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Abbreviations and Definitions of Terms

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
| CR monitor |  | Cardiorespiratory monitor |
| SpO2 |  | Peripheral oxygen saturation as measured by pulse oximetry |
|  |  |  |
|  |  |  |

Abstract

Please refer to abstract in eIRB.

**STUDY DIAGRAM**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Intervention** | **Unit 1-i** | Baseline data collection(16 weeks) | units paired and randomized to i/c | Phased intervention implementation (4-12 weeks) | Post-implementationdata collection(16 weeks) |
| **Unit 2-i** |
| **Unit 3-i** |
| **Unit 4-i** |
| **Control** | **Unit 1-c** | No implementation(4-12 weeks) | Post-implementationData collection(16 weeks) |
| **Unit 2-c** |
| **Unit 3-c** |
| **Unit 4-c** |

Figure 1. Study diagram. i = intervention, c = control.

# Background Information and Rationale

## Introduction

Hospital physiologic monitors can alert clinicians to early signs of physiologic deterioration, and thus have great potential to be life-saving. However, monitors generate frequent alarms, most of which are non-actionable.

 When clinicians become overburdened with alarms, they begin to exhibit alarm fatigue: responding more slowly to alarms or ignoring alarms entirely. **In this protocol we outline the methods we will use to evaluate the impact of a safety huddle-based intervention on physiologic monitor alarm rates using a pragmatic, paired, cluster-randomized controlled trial with the intervention delivered at the unit level.** This work is considered quality improvement research, and some of the approaches described in this protocol are from the field of quality improvement.

## Description of Intervention

The intervention consists of a monitor alarm dashboard that displays the numbers and types of alarms for each patient, and an accompanying huddle guide (part of appendix material) to guide data-driven discussion of 2-4 patients who had high alarm rates in the preceding 4 hours. Using the huddle guide, If the primary team confirms that the patient’s recent alarms were non-actionable, discussion will focus on a plan for reducing non-actionable alarms using interventions proven effective in other studies, such as adjusting alarm threshold values to actionable levels,1 changing delay time between when the threshold is crossed and when the alarm fires,2,3 and regularly changing leads.4

## Relevant Literature and Data

Hospital physiologic monitors can alert clinicians to early signs of physiologic deterioration, and thus have great potential to be life-saving. However, monitors generate frequent alarms, most of which are non-actionable.5–7 In a pilot study, our research team used video-based methods8 to determine that **87.1% of PICU and 99.0% of general inpatient unit clinical alarms were non-actionable**, meaning that they did not warrant clinical intervention or consultation.6

We know from the field of experimental psychology that humans rapidly learn to respond more slowly to alarms after being exposed to many false alarms, exhibiting “alarm fatigue.”9,10 Our research team aimed to determine if this phenomenon existed in the hospital during actual patient care. Using video, we found that **nurses had incrementally slower response time as the number of non-actionable alarms they experienced in the preceding 120 minutes increased, exhibiting behavior consistent with alarm fatigue**.6 In response to mounting evidence, in 2013 the Joint Commission named alarm fatigue the most common contributing factor to alarm-related sentinel events in hospitals11,12 and the ECRI Institute, a non-profit patient safety organization, named clinical alarms the top health technology hazard.13

Our **conceptual framework** for thecausal pathway between high rates of non-actionable alarms and patient harm, below, was informed by research and expert guidance. False (non-actionable) alarms lead to alarm fatigue, delaying responses to alarms that may represent true signs of deterioration, and interrupt error-prone tasks leading to potential patient harm.

**Figure 2.** Conceptual framework.

All patients do not contribute equally to the burden of non-actionable alarms. **Most alarms are caused by a small proportion of patients.** For example, the figure to the left displays data from one inpatient unit. Each bar is a patient, and the height of the bar represents the number of alarms in the previous 4 hours. Of the 14 monitored patients, 2 had extremely high alarm rates exceeding 100 alarms in 4 hours, or more than 1 alarm every 3 minutes.

Figure 3. Unit alarm burden.

Currently, at most hospitals data like this on the numbers of alarms that patients generate are only available to researchers with the software tools needed to interrogate and record data from the monitor network. **Our goal in this proposal is to bring this data to the safety huddles occurring daily on inpatient units in an accessible format to help teams make informed decisions about monitoring and minimize the potential of harm from alarm fatigue.**

## Compliance Statement

This study will be conducted in full accordance with all applicable Children’s Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, 21 CFR Parts 50, 54, 56, 312, 314 and 812. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent unless the requirements are waived, and will report unanticipated problems involving risks to subjects or others in accordance with The Children’s Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

# Study Objectives

## Primary Objective (or Aim)

Specific Aim 1: To evaluate the impact of a safety huddle-based physiologic monitor alarm reduction intervention on *unit-wide* alarm rates. The following rates will be evaluated:

1a. Alarms per patient-day

1b. Alarms per *monitored* patient-day

## Secondary Objectives (or Aim)

Specific Aim 2: To evaluate the impact of a safety huddle-based physiologic monitor alarm reduction intervention on the alarm rates *of the individual patients* whose alarms are discussed in the huddle.

Specific Aim 3: To evaluate the adoption and implementation fidelity of the intervention.

# Investigational plan

This study is on the pragmatic end of the pragmatic–explanatory trial continuum.

Table 1. Position of this study on the pragmatic–explanatory study continuum, adapted from Table 1 of Thorpe et al.14

|  |  |  |
| --- | --- | --- |
| Domain | Features of this study | Location on the pragmatic–explanatory trial continuum |
| Participants |  |  |
| Participant eligibilitycriteria | All participants who have the condition of interest are included in the unit-wide analysis in the primary outcome. The patients discussed in huddles on the intervention units will be suggested by research team members based on the numbers of alarms over the preceding 4 hours, but ultimately the decision about who to discuss in the huddle falls to the clinicians present. | more pragmatic than explanatory |
| Interventions and expertise |  |  |
| Experimental intervention — flexibility | The huddle intervention will be incorporated into the safety huddles already occurring on each unit in a flexible way that takes into account the existing structure of the huddle and the preferences of the unit staff. | more pragmatic than explanatory |
| Experimental intervention — practitioner expertise | The experimental intervention will be applied by the full range of clinicians involved in the safety huddle, regardless of their expertise. Research assistants will be available for guidance but will not run the huddle or dictate exactly how the intervention will be implemented or carried out.  | more pragmatic than explanatory |
| Comparison intervention—flexibility | The comparison, or control units will perform their huddles according to their usual routines. Since alarm management is a current Joint Commission National Patient Safety Goal, there may be interventions that arise on units related to alarm management that are out of our control. The PI is a member of the hospital-wide team charged with addressing this goal. We will monitor for new interventions on the study units and track their activities if and when they arise so that those factors can be accounted for in the analysis. | more pragmatic than explanatory |
| Comparison intervention — practitioner expertise | The comparison, or control units will perform their huddles according to their usual routines with the usual practitioners. | more pragmatic than explanatory |
| Follow-up and outcomes |  |  |
| Follow-up intensity | Follow-up of individuals discussed in huddles will be intense as a measure of intervention effectiveness at the individual patient level. | more explanatory than pragmatic |
| Primary trial outcome | The primary outcome of unit-wide alarm rates is an objectively measured, clinically meaningful outcome to the study participants. | more pragmatic than explanatory |
| Compliance/adherence |  |  |
| Participant compliance with “prescribed” intervention | Huddle participants’ use of the huddle dashboard and huddle guide will be monitored as a measure of fidelity. If unit compliance with the intervention is low, the research team will work with the unit to improve participation. | more explanatory than pragmatic |
| Practitioner adherence to study protocol | As above- practitioner is the participant. | more explanatory than pragmatic |
| Analysis |  |  |
| Analysis of primary outcome | The unit-wide primary analysis includes all patients and attempts to see if the intervention works under the usual conditions, with all the noise inherent therein. | more pragmatic than explanatory |

## General Schema of Study Design (see Figure 1)

This is a pragmatic, paired, cluster-randomized controlled trial with the intervention delivered at the unit level. The 8 participating medical units for the trial will be grouped into 4 pairs of units. Pairing will be based on (1) participation in hospital-wide alarm management quality improvement initiatives [2 of the 8 units that we will pair together], (2) baseline rates of alarms per patient-day, and (3) baseline monitoring practices including use of the mobile messaging gateway technology. One unit from each pair will be randomized to the intervention, and one will be randomized to control (no intervention). There are no patient- or staff-level exclusions.

### Baseline data collection (16 weeks)

In this period, baseline alarm data will be collected from all participating units. This will provide data that will be compared to the post-implementation data collected later. The baseline data to inform the unit pairings will also be obtained during this period.

### Phased intervention implementation (4-12 weeks)

During phased implementation, we will spend 1-3 weeks on each of the 4 intervention units intensively implementing the intervention, working closely with charge nurses and other staff to integrate alarm discussion into each unit’s existing safety huddles. The number of weeks we spend on implementation on each unit will depend on the needs and readiness of each unit as well as other factors that could delay readiness such as holidays.

### Post-implementation data collection (16 weeks)

During post-implementation data collection, we will continue to work closely with staff on each intervention unit to continue integration of alarm discussion into each unit’s existing safety huddles. We will simultaneously collect data from all intervention and control units.

## Allocation to Treatment Groups and Blinding

See Section 3.1 for the general schema of paired randomization. In order to keep the investigators blinded during the baseline data collection process, unit pairing and randomization within pairs will occur during the final 6 weeks of baseline data collection. Coin flip will determine which unit in the pair receives the intervention.

## Study Duration, Enrollment and Number of Sites

### Duration of Study Participation

Study participation will be at the unit level. Each unit will be involved for 16 weeks of baseline data collection, 4-12 weeks of phased implementation, and 16 weeks of post-implementation data collection **(up to 44 weeks total).**

### Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted on 8 medical inpatient units at The Children’s Hospital of Philadelphia only. The units are:

1. 4 West Seashore House
2. 5 East
3. 5 South
4. 5 West A
5. 5 West B
6. 8 South
7. 9 South
8. 7 West Medical Hospitalist Team

Primary subjects (clinicians):

Since we will be providing patient alarm information aimed at changing behavior of clinical staff and monitoring whether short-term behavior change in response to huddles occurred, **nurses and providers** (defined as physicians, nurse practitioners, and physician assistants) **are the primary subjects**. However, since the intervention is occurring at a unit-wide level and we are not collecting any identifiers on these primary subjects and all huddles will not be observed, it is not possible to accurately determine the actual number of nurses and providers whose behavior could potentially have been impacted by the intervention. It also will not be possible to identify when nurses and providers are exposed to the intervention repeatedly over time. In order to best estimate this number, we will “count” the involvement of 4 nurse and 1 provider subjects (5 clinical staff subjects) on each day that a huddle included discussion of alarms, acknowledging that this number will not be completely accurate but is a fair (over)estimate. Since the intervention is occurring on weekdays on 4 units over a 4-12 week implementation period and a 16 week post-implementation data collection period, and we will estimate that a huddle could occur up to 5 days/week on those days, we will estimate enrolling 28 weeks \* 5 days per week \* 4 intervention units \* 5 clinical staff per huddle = **2800 clinical staff subjects (a combination of nurses and providers).** When we report the “actual” number of primary subjects involved for continuing reviews and study closure, we will report the number of intervention huddles that we either attended or obtained a data collection sheet from the charge nurse on, multiplied by the estimated 5 clinical staff subjects, acknowledging that this may be an over estimate.

Secondary subjects (patients):

Aim 1a: For the Aim 1a unit-level outcome alarms per patient-day, we will, in a semi-automated fashion, collect bed occupancy (using patient-days) and alarm data from all patients hospitalized on the control and intervention units every day over the course of the 44 week study period in order to generate unit-level estimates. **Estimating 24 occupied beds per unit \* 8 units \* 44 weeks \* 7 days = 59,136 patient-days.** This is an overestimate of the number of patients impacted because most patients will stay more than 1 day. Since our alarm data source features patient identifiers (name and MRN) as an optional field that is not reliably nor accurately completed by nurses on the inpatient units, we will only consistently have bed number and date/time as identifiers on most patients. So, we will not be able to accurately report the number of unique patients contributing to the entire dataset of alarms. Thus we will report the number of actual patient-days over the course of the study period as the number of secondary subjects in continuing reviews and for study closure.

We will be collecting identifying data on each patient whose alarms are discussed in each huddle. We estimate discussing up to 4 patients per huddle \* 4 intervention units \* 5 huddles per week \* up to (16+12=28 weeks of huddles) = 2240 patients actively discussed in huddles and tracked. These patients are nested within all the eligible patients who contribute alarm data described above.

Aim 1b: Each pair of units will have one randomly-selected non-holiday weekday per week in the final 6 weeks of the baseline data collection period and one day per week in each week of the 16 week post-implementation data collection period that will be a “point prevalence of monitoring data collection day.” The random selection of dates will occur during the first week of each period. On these days, for the Aim 1b unit-level outcome alarms per *monitored* patient-day, we will, in a manual fashion, collect bed monitored status. These monitored patients are nested within the patient subjects described in Aim 1a above. This also will not involve collecting unique patient identifiers.

Aim 2: Also nested within the patients described in Aim 1a are the patients used to determine the Aim 2 patient-level outcomes. These patients will be studied on 16 “intensive patient data collection days” in the post-implementation data collection period.

On each intensive patient data collection day in the post-implementation data collection period, the 4 monitored patients currently hospitalized on each intervention and control unit with the highest number of “crisis” and “warning” alarms (the alarms that are generally high acuity and audible on the unit) at the time of the huddle— regardless of whether or not they were discussed in a huddle— will be identified for alarm data collection for patient-level comparison. We estimate that this will be 4 patients per unit \* 8 units \* 16 intensive patient data collection days = 512 patient subjects with identifiers collected, drawn from within the 59,136 potential subjects listed above.

Aim 3: Uses the same patients as above.

## Study Population

### Inclusion Criteria

Primary subjects (all Aims): Any nurse, physician, nurse practitioner, or physician assistant caring for a patient whose alarms are discussed in a safety huddle on an intervention unit.

Secondary subjects for Aim 1 analysis: All patients hospitalized on a control or intervention unit during the study period.

Secondary subjects for Aim 2 analysis: the 4 monitored patients hospitalized on each intervention and control unit with the highest number of “crisis” and “warning” alarms (the alarms that are generally high acuity and audible on the unit) at the time of the huddle (typically around 11AM).

* Intervention patients: those patients discussed in a huddle on intervention units
* Monitored patients on intervention units whose alarms are not discussed in the huddle
* Monitored patients on control units

### Exclusion Criteria

Primary subjects (all Aims): none.

Secondary subjects for Aim 1 analysis: none.

Secondary subjects for Aim 2 analysis (patients discussed in huddle and their controls): Discharge anticipated for the same day (determined by “anticipated discharge” column in Epic and review of Epic progress notes).

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

# Study Procedures

## Baseline data collection period (16 weeks)

* All intervention and control units performing data collection only

### In final 6 weeks of baseline data collection period:

* + Baseline data used to organize the units into matched pairs
	+ Randomized to control and intervention unit within each matched pair

## Phased intervention implementation period (4-12 weeks)

### Implementation phases

#### Unit 1-i implementation phase (1-3 weeks)

* Unit 1-i in active implementation
* All other intervention and control units in data collection only

#### Unit 2-i implementation phase (1-3 weeks)

* Unit 2-i in active implementation
* Unit 1-i in implementation support
* All other intervention and control units in data collection only

#### Unit 3-i implementation phase (1-3 weeks)

* Unit 3-i in active implementation
* Units 1-i and 2-i in implementation support
* All other intervention and control units in data collection only

#### Unit 4-i implementation phase (1-3 weeks)

* Unit 4-i in active implementation
* Units 1-i, 2-i, 3-i in implementation support
* Control units in data collection only

## Post-implementation data collection period (16 weeks)

* All intervention units in implementation support
* Control units in data collection only

# Study Evaluations and Measurements

## Descriptions/Definitions

In each period described above, the terms below are used to describe a set of procedures, evaluations, and measurements which we have called stages. The descriptions below state exactly what is entailed for each stage.

### Data collection only stage

* No intervention

#### Data collected every day

* + Bed occupancy data comes from Epic and the CHOP financial dashboard
	+ Data elements extracted from Epic:
		- date
		- time
		- unit
		- room
		- bed
		- occupied (yes/no)
	+ Data elements extracted from the CHOP financial dashboard:
		- unit
		- date
		- patient-days
	+ Alarm data comes from the GE monitor network, queried using Bedmaster software and/or the CHOP data warehouse (when available- incorporation into data warehouse is in progress at the time this protocol is being submitted). CHOP has been using Bedmaster in Biomedical Engineering for many years.
	+ Data elements extracted from the GE monitor network:
		- date
		- time
		- unit
		- room
		- bed
		- patient ID (a place where nurses can enter patient’s MRN; this practice varies by unit and is often unreliable; this element will therefore not be retained)
		- patient name (a place where nurses can enter patient’s name; this practice varies by unit but is often unreliable this element will therefore not be retained)
		- alarm start date and time
		- alarm level (the acuity of the alarm)
		- alarm message (the text of the alarm)
		- alarm duration

#### Point prevalence of monitoring data collection days in data collection only phase

* + Collect all data described above, plus:

##### Data for ascertainment of alarms per monitored patient-day

* + Occupied and monitored beds will be counted in the morning (6-9AM), afternoon (2-5pm), and evening (9PM-midnight)
		- Monitored status will be assessed by remotely viewing the monitor using Bedmaster and/or GE software. As a backup method if software is experiencing a downtime (unlikely), a member of the research team will assess monitored status by briefly walking into each patient room and visualizing the monitor to see if it is in use.

### Active implementation stage

#### The intervention

* Identify eligible patients for alarm huddle discussion and generate a corresponding alarm dashboard each weekday
	+ Eligible patients for whom an alarm dashboard will be generated include the 4 patients on each intervention unit with the highest number of crisis and warning alarms for that unit in the 4 hours preceding the huddle as determined using GE/BedMaster systems.
	+ The dashboard is available in paper and electronic formats. The electronic format uses QlikView and may be challenging for some units to access and use; we will therefore start with paper and then introduce electronic dashboard if there is interest from the units.
* Member of our team will attend and help facilitate alarm discussion in safety huddles each weekday using huddle guide
	+ Up to 4 patients per huddle will be discussed.
	+ Huddle guide is attached in the appendix. Given the pragmatic nature of this study (Table 1), the huddle guide may undergo minor modification or adaptation in a way that takes into account the existing structure of the unit huddle and the preferences of the staff. The “core components”15 of the huddle guide are shown in the algorithm figure below. Any other aspects of the huddle guide not considered core components will be considered “adaptable periphery.”15 If the modification or adaptation represents changes to the core components (for example, a change to the core components would be discussing alarms from a different type of medical device), we will submit an IRB amendments. If the minor modifications or adaptations represent changes to the adaptable periphery only, we will not submit IRB amendments.



Figure 4. Core components of huddle guide used to outline the discussion of monitor alarms.

* + In response to the discussion, care team may choose to do nothing, or may choose to take an action to reduce non-actionable alarms if clinically appropriate, including but not limited to widening alarm threshold values, lengthening delay time between when threshold is crossed and alarm, changing leads, or discontinuing monitor entirely
	+ Care team will be encouraged to enact the changes as soon as possible so they are not forgotten (e.g. place order, change settings)
* Charge nurse or designee will complete “huddle worksheets” (see appendix) with the following elements:
	+ Unit
	+ Date
	+ Patient names and room numbers of patients discussed
	+ Recommendations made for each patient (such as no changes, monitoring discontinuation or changes in intensity, specific changes to parameters, delay times, CR monitor lead changes, meticulous skin preparation, SpO2 lead changes, other)
	+ Whether or not the changes discussed were made, with a place to document the date and time the changes were made

#### Data collection during huddle

* + Patients discussed in huddle will have the following data collected by research staff at the time of the huddle and entered into REDCap:
		- Name
		- Unit/bed
		- Date of birth
		- Medical record number
		- Illness severity using pediatric early warning score (a score used in clinical care at CHOP) at the time of the huddle as a proxy
		- Primary diagnosis
		- Was the patient’s bedside nurse present in huddle?
		- Was a front line ordering clinician on the team caring for this patient present (resident physician, nurse practitioner, physician assistant, hospitalist physician)?
		- Was this patient’s attending physician present?
		- What recommendations and decisions were made regarding changes to monitoring?

#### Data collection 4 hours after huddle

* + Patients discussed in huddle will have the following data collected 4 hours after the time of the huddle (these are primarily focused on evaluating adoption and fidelity for Aim 3 and identifying barriers to high fidelity):
		- Which changes that were discussed were enacted within 4 hours of the huddle (such as parameters changed, delay times introduced, leads changed)? This may require briefly walking into each patient room and visualizing the monitor and/or asking the patient/family/nurse if leads were changed.
		- In situations where the changes were not enacted as discussed, a member of the research team will, in a non-confrontational way, ask the bedside nurse why they were not instituted in order to better understand and address barriers to the quality improvement intervention’s fidelity as early as possible (prior to Implementation support stage). Barriers identified will be recorded as field notes without clinicians’ identifiers and stored in a REDCap database.

#### Unit-wide data collection

#### Continues as in 5.1.1 Data collection only stage

#### Surveillance for code blue events, critical assessment team activations, and near miss events on patients discussed in huddles

* + At the beginning of each huddle guide, there is a prompt that screens for any recent critical assessment team activations, code blue calls, or near miss events related to monitoring or alarms (see appendix). The near miss definition is also on the huddle guide.
	+ In addition to prompting staff, we will, on a weekly basis, also screen the critical assessment team and code blue event hospital database maintained by the Resuscitation Committee. We will be looking for any events on patients previously discussed in huddles. The PI is a member of the Committee and has access to the database.

### Implementation support stage

* Member of our team will identify eligible patients for alarm huddle discussion and generate a corresponding alarm dashboard each weekday as described in section 5.1.2.1, The intervention.
* Member of our team will check in with charge nurse and provide alarm data to inform their alarm huddle discussion each weekday in person prior to huddle
* Member of our team will follow up with charge nurse after huddle to determine if a huddle occurred, collect the huddle worksheets documenting if alarms were discussed and in which patients, and to answer questions and provide feedback and guidance
* Data collection continues as in the baseline data collection period, see section 5.1.1.1 Data collected every day.
* Surveillance for code blue events, critical assessment team activations, and near miss events on patients discussed in huddles continues as in section 5.1.2.5.

#### Point prevalence of monitoring data collection days in implementation support stage

* Collect data for ascertainment of alarms per monitored patient-day as described in 5.1.1.2.1

#### Intensive patient data collection days in implementation support stage

* Research team member attends huddle and directly collects data described above in 5.1.2.2
* Collect additional data elements for fidelity evaluation on intensive patient data collection days as discussed in 5.1.2.3 and 5.1.2.4.

##### Data for patient-level comparisons

* + The 4 monitored patients hospitalized on each intervention and control unit with the highest numbers of “crisis” and “warning” alarms at the time of huddle will have the following data extracted into REDCap by research staff in addition to the data in the above sections. The focus is on evaluating changes in alarm rates between the 24h preceding the huddle time and the 24h following the huddle time.
		- Name
		- Reference date/time of huddle
		- Unit/Room/Bed
		- Was this patient in this bed for the 24h prior to the date/time of huddle?
		- Date of birth
		- Medical record number
		- Alarms discussed in a huddle (Y/N)
		- Illness severity using pediatric early warning score (a score used in clinical care at CHOP) at the time of the huddle as a proxy
		- Primary diagnosis
		- Was this patient in this bed for the 24h after the date/time of huddle?

## Safety Evaluation

Please refer to description of surveillance for code blue events, critical assessment team activations, and near miss events on patients discussed in huddles in section 5.1.2.5.

# STATISTICAL CONSIDERATIONS

## Primary Endpoint (Aim 1)

The primary endpoint is:

* The change in the unit-wide rate of alarms *per patient-day* between the baseline data collection period and the post-implementation data collection period for intervention versus control units.

## Secondary Endpoints

### Aim 1

* The change in the unit-wide rate of alarms *per monitored patient-day* between the baseline data collection period and the post-implementation data collection period for intervention versus control units.
* The change in the unit-wide number of minutes of alarms *per patient-day* and *per monitored patient-day* between the baseline data collection period and the post-implementation data collection period for intervention versus control units.

### Aim 2

* The difference in the rate of alarms in individual patients in the 24 hours after discussion in a huddle compared with:
* Themselves in the 24 hours before the huddle
* Patients on the same unit as the huddle but whose alarms are not discussed
* Patients on units without the alarm huddle intervention

## Secondary Endpoints (Aim 3)

* Adoption
* Proportion of huddles in post-implementation data collection period that included discussion of at least 1 patient’s alarms
* Fidelity
* Proportion of patients in whom lead changes were recommended who had leads changed within 4 hours
* Proportion of patients in whom parameter changes were recommended who had parameters changed in a direction consistent with the recommendations within 4 hours
* Proportion of patients in whom a change in monitor delay time was recommended who had delay time changed in a direction consistent with the recommendations within 4 hours
* Proportion of patients in whom monitoring discontinuation was recommended who were off monitor within 4 hours

## Statistical Methods

### Aim 1

We will first evaluate the primary endpoint using a 2-sample test of proportions. Next, we will perform an interrupted time series analysis using piecewise negative binomial regression accounting for the pairs of intervention and control units.

### Aim 2

Using a negative binomial regression model, will compare alarm rates over time, making (1) within-subject comparisons evaluating the numbers of alarms and the trajectories of alarm rates in the 24 hours before and 24 hours after each huddle, (2) between-subject comparisons of the difference in alarm rates in the 24 hours before and after each huddle among intervention patients and control patients (a) from the same unit as the huddle intervention but whose alarms are not discussed, and (b) from units without the huddle intervention. We will account for clustering by unit and adjust for age group and illness severity using pediatric early warning score at the time of the huddle as a proxy.

### Aim 3

We will analyze and report these rates as simple proportions stratified by unit and patient age. We will also generate a composite fidelity score that combines the numerators and denominators from all 4 of the fidelity outcome measures to summarize the total number of times the intervention was followed through divided by the number of opportunities.16

## Sample Size and Power

We have powered the study based on Aim 2 (patient-level outcomes) because it draws data only from the post-implementation data collection period.

Since there have not been any studies on huddle interventions for alarm management before, we have little data to guide power calculation. However, Dandoy and colleagues evaluated the impact of a standardized cardiac monitor care process on a pediatric bone marrow transplant unit at Cincinnati Children’s and found a reduction from a median of 180 alarms per patient-day to 40 during the study period, a 78% reduction.16 A starting median of 180 is high, and their effect was the result of multiple interventions, so the estimates we use below are more conservative.

 To estimate sample size, we used a two-sample paired means test based on detecting the *difference in differences* between pre- and post-huddle alarms per 24 hours among control and intervention patients. CHOP’s baseline alarm rate on wards is approximately 90 alarms per monitored patient-day. We will be purposefully recruiting high alarm patients. We will therefore conservatively estimate a baseline mean of 100 alarms over the preceding 24 hours. We hypothesize that both intervention patients discussed in huddles as well as control patients not discussed in huddles will have fewer alarms in the 24 hours after huddles because most will be clinically improving, and some controls will have changes made to their alarm parameters to reduce non-actionable alarms even without having been discussed in a huddle. So, we will estimate that, in the 24 hours after the huddle, control patients will have a mean of 75 alarms. **We hypothesize that intervention patients will have 20% fewer alarms than controls** (mean of 60 in the 24 hours after the huddle). We have conservatively estimated the standard deviation of the difference between intervention and control over 24 hours to be 50-75 alarms. The number of intervention-control pairs of patients needed based on different combinations of the delta in alarms/24 hours and standard deviation are shown in the table below.

|  |
| --- |
| **Table. Sample size needed for 80% power to detect difference in differences, alpha = .05.** |
|  | Baseline mean number of alarms in 24h prior to huddle | Discussed in safety huddle? | Mean number of alarms in 24h after huddle | Difference compared to controls | # of intervention-control pairs needed if SD of difference is 50 alarms | # of intervention-control pairs needed if SD of difference is 75 alarms |
| Control | 100 | No | 75 | -reference- | -reference- | -reference- |
| Intervention (Estimate #1) | 100 | Yes | 68 | 10% lower | 403 | 903 |
| **Intervention (Estimate #2)** | **100** | **Yes** | **60** | **20% lower** | **90** | 199 |
| Intervention (Estimate #3) | 100 | Yes | 53 | 30% lower | **43** | **94** |
|  |  |  |  |  |  |  |
| Note: Calculations performed in Stata 13.1 using “power pairedmeans” command. |

In the post-implementation data collection period we will have:

* 16 intensive patient data collection days per unit
* 16 point prevalence of monitoring data collection days
* 4 intervention-control unit pairs
* On each intervention unit, on each intensive patient data collection day, at least 2 patients discussed in a huddle
* On each control unit, on each intensive patient data collection day, at least 2 monitored patients to serve as controls for those discussed in huddles

Therefore we will have 16\*4\*2= 128 intervention-control pairs for the patient-level analysis. This anticipated sample size will be adequate to detect a 20% difference between controls and intervention patients as we hypothesize (see table above) assuming a standard deviation of 50.

# SAFETY MANAGEMENT

## Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

## Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

## Special Considerations

In this study, we will regularly evaluate the safety of the huddle interventions, since the intervention may lead to less intensive monitoring and fewer alarms for some patients. As described above in Section 5.1.2.5, Surveillance for code blue events, critical assessment team activations, and near miss events on patients discussed in huddles, we will monitor for code blue events and critical assessment team activations in patients previously discussed in huddles and, if any are identified, we will discuss each event with unit staff to determine if the event was considered *at least* *possibly related* to the study intervention using the IRB’s scale of definitely related, probably related, possibly related, unlikely to be related, or unrelated. In addition, we will inquire at the start of each huddle about recent monitoring-related patient safety “near miss” events17 (situations that did not produce patient injury only because of a chance occurrence, such as a medical student walking into the room of a patient whose monitoring was discontinued and finding them cyanotic). All reported near misses and code blue and rapid response team activations in patients discussed will be considered, in IRB terms, *Adverse Events*, whether or not they are related to the research intervention. Each Adverse Event will be reviewed by the study team to determine if it meets criteria as an Unanticipated Problem Involving Risks to Subjects using definitions provided in the CHOP IRB’s Standard Operating Procedure #408. Adverse Events that meet the definition of Unanticipated Problem Involving Risks to Subjects will be reported promptly to the IRB and the study will be suspended pending review of the event by the IRB. Following the review, we will work with the IRB and staff from the inpatient units to determine if the study should be modified to improve the safety of patients.

# STUDY ADMINISTRATION

## Treatment Assignment Methods

Please see sections 3.1 and 3.2 for details of unit pairing, randomization, and blinding during baseline data collection.

## Data Collection and Management

REDCap will be used as the primary source for data collection and management. Other electronic files generated as part of the study (such as BedMaster output) will be stored on the CHOP Research SAN on a server with access limited to the research team. Following final study publication or 3 years after study completion (whichever occurs first), the REDCap project will be moved to an inactive status and archived in that system. Any data files with PHI outside of REDCap will either be destroyed completely or stripped of PHI.

## Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. No identifiable data will be used for future study without first obtaining IRB approval. The investigator will obtain a data use agreement between the provider (the PI) of the data and any recipient researchers (including others at CHOP) before sharing a limited dataset (PHI limited to dates and zip codes).

## Regulatory and Ethical Considerations

### Data and Safety Monitoring Plan

The Principal Investigator will oversee the Data and Safety Monitoring Plan outlined above in Section 7.3.

### Risk Assessment

This study is minimal risk. Risks include:

***Delay in recognition of clinical deterioration***

The primary risk is a delay in recognition of clinical deterioration because an alarm threshold was changed or disabled following the intervention in such a way that an alarm did not fire or fired later than it would have prior to the intervention.

##### Risk mitigation

The intervention consists primarily of a tool that structures discussion of monitor alarms and brings data on alarm frequency that was previously only available to researchers and biomedical engineers to clinicians who can use it to make more informed decisions about alarm management. Conversations about making changes to monitor settings occur on the wards daily, the only differences are that in current state they are not structured and are not informed by actual alarm data. To mitigate risk, we have designed the study such that the intervention does not involve the research team making any changes to the alarm orders or any changes on the actual devices. It is up to the primary medical team to determine if any adjustments will be made and if so, what the adjustments will be.

### Potential Benefits of Study Participation

#### Direct

Patients and the providers caring for them have the potential to benefit from fewer alarms. The patients may benefit from fewer interruptions from alarms, which may wake them from sleep and cause unnecessary anxiety in them and their loved ones. The patients also may have a lower risk of harm due to a reduction in the probability of the clinicians caring for them experiencing the alarm fatigue that can result from high alarm rates.

The clinicians caring for the patients may also benefit from experiencing a lower burden of alarms, allowing them to spend more time completing important tasks such as medication administration and performing patient assessments that benefit from having fewer interruptions.

#### Indirect

The study outlined in this proposal will generate important knowledge that will be applied to future projects aimed at addressing the burden of physiologic monitor alarm rates in centers across the country.

#### Risk-Benefit Assessment

Based on the discussion above and the lack of deviation from standard clinical care, the benefits of this study far outweigh the minimal risks. Given that the risks of the study are minimal, it is reasonable to proceed with the project.

## Informed Consent/Assent and HIPAA Authorization

### Waiver of informed consent

The study will seek a waiver of informed consent. This is an acceptable approach under 45 CFR 46.116(d), which states that the IRB may approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the following four criteria are met: (1) the research involves no more than minimal risk to the subjects, (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, (3) the research could not practicably be carried out without the waiver or alteration, and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The primary purpose of this study is quality improvement at CHOP that is generalizable (and thus constitutes QI research). This study is minimal risk.

The primary subjects, the clinicians whose behavior we aim to impact (specifically the intervention may encourage them to make appropriate, safe changes in monitoring orders), will be informed and educated about the project during the existing huddles. **Any physician or nurse practitioner can opt out of study participation at any time simply by not participating in huddle discussions about alarms and/or by not changing any monitor orders in response to recommendations discussed in the safety huddle, thus not adversely affecting their rights.** A consent process prior to the safety huddle would not be practicable due to the large number of care providers who could be involved in the collaborative multidisciplinary care of the patients involved. In addition, the act of consenting the providers may change their behavior and make them more likely to change the order in the computer to please the researchers. Second, since no identifying information is being kept on the clinicians, there is minimal risk.

For the secondary subjects, both the intervention and control patients, we seek a waiver of informed consent. The rights and welfare of the subjects would not be adversely affected because conversations about making changes to monitor settings occur on each of the study units daily, the only differences are that in current state they are not structured and are not informed by actual alarm data, thus this is usual care. Informed consent would not be practicable for these patients due to the following: The intervention patients will be chosen using rapidly changing alarm data, and then discussed minutes later. Based on clinical experience caring for patients on these units, It is unlikely that most parents would be available to consent during this time. Because we are performing research to evaluate a quality improvement intervention, we want to simulate as closely as possible the way that the intervention will be used in practice therefore the timeliness of alarm information is vital to the study.

After participation, nurse and physician participants will be informed of the study’s findings in the following situation: If the results support that the intervention is effective, it is likely that the hospital will roll out a version of this intervention house-wide. If that occurs, the findings of this study will be key supporting information in the educational presentations associated with the roll out.

### Waiver of HIPAA Authorization

No personal health information will be collected on the primary subjects (the physicians and nurse practitioners) so no HIPAA authorization is necessary for the primary subjects. A waiver of HIPAA Authorization is requested for the secondary subjects for the same reasons as we are requesting waiver of consent as acquiring HIPAA authorization would present significant difficulties as it is unlikely that parents would be available to consent during this time.

A waiver of HIPAA Authorization is sought for this study and is in agreement with 45 CFR 164.512(i.)(2)(ii) Since it fulfills all of the following:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(1) An adequate plan to protect the identifiers from improper use and disclosure;

* Please refer to Sections 8.2 and 8.3 above

(2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;

* Please refer to Section 8.2 above

(3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

* We confirm that PHI will not be reused or disclosed to any other person or entity, except: as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA

(B) The research could not practicably be conducted without the waiver or alteration;

* Please see above reasons under Waiver of Informed Consent

(C) The research could not practicably be conducted without access to and use of the protected health information

* In order to track potential alarm-associated adverse events in intervention patients discussed in the huddles as well as to link to clinical data (such as diagnosis, early warning score) documented in Epic, we need to collect PHI as outlined in Section 5.

## Publication

Peer-reviewed publication is planned.

## Payment to Subjects/Families

None.

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