affiliated providers and hospitals. There are plans to use this network to spread the innovations developed from this project.<sup>27</sup>

Within BIDMC there are eight ICUs, of which three ICUs – medical ICU A (MICU A), trauma surgical ICU (TSICU), and surgical ICU were the pilot sites of the project's interventions. MyICU (version 1) was piloted in the MICU A and TSICU units, Standardizing Room Entry was piloted in the SICU only, and Rounds Redesign was designed with participation from and implemented in all ICUs. MICU A is a closed unit with eight beds and an average length of stay of three days. TSICU is a semi-closed unit with 10 beds and an average length of stay of three days. Of the interventions piloted in these two units, several projects have been spread to the remaining six ICUs within the medical center. Policies and procedures are also available to community hospital affiliates as they can be accessed through the common electronic system.

A unique characteristic of BIDMC is its strong culture of patient and family engagement. BIDMC has utilized Patient and Family Advisory Councils (PFACs) for many years and were the first in the nation to have an adult critical care PFAC. This is a source of great pride for the organization. The hospital's experience of working with PFACs has led to a heightened understanding of the importance of engaging with the PFAC early on when planning service changes. PFAC members can also become very engaged in research itself; a patient involved in this project was included as a co-author on several papers as a result of her involvement. This level of PFAC involvement and patient engagement was the highest seen at all four sites and underpinned many of the innovation developments at BIDMC.

## Experience of implementation

The overall experience of implementation at BIDMC was characterized by a culture of work which highly values the role of nurses and input from patients and family. This approach was reflected in many of the innovations and how they were developed. In particular, Standardizing Room Entry, Rounds Redesign, and the MyICU patient portal are reflective of the concerns of patients and families regarding hand hygiene and informational needs, and the desire to ensure full representation by nurses in care decision making. This culture of work has been established at BIDMC over decades, in particular by the tumultuous merger between Beth Israel and New England Deaconess which has helped to embed the emphasis on collaboration and nursing, as well as the patient engagement culture in which staff either thrive or leave.

At BIDMC, it was accepted that the innovations in the project would take place through an iterative, deliberately slower-paced learning process than is typical in the usual health services research cycle. This seems to reflect the site's greater emphasis on quality improvement initiatives and appears to be more of a strength than a weakness. By viewing the development of the innovations in this manner, they were not seen to be tied to a project timescale, but rather the focus was on getting innovations

right for long term sustainability and change of practice. The next sections describe the reach and adoption process for the innovations within each of the work streams.

#### Managing risky states to prevent harm (Risky States and Patient-Specific Checklist)

**Both Risky States and the Patient-Specific Checklist are currently undergoing development and have not yet been implemented.** The Risky States model was created through a partnership between BIDMC, MIT, and Aptima, which is a human factors and software engineering firm. The Risky States model, which will populate an application imbedded in the clinician workspace on the hospital's EHR, aims to provide real time data to quantify the risk of each ICU every four hours. At present, the focus is on validating the concept of quantifying the state of risk and there is no clear plan in terms of what actions might follow the identification of a "risky state". However, it seems evident that if valid, the model would be useful across the hospitals' ICUs by identifying high-risk units and taking action to reduce the risk, such as allocating higher acuity patients to units that are not experiencing a "risky state".

Likewise, the Patient-Specific Checklist is still going through a process of refinement for implementation later this year. The aim is for the checklist to be used during rounds and is limited to drawing attention to issues relevant to the patient, rather than just being a generic, all-inclusive checklist which is not tailored to individual patient needs. Adoption of the checklist may be facilitated by a single sign-on process for providers, and that the checklist can be accessed from the EHR menu. However, information flow for the checklist will remain "one-way", meaning that actions taken as a result of problems identified in the checklist will have to be corrected directly in the EHR as the checklist does not push information to the EHR.

#### Engineering care to prevent harm (Rounds Redesign, Standardizing Room Entry, Access to Policies and Procedures, and Consult Quality)

**Three care interventions were robustly implemented and adopted across all 8 ICUs. Consult Quality is still under development.**

The overall focus of this work stream was to redesign work processes done on an industrial level within the hospital; i.e. processes that are performed repeatedly every day, on every unit. All innovations within this work stream, except Consult Quality, are now live on all ICUs.

Rounds Redesign was initiated to increase the inclusion of non-physician clinicians on rounds so as to encourage open communication in patient care decision making. There was felt to be a high appetite for making changes to the rounding process, and this led to full adoption by the clinical teams. The team spent six months collecting data, developing, and testing the intervention with a group of frontline staff from all units. The resulting intervention was refined and then rolled out across all ICUs. The intervention was intentionally designed to be simple and flexible enough to be adapted to local workflow. Rounds were redesigned to include the following three features:

1. Overnight resident writes a predetermined order of rounds on the white board prior to morning rounds. The order is determined based on patient acuity/need for decision-making and schedule. Ordering the patients enables nurses to plan their time to be present on rounds when it is their patient's turn.
2. Each patient presentation has a designated hard stop for RN and other clinician (usually pharmacist) input.
3. At the end of rounds there is a summary of the plan of care, which is performed by the resident.

We observed that the redesign of rounds was strongly adopted in the ICUs we visited and that the nurses, in particular, viewed this as a highly successful program.

*It gives you a platform to talk about what's at the forefront of the nurse's mind that may not be at the forefront of the rest of the team's mind. (Notes from Interview BIDMC 05)*

Visual cues, such as rounding elements checklists, were laminated and attached to a number of the mobile computer stations in the units we visited. Overall, among nurses, the new process has led to a greater sense of the importance of their role on the team such that rounds are organized to include them.

Implementation metrics reported by the BIDMC team for Rounds Redesign included<sup>28</sup>: 1) improved order; 2) participation of nurses; and 3) communication with patients/families. To assess degree of uptake, observations of rounds were conducted by nurse consultants over a two-month period and a survey was sent to nurses and physicians. A total of 120 and 292 rounds were observed in the pre and post periods, respectively, by the BIDMC team. The observations showed dramatic improvement in: communicating order of rounds (64% to 100%); nurse presence entire time (66% to 83%); nurse participation (40% to 87%); and nurse participation during plan for the day (33% to 88%). The survey results did not indicate as strong an uptake as the observations, however they did indicate significant and important improvement from baseline, particularly for nurses. The BIDMC team reported there were 129 and 112 surveys completed by physicians in the pre and post periods, respectively, and 107 and 91 by nurses in the pre and post periods, respectively. Although the survey results showed significant improvement in the nurses' scores for most of the questions, all of the 'post' scores were less than 50% suggesting there is still room for improvement. The BIDMC team found that only one of the questions, 'I am notified when rounds begin on my patients,' improved significantly in responses of all providers, which went from 38% to 51%, suggesting that nurses were impacted more by Rounds Redesign than other providers. The response rate reported for both the pre and post surveys was about 26%, so it is possible that responders are not representative of the whole unit.

Although patient/family participation and communication are key components of the Rounds Redesign, patients were not surveyed nor was communication to them during observations of rounds collected. It is, therefore, not possible to assess the degree to which Rounds Redesign impacted communication to patients/families.

Standardizing Room Entry was driven by 1) a perception that hand hygiene is an area needing perpetual attention in any hospital; and 2) recognition that it is an industrial-scale operation happening thousands of times a day. As the project evolved, the BIDMC project team learned through the PFAC that patients had concerns about whether and how clinicians introduced themselves upon room entry. Patients expressed distress about instances where clinicians would physically touch the them to do clinical care without asking permission. This latter example became a strong driver for the project team, as it was felt to represent a flagrant violation of patient respect.

*The voice of patients and families have been screaming the past two years: "This is what it feels like when an attending switches to a new attending"; "This is what it feels like when you enter my room at night and touch me" (Notes from Presentation BIDMC 01)*



The use of the patient voice in this project is an example of how patient and family feedback drives care delivery change-planning and implementation throughout the institution. Redesigning the room entry process involved the creation of a standard, multi-step process and a cart to be placed within rooms for performing hand hygiene and gowning, as necessary, in full view of the patient. However, subsequent changes in requirements for gowning for infections has meant that the cart is now used primarily for hand hygiene and can be more of an encumbrance, particularly in older rooms which lack square footage. Also, staff are required to identify themselves each time they enter the room and explain what they are doing. However, some staff reportedly feel that this is unnatural as they enter in and out many times and do not want to disturb the patient each time. The observational evaluation carried out by the BIDMC team showed mixed adherence to the standard entry process, with RNs seemingly having greatest compliance and MDs poorest. During the site visit, it was observed on one occasion that a nurse entered the room to check the monitor screen and left within five seconds, and though she sanitized her hands, she did not say who she was or what she was doing to the patient who was unconscious (Observation BIDMC 02). Reflecting on the site documentation, our observations, and feedback from staff, it seems that the process for Standardized Room Entry has not been consistently adopted.

Implementation metrics for Room Entry included<sup>29</sup>: 1) percent of entries complying with observable communication elements of the process; 2) hand hygiene scores; 3) decrease in non-value time added to room entry; and 4) percent perfect compliance. Room entry was implemented in all eight ICUs. Data were collected via spot checks conducted over a six-month implementation period for each ICU. Run charts were made and ICU-specific results were shown and discussed regularly at each ICU monthly staff meeting to encourage compliance and identify improvement strategies. In general, all except one ICU had clinically meaningful improvement in all the metrics measured. The metric with the most variable uptake was hand hygiene after entering the room, which clearly improved in three ICUs, showed considerable variability in three, and decreased in one. The metrics related to communication with patients and families showed the most consistent and significant improvements and included: verbal communication with patients and families (separate metric for each), and communicating with patients prior to touching them.

Accessing Policies and Procedures was not a new innovation in the same way that Rounds Redesign and Standardizing Room Entry were. Policies and Procedures existed previously, but they were updated for the project. The system for searching for policies and procedures using keywords was also improved so that they could more easily be found when needed. Better access to the procedures means that they are more likely to be used by staff and the improved quality of the content instills confidence in the staff to use them when needed. No data was available on how often these procedures are used and what impact they make. In addition, while policies and procedures are available at the three community hospitals in the integrated delivery system, it is unknown how they are used in these settings.

#### Partnering with patients and family (MyICU)

***MyICU was piloted, had lower than desired uptake, and then was redesigned for optimized deployment on patient and caregiver personal devices. The pre/post study is currently underway for the redesigned tool.***

The BIDMC team conducted the initial pilot of MyICU from Oct. 14, 2015 through Jan. 14, 2016 and included two ICUs (MICU A and TSICU) with a total of 20 beds and 352 eligible admissions. Of these, 77

(22%) patients/families were approached, of whom 36% declined, for an overall uptake of 14% (49 of 352).<sup>30</sup> The portal was predominantly used by families, due to the poor health of the patients. Families were not approached for reasons similar to those stated at other sites, such as lack of family member/poor family situation, technical issues, discharge before patient could be approached, and not clinically appropriate. The BIDMC team found that the most common reason patients were not approached (35%) was patient discharge before s/he could be approached. Enrollment required an onsite support team to actively enroll patients and so was a resource intensive effort. iPads were provided in each room for patient/family use during the pilot; MyICU could also be accessed from computers, but was not optimized for use on mobile devices.

Following the pilot period, clinicians and patient/family users were surveyed regarding their experience and in-person feedback was gathered from staff. The conclusion was that the first version provided too much information up front, which overwhelmed users who then found it difficult to navigate to key features. Additionally, while the tool could potentially be accessed from anywhere, too much emphasis was placed on using the iPads, which were often unreliable and difficult to use due to necessary security restrictions. Version 2 of MyICU was launched in July 2016 across all eight ICUs. While retaining the tool's emphasis on providing patient/family users with information about the ICU and what was happening on a day to day basis, several modifications were made to improve the usability and user interface between versions 1 and 2. Version 2 was designed to be mobile friendly so it could be accessed on any device and the information contained was restructured into "layers" so that users would be presented with only the information they were interested in. Some original features, most notably an interface to schedule a family meeting, were simplified and some new features were added allowing patients to request certain services (e.g. Spiritual Care, Pharmacy, Social Work).

*This [MyICU] system is a byproduct in the fact that it's devoid of PHI which allows us to not require consent or create privacy issues with log-ons. There are some limitations related to this. Brigham has more clinical content and have people consent and have paid a price in the number of people they are able to consent. There are compromises in both directions but they've landed on this because they'd rather have it available to people broadly. (Observation BIDMC 01)*

It was viewed that having a dedicated person to enroll patients in the portal was not sustainable, and therefore signs have been put up so that patients and families can enroll themselves. At the time of our visit, within the first month of rolling out version 2, only 29 of 501 (6%) potential patients/families across all eight ICUs had enrolled (Notes from Presentation BIDMC 01) suggesting that an active enrollment strategy is likely needed. In one ICU, two staff members had self-selected to be responsible for encouraging patients and families to enroll, which shows moderate acceptance and adoption by staff. It was only the early days of implementation during our site visit; going forward, the BIDMC team will monitor adoption to determine what strategies may be needed to optimize adoption.

Data, such as the number of staff using the MyICU portal, are not yet available because implementation is still in progress. While MyICU requires little input from staff, it is important that they add themselves to the care team and post what procedures or tests are scheduled for that day. It is not clear yet how many clinicians are actually viewing the "About Me" information which is put into the portal by the patients. The study team hypothesizes that this module in particular, and the tool in general, are most likely to impact patient dignity and respect, and facilitate greater communication and engagement with

the care team, particularly around goals of care. The purpose of MyICU was to facilitate patient orientation to the ICU, communication, and understanding of the humanity of the patient via viewing the descriptive facts about the patient; it was not intended to replace in-person communication:

*it's not replacing in person communication which is most valuable, it's actually enhancing it, and I think that's key (Interview BIDMC 03)*

The MyICU portal did not include an element related to goals of care. The BIDMC team tested the goals of care concept with the PFAC and were told that patients felt that if they were asked about their goals of care this meant that their care team had given up on them. The team felt that the Haberle instrument used by some of the other sites was inadequate because the patient/family is forced to pick a single goal, but “every patient and family have all five goals” (Presentation BIDMC 02). Thus the approach to designing the MyICU tool was to provide a place where patients and families can help staff get to know the patient better, rather than to initiate a goals discussion.

### *Facilitators*

Not all interventions had been implemented at the time of the site visit, therefore few facilitators and barriers to implementation were identified.

**Patient engagement culture embedded at all levels:** A common message that was received and consistent at all levels, from the patient level to the CEO, was how valued and central the patient voice is to the organization. There was genuinely a different philosophy to patient engagement in that they are not a group from which advice is sought on a topic, but rather a voice that drives what topics are discussed. Therefore, for interventions such as MyICU, adoption almost seemed to come naturally as clinicians felt the MyICU tool was an extension of their philosophy of valuing patient participation.

*I do think here Beth Israel providers, it's a little bit different and I do think that because patient family engagement has been around here for a long time they didn't need to buy into it so much as, 'cause I do think they know that patients and families, their voice is integral [...] in terms of engagement, there was already a buy in (Interview BIDMC 03)*

**Participatory design across all adopting units:** Teams from all adopting units were involved in the design process for both Rounds Redesign and Standardizing Room Entry. The teams focused on agreeing on a set of core elements that could be simple, but flexible enough to be implemented in any unit regardless of the differences in local unit-based workflow. This was viewed as highly successful, especially for Rounds Redesign, where each of the eight ICUs has been able to implement the rounding process and, as a result, reliably incorporate the nurse's voice for most patients each day.

**Common governance structure across critical care:** Within BIDMC, there is one common governance structure across all intensive care units, and alignment of key practices and processes in all units. This set-up has enabled the innovations to scale to all units, following piloting in just two.

**Acceptance of learning process:** The process of innovation development and implementation was planned to be iterative and paced at a speed to allow for learnings to be incorporated into design. There was acceptance that a lack of experience in IT design for MyICU would require extra time to learn. Rather than this putting pressure on the team, their experience as a learning environment meant that

any potential problems were viewed as a learning opportunity which could be incorporated into the implementation process, rather than as a setback.

**Progressive policy and regulatory context:** The wider policy context in which this project was implemented was characterized as progressive and forward thinking in health care. There are only three commercial payers in Massachusetts and all are local and non-profit. Over 70% of patients in the state are under some sort of global payment arrangement,<sup>31</sup> which has forced the health system to be innovative and forward thinking to survive. This, in turn, was seen to allow BIDMC to focus on value-based care and be progressive in the design of their innovations, such as Risky States. In addition, Massachusetts has mandated patient and family advisory councils in all of its 83 hospitals, illustrating progressiveness in incorporating the patient voice into health care.

## Barriers

**Lack of alignment between business cycle timeframe and health service innovation:** It was felt that the typical three-year business cycle timeframe was not practical for health service/technology innovation and real world implementation. It was felt to be unrealistic to expect hospitals to deliver something impactful within such a time frame, especially when innovations are starting from scratch.

*The expectation that you'd be able to get something dramatic signed, sealed, and delivered at three years isn't realistic. We're at a point now where people are hitting their stride and have the ground work done and are ready to take opportunities to spread. (Notes from Interview BIDMC 02)*

## Clinical effectiveness

Because not all of the interventions have been implemented, the data presented in Table 12 below are not conclusive, rather they are reflective of any progress so far in the metrics of interest to the foundation. The data below represents data collected and reported by the site.<sup>32</sup>

<b>Table 12. Results: BIDMC All 8 ICUs<sup>32</sup></b>				
	<b>Pre-implementation (Jan-Jun 2014)</b>	<b>Post-implementation (Jan-Jun 2016)<sup>b</sup></b>	<b>Absolute Change</b>	<b>P-value</b>
<b>Physical Harms</b>				
CLABSI (per 1000 line days)	0.26 (n=6499)	0.76 (n=7457)	0.5	0.4
VAE <sup>a</sup> (per 1000 ventilator days)	25.4 (n=5416)	16.7 (n=5797)	-8.7	0.001
Delirium <sup>c</sup>	60% (n=4435)	56.4% (n=5110)	-3.4%	<0.001
<b>Patient Satisfaction</b>				
HCAHPS Overall Hospital Rating	Score of 9 or 10 72.3% of the time (n=3,653)	Post period Jul-Dec 2016	N/A	N/A
<b>Family Satisfaction</b>				
FS-ICU 24 Total Satisfaction Score	Mean = 86 (n=89)	Mean = 88.5 (n = 49)	1.5	0.8
<b>Goal Concordance</b>				
Received care consistent with goals	Mean 4.69 (n=118)	Post period Jul-Dec 2016	N/A	N/A

<b>Costs</b>	N/A	N/A	N/A	N/A
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<sup>a</sup> Includes ventilator-associated conditions, infection-related, ventilator-associated conditions and possible/probable ventilator-associated pneumonia.

<sup>b</sup> For post-implementation period, all ICUs implemented Standardized Room Entry, Rounds Redesign, and Policies and Procedures; MyICU v.1 was only present in MICU A and TSICU.

<sup>c</sup> Percentage based on total number of ICU days

The data presented here are aggregated from the BIDMC scorecard submitted to the foundation in August 2016. Aggregate pre and post periods were constructed from the BIDMC quarterly report as January-June 2014 and January-June 2016, respectively. This was done to maximize the amount of information used in the analyses and make the pre and post time periods similar. The post-period reflects the period in which both the Rounds Redesign and the Standardizing Room Entry interventions were completely implemented (Room Entry was completed in December 2015). ***The three projects that are likely to have the biggest impact on physical harms, dignity and respect, and goal concordance (MyICU, Patient-Specific Checklist, Risky States) are either in the early stages of implementation or have not yet been deployed. Though we report interim data below, we are unable to discern whether there has been an impact on the clinical harm outcomes, the patient and family engagement measures, or goal concordance.***

The results in this section, therefore, only reflect the three implemented interventions (Rounds Redesign, Policies and Procedures, and Standardizing Room Entry). These interventions were expected to positively impact physical harms; Room Entry was also expected to positively impact patient/family dignity and respect.

## Physical Harms

### Outcomes reported and methods:

The physical harm outcomes measured by the BIDMC team in both the pre and post periods were CLABSI, VAE and delirium. As mentioned above, the data collected by BIDMC and reported on the August scorecard were aggregated for the period of January-June 2016 as a post period to reflect when both interventions (Rounds Redesign and Standardized Room Entry) were completed. This was compared in a simple, unadjusted z-test to pre-intervention data aggregated from January-June 2014, also reported on the BIDMC scorecard.

### Results:

Both VAE and delirium decreased significantly. The improvement in VAE translates to about nine fewer harms per month as there are about 1000 ventilator days per month. The improvement in delirium appears smaller because it is reported as a percentage, but when converted to a rate translates to 34 fewer patients with delirium for every 1000 assessed.

### Conclusions and limitations:

These analyses are preliminary because they are unadjusted pre/post values and it is difficult to attribute the improvements specifically to Rounds Redesign or Standardizing Room Entry. There was an increased focus on measuring delirium consistently in the ICU, however, as well as process measures, such as the percent of patients on benzodiazepines and the percent of patients who had a daily sedation

interruption, which may have contributed to the results. The results should not be over-interpreted, however, and it is best to wait for the adjusted comparisons at the end of the study.

### *Patient/ Family Engagement*

#### **Outcomes reported and methods:**

A subset of HCAHPS questions collected by the site will be used to assess patient dignity and respect. Data for the post-implementation period have not yet been collected.

The FS-ICU 24 is being used by the site to evaluate family dignity and respect. However, the main intervention for this, MyICU, is in the process of being fully implemented.

#### **Results:**

There is not any post-implementation data yet for the HCAHPS survey, so no assessment of patient dignity and respect can be made.

#### **Conclusions and limitations:**

The main intervention expected to affect patient/family dignity and respect, MyICU, is currently in the post-implementation period with data collection ongoing. The Standardizing Room Entry project did not, on its own, significantly impact dignity and respect. However, beginning scores were quite high which may impact the ability to measure improvement.

### *Goal Concordance*

#### **Outcomes reported and methods:**

A five-point scale question was designed and is being collected by the site to assess the extent to which patients felt the care they received during hospitalization was consistent with their goals. Patients were surveyed after being discharged from the ICU, but before being discharged from the hospital.

#### **Results:**

No post-implementation data yet.

#### **Conclusions and limitations:**

No post-implementation data yet. Small sample sizes could pose a problem in assessing impact, as it is difficult to obtain responses from a large, representative sample of patients and families.

### *Costs*

Costs were not measured.

### *Maintenance and sustainability*

***Maintenance and sustainability cannot be assessed because only about half of the innovations have been implemented. However, of the three interventions that have been completed, Rounds Redesign and Access to Policies and Procedures are most likely to be maintained in their current form.*** For Rounds Redesign, the aim to have nurses attend and contribute to rounds regularly is seen almost to be a “rule” and has created a sense of teamwork which seems likely to continue.

In contrast, Standardizing Room Entry is perhaps less sustainable over time as we have already seen that changes in gowning for infection control have had a perceived negative impact on the utility of the carts in patient rooms.

*They need the carts and all of the pieces a little less now because before 80-90% of our patients were on the cautions [for BRE and MRSA] but now they use gowns significantly less and there's this big cart in the room filled with gowns they don't use.*  
(Notes from Interview BIDMC 06)

There was no evidence collected for whether the changes to Policies and Procedures improved their use, but it was perceived that the improved search function made them more useable, and it seems likely that their use will continue to be as before the intervention or possibly improved.

It is too early in the implementation of version 2 of MyICU to say how it will be adopted and what level of use will be sustained. However, in at least one unit, the staff are keen for patients to use the system and have spontaneously created their own system for encouraging patients to use MyICU. Without a targeted adoption effort for patient enrollment, as was carried out for version 1, it is unclear at this point what the adoption and maintenance of MyICU version 2 will be as it transitions from a pilot project to the standard of practice. The BIDMC team will be monitoring adoption to assess what strategies are needed to increase adoption.

The above interventions are the only ones which have been implemented and for which we may have some insight into their sustainability over time. Thinking more widely about potential issues which may influence maintenance of the project as a whole, we have identified three possible points of influence. First is the legislative mandate for ratios for critical care staffing which exist in Massachusetts.<sup>33</sup> This may help spread and sustain the use of the Risky States model because of the requirement to staff units according to patient acuity, and with the known limitations of existing traditional acuity tools for this purpose, the Risky States model provides a more robust assessment of actual unit intensity. Should the Risky States model prove valid, it would be an evidence-based method for decision-making about staffing levels. Second, the grant funded three nurse project consultants who participated as team members on each of the Moore projects. These nurse project consultants also acted as a bridge between the project and frontline staff throughout the design, development, and implementation of key activities in order to get feedback and provide front-line staff with updates on overall progress. In this role, they were clinical champions for the project innovations on the ICU floor. As part of the grant, the nurse project consultants worked with the clinical nurse specialist, whose role it is to stay current on policies and procedures, to update the critical care Protocols and Procedures. The nurse consultants and nurse specialist completed this work as part of a collaborative team of nurses, physicians and clinical educators, through the Critical Care Practice Committee. Their work not only established a uniform template for this purpose, but updated each of the policies and protocols to include a current evidence base. It was stated that the evidence base for the protocols would be updated every two years. While the funded nurse project consultants had the protected time to do a global update of these practices, going forward this work will be managed by the Critical Care Practice Committee, led by the Clinical Nurse Specialist with input from clinical nurses, including but not limited to the former nurse project consultants. Third, within the elements of the project implemented thus far, there has been an emphasis on measuring process outcomes rather than patient harms or service outcomes, though these were also measured. This was not perceived as a barrier by the BIDMC project team. However, from an external point of view, it is difficult to understand what has been the impact of the interventions; for example, we cannot be sure of the impact of Rounds Redesign on safety culture, though we can see from the process outcomes that nurses are included in rounds more often. This may make assessing

maintenance of changes in practice difficult and could affect the potential for spread, as other organizations may not wish to adopt a practice for which the impact has not been identified.

## Lessons learned

**Relationship between academic medical centers and community hospitals:** One of the key lessons learned at BIDMC, through this work and in general, is the important relationship between academic medical centers and their affiliated community hospitals. There is a sense that the system-wide organization of BIDMC's affiliation with a network of community hospitals is an important model for spreading innovation. At the same time, BIDMC realizes that within this system there is a two-way learning process. BIDMC has learned that community hospitals have their own culture which may, in fact, be better than that of the academic center and so there are things both could learn from each other. BIDMC has learned to 'listen' to the affiliates and their needs, rather than presuming that the model of work developed in an academic setting is superior.

*A mistake that academic medical centers make frequently is to think that their way is the only way [...] As we move out into the community and want to propagate some of the really important cultural pieces that we have here, it's got to be done with sensitivity and it's got to be done with the acknowledgement that it's a two-way street. (Interview BIDMC 04)*

## Conclusions from BIDMC

Three of the seven innovations are still in development and the second version of MyICU had only just been released at the time of the site visit, therefore we are unable to draw firm conclusions at this time. One of the key findings at BIDMC was how strongly the PFAC and patient engagement culture seemed to drive the innovations developed and how they were refined. There is a real culture of partnership with patients and families and strong nursing engagement at BIDMC, which was evident in all interviews and observations. This suggests a more bottom-up approach to innovation development and implementation. BIDMC was also the one site in which the innovations were rolled out onto all ICUs, with some innovations even moving into the community hospital setting. This seems to be the result of a common governance structure and provider network across sites. Of the interventions implemented thus far, the approach to Rounds Redesign seems to be the best candidate for spread, though it is unclear to what extent hospitals engaging in the approach used by BIDMC would get the same result without the strong culture of collaboration and nursing engagement.



## Johns Hopkins Medicine (JHM)

### Data sources and limitations

The data for the evaluation of Johns Hopkins Medicine (JHM) includes the following:

- Five group interviews conducted in person during the site visit.
- 26 documents: Documents submitted to the Moore Foundation and received directly from the site were analyzed for their content, and quantitative data was extracted for the assessment of effectiveness.
- Five presentations: Four of the presentations contained discussion of interview questions, but are included under presentations as the content of the discussion was largely driven by the presenters rather than the researchers. Notes taken during the presentations were used to help clarify points raised in project documentation.

The site visit took place during August 2016, which was approximately nine months after the site project had concluded and a month after the technological innovations had been switched off for the hospital-wide changeover to Epic. This meant we did not have an opportunity to observe the innovations live and there were few physicians to speak to because residents and fellows had just turned over in July. Additionally, Project Emerge was envisioned as a demonstration project rather than an implementation project, which meant the focus of the visit was on the development process rather than on implementation. As a result, we have less data regarding implementation compared to the other sites. Our findings on the implementation process are therefore limited to the perspectives of the Emerge research team and one frontline implementer.

### Summary of site projects and innovations

Project Emerge at JHM had three goals: 1) to engineer the processes behind identified harms including workflow, technology, culture, and learning and accountability, to eliminate preventable harm in the ICU; 2) optimize patient and family outcomes and experiences; 3) reduce healthcare costs. The approach employed to achieve these aims was based on an applied systems engineering approach to integrate technologies, workflow, and culture in a system of systems. The approach used to achieve this system of systems, called “concept of operations” or CONOPS, is most commonly used in fields with an engineering focus, such as aeronautics and manufacturing, but in theory could be applied in any setting. To achieve this vision, the JHM hospital team partnered with the Applied Physics Lab (APL) which provided the expertise on systems engineering. This is a fundamentally different approach to creating sustained change than was seen at the other sites and represents more of a transformation of the current state, rather than instituting incremental change. The original intention was not to develop services or innovations for immediate use to reduce harm, but rather the project attempted to develop the process and science of applying systems engineering to the ICU environment. The project was designed as a proof of concept of using systems engineering in healthcare to eliminate harms, and therefore additional basic research was included to explore important domains within the system including: respect and dignity, team culture, and learning and accountability.

A cornerstone of this vision was to create an intelligent system where multiple sources of information are integrated and output generated supports situational awareness. Within this system, the EHR is only one source of information; additional information would come from integrating data from sensors and ICU equipment such as ventilators. The Emerge technology, which was the IT solution developed as a

prototype to support the integrated system envisioned by the project, was aimed at demonstrating a part of this vision with regards to seven harms. The Emerge technology had three components: the Care Team Portal, the Patient Family Portal, and the Administrator Portal. The Emerge technology was intended to be a demonstration for what might ultimately become a suite of apps to transform care in the ICU and beyond. The strategy implemented to achieve scalability for this vision was development of a middleware, called Topaz.

In addition to the technology elements, the JHM team carried out basic research projects to understand how respect and dignity are conceptualized and measured in the ICU and to develop a behavioral marker system to evaluate teamwork. These elements of the project were research rather than development of interventions for implementation. The project also included the Comprehensive Unit Safety Program (CUSP), which has been embedded at JHM for over a decade as its safety culture element. It was included in the Emerge Project package as it was seen to be a fundamental part of the safe ICU environment and would be spread to UCSF. Table 13 describes the collection of interventions.

<b>Table 13. Description of JHM innovations including current status and implementation period</b>			
<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (August 2016)</b>
Emerge technology - Care Team Portal	Displays an interactive “harms monitor” for each patient by integrating data from EHR and other data sources for five clinical and two non-clinical harms: ICU-acquired weakness, ventilator associated harms and infections, VTE, pain and delirium, CLABSI, and respect and dignity, goals of care.	Initial working version deployed July 2014, iterations continued through Q1 2016.	Not live due to transition to Epic.
Emerge technology - Patient Family Portal	Electronic patient portal, accessible by iPad, with information specific for the patient/ family including: information about the patient room, FAQs about ICU care, care team member identification, ICU policies, journal and image upload, Family Involvement Menu (allows families to select which tasks they’d like to do each day), and ability to ask questions. The Patient Family Portal was accessible by iPads.	Initial working version deployed July 2014, iterations continued through Q1 2016.	Not live due to transition to Epic.
Emerge technology - Administrator Portal	Allows hospital administrators to manage user accounts, deliver surveys, and export data.	Initial working version deployed July 2014, iterations continued through Q1 2016.	Not live due to transition to Epic.

<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (August 2016)</b>
Sensors	Commercial-off-the-shelf (COTS) sensors were initially tried (such as Fitbit), but were not able to be integrated due to problems with API. APL subsequently designed four sensors which were integrated into the Emerge technology monitor: head of bed, ambulation, cyclometer, and grip strength. However, IRB process required patients to consent to data being pulled for each sensor, which ultimately reduced overall consent to using the Patient Family Portal. The sensors were therefore scrapped.	COTS not implemented due to issues with API. Four additional sensors were live for short period at end of 2014, but removed because of IRB consent problems.	Not live.
Topaz platform	Middleware solution to act as a buffer between EHR and applications such as Emerge IT platform. Enables integration and conversion of data from the EHR and other data sources, including sensors, into the Emerge integrated control and display system or other apps. Allows for scale of Emerge to other health systems.	Implemented with Emerge technology, continued through Q1 2016.	Not turned on because Emerge IT platform not live.
Comprehensive Unit Safety Program (CUSP)	Standardized program in which environmental, team, or work process defects are identified and supported by management processes to rectify to improve patient safety. Engages the entire workforce in harm identification and rectification, thereby creating a safety culture. 170 CUSP teams operate in Johns Hopkins Hospitals; has spread to other hospitals nationally and internationally.	Implemented 13 years prior to Project Emerge.	Live, embedded.
CONOPS	Process intervention in which desired outcomes are first stipulated and then the steps to achieve the outcomes are worked out in reverse at a systems level.	Used for all harms, most effective for physical therapy.	Completed for all 7 harms.

A hospital-wide PFAC was engaged in providing feedback on the developments within the project through their monthly meetings. The Berman Institute of Bioethics seemed to work most closely with

the PFAC, and patients and families more generally, in their work on defining respect and dignity in the ICU.

Six grants were given to JHM (#3186, 3186.01, 3186.02, 3186.03, 3937, 4608) for a total of approximately \$14.6 million. This included an eight-month planning grant for \$457,000, the main project grant for 24 months for \$8,965,000, an implementation and evaluation grant for 10 months for \$2,209,619, a maintenance grant for Emerge for nine months for \$259,409, a grant to develop Topaz for \$2,362,170, with an extension of \$52,534, and a grant for participation in the Libretto Consortium for 17 months for \$342,500.

## Context

Johns Hopkins Hospital is a non-profit academic teaching hospital within the broader Johns Hopkins Medicine system. As one of six academic and community hospitals within Johns Hopkins Medicine, the 1,192-bed Johns Hopkins Hospital is staffed by over 1,950 full-time attending physicians. The hospital houses six intensive care units.<sup>34</sup> The surgical intensive care unit (SICU) where Project Emerge was implemented contains 12 beds and has an average patient stay of two days.<sup>35</sup> Plans to implement at a second site (Johns Hopkins Bayview Medical Center's medical ICU) were scrapped because of technical, financial, and human resource complications that slowed implementation and resulted in a strategic decision by the foundation to go straight to UCSF as the next site.

Three partners within Johns Hopkins University were involved in the project:

- 1) Armstrong Institute for Safety and Quality, which led the project, develops interventions and training opportunities to reduce preventable harms, improve clinical outcomes and patient experiences and reduce health care waste.<sup>36</sup>
- 2) Applied Physics Laboratory (APL), which provides applied research support, analysis and practical solutions to various organizations, academic institutions and the U.S. government, primarily in the fields of defense, space, and national security.<sup>37</sup>
- 3) Berman Institute of Bioethics, which works to address bioethical issues across all areas of health and science. The institute provides education, training programs, and research support through IRB roles and policy advisory committees.<sup>38</sup>

Important context for this project is that JHM, and particularly the Armstrong Institute, is considered a world leader in ICU patient safety and quality, having developed the Comprehensive Unit Safety Program among other interventions.

## Experience of implementation

Project Emerge was originally intended as a proof of concept project with the IT platform as a prototype. The focus was not initially on implementation, but rather testing the application of systems engineering in the ICU environment. Such a vision for changing care does not fit the traditional business cycle, but was felt to require a 10 year or longer commitment with a substantial period of design work and financial investment. Early in the project, the site perceived a strong emphasis from the program team on implementation and outcomes over the short term. As a result, there was an effort to go live in the ICU before the system was operable enough to fit into workflow. Issues faced in the implementation process of the Emerge technology are described below.

*The foundation was very focused on results rather than design so we had to kinda go very short on that phase to get projects implemented because they wanted 'show me that you can do something'*

*Interviewer: Was that a barrier, that focus on [results]?*

*Completely, because it's a medical mindset not a system engineering mindset  
(Interview JHM 02)*

The project utilized a transdisciplinary approach pulling in expertise from not only different areas of healthcare, but also different fields including engineering, bioethics, and human factors psychology. The relationship with engineers at APL was central to the project and informed all aspects of development. It is important to note that some project elements were already in place in the ICU prior to the start of the project, and were wrapped up into the Emerge project package. This included the Comprehensive Unit Safety Program (CUSP) which had been established years earlier and had already led to an improved culture of safety in the SICU. Also, the Family Involvement Menu deployed in the Patient Family Portal existed in a paper format prior to the project. Therefore, JHM had already begun developing a culture of safety, and patient and family engagement which provided a foundation for Project Emerge.

[Experience of using a systems engineering approach in the ICU](#)

***Systems engineering provided a framework for the project and was deployed across all five physical harms of interest to JHM, which culminated in the development of the Emerge prototype. The process was perceived as effective but initially required extra time to bring all stakeholders together.***

The approach of collaborating with applied systems engineers in healthcare is innovative and it is worth considering to what effect this approach was used in the project. CONOPS was used across all harms except respect and dignity as this concept was felt to be ill-defined in the ICU setting and with no outcome or output to use as a starting point. CONOPS was seen to be most effective in areas where there were gaps in practice. ICU mobility was considered a gap area and one in which the standard workflows could be engineered to facilitate improvement in ICU-acquired weakness. Workflow changes were introduced to engage physical therapists and nurses in mobilization activities commensurate with their licensure so that the maximum number of patients could be mobilized with the fewest resources, with clear accountability and mobility targets.

*We're going there, we're rounding with nurses, we're doing these activities. We're finding it's formalizing a process [...] we're finding that it makes us efficient as therapists - I'm seeing the right patient at the right time, they know I'm coming, they know I'm here and that we're also being able to balance that out with identifying people that really do need us and really don't need us. (Interview JHM 04)*

In contrast, in outcome areas such as CLABSI where the infection rate was already low and processes were viewed as fairly well optimized, there was not as much opportunity gain from the CONOPS approach, though there were some improvements in process measures. Use of CONOPS was facilitated by APL, with the intention of producing a prototype system rather than a production level system.

*APL builds prototypes they don't do production things – they made that clear up front – they need a [commercial company] to come on board at some point to transition*

*stuff to so that [commercial company] can finish it up and disseminate it (Notes from Presentation JHM 04)*

### Care Team Portal

***The Care Team Portal effectively demonstrated the concept of creating a harms monitor, but was not adopted independently by all providers. It was not able to be used in its ideal form due to issues with integrating sensor data and integrating with provider workflow around the electronic medical record.***

The Care Team Portal was reported to be used primarily used on rounds, and for a good portion of the implementation the tablet info was reviewed in front of the larger team by a research assistant, though there were some providers that used the tablet on rounds without assistance from the research team. Physical therapy (PT) and occupational therapy (OT) groups used the portal as they carried out mobility rounds, independently. The JHM team found that, beginning in July 2014, PT and OT staff used the portal on 88% of patients in the SICU, while physicians consulted the portal on 80% of patients during rounds. Over the following year and a half, these numbers decreased to 55% and 40%, respectively.<sup>35</sup>

Four iterations of the Care Team Portal were implemented over the course of a year. It is important to view the implementation of the portal through the lens of the care team's intention for this to be a prototype/proof of concept rather than a fully functioning integrated tool. The first iteration (implemented April 2014) required data to be input by hand three times a day by research assistants because it was not connected to the EHR. This version of the portal was not viewed to be useful by the clinicians because the data pulled by the research assistants was of variable quality, and by the time the patient case was reviewed on rounds the entered data could be already outdated. The Emerge team felt this negative initial first impression made it more difficult to get adoption of subsequent, more robust versions of the Care Team Portal.

*One of the things that limited engagement was we had periods of time when the data just wasn't very timely, it wasn't very accurate [...] well it turns out if you get used to seeing red on every screen and half the time it's an error and half the time it's right, you just learn to ignore it. (Interview JHM 01)*

By the fall of 2014 the portal was connected to the EHR which increased data frequency. However, data accuracy was not improved until about January of 2015.

The physical therapy team was one area of success in adoption of the portal. This is reflected more broadly in the success of the CONOPS process to increase the proportion of ICU patients who were mobilized to goal in the ICU. In addition, mobility targets were already not being set in a structured way in the EHR and so the implementation in the Care Team Portal provided a more straightforward approach. Overall, the combined team was focused on developing a prototype over a production model because the portal was viewed as a demonstration of a larger principle which would take much longer than two years to show outcomes.

### Patient Family Portal

***The Patient and Family Portal had poor adoption in the ICU likely due to issues with the long consent process, limited patient eligibility, and lower than desired access to hardware.***

The Patient Family Portal was accessed via tablets kept within the ICU. The number of patients who were eligible to use the portal in the SICU was limited because the portal was thought to be less

beneficial for short-stay patients, and most surgical patients do not stay longer than two days. Additionally, adoption by patients and families was hampered by an intensive consent process, imposed by the IRB, because the project was classed as research and not quality improvement. Patients and families were asked to read a 12-page consent form for what was felt to be minimal risk.

*One of the barriers for us [...] is our approach to IRB [...] this consent process they approved was so onerous, I mean I've done actual invasive research that was less onerous than the consent process that they were making us put patients through.*  
(Interview JHM 01)

Ultimately the consent process was reduced to a verbal consent process which increased the number of patients and families who signed up to use the portal.

### Sensors

***The team was not able to integrate sensor data into the Emerge harms monitor due to vendors refusing to provide an application program interface (API) for commercial-off-the-shelf (COTS) products. Four sensors developed by APL were integrated, but were dropped due to IRB consent barriers.***

The utility of the Care Provider Portal was also hampered by lack of interoperability between COTS medical devices and the EHR. Companies that manufacture the devices would not provide the API necessary to integrate the sensors. As an alternative, APL developed four sensors (head of bed, ambulation, cyclometer, and grip strength) which automated the identification of some common measures to feed into the identification of harms. However, patients had to consent to data being pulled for each sensor, which resulted in a long, burdensome consent process. This also deterred patients from using the Patient and Family Portal and so sensors were ultimately removed from the system. This prevented realization of the vision of the true integrated data system approach to harm prevention.

### Facilitators

**Experience with research and innovation in patient safety:** The SICU at JHM has a long standing history of research which meant that the unit was open to trying out the interventions. There is also an established culture of patient safety, through CUSP, which may have increased acceptance of innovations aimed at improving patient safety.

**Transdisciplinary partnerships:** The project drew on expertise from the Armstrong Institute and their human factors experience, the APL team which provided systems engineering knowledge, and the Berman Institute of Bioethics which led the work on defining and measuring patient dignity and respect. These relationships were not peripheral, but worked as an integrated group to provide a holistic view of re-engineering safety in the ICU.

**Co-location of transdisciplinary project management:** A project manager from APL was co-located within the Armstrong Institute with the clinical project manager. This allowed co-transfer of important techniques and information to successfully work across disciplines.

**Working with a prototype:** It was perceived that, for development purposes, it was easier to build a prototype and let stakeholders comment on it than to ask people for feedback on abstract ideas.

**Funding:** It was felt that the vision of bringing systems engineering to ICU redesign would not have been possible without funding from the foundation as no funding opportunities for this type of work exist elsewhere.

## *Barriers*

**Tension between scope of vision and requirement to produce outcomes:** The purpose of the project was to demonstrate that systems engineering approaches can be used to eliminate or reduce the occurrence of seven harms, and improve the patient and family experience in the ICU. The mechanisms for this relied on working with busy clinicians, developing novel technology, and working with engineers who had not previously worked within a healthcare system. In general, the project teams did not feel that the milestone targets, especially the emphasis on having a working model fully integrated to where it could impact clinical outcomes, were aligned with the complexity of the project, especially the time needed to build relationships and test prototypes.

*We came in thinking we were developing a prototype and suddenly we were building for production and you have to think about that differently. (Notes from Presentation JHM 04)*

**Lack of application program interface (API):** The lack of an API for medical devices prevented true systems integration between the devices via sensors, EHR and Emerge technology. Changes to policy and regulations could potentially rectify this issue if ICU equipment vendors were required to provide an API for their products.

**Building relationships among experts:** Building relationships between experts who have not worked together previously was understandably found to be both fundamental and time consuming for this project.

*A sustained collaborative approach among all the stakeholders is crucial in this process. Knowing that each stakeholder may have his/her own agenda within the project, it would be imperative to understand the risks and benefits as early as possible. (Doc 'Project Emerge: Final Report', pp. 100)*

**Lack of fit of prototype into provider and clinician workflows:** A major barrier to adoption was the fact that the Emerge technology did not fit well into provider use of technology at existing work stations. The platform was deployed on a tablet because the design team felt using Google Chrome would create a more scalable system (outside of JHM), but JHM only allowed use of Internet Explorer on work stations. This made it difficult to integrate into electronic charting or rounding workflow as additional hardware and clicks were needed to work between the systems.

*Emerge right now does not replace anything, so they still do their documentation in another system, there's still other things. The idea is that it's a two-way thing so in Emerge when you do something it makes documentation easier, you're there, you just click on it and push information in. When that happens I think there's gonna be a lot more nurse buy-in because it helps them do their work (Presentation JHM 03)*

The physical restrictions accessing the tablets (which had to be locked up when not in use) also created a barrier.



**Clinical systems updates corrupting Emerge outputs:** At times updates and modifications to the hospital clinical information systems corrupted the outputs of Emerge, and this was caught only after the fact. This was felt to be an important issue because the outputs of Emerge are meant to guide clinical decision making, and it is important that clinicians have full trust in the reliability and validity of the outputs.

**Lack of relationship with Enterprise IT:** The project team had difficulty identifying the right team in IT to support integration of the EHR with Topaz and the Emerge technology. This may have been a result of the fact that there was not embedded Enterprise IT on the team, or because the APL team had not worked in healthcare in the past and did not have the connections and network needed to identify the correct team.

**Conversion to Epic EHR:** At the outset of the project, there were plans to switch the EHR from Sunrise Clinical to Epic. Enterprise IT was therefore focused on the transition to Epic, rather than on supporting the Emerge project, which hindered the development process. Once Epic went live, the Emerge technology had to be shut down, and it has not yet been adapted to the new system.

**IRB consent processes:** Testing of the Patient Family Portal and the sensors were designated as research which meant that patients and families had to endure a lengthy consent process which was off-putting and hindered adoption. Adoption of the portal improved once the sensors were removed from the system and the consent process was changed from a 12-page written format to verbal consent.

**Lack of readiness for workflow changes at Bayview:** The project was significantly slowed at the Bayview site and eventually cancelled because of a lack of available physical therapy resources to implement key parts of the project.

**Uncertainty about future funding:** At the outset, the project was felt to need a bigger investment than funded through the first grant. In the second half of the project there began to be uncertainty about follow-on funding and commitment from the foundation, leading to turnover in fundamental staff. This is a reflection of the soft-money environment in academics, and a need for staff to know how their salary is going to be funded over the coming months.

## Clinical effectiveness

A 'scorecard' evaluation was conducted based on recommendations from the Moore Foundation. The scorecard baseline period was October - December 2013 and quarterly measures began in July 2014<sup>39</sup>, aligning with the start of the intervention period.<sup>35</sup> In order to align the case studies, our team aggregated the data reported by the JHM team to report a more typical pre/post evaluation within the restrictions of the data available to us. We used the first two quarters of 2015 (January - June 2015) as the post-period because that is the time period reported to have had the highest uptake of the Care Team Portal. As noted above, the study was conducted on one 12-bed surgical intensive care unit.<sup>35</sup> Table 14 below lists the primary outcomes and the unadjusted pre/post analyses that were possible.

<b>Table 14. Results: JHM SICU<sup>39</sup></b>				
	<b>Pre-implementation (Oct-Dec 2013)</b>	<b>Post-implementation (Jan-Jun 2015)</b>	<b>Absolute Change</b>	<b>P-value</b>
<b>Physical Harms</b>				

CLABSI (per 1000 line days)	0 (n=601)	0.087 (n=1149)	0.087	0.8
VAE (per 1000 ventilator days)	0 (n=260)	0 (n=581)	0	N/A
DVT-PE <sup>d</sup>	4.6% (n=547)	4.6% (n=579)	0	1
Delirium <sup>e</sup>	38% (n=412)	28% (n=1579)	-10%	<.001
Mobility- % days mobility sessions completed	50% (n=482)	72% (n=910)	22%	<.001
<b>Patient Satisfaction</b>				
HCAHPS Overall Hospital Rating	Numbers too small to be meaningful	Numbers too small to be meaningful	N/A	N/A
<b>Family Dignity and Respect</b>				
ICU-Respect Survey	N/A	81 (n=43) <sup>c</sup>	N/A	N/A
<b>Goal Concordance</b>	No data	Numbers too small to be meaningful	N/A	N/A
<b>Costs</b>				
Total variable direct costs <sup>a</sup>	\$32,687	\$32,598 <sup>b</sup>	-\$89	N/A

<sup>a</sup> Services included drugs, labs, operating room, radiology, routines, supplies, and therapy.

<sup>b</sup> Calculation based on the average of the sum of Q1 and Q2, 2015.

<sup>c</sup> Post-implementation period is from April-September 2015

<sup>d</sup> Percentage based on number of SICU patient days

<sup>e</sup> Percentage based on total number of CAM-ICU screens

## Physical Harms

### Outcomes reported and methods:

Physical harm outcomes measured by the JHM team included: CLABSI, VAE, DVT-PE, delirium, and mobility. Event rates at baseline for both CLABSI and VAE were zero and remained low throughout the study period. Therefore, focus of the effectiveness of the intervention on physical harms is limited to changes in DVT-PE, delirium and mobility.

### Results:

Both delirium and mobility improved significantly. The strong uptake of the portal by the Mobility Team (93%) may have positively impacted delirium and mobility. Delirium decreased from 38% to 28% while mobility, as measured by a process measure showing improved completed mobility sessions, increased from 50% to 72%. There was no change in any of the other outcome measures.

### Conclusions and limitations:

The innovations, particularly CONOPS and possibly the Care Team Portal, seem to have facilitated the improvement of both delirium and mobility in the SICU during the 6-month period in which its use was high (January-June 2015). The mobility team used the portal on approximately 93% of patients during this time period. Since the pre/post rates are not adjusted for patient acuity or demographics, however, makes it difficult to conclusively verify a statistically significant difference. It is not possible to evaluate the other physical harm outcomes because their baseline values were very low. Additionally, very large samples sizes would be needed to identify meaningful improvement in CLABSI, VAE, and DVT-PE.

## *Patient and Family Engagement*

### **Outcomes reported and methods:**

The intended outcome measure for patient dignity and respect was composed of selected measures from the HCAHPS survey. The number of responses specific to the SICU during the periods of interest (reported values were for patients who were discharged directly from SICU), however, were too small to have any meaning (<12 surveys). HCAHPS surveys were collected using the normal procedure involving a complex algorithm that sends the surveys, via email or post mail, to patients within six weeks of their hospital discharge. Efforts to collect additional HCAHPS surveys from SICU patients more than six weeks post-discharge were not undertaken.

The outcome measure for family dignity and respect was a tool called ICU-Respect, which was developed by the Berman Institute for this project. However, the ICU-Respect survey was not available during the baseline period. Ultimately, the questions were built into the patient portal which required uptake of that portion of the portal for patient response. Through the portal, patients had the ability to answer the dignity/respect questions daily.

### **Results:**

Due to low response rates, there is no meaningful data to assess patient dignity and respect.

Due to tool development in the baseline period, there is no data to evaluate family dignity and respect.

### **Conclusions and limitations:**

We are unable to make conclusions, due to lack of data.

## *Goal Concordance*

### **Outcomes reported and methods:**

The intended measure of patient and provider goal concordance was the match of the patient/family care goal entered in the patient portal to that of the intensivist or primary attending. However, very low uptake of the portal by families for this purpose prevents this measure from being useful for evaluation.

### **Results:**

Due to low response rates, there is no meaningful data to assess goal concordance.

### **Conclusions and limitations:**

Due to low response rates, there is no meaningful data to draw conclusions.

## *Costs*

### **Outcomes reported and methods:**

The JHM team calculated seven different variable direct costs, at baseline and quarterly, for the following items: drugs, labs, operating room, radiology, routines, supplies, and therapy. Data were obtained from the financial and value analytics teams.

### **Results:**

The total variable direct costs for the outcomes differed by only \$89 between the baseline and post-implementation periods. Due to the complexity of the data compared to its reporting, it is not possible to calculate an appropriate p-value, but it is clear that there was no meaningful cost change over the time period of interest.

## Conclusions and limitations:

The testing and implementation of Emerge, from baseline to the first half of 2015, did not impact the variable direct costs that were reported. The actual costs of implementation were not available, although a business case was created as part of the grant requirements. Estimates based on assumptions about potential outcomes found that, despite expectations of improved outcomes and costs, the program costs would likely be higher than the benefits at the hospital level in Maryland. It was felt that program cost savings could potentially be higher if outcomes were looked at with a population/longitudinal lens and if cost savings were not attributed at the hospital level, but at the population or payer level.

## Maintenance and sustainability

***The project team was not able to test the sustainability of the Emerge technology because it was developed as a prototype and is still seen in development stages, and thus is not ready for maintenance. The Epic EHR transition disrupted the maintenance of the technology interventions. CONOPS has been adopted by the team and is being applied to new projects. The Berman Institute has developed three ways of measuring respect in the ICU, which will be ready for broader validation and uptake.***

Project Emerge was developed as a proof of concept to demonstrate the utility of a systems engineering approach for the ICU environment and therefore implementation, and subsequently maintenance, were not focal points. The project team was not able to test the sustainability of the Emerge technology as it was developed as a prototype and is still seen in development stages, and thus is not ready for maintenance. Also, the hospital transitioned to Epic in mid-2016 and so the technology must be re-configured to adapt to the JHM Epic build. JHM's Epic build will be different from UCSF's build, even though they have also transitioned to Epic. The CONOPS approach used to redesign mobility care was implemented successfully, though it seems to have been driven by one of the physical therapists, as uptake fell when the person was assigned other duties. As described previously, CUSP had already been embedded in the ICU and the Family Involvement Menu existed in paper format on the unit prior to the project, which indicates that some of the cultural elements around safety and patient/family engagement already exist and will continue to be sustained. Importantly, there appears to be a high level of passion and interest in pursuing the systems engineering approach and proving that, as a concept, it can work in the ICU setting. This enthusiasm has transferred to APL, which has now established a unit to continue such work in healthcare, so this type of work seems likely to be sustained. Subsequently, the project team has a number of plans for taking the work carried out in this project forward, which may contribute to future sustainability including:

1. **Systems engineering:** The JHM team received an AHRQ P30 grant of \$4 million to develop learning lab functionality to test solutions and integrate them before dropping them into a production environment, and to develop a simulation lab based at APL simulation. Of note, this seems to be a better fit with APL culture in that they generally approach innovation in simulation environments, rather than in real world environments. There are other grants which have been applied for to accelerate the Project Emerge work.
2. **Respect and Dignity Measure:** The Berman Institute has developed ICU-RESPECT, a patient-reported measure of respect, which is currently being implemented at UCSF. The team has also submitted a Direct Observations checklist, designed to be used as a way to independently detect

behaviors associated with respect, to be published. The Institute also continues to draft a “Respect Climate” instrument that is based on clinician-specific data. The instrument aims to measure the clinical environment in which care takes place. They have surveyed a large number of physicians and are working on the psychometric analysis at this time.

3. **Behavioral marker system:** The human factors team received a grant from NASA to study team behavior, which is being used to look at ICU and anesthesia teams, to capture team coordination patterns through use of sensors to provide situational perspective. This work will begin in December 2016.
4. Work is also progressing to commercialize the Emerge technology; JHM has been engaged in talks with private companies to take the work forward, most notably through a deal being made with Microsoft.<sup>40</sup>

## Lessons learned

**Building relationships among stakeholders takes time:** The team indicated the importance of needing to identify all relevant stakeholders earlier in the project, as it took time to build relationships with the right people which slowed the process of development and implementation. JHM has developed a readiness assessment, including the identification of necessary stakeholders, to ensure that these lessons learned are applied in the future.

**Learning curve and culture differences between health care delivery and systems engineering:** There was a learning curve with respect to working across disciplines with APL. While APL provided enormous value, it was their first time working in a hospital system. In addition, APL has a culture of building prototypes in a simulated environment and then partnering with a commercial vendor for production. It was felt that this environment of using a mock ICU would have been more helpful than having to work in a live environment.

*The majority of the work we did here [in SICU] should never have been done here because it's less efficient. It could have been done at a simulation lab, something like you saw at APL, or something we would like to build here. So testing and getting people to just to look at workflow and process, rather than doing it here is the first step. (Interview JHM 01)*

This created a disconnect between the plan for development and deployment directly in the healthcare environment. It was felt that having a partner at the foundation with systems engineering expertise, or a transdisciplinary advisory board, could have helped to smooth some of the tension regarding prototype development and product implementation.

## Conclusions from JHM

The vision for ICU redesign at JHM was by far the most ambitious and far reaching in scope, and use of transdisciplinary partnerships provided the project with the ability to be truly transformative. One of the key takeaways from JHM is the different culture of work at the Applied Physics Lab compared to a health care organization. JHM, and specifically APL, was focused on developing an alpha version of the Emerge technology; a beta version would have involved a deeper observation of provider workflows and adaptation to allow for seamless integration. This is in keeping with how APL typically develops systems. It seems evident that technology development cannot be rushed into production, as this was detrimental to provider acceptance and adoption. This perhaps reflects misalignment of expectations

and priorities across the disciplines involved, as in healthcare there is often an expectation that outcomes should be achieved quickly. Learnings needed to take place across all partners and even the foundation, especially as this was APL's first foray into the healthcare environment. As has been seen elsewhere, it is difficult to make technological changes when changes in the hospital-wide EHR are planned because the EHR is prioritized over other changes. JHM has also made steps towards commercializing the innovations developed as part of the project.

## University of California, San Francisco (UCSF)

### Data sources and limitations

The data for the evaluation of University of California, San Francisco (UCSF) includes the following:

- Three one-to-one interviews and two group interviews conducted in person during the site visit.
- Two observations: One tour of a unit which included a demonstration of the Emerge Care Team Portal, and one of rounds including a demonstration of patient enrolment in Emerge.
- Two field surveys during the tour of the unit.
- 17 documents: Documents submitted to the Moore Foundation and received directly from the site were analyzed for their content, and quantitative data was extracted for the assessment of effectiveness.
- Two presentations: Notes taken during the presentations were used to help clarify points raised in project documentation.
- One demonstration of Emerge Patient Portal.

The site visit was carried out in August 2016 and all innovations were live at the site which meant we could see all innovations in action.

### Summary of site project and innovations

UCSF implemented the Emerge technology, including the Care Team and Patient Portals, the Comprehensive Unit Safety Program (CUSP) which provides the culture change element, and the Topaz platform (see Johns Hopkins Medicine section for full description). UCSF has instigated some changes in the Emerge application to better fit the needs of UCSF staff, patients and families, and aimed to fully integrate and automate the Emerge system with the Epic EHR system. UCSF also established a PFAC to help adapt Project Emerge to the local setting; this was the first adult inpatient PFAC established at UCSF and was felt to be a key achievement of the project. The PFAC contributed to multiple elements of the project, but we primarily heard about their involvement with the development of the Critical Care Innovations Group website. Table 15 summarizes the interventions and their status at the time of the site visit.

<b>Table 15. Description of UCSF innovations including current status and implementation period</b>			
<b>Intervention</b>	<b>Description</b>	<b>Implementation Period</b>	<b>Status at the time of Site Visit (Aug 2016)</b>
Emerge technology - Care Team Portal	Displays an interactive “harms monitor” for each patient by integrating data from EHR and other data sources for five clinical and two non-clinical harms: acquired ICU weakness, ventilator-associated harms and infections, VTE, pain and delirium, CLABSI, and respect and dignity, goals of care.	Went live in March 2016.	Live.
Emerge technology - Patient Family Portal	Electronic Patient Family Portal, accessible by iPad, with information specific for the patient/family including: information about the patient room, FAQs about ICU care, care	Went live in March 2016.	Live

Intervention	Description	Implementation Period	Status at the time of Site Visit (Aug 2016)
	team member identification, my notes, and Family Involvement Menu (allows families to select which tasks they'd like to do each day. The Patient Family Portal allows patients and families to input data about themselves in a profile to enable staff to provide more respectful care. The Patient Family Portal is accessible by iPads kept in a locked central location within the ICU.		
Topaz platform	Middleware solution to act as a buffer between EHR and applications such as Emerge IT platform. Enables integration and conversion of data from the HER, and other data sources, into the Emerge integrated control and display system, or other apps. Allows for scale of Emerge to other health systems.	Went live in February 2016.	Live
Comprehensive Unit Safety Program (CUSP)	Standardized program in which environmental, team, or work process defects are identified and supported by management processes to rectify to improve patient safety. The CUSP team is a multidisciplinary team that meets once a month and uses CUSP tools to analyze, implement, and evaluate defects. The work of CUSP has spread beyond the ICU and is hospital-wide.	Training completed for 208 of 318 clinicians and staff. Went live November 2014.	Live.
Critical Care Innovations Group (CCIG) website	Publicly accessible website with information about critical care for patients and families (about arrival at ICU, ICU care, discharge), and for providers (e.g. preventing harms in the ICU).	Went live fall 2014.	Live.
PFAC	ICU-specific PFAC, first PFAC for adult inpatient care at UCSF.	Went live in September 2014.	Live

Six grants (#3905, 3905.01, 4358, 4358.01, 4766, 4192) were provided to UCSF which totaled approximately \$6.23 million. The grants included: a planning grant to support implementation of Project Emerge for \$397,848 over 10 months, an interim implementation grant for \$999,996 over 6 months, the implementation grant for Emerge for \$4,000,000 over 12 months, an extension grant for data collection and analysis of \$490,281 for 6 months, \$37,500 for participation in the Libretto Consortium task forces for 10 months, and \$305,000 for participation in the consortium for 12 months.



## Context

The University of California, San Francisco hospital is a not-for-profit, quaternary care academic hospital system comprised of three main medical campuses. The grant funded projects were implemented at the Parnassus campus in a mixed/medical surgical ICU on two floors with a combined 32 beds.<sup>41</sup> The ICU model is semi-closed in that there is mandatory intensivist consultation for all medical and general surgical patients, and the intensivists are primary for some surgical subspecialty and hematology patients. However, in many cases there is a primary medical or surgical team co-managing the patient. These teams have responsibility for patients both inside and outside the ICU.

## Experience of implementation

The UCSF ICUs are characterized by their interprofessional approach to care which pre-dated the implementation of the ICU redesign projects. The research, development, and implementation team included physicians (critical care intensivists and hospitalists), nurse practitioners and nurses, physical therapists, pharmacists, health informatics specialists, engineers from dataFascia, and application developers. This approach was felt to potentially improve the fit of the final Emerge package with UCSF workflow and is predicted to impact the ultimate effectiveness of the innovations. The site has a history of innovation in ICU safety and culture, for example in the area of Rounds Redesign, and there was appetite to do further work.

While it was envisioned that UCSF would act as a replication site for Project Emerge, it does not precisely fit the definition of ‘spread’. First, UCSF was instrumental in conceptualizing the Emerge portal and contributing to the development process, although they would have preferred to have had greater input during the development period. Second, the Emerge technology had to be integrated with Epic at UCSF, which required a significant amount of development work. Third, some of the clinical parameters and outputs for Emerge had to be further specified to allow the application to adapt to an ICU with complex medical patients (JHM built the prototype primarily for the surgical ICU). Finally, while UCSF adopted the safety culture (through CUSP) and further developed and implemented the Emerge technology, there was little collaboration with systems engineers to achieve integration of technology, workflow, and culture, except with regards to data integration up to July 2016. Whereas this type of collaboration was a fundamental component of the JHM approach to ICU redesign, it was not replicated at UCSF.

*My idea of spread is you have a finished product and then you try it somewhere else. That just wasn't the case. I mean what we got from Hopkins needed a huge amount of work. (Interview UCSF 05)*

While the Emerge technology has been adapted to suit many of the needs at UCSF, it is felt that work is still needed to optimize the use and adoption of the system. Therefore, the technology is viewed as a pilot version which is not ready for sustainability or scale within the UCSF system.

## Emerge Care Team Portal

***Adoption of the Care Team Portal has been primarily on morning rounds. The portal is not fully functional; the Harms Monitor is not continually displayed and interacted with by care team members due to hardware and software issues that are being resolved.***

The Emerge Care Team Portal launched in February 2016. There was no data available on the number of providers who actively use the Care Team Portal, but it was reported that they represent the full range of adopter attitudes, from those who are enthusiastic to some who just refuse to adopt new innovations.

*Out of a 150 there's always gonna be- you have your adopters, your negatoids and your positoids, these are the people that are out there [...] like 'this is great you guys if everyone uses it-', and those who are like 'OK I'll use it once in a while' and then those who are like 'I am not doing that' but they're the same people that wouldn't do a care plan that's essential. (Interview UCSF 02)*

It was felt that these individual characteristics play a significant role in uptake and adoption at the site. The Care Team Portal has primarily been used during morning rounds, on weekdays, by the rounding intensivist team. It is usually presented by a fellow, pharmacist, or nurse practitioner as these roles are more constant on the unit, whereas residents come and go. It was observed that clinicians on rounds actively engaged in looking at Emerge during the review of the checklist portion of rounds and some actions were taken based on issues raised by the tool.

*Emerge is used at the end of rounds by a pharmacist, she runs through most of the elements, there is not a clear order. On one patient it sparks a conversation about the line. Otherwise most of the elements are scripted into the rounds, and so there is a bit of redundancy when the Emerge is presented. (Observation UCSF 02)*

However, overall, the tool is still not being used exactly as intended, i.e. throughout the day to determine the safety situation of the patient. Nurses and teams coming in and out of the ICU (e.g. hospitalists) do not use the portal outside of intensivist rounds during the checklist reviews. In general, clinicians find the portal fairly intuitive and easy to use, and minimal training is needed.

*Says he received training, then there was a gap before it arrived in the unit to use, though doesn't feel this was really a problem because it's quite simple. (Field Survey UCSF 01)*

The portal is accessible from the work stations (as opposed to at JHM where it was only available on tablets). A “single sign on” at the work stations makes it easier for providers to access the Emerge Care Team Portal through an internet link. However, the link is not integrated into the Epic work area (as it was at BIDMC and BWH), and requires clinicians to open a separate tab. Another technical challenge has been that updates to Google Chrome cause the portal to ‘break’ and updates to the enterprise EHR cause some elements of the portal to be out of sync. These issues are not infrequent and therefore require constant maintenance and vigilance to keep the app up and running.

As is the case with all the Care Team Portal applications across the sites, there is only one-way information available: information comes into Emerge, but clinicians have to document any changes to care in Epic which is then reflected back into Emerge. This presents a barrier to adoption.

*From a safety standpoint as well which is you see something that's red and you say 'yeah OK' and acknowledge it for example, but that's not safe. The only way to turn something from red to green is you go into Epic, order the proper thing and then the*

*nurse or pharmacist does the proper thing, and then it goes to green. (Presentation UCSF 01)*

In order to use the situational awareness feature of the platform to its full extent, it was intended that the tablets would be always on and placed in a patient room. The team felt this would potentially allow nurses to interact with the portal more frequently and would also allow other teams rounding in the open ICU configuration to interact with the portal. The hospital IT infrastructure delayed the deployment in this intended way, to date. There were also other issues with the iPads locking and turning off automatically, and light from the iPad interfered with patient sleep. There are plans to correct the locking issue and to move the iPad outside of the patient room. It is felt that not having the situational awareness feature has potentially reduced provider engagement with the portal:

*He used to remember to use Emerge more when it was on the bedside monitor, but it has just been about establishing the routine in his work. (Field Survey UCSF 01)*

### Emergence Patient Family Portal

***During the visit, our team perceived adoption of the Patient Family Portal as being challenged by hardware and software glitches, inaccessibility of the tablets, and the project being perceived as “research”, which limited adoption by unit staff.***

The adoption of the Patient Family Portal between March and September 2016, reported by the site after our visit, was 52 accounts created by patients and 88 by families<sup>42</sup>; however, there is no denominator to indicate what percentage of patients and family have used the portal. The most common reason for patients not enrolling was that the patient was “unable to participate” which was usually related to altered mental status or no family at the bedside. Adoption is currently driven by two super-users who make a targeted effort to enroll patients and families in the portal. However, they have noted a number of glitches with the hardware and software which hamper adoption, such as: loss of connectivity to Wi-Fi, forgetting to charge iPads overnight, patients forgetting their passwords, and glitches due to updates in the Chrome browser which then causes the portal to go down.

*[The superuser] has her own rounding form which she uses to identify patients that might be suitable to approach for the portal, but this doesn’t always prove accurate. She says the main barriers to getting people to sign up is time in terms of finding a good time to sign patients up, patients not being alert, and family not being present. (Observation UCSF 02)*

A suggested next step in development is a ‘bring your own device’ system (as we heard across other sites), which would address some of these issues. One difficulty with moving to personal devices is that the Patient Family Portal is linked to the EHR and PHI, and therefore requires additional security steps which are difficult to implement on personal devices. It was also reported that the diversity of patients and families in the area has also affected adoption as it is only available in English.

It was reported that the most useful parts of the Patient Family Portal to families are: My profile, My ICU, and care team identification. These parts contain no PHI, apart from the patient’s name, so could potentially exist in front of a firewall. The UCSF team felt that the Patient Family Portal is not yet in an ideal state. The ICUs have incorporated activities similar to the Patient Family Portal so it is seen as an extra tool to reinforce what they are already doing. For example, ICUs keep a white board in the

patient's room that patients can fill in to communicate "get to know me" information about themselves (similar to the portal) and also includes information about their stay. The board essentially acts as competition for the Patient Family Portal and both are meant to help providers get to know their patients. The ICU also gives patients a paper ICU diary to use during their stays. At the time of our visit, looking at the patient-entered information from the portal does not seem to be a routine part of provider workflow. Indeed, one provider commented that they had only seen it completed for one patient and seemed to imply that they do not think it is routinely used by patients and so is not checked regularly by providers (Field Survey UCSF 02).

#### Comprehensive Unit Safety Program (CUSP)

***CUSP has been robustly adopted in the pilot ICUs.***

CUSP was rolled out in two medical/surgical ICUs beginning around January 2014; as of August 2016, the UCSF team reported that about 80% of the nurses had been trained. The goal is to include CUSP training as part of the onboarding process for new hires to ensure that a culture of safety is embedded from the point of hire. Changes to the onboarding process started in August 2016 and are expected to be completed by late November 2016.

CUSP seems to have been readily adopted and is a part of the system in the pilot ICUs.

*I'd say the people for whom [CUSP has] had the biggest impact would be people who didn't necessarily have a concentrated resource or leadership or so forth in the ICU. Like when you ask that question I think primarily of the respiratory therapists who've been great with CUSP saying like 'you know I've identified this and now I know why don't I talk to [X] and then we'll talk to [Y] and then we'll see what [Z] thinks and then we'll all work together to solve this problem kind of in a more systematic fashion, whereas before I think maybe it would have just been grumbling within a particular group (Interview UCSF 04)*

During the first training session it was reported that approximately 200 defects in care were identified (this is a core activity in CUSP), though some of these were duplicates. This demonstrated that there is a need and appetite for making improvements. While the staff we spoke to have not personally identified defects, they each could easily name one way that their workflow had improved by way of CUSP. Examples include: reducing the number of x-rays ordered for patients and the addition of a permanent wheelchair in the unit to have ready when patients are mobilized. Evidence of the ongoing CUSP intervention was observed in the ICU as there was location set up for staff to identify "defects" in care.

*Box on wall by spotlight board where bright orange CUSP forms are located, completed, and submitted in the locked box. (Observation UCSF 01)*

#### Critical Care Innovations Group (CCIG) website

***The website is not widely advertised, but it appears it is being used by UCSF ICU patients for information.***

The CCIG website was developed with deep engagement of the Patient and Family advisory group; in fact, the PFAC caused a complete revamp of the website. There is uncertainty as to the adoption and use of the website by either providers or patients, though the site researchers estimated through

Google analytics that the website receives approximately 10 good hits a day from patients in the UCSF system. At present it is only advertised to the two pilot ICUs. There are plans to enhance functionality before it is spread to other ICUs and it was believed that it will require human resource to make people aware of its existence. However, it is a publicly available website and the content does not go out of date rapidly, so to spread it to other units, even passively through posters, does not seem like it would require much resource.

## PFAC

***The ICU-specific PFAC was widely viewed as a successful implementation. The PFAC is still not tightly integrated into all ICU activities for Emerge.***

Establishment of the Patient and Family Advisory Council for the ICU was viewed as a success by the UCSF team and was the first adult inpatient PFAC at UCSF. The PFAC was instrumental in helping to develop the content for the CCIG website, which prior to their involvement, was seen to be heavily provider-focused rather than geared towards patient and family informational needs. The PFAC is also used as a sounding board for CUSP interventions. It is not being used as frequently for the Emerge Patient Family Portal, likely because the team was not funded to iterate on the design.

## Facilitators

**Interprofessional culture of working:** The UCSF ICU team is used to working collaboratively with multiple types of clinicians, and the unit values interprofessional teamwork. This culture carried over into the project and skilled people were allowed to be equal partners on the project team. The project fully involved pharmacists, nurses, physicians, and physical therapists in all aspects of development, research, and implementation. It was viewed as an extraordinary opportunity to develop talented people across the organization.

**Situational awareness:** Although the open ICU environment is a challenge with respect to implementation, the team felt that improvements in situational awareness using the Emerge technology would have tremendous value.

**Emerge super-users:** Super-users who support the adoption and use of both the Care Team and Patient Family Portal were felt to be instrumental in garnering adoption on the unit.

**Working with JHM:** The relationships with JHM were strong and the UCSF team felt the project was enhanced by these relationships. For example, it was easier to adopt CUSP because of the connections with the Armstrong Institute team. In addition, the Berman Institute work on measuring dignity and respect was extremely helpful in conceptualizing the area and operationalizing the measure into the study.

**Aligned institutional priorities:** The UCSF institutional goal is zero harm, this year, and the aims of the project are aligned with this institutional goal which makes adoption and maintenance easier.

*Interviewer: Are those, the seven harms, are those the best harms to make your case or are there other priorities in the ICU, how do those compare to what are the real drivers in the ICU? Or the institutional priorities?*

*Well actually, yes, very much so because the institutional overarching goal this year is zero harm- of not the ICU, of the whole place. So absolutely aligned. So I think that's*

*great, because if that's what you really mean as an institution, and by that, by institutional goals I mean that there are, so we have incentives for employees, we have incentives for all the house staff, that are quality incentives, so it's very much aligned with all those things. (Interview UCSF 01)*

## **Barriers**

**Cost of implementation:** The cost of implementing and maintaining Emerge is seen to be a barrier to spreading in the UCSF system. Costs include implementing the software, training staff in its use, the human resource in the form of the super-users to both support providers and enroll patients, and the ongoing IT maintenance costs.

**IT glitches:** There were a number of glitches with the Emerge technology, including: loss of connectivity to Wi-Fi, patients forgetting their passwords, and updates to Google Chrome which 'broke' the application. These have slowed uptake and integration into regular ICU workflow, and some are being addressed in the most recent changes to the system. There are a range of challenges with integrating EHR data elements into the application which requires complex data testing and resources.

*[the super user] was trying to create the patient account and walk me through at the same time, but it came up with a 'still loading' alert on the patient name page for quite a while. She then had to get a username and password from the patient so she went in to see the patient. [...] When she came out of the room, she then completed the sign up process, then went back in to make sure the patient could log in. Unfortunately, the patient couldn't. She said it happens a lot that patients can't remember their passwords. (Observation UCSF 02)*

**Cycle time for software iteration and costs of ongoing changes:** The cycle time for making changes to software was perceived as a barrier to rapid implementation. UCSF felt that quite a few changes were needed for the Emerge technology to be implemented successfully in their setting, but the development resources were expensive and therefore limited. There was a fairly quick turnaround time with dataFascia, but they did not have access to the Emerge code from APL to speed up the work. This is another example of the tension between prototype and production in the Emerge project in that APL was focused on making a prototype, but in order for the software to be fully functional in an ICU setting it needed another layer of design work to adapt and optimize fit with workflow.

*Knowing that this would make it even better but we can't go there because we don't have a contract with APL to optimize. And we knew that, this is the best it's going to be. Sure it'd be nice to have, you know, this other added feature [...] [Other team members] want everything over here perfect. And I'm like we can't only do this, this is a part of this project, if we keep only doing this, we'll never be able to evaluate and we don't have the resources to do it. (Interview UCSF 02)*

**Turnover at the Moore Foundation:** Turnover at the foundation introduced uncertainty into the project and delayed certain aspects of implementation by about six months. At points there was uncertainty about ongoing funding and key people left the project because members of the team were funded on soft money.

**Tension between scope of vision and requirement to produce outcomes:** Both JHM and UCSF cited this as a barrier to the work. There was a feeling that it was unrealistic to expect outcome changes in a project of this scale over a short period of time.

### Clinical effectiveness

The planned evaluation is a pre/post analysis. The pre (baseline) period varied depending on the specific outcome, with some covering the full time period July-December 2015 and others including a shorter subset of time within this window. The post-period is September-November 2016, or a subset depending on the outcome. At the time of the site visit it was not possible to evaluate the success of the interventions in a quantitative manner. In addition to the primary outcomes listed below in Table 16, the site is also conducting a pre/post time and motion study to determine how long, and the number of 'clicks', it takes ICU nurses, fellows and pharmacists to find specific risk information before and after implementation of the Emerge Care Team Portal. Baseline values are shown in Table 16 below.

<b>Table 16. Results: UCSF M/SICU (2 units combined)<sup>43</sup></b>				
	<b>Pre-implementation (Jul-Dec 2015)</b>	<b>Post-implementation (Sep-Nov 2016)</b>	<b>Absolute Change</b>	<b>P-value</b>
<b>Physical Harms</b> CLABSI (per 1000 line days) VAE <sup>a</sup> (per 1000 ventilator days) Delirium <sup>b</sup>	1.73 (n=2888) 0 (n=1529) 56% (n=89)	N/A	N/A	N/A
<b>Patient Satisfaction</b> HCAHPS	26-88% (n=67)	N/A	N/A	N/A
<b>Family Satisfaction</b> FS-ICU 24 Total Satisfaction Score	Mean = 86 (n=89)	N/A	N/A	N/A
<b>Goal Concordance</b> CollaboRATE (top box)	46% (n=89)	N/A	N/A	N/A

<sup>a</sup> Includes ventilator associated conditions, infection-related ventilator associated conditions and possible/probable ventilator associated pneumonia.

<sup>b</sup> Percentage based on total number of CAM-ICU screens

### Physical harms

#### Outcomes reported and methods:

The three physical harm outcomes being reported by the UCSF team are: CLABSI rate, VAE rate, and delirium. It was perceived that the Emerge project brought rigor to harms assessment, especially delirium.

#### Results:

Data are currently being collected for the implementation period. There are no results to report.

#### Conclusions and limitations:

No conclusions are possible at this time because no post data are available. There are, however, a number of concurrent initiatives that will make it difficult to attribute change in outcomes to the ICU redesign grant funding. UCSF is participating in the ICU Liberation Collaborative through SCCM, funded

by the Moore Foundation, which brings additional attention and process change to the areas of mobility, delirium, and pain. Additionally, the baseline period for these measures is short, about one month, and is primarily based on observation or limited chart review.

### *Patient and Family Engagement*

#### **Outcomes reported and methods:**

The UCSF team is measuring patient engagement, dignity, and respect using a subset of the HCAHPS questions. Surveys were administered by the UCSF team under a research project protocol and IRB approval rather than as part of a quality improvement initiative. Research assistants consented patients and families before discharge from the ICU and at least three days into admission. The selected HCAHPS questions were administered after patients were discharged from the ICU, but were still in hospital. The baseline period for HCAHPS was June-December 2015. Seven HCAHPS questions are administered with no overall hospital rating score, so the range of top box scores is presented in Table 16.

The UCSF team measured family engagement, dignity, and respect using the FS-ICU 24. Questionnaires were administered to families either in-person at the hospital, via phone, mail, or email in the same manner as patients.

#### **Results:**

Data are currently being collected for the implementation period. There are no results to report.

#### **Conclusions and limitations:**

No conclusions can be drawn at this time because only baseline data have been reported. The number of patients and families that responded to all the surveys is low compared to the total number of patients admitted to the ICU in the six-month baseline period. This will limit the generalizability of the findings even when complete data are available.

### *Goal Concordance*

#### **Outcomes reported and methods:**

The UCSF team is using the CollaboRATE tool to measure goal concordance. Data were collected as described above for the HCAHPS.

#### **Results:**

Data are currently being collected for the implementation period. There are no results to report.

#### **Conclusions and limitations:**

No conclusions can be drawn at this time because only baseline data have been reported. Limitations are comparable to those above mentioned for the HCAHPS surveys.

### *Costs*

Costs are not being measured.

### *Maintenance and sustainability*

***The CUSP and PFAC interventions seem highly likely to be sustained. The Emerge technology will likely need further iteration to be maintained after the grant period ends, but is felt to compliment the CUSP intervention.***



Of the interventions, CUSP seems the most likely to be sustained, as it has been incorporated into regular workflow on the units. Though it has not yet been spread to the other ICUs in the UCSF system, there was the opinion that it would take minimal start-up costs to do the JHM “flavor” of CUSP elsewhere in the system. In addition, the PFAC was viewed as very successful, and there are currently plans to expand the PFAC activities to be inclusive of all five ICUs.

Sustainability of the Care Team Portal at UCSF is not a given, because although some minimum requirements will be funded through the duration of the grant cycle, there will still be outstanding enhancements that will need to be done in order to optimize its use as intended in the ICU.

*I think there are some things that it's working really well for. I think there are a few things we could do to reduce the barrier of access to it that would make just an enormous difference in terms of its ease of use and therefore like, people continuing to do it without being prompted. (Interview UCSF 04)*

There are no current plans to house the costs/staffing for maintenance and further development of the portal into the operating budget of UCSF Enterprise IT. Furthermore, the ultimate interoperability of the portal has the same limitations we saw with the Emerge project at JHM in that the potential is so much greater than the current prototype, but to achieve that potential vendors of clinical data systems and equipment will need to provide APIs for their products.

The Patient and Family Portal is unlikely to be sustained in its current form at UCSF. Similar to other sites, there is a feeling that a version two, that can be accessed on a personal device with modification of some of the features, will be needed to get maximum uptake and impact. There has been limited staff engagement so far for the portal, outside of the super-users whose job it is to enroll patients onto the portal, as the Patient Family Portal part of the project is viewed largely as a research project and the jury is still out on how much value it will add in the ICU environment.

*I don't think the tech, that patient and family portal, it helps somehow but it's not the end all be all because it's in the- not everyone just uses technology solely. (Interview UCSF 02)*

The CCIG website was a relatively small investment, but with input from the PFAC has become a resource used daily by UCSF patients. The website is in the public domain and could be spread to the other ICUs in the system with minimal additional outlay of costs or time. The site would need maintenance over time, however, and the team feels that it needs some additional, unique features in order to be worth spreading more widely.

## Lessons learned

**Working across the two institutions was felt to be a project strength:** The UCSF team felt that developing the Emerge technology in both institutions resulted in a tool that they feel will be more generalizable to other ICUs. Also, adopting CUSP was made easier by the strong working relationships between the two institutions.

**Physician engagement and satisfaction is an essential part of improving patient safety:** There is a crisis of provider satisfaction due to workload, and it is hard to optimize patient safety without directly

addressing physician engagement and workflow issues. A key benefit of the optimized Emerge technology should be to create more efficiency.

*he said 'what is your number one goal for the next year?' I said 'it's provider satisfaction', it's not patient safety. But it doesn't mean that those are separate things [...] I don't think we can do much more for the patients in terms of brute force without unloading the providers a little bit. (Interview UCSF 01)*

**Emerge technology is not a standalone; it needs to be implemented along with CUSP to have impact:**

The team at UCSF felt that CUSP, or a similar culture of safety program, should be in place as a prerequisite to the technology. In addition, ICUs and the hospitals in which they are situated need to feel comfortable using data to drive change.

*I think you couldn't just plug [the Emerge technology] in. I think you have to do two things. You have to do obviously app training, how you actually use Emerge, but I don't think- I think you got to have some CUSP. (Interview UCSF 01)*

**Community hospitals would be good testing ground for version “3” of Emerge package (CUSP and technology):** The feeling is that implementation would be simpler and Emerge would be very impactful in a community hospital because 1) there is less complexity in terms of staff coming in and out of the unit, and 2) the hospital would have the benefit of all of the development of the clinical process, outcomes, and data integration done at the academic centers.

*if you look at how quality improvement stuff, at least in critical care, has gone, the innovation tends to occur in a place like ours, but sometimes the uptake and consistency is better in community hospitals. It's a finite number of people. So they can actually do really well with those things. (Interview UCSF 01)*

**Interprofessional nature of the project was a great asset for clinician development:** The project allowed talented clinicians, including nurses, to develop new skills in research, technology, data integration, project management, and more. The kind of opportunity that the grant provided is fairly unique and it is thought that it will have lasting impacts by having these newly skilled clinicians available for other institutional projects.

## Conclusions from UCSF

The jury is still out on the impacts of implementing the CUSP and technology aspects of Project Emerge at UCSF as the site is currently collecting data for the “post” period. Any changes seen in the data on patient harms will likely reflect the implementation of CUSP, the implementation of concurrent initiatives such as the ICU Liberation project, and changes in provider awareness of patient respect and dignity brought about by the attention the grant brought to the project; they will reflect less the implementation of the Emerge technology which is still undergoing some optimization. There are planned adjustments that are likely to improve adoption, but they will be completed after the data collection period. In general, there was strong enthusiasm for the work done so far on Emerge technology and the team sees tremendous promise for the future of the work. As such, they have a strong desire to take it to the next level in terms of ‘hardwiring’ it and even creating some additional functionality that would allow different specialties to use the tool. This vision is at risk, however,

because, there is not currently any planned funding for maintaining or further developing the technology at the end of the grant period.

## Abbreviations

AHRQ: Agency for Healthcare Research and Quality

API: Application Program Interface

APL: Applied Physics Laboratory

BIDMC: Beth Israel Deaconess Hospital

BWH: Brigham and Women's Hospital

BYOD: Bring Your Own Device

CAUTI: Catheter-Associated Urinary Tract Infections

CCIG: Critical Care Innovation Group

CFIR: Consolidated Framework for Implementation Research

CLABSI: Central Line-Associated Blood Stream Infection

CONOPS: Concept of Operations

CUSP: Comprehensive Unit Safety Program

DVT-PE: Deep Vein Thrombosis – Pulmonary Embolism

EMR: Electronic Medical Record

FS-ICU 24: Family Satisfaction in the Intensive Care Unit

HCAHPS: Hospital Consumer Assessment of Healthcare Providers and Systems

ICU: Intensive Care Unit

IRB: Institutional Review Board

IT: Information Technology

JHM: Johns Hopkins Medicine

MD: Doctor of Medicine

MICU: Medical Intensive Care Unit

MIT: Massachusetts Institute of Technology

PA: Physician's Assistant

PCP: Primary care provider

PCTK: Patient-Centered Toolkit

PFAC: Patient and Family Advisory Council

PHI: Protected health information

PROSPECT: Promoting Respect and Ongoing Safety through Patient-centeredness, Engagement, Communication, and Technology

QI: Quality Improvement

R&D: Research and Development

RCT: Randomized Controlled Trial

RE-AIM: Framework defined by 5 steps: Reach, Effectiveness, Adoption, Implementation, Maintenance

RN: Registered Nurse

SCCM: Society of Critical Care Medicine

SICU: Surgical Intensive Care Unit

TSICU: Trauma Surgical Intensive Care Unit

UCSF: University of California, San Francisco

VAE: Ventilator-Associated Event

## Glossary

**Adoption:** The extent to which intervention agents, communities, or organizations commit to initiating an intervention (paraphrased from RE-AIM framework).<sup>3</sup>

**Clinician:** Any person doing direct clinical care, including physicians, nurses, physical therapists and others.

**Closed unit:** A closed unit differs from an open unit in that responsibility for a patient and his/her treatment is transferred from the patient's primary physician to the intensivist in the closed unit.<sup>44</sup>

**Enterprise IT:** Information technology resources and data that are shared across an entire organization.<sup>45</sup>

**Fidelity:** The degree to which an intervention or program is delivered as intended.<sup>46</sup>

**Inner context/setting:** Features of the structural, political, and cultural contexts within an organization through which the implementation process proceeds.<sup>47</sup>

**Interdisciplinary:** A mode of collaboration by teams or individuals that integrates information, data, techniques, tools, perspectives, concepts and/or theories from two or more disciplines or bodies of specialized knowledge.<sup>48</sup>

**Interoperability:** The extent to which systems and devices can exchange information, and use the information exchanged.<sup>49</sup>

**Interprofessional:** A group of individuals from different disciplines within a field (such as healthcare) working and communicating with each other.<sup>50</sup>

**Maintenance:** For the purpose of this report we define sustained impact as evidence that the desired health benefits remain at or above the level achieved during implementation, and that there is evidence that this impact can be attributed to maintenance of the program. Maintenance of the program is determined if the core elements are in place and remain recognizable after the implementation period/grant support is withdrawn.**Error! Bookmark not defined.**

**Middleware:** Software that mediates between an application program and a network and manages the interaction between disparate applications across heterogeneous computing platforms.<sup>51</sup>

**Provider:** For the purpose of this report we define a provider as a physician, nurse practitioner, or physician assistant.

**Rapid appraisal approach:** A way of gathering, analyzing, and interpreting high quality ethnographic data expeditiously so that action can be taken as quickly as possible.<sup>1</sup>

**Reach:** As defined in the RE-AIM model, reach describes the percentage of a population receiving an intervention.<sup>3</sup>

**Scale:** The ability of a health intervention shown to be efficacious on a small scale and or under controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population, while retaining effectiveness.<sup>52</sup>

**Spread:** Horizontal diffusion of an intervention or innovation.<sup>47</sup>

**Sustainability:** While a definition of sustainability is not readily agreed upon within the field of implementation science, for the purposes of this report sustainability is defined as the continuation of all or part of the program/intervention after initial external funding ends.<sup>15</sup>

**Theory of change:** The idea that the beliefs and assumptions underlying an intervention can be expressed in terms of a phased sequence of causes and effects.<sup>53</sup>

**Transdisciplinary:** A process in which members of different fields work together over extended periods of time.<sup>54</sup>

## Definitions of harms

### Medical (physical) harms:

Measure	Definition	Standard Measurement
Central line-associated bloodstream infections (CLABSI)	A laboratory-confirmed bloodstream infection (LCBI) where central line (CL) was in place for >2 calendar days on the date of event. ( <a href="http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf">http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf</a> )	There is a standard in place for measuring and reporting CLABSI. It is monitored by the CDC
Catheter associated urinary tract infections (CAUTI)	A UTI where an indwelling urinary catheter was in place for >2 calendar days on the date of event, with day of device placement being Day 1, and an indwelling urinary catheter was in place in the date of event or the day before. ( <a href="http://www.cdc.gov/nhsn/pdfs/pscmanual/7psc_cauticurrent.pdf">http://www.cdc.gov/nhsn/pdfs/pscmanual/7psc_cauticurrent.pdf</a> )	There is a standard in place for measuring and reporting CAUTI. It is monitored by the CDC.
Ventilator-associated events (VAE)	In 2013, a new definition of VAE was developed and implemented by the CDC which includes ventilator associated conditions (VAC), infection-related ventilator-associated condition (IVAC), and possible/probably ventilator-associated pneumonia (VAP). All of VAC, IVAC and VAP were counted towards enumeration of VAE for each site. ( <a href="https://www.cdc.gov/nhsn/pdfs/newsletters/vae-newsletter-september2012.pdf">https://www.cdc.gov/nhsn/pdfs/newsletters/vae-newsletter-september2012.pdf</a> --see page 5 for detailed definitions of each)	The definition for VAE changed in 2013 due to difficulties with the previous definition which included only ventilator-associated pneumonia. The current VAE algorithm developed by the CDC is a surveillance algorithm and not intended for use in the clinical management of patients. National, standardized reporting is not required for VAE.
Deep vein thrombosis-pulmonary embolism (DVT-PE)	Deep vein thrombosis (DVT) is a medical condition that occurs when a blood clot forms in a deep vein. These clots usually develop in the lower leg, thigh, or pelvis, but they can also occur in the arm. It is an underdiagnosed but preventable condition and hospitalized patients are at increased risk. ( <a href="http://www.cdc.gov/ncbddd/dvt/ha-vte.html">http://www.cdc.gov/ncbddd/dvt/ha-vte.html</a> )	Standard approaches for monitoring, measuring and reporting incidence are under development.
Mobility	Studies show that early mobility is safe and feasible in the ICU and decreases days of delirium. There are not standard approaches to improving mobility but there are protocols available to facilitate implementation of best practices. <a href="http://www.icudelirium.org/earlymobility.html">http://www.icudelirium.org/earlymobility.html</a> <a href="http://www.aacn.org/wd/csi/docs/FinalProjects/EarlyProgressiveMobilityinICU-DukeRaleighHosp-Raleigh-Presentation.pdf">http://www.aacn.org/wd/csi/docs/FinalProjects/EarlyProgressiveMobilityinICU-DukeRaleighHosp-Raleigh-Presentation.pdf</a>	Standard measures for mobility do not exist. It was reported as a process measure by one site (JHM) which reflected completion of mobility session by the mobility team

Measure	Definition	Standard Measurement
Delirium	Delirium is challenging to assess and measure consistently. This link describes the four levels of delirium assessed by the Confusion Assessment Method (CAM) for the ICU. <a href="http://www.medscape.com/viewarticle/810233_4">http://www.medscape.com/viewarticle/810233_4</a>	Standard measures do not exist but the CAM- ICU is a validated and commonly used tool that helps monitor patients for development of delirium. ( <a href="http://www.aacn.org/wd/elearning/docs/elearningpdf/delirium-cam-icu.pdf">http://www.aacn.org/wd/elearning/docs/elearningpdf/delirium-cam-icu.pdf</a> )

*Loss of dignity and respect:* The foundation defined “failure to provide dignity and respect” as a harm. Because there was not an ICU-specific measurement instrument available, there was an agreement that sites would use HCAHPS and the Family Satisfaction in the ICU-24 (FS-ICU 24) measures across the sites. Although a range of other metrics were also reported at different sites to make up for the known deficit that HCAHPS and FS-ICU 24 present with respect to measuring dignity and respect, we will focus only on the measures listed above for the sake of simplicity and comparison across sites. The Berman Institute at Johns Hopkins University concurrently developed a new measure called ICU-RESPECT, which is being tested at UCSF, but was not ready to be deployed in the baseline period.

*Goal Concordant Care:* Most sites measured Haberle Global Concordance or the CollaboRATE Measure.<sup>55</sup>



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## End Notes

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# Appendices

## Appendix 1 – Knowledge advisory group bios

### *Dr. Richard Mularski (Advisory Group Chair)*

Dr. Mularski is an academic physician boarded in pulmonary, critical care, and palliative medicine who practices inpatient pulmonary and critical care medicine at Kaiser Sunnyside Medical Center and leads health services research at The Center for Health Research, Kaiser Permanente and Oregon Health and Science University in Portland, Oregon. He also serves as the Kaiser Northwest Regional Clinical Quality Lead for COPD, Medical Director of Inpatient Respiratory Care, and a National Methodologist for heart/lung portfolio of Kaiser Guideline Program at KP Care Management Institute, Center for Clinical Information Services.

He has expertise in research methodology, quality measurement, quality improvement, translational medicine, and implementation of evidence-based medicine in the areas of obstructive lung disease, dyspnea, and palliative & end-of-life care.

He led the RAND Health pulmonary quality review for the QA Tools project and was lead author on a consensus statement for 18 proposed quality measures for palliative and end-of-life care for the critically ill hospitalized patient that has now been operationalized and placed in the public domain.

Among his leadership roles in science, he is a PI and founding steering committee member for the multi-center collaboration of investigators (COPD Outcomes-based Network for Clinical Effectiveness & Research Translation or CONCERT) whose mission is to employ effectiveness and translational research methodologies to improve the care and outcomes of patients with COPD. Over the last few years, he led an effort to build national infrastructure for patient led research in COPD as the PI of the COPD Patient Powered Research Network, one of 31 entities funded by PCORI to build a national research infrastructure for patient-centered research (PCORnet).

### *Dr. Derek Angus*

Dr. Angus is Chair of the Department of Critical Care Medicine of both the University of Pittsburgh School of Medicine and the UPMC Healthcare System. At the University, he holds the rank of Distinguished Professor and the Mitchell P. Fink Endowed Chair in Critical Care Medicine with secondary appointments in Medicine, Health Policy and Management, and Clinical and Translational Science and he directs the CRISMA (Clinical Research, Investigation, and Systems Modeling of Acute Illnesses) Center. He also co-directs the UPMC ICU Service Center, responsible for the provision of ICU services across the 20-plus hospital system.

Dr. Angus' research interests include clinical, epidemiologic and translational studies of sepsis, pneumonia, and multisystem organ failure and health services research of the organization and delivery of critical care services. Dr. Angus has led several large NIH-funded multicenter studies in the critically ill, the most recent of which is ProCESS (Protocolized Care for Early Septic Shock), a 40-center study focusing on how to best provide early resuscitation for septic shock. Dr. Angus has published several hundred papers, reviews, and book chapters, is currently section editor for "Caring for the Critically Ill" for JAMA, and is the recipient of numerous awards, including the American College of Critical Care Medicine Distinguished Investigator Award.

#### *Dr. Shannon Carson*

Dr. Carson joined the faculty of the University of North Carolina School of Medicine in 1999 and currently serves as Professor and Chief of the Division of Pulmonary and Critical Care Medicine. His research interests include health services research and clinical trials in critical illness and comparative effectiveness research in COPD. His research is supported by grants funded by the NHLBI, NINR, and PCORI. He has a particular interest in patients requiring prolonged mechanical ventilation and is part of a research network (the ProVent Investigators) that is currently conducting randomized controlled trials of interventions to improve physician-family communication in the management of these challenging patients. He has been a co-investigator in the NHLBI ARDS Network, and he was also a co-PI in the COPD Network for Comparative Effectiveness Research and Translation (CONCERT Network). Dr. Carson is an active member of the American Thoracic Society and served as the Chair of the Critical Care Assembly. He serves on the Quality Improvement Committee and served on writing groups for statements on Pay-for-Performance, Comparative Effectiveness Research, and Implementation Science. He has been a consultant on projects for the Centers for Medicare and Medicaid Services using Medicare data to assess the role and function of Long-term Care Hospitals in the care of patients with complex acute illness.

#### *Mary Sue Collier, MSN, RN, FABC*

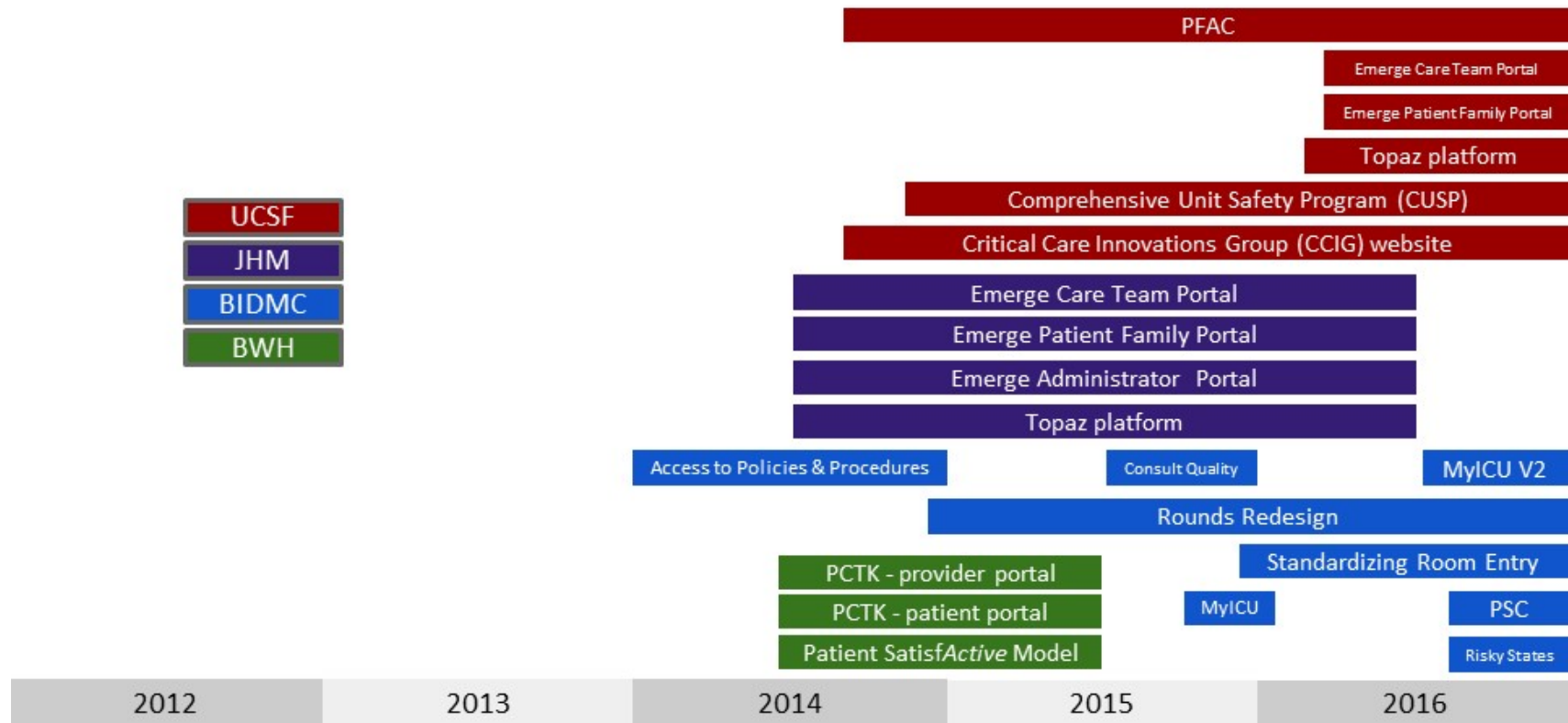
Sue joined the American Hospital Association/Health Research Educational Trust in September 2014 and serves as a Clinical Content Development Lead. In this role, Sue provides clinical content support for several national quality improvement projects, including the AHRQ Safety Program for Long-Term Care: HAIs/CAUTI, AHRQ Safety Program for Ambulatory Surgery, AHRQ TeamSTEPPS, AHRQ Safety Program for ICUs: CLABSI/CAUTI, and CDC's Engaging Partners in Infection Prevention and Control in Acute Care Hospitals. Prior to joining HRET, Sue worked at Vidant Health, a multi-hospital healthcare system in NC, for over 32 years. She held numerous clinical and executive leadership positions, including corporate vice president for planning and vice president for patient-family experience. Vidant Health achieved national recognition for innovative work in patient and family engagement during Sue's leadership. Sue also worked with the North Carolina Quality Center/NC Hospital Association as a Performance Improvement Specialist in Patient and Family Engagement. Sue has led state and national initiatives to improve patient safety performance and advance patient and family engagement. She is a TeamSTEPPS Master Trainer and co-developer of the new TeamSTEPPS Advanced Training Course. Sue collaborated with patient family advisors and patient engagement leaders to develop an education program designed to integrate TeamSTEPPS tools and strategies with patient and family engagement initiatives. Sue received her BSN and MSN from East Carolina University.

#### *Dr. Adam Wilcox*

Adam Wilcox, PhD is the Chief Analytics Officer at UW Medicine, and a Professor of Biomedical Informatics at the University of Washington. He has broad experience in both applied and research informatics, with experience both in academia and healthcare delivery organizations. At UW, he leads efforts to develop and implement a data and analytics strategy to help UW Medicine effectively use data to improve care delivery and transformation. Nationally, he is noted for his work with designing, developing and sustaining research data systems for populations with research and electronic health record data; for design and implementation of health information systems; and for advancing methods in sustainability of data systems. Previously he was a Director of Medical Informatics at Intermountain

Healthcare, where he led Intermountain's clinical decision support efforts and directed its analytic health repository. At Columbia University and New York Presbyterian Hospital, he designed research systems that advanced patient-reported data for population health, and was the Director of Clinical Databases, managing both the clinical data repository and data warehouse. Prior to this role he worked at Intermountain Healthcare where he led efforts in development of primary care and care management systems. He is an elected fellow of the American College of Medical Informatics, a senior editor for eGEMs, and Clinical Informatics Subcommittee member for the American Board of Preventive Medicine, which administers the board examination for the clinical informatics subspecialty. He has authored over 100 book chapters, peer-reviewed articles and abstracts in clinical informatics. In 2015, he was appointed a member of the PCORI Methodology Committee, where he is a leader among that committee in informatics and investigating issues with the use of secondary data for outcomes research.

## Appendix 2 – Innovation implementation timeline



### Appendix 3 – Hospital site profiles

Hospital Characteristics	BWH		BIDMC			JHU	UCSF
Hospital type	Not-for-profit, academic teaching hospital		Not-for-profit, academic teaching hospital			Not-for-profit, academic teaching hospital	Not-for-profit, academic teaching hospital
Number of staffed in-patient beds	793		672			1,145	712
Annual Emergency Department visits	56,000		55,244			350,000	34,900
Hospital system structure	Integrated delivery system		Multi-hospital			Integrated delivery system	Multi-hospital
Number and type of ICUs	<ol style="list-style-type: none"> <li>1. Cardiac</li> <li>2. Cardiac surgical</li> <li>3. Medical</li> <li>4. Burn trauma/Surgical</li> <li>5. Neonatal</li> <li>6. Neuroscience</li> <li>7. Thoracic</li> </ol>		<ol style="list-style-type: none"> <li>1. Medical (2)</li> <li>2. Coronary Care Unit</li> <li>3. Surgical</li> <li>4. Neuro</li> <li>5. Trauma/Surgical</li> <li>6. Cardiovascular</li> <li>7. Finard Medical/Surgical ICU (FICU)</li> </ol>			<ol style="list-style-type: none"> <li>1. Cardiovascular Surgical ICU</li> <li>2. Medical ICU</li> <li>3. Neonatal ICU</li> <li>4. Pediatric ICU</li> <li>5. Surgical ICU</li> <li>6. Weinberg Surgical ICU</li> </ol>	<ol style="list-style-type: none"> <li>1. Adult Med-Surg ICU</li> <li>2. Adult Med-Surg ICU</li> <li>3. Adult Neuroscience ICU</li> <li>4. Adult NeuroScience ICU</li> <li>5. Adult Cardiac ICU</li> <li>6. Adult Surg/Onc ICU/MBICU</li> <li>7. Neonatal ICU</li> <li>8. Pediatric ICU</li> <li>9. Pediatric Cardiac ICU</li> </ol>
Unit characteristics	MICU	Oncology	MICU	SICU	TSICU	SICU	9ICU & 13ICU
Number of staffed patient beds	20	130	8		10	12	32
Is the unit open or closed?	Closed	Open	Closed		Semi-closed	Mixed	Mixed
Average length of stay for patients	~ 5 days	14 days	3 days		3 days	2 days	4 days



Hospital Characteristics	BWH		BIDMC			JHU	UCSF
Have you received the AACN Beacon Award? If so, what level?	Currently applying for award					No	Yes, 2010, renewal application in review
How do the staffing ratios (including physicians) change between day and night?	Day: 1 attending Night: 1 attending		Day: 1 ICU attending Night: 1 covering in-house ICU attending		Day: 1 ICU attending Night: 1 covering in-house ICU attending	Nursing ratios remain the same. Physician ratios decrease at night	RN staff based on acuity MD – set schedule
Unit physician staffing	MICU	Oncology	MICU	SICU	TSICU	SICU	9ICU & 13ICU
Number of attending physicians who actively staff the unit	1 physician	11 physicians	1 physician		1 physician	16 physicians	39 physicians
ICU attendings certified in critical care			100%		100%	15 (94%)	39 (100%)
Specialties of attending physicians staffing the unit			Pulmonary Critical Care, Emergency Medicine & Critical Care		Anesthesia Critical Care, Surgical Critical Care, Medical Critical Care	Anesthesiology, Surgery, Medicine	Anesthesia, Pulmonary, Critical Care, Neurovascular, Nephrology, Surgery
Residents assigned to the unit per month and length of rotation		4-5 residents. 6 week rotations.	6 (month long rotation)		3 (month long rotation)	6 residents (4 week rotation)	4 residents (2 month rotation)

Hospital Characteristics	BWH		BIDMC			JHU	UCSF
Daily rounds by an ICU physician	Yes		Yes		Yes	Yes	Yes
Are family members included in multidisciplinary daily rounds?	Upon request	Yes, if they are present	Yes		Yes	Yes	Occasionally, if they are present and request to be present
Unit nurse staffing	MICU	Oncology	MICU	SICU	TSICU	SICU	9ICU & 13ICU
ICU staff nurses certified in critical care	28		10% (15/150)	9.5% (6/63)	7.5% (3/40)	4 – CCRN	43% (60/140)
Proportion of nurses who are travel nurses versus regular staff of the hospital	Average 3 out of 94 nurses	If present, maybe 1-2 travel nurses of 375 nurses.	2% (3/150)	3.2% (2/63)	2.5% (1/40)	No travelers currently	7%
Nurse:patient ratio during the day	1:1 or 1:2 depending on acuity	2-3 patients/nurse	1:1 or 1:2	1:1 or 1:2	1:1 or 1:2	1:1-2	1:2 and 1:1
Nurse:patient ratio during night	01:01.1	3-4 patients/nurse	1:1 or 1:2	1:1 or 1:2	1:1 or 1:2	1:1-2	1:2 and 1:1
Patient characteristics	MICU	Oncology	MICU	SICU	TSICU	SICU	9ICU & 13ICU
Patient acuity (Apache score)	Mean Charlson Score: 4.03	Mean Charlson Score: 4.03	Not available		Not available	N/A	Apache score: 20-24

#### Appendix 4 – Dissemination activities by site

Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
<b>BIDMC</b>	Standard work for room entry: linking lean, hand hygiene, and patient centeredness	Healthcare	journal article	2016	0
<b>BIDMC</b>	Beth Israel Launches Big Data Effort to Improve ICU Care	Health Data Management	media	2015	n/a
<b>BIDMC</b>	BIDMC introduces MyICU	online announcement	media	2015	n/a
<b>BIDMC</b>	Boston hospital aims to redefine care and prevent emotional harm	Boston Globe	media	2015	n/a
<b>BIDMC</b>	Comfort Managing End-of-Life Pain Does Not Match Training	Medscape	media	2016	n/a
<b>BIDMC</b>	Doctors need to treat their patients with respect	Globe	media	2015	n/a
<b>BIDMC</b>	Doctors strive to do less harm by inattentive care	The New York Times	media	2015	n/a
<b>BIDMC</b>	Efforts to improve quality of care and patient satisfaction	Health Affairs	media	2016	n/a
<b>BIDMC</b>	Eliminate emotional harm by focusing on respect and dignity for patients	BIDMC press release	media	2015	n/a
<b>BIDMC</b>	Hospitals focus on doing no harm	The New York Times	media	2016	n/a
<b>BIDMC</b>	Hospitals working to make intensive care less terrifying	Boston Globe	media	2016	n/a
<b>BIDMC</b>	Critical care rounds: standardizing key elements to ensure success	Critical Care Medicine	presentation	2015	0
<b>BIDMC</b>	Design of a communication portal in the ICU: surveys of potential stakeholders	Critical Care Medicine	presentation	2014	1
<b>BIDMC</b>	Interest in direct participation in care in the ICU: results of an internet survey	American Journal of Respiratory and Critical Care Medicine	presentation	2015	0
<b>BIDMC</b>	Measuring the Quality of Consultations in the Intensive Care Unit: Family and Nursing Perspectives on Communication	American Thoracic Society 2016 Conference	presentation	2016	0
<b>BIDMC</b>	MyICU: An Electronic Patient Engagement Portal for ICU Patients and Families	New England Nursing Informatics Consortium	presentation	2015	0

Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
<b>BIDMC</b>	Speaking up about care concerns in the ICU: patient and family attitudes	American Journal of Respiratory and Critical Care Medicine	presentation	2015	0
<b>BIDMC</b>	Variations in perceptions of inpatient consultation quality in the intensive care unit	American Journal of Respiratory and Critical Care Medicine	presentation	2016	0
<b>BIDMC</b>	Variations in Perceptions of Inpatient Consultation Quality in the Intensive Care Unit	American Thoracic Society 2016 Conference	presentation	2016	0
<b>BIDMC</b>	Family satisfaction with care in the ICU: A report on FS-ICU data from BIDMC (2008 - 2014)		report	2015	n/a
<b>BIDMC</b>	Clinician Perspectives on an Electronic Portal to Improve Communication with Patients and Families in the Intensive Care Unit	Annals of the American Thoracic Society	research	2016	0
<b>BIDMC</b>	Preferences of current and potential patients and family members regarding implementation of electronic communication portals in ICUs	Annals of the American Thoracic Society	research	2016	0
<b>BIDMC</b>	Emotional harm from disrespect: the neglected preventable harm	BMJ Quality & Safety	thought piece	2015	6
<b>BWH</b>	Information technology for patient empowerment in healthcare		book	2015	5
<b>BWH</b>	Care team identification in the electronic health record: A critical first step for patient-centered communication.	Journal of Hospital Medicine	journal article	2016	3
<b>BWH</b>	Clinical workflow observations to identify opportunities for nurse, physicians and patients to share a patient-centered plan of care	AMIA Annual Symposium Proceedings	journal article	2014	2
<b>BWH</b>	Nursing leadership in development and implementation of a patient-centered plan of care toolkit in the acute care setting	Computers Informatics Nursing	journal article	2015	4

Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
<b>BWH</b>	Participatory design and development of a patient-centered toolkit to engage hospitalized patients and care partners in their plan of care	AMIA Annual Symposium Proceedings	journal article	2014	14
<b>BWH</b>	Strategies for managing mobile devices for use by hospitalized patients	AMIA Annual Symposium Proceedings	journal article	2015	0
<b>BWH</b>	Brigham and Women's opening access to the medical record	Boston Business Journal	media	2014	n/a
<b>BWH</b>	Brigham and Women's provides patients' bedside access to EHRs	FierceHealthcare	media	2014	n/a
<b>BWH</b>	Brigham and Women's tries microblogging for care continuity	MedCity News	media	2015	n/a
<b>BWH</b>	A web-based and mobile patient-centered "microblog" messaging platform to improve care team communication in acute care	Journal of the American Medical Informatics Association	research	2016	0
<b>BWH</b>	A web-based, patient-centered toolkit to engage patients and caregivers in the acute care setting: a preliminary evaluation	Journal of the American Medical Informatics Association	research	2016	8
<b>BWH</b>	How often are hospitalized patients and providers on the same page with regard to the patient's primary recovery goal for hospitalization?	Journal of Hospital Medicine	research	2016	1
<b>BWH</b>	Nurses' perspectives on patient satisfaction and expectations: an international cross-sectional multicenter study with implications for evidence-based practice	Worldviews on Evidence-Based Nursing	research	2016	0
<b>JHM</b>	Data driven patient safety and clinical information technology: cases strategies, and solutions	Healthcare Information Management Systems	book chapter	2016	n/a
<b>JHM</b>	3D sensing algorithms towards building an intelligent ICU	AMIA Joint Summits on Translational Science	journal article	2013	8
<b>JHM</b>	A model selection approach for clustering a multinomial sequence with non-negative factorization	IEEE Transactions on Pattern Analysis and Machine Intelligence	journal article	2013	0

Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
JHM	An integrative framework for sensor-based measurement of teamwork in healthcare	Journal of the American Informatics Association	journal article	2014	5
JHM	Developing predictive models using electronic medical records: challenges and pitfalls	AMIA Annual Symposium Proceedings	journal article	2013	27
JHM	Development of a behavioral marker system to assess intensive care unit team performance	Proceedings of the Human Factors and Ergonomics Society	journal article	2015	1
JHM	Enhancing the quality of care in the ICU: a systems engineering approach	Critical Care Clinics	journal article	2013	11
JHM	Toward treatment with respect and dignity in the ICU	Narrative Inquiry in Bioethics	journal article	2015	6
JHM	Innovator spotlight: JHM develops app to improve ICU patient safety	National Quality Forum	media	n.d.	n/a
JHM	Putting care back in the ICU (interview)	NPR - Only Human	media	2015	n/a
JHM	Transforming patient safety: a sector-wide systems approach		report	2015	4
JHM	A Direct Observation Checklist to Measure Respect and Dignity in the ICU	Critical Care Medicine	research	2016	0
JHM	A systematic review of behavioural marker systems in healthcare: what do we know about their attributes, validity and application?	BMJ Quality & Safety	research	2014	12
JHM	A systematic review of teamwork in the ICU: what do we know about teamwork, team tasks, and improvement strategies?	Journal of Critical Care	research	2014	18
JHM	Health care professionals' perceptions and experiences of respect and dignity in the ICU	Narrative Inquiry in Bioethics	research	2015	4
JHM	Measuring patients' experiences of respect and dignity in the ICU: a pilot study	Narrative Inquiry in Bioethics	research	2015	2
JHM	Observations of respect and dignity in the ICU	Narrative Inquiry in Bioethics	research	2015	3
JHM	Patient and family perspectives on respect and dignity in the ICU	Narrative Inquiry in Bioethics	research	2015	9

Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
JHM	Respect and dignity: a conceptual model for patients in the ICU	Narrative Inquiry in Bioethics	research	2015	5
JHM	Towards expanding the acute care team: learning how to involve families in care processes	Families, Systems, and Health	research	2015	3
JHM	Understanding treatment with respect and dignity in the ICU	Narrative Inquiry in Bioethics	research	2015	5
JHM	From heroism to safe design: leveraging technology	Anesthesiology	thought piece	2014	19
JHM	Patient safety and the problem of many hands	BMJ Quality & Safety	thought piece	2016	2
JHM	Preventing patient harms through systems of care	Journal of the American Medical Association	thought piece	2012	52
UCSF	How to Get the Best Care From the Hospital Nursing Staff	The Wall Street Journal	media	2016	n/a
UCSF	More common and more harmful than once believed, delirium takes center stage	Science of caring	media	2016	n/a
UCSF	Agreement between patients and nurses about admitting illnesses and treatments in the ICU	Critical Care Medicine	presentation	2015	0
UCSF	Engaging an ICU patient and family advisory council to redesign a patient-oriented website	Critical Care Medicine	presentation	2015	0
UCSF	ICU clinician perspectives on involvement of family members in the care of critically ill patients	American Journal of Respiratory and Critical Care Medicine	presentation	2016	0
UCSF	The effect of a comprehensive unit-based safety program on systems thinking in adult ICU providers	Critical Care Medicine	presentation	2015	0
UCSF	The effect of an ICU patient safety program on staff engagement and perceptions of safety	Critical Care Medicine	presentation	2015	0
Collaborative <sup>b</sup>	Developing a comprehensive model of ICU processes: concept of operations	Journal of Patient Safety	journal article	2015	2

Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
<b>Collaborative</b>	Ambitious app comes as hospitals struggle with basic checklists	Modern Healthcare	media	2014	n/a
<b>Collaborative</b>	Eliminating preventable harm in academic medical centers: the Libretto Consortium and the Gordon and Betty Moore Foundation	Health Affairs Grant Watch Blog	media	2014	n/a
<b>Collaborative</b>	Hospital ICUs mine big data in push for better outcomes	Wall Street Journal	media	2015	n/a
<b>Collaborative</b>	Hospitals bring patient engagement to the ICU	FierceHealthcare	media	2015	n/a
<b>Collaborative</b>	Hospitals look to technology to communicate, reduce errors	San Francisco Chronicle	media	2016	n/a
<b>Collaborative</b>	Hospitals turn to big data to identify risks in the ICU	FierceHealthcare	media	2015	n/a
<b>Collaborative</b>	Intensive care gets friendlier with apps, devices	The Wall Street Journal	media	2015	n/a
<b>Collaborative</b>	Meet the cancer patient in room 52: his name is Joseph but call him Job	The Washington Post	media	2015	n/a
<b>Collaborative</b>	Raising an alarm, doctors fight to yank hospital ICUs into the modern era	Stat News	media	2016	n/a
<b>Collaborative</b>	Barriers to providing quality end-of-life care in the ICU - Results of a multicenter survey	Critical Care Medicine	presentation	2015	0
<b>Collaborative</b>	Factors related to nurses' comfort managing pain at the end of life: a multicenter survey	American Journal of Critical Care	presentation	2016	0
<b>Collaborative</b>	Acute care patient portals: a qualitative study of stakeholder perspectives on current practices	Journal of the American Medical Informatics Association	research	2016	0
<b>Collaborative</b>	ICU-RESPECT: an index to assess patient and family experiences of respect in the ICU	Journal of Critical Care	research	2016	0



Site	Title	Journal/ Source	Type	Date	Citations <sup>a</sup>
<b>Collaborative</b>	Balancing digital information-sharing and patient privacy when engaging families in the ICU	Journal of the American Medical Informatics Association	thought piece	2015	3
<b>Collaborative</b>	Care partners and online patient portals	Journal of the American Medical Association	thought piece	2014	34
<b>Collaborative</b>	Defining patient and family engagement in the intensive care unit	American Journal of Respiratory and Critical Care Medicine	thought piece	2015	11

<sup>a</sup> Citations search October 5, 2016.

<sup>b</sup> Collaborative refers to papers or media reports with authorship from two or more sites.

## Appendix 5 – Qualitative methods and field guide

The qualitative portion of the evaluation utilized a rapid appraisal approach during two-day site visits which was chosen for its suitability to produce information quickly through streamlining the data collection, analysis, and interpretation processes<sup>1</sup>. Rapid assessment techniques produce a contextually defined picture of what is happening within a setting from the point of view of those doing the work and who are best positioned to explain what works or not. The approach used in this study combined the participatory elements of rapid appraisal with the cultural (organizational) focus of rapid ethnographic assessment<sup>2</sup>. Multiple data collection methods were used including: interviews, observations, field survey, and document review. We relied heavily on a well-developed field guide to “to define the gaze to enable focused research”<sup>3</sup> which was based on the example provided by McMullen and colleagues<sup>4</sup>. The field guide was developed using: site documents submitted previously to the foundation, the theory of change logic model, and implementation frameworks including RE-AIM<sup>5</sup> and the Consolidated Framework for Implementation Research (CFIR)<sup>6</sup>. The field guide was iteratively refined following each site visit and included interview questions and topic guides, consent forms, a matrix for structuring observations (including demonstrations), a field survey, blank paper for notes, and RE-AIM/CFIR analysis tables. The researchers who attended each site visit were trained in the method and process by the project’s qualitative expert prior to the site visits and the same three researchers carried out each visit. We worked closely with a collaborator at each site to prepare for the visit and relied on their expertise as inside informants to ensure that all necessary data was collected.

Interviews were recorded with permission and used for reference to supplement detailed notes that were typed during the interviews by one researcher. Shorthand notes taken during observations, during the field survey, or during demonstrations were written up or typed in full later in the day. Photos were taken where possible during observations and used to supplement observational data. Documents included in our review had been previously submitted to the foundation or received directly from the sites. All sites were invited to give presentations of their projects at the beginning of the first day which also often included a question and answer session; typed and written notes taken during presentations were treated in the same way as notes from interviews.

Analysis and data collection proceeds simultaneously in an iterative process in rapid appraisal. At the end of each day (and during the day where possible), the researchers convened to compare notes and discuss emerging themes which were then sifted into a RE-AIM/CFIR analysis framework (one for each

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<sup>1</sup> Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: A fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Education and Counseling*. 2013;93(1):102-107. doi:10.1016/j.pec.2013.05.009.

<sup>2</sup> Annett H, Rifkin SB. Guidelines for rapid participatory appraisals to assess community health needs. WHO.

<sup>3</sup> Manderson L, Aaby P. An epidemic in the field? Rapid assessment procedures and health research. *Social Science & Medicine*. 1992;35(7):839-850. doi:10.1016/0277-9536(92)90098-b.

<sup>4</sup> McMullen CK, Ash JS, Sittig DF, et al. Rapid Assessment of Clinical Information Systems in the Healthcare Setting [Sample Fieldwork Guide]. *Methods Inf Med*. 2011;50(4):299-307. doi:10.3414/me10-01-0042.

<sup>5</sup> Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal of Public Health*. 1999;89(9):1322-1327. doi:10.2105/ajph.89.9.1322.

<sup>6</sup> Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Sci*. 2009;4(1). doi:10.1186/1748-5908-4-50.

data source) through a consensus process; questions to be followed up the next day with site informants were also noted. In keeping with the participatory approach, at the end of each visit, one researcher presented the synthesized findings from the visit to one or more members of the site team for confirmation and clarification of our findings as a validation check. As an additional validation check, the written case summary was sent to each site to confirm the accuracy of our findings.

In addition to the rapid appraisal site visits, interviews were carried out with key informants and documents were reviewed regarding the history of the portfolio, Libretto Consortium, and portfolio design and implementation. Data were handled in the same way as above.



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ICU Redesign Evaluation

# Fieldwork Guide

## CONTENTS

Document	Description
Site visit preparation schedule	Provides a timetable for what needs to be done, by when and by whom prior to each site visit.
Site visit plan	Plan for what will be done each day of an average 2 day site visit.
Itinerary	Itinerary for the whole trip, including flight and hotel information.
Site schedule	Provided by site.
Site summary and results	Overview of site projects including results of intervention implementation.
Informant list	List of project people and roles at each site including list of people to be interviewed.
Questions for team during Q&A	Questions for clarification to be posed to the whole team to answer during first half day.
Big picture questions	The main questions that this evaluation seeks to address.
Hospital site profile instrument	One profile to be initially completed by evaluation team which gives a contextual overview of that site. Will be given to the site lead during the visit for correction and completion.
Interview guides	<p>Topic and question guide for:</p> <ul style="list-style-type: none"> <li>• PI</li> <li>• Co-I's and project managers</li> <li>• Clinical leadership, administrative leadership, implementers</li> <li>• C-Suite (executives)</li> <li>• Patient and family advisers</li> </ul>
Field survey form/ Interview guide - implementers	To be administered to ICU staff/providers about their experience of using the interventions during observational periods. Contains some structured questions and open-ended questions to be used like an interview and used as suitable.
Field note form	For use for summarizing observation sessions. Use with CFIR and RE-AIM cheat sheets as aide memoires. Observational notes to be recorded on blank paper and notes summarized using form.
RE-AIM and CFIR table	To be used to summarize findings and interpretations from interviews or observations in a structured way to facilitate analysis. Refer to RE-AIM cheat sheet and CFIR constructs with short definitions to identify sub-constructs.
CFIR constructs with short definitions	Cheat sheet for reference.
RE-AIM cheat sheet	Cheat sheet for reference.
Agenda for debriefing meeting	Plan for meeting at the end of each day.

## SITE VISIT PREPARATION SCHEDULE

### 1 Month Before Visit

	Task	Person Responsible	Status
1.	Decide on dates for visit		
2.	Phone call with site leads for introduction		
3.	Find out about IRB needs, if any		
4.	Identify site lead		
5.	Book plane tickets, rental cars, hotel		
6.	Discuss informant selection process with site lead		
7.	Draft list of informants/ interviews		

### 2 Weeks Before Visit

	Task	Person Responsible	Status
1.	Provide each site with condensed letter for interviews and fact sheet for observations to inform participants of evaluation and aims		
2.	Schedule for site visit confirmed by site lead		

### 1 Week Before Visit

	Task	Person Responsible	Status
1.	Prepare site visit interview and observation protocol handouts and interview guides specific for the site		
2.	Design site-specific field survey		
3.	Complete Hospital Site Profile Instrument, to be finalized during visit		
4.	Print out and assemble field guides		

# SITE VISIT PLAN

## Preparation:

Projects/ interventions in each site have been summarized, review prior to visit.

Pack appropriate clothing for ICU visit, e.g. closed toe shoes. Bring Stanford ID tag and driver's license.

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## Day One

Goal: Gain a more comprehensive understanding of the projects and organization, and conduct initial interviews and observations

- Opportunity for site to present their project.
  - Begin the day with a tour from the site lead.
  - Give site lead Hospital Site Profile Instrument for completion and checking.
  - Demonstration by the lead of the interventions.
  - Over lunch, revise interview guide and other forms if necessary
  - In the afternoon, begin interviews and field observations
    - Two team members will conduct interviews with key informants that have been arranged by site lead, one to take notes.
    - Two observers will shadow clinicians according to pre-arranged schedule and also find others to shadow. Observers will use the field notes form for jotting notes and gathering field survey data. After shadowing to see interventions in use, roam around unit for wider impressions.
  - Debrief in the evening, share initial impressions, plan details of Day 2
  - Work on field notes
- 

## Day Two:

Goal: Gather data intensively, reach the point where preliminary analysis can be done

- Continue interviews and observations.
  - At end of day, debrief with the organizational leader most appropriate/ site lead. Serve to clarify and validate impressions.
  - Collect Hospital Site Profile Instrument
  - Debrief in the evening, develop initial ideas about patterns and themes and what to include in the site visit report.
  - Work on field notes.
- 

## Day Three (if needed):

- Repeat activities for Day Two, striving to confirm or invalidate Day Two impressions

## **ITINERARY**

Flights, hotel, etc.

## **SITE SCHEDULE**

Provided by site.

## **SITE SUMMARY AND RESULTS**

Overview of site projects including results of intervention implementation. Prepared in advance using site documents and scorecards.

## **INFORMANT LIST**

List of project people and roles at each site including list of people to be interviewed.

## **QUESTIONS FOR TEAM DURING Q&A**

To be added from site summary documents.



## BIG PICTURE QUESTIONS

**Overall:** to what extent did the work of the foundation through the grantees achieve the following:

- Reduction in patient harms
- Improve dignity and respect
- Improve care concordance w goals
- Scale to other ICU
- Potential for generalizability

### Effectiveness

#### 1. Clinical effectiveness, process, outcome

- Aggregate reduction in patient harm
- Patient reported measures of dignity and respect
- Care concordance with goals
- Costs

#### 2. Implementation challenges, lessons learned, impacts

- Barriers and facilitators to implementation
- Potential for maintenance scale and spread
- Impacts on the field

#### 3. Libretto

- Degree to which the consortium achieved the desired outcomes
  - Accelerating the speed of innovation and quality of implementation
    - Through facilitation of knowledge transfer
  - Increase public awareness of the work as a path to adoption and scale of the portfolio
- Assessment of the adoption of the Topaz platform

### Portfolio design and implementation

- Alignment with the field
- Portfolio design and execution
- Standout grantees, grant making approaches, interventions

### Potential for Scale and Spread

- To what extent were interventions spread to other ICUs?
- What is the potential for spread for currently developed interventions and any interventions in progress?
- What are opportunities for further exploring the work?
- How may work to date shape safety work in settings outside the ICU?
- What would it take to drive broad adoption of the innovations?

## HOSPITAL SITE PROFILE INSTRUMENT

**(profile to be completed by evaluation team prior to visit and confirmed by one representative during site visit)**

This survey is designed to help the evaluators develop an understanding of your hospital organization as a whole and specifically the units in which innovations were designed and implemented as part of the Gordon and Betty Moore Foundation grants. Please take a few minutes to check through the data to confirm whether it is correct and add data where it is missing, if possible.

Date:

Hospital site:

Who completed the form (for further questions):

<b>Hospital Characteristics</b>	
Hospital type (not-for-profit; for-profit; govt.; VA; academic teaching hospital)	
Number of staffed in-patient beds	
Annual in-patient discharges	
Annual Emergency Department visits	
Clinical service profile (adult, peds, ICU, OB)	
Hospital system organizational structure (stand- alone; integrated delivery system; multi-hospital)	
Payer mix	
Number and type of ICUs	

<b>ICU characteristics (table to be replicated for each unit implementing the interventions)</b>	
Number of staffed patient beds	
Is the unit open or closed?	
Average length of stay for patients	
Have you received the AACN Beacon Award? If so, what level?	
How do the staffing ratios (including physicians) change between day and night?	
Average number of ICU patients / day (report months Nov / Mar / Jul)	
Average number of vented ICU patients / day (report months Nov / Mar / Jul)	
Average number of ICU patients / day on RRT (report months Nov / Mar / Jul)	
<b>ICU physician staffing</b>	
Number of attending physicians who actively staff the unit	
ICU attendings certified in critical care	
Specialties of attending physicians staffing the unit	

Residents assigned to the ICU per month and length of rotation	
Daily rounds by an ICU physician	Y/N
Are family members included in multidisciplinary daily rounds?	
<b>ICU nurse staffing</b>	
ICU staff nurses certified in critical care	
Proportion of nurses who are travel nurses versus regular staff of the hospital	
Nurse:patient ratio during the day	
Nurse:patient ratio during night	
<b>Patient characteristics</b>	
Patients/ families who are non-English speaking in last month	
What is the breakdown of the demographics of your patient population in terms of race/ethnicity, gender, age, and socioeconomic status?	
Patient acuity (Apache score)	

## INTERVIEW GUIDE – PI (example)

---

Interviewee: \_\_\_\_\_

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Setting: \_\_\_\_\_

### 1. About you

First, we'd like to learn a little about you. Could you briefly summarize what your role in the project has been and how long you've been with the organization?

### 2. About the site project portfolio

We'd like to understand a bit more about the portfolio of work here:

- Why did you decide to implement this set of interventions?
- What alternatives were considered?

When you undertook the work, in what ways was it aligned or not aligned with the state of the art in the fields of patient safety, patient engagement, and ICU care?

### 3. Implementation period

Could you briefly summarize for me how you think the overall implementation of the project went? Did it go as planned? Why, why not?

- Were you able to reach all of the patients you wanted?
- Did all the providers adopt the innovations?
- How did the culture of the organization/unit affect implementation?

What kind of infrastructure changes to the organization had to be made to implement the interventions? How did the infrastructure of your organization affect the implementation of the intervention?

Were the resources you had sufficient for implementation? Is there anything else you needed that would have made implementation smoother?

How transformative do you think the interventions were in reducing patient harms, improving dignity and respect, and improving care concordance with goals?

- Was there anything about the project or interventions that was particularly transformative?

What were some of the challenges you faced during implementation? How did you overcome them?

What were some of the things or activities that helped you deliver the intervention/project?

On a scale of 1 to 10, 10 being totally, how confident are you that the innovations will be maintained?

- Potential challenges to maintenance

#### **4. Scale, spread, and generalizability**

What impact do you think your projects or innovations have made on the field?

Is there a plan to implement the innovations in other ICUs in your organization? What would it take for ICUs outside of the organization to adopt your innovations? (Scale/ spread)

- What are the barriers to adoption inside and outside of the organization?

Is there a plan to implement the innovations in non-ICU settings in your organization? Do these innovations have potential to spread outside of the ICU setting? What would it take to spread? (Scale/ spread)

- What are the barriers to spread?

#### **5. Libretto consortium**

How has your involvement with the Libretto Consortium impacted on your project/interventions?

- Did it accelerate the speed of innovation and quality of implementation?
- Is there anything that could have made the Consortium more impactful?
- Is there anything about the Consortium that was particularly transformative?

Do you think the work of the Consortium helped to increase public awareness of the portfolio of work as a path to adoption and spread of the innovations? In what ways?

Can you tell me from your perspective what happened with the Topaz platform?

- Adoption and implementation

What do you think should be the future of the Consortium?

#### **6. Portfolio design and execution**

So thinking more widely about the whole portfolio for the ICU redesign, what do you see as the next steps for further exploring this work?

- What are opportunities for further exploring the work?
- How might work to date shape safety work in settings outside the ICU?
- What would it take to drive broad adoption of the innovations?

What should the Moore Foundation support, going forward?

#### **7. Additional questions based on fieldwork**

(To be added each day)

Is there anything that I haven't asked about that you think is important to mention about the interventions you implemented or your work with the foundation?

#### **8. Summarize discussion, key points for validation.**



# INTERVIEW GUIDE – Clinical leadership, administrative leadership, implementers (example)

---

Interviewee: \_\_\_\_\_

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Setting: \_\_\_\_\_

## 1. About you

First, we'd like to learn a little about you. Could you briefly summarize what your role in the project has been and how long you've been with the organization?

## 2. About how things work in your unit, organization

How would you describe the culture of your unit and organization?

To what extent do you feel like you can try new things to improve your work processes?

How often do you undertake quality improvement initiatives within your unit?

## 3. Implementation period

What was the general level of receptivity in your unit for implementing the intervention? Were there other competing priorities at the same time?

How well did the intervention fit with the existing work practices in the unit?

How complicated is/was the intervention to implement?

What were some of the challenges you faced during implementation? How did you overcome them?

- R&D and implementation together

What were some of the things or activities that helped you deliver the intervention/project?

Were the resources you had sufficient for implementation? Is there anything else you needed that would have made implementation smoother?

What supporting materials were produced to help with implementation, such as online resources or toolkits? What was the response to these materials?

Is there anything about the interventions that has been particularly transformative?

Have you been able to reach all groups of patients?

Were there any other unintended outcomes from implementing the interventions?

## 4. Scale, spread, and generalizability

What impact do you think your projects or innovations have made on the field?

What would it take for other ICUs to adopt your innovation? What are the barriers to adoption?

Do you think these innovations have potential to spread to non-ICU settings? What would it take to spread?

- What are the barriers to spread?

#### **5. Additional questions based on fieldwork**

To be added each day

Is there anything that I haven't asked about that you think is important to mention about the interventions you implemented or the portfolio work more widely?

#### **6. Summarize discussion, key points for validation.**



# INTERVIEW GUIDE – Patient and Family advisers (example)

---

Interviewee: \_\_\_\_\_

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Setting: \_\_\_\_\_

## 1. About you

First, we'd like to learn a little about you. Could you give us a few words about your background?

Would you please describe your role here?

How long have you been a patient and family advisor?

## 2. About the design of the site project/ interventions

Could you tell me a bit about how patients and family were involved in the design of the interventions?

- Do you think there was enough involvement from patients and families during the design phase?

To what extent do you think the interventions address the needs and preferences of patients and families?

- Can you give specific examples?

## 3. Implementation period

Were patients and family involved in the implementation of the interventions? How?

What supporting materials were produced to help with implementation, such as online resources or toolkits? What was the response to these materials?

Were there any changes made to the project/intervention during implementation and if so why?

How effective was the intervention/ project in reducing patient harms?

- Improving dignity and respect?
- Improving care concordance with goals?
- Were you able to target or reach all groups of patients?
- Was it effective for all groups of patients?
- What are the key challenges from a patient and family point of view in improving care in each of these aspects?
- What practices do you think need to be sustained in order to maintain any improvements?

Were there any unintended consequences from implementing the interventions?

What is your understanding of what changes in practice have been sustained in the units?

## 4. Potential for spread

How relevant do you think the interventions are to patients in other departments of the hospital?

**5. Libretto consortium (if involved)**

How has your involvement with the Libretto Consortium impacted on your project/interventions?

- Did it improve the quality of implementation?
- Is there anything that could have made the Consortium more impactful?
- Is there anything about the Consortium that was particularly transformative?

Do you think the work of the Consortium helped to increase public awareness of the portfolio of work as a path to adoption and spread of the innovations? In what ways?

What do you think should be the future of the Consortium?

**6. Additional questions based on fieldwork**

To be added each day

Is there anything that I haven't asked about that you think is important to mention about the interventions you implemented or the portfolio work more widely?

**7. Summarize discussion, key points for validation.**

## FIELD SURVEY FORM/ INTERVIEW GUIDE - Implementers

Could you take a few minutes to talk with me about your views on [intervention]

1) What is your role? ☐ PHYSICIAN.....☐ APP .....☐ Staff nurse .....☐ OTHER: SPECIFY

2) How many years have you worked here?

3) How often do you use [intervention]?

Never	Occasionally	Sometimes	Often	Always
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4) Would you say you use [the intervention] now less than, the same, or more than you did when it was first introduced?

### Potential questions to guide conversation:

How effective do you think the intervention is/was in reducing patient harms?

- Improving dignity and respect?
- Improving care concordance with goals?

Has the intervention affected the way you practice/ your work? How?

How well did the intervention fit with the existing work practices in the unit?

- Do the interventions require additional clicks?

What kind of training or information did you receive for implementing the interventions? Was it sufficient?

How did you feel about implementing something which was still being developed?

What were the challenges in implementing the interventions? What was done to overcome them?

What do you see as the issues for sustaining the use of the interventions?

Who led the implementation of the intervention? Were they the right person to lead it?

What level of endorsement for the intervention have you seen or heard from leaders?

How would you describe the culture of your unit and organization? Do you think the culture affected the implementation of the intervention?

Were you given feedback or reports about the implementation process or the intervention itself?

Date:

## FIELD NOTE FORM

Page #:

Time start:

End:

Location:

Observed and role:

Observer:

REMINDER: note all  
assumptions, personal  
reflections, methods, theory  
notes

Summary of observations (feed back to observed for validation):

Topics for debrief:

# RE-AIM and CFIR table

Table to be used to summarize individual interviews or observations under CFIR headings to facilitate the analysis process. One table per data source. Use attached document with short descriptions of CFIR constructs and RE-AIM cheat sheet for reference.

Data source: \_\_\_\_\_

Date: \_\_\_\_\_

Site: \_\_\_\_\_

REACH
EFFECTIVENESS
ADOPTION
MAINTENANCE

INTERVENTION CHARACTERISTICS
OUTER SETTING
INNER SETTING
CHARACTERISTICS OF INDIVIDUALS
PROCESS

SCALE/ SPREAD
LIBRETTO
LESSONS LEARNED
IMPACTS ON THE FIELD
OTHER

## CFIR construct short definitions

(insert pdf print out)

## RE-AIM cheat sheet

Questions to consider while observing/ engaging with ICU providers/staff:

<b>Reach:</b> those of the target population who participated in the intervention	What are the factors and processes underlying barriers to patients/families using the interventions? How can they be addressed?
<b>Effectiveness:</b> Intervention impact on outcomes	What are the conditions and mechanisms that lead to effectiveness? Why did the intervention work or not? What are the factors and processes underlying barriers to implementation and how were they addressed?
<b>Adoption:</b> those who adopted the intervention	Why don't providers/ staff participate? How engaged are providers? What were the barriers to patient adoption?
<b>Implementation:</b> Extent intervention is implemented as intended	What are unit specific issues that might influence implementation? What were the problems with key implementation processes? CFIR constructs: see CFIR construct definitions.
<b>Maintenance:</b> extent to which intervention is sustained over time	Has the program been/ Can the program be sustained after the grant period? What is the perception of program value among stakeholders?



## **AGENDA FOR DEBRIEFING MEETINGS**

1. Each person reports about “topics for debrief” on their field notes forms and summary of notes from RE-AIM/CFIR table
2. Review effectiveness of interview questions and revise if needed
3. Review field survey results and effectiveness of questions and modify if needed
4. Develop brief description of day’s findings
5. Develop new assignments and/or strategies for next day if needed