TITLE PAGE

Title of Project:

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

Team Members:

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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) U

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

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<tr><td>We administered (1) a clinical alarms survey measuring attitudes and perceptions of alarms and (2)</td><td></td></tr>
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of specific experiences. The team highlighted specific deficiencies, gaps, and opportunities for redesign W K D W 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.

$ O W K R X J K we were not able to convene in-person prototyping sessions as originally planned due to the timing of the Design phase relative to restrictions R I 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.

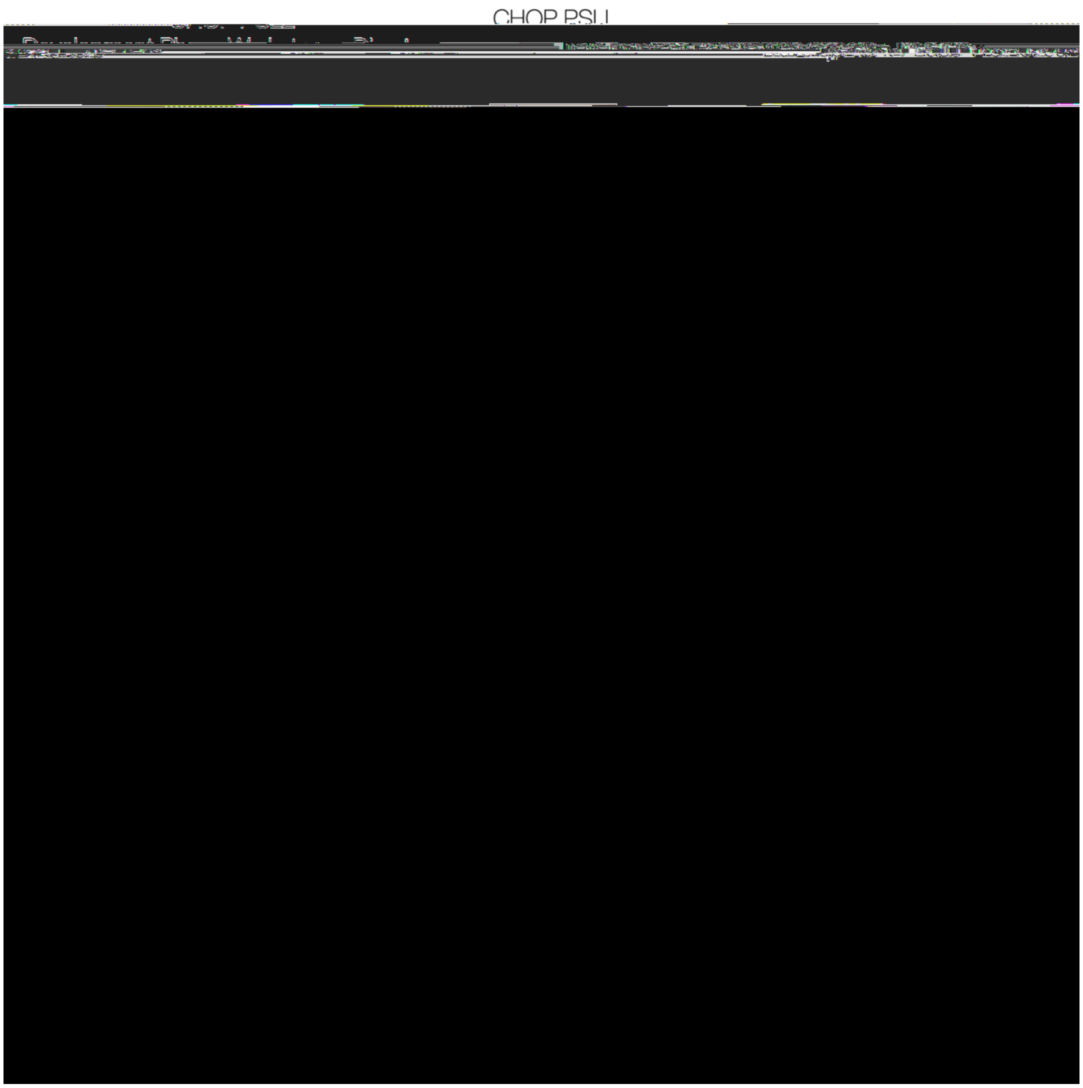

Figure 1 . Development Phase Workstreams.

In the Implementation phase, we focused on taking the primary outputs from D evelopment and (a) identifying key institutional partnerships that would aid in further testing, stakeholder engagement, and ultimately institutionalization of successful 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 bo th specific aims are detailed in the results section of this report for ease of navigation.

RESULTS

Results of P roblem A nalysis for S pecif ic Aim 1 (hospital monitoring) :

National hospital monitoring guideline review and development: We reviewed availabl e national guidelines focused on physiologic monitoring in pediatric hospital care outside the ICU setting. The only existing guidelines were focused on avoiding continuous SpO_2 in a very common pediatric condition, acute viral bronchiolitis. The PI, Dr. Bonafide, contributed PSLL 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 D O W K R X J K 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 t K D W Where 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 hos ted successful ECRI Institute site visits in May 2019. ECRI engineers investigated nurse workflow and alarm effectiveness. They provided a written report summariz1 Tc 0 T1h(pr)0.674 (ov)-1.821 (i)-1.13Tj 0.011 Hn op <0057>]TJ (o.297 -18.655 Td (pol)Tj)]TJ 0.019 Tj -0.0

Nurse questionnaire

We administered an in-person questionnaire to 98 bedside nurses, inquiring about practices and attitudes

Hospital clinician focus groups

We conducted W K U H H 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 non Lnformative 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) Lmprovements to monitoring devices (e.g. better probes, “smarter” devices that could “learn” profile of patient, video stream to add context) 3) Lmprovements in ease of data accessibility and display (e.g. trends over time, ability to connect to mobile devices) D Q G 4) Lmprovement V 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 W K D W D 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 PSLL 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 E H F D X V H 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 P roblem Analysis for S pecif ic Aim 2 (Home Monitoring):

Qualitative interview s with clinical staff involved in monitoring infants with bronchopulmonar y 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 SpO_2 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.e.g.

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.

Specif ic Aims 1&2: D esign

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 3below for an example).

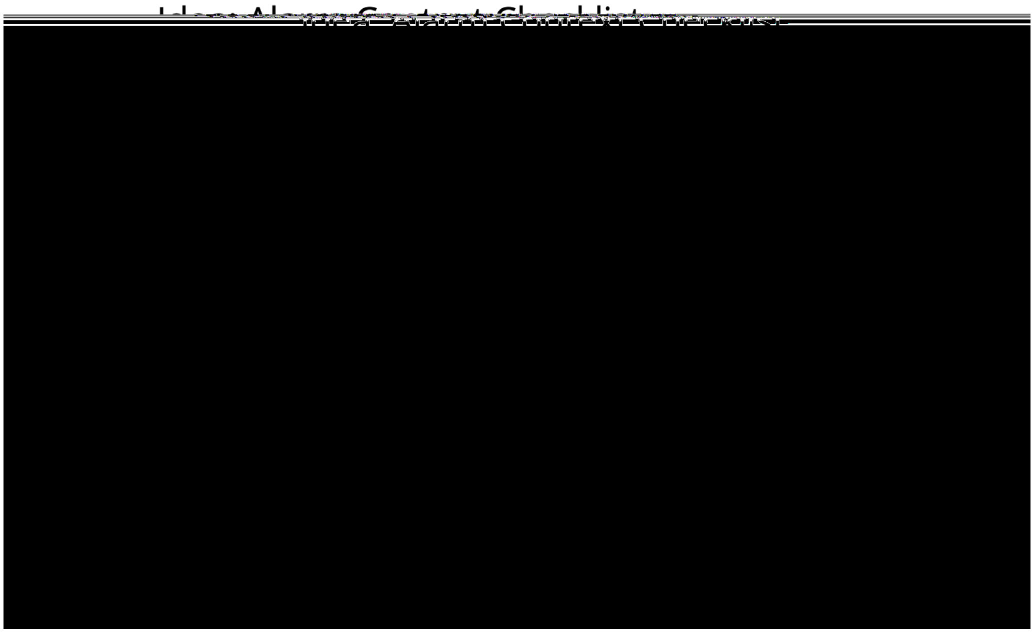

Figure 3. Alarm Context Checklist.

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.

Specif ic 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 V L [PSLL members on the taskforce.

- The <u>Optimizing Existing Technology</u> workstream focused on W K U H H 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 <u>Clinical Decision Support</u> 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 SpO_2 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 <u>Workflow Integration, Redesign, and Optimization</u> 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 D Q G W R (b) actively participate in development, configuration, and simulation of Connexall alarm middleware and Epic Clinical Communication systems W K D W 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

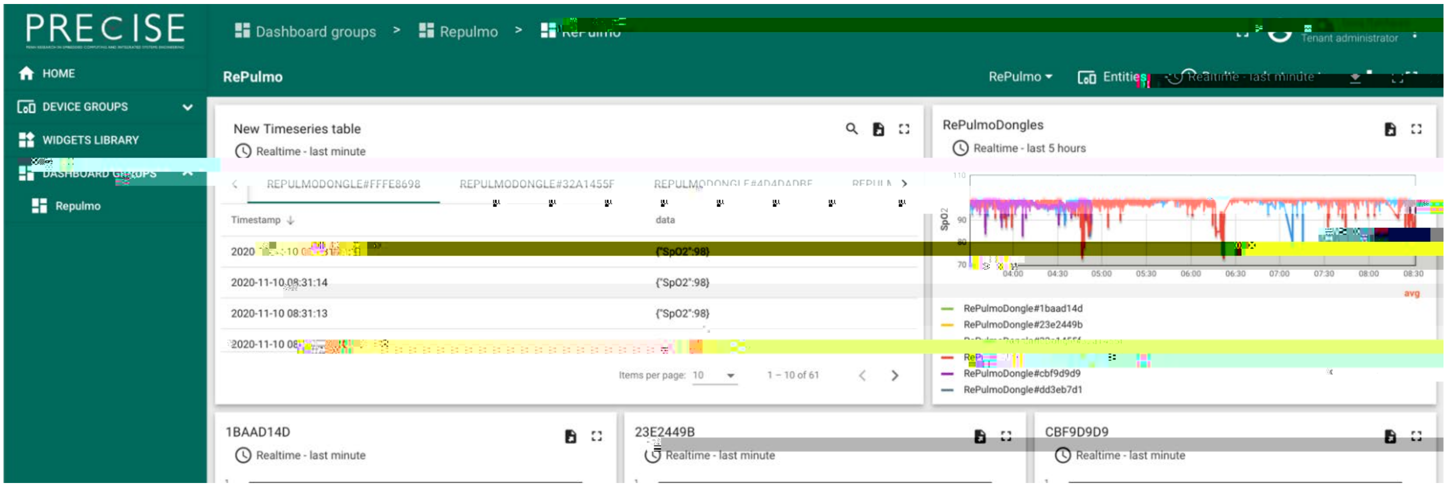

Figure 4. Data visualization with Thingsboard.

- 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 SpO_2 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 PSLL. Ultimately the timing of the PCORI study with the PSLL 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

Epic for the home SpO_2 monitor ordering process at the time of discharge from the hospital. For the home setting, implementation of new decision support for the home SpO_2 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.

Specif ic Aim 1: E valuat ion Phase

Evaluation #1: Building upon all of the prior PSLL 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. PSLL 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 providera5 rl

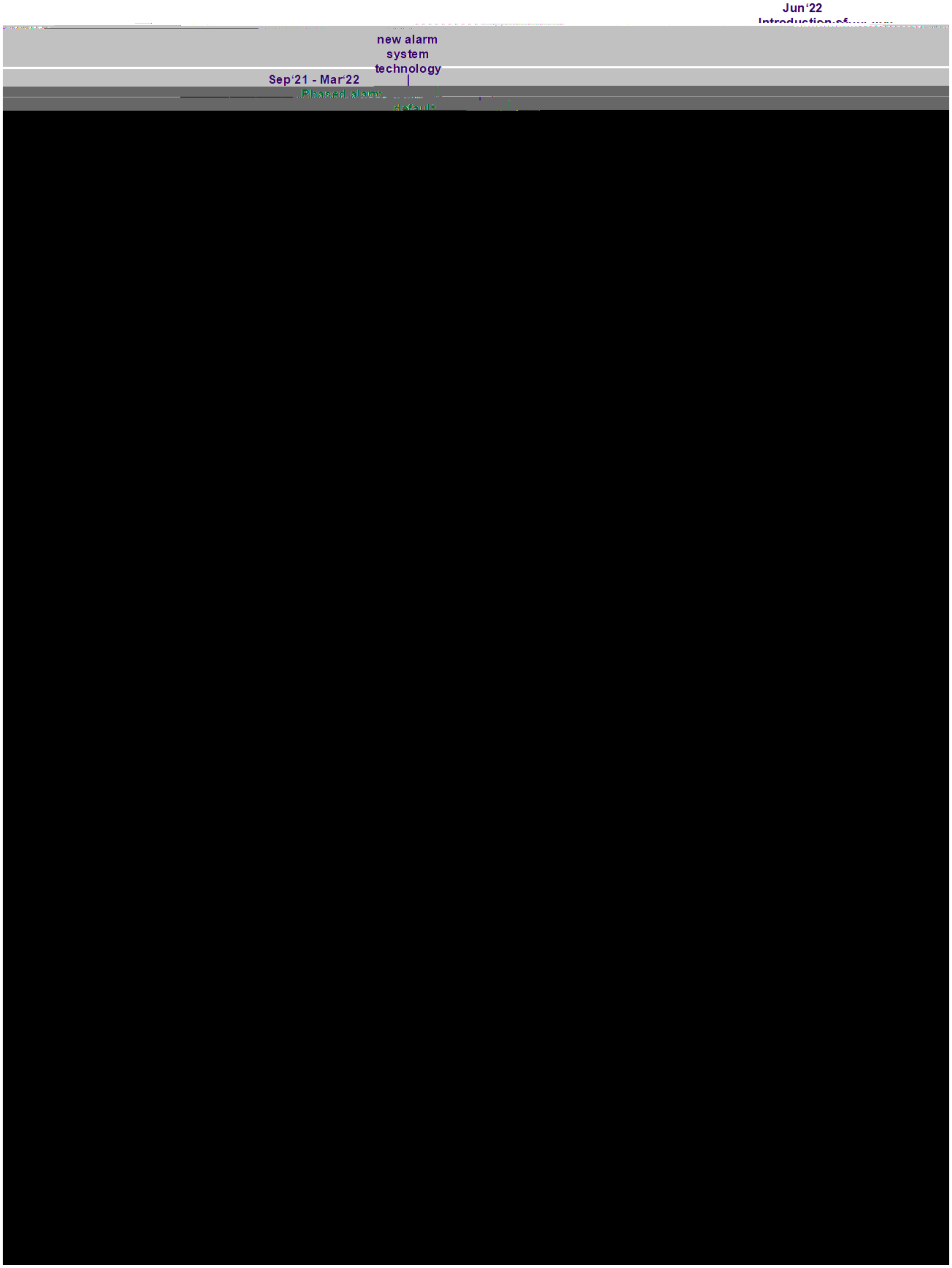

Figure 6. Alarm response process and experience map.

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 L Q   Z K L F K 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 th

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 phone V (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 DIWHU ×PLQ QRQUHVSRQVHZD6 XGFHHLVQVH%ODUHHLSWRQVUH UHVSRQV DODUP RU 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 PSLL 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 UHVSRQVH WLP$HOZDUVHV5RQGHUV ZHUH QXUZDHVV 1RQ-UHVSRQVH UDWH

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

Secondary notification of an alarm on nurses' phones was the leading means of alarm perception, observed in 82% (32 of 39) of instances LQ ZKLFK 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).

,QWeam-based care, observed in 15% (6 of 39) of instances LQ ZKLFK 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.

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 UHVSRQVH &RPSDUDWLYHO\ LQ PHGLFDO VXUJLFDO XQLWV ZKH GLVSHUVHG throughout the unit)

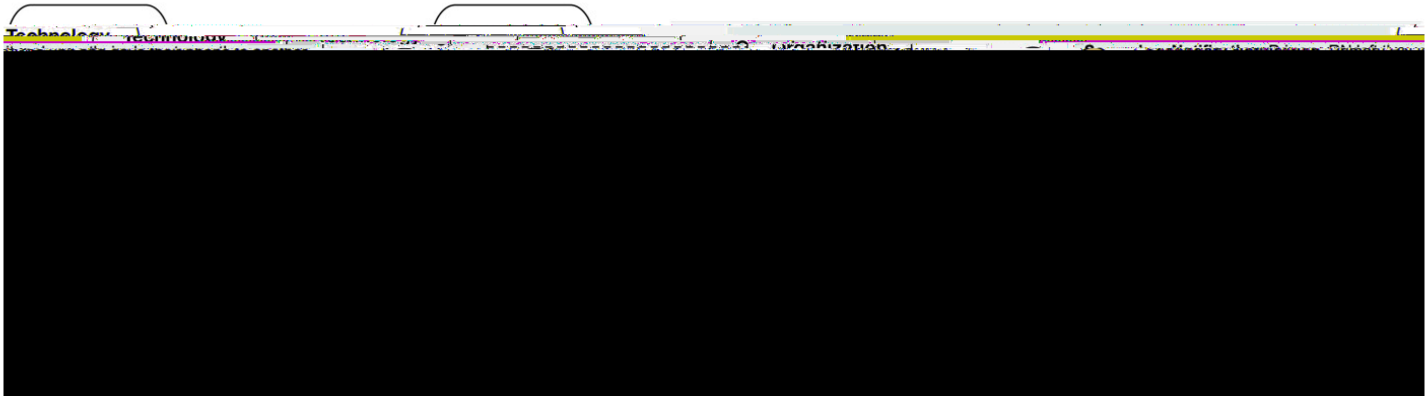

Figure 7. SEIPS interactions diagram highlighting sources of system resilience. The SEIPS framework (

(5) Brooke Luo, MD, PSLL 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

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.