

Safety Innovations

Cardiopulmonary Monitors And Clinically Significant Events in Critically Ill Children

Children's National Medical Center

A team of nurses, biomedical engineers, physicians, and biostatisticians were assembled to assess the conditions associated with the generation of cardiopulmonary monitors (CPMs), including false positive alarms signals in critically ill children, and to define alternative alarm parameters that would improve CPM alarm performance.

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Note to the reader: Cited definitions in this paper do not necessarily reflect those as stated in published industry standards. See box on page xx for definitions as published in the standard, IEC 60601-1-8:2006+A1:2012, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

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Cardiopulmonary Monitors and Clinically Significant Events in Critically Ill Children

At a Glance

Subject: Children’s National Medical Center
Location: Washington, D.C.
Description: 24-bed, Level I Pediatric Intensive Care Unit (PICU) with an average daily census of 20 children

Background

Cardiopulmonary monitors (CPM) are currently designed with flexible alarm parameters to warn providers about patient conditions, events, or devices that deviate from a predetermined “normal” status.¹ When an alarm signal is triggered, the provider is expected to respond to the signal, identify its cause, and intervene as necessary.^{2,3} According to the American College of Clinical Engineering (ACCE) Healthcare Technology Foundation, clinical alarm signals should deliver information that is accurate, intuitive, and provide alerts which are readily interpreted and acted upon by clinicians.⁴ However, the ACCE Healthcare Technology Foundation reported in its 2006 article, “Impact of Clinical Alarms on Patient Safety,” that CPM alarm signals were not performing as expected because of a complex set of interdependent issues.⁴

Some alarm signals may reflect a change in the patient’s condition (true-positive) while many others are not clinically significant and/or reflect poorly set monitoring parameters (potentially causing false-positive/nuisance alarms).³ A false-positive or clinically insignificant alarm signal is defined as one that occurs in the absence of an intended, valid patient or alarm system trigger.⁴ The sheer volume of clinically

insignificant alarm signals in the hospital setting is an important safety issue.⁵ False-positive alarm rates have been reported ranging from 85%–99% with few representing significant clinical events requiring provider intervention.^{4,6} In one report, the number of alarm signals in a medical progressive care unit was documented during an 18-day period (patient census of 12). The number of signals totaled 16,953 or 942 alarms/day with one alarm signal occurring every 92 seconds.⁷ Data from one of our critical care units in 2009 were similar over a 30-day period (patient census of 35). A total of 39,000 alarm signals occurred or 1300 alarms/day and one alarm signal sounding every 66 seconds.⁸

Paradoxically, CPM may contribute to the generation of adverse patient events. Because of the disproportionate number of false-positive alarm signals, there is a lower likelihood of effectively responding to a signal if the false-positive alarm rate is high.^{7,11,12} Despite regulatory and accreditation guidelines regarding CPMs established by The Joint Commission in 2002, CPM-related adverse events including patient death continue to occur.¹³ Although reporting of sentinel and adverse events is sparse in the literature, the authors have experienced incidents of inattention to alarm signals with significant adverse patient outcomes.

ACRONYMS:

Children’s National Medical Center (CNMC)
Cardiopulmonary monitors (CPM)
Pediatric intensive care unit (PICU)
Clinically significant events (CSEs)
Philips Patient Information Center (PIC)
Receiver-operator characteristic (ROC) analyses
Confidence interval (CI)

We conducted an eight-month study on multiple units at our pediatric medical center and found that the mean monitor alarm response time exceeded three minutes in 50% of the cases (range 25–65%). These findings led to the assignment of a monitor technician stationed at a central monitoring bank for the purposes of notifying nurses of CPM alarm conditions and corresponding signals. These efforts did not result in any detectable improvement in provider alarm response time. In addition, at our institution, although the CPM alarm parameters are to be ordered by a physician or licensed independent prescriber every 24 hours, a recent evaluation documented poor compliance with this policy with less than 50% of our physicians/providers ordering CPM parameters.¹⁴

The overwhelming number of false-positive alarms signals has been likened to the Aesop's fable of the boy who cried wolf. Alarm fatigue can occur when the large number of monitor alarm signals overwhelms and desensitizes providers,⁷ causing them to divert attention away from clinically significant events.³ With such fatigue, providers often ignore the sound, lower the volume, extend alarm limits outside of a reasonable range, or disable the signals.^{3,10-12}

The CNMC Challenges:

- In 2009, data from one of CNMC's critical care units showed that a total of 39,000 alarm signals occurred over a 30-day period (patient census of 35). This is the equivalent to an average of 1300 alarms/day and one alarm signal sounding every 66 seconds.
- The mean monitor alarm response time exceeded three minutes in 50% of the cases (range 25–65%).
- When staffing a central monitoring bank with a monitor technician for the purposes of notifying nurses of CPM alarm conditions and corresponding signals, there was no detectable improvement in provider alarm response time.
- Less than 50% of physicians/providers complied with CNMC's policy to order/set CPM alarm parameters every 24 hours.

In this study, a team of nurses, biomedical engineers, physicians, and biostatisticians was assembled to develop a project to assess the conditions associated with the generation of CPM alarm signals including false-positive alarm signals in critically ill children. In addition, this team set out to define alternative alarm parameters that would improve CPM alarm generation performance. We hypothesized that the sensitivity, specificity, and positive predictive value of CPM alarm signals could be optimized resulting in a significant reduction in false-positive signals. The purpose of this paper is to describe the study methodology, lessons learned, and implications for future research and practice.

Study Hypothesis: Sensitivity, specificity, and positive predictive value of CPM alarm signals could be optimized resulting in a significant reduction in false-positive signals.

Specific aims of the study:

Aim 1. Compare CPM alarm signals to clinically significant events (CSEs) in the pediatric intensive care unit (PICU) to estimate sensitivity and specificity of alarm conditions based on current procedures.

Aim 2. Improve the performance of the CPM alarm system by using a statically guided approach for manipulating alarm settings for the optimized triggering of true-positive and true-negative signals for CSEs, and thereby, minimizing the rate of false-positive alarm signals.]

In this study, a team of nurses, biomedical engineers, physicians, and biostatisticians was assembled to develop a project to assess the conditions associated with the generation of CPM alarms, including false-positive alarms in critically ill children.

Methods

Inclusion Criteria

This externally funded study was approved and deemed exempt by the hospital's Institutional Review Board. The study was conducted in a 24-bed, Level I Pediatric Intensive Care Unit (PICU) with an average daily census of 20 children. All children with severe or potentially life-threatening diseases and those with multisystem as well as postoperative severe conditions were eligible for inclusion in the study. Patients were excluded from the study if they were admitted pending organ donation, were admitted for less than 12 hours, or had an anticipated length of stay of less than 24 hours.

Clinically Significant Event (CSE)

A focus group of PICU nurses was convened to explore and develop the definition of a CSE. The nurses were asked to describe what types of patient events prompt a monitor alarm signal, what types of clinical

events require them to intervene on the patient's behalf and to describe the times when their patients may have had a CSE but the nurse was not alerted by a CPM alarm condition. From this consensus work, a CSE was defined as an event that requires intervention without which the patient's condition would worsen or deteriorate.

CSEs were confirmed by the research data collection nurse and bedside nurse and then recorded. Events or data that were in question or difficult to interpret were reviewed by two co-investigators and two independent critical care nurses and physicians for analysis and adjudication.

Food for thought: CNMC defined a clinical significant event as one that requires intervention without which the patient's condition would worsen or deteriorate. Does your facility have a definition of a clinically significant event? If so, what are the ways these events are categorized and monitored?

Cardiopulmonary Monitoring Equipment

The bedside CPM devices used for the study were the same devices used for patient care (Philips MP70 devices with individual parameters available for heart rate, cardiac monitoring, pulse oximetry, non-invasive blood pressure measurement, invasive pressure measurements, temperature, and respiratory rate). The bedside devices (MP70) were connected to a networked central station (Philips Patient Information Center - PIC) that saved vital sign results, graphs, and alarm data associated with each monitor on a database server and were automatically exported from the database server to the Philips Research Data Export Tool every four hours and stored indefinitely for all patients in the PICU. A script was used to extract patient information from the database and store it in a lookup table. These data were electronically filed by patient lookup number on the system server until a potential study patient was identified. When a study patient was identified, biomedical engineering extracted the two files associated with that patient (alarm file and vital signs file) and sent them to the study coordinator.

The alarm file was a text file containing a time stamp and a description of the alarm condition that occurred and the type of alarm signal (Philips classifies alarms as one-, two-, or three-star alarms).

- Three-star alarm signals were defined as a cardiac arrhythmia, apnea, or oxygen desaturation.
- Two-star alarm signals were defined as vital signs that exceeded high/low parameter settings.
- One-star alarm signals represented equipment alerts.

There were two available files for each device (patient): a list of alarm conditions and a minute-by-minute table for all of the vital sign parameters that were measured. The specific data sent from the monitor to the research data export tool were configured at the PIC central station.

The vital signs file was a text file listing the measured vital signs in one-minute intervals and only displayed/recorded vital signs that were being measured by the patient monitor. For example, the vital signs for non-invasive blood pressure were not displayed if that blood pressure connection was turned off on the monitor. The one-minute vital sign recorded was an average of the vital signs measurements over that one-minute period.

There were three routes of data acquisition:

1. Direct data recording witnessed by the research data collection nurse;
2. Indirect data recording obtained from the bedside nurse when not observed by the data collection nurse during the study period;
3. Extraction through daily electronic medical record review.

The Data Collection Instrument:

Prior to the collection of data, a standardized case surveillance data sheet (i.e., the monitor data collection form) was developed and piloted with the nurses that were trained to perform study functions. The case surveillance data sheet was then refined to accommodate clinically necessary changes and add validity to the measures being recorded. Data collected were recorded on the form shown in Table 1. In addition:

- Data from the CPM were collected for each patient for up to 72 hours per patient using Philips Intellivue Trend and Alarm monitor query software to allow full disclosure review of data. CSEs were characterized independently of the CPM alarm signal.
- There was no attempt at the bedside to establish whether an alarm signal was false- or true-positive. That decision was based solely on whether the alarm signal was coincident or occurred within several minutes of the CSE.
- Occurrence, type, and timing of alarm signals were based on the CPM data retrieval and analysis during the observation period.
- Data collectors were trained on how to complete the case surveillance data sheet to promote a standard methodology that minimized variability.
- The principal investigator met regularly with the data collectors and provided oversight and periodic review of data collection.
- The PICU staff was provided with an overview of the study purpose and design.

Procedure

At the beginning of each direct data observation, the research data collection nurse notified Biomedical Engineering of the need to extract CPM data for all eligible patients enrolled in the study that day. Demographic and clinical data were then recorded for each patient. Data collection rounds were performed at least hourly. The direct data observation periods ranged from

two hours to seven hours (average five hours) per day over the course of three days per patient. The bedside nurses were informed of the patient's participation in this study and were asked to report CSEs not observed by the data collector during the direct data recording period.

Data Analysis for Aim 1:

Cross tabulations were developed to assess the sensitivity, proportion positive by the gold standard CSE that are CPM positive, and specificity, proportion negative by the gold standard that are CPM negative and set the 95% confidence interval (CI) around each estimate. We defined cut-points for acceptable levels of sensitivity and specificity. In addition to an overall analysis based on all types of CSE, we planned to estimate sensitivity and specificity for selected subtypes of these events. The purpose behind this type of subgroup analysis was to identify whether CPM performance varied greatly by subtype of event.

Data Analysis for Aim 2:

We planned to use receiver-operator characteristic (ROC) analyses on each CPM clinical parameter being monitored to identify the best cut-point(s) to maximize sensitivity and specificity for CSEs overall and by subtype. ROC analysis was used to evaluate sensitivity versus 1- specificity (false positivity) associated with moving the cut-point for signaling an event warning (alarm) across the full range of values of each monitored parameter. Based on ROC analysis, we planned to choose a single cut-point or set of cut-points that met pre-specified criteria. We defined these selection criteria as 1) that set of cut-points for which the specificity was $\geq 70\%$, and 2) where the sensitivity was $\geq 90\%$. We intended to repeat this testing for each parameter defining the set of values that met the defined criteria or designate that no such criteria existed.

Results:

Prior to the study, clinically significant events (CSEs) were defined and validated.

Understanding Factors Associated with Monitor Alarm Generation in Critically Ill Children - CSE Observations - Form 9

Study ID #: [redacted] PID #: [redacted] Patient Initials: [redacted] Day #: [redacted] Room #: [redacted] Today's Date: [redacted] / [redacted] / [redacted]
(Admission = Day 1) MM DD YYYY

CSE Type 1- Observed 2- Reported	CSE Date / Time Event Prompt: 1-Observed 2-Monitor 3-Both	CSE(s)	Type of Intervention (select all that apply) 1- Stimulate 2- Suction 3- Reposition 4- Hand Bag 5- Suction 6- Desaturation 7- Sucks 8- Call 9- Code 10- Seizure Free 11- Seizure Free 12- Other	Monitor Setting - Alarm that RESPONDED TO the CSE ONLY; CHECK ALL THAT APPLY					Other CSE Type
				HR	RR	Systolic BP low	Systolic BP Normal	SpO2 Sat.	
1 2	[redacted] / [redacted] / [redacted] [redacted] : [redacted] am/pm Event Prompt: [redacted]	*CSE(s) [redacted]	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	H [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1 2	[redacted] / [redacted] / [redacted] [redacted] : [redacted] am/pm Event Prompt: [redacted]	*CSE(s) [redacted]	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	H [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1 2	[redacted] / [redacted] / [redacted] [redacted] : [redacted] am/pm Event Prompt: [redacted]	*CSE(s) [redacted]	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	H [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
1 2	[redacted] / [redacted] / [redacted] [redacted] : [redacted] am/pm Event Prompt: [redacted]	*CSE(s) [redacted]	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	H [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

10/08 CSE Lead 6-Other 3-Hypoxia 6-Arhythmia 9-Cumulative pt 12-Code
1-Apnea 4-Pneumothorax 7-Seizure 10-Pt crying/scramming
2-Cyanosis 5-Undertended evaluation 8-Change in LOC/Mental Status 11-Pain crisis

Completed by: [redacted] Initials [redacted]

Table 1. Clinically Significant Event Observation Form, © 2011, Children's National Medical Center, Washington DC. For permission to use or adapt, contact Linda Talley, ltalley@cnmc.org

In this study of pediatric critical care patients, it was not surprising to discover that respiratory CSEs, including hypoxia and apnea, comprised the majority of the events.

Over a seven-month period in 2009, critically ill children underwent evaluation of CSEs while connected to a CPM (MP70, Philips Healthcare, Andover, MA). Comparative CPM and CSE data were analyzed with an aim to estimate sensitivity, specificity, and positive and negative predictive values for CSEs.

CPM and CSE data were evaluated in 98 critically ill children. During the observation period, 2,245 alarm signals were recorded with 68 CSEs noted in 45 observational days. Types and characteristics of CSEs are noted in Table 2.

During the course of the study, the team developed a firm understanding of CPM functionality, including the pitfalls associated with aggregation and analysis of CPM alarm data. One significant challenge included the inability to query all levels of CPM alarm data. The alarm file for each patient only recorded three-star alarm signals but did not record the one-star and two-star alarm signals secondary to a setup issue with the Philips central station. Accordingly, the association between CPM alarm signals and CSEs could not be fully evaluated with the anticipated ROC analyses.

Investigational time stamps were also noted to be problematic in that the time posted on the data collection sheets did not always match the time on the two study files and were in error by up to four minutes. The Philips bedside monitors, the Philips database server, and the hospital time devices (computers and phones) were not problematic as they were all on the same time server.

In addition, there were some patients whose medical record number was not recorded on the bedside monitor. Therefore, when there was an attempt to match these two files, they could not be validated and were, therefore, excluded from study analysis.

Discussion

CSEs are common in critically ill children.¹⁵ In this study of pediatric critical care patients, it was not surprising to discover that respiratory CSEs, including hypoxia and apnea, comprised the majority of the events. We set out to examine the relationship between CPM and CSEs. The largest impact to the study was related to the recording of alarm signals. Although CPM data can be

CSEs	Number of Events (Rate)	Interventions
Hypoxia	36 (53%)	Repositioned x 13 Adjust O ₂ delivery x 12 Suctioned x 11 Handbagged x 4 Stimulated x 2 Medicated x 1 Repositioned ETT* x 1 Intubated x 1
Apnea/low RR	12 (17.6%)	Stimulated x 8 Suctioned x 3
Combative/agitated pt.	6 (8.8%)	Suctioned x 3 Repositioning x 2 Extubated x 1
Hypotension	5 (7.4%)	Increased inotropes x 3 Fluid bolus x 2 Stimulated x 1
Vomiting	4 (5.9%)	Suctioned and repositioned x 4
Unintended extubation	1 (1.5%)	Rescued and reintubated x 1
Patient Crying/screaming	1 (1.5%)	Repositioned x 1
Pain crisis	1 (1.5%)	Medicated x 1
Hypertension	1 (1.5%)	Decreased inotropes x 1
Arrhythmia	1 (1.5%)	Suctioned x 1

Table 2. Clinically Significant Event (CSE) Rates and Associated Interventions

easily queried, reporting configuration default settings can exclude critical information that is necessary in compiling a coherent denominator database.

During the study, we were unaware that all alarms were not saved into the alarm file because the central station patient information center was defaulted to send only three-star alarm signals to the research data export tool to limit the file size. Because this issue was not identified by the research team until all study data had been collected, the data stored did not definitively identify all alarm conditions that occurred with each study patient. As a result, our inability to capture all relevant CPM data impeded our ability to rigorously test the relationship between CPM and CSEs. Initial impressions, however, from this investigation are that many, but not all, CSEs can be detected with the CPMs currently in use.

This investigation has resulted in improved awareness of CPM alarm parameter settings, associated false-positive alarm rates, and the potential impact on quality care delivery. In addition, this information has been incorporated into annual education for all nursing staff regarding bedside monitoring.

Implications for Future Research and Practice

CPM devices are physiological parameter screening tools that attempt to identify patients whose condition is deteriorating for early preventative intervention. There are well-established criteria for the use of clinical monitoring screening tools.¹⁶

We recommend that researchers consider these criteria in designing future studies.

1. The screening outcome should be an important patient-specific health issue. Clearly, CSEs in a critically ill population meet this criterion. However, in conducting CPM studies, it is important to clearly define the clinical events that necessitate prevention. In the absence of such clarity, the study methodology would likely characterize clinical deterioration only in terms of the monitor setting parameters. In the

current study for example, one type of CSE was defined as oxygen desaturation. In this case, data also could be recorded to determine whether deterioration is occurring based on the patient's clinical status.

2. The investigative team should have a clear definition of whom to screen for the study. In this study, most patients were included if admitted to the PICU, despite marked variability in severity of illness and, therefore, the likelihood of developing a CSE.
3. There should be an acceptable treatment or preventative intervention that alters the outcome should a CSE occur. For example, performing tracheal intubation for a patient who develops apnea would represent such an intervention, whereas it is not clear that calming a crying child who has developed tachycardia represents an intervention of the same importance.
4. There must be a valid and acceptable screening test that will identify persons at risk of a CSE in which an intervention can be applied successfully. A valid monitoring tool must have adequate sensitivity and specificity. In this preliminary analysis, it appears that the CPM, as currently used, has high sensitivity but poor specificity and, therefore, a high false-positive rate.

Because of the complex and interdependent issues involved in CPM alarm conditions and signals, we believe one of the strengths of our project was the interdisciplinary nature of our study team. The clinical and technical expertise and contributions of our frontline and research nurses, biomedical engineers, physicians, and biostatisticians were critical in expanding our knowledge and understanding of the relationship between CPM alarms and CSEs.

This investigation has resulted in improved awareness of CPM alarm parameter settings, associated false-positive alarm rates, and the potential impact on quality care delivery.

Food for thought

Has your facility developed criteria for use of clinical monitoring screening tools?

Key Findings:

Despite the analytical challenges, several important findings in our study design were illuminated for future investigation:

- Improved methodology in conducting the next iteration of this study so that all appropriate monitor alarm categories are accurately and reliably captured to ensure comprehensive data analyses,
- Appropriate design in defining and measuring CSEs in the PICU,
- The relationship between PICU CSEs and CPM data.

Definitions from IEC 60601-1-8:2006+A1:2012, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Alarm condition: State of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS situation exists for which OPERATOR awareness or response is required.

NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

FALSE NEGATIVE ALARM CONDITION: Absence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE An ALARM CONDITION can be rejected or missed because of spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the equipment itself.

FALSE POSITIVE ALARM CONDITION: Presence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM.

NOTE A FALSE POSITIVE ALARM CONDITION can be caused by spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ALARM SYSTEM itself.

Alarm signal: Type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

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Contact Us

Has your healthcare organization implemented any of the strategies discussed in this publication?

Do you know of a healthcare facility that has dealt with a technology-related issue and has a story to share?

If so, we would love to hear from you!

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