

ENSURING SPECIFICITY AS A STRATEGY FOR INCREASING ALARM SAFETY

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Received: 14.02.2023; **Accepted:** 20.06.2023; **Available Online Date:** 30.09.2023

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Cite this article as: Gul G, Seren-Intepeler S. Ensuring Specificity as A Strategy for Increasing Alarm Safety. J Basic Clin Health Sci 2023; 7: 139-147.

ABSTRACT

Background: Alarms are systems created to ensure patient safety. However, when its specificity is not ensured, false positive alarms occur, causing the crying wolf phenomenon and compromising patient safety.

Purpose: This study aimed to decrease the number of false-positive alarms by ensuring the standardization and specificity of alarms.

Methods: This prospective, quasi-experimental study with a pre/post intervention study was conducted in the adult intensive care unit of a training and research hospital through repeated measurements at the beginning and after the intervention.

Results: The total alarm load decreased by 46% after the intervention, with the heart rate, saturation, and blood pressure alarms being reduced at a rate of 59%, 56%, and 23%, respectively. The hourly mean number of alarms decreased from 16.8 to 9. Differences between heart rate, oxygen saturation, and blood pressure alarms in terms of the parameter were statistically significant ($p < 0.05$).

Conclusion: The study showed that the number of alarms could be decreased by standardizing the alarms and ensuring specificity in the adult intensive care unit.

Keywords: Clinical alarms, Critical care, Patient monitoring, Alarm management

INTRODUCTION

Monitor alarms are significant data resources during patient follow-up in postoperative intensive care units where acute hemodynamic changes occur in patients (1). The American Society of Anesthesiologists (ASA) indicates that the hemodynamic parameters of patients should be monitored continuously in postoperative intensive care units (2,3). In ensuring patient safety, it is important that nurses trust and manage the monitor alarms, as they serve as the primary information resource for clinical diagnosis and treatment and thus help to direct patient care (4-6). However, studies show that 48% to 88% of the

monitor alarms in the intensive care units are false positives (7-11).

Alarms should be designed to work with 100% sensitivity to never miss a clinically significant incident and with 100% specificity to not ring when no significant incident occurs (5,12). While sensitivity is ensured by biomedical engineers, healthcare personnel should ensure specificity (13). However, in critical care environments, threshold values are not arranged and compromises are made on specificity (11,13). Low specificity may result in correct, but clinically insignificant, alarms defined as false positives, which require no action. The constant sound of alarms going off and the fact that most of them are

inactive/false alarms can cause alarm fatigue, a concept best understood as the "crying wolf" phenomenon (1,8,14-17).

As a response to the patient safety problem resulting from alarm fatigue, the Joint Commission made it compulsory that there are safety processes in place related to monitoring systems (18). International patient safety organizations report that processes differ by hospital unit and that improvements should be developed based on the unit (19-22). Institutional policies should be created, alarm settings should be customized for specific patient populations (23), and steps should be taken to ensure that the personnel are only exposed to the alarms that require clinical intervention (18). Studies show that decreasing the number of alarms and/or improving the positive estimation value may reduce alarm fatigue (11,24,25).

The literature shows that when the respiratory threshold alarm level increases from 30 to 35 and the O₂ threshold alarm level decreases from 94 to 89, the total number of alarms decreases by 40% (11). Gross et al. (2011) found that increasing the heart rate threshold alarm from 120 to 130 led to a 50% decrease, decreasing the SpO₂ threshold alarm from 90% to 85% led to a 36% decrease, and decreasing SpO₂ to 80% led to a 65% decrease (26). In another study, alarms were decreased by 43% by removing the repeated alarms and adjusting the alarm limits (27). A study conducted as a quality improvement project found that the number of alarms decreased from 88 to 59 on average in a patient day when the alarm settings of the monitors are adjusted (28). A qualitative study indicated decreasing false alarms and creating hospital/unit-based procedures as two of the strategies for improving alarm management (29). Implementation of these interventions, which are proven to be effective, will decrease alarms and increase patient safety. This study aims to decrease the number of false-positive alarms by standardizing the specificity of alarms.

METHODS

Research question

1. Does standardizing the alarm parameters and ensuring specificity decrease the number of false-positive alarms in adult intensive care units?

Design

The study was conducted in a prospective, quasi-experimental design with a pre/post intervention study.

Settings

The study sample consisted of the monitor parameters of the patients who underwent major thoracic surgery (pneumonectomy, lobectomy, pleurectomy, etc.) and were treated in an adult intensive care unit (pre-intervention n: 1361, post-intervention n: 739). A literature review on the sample size indicated that studies have been conducted with the monitor parameters ranging from a minimum of a week to a maximum of three months before and after the intervention (13,27,28,30).

The present study was conducted for three months before the intervention and three months after the intervention, which was the longest period in the literature, to assess the parameters.

Thus, the three-month monitor parameters before (to determine the situation) and after (to implement the alarm safety strategy) the intervention constituted the study sample. The monitor parameters within 162 hours were included in the study: 81 hours corresponding to the pre-intervention three months for determining the situation and 81 hours corresponding to the post-intervention three months for implementing the strategy.

The study included the monitor data of the patients with the lowest heart rate, invasive or closely monitored non-invasive arterial blood pressure, and oxygen saturation. When there was a patient who required a different clinical intervention and/or alarm parameter, the alarms were adjusted accordingly, and the alarm data of these patients were not included in the study.

Participants

The study was conducted in the second level intensive care unit in a training and research hospital between September 2018 and June 2020. This intensive care unit, where 11 nurses work, is classified as a secondary thoracic surgery intensive care unit and has seven beds separated with curtains to ensure privacy. The patients are generally treated in the intensive care unit for 24 hours postoperatively, and then, those whose medical conditions become

stabilized are transferred to a lower level of care. The patients are monitored through the bedside monitor system. There are no nurses with a described task of continuously checking the alarms. In the intensive care unit, measures are taken for general patient safety; however, there are no procedures that cover the alarm load, alarm notification, and alarm content to ensure alarm safety.

Data collection tool

The data were collected using the Monitor Alarm Record Form prepared in line with the literature (1,14,27,28).

Monitor Alarm Record Form: The form was prepared by the researchers and included the categories of date, day, time, monitor number, physiological parameters (heart rate, oxygen saturation, blood pressure, and pulse number), and alarm type (threshold alarm or crisis alarm).

All data were collected by the researcher in the study. Monitor data were obtained for each hour within 24 hours to correctly determine the situation. Thus, the effect of time was eliminated. Research staff selected the patients for data collection for each period and included the day and night shifts equally in the study. Data were collected randomly from all monitors to represent 7 days and 24 hours including different days, hours, and shifts. The possibility of causing a systematic selection bias was eliminated.

Determination of the Pre-Intervention Situation

In the first stage, alarm data were collected from the physiological monitors to determine the pre-intervention situation. The information including alarm load, alarm notification, and alarm content were recorded using the Monitor Alarm Record Form in line with the specified data collection principles.

Intervention

The data obtained in the second stage of the study were assessed by being submitted to the administration and the unit personnel. An improvement process was planned with the intensive care unit personnel within the scope of the strategies recommended by international patient safety institutions to increase alarm safety: creating institutional policies, customizing the alarm settings for specific patient populations (23) and taking steps to ensure that the personnel are only exposed to the alarms that require clinical intervention (18). In this

regard, it was decided that the strategy of standardizing and expanding the alarm parameters within the safe limits based on the literature would be used. A study on alarms conducted with anesthesiologists the physician responsible for the patient concluded that it was safe to expand the limits with the optimal values of +/- 20% for heart rate and systolic arterial pressure, while another study indicated that +/- 30% was safe (31-33). The upper and lower limits were determined as follows: a lower limit of 90% for partial O₂, upper and lower limits of 120 and 50/minute for heart rate, upper and lower limits of 120 and 50/minute for partial pulse, a blood pressure systolic upper limit of 160 mmHg and lower limit of 90 mmHg, a blood pressure mean upper limit of 120 mmHg and lower limit of 75 mmHg, and a blood pressure diastolic upper limit of 90 mmHg and lower limit of 50 mmHg. Then, alarm data were obtained from the physiological monitors for the determined time periods for three months.

Data analysis

The alarm data were analyzed under the categories of alarm load (the number of alarms the personnel are exposed to), alarm notification (whether the alarms are transmitted from the medical device to the personnel), and alarm content (the information transferred to the caregiver with the alarm signal), which are the factors recommended by the Emergency Care Research Institute for comprehensive alarm inspection (20). The collected data were analyzed with SPSS v.21. Central indices and data distribution were measured using descriptive statistics, which included mean (for both quantitative and qualitative variables), standard deviation, frequency, and percentage.

The Mann-Whitney test was applied to evaluate the impact of the interventions. Statistical level of significance for the tests was set at 0.05, and the confidence interval was 95%.

Ethical considerations

This study was conducted in accordance with the Helsinki Declaration. The study was approved by the Non-Invasive Clinical Research Ethics Committee (Decision Date: 3.1.2018, Decision No: 2018/06-10). Institutional permission was obtained from the Training and Research Hospital (decision date: 6.22.2018; number: 49109414-806.02.02) to conduct the study

Table 1. Pre-intervention and post-intervention alarm parameters' threshold levels and sound pressures

Alarm Type	Physiological Parameter	Alarm Threshold Level		Sound Pressure Level	
		Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention
High Priority	Asystole	Open	Open	Highest	Highest
	Desaturation	On	On	Highest	Highest
	Heart Rate Upper Limit	Undetermined, Different in Every Monitor	120/min	Different in Every Monitor or Off	Medium
	Heart Rate Lower Limit	Undetermined, Different in Every Monitor	50/min	Different in Every Monitor or Off	Medium
	O ₂ Saturation Lower Limit	Undetermined, Different in Every Monitor	90%	Different in Every Monitor or Off	Medium
	Blood Pressure Systolic Upper Limit	Undetermined, Different in Every Monitor	160 mmHg	Different in Every Monitor or Off	Medium
	Blood Pressure Systolic Lower Limit	Undetermined, Different in Every Monitor	90 mmHg	Different in Every Monitor or Off	Medium
	Blood Pressure Mean Upper Limit	Undetermined, Different in Every Monitor	120 mmHg	Different in Every Monitor or Off	Medium
	Blood Pressure Mean Lower Limit	Undetermined, Different in Every Monitor	75 mmHg	Different in Every Monitor or Off	Medium
	Blood Pressure Diastolic Upper Limit	Undetermined, Different in Every Monitor	90 mmHg	Different in Every Monitor or Off	Medium
	Blood Pressure Diastolic Lower Limit	Undetermined, Different in Every Monitor	50 mmHg	Different in Every Monitor or Off	Medium
	Peripheral Pulse Upper Limit	Undetermined, Different in Every Monitor	120/min	Different in Every Monitor or Off	Medium
	Peripheral Pulse Lower Limit	Undetermined, Different in Every Monitor	50/min	Different in Every Monitor or Off	Medium

RESULTS

The alarm data were presented under the categories of alarm load, alarm notification, and alarm content. Table 1 shows the pre-intervention and post-intervention threshold values and sound pressure of the physiological parameters. For the pre- and post-intervention alarm notification and content in the monitors in the intensive care unit, it was observed that alarms were transmitted for two physiological parameters that gave the high priority crisis alarm (asystole and desaturation) and that the alarms were transmitted in all monitors with the highest sound pressure. The alarm thresholds were different in every monitor for 11 physiological parameters with medium priority before the intervention. The sound pressure was different in every monitor or off for the peripheral pulse upper limit, peripheral pulse lower limit, blood pressure means upper limit, and blood pressure mean lower limit alarms.

Table 2 shows the number and percentage distributions of the status alarm parameters according to shift before the intervention. Monitor data consisted of 81 patient hours: 40 hours in the day and 41 hours at night. A total of 1361 alarms occurred: 716 alarms during the day shift and 645 alarms during the night shift. Of the alarms, 48% were oxygen saturation, 25% were heart rate, 14% were blood pressure, and 13% were partial pulse alarms. In terms of alarm load, the personnel were exposed to 16.8 alarms per hour on average. The alarm thresholds were standardized within the safe limits in every monitor for 11 physiological parameters with medium priority: heart rate upper limit, heart rate lower limit, O₂ saturation lower limit, blood pressure systolic upper limit, blood pressure systolic lower limit, blood pressure mean upper limit, blood pressure mean lower limit, blood pressure diastolic upper limit, blood pressure diastolic lower

Table 3. Distribution of the number of alarms according to shift after the intervention (n: 739)

Shift	Oxygen Saturation (O ₂)		Heart Rate (HR)		Blood Pressure (TA)		Pulse Rate (PR)		Total	
	N	%	n	%	n	%	n	%	n	%
Day	153	21	79	11	119	16	62	8	413	56
Night	138	19	61	8	25	3	102	14	326	44
Total	291	40	140	19	144	19	164	22	739	100

limit, peripheral pulse upper limit, and peripheral pulse lower limit. Sound pressure was adjusted to the medium sound level for the heart rate upper limit, heart rate lower limit, O₂ saturation lower limit, blood pressure systolic upper limit, blood pressure systolic lower limit, blood pressure means upper limit, blood pressure means lower limit, blood pressure diastolic upper limit, blood pressure diastolic lower limit, peripheral pulse upper limit, and peripheral pulse lower limit alarms.

Table 3 shows the numbers and percentages for the alarm parameters after the intervention. A total of 739 alarms occurred within 81 hours - 41 hours during the day shift and 40 hours during the night shift - and an average of nine alarms were recorded per hour in terms of alarm load. Of the alarms, 40% were oxygen saturation, 22% were partial pulse, and 19% were heart rate and blood pressure alarms.

Table 4 shows the pre- and post-intervention number of alarms and the change percentages based on the parameters. According to the parameters, the alarms decreased by 59% for heart rate, 56% for oxygen saturation, 23% for blood pressure, and 7% for partial pulse. The total alarm load decreased by 46%.

Results of the non-parametric Mann Whitney-U test, which was performed to determine whether the change based on parameters differed significantly or not, showed that there was a statistically significant difference at the p<0.05 level in the post-intervention heart rate, oxygen saturation, and blood pressure parameters.

DISCUSSION

Monitor alarms are significant data sources for following the acute hemodynamic changes in patients in postoperative intensive care units (1,38). The American Society of Anesthesiologists (ASA)

recommends that patients' hemodynamic parameters are continuously followed (2,3). In this process, false-positive alarms jeopardize patient safety. Safe patient care can only be possible by ensuring the alarms' specificity. The present study developed a process to ensure alarm standardization and specificity and to reduce alarm load. The program, which was implemented to increase alarm safety in the adult intensive care unit, was observed to successfully decrease the alarms.

The study indicated that crisis alarms were customized in terms of alarm notification and content but the threshold alarms were not standardized in the monitors before the intervention. Alarm notifications and contents were standardized within safe limits and specificity was ensured after the intervention (Table 1). The changes in the monitor alarm settings were made within the safe limits for the monitored patient populations in line with the recommendations of the supervisor physician in the intensive care unit and the literature (5,31,32,34,35,39). The alarms were carefully balanced so that the healthcare personnel could not ignore relevant clinical alarms. Standardization of the alarm threshold settings and adjustment of the sound pressure levels were made considering the potentially fatal results of a single adverse event. During the process after the interventions, no patient safety adverse events regarding the alarms occurred in the intensive care unit.

Assessment of the physiological parameters according to shift in terms of alarm load indicated that the alarm rates were balanced (Tables 2-3). The Emergency Care Research Institute reported that alarm-related damages occur in all health institutions almost every day and every minute (36). Within the

Table 3. Distribution of the number of alarms according to shifts after the intervention (n= 739)

Shift	Oxygen Saturation (O ₂)		Heart Rate (HR)		Blood Pressure (TA)		Pulse Rate (PR)		Total	
	n	%	n	%	n	%	n	%	n	%
Day	153	21	79	11	119	16	62	8	413	56
Night	138	19	61	8	25	3	102	14	326	44
Total	291	40	140	19	144	19	164	22	739	100

improvement studies, assessment of the data at all hours of the day and night and carrying out personnel planning based on these data are recommended by international institutions (4,36,37). Planning the improvement processes through assessments in the day and night shifts may provide a significant contribution to ensuring alarm safety.

Assessment of the alarm frequencies for physiological parameters indicated that oxygen saturation caused the highest rate of alarms (48%-40%) before and after the intervention (Table 2-3). While the oxygen parameter is ranked first in some studies conducted in adult intensive care units (11,26), other studies ranked the alarm parameters of pulse alarm (27), heart rate alarm (9), or blood pressure alarm (28) first. The result obtained in the present study supported that unit-based interventions recommended by international institutions should be improved to ensure alarm safety (18,23). While managing the patients' care and treatment process in the intensive care unit, the oxygen parameter, which yielded the highest alarm load, can be assessed together with other clinical data and observations and effective management schemes can be developed.

Assessment of the personnel's alarm exposure indicated that the mean number of alarms decreased

from 17 before the intervention to 9 after the intervention. Assessment of the reflection of the improvement on the parameters indicated that the heart rate and oxygen saturation alarms decreased by over 50%. The total alarm load decreased almost as much as the pre-intervention number of alarms. Differences between heart rate, oxygen saturation, and blood pressure alarms based on the parameter were statistically significant ($p < 0.05$). (Table 4). Many previous studies have obtained similar results (5,13,30,33,34). Examined together with the results of previously published studies, the findings of the present study show that the number of alarms can be decreased by ensuring the specificity of the alarms that occur most frequently.

This study enabled the digitization of the alarms that may pose a risk for patient and personnel safety by increasing the alarm load. These data indicate that specified true positive alarms can be obtained, which constitutes the first step in managing the alarm life cycle (alarm, transmission to the personnel, and response) based on safety.

CONCLUSION

This study constituted the first step to assess and improve the management of clinical alarms in the

Table 4. Mann Whitney-U test results on number of alarms and modification rates before and after intervention

Alarm Parameter	Before Intervention	After Intervention	Change %	z	p
Heart Rate (HR)	341	140	-59	-5.153	.001
Oxygen Saturation (O ₂)	658	291	-56	-4.016	.001
Blood Pressure (TA)	186	144	-23	-2.099	.036
Pulse Rate (PR)	176	164	-7	-1.757	.079
Total	1361	739	-46		

other intensive care units in the institution. Improving clinical alarm management is a long process involving different institutions and unit-based improvement strategies. With the continuously developing technologies and caregiving standards, there will be no defined endpoint where all alarm dangers are eliminated. It should be accepted that alarm dangers are not only technological problems, but organizational culture and processes should also be investigated. It should be ensured that the strategies help adaptation to the needs and workflow in every clinical environment by ensuring participation by the personnel in the identification and implementation of improvement strategies. Institutions should consider alarm problems beyond alarm fatigue and prioritize alarm management in patient safety as the first step in process improvement. It is recommended that the results of this study are assessed in different intensive care units to be effectively used in practice.

Limitations

In this study, the results were limited to the monitor alarms because ventilators and other devices were not continuously used in the intensive care unit depending on the patient status. In addition, the fact that the study was conducted only in a surgical intensive care unit, not in a neonatal, pediatric, or adult intensive care unit, may constitute a limitation for the generalizability of the results.

Acknowledgement: We thank the hospital's nursing services director, Health Sciences University, Dr. Suat Seren Chest Diseases and Surgery Education Research Hospital administrations and intensive care unit nurses for their support in all the processes.

Author contribution: AYY, VAÖ and ÖA designed the study. AYY, VAÖ and ÖA collected the data. AYY analyzed the data. AYY, VAÖ and ÖA prepared the manuscript. All authors approved the final version for submission.

Conflict of interests: All authors have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethical approval: This study was conducted in accordance with the Helsinki Declaration. The study was approved by the Non-Invasive Clinical Research Ethics Committee (Decision Date: 3.1.2018, Decision No: 2018/06-10). Institutional permission was obtained from the Training and Research Hospital (decision date: 6.22.2018; number: 49109414-806.02.02) to conduct the study.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Peer-review: Externally peer-reviewed.

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