

TITLE PAGE

Title of Project:

Pediatric patient safety learning laboratory to re-engineer continuous physiologic monitoring systems

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Organization:

Children's Hospital of Philadelphia was the prime site. University of Pennsylvania was a secondary site.

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STRUCTURED ABSTRACT

Purpose: The goal of the project was to re-engineer the ways we use physiologic monitoring in children, with the ultimate objective of making alarms more informative.

Scope: (1) Re-engineer the system of monitoring hospitalized children on acute care wards, with a focus on reducing noninformative alarms and accelerating nurse responses to critical events, and (2) re-engineer the system of monitoring infants with bronchopulmonary dysplasia at home, with a focus on reducing noninformative hypoxemia alarms.

Methods: We followed the planned, five-step phased approach of Problem Analysis, Design, Development, Implementation, and Evaluation for each aim. Our team included a diverse set of physicians, nurses, scientists, engineers, designers, and support staff.

Results: Using a systems engineering approach, we gained an in-depth understanding of the problems associated with current systems of physiologic monitoring and iteratively test solutions. In the hospital setting, partnership with the operational Patient Monitoring Task Force was critical in implementing interventions that improved outcomes, including reduction in alarm notifications, reductions in nurse reports of having to delay their responses to alarms, and reduction in simulated critical alarm response time. In the home setting, we used data from children with BPD on monitors at home to understand the burden of monitor alarms on families as well as make recommendations on how to curb unnecessary alarms. We then were able to implement clinical decision support to align home monitor alarm limits with the data-driven recommendations we derived.

Key Words: Alarm fatigue, pulse oximetry, bronchopulmonary dysplasia, lung, heart, human factors engineering, pediatrics, child, hospital.

PURPOSE

In this project, our transdisciplinary, systems engineering-based Pediatric Patient Safety Learning Laboratory bridging Children's Hospital of Philadelphia, University of Pennsylvania, and the ECRI Institute aimed to re-engineer hospital and home monitoring systems by optimizing the use of existing technology and then, when gaps remained, complement existing technology with medical device innovation, workflow redesign, and decision support interventions to maximize alarm informativeness through the following Specific Aims:

Specific Aim 1: Re-engineer the system of monitoring hospitalized children on acute care wards, with a focus on reducing noninformative alarms and accelerating nurse responses to critical events.

Specific Aim 2: Re-engineer the system of monitoring infants with bronchopulmonary dysplasia at home, with a focus on reducing noninformative hypoxemia alarms and improving clinicians' access to usable longitudinal pulse oximetry data to inform supplemental oxygen treatment.

SCOPE

Systems used to continuously monitor children's vital signs in hospital ward and home settings generate alarms intended to warn caretakers—nurses in the hospital and parents at home—of conditions that warrant their immediate attention. However, both systems suffer from *low informativeness* and thus pose patient safety risks relevant to critical illness detection, diagnosis, and treatment. Informativeness represents the ability of an alarm system to discriminate between signals that warrant attention and those that do not, analogous to the positive predictive value of a test. Clinical alarm fatigue, broadly defined as desensitization and distrust of alarms from overexposure to nonactionable alarms, is the end result of a process of learning, recalibrating, and redirecting attention away from alarms with low informativeness.

On pediatric wards, 26-48% of children are continuously monitored, and these children generate between 42 and 155 alarms per day. Just 1% or fewer are considered actionable or informative. This generates alarm fatigue, with studies demonstrating median 7- to 10-minute delays in responses on pediatric wards for alarms indicating potentially life-threatening conditions, such as oxygen desaturation and bradycardia. In order to manage alarms when workload is high, nurses rely on heuristics to decide how quickly to respond. Though heuristics are often correct, they are also prone to error. Delayed responses can have catastrophic results. Alarm fatigue has been linked to clinicians' failure to diagnose critical events leading to patient deaths. There is

an urgent need to re-engineer physiologic monitoring systems to produce more informative alarms with less risk of error, faster responses, and more resilient performance.

Bronchopulmonary dysplasia (BPD) is a condition that illustrates many of the challenges associated with current systems for monitoring technology-dependent patients at home. BPD is a chronic lung disease resulting from premature birth. Infants with moderate or severe BPD who have been discharged home are monitored with pulse oximetry (SpO₂) to detect three different scenarios: (1) severe, immediately life-threatening hypoxemia; (2) prolonged, intermittent hypoxemia events that are associated with long-term disability; and (3) brief, mild hypoxemia events that are not associated with adverse outcomes but that impact clinician decision making surrounding long-term supplemental oxygen treatment. Although the first and second scenarios warrant immediate responses from parents, the third is not harmful on its own but may inform care over time if patterns are observed. In order to detect all three scenarios, alarm parameters are set conservatively to prompt parents to manually document all desaturations, even mild events that are only meaningful in aggregate. Parents then share their observations with clinicians at monthly clinic visits or by telephone. This system of awakening parents to perform manual documentation is necessary because of device limitations. The result is a system estimated to generate a median of 10 alarms per night, a burden for parents that may create anxiety, sleep disruption, or alarm fatigue and lead them to miss true events or stop using the monitor altogether. Thus, there is an urgent need to maintain the salience of audible alarms for life-threatening events and prolonged hypoxemia while allowing brief events only informative in aggregate to be interpreted by the treatment team in a longitudinal format without generating alarms at home.

This project employed a framework based on the Systems Engineering Initiative for Patient Safety (SEIPS) model and Dual Process Theory and applied innovative methods such as forensic accident investigation and Kobayashi in situ simulation to analyze and evaluate monitoring systems. The findings of Aim 1 are relevant to the care of the 1.8 million children admitted to hospitals annually. The findings of Aim 2 are relevant to not only the 10,000-15,000 infants who develop BPD each year but also the thousands of other technology-dependent children and adults living at home who rely on SpO₂ monitoring.

METHODS

In accordance with the Patient Safety Learning Lab (PSLL) RFA, we followed the prescribed approach for each Specific Aim, progressing through Problem Analysis, Design, Development, Implementation, and Evaluation phases. Given that there were more than 20 small projects conducted in the Problem Analysis phase alone, in order to comply with page limits for this report, we will provide an overview of the methods in this section and then provide additional details in the results section.

The goal of **Problem Analysis** was to understand work systems, processes, and adaptations in hospital and home monitoring and explore associated hazards and harms using the SEIPS framework. We used Cognitive Task Analysis (CTA) methods in our approach, focusing on knowledge elicitation and data analysis. Knowledge elicitation is obtaining information about what people know and how they know it, specifically eliciting judgments, strategies, and knowledge that explain their behavior. Analysis entails identifying key findings and determining their meaning. We collaborated with engineers from the ECRI Institute, drawing upon their experience performing hundreds of forensic accident investigations involving medical devices, including monitoring systems in hospitals and homes that failed to notify caregivers or when caregivers failed to respond. We employed the following steps:

Table 1. Steps in Problem Analysis for Aims 1 and 2.	
Aim 1	Aim 2
Knowledge Elicitation: Artifact Analysis	
We conducted SWOT analyses of national monitoring guidelines and existing hospital policies related to continuous monitoring.	We examined and extracted relevant data from national guidelines for home SpO ₂ monitoring in infants and analyzed CHOP Home Care records of prescribed pulse oximeters, probes, and alarm settings from the preceding 3 years.

Knowledge Elicitation: Questionnaires	
We administered (1) a clinical alarms survey measuring attitudes and perceptions of alarms and (2) NASA task-load index (TLX) to measure subjective workload to a sample of ward nurses at CHOP, and we (3) combined NASA-TLX data with patient load and alarm exposure data to explore associations.	We conducted focus groups with parents of infants with BPD currently or previously SpO ₂ -monitored overnight or continuously, characterizing (1) actual use of SpO ₂ , (2) perceived alarm burden, and (3) barriers to SpO ₂ use as prescribed.
Data Review	
(1) We sought to understand hospital alarm burden by existing monitor alarm data stored in a data warehouse and estimate the extent of current hospital SpO ₂ overmonitoring by reviewing charts of patients in whom monitoring is not indicated according to existing guidelines.	We reviewed emerging findings of wirelessly collected home SpO ₂ data from BPD STAR Trial led by Co-I DeMauro to better understand the incidence of intermittent hypoxemia at home and the alarm burden.
Independent Third-Party Forensic Investigation by the ECRI Institute	
ECRI engineers conducted in-person observations of nurses responding to and managing monitor alarms, interviewed nurses to enhance understanding of behavior, and generated a written report summarizing findings and outlining recommended design objectives and key outcomes.	Due to the onset of the coronavirus pandemic coinciding with Aim 2 problem analysis, ECRI was unable to conduct in-home forensic investigation of home monitoring.
Knowledge Elicitation: Observations, Interviews, Focus Groups	
To validate and extend the early findings of problem analysis, we estimated response time to critical alarms by performing simulations of prolonged desaturations to $\leq 80\%$ using a modification of Kobayashi's method of connecting a simulator device to a bedside monitor on an active patient care unit. The device generates a waveform, resulting in central alarms and alarm messages sent to nurses' phones without alarming at the bedside. We observed responses for problems as well as best practices (aligned with Safety-2 principles). A debriefing focused on problems and barriers to responding immediately as well as adaptations that facilitated more rapid responses. (2) We conducted focus groups of physicians and nurses to delineate requirements for a re-engineered system of hospital monitoring, analyzing the findings with NVivo software.	To validate and extend the early findings of problem analysis, we performed semi-structured interviews with interview guides designed to explore in-depth the early findings of problem analysis with (1) 13 parents of patients with BPD currently monitored with SpO ₂ at home and (2) 12 physicians and nurses who manage oxygen and other respiratory support at home. Interviews with parents focused on their experiences with home SpO ₂ alarms, their work processes for logging hypoxemia events, overnight awakenings, alarm fatigue, and other barriers to using the oximeter as prescribed.

Our approach to the **Design** phase for both Aims was transdisciplinary and involved active collaboration between the Penn Integrated Product Design (IPD) Program, Penn Research in Embedded Computing and Integrated Systems (PRECISE) Center, and other members of the PSL and community. For both Specific Aims, we applied a same human-centered, participatory design approach. We began with experience mapping. We developed broad design objectives through an experience mapping process led by designer Sarah Rottenberg, Executive Director of the Penn IPD Program. Experience maps are tools used to visualize experiences over time from different perspectives and are developed based on qualitative and quantitative data with the aim of providing an actionable basis for design. Ms. Rottenberg and a group of IPD graduate students performed an in-depth review of the findings of problem analysis, including reports and source documents (e.g., interview transcripts). They also engaged other members of the Lab, Advisory Committee, and stakeholders previously engaged in problem analysis at points in the process to seek a deeper understanding

of specific experiences. The team highlighted specific deficiencies, gaps, and opportunities for redesign that were carried forward into development. Empathy in design was emphasized; this involves learning about the challenges people face, appreciating their emotional and physical needs, and understanding their environment and context. By articulating stakeholder needs in visual forms (stakeholder maps and storyboards), we grounded the entire team in a common understanding of the problem and the issues that mattered to stakeholders as we designed interventions.

Although we were not able to convene in-person prototyping sessions as originally planned due to the timing of the Design phase relative to restrictions of in-person research activities in the early coronavirus pandemic, we were able to convene a series of *virtual* design sessions followed by design selections to move forward into the Development phase. Design selection led by Rottenberg’s team entailed modified Delphi-style group discussion of candidate design ideas across both aims with scoring by stakeholders across effort and impact dimensions. Taking into account the scoring, final discussions were convened to reach consensus on the final items to carry forward into Development.

In the **Development** phase, we formed workstreams, with local experts directing each distinct workstream (Figure 1 below). These workstreams cut across both Specific Aims and pursued the further development of ideas brought forward from the Design phase. Each workstream ultimately narrowed their focus to ~1-3 Design phase ideas per aim.

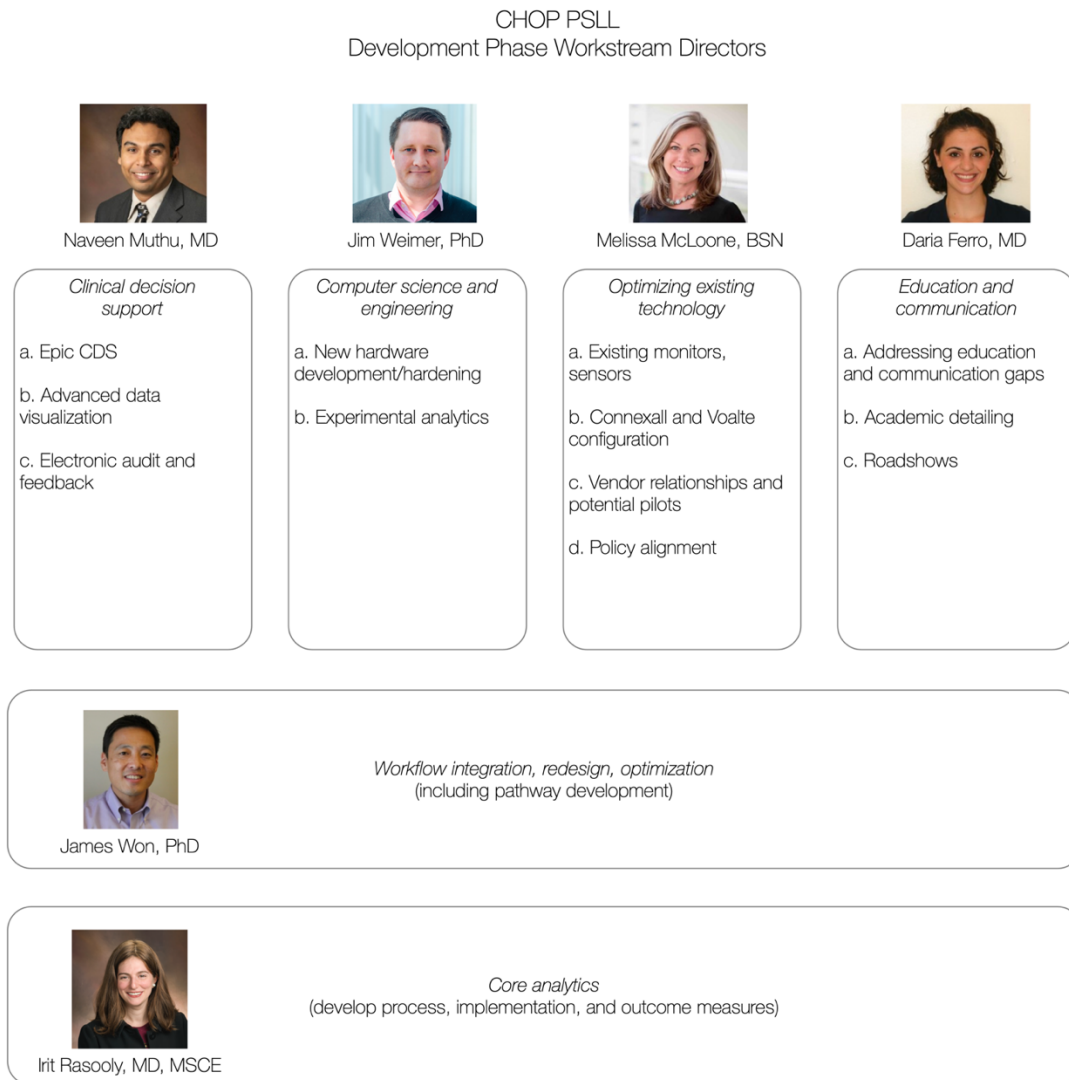


Figure 1. Development Phase Workstreams.

In the **Implementation** phase, we focused on taking the primary outputs from Development and (a) identifying key institutional partnerships that would aid in further testing, stakeholder engagement, and ultimately institutionalization of successful components; (b) working with key institutional committees and teams whose missions/goals/charters aligned with PSLL’s; and (c) testing Development outputs and then sharing the results

with key stakeholders poised to make decisions about institutional adoption. Given the wide range of activities and associated methods, please refer to the results section for full details.

Comprehensive details of methods and results of all components of the **Evaluation** phase for both specific aims are detailed in the results section of this report for ease of navigation.

RESULTS

Results of Problem Analysis for Specific Aim 1 (hospital monitoring):

National hospital monitoring guideline review and development: We reviewed available national guidelines focused on physiologic monitoring in pediatric hospital care outside the ICU setting. The only existing guidelines were focused on avoiding continuous SpO₂ in a very common pediatric condition, acute viral bronchiolitis. The PI, Dr. Bonafide, contributed PSLI effort to overseeing the collaborative writing of a new set of national guidelines for pediatric monitoring based on evidence and consensus. The project, called Best Evidence for Effective Pediatric monitoring (BEEP), was led by Amanda Schondelmeyer, MD, MSc, of Cincinnati Children's hospital. Dr. Bonafide was senior author.

Hospital policy analysis: We explored what CHOP policies, guidelines, and job aids say about who should be continuously monitored with continuous monitoring and when. We also examined whether CHOP's policies and guidelines are in alignment with national recommendations. Results of a Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis showed that, although institutional policies and guidelines exist, they are infrequently followed. They also don't cover a wide variety of diagnoses or severity of conditions. We discovered that there is an opportunity for the use of sophisticated clinical decision support in the EHR to mitigate current misalignment of guidelines with practice.

ECRI Hospital site visit and forensic analysis: We hosted successful ECRI Institute site visits in May 2019. ECRI engineers investigated nurse workflow and alarm effectiveness. They provided a written report summarizing their findings and outlining recommended design objectives and key outcomes. An illuminating finding from their visit was the use of continuous SpO₂ monitoring as a means of "babysitting" patients who are unaccompanied at the bedside during overnight hours. The recommendations based on their findings shaped our Development phase efforts in the Optimizing Existing Technology workstream, specifically in the area of alarm notifications sent to nurses' phones.

Alarm data warehouse analysis: We analyzed data including approximately 3 million physiologic monitor alarms occurring over an 11-month period on 15 non-ICU units at CHOP. Using these data, we gained an understanding of our hospital alarm exposure burden, with a typical patient who is continuously monitored generating 60-100 alarms per 24 hours. Because, at any given time, 30-50% of patients are continuously monitored at CHOP, a nurse caring for four patients would typically experience 36-100 alarms per 12-hour shift.

Relationship of alarm exposure to nurse workload: We analyzed the relationship between alarms and nurse workload on two inpatient units. Twenty-six nurses provided repeated reports (n=394) of their subjective workload in the preceding 2 hours using the NASA Task Load Index (TLX), a validated tool for reporting the experience of workplace situational demand. We also obtained alarm counts for the nurses' assigned patients during that time period and other demographic, patient, and unit characteristics. We used multivariable linear mixed effects regression and found that, after adjustment for acuity and patient load, nurses exposed to 40+ alarms in the preceding 2 hours (the highest decile of alarm counts) experienced statistically significantly higher subjective workload than nurses with lower alarm exposure rates.

Kobayashi alarm response time simulation: In order to determine accurate response times to alarms on our general inpatient pediatric units, we developed an in-situ simulation modeled after prior work by Kobayashi et al that allowed us to evaluate the performance of the established work system's ability to detect and respond to simulated life-threatening critically low SpO₂ (<70%) alarms that appeared to be originating from actual patients. We completed 19 simulations on two units. Of the 19 simulations, nine (47%) simulations resulted in a positive recognition and response to the bedside to the critical alarm within 10 minutes. Seven (37%) concluded at 10 minutes with no response. In three (16%), the simulations ended due to a caregiver arriving to the room to provide routine care without having noticed the critical alarm.

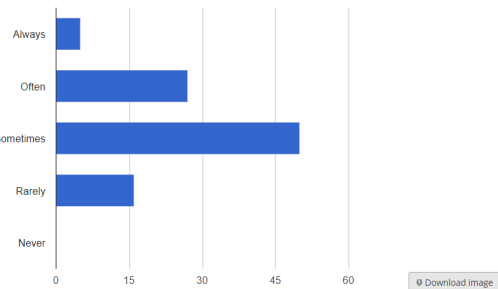
Nurse questionnaire

We administered an in-person questionnaire to 98 bedside nurses, inquiring about practices and attitudes related to physiologic monitoring. Sample results are shown below:

In the past month... I had to ignore alarms sent to my phone so that I could safely perform other important tasks. (*ignore_alarms*) [Refresh Plot](#) | [View as Bar Chart](#)

Total Count (N)	Missing	Unique
98	0 (0.0%)	4

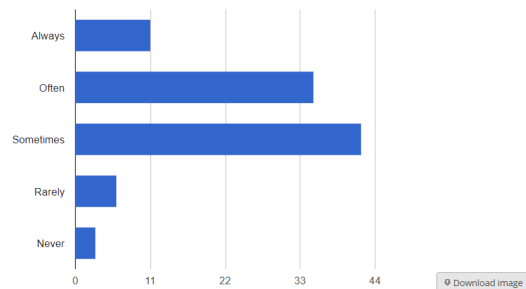
Counts/frequency: Always (5, 5.1%), Often (27, 27.6%), Sometimes (50, 51.0%), Rarely (16, 16.3%), Never (0, 0.0%)



In the past month... I felt overwhelmed with the number of alarm messages I received on my phone. (*felt_overwhelmed*) [Refresh Plot](#) | [View as Bar Chart](#)

Total Count (N)	Missing	Unique
97	1 (1.0%)	5

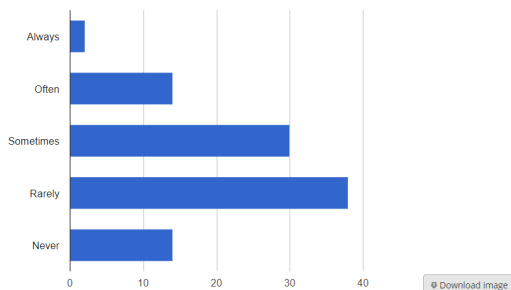
Counts/frequency: Always (11, 11.3%), Often (35, 36.1%), Sometimes (42, 43.3%), Rarely (6, 6.2%), Never (3, 3.1%)



In the past month... I have had to make sacrifices in the care I deliver to patients because of the number of alarms I experienced. (*sacrifices_in_care*) [Refresh Plot](#) | [View as Bar Chart](#)

Total Count (N)	Missing	Unique
98	0 (0.0%)	5

Counts/frequency: Always (2, 2.0%), Often (14, 14.3%), Sometimes (30, 30.6%), Rarely (38, 38.8%), Never (14, 14.3%)



In the past month... Families expressed frustration to me about their experience with monitor alarms. (*families_alarms*) [Refresh Plot](#) | [View as Bar Chart](#)

Total Count (N)	Missing	Unique
98	0 (0.0%)	5

Counts/frequency: Always (8, 8.2%), Often (37, 37.8%), Sometimes (33, 33.7%), Rarely (13, 13.3%), Never (7, 7.1%)

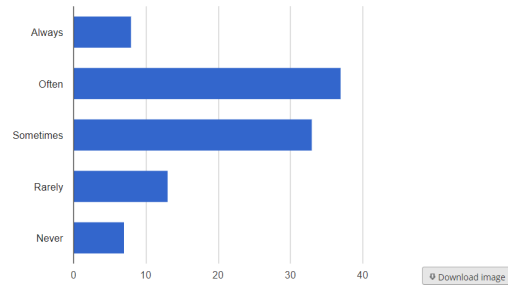


Figure 2. Representative results from Aim 1 Problem Analysis nursing questionnaire about monitor alarms.

Overmonitoring extent measurement

We used SpO₂ data automatically transmitted from monitors to the electronic health record (EHR) to determine the extent of SpO₂ use in children with bronchiolitis. We analyzed 627 inpatient stays for bronchiolitis between 9/1/2019 and 1/1/2020, representing over 16,000 hours of continuous monitoring data. The average length of stay was 2.43 days. Analyzing exclusively time spent continuously monitored outside of guideline recommendations, patients were monitored for more than 4 excess hours in 46% of hospitalizations and for more than 12 excess hours in 18% of hospitalizations. On average, 14.5% of patients' total length of stay involved continuous monitoring outside of guideline recommendations. We concluded that the use of EHR-extracted monitoring data demonstrates high rates of continuous SpO₂ overuse in hospitalized children with bronchiolitis. This automated method has excellent potential to provide real-time, comprehensive assessments of actual monitoring practices without requiring in-person observation.

We also gained an understanding of the extent of current hospital SpO₂ overmonitoring by benefiting from a separate project for which Dr. Bonafide was PI, U01HL143475, Preparing for a hybrid trial of SpO₂ de-implementation in stable infants with bronchiolitis. In this study, the team used direct observational methods in 58 hospitals in the U.S. and Canada to measure overuse. In this project, we found that important predictors of SpO₂ overuse were patient age, recent transition off of supplemental oxygen, and night shifts. The U01 team collected 3,612 total observations nationwide and 154 at CHOP. The overuse rate (percent of patients who should not be continuously monitored according to Choosing Wisely and American Academy of Pediatrics but are monitored anyway) was 46% nationwide and, at CHOP, was 23%.

Hospital clinician focus groups

We conducted three focus groups of hospital clinicians (each a mix of physicians and nurses of varying experience) to delineate requirements for a re-engineered system of hospital monitoring focused on reducing noninformative alarms and accelerating nurse responses to critical events. The following recommendations were suggested directly from the focus groups: 1) Improvements to protocols (e.g., more guidance on re-evaluation and discontinuation criteria, parameter suggestions that incorporate more patient-specific variables, protocol suggestions embedded into ordering and other clinical workflows); 2) improvements to monitoring devices (e.g., better probes, “smarter” devices that could “learn” profile of patient, video stream to add context); 3) improvements in ease of data accessibility and display (e.g., trends over time, ability to connect to mobile devices); and 4) improvements in physical layout of patient care areas/units (e.g., monitored patients with less distance for nurses to silence alarms). There were some suggestions for improving the alarms themselves (e.g., different tones, longer alarm delays), but overall clinicians felt that a focus on the other aspects of the alarm system would likely improve the alarms as an outcome of the system change.

Overall, the focus groups confirmed the experience of hospital clinicians dealing with alarms at CHOP (our local context) is consistent with the literature findings (more general context) and the PSLT team’s understanding of the current system and local clinician experience. The focus groups also validated/reinforced some of the team’s initial ideas regarding potential areas of improvement. Finally, the focus groups have helped provide our team with confidence that we would be designing with empathy, because we learned directly from a representative sample of end users whose language we could adopt in education and communication with providers and hospital leaders to describe pain points and impact of solutions when we moved into the Implementation and Evaluation phases.

Results of Problem Analysis for Specific Aim 2 (Home Monitoring):

Qualitative interviews with clinical staff involved in monitoring infants with bronchopulmonary dysplasia at home: We conducted 12 semi-structured interviews with clinical staff (physicians, nurses, respiratory therapists) with a wide range of experience. Our goal was to elucidate themes regarding workflows for accessing SpO₂ values and alarm data for patients monitored at home and how that data is used to make medical decisions. Furthermore, we probed interviewees for their ideas related to requirements for a re-engineered system of home monitoring that would improve patient and care provider experience. Interviewee needs fell into several categories: 1) easier access to patient data, 2) more reliable/detailed data outputs, 3) “self-correcting” or “smarter” technology, 4) incorporation of an additional modality to provide context for home monitor data (e.g., video), 5) hardware improvements (e.g., more portable machines, connections to personal devices, better probes, etc.), 6) more home nursing staff, 7) prompts/best practices for re-evaluation of home monitoring needs, and 8) improvements to electronic health record interfaces (e.g., ordering). These interviews, the extracted themes, and potential ideas were subsequently used in the Design phase to create experience maps and begin to explore small tests of change for improvements to the home monitoring system.

Qualitative interviews with parents of monitored infants with bronchopulmonary dysplasia at home: We completed 13 semi-structured interviews with families of children prescribed home monitoring to elucidate the “lived experience” of home monitoring. The analysis revealed that families of children with home monitoring have a complex relationship with the requisite devices and alarms. They experience competing priorities that begin upon initiation of home monitoring. This was associated with a wide range of feelings about the monitors, unique reasoning to assess alarm veracity, and the development of various adaptations used to make home monitoring less burdensome. These topics were explored through a framing of the SEIPS framework. Suggestions for improvement and advice for other families tended to be focused around the reduction of false alarms and an increase in consistent probe connectivity. This included emphasis on increased user friendliness, such as reducing the number of cords, improving portability, and having “remote control” (e.g., silencing from a distance). Additional suggestions included improvements to 1) communication/expectations (e.g., clearer goal setting, better transparency about how data and information is related to medical team from the devices) and 2) education/contingency planning (e.g., developing individualized patient-specific “logic models” for interpreting alarms). These findings will be the launch point for the Design and Development phase.

Analyze home care SpO₂ monitor prescribing data: We examined and extracted relevant data from CHOP Home Care records of prescribed pulse oximeters from the prior 3 years. We discovered an incredible variability in alarm prescribing practices (specifically, wide variation in low SpO₂ alarm thresholds and instructions on when specifically to apply the monitor) and the frequent authoring of prescriptions by trainees, who may not give extensive consideration to the alarm burden families face at home. These findings suggest

opportunities for interventions, such as clinical decision support and education, to standardize appropriate monitor use and configuration at home in order to reduce the number of unnecessary alarms that families experience at home.

Specific Aims 1&2: Design

We completed the Design Phase collaboration with the Integrated Product Design program at the University of Pennsylvania in which we re-imagined and re-designed aspects of physiologic monitoring systems for hospital and home. We conducted extensive experience mapping exercises as well as virtual ideation sessions with stakeholders using Zoom with breakout rooms. The ideation process resulted in a total of 36 design ideas for Aim 1 (hospital monitoring), and 20 design ideas for Aim 2 (home monitoring).

We then engaged in processes to combine and downselect design ideas, including plotting potential ideas in an impact/effort matrix in order to help decide which processes to bring into the Development Phase. We also continued collaboration with the Integrated Product Design program to ideate promising ideas in low-fidelity and higher-fidelity storyboards (see Figure 3 below for an example).

Idea: Alarm Context Checklist

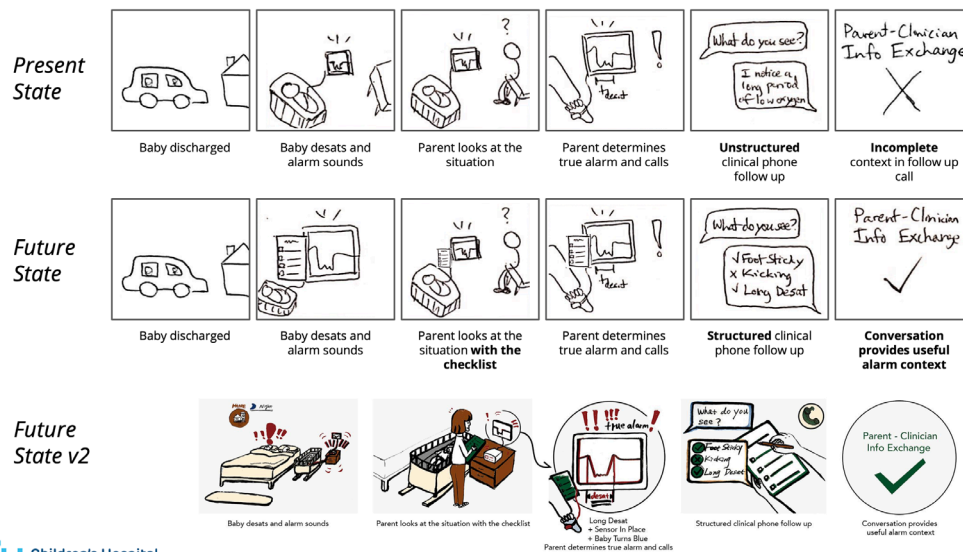


Figure 3. Alarm Context Checklist.

Comprehensive overviews of our PSLL’s Design Phase work were presented in the national PSLL Webinar Series as well as in a formal presentation at the Design Management Institute’s virtual Academic Design Management Conference, importantly shedding light on the value of partnerships between academic design organizations and the healthcare system.

Specific Aim 1: Development and Implementation

- The Education and Communication workstream has focused on academic detailing to promote effective alarm management within the organization. According to the AHRQ toolkit, “Academic detailing’s peer-to-peer visits help build leadership’s buy-in to the proposed practice changes and help them understand the role of practice facilitators, what they can and cannot do, and how they can help practices implement these changes.” The long-term goal of the CHOP PSLL was to remain as a sustainable structure for iterative problem analysis, design, development, implementation, and evaluation in order to solve challenging pediatric patient safety problems after the grant ended. As such, we devoted substantial effort to meeting with hospital leaders and peer stakeholders, using our data and promising results to promote integration of PSLL recommendations into new hospital governance structures and processes, including important evaluation infrastructures (technical, data) and methodology. We are collaborating extensively with hospital operations to establish new structures and/or reinforce existing structures that support patient safety. For example, we partnered with hospital operations to shape the newly formed CHOP Center for Healthcare Quality and Analytics Patient Monitoring Taskforce, which focused on minimizing unnecessary hospital physiologic monitor alarm burden to optimize patient safety and included six PSLL members on the taskforce.

- The Optimizing Existing Technology workstream focused on three main initiatives: (1) re-examining bedside monitor defaults to reduce nonactionable alarms; (2) actively participating in development, configuration, and simulation of new Connexall alarm middleware that replaced CHOP's outdated system of passing monitor alarm messages to nurses via mobile phones, a process which must be thoughtfully managed in order to avoid sending too many alarms and worsening alarm fatigue; and (3) in consultation with one of the foremost academic researchers in alarm sounds (Joe Schlesinger, MD), we played a crucial role in helping CHOP select optimal notification tones for the nurses' devices.
- The Clinical Decision Support workstream focused on capturing real-time physiologic monitor data along with real-time data from the Epic electronic health record in a cloud application in order to use these data for clinical decision support applications, including development of a dashboard to identify patients who are continuously monitored with ECG and/or SpO₂ and display these patients with other contextual data (e.g., supplemental oxygen status). We envisioned the dashboard being paired with other Epic electronic health records updates, such as structured ordering of continuous monitoring, to allow for decision support for both appropriate initiation and timely discontinuation of physiologic monitoring.
- The Workflow Integration, Redesign, and Optimization workstream developed a personnel-based solution to excessive nonactionable alarms: the "alarm manager." Inspired by earlier descriptions of "monitor watchers" in the literature, but recognizing the vigilance challenges of the watcher task, the alarm manager was designed to be different by serving as an active participant in the management of secondary alarms to the nurse. Managing an entire unit's alarms simultaneously, the alarm manager actively filters nonactionable alarms by suppressing them before they reach the bedside nurse while amplifying actionable, critical alarms by directly calling the nurse when actionable alarms do occur. By doing so, the expectation is that the bedside nurse's cognitive workload will decrease while increasing their situational awareness – ultimately resulting in improved attention and care to patients. Early results were promising: we demonstrated a 97% decrease in alarms received by the bedside nurse, a 55% decrease in perceived workload as measured by the NASA TLX, and a 39% increase in perceived situational awareness. These promising initial results will be leveraged to develop a structured intervention of the alarm manager for subsequent evaluation.

Ultimately, in the hospital setting, the Optimizing Existing Technology workstream had the most successful interventions with the broadest operational support in the Development phase; therefore, the majority of efforts in the hospital setting focused on collaborating with the Physiologic Monitoring Task Force at CHOP to (a) re-examine and adjust bedside monitor alarm limit defaults to reduce nonactionable alarms and to (b) actively participate in development, configuration, and simulation of Connexall alarm middleware and Epic Clinical Communication systems that replaced CHOP's outdated system of passing monitor alarm messages to nurses via mobile phones, a process that required thoughtful management in order to avoid sending too many alarms and worsening alarm fatigue. Implementation of broader hospital alarm limits and the new alarm secondary notification system went live in the CHOP Main Hospital as well as at our new King of Prussia community hospital toward the end of the Implementation phase. This was made possible by our very close collaboration with the CHOP Physiologic Monitoring Task Force and hospital leaders.

Specific Aim 2: Development and Implementation

- The Computer Science and Engineering workstream launched development of front-end user dashboards for aggregating and visualizing home SpO₂ monitor data, with pulmonologists and nurses who manage home supplemental oxygen for infants with BPD as the target users. We developed the dashboards using a new platform called "Raprot: Rapid Prototyping Platform for the Internet-of-Medical-Things." This platform used a software foundation called ThingsBoard (<https://thingsboard.io/>) that provided an all-in-one data capture, storage, and visualization for the internet-of-medical-things. For this work, Thingsboard used real SpO₂ data that flowed from oximeters in children's' homes who were part of Co-I DeMauro's Thrasher Foundation-funded "Bronchopulmonary Dysplasia Saturation TARgeting (BPD STAR) Trial" (see **Figure 5**), which enabled the PSL to do the distinct, nonoverlapping work of dashboard development with live data feeds. Benefits of real-time visualization in this setting include confirmation of device connection and providing fine-grain monitoring for immediate feedback and system setup debugging by clinical staff without requiring engineering support.

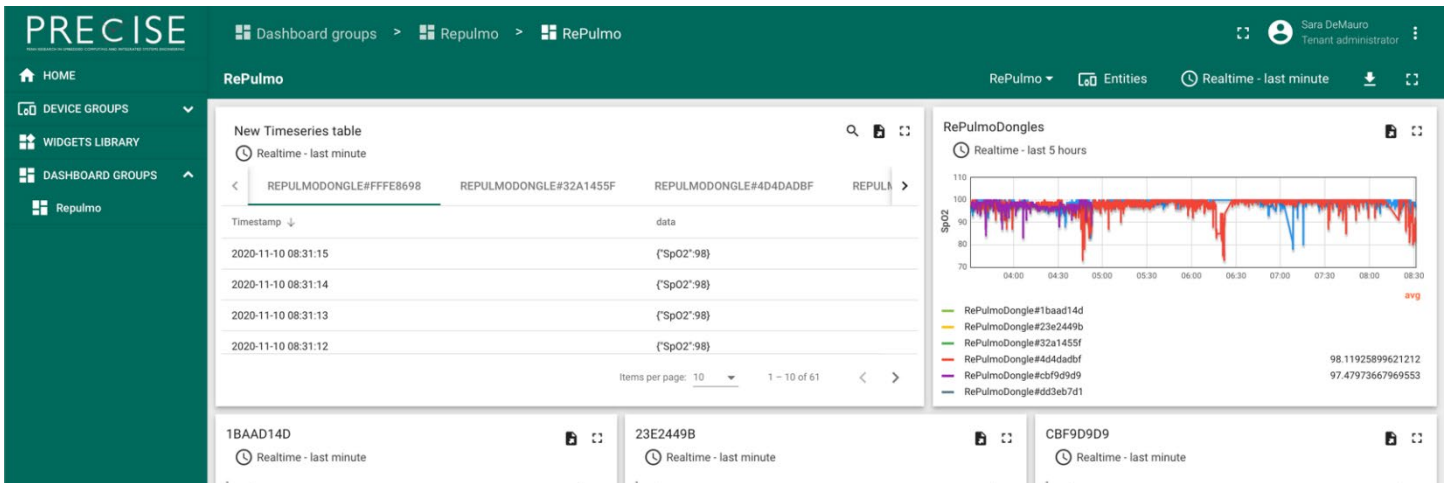


Figure 4. Data visualization with Thingsboard.

- In a related initiative, the Optimizing Existing Technology workstream explored a potential collaboration with the PCORI-funded “Implementation of Effective Home Oxygen Weaning Strategies in Premature Infants” study led by Lawrence Rhein, MD, MPH, of the University of Massachusetts Medical School, for which CHOP is a participating center. This study tested the implementation of a commercial system for remote home monitoring with Masimo pulse oximeters and measure the implementation and clinical outcomes. We developed a collaboration with the UMass team to expand this system at CHOP to also incorporate home monitor alarm data (in addition to SpO₂ values and trends) to further inform clinical decision making, a question distinct from the goals of the PCORI study that entirely aligned with Aim 2 of PSL. Ultimately the timing of the PCORI study with the PSL did not optimally align, but we have remained in touch with this group and may explore future collaboration opportunities.
- The Education and Communication workstream focused on development of the storyboarded alarm context checklist shown in the Figure. Using data from Problem Analysis parent interviews, we worked with the Integrated Product Design team at UPenn to ideate and storyboard potential solutions to help parents of children monitored at home with pulse oximeters. These storyboards were presented to families and clinicians to get their feedback on which to develop more. The concept of a home alarm decision aid that might help parents and caregivers more quickly learn and remember “algorithms” for addressing alarms in the home setting was highly favored. We developed a prototype of such a tool and rapidly iterated based on feedback from families and clinicians. Along with the tool, we designed and iterated on the implementation and evaluation. We piloted the intervention with families at the bedside prior to discharge and evaluated the experience from the educator and learner perspectives, with additional evaluation with families after they had been home to follow up on use and value of home decision aid. Although the tool was viewed favorably at first, subsequent discussions after families were home suggested that perhaps the value of such a tool was less than originally appeared, and this tool was not carried forward into Evaluation.
- The Clinical Decision Support workstream focused on developing decision support for the home SpO₂ monitor ordering process at the time of discharge from the hospital. As demonstrated during our Problem Analysis work, there is a high degree of variability in prescribed monitor settings at the time of discharge, and the prescribing provider is most often a trainee who may have limited understanding of appropriate alarm thresholds at home. The goal of this development was to streamline the discharge process and provide additional decision support prompting clinicians to set the alarm limits more broadly than they are set in the hospital to promote a lower rate of nonactionable alarm generation. To inform development, the workstream conducted 13 interviews with clinicians who are active in the discharge process (neonatology attendings and fellows, hospitalists, pediatric residents, nurses, home care staff, and case managers). Key findings were that the process for home monitoring is often driven by the case managers with the greatest opportunity to provide decision support at the junction of the case manager and the physician. The workstream focused on building an order for discharge inclusive of alarm parameters (with prompting for broader parameters at home than within the hospital) and supporting the appropriate ordering of home monitoring interventions.

In the home setting, ultimately the Clinical Decision Support workstream had the most successful interventions in the Development phase; therefore, the majority of efforts focused on developing decision support in

Epic for the home SpO₂ monitor ordering process at the time of discharge from the hospital. For the home setting, implementation of new decision support for the home SpO₂ monitor ordering process at the time of discharge from the hospital has been implemented and integrated into the workflows of ordering providers and home care staff who manage the acquisition of devices for use at home.

Specific Aim 1: Evaluation Phase

Evaluation #1: Building upon all of the prior PSL phases, we aimed to evaluate a set of interventions intended to reduce alarm rates, improve nurses' experience of alarms, and decrease alarm response time in 14 medical-surgical units at CHOP, using longitudinal data spanning from 2018 to 2023. For this phase, we critically partnered with the operationally led Alarm Management Task Force. PSL served as a close, collaborative partner functioning as the academic arm, and the Task Force supplied the additional stakeholder engagement and muscle to institutionalize the interventions in a way that would be incredibly difficult without their partnership. The interventions included alarm limit default reconfiguration and standardization across all medical-surgical units; updates to policies and provider order entry; clinician education; and introduction of new alarm system technology (middleware and smartphones). We triangulated three metrics of alarm system effectiveness: alarm rates (alarm notifications delivered to nurses' smartphones per occupied bed day); nurses' experience of alarms (survey); and critical alarm response time (in-situ simulation). We found that the interventions were associated with a 21% reduction in alarm notifications (27.4 to 21.6 per occupied bed day). At baseline, 68% of nurses agreed they had to delay response to alarms longer than they would have liked, decreasing to 46% after reconfiguration of alarm limits, and rebounding to 59% after introduction of the new alarm system technology ($p < 0.05$). Simulated critical alarm response time decreased from 5.6 (± 3.9) to 4.4 (± 4.3) minutes following reconfiguration of alarm limits, although this change was not statistically significant ($p = 0.35$). In summary, in the Evaluation phase, we observed modest improvements in the alarm system across three metrics post-intervention. However, the effects of the concurrent COVID-19 pandemic on patient volume and monitoring practices cannot be fully disentangled from the results (Figure 5 below).

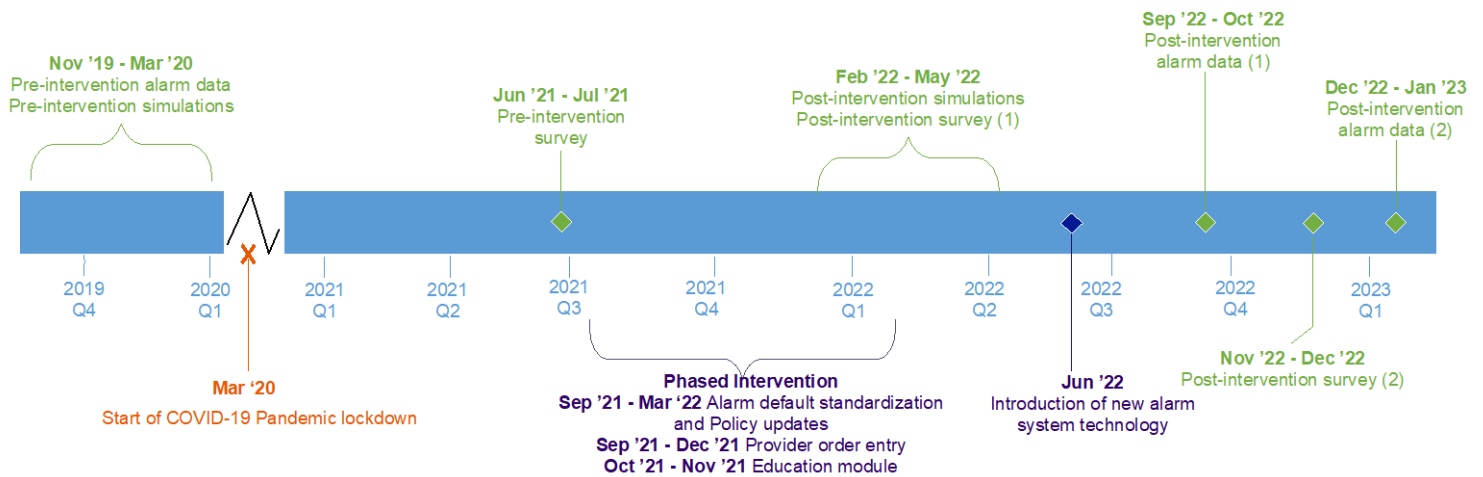
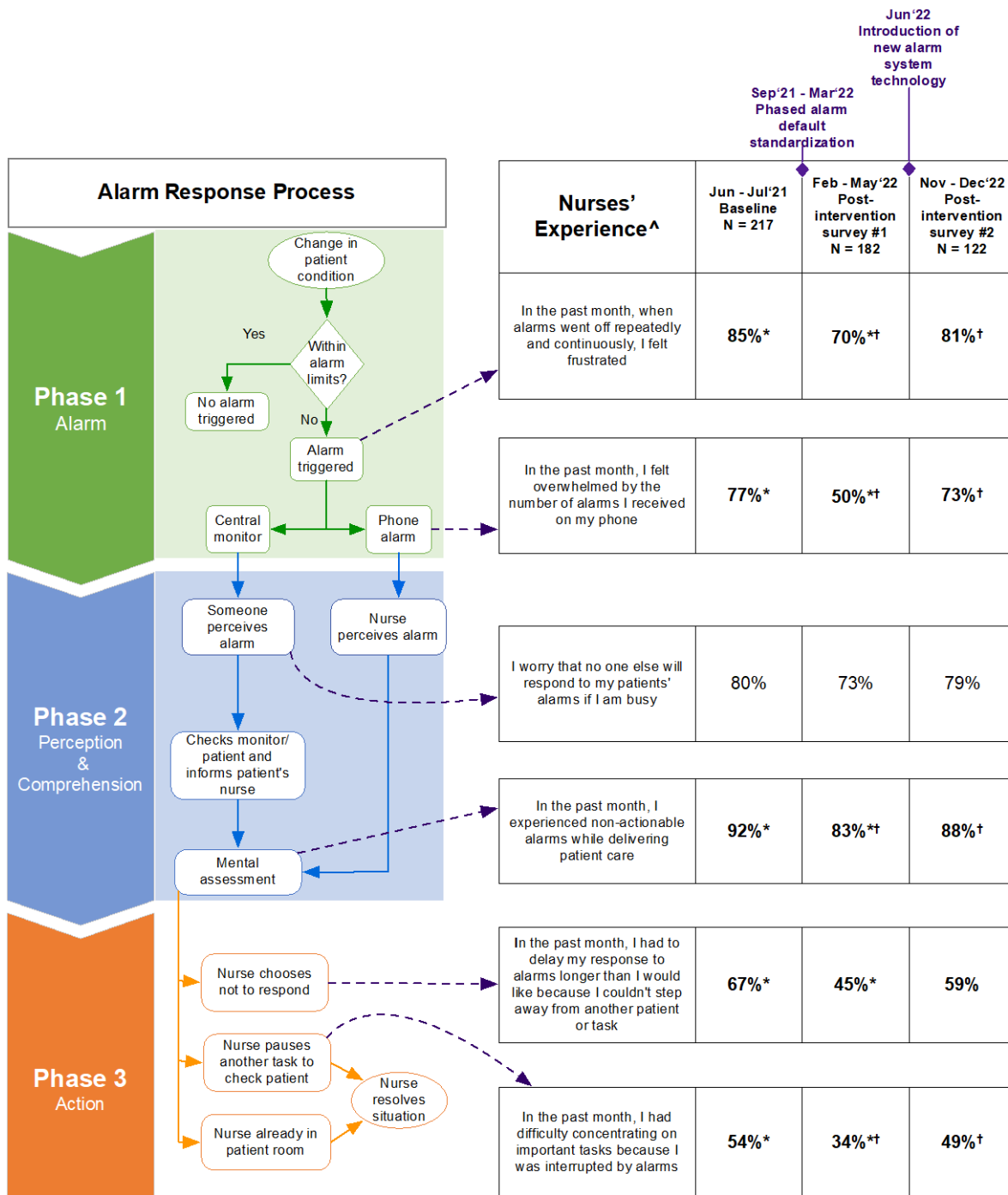


Figure 5. Timeline of alarm quality improvement project data collection and interventions.



Legend:

[^] Nurses' experience: percentage of survey respondents who selected always / often or strongly agree / agree. See Supplemental Table 2 for full list of survey items.

Bold: Kruskal Wallis rank sum test p value <0.05

*,† post hoc between-group Dunn test with Bonferroni correction <0.05

Figure 6. Alarm response process and experience map.

Evaluation #2: Consistent with routine hospital practices, our institution historically has applied established methods, such as root-cause analysis and failure mode effect analysis, to learn from events in which a patient experienced harm following nonresponse to a critical, actionable alarm. Although such strategies (categorized as Safety-1) are helpful, they generally conceptualize systems as predictable and composed of linear cause-and-effect relationships and thus incompletely account for the variability and complexity of clinical tasks, such as alarm response.

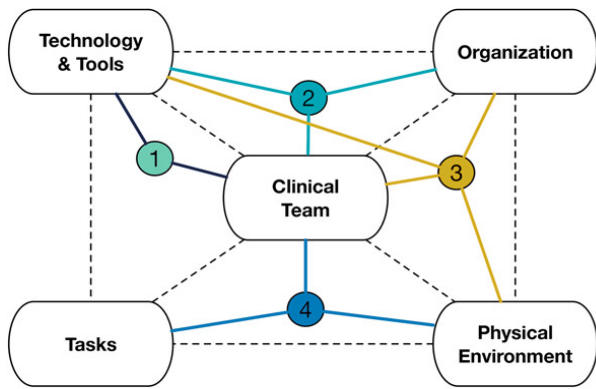
The tendency of Safety-1 approaches to oversimplify complex work has limited their impact and utility. Increasingly, safety scientists have argued for frameworks that recognize the inherent variability of healthcare, viewing the adaptations made by clinicians under varying conditions as sources of resilience rather than undesirable process deviations. Safety-2 approaches recognize that “things go right much more often than they go wrong” and thus seek to learn from everyday work instead of from (rare) adverse events. Understanding sources of system resilience (Safety-2) and supporting those features may prevent system failures. We sought to conduct in situ simulations to evaluate response to critical alarms in medical-surgical and critical care units of a pediatric hospital.

To accomplish this, we generated fictitious critical hypoxemic event alarms (simulated alarm) and routed the resultant notification to nurses' mobile phones (secondary notification) and the unit's centralized, remote display monitors (central monitors). The simulated alarms appeared to originate from an actual patient's bedside monitor but did not sound in the patient room nor alter the actual patient's physiologic waveform or numeric vital sign readout on the bedside monitor. Simulations concluded when a staff member responded to the simulated alarm (simulated-alarm response), arrived at the bedside for routine care (routine care), or elapsed after 10 min (nonresponse). Successful response was defined as either response to the simulated alarm or routine care; we considered arriving at the bedside (for any reason) to be alarm response because it is unlikely alarms would go unnoticed at the bedside.

Throughout the PSL award period, we conducted 59 critical hypoxemic-event alarm simulations, 39 in medical/surgical units and 20 in intensive care units (ICUs), between December 2019 and May 2022, with an overall successful response rate of 78% (46 of 59). Of the 46 responses, staff members responded to the simulated alarm in 85% (39 of 46) and arrived at the bedside for routine care in 15% (7 of 46). The median response time was 40 s. All responders were nurses. Nonresponse rate was 22% (13 of 59).

We observed four modes of critical alarm response that informed resilience:

- (1) Secondary notification of an alarm on nurses' phones was the leading means of alarm perception, observed in 82% (32 of 39) of instances in which staff members responded to the simulated alarm. During debriefs, nurses described utilizing device features to enhance perception of notifications—for instance, using auditory and/or vibratory manipulations and strategic positioning of phones (e.g., clipping phone to collar).
- (2) In team-based care, observed in 15% (6 of 39) of instances in which staff members responded to the simulated alarm, the respondent was not the primary nurse (e.g., leadership nurses, a nurse holding the primary nurses' phone). Observed team-based behaviors included nurses checking on each other, nurses checking on other nurses' patients, and phone handoffs when nurses left the unit.
- (3) Direct visualization of bedside monitors from outside the patient room. Particularly in the ICU, where nurses typically care for one to two closely roomed patients, direct visualization of patients and bedside monitors was a frequent mode of alarm response. Most ICU nurses (60%, 12 of 20) were directly outside the patient room at the time of simulation, allowing for instantaneous alarm perception and response. Comparatively, in medical-surgical units (where nurses typically care for ≥ 3 patients dispersed throughout the unit), nurses were most frequently observed to be working at centralized nursing stations (49%, 19 of 39).
- (4) Frequent presence at the bedside. In 12% (7 of 59) of simulations, the responding nurse did not perceive the simulated alarm via secondary notification, direct visualization, or a central monitoring station but nonetheless presented to the bedside for a different reason as part of routine care (e.g., medication administration) and would have been positioned to respond to a critical alarm. Organizational features (e.g., staffing models), tasks, and physical environment characteristics (e.g., size of unit and proximity to patients) facilitate the frequency of bedside interactions and contribute to resilience in alarm response.



1	Secondary Notification. Primary RN left the unit and gave their phone to another RN, who responded to an alarm for the Primary RN's patient.
2	Team-based care. RN spent over 1 hour in the patient's room prior to the initiation of the simulation. The observation team observed that during that time, the patient's ventilator alarmed three times. Another RN checked on the room/nurse each time to ask if the bedside RN needed any help.
3	Direct visualization of bedside monitors. Alarm occurred while RN was working on a computer. RN looked at phone for patient's alarm message information, then looked into patient's room via glass window next to computer to visualize the patient and the primary monitor, to determine if the alarm was valid.
4	Presence at the Bedside. The RN was in the nourishment room when the simulated alarm was sent. RN returned to room in less than 2 minutes. The RN expressed receiving a large number of alarms and that they did not perceive the simulated alarm. RN had returned to the patient room for other patient care.

Figure 7. SEIPS interactions diagram highlighting sources of system resilience. The SEIPS framework (left, dotted lines) overlaid with examples of sources of system resilience for alarm response observed during the simulations. The diagram highlights system interactions that contribute to successful alarm response.

Specific Aim 2: Evaluation Phase

Evaluation #1: Prior to our PSL, the true burden of home oximeter alarms and the impact of alarm parameters on alarm incidence was largely unknown in patients with BPD. In the Evaluation phase, we set out to assess the association of low SpO₂ limits, alarm delays, and averaging times with alarm incidence by simulating threshold adjustments using data from a clinical trial of continuous home SpO₂ monitoring among infants with BPD (The BPD Saturation Targeting Trial, NCT03385330). Among 20 infants, under typical post-discharge oximeter settings at our institution (90% limit, 0-second delay, 8-second averaging time), patients would experience a median (IQR) of 23.1 (16.0-53.0) alarms per 8 hours. Patients would experience a median of less than one alarm per 8 hours with an SpO₂ limit of 80%, a 15-second delay, and an averaging time of 8 or 16 seconds. Within each delay, lower SpO₂ limits were associated with lower alarm rates for both 8- and 16-second averaging times ($P < .001$). Within a given SpO₂ limit, longer alarm delays were associated with lower alarm rates (8-s averaging time: $P < .001$ for all SpO₂ limits; 16-s averaging time: 80%, $P < .001$; 85%, $P = .001$; 90%, $P = .003$). With a 0-s delay and a 90% SpO₂ limit, there was no significant difference in alarms per 8 hours between 8- and 16- second averaging times. We concluded that broadening SpO₂ limits and/or adding alarm delays can significantly decrease alarm rates while preserving alarms for episodes of potentially critical hypoxemia. Typical home oximeter settings (90% limit, 0-s delay) seem to create an untenable alarm burden for caregivers. Future studies to follow this PSL will need to assess the outcome of liberalizing home parameters to reduce alarm rates, which may include more uninterrupted sleep, decreased caregiver alarm fatigue, and improved compliance with home monitoring to optimize health and developmental outcomes.

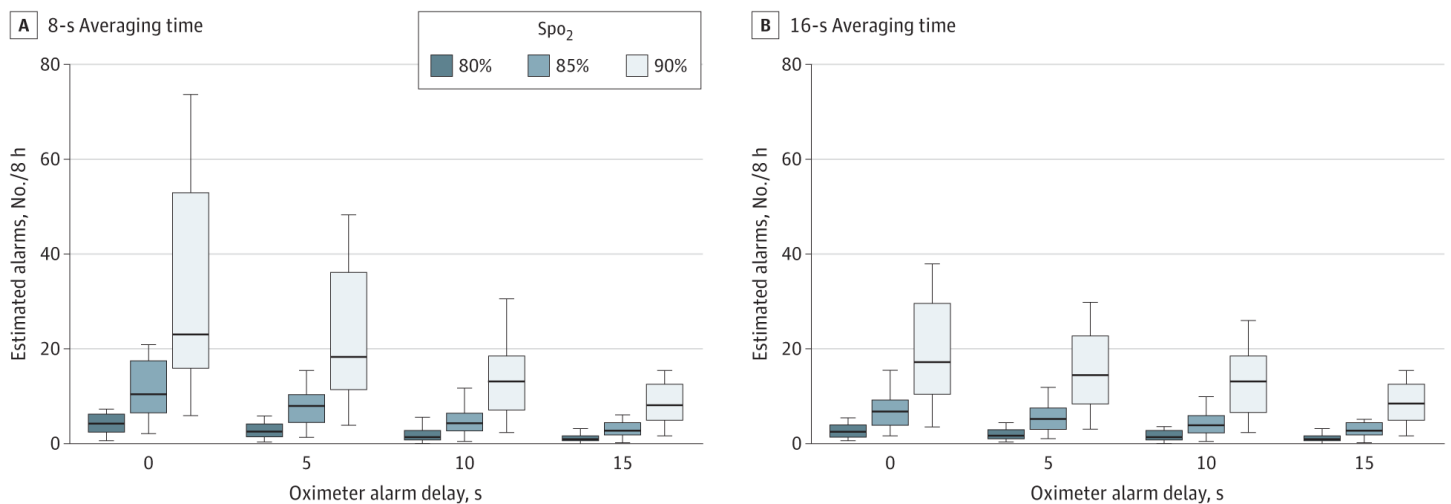


Figure 8. Low oxygen saturation (SpO₂) alarms across various saturation thresholds and alarm delays. The boxes represent the IQRs, with the horizontal lines indicating the medians. Whiskers indicate the ranges.

Evaluation #2: Building on learnings throughout the PSLL period, we aimed to improve the home oximetry ordering process using electronic health record clinical decision support (CDS), supporting more liberal oxygen saturation alarm limits. Therefore, we set out to compare home care oximetry orders of discharged children before and after CDS implementation. Order parameters included low SpO₂ limit, specification of intensity of use, an intervention plan, SpO₂ probe prescription, and order completeness. We extracted order details 6 months pre-CDS and 6 months post-CDS with a 1-month washout period. The CDS intervention used a letter template to include all required home oximeter order elements and provide more liberal age-specific default alarm limits. We found that there were 100 orders in the pre-CDS epoch (7/1/2021-12/31/2021) and 112 orders in the post-CDS epoch (2/1/2022-7/31/2022). The median low SpO₂ alarm limit post CDS implementation (87%, IQR 87%-90%) was significantly lower than the pre-CDS limit (90%, IQR 90%-90%, $p < 0.001$). In the post-CDS epoch, significantly more orders included an intervention plan (80% versus 31%, $p < 0.001$), prescribed pulse oximeter probes (85.7% versus 52.0%, $p < 0.001$), and were complete (68.8% versus 13.0%, $p < 0.001$). We concluded that CDS implementation resulted in a significant decrease in median low SpO₂ limit and a significant increase in home oximetry order completeness. In the context of our other findings of this PSLL, we believe that these changes may decrease home oximetry alarm burden and improve caregiver experiences with home SpO₂.

Summary and Next Steps

By proceeding through a five-step, systems engineering approach of Problem Analysis, Design, Development, Implementation, and Evaluation for hospital and home monitoring, we were able to gain an incredibly in-depth understanding of the problems associated with the current systems of physiologic monitoring and iteratively test solutions. In the hospital setting, close partnership with the operational Patient Monitoring Task Force was critical in implementing interventions that impacted key indicators of success, including reduction in alarm notifications, improvements in nurse reports of having to delay their responses to alarms, and a nonsignificant reduction in simulated critical alarm response time. We also used Safety-2 measures to capture best practices associated with alarm response resilience. In the home setting, we were able to use real data from children with BPD who were on monitors at home to deeply understand the burden of monitor alarms on families as well as make recommendations on how to curb unnecessary alarms. We then were able to implement clinical decision support to more closely align home monitor alarm limits with the recommendations we made. We view these accomplishments as highly successful, perhaps even more so given the challenges associated with conducting stakeholder-engaged research during a worldwide pandemic.

We are pleased to report that PSLL is now institutionalized at CHOP in 5 important ways:

- (1) Halley Ruppel, PhD, RN, a collaborator on our PSLL, was recently awarded a new PSLL award, also in the health technology space. The award, Resilient Communication Systems: A Pediatric Patient Safety Learning Lab (R18 HS029473), is to (1) conduct a problem analysis of the interprofessional communication work system and work processes used in the care of hospitalized children; (2) design and develop interventions to engineer a safer, more effective, and more resilient interprofessional communication work system; and (3) implement and evaluate the interventions in the clinical environment to gauge real-world impact. Bonafide is a Co-I on this grant and will ensure that the learnings from this PSLL directly inform and accelerate Dr. Ruppel's progress.
- (2) The Patient Monitoring Taskforce that was pivotal in our Aim 1 success has been institutionalized as the Patient Monitoring Committee and is now being led by one of our PSLL Nurse Collaborators: Melissa McLoone, BSN, RN.
- (3) The other of our critically important nurse collaborators, Meghan McNamara, BSN, RN, was recently named the Department of Nursing Safety and Quality Specialist for Informatics. McNamara will take the learnings and methods from PSLL and apply them to numerous incoming thorny challenges in health informatics at CHOP.
- (4) The Human Factors Program at CHOP, which was made up of one individual (PSLL Scientific Co-Lead James Won) when we wrote the PSLL grant, has now expanded to become the Human Factors and Systems Design Program and added SEVEN additional human factors engineers. Although we cannot take full credit for this growth, our collaboration with James and his team was one way that we introduced the value of human factors engineering paired with rigorous analytic methods to the CHOP organization.

(5) Brooke Luo, MD, PSLC Co-I, was named the Director of the Health IT Safety Program at CHOP, which will apply similar systems engineering approaches to (a) understand and solve major challenges in health IT that threaten patient safety as well as (b) find ways to use health IT to mitigate existing threats to safety that originate outside of health IT.

Inclusion of AHRQ priority populations: This project, conducted in a Children's Hospital care network, exclusively focused on children and adolescents, who are considered AHRQ priority populations.

LIST OF PUBLICATIONS AND PRODUCTS

In preparation or under review

Ruppel H, Luo B, Rasooly I, McNamara M, McLoone M, Kern-Goldberger A, Ferro DF, Brent C, Cieplinski JA, Irizarry J, Rottenberg S, Hehir D, Stinson HR, Makeneni S, Hamershock RA, Won J, Bonafide CP. A Systems Engineering Approach to Improving Alarm Management in Pediatric Medical-Surgical Units. *In preparation*.

Herrick H, McNamara M, Albanowski K, Pohl E, DeMauro S, Bonafide C, Muthu N. Clinical Decision Support for Pediatric Home Pulse Oximetry Orders. *Under review*.

Published

McLoone M, McNamara M, Jennings MA, Stinson HR, Luo BT, Ferro D, Albanowski K, Ruppel H, Won J, Bonafide CP, Rasooly IR. Observing sources of system resilience using in situ alarm simulations. *J Hosp Med*. 2023 Oct 9; doi: 10.1002/jhm.13217. [Epub ahead of print] PubMed PMID: 37811956.

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Herrick HM, Passarella M, Weimer J, Bonafide CP, DeMauro SB. Alarm Burden in Infants With Bronchopulmonary Dysplasia Monitored With Pulse Oximetry at Home. *JAMA Netw Open*. 2022 Jun 1;5(6):e2218367. doi: 10.1001/jamanetworkopen.2022.18367. PubMed PMID: 35737392; PubMed Central PMCID: PMC9227001.

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Kern-Goldberger AS, Rasooly IR, Luo B, Craig S, Ferro DF, Ruppel H, Parthasarathy P, Sergay N, Solomon CM, Lucey KE, Muthu N, Bonafide CP. EHR-Integrated Monitor Data to Measure Pulse Oximetry Use in Bronchiolitis. *Hosp Pediatr*. 2021 Oct;11(10):1073-1082. doi: 10.1542/hpeds.2021-005894. PubMed PMID: 34583959; PubMed Central PMCID: PMC8487905.

Rasooly IR, Kern-Goldberger AS, Xiao R, Ponnala S, Ruppel H, Luo B, Craig S, Khan A, McLoone M, Ferro D, Muthu N, Won J, Bonafide CP. Physiologic Monitor Alarm Burden and Nurses' Subjective Workload in a Children's Hospital. *Hosp Pediatr*. 2021 Jul;11(7):703-710. doi: 10.1542/hpeds.2020-003509. Epub 2021 Jun 1. PubMed PMID: 34074710; PubMed Central PMCID: PMC8478695.

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Rasooly IR, Bonafide CP. Making the Case for Limited Physiologic Monitoring in a Data-Hungry World. *Pediatrics*. 2020 Aug;146(2). doi: 10.1542/peds.2020-003756. Epub 2020 Jul 16. PubMed PMID: 32675333; PubMed Central PMCID: PMC7478855.

Awards

Our PSLI received two national awards for our AHRQ-funded work including:

- The 2021 AAMI & Becton Dickinson's Patient Safety Award, which recognizes outstanding achievements by healthcare professionals who have made a significant advancement toward the improvement of patient safety.
- The Biomedical Instrumentation & Technology Journal Editorial Board's Best Article of 2020 for our paper "Protocol for a New Method to Measure Physiologic Monitor Alarm Responsiveness."