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ORIGINAL INVESTIGATION

Decreasing inconsistent alarms notifications: a pragmatic clinical trial in a post-anesthesia care unit

Saullo Queiroz Silveira[a], Rafael Sousa Fava Nersessian[a], Arthur de Campos Vieira Abib[a], Leonardo Barbosa Santos [a,b], Fernando Nardy Bellicieri [a], Karen Kato Botelho[c], Helidea de Oliveira Lima[b], Renata Mazzoni de Queiroz[a], Gabriel Silva dos Anjos[a], Hermann dos Santos Fernandes[d], Glenio B. Mizubuti [e], Joaquim Edson Vieira [f], Leopoldo Muniz da Silva [a,b,*]

[a] *Hospital São Luiz Unidade Itaim, Rede D'Or — Equipe de Anestesia CMA, Departamento de Anestesiologia, São Paulo, SP, Brazil*
[b] *Rede D'Or, Instituto D'Or de Pesquisa e Ensino (IDOR), Rio de Janeiro, RJ, Brazil*
[c] *São Luiz Hospital (ITAIM), Rede D'Or, Departamento de Enfermagem, São Paulo, SP, Brazil*
[d] *University of Toronto, Mount Sinai Hospital, Department of Anesthesiology and Pain Medicine, Toronto, Canada*
[e] *Queen's University, Department of Anesthesiology and Perioperative Medicine, Kingston, Canada*
[f] *Faculdade de Medicina da Universidade de São Paulo (FMUSP), Departamento de Cirurgia, Anestesiologia, São Paulo, SP, Brazil*

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Abstract
Background: Alarms alert healthcare professionals of deviations from normal/physiologic status. However, alarm fatigue may occur when their high pitch and diversity overwhelm clinicians, possibly leading to alarms being disabled, paused, and/or ignored. We aimed to determine whether a staff educational program on customizing alarm settings of bedside monitors may decrease inconsistent alarms in the Post-Anesthesia Care Unit (PACU).
Methods: This is a prospective, analytic, quantitative, pragmatic, open-label, single-arm study. The outcome was evaluated on PACU admission before (P1) and after (P2) the implementation of the educational program. The heart rate, blood pressure, and oxygen saturation alarms were selected for clinical consistency.
Results: A total of 260 patients were included and 344 clinical alarms collected, with 270 (78.4%) before (P1), and 74 (21.6%) after (P2) the intervention. Among the 270 alarms in P1, 45.2% were inconsistent (i.e., false alarms), compared to 9.4% of the 74 in P2. Patients with consistent alarms occurred in 30% in the P1 and 27% in the P2 ($p = 0.08$). Patients with inconsistent alarms occurred in 25.4% in the P1 and in 3.8% in the P2. Ignored consistent alarms were reduced from 21.5% to 2.6% ($p = 0.004$) in the P2 group. The educational program was a protective factor for the inconsistent clinical alarm (OR = 0.11 [95% CI 0.04–0.3]; $p < 0.001$) after adjustments for age, gender, and ASA physical status.

* Corresponding author.
E-mail: leopoldo.muniz@saoluiz.com.br (L.M. da Silva).

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Conclusion: Customizing alarm settings on PACU admission proved to be a protective factor against inconsistent alarm notifications of multiparametric monitors.

Introduction

Clinical alarms on multiparameter monitors are important to ensure safety. They aim to alert healthcare professionals to vital sign changes that indicate something is out of the ordinary and direct them to take immediate action.[1] With new technologies, the number of clinical alarms has increased significantly.[2] Many of these alarms, however, have no clinical significance due to factors such as patient characteristics or monitoring errors, often leading to alarm fatigue. This is the phenomenon by which sensory overload leads to desensitization and makes the healthcare professional less likely to respond to alarms that indeed may warn of real risks to the patient.[1,3–5] It is important to note that alarms are specifically designed to cause cognitive distress,[5] thereby drawing the healthcare professional's attention to a potential issue.

Much has been written about this issue in intensive care units,[3,6–7] progressive care units,[8] emergency rooms,[9] and even in pediatrics.[7,10] However, there are limited similar studies on the surgical environment, particularly in the Post-Anesthesia Care Unit (PACU).

Potential causes of alarm fatigue include technical, organizational, and educational factors.[5,11] Therefore, its solution involves actions that impact one or more of these dimensions. Selecting appropriate monitors for each patient (avoiding over-monitoring), judicious selection of alarm limits, and using multimodal alarms can all reduce the number of nuisance alarms.[5]

Customizing alarm limits based on patients' initial vital sign values is a strategy to optimize monitors and more reliably detect real variations from the baseline. Alarm limit customization around patient's baseline values or baseline changes is a strategy to limit alarms to changes that are clinically significant.[12–20] PACU is an environment in which the anesthesiologist can guide the customization of alarms based on preoperative conditions, intraoperative events, and postoperative goals. It is worth noting that at this stage of care, very narrow limits may increase non-clinically significant alarms, as some degree of baseline variation is expected due to the effects of anesthesia and surgical intervention.

We hypothesized that PACU in a general tertiary hospital is a high-risk environment for alarm fatigue, and that customizing alarm limits based on each patient's baseline values by the anesthesiologist could reduce the number of non-clinically significant alarms, increase the rate of clinically significant alarms, and ultimately improve patient safety. The objective of this study was to determine if a staff educational program on customizing alarm settings on bedside monitors decreases inconsistent alarms in the PACU.

Methods

This investigation was approved by the Institutional Research Ethics Committee (Protocol # 5,188,464; CAAE: 54253821.6.0000.0087). This report is in compliance with the CONSORT Extension for Pragmatic Trials Checklist.[21]

This is a prospective, analytic, quantitative, pragmatic, open label, single-arm study, for which the outcome was evaluated on PACU admission before (P1) and after (P2) the implementation of the educational program on customizing alarm settings of bedside monitors. The outcomes of interest were evaluated through direct observation of the multiparametric monitors and patients during 30 consecutive day shifts: 13 in the pre-intervention period (P1), and the remaining 13 in the post-intervention period (P2) (Fig. 1). The educational program was conducted over 4 days between P1 and P2. During each 6-hour shift, two researchers not otherwise involved in patient care, observed 10 patients and were responsible for data collection. Patients were recruited based on convenience, according to the spontaneous demand for admissions and discharges.

Standard care in PACU

Clinical care in the PACU was provided by anesthesiologists, two registered nurses and four nurse technicians. Each anesthesiologist was responsible for his/her patients until PACU discharge. The total number of anesthesiologists in the study was 38. The PACU consisted of 18 bays and a centrally located nursing station. It is noteworthy that the composition of the PACU healthcare team fulfilled the existing legislation and that, at the time of data collection, each professional category was complete. This unit uses the GE Solar 8000i monitoring platform (General Electric Healthcare, Chicago, IL), which allows multilead continuous analysis. Monitoring capabilities at each bedside included a range of physiological parameters, with all patients monitored for Electrocardiogram (ECG) (Heart Rate [HR] and rhythm), Noninvasive Blood Pressure (NIBP), and Oxygen Saturation (SpO_2). Oxygen saturation monitoring was done with a finger probe connected to a specific module. The temperature was measured periodically by a separate thermometer (no temperature alarm system was installed).

Each monitor parameter was programmed with default values for alarm settings common to all monitored beds in the PACU. The default values were based on the monitor manufacturer's suggestions and consensus opinion of expert medical clinicians in the PACU. Default settings take effect each time a patient is discharged, and a new patient is admitted to the bed with that monitor. Bedside alarm settings could be customized by bedside clinicians based on individual patient care situations. When alarm settings

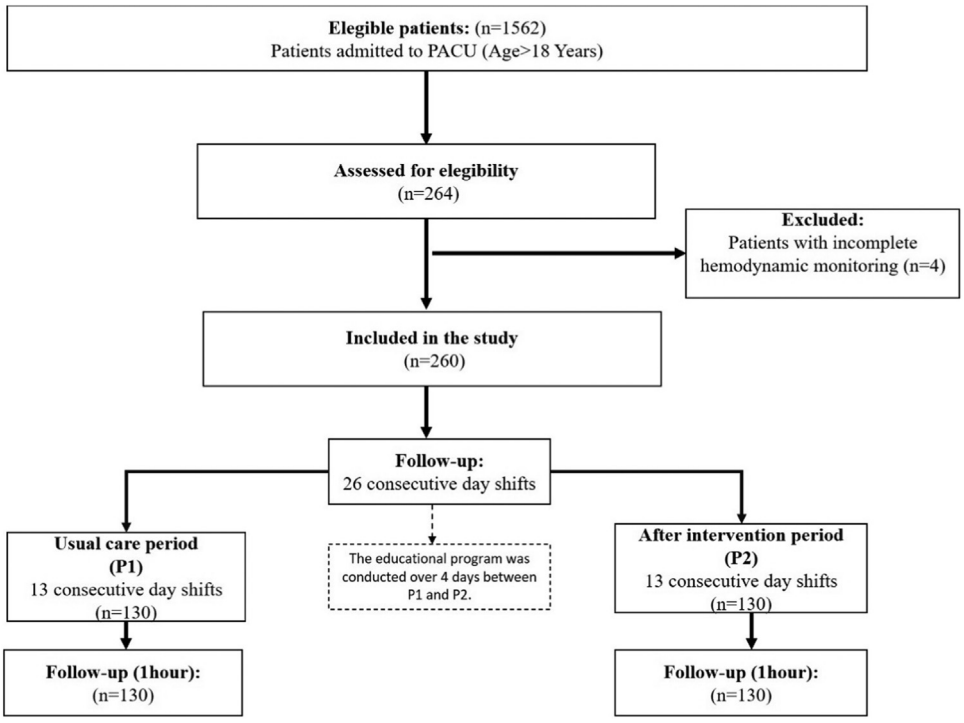

Figure 1 Study flow chart in accordance with the CONSORT Extension for Pragmatic Trials Checklist (www.consort-statement.org).

ranges were exceeded, audible alarms occurred at the bedside. The sound of the alarm was unique and customized to be a continuous double beep alarm.

Study intervention

The P2 intervention had multiple components aimed at achieving behavioral changes to reduce alarm fatigue and inconsistent alarms: 1) A 15-minute session educational program on alarm management designed to review the rationale for minimizing alarms and provide strategies for customizing alarm settings to reduce inconsistencies; 2) Nurses and anesthesiologists were educated on the management of monitor alarms: using appropriate age-specific profiles, customizing parameter thresholds for individual patient needs, and proper electrode placement; 3) Staff reeducation on how to admit, discharge, and readmit a new patient to the monitor to reduce unnecessary alarms.; 4) A summarizing key information for setting alarm limits individualized to each patient according to baseline vital signs and based on current literature data[22,23] on safe values for physiological parameters (Supplementary Table 1) — validated by a group of 24 physicians with expertise and experience in anesthesiology and/or intensive care; 5) Provision of a pocket card summarizing key information for setting alarm limits individualized for each patient; 6) Pocket card attachment to all bedside monitors.

Outcomes

For the purposes of this study, HR, NIBP, and SpO_2 alarms were selected as outcomes to be assessed. HR, NIBP and SpO_2 were recorded prior to anesthetic induction (baseline vital signs), upon admission to PACU, and every 15 minutes thereafter until PACU discharge. As per institutional routine, all patients remained in the PACU for a minimum of one hour, during which data collection took place. For those who remained in the PACU for less than 1 hour, data were collected during the first hour upon PACU admission. Patients with incomplete hemodynamic monitoring (any monitor connected to the patient with less than five ECG leads, absence of NIBP cuff or SpO_2 probe) were excluded. Each clinical alarm was classified as consistent or inconsistent, and the professionals' response to the alarm(s) was defined as: (i) Individualized customization; (ii) Pause (disable/mute); (iii) Warrants intervention or consultation for a clinical condition — this event could be considered benign with no further evaluation necessary or alarming, requiring some form of diagnostic or therapeutic intervention; (iv) No action (ignored); or (v) Checking leads and probes.

The alarm classification as inconsistent or consistent was applied prior to clinical evaluation by the attending team and it was not conditioned to their actions. Alarms were deemed inconsistent when they were triggered improperly because there was no individualized parameterization. If the alarm reflected a relevant clinical condition, representing a potential threat to the health status of the patient, or if the parameter was outside of the range (pre-)set for the patient on the bedside monitor, the alarm was considered consistent.

Data collection was done as follows: when hearing the alarm activation, the researcher responsible for data collection specifically identified the sound and visual signals originating from the monitor device, and carefully observed the actions adopted by the attending healthcare team. The number of alarm signal events was reconfirmed through review of existing bedside monitor computer alarm history for each monitored patient on the unit. The alarms were

quantified by the number of automatic activations until some action was taken by the attending team. The duration of each alarm was not recorded. Two types of alarms were not included in this study: (i) Those originating from manipulation of the patient or monitoring system by staff; and (ii) Those occurring until the device or system was properly set immediately after being switched on or reconnected. Two PACU beds were predefined (by the researchers responsible for data collection) at the beginning of each shift to receive patients to be included in the study. Notably, on admission to PACU, the anesthesiologist was unaware that his/her patient's bed would be included in the study.

Statistical analysis

The minimum required sample size was calculated using the online software G*POWER (https://g-power.apponic.com),[24] based on the distribution of the frequency of inconsistent alarms, before and after the parameterization by hemodynamic parameter, with a minimum difference of 30%.[25] For a power of 80%, effect size of 0.3 and a significance level of 5%, using a $\chi 2$ test, 110 participants per period was estimated as needed.

The measure of central tendency and dispersion for the number of alarms was the median and 25–75th percentiles (%), respectively, after analyzing the distribution in the normality curve. Categorical variables are presented as absolute values and percentages. The Mann-Whitney test was used for comparisons between study periods delimited by the interventions. The Pearson Chi-Squared test was employed for categorical variables, and partitioning Chi-Square when value of $p < 0.05$. The analysis of variables related to inconsistent alarms was presented as Odds Ratios (OR) with 95% Confidence Intervals (95% CI) as a measure of the association between P1 and P2, with adjustments for age, sex, and American Society of Anesthesiologists (ASA) physical status. Multivariate logistic regression by the direct method was used for this purpose. A 95% CI and p-value < 0.05 represented statistical significance. Statistical analysis was performed using the Statistical Package for Social Sciences 20.0 (SPSS 20.0 Mac, SPSS Inc., Chicago, Illinois, USA). Box plot with jittered data points was performed using R software version 3.4.4 (R Foundation for Statistical Computing, Austria).

Results

A total of 260 patients were included, 50.4% were ASA I, 45.4% ASA II, and 4.2% ASA III. Most of the participants were under the age of 40 years (57.1%) and 55.5% were women. There was no difference between P1 and P2 regarding ASA physical status ($p = 0.55$), age ($p = 0.30$), and gender ($p = 0.79$) (Supplementary Table 2). There was no statistically significant difference between comorbidities between P1 and P2 (Supplementary Fig. 1). A total of 344 clinical alarms were collected: 270 (78.4%) in P1 and 74 (21.6%) in P2. Among the 270 alarms in P1, 45.2% were inconsistent, compared to 9.4% of the 74 in P2. The median of consistent alarms per patient was 2 (1–5.5) in P1 and 2 (1–2) in P2 ($p = 0.05$). The median of inconsistent alarms per patient was 3 (2–4.0) in P1 and 1 (1–2) in P2 ($p = 0.02$)

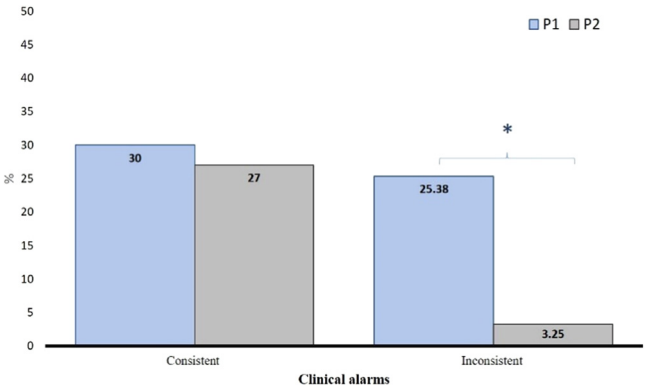

Figure 2 Classification of clinical alarms in the pre-intervention period (P1) and in the post-intervention period (P2). Values expressed in % – Chi-Square test; * $p < 0.05$.

(Supplementary Fig. 2). Consistent alarms occurred in 30% of individuals in the P1 and in 27% in the P2 ($p = 0.08$). On the other hand, inconsistent alarms occurred in 25.4% in the P1 and in 3.8% in the P2 ($p < 0.001$) (Fig. 2). NIBP represented the most alarmed parameter in the P1 and P2 groups (Supplementary Fig. 3). Based on baseline vital signs, individualized parameterization was indicated in P1 for 16.9% and in P2, for 20.8% ($p = 0.42$). In the P1, individualized parameterization was performed in 2.3% and in the P2 in 18.5% ($p = 0.001$) (Table 1). Regarding the clinical consistency of the alarms, there was less inconsistency concerning all parameters in P2. This represents more than 50% reduction in alarms by instituting targeted default monitor alarm limits. In addition to a significant reduction in the total number of clinical alarms that went off, the maintenance in consistent alarms, and decrease in inconsistent alarms, P2 was associated with a protective factor against inconsistent clinical alarms (OR = 0.11 [95% CI 0.04–0.3]; $p < 0.001$) after adjustments for age, gender, and ASA physical status (Fig. 3).

In P1, most inconsistent alarms remained active without any action by care providers (68.5%). In P2, this rate was reduced to 28.5% ($p < 0.001$). Faced with an inconsistent alarm, the two correct actions are individualized customization of the alarm or checking multileads and electrodes. In this scenario, customization occurred in 0% in P1 and 14.3% in P2 ($p < 0.001$), while checking multileads and electrodes was performed in 1.5% in P1 and 28.9% in P2 ($p < 0.001$). For consistent alarms, the expected course of action is clinical intervention or consultation for a clinical condition. In this sample, this action pattern occurred in 19.5% in P1 and 61.6% in P2 ($p < 0.004$) – a significant improvement. Consistent alarms sounding without action reduced from 21.7% to 2.6% ($p = 0.004$) (Fig. 4). No patient required noninvasive mechanical ventilation during the study period. No adverse events occurred in both groups.

Discussion

This study showed reduced bedside alarm inconsistency, lowered sensory overload and less alarm fatigue in the PACU from an educational program on customizing alarm settings to each patient's physiological condition.

Table 1 Need to alarm parameterization by professionals responsible for data collection and rates of individualized parameterization performed by the assistant team in the pre intervention period (P1) and in the post intervention period (P2).

	Period*		*p*-value
Individualized parameterization indicated	P1 % (n)	P2 % (n)	
No	83.08 (108)	79.23 (103)	0.52
Yes	16.92 (22)	20.77 (27)	
Individualized parameterization performed	**P1 % (n)**	**P2 % (n)**	***p*-value**
No	97.69 (127)	81.54 (106)	<0.001
Yes	2.31 (3)	18.46 (24)	

* Values are expressed as relative and absolute frequencies (χ2 test).

Customization of alarm limits is increasingly recognized as an effective solution to reduce inconsistent alarms. This is the first study to analyze an intervention to decrease inconsistent alarm signal events in the PACU. Inconsistent alarms annoy and stress healthcare workers, which may interfere with patient care once the sensory overload from false positive alarms leads to desensitization and makes the health professional more likely to ignore alarms warning of real risks to the patient.[1,3–5] The high rate of inconsistent alarms in the PACU is an issue that impairs the quality of patient care, increases the staff's stress, and the probability of sentinel events. For 2020, the ECRI Institute listed an alarm-related hazard among their Top 10 Health Technology Hazards (ECR). Our intervention, applying a quality-improvement methodology based on an educational program on alarm management, safely reduced the total number of alarms (270 to 74) and reduced the incidence of inconsistent alarm notifications (from 45.2% before, to 9.4% after program implementation). The evidence-driven interventions included high-reliability changes such as implementing alarm logic and changing the alarm notification process. The combination of these interventions enabled sustained improvements in individualized parametrization for 13 shifts in the post-intervention period.

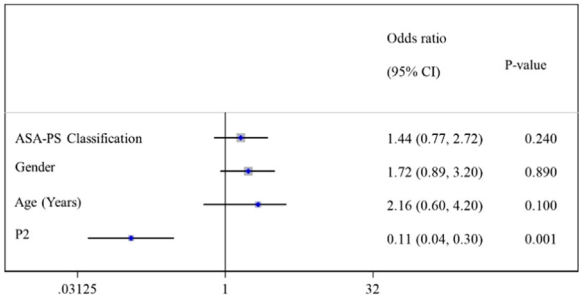

Figure 3 Variables associated with inconsistent alarms (Multivariate logistic regression by the enter method). P2 – post-intervention period.

Although individualizing alarm thresholds might seem trivial, before the intervention there was a significant number of staff members that followed the default thresholds of the monitoring devices and did not adjust the thresholds according to individual patient needs. Our results showed that individualized parameterization was performed in only 2.3% (Table 1). This might be either due to lack of time, will or know-how. According to a previous study, 3—40% of healthcare workers had never used many of the monitoring functions of a monitor.[26]

Alarm fatigue is a significant concern in healthcare settings due to high rates of false positive alarms, poor positive predictive value, and lack of standardization. These issues can lead to desensitization and reduced responsiveness to alarms, which compromise patient safety. While alarms are intended to increase sensitivity and reduce missed events,

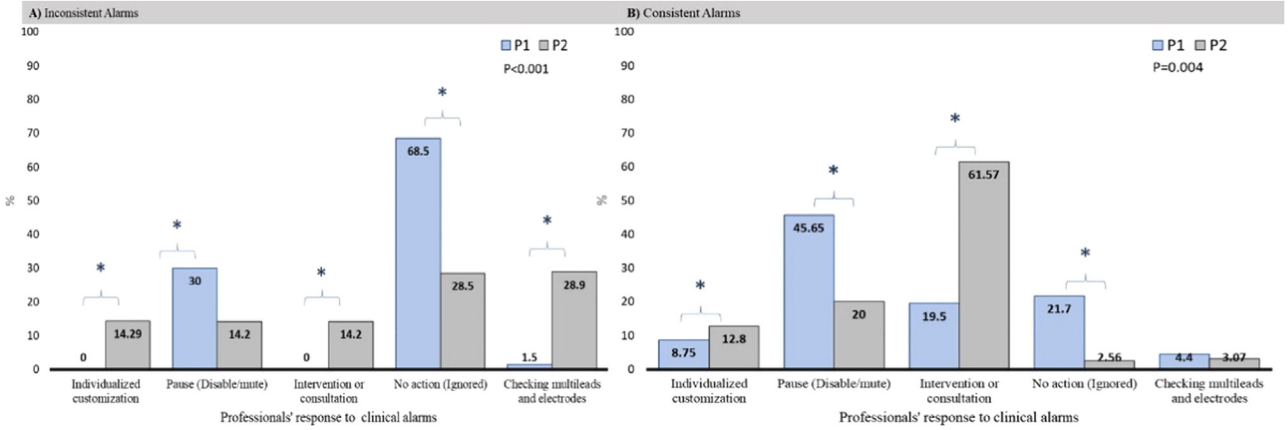

Figure 4 Professionals' response to clinical alarms between the pre-intervention period (P1) and in the post-intervention period (P2). Values expressed in % – Chi-Square test; * Chi-Square test ($p < 0.05$) — partitioning test.

excessive and inconsistent alarms can overwhelm healthcare staff and lead to inattention, distraction, and errors. In fact, there have been reports of alarm fatigue contributing to patient deaths.[12]

Our intervention successfully reduced inconsistent alarms, and also addressed the issue of neglected alarms. Neglected alarms decreased significantly in both the consistent (21.7% to 2.6%; $p < 0.004$) and inconsistent (68.5% to 28.5%; $p < 0.001$) groups after the intervention. After the intervention, the staff was more likely to correctly deal with an inconsistent alarm ($p < 0.001$). There was also an increase in the correct course of action after a consistent alarm ($p < 0.004$) (Fig. 3). Our intervention not only improved patient safety but also reduced alarm fatigue. Similar results have been reported in previous studies conducted in intensive care units.[5,12,27]

The customization of alarm limits studied did not affect the sensitivity of the monitor to detect adverse clinical conditions. The parametrization protocol did not reduce the number of consistent alarms, which is important since inappropriate customization could result in missing critical events. The results from our study indicated that the intervention resulted in no interference on the evaluation of true critical alarms.

The study aimed to develop a monitoring plan that met the patient's target values with joint decision-making of the attending team. A customization table based on baseline vital signs was used to standardize care and reduce individual bias of PACU professionals. How to customize safely is still a challenge in the postoperative period.[28] A recommendation guide on how to customize alarms was used to increase safety and avoid wider alarm limit ranges that could miss a clinically significant change in the patient's HR.[28] Wider alarm limit ranges create the potential for a clinically significant change in the patient's HR to be missed.[29] A recommendation guide on how to customize alarms increased safety in this study and did not reduce consistent alarms.

This study has several limitations. The presence of the research team may have interfered with the response to consistent alarms due to the Hawthorne effect.[30] Secondly, most patients had low complexity, and the findings may not be generalizable to other populations or institutions. Thirdly, patient and family experiences were not measured over the course of this study. Fourthly, the study did not evaluate the effect of the intervention on response time. Finally, as a complex sociotechnical phenomenon there was not a qualitative approach to this phenomenon. Future research should explore other factors, such as night shifts, for instance.

In conclusion, this study demonstrated that a simple staff-based educational program on customizing alarm settings to each patient's physiological condition, rather than using standard alarm values, significantly decreased the most common bedside inconsistent alarms, reduced sensory overload, and consequently alarm fatigue in the PACU, which can be a patient safety risk factor. Our findings, in addition to previous studies, are an important step towards developing alarm management strategies incorporating patient-specific characteristics. We hope that this study encourages further research towards patient-specific effects on monitoring alarms for surgical patients at the PACU.

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Disclosure statement

This study did not receive or require any funding sources. The authors have no commercial or non-commercial affiliations representing potential conflicts of interest, nor do they have any associations with consultancies of any type.

Ethics statement

This investigation was approved by the Hospital São Luiz & Rede D'or and Affiliated Teaching Hospitals Research Ethics Committee (Protocol # 5,188,464; CAAE: 54253821.6.0000.0087). Patient consent for publication was not required.

Conflicts of interest

The authors declare no conflicts of interest.

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.bjane.2023.07.013.

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