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USABILITY OF MECHANIC VENTILATORS CLINICAL ALARMS IN INTENSIVE CARE[1]

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ABSTRACT
Problems inherent in the usability of medical and healthcare equipment (MHE) and patient safety in intensive care units (ICU) go beyond those described among the six international goals patient safety from the National Institutes of Health (NIH). The mechanical ventilators (MV) generate many audible alarms, some with inconsistent data. The objective was to analyze the usability of audible alarms triggered by VM in ICU. Descriptive observational research, study case type with a quantitative approach, developed in the ICU of a university hospital located in Rio de Janeiro. Data were analyzed with descriptive statistics. During 30 hours of observation, 129 alarms triggered by MV were recorded, of which only 05 had a response and 124 fatigued. Respiratory high frequency (n=31), followed by low volume alarm (n=26), high airway pressure (n=24), low airway pressure (n=23), circuit disconnection (n=18), and alarm FiO2 (n=7) were the most prevalent. Only 36 were classified as consistent. The alarms have become increasingly trivialized by the team in the ICU. It is necessary to change the attitude towards them, improving their effectiveness.

Keywords: Clinical alarms. Patient safety. Intensive care.

INTRODUCTION

The central themes of this study are the usability of clinical alarm systems, fatigue alarms and patient safety in invasive mechanical ventilator support. It is assumed that usability evaluations are needed to improve the quality of interactive systems, and they can contribute significantly to improving safeguard systems and minimizing fatigue alarms on ventilator support. This is because the Mechanical Ventilators (MV) are systems with high levels of criticality, especially from human action and the hospital setting where they are used with specific contexts of work that can significantly affect the use and safety of Medical-Healthcare Equipment (MHE).

According to ISO 9241-11, from the perspective of ergonomics, usability is defined as the ability of a product to be used by specified users to achieve different goals with effectiveness, efficiency and satisfaction in a specified context of use(1).

The Methodological Guidelines for Assessment Study of MHE recommends to get information and evaluate it before clinical, eligibility, technical, operational, economic and innovation areas(1).

The operational domain analyzes the external and internal variables that influence the performance of the technology and service using technology and constituting the usability of its items. It can be understood as a characteristic of a human factor related to ease of use, effectiveness, efficiency and user satisfaction.

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The problems of patient safety in intensive care units (ICU) go beyond the adverse events related to errors in medication administration or failures in aseptic during invasive procedures. The monitoring of an increasing number of physiological variables, the resulting increase in the number of audible alarm signals triggered by MHE and its misuse threaten patient safety[2].

Several studies have shown how high is the number of audible alarm signals triggered by MHE in the ICU and how much the Mechanical Ventilators compete for it. The consequence is the extension of time to respond to these alarms, showing that fatigue alarm is indeed a recurring problem in the units studied[2-4].

Fatigue alarms are a phenomenon in which health professionals become insensitive to alarms, ignoring them or delaying the response time, being a major problem present in the ICU. Studies reveal that this is a phenomenon related to misuse of inconsistent alarm systems, enabling consistent alarms can get lost in a cacophony of noise in the unit[4-6].

Concerned about the impact of increasing the number of audible alarms triggered by MHE and especially with inconsistent alarms, and the resulting cacophony of noise that they create and their consequences for patient safety in critical units, the Joint Commission in January 2014 reviewing the goals for patient safety - National Patient Safety Goals (NPSG) recommends focusing on alarm management in critical care units to reduce the damage associated with alarm systems (Goal 6) 2016[7]. In this perspective, the MV have been highlighted as one of the responsible for firing inconsistent alarms contributing significantly to this cacophony of noise[7].

Mechanical ventilators generate a significant number of audible alarms, and many of them do not have an answer, becoming fatigued. In part, this is due to its short duration, so even before they can be answered or even perceived by professionals, they have silenced automatically as soon as the variable physiological values violated, return to the values considered acceptable[3,4].

The problem of alarms triggered by MV made the Association of Medical Instrumentation - AAMI Foundation in March 2014, warn health professionals through a Webinar titled "Current Challenges with Ventilator Alarms" on problems with alarms, pointing out some possible ways to improve practices in safety and quality alarms such equipment, its limitations and barriers to safety, with emphasis on the need to manage them and use them better[8].

The problem highlighted in the "Current Challenges with Ventilator Alarms" is that many of these alarms get fatigued due to usability problems and more often as a result of failures in the settings/parameterization of neighboring alarm values, whose very wide limited values may result in significant events loss[8].

About alarm systems on mechanical ventilators, like any other system, also aimed at alerting staff to changes in the patient´s condition or malfunction of the ventilator, including changing the gas mixture (FiO2).

When combined with another usability MHE, this usability of MV alarm systems can significantly increase the number of alarms triggered on the unit and potentially compromising consistent audibility alarms. National studies show that audible alarms triggered by MV may represent 30-33% of all alarms of an ICU, and the elevation alarm respiratory rate and elevation of airway pressure are the most prevalent. In is highlighted it should be cause for concern that only just over 7% of these alarms are assisted by the teams in the units[3,4], since they may be representing a problem in relation to ventilator support employed to the patient and that when dropped, they put the patient´s life at risk to an imminent condition.

This study has the objective to analyze the usability of audible alarms triggered by mechanical ventilators in intensive care units.

METHODOLOGY

Observational and descriptive study, a case study type of a quantitative approach, developed in an Intensive Care Unit with seven beds of a large university hospital, located in the municipality of Rio de Janeiro (RJ), with active operational capacity of six hundred beds of which only the beds from one to six are equipped with mechanical ventilation, SERVO-S® model and object of the usability evaluation.

For the production of the field observation data, a script that allowed the register of professional response time to the mechanical ventilator alarms was used, as well as the consistency of triggered alarms. The efficacy/effectiveness and safety metrics allowed us to analyze how effective and safe are the clinical alarm system of the MV, if it generates risks or, on the contrary, it reduces risks, given the recommendation of ISO 9126-4/2004 for quality assessment studies in use.

About efficiency/effectiveness, it was considered the ratio between the number of consistent and inconsistent alarms. Consistent alarms were those that reported data quality; that is the alarms were related to an organic instability of the patient or malfunction of the mechanical ventilator. Inconsistent alarms were those not informing the quality of data, which had no relation to the malfunction ventilator or organic patient instability.

Concerning to security metric, the users' response time to alarms triggered by the MV and the ratio between the number of alarms and answered fatigued was evaluated. Those who were with stimulus-response time greater than 04 minutes and those who silenced automatically were recorded as fatigued, considering the worst outcome for the patient (decrease survival and neurological sequels)[9,10].

The observation was not participatory, in which the researcher was around the beds of patients who were in invasive ventilator support, recording and featuring audible alarms triggered by MV and timing the time of the team's professional response. If apnea alarms were triggered and identified by the researcher, they were immediately communicated to staff to safeguard the life of the patient.

There were 30 hours of observation in the period of 01/15/13 to 03/21/13, only during the daytime shifts for nine days from discontinued observations on different days and times. The observation was held in five days in the morning and four in the afternoon.

The professional response time to the alarm was measured with a digital timer that was triggered immediately from the moment the buzzer was perceived by the researcher. The timer was paused (time stimulus-response) from two possibilities or conditions: 1- as soon as the professional had reached the bed of the patient, but not take other action that would not observe the patient and the MV; 2- as the alarm will automatically stop sounding independent of a professional answer.

The sound pressure of the MV alarm and the noise level in the environment were measured with the help of an industrial decibel (professional) meeting as recommended by national technical rules, allowing to observe the audibility of mechanic ventilator alarms. The equipment used was digital sound level meter H811-416 408A HOMIS model. There were 30 measurements over nine days of observation in the morning and afternoon.

The decibel meter equipment used has switchable measuring ranges from 35 to 100dBA (low) to 130dBA (high), with basic accuracy with the ambient temperature between 18 and 28 Celsius degrees, plus or minus 1,5dBA. Calibration was made using the calibrator 895-decibel meter-HOMIS model before each measurement.

The normal range and the highest peak intensity scale were used to record the noise level. The first one is to the most frequent values recorded by the equipment at the time of the sound pickup and the second refers to the highest value detected in the same period.

For the classification of noise, values established by the Brazilian Association of Technical Standards were used, establishing the allowed noise level of 50dBA during the daytime and 40dBA during the night for hospital environments like apartments, hospitals, nurseries and operating room. The recommendation is to keep the noise level between 35 and 45dBA, the first being considered the level of listening comfort and according to the acceptable limit[11].

After checking the calibration, the equipment was placed on a flat surface at the level of the patient´s bed, always in the same place of the nursing station in all measurements performed.

The measurement of the level of SERVO-s ventilator alarm noise was also done in a separate room of the Intensive Care Unit to ensure that there was no interference from other noises. In this room, the ventilator was induced to alarm, and the volume was adjusted in a range of 10 to 100%. The noise meter was placed on a

rigid surface at the height of the machine and a distance of 1 meter from this and walls.

For analysis, the data were organized in a spreadsheet of Microsoft Office Excel 2007, processed and analyzed using the R program in version 2.15.1. A descriptive statistical analysis was performed for the study variables.

The study met the specifications of Resolution 466/2012[12] and was approved by the Research Ethics Committee of the Federal University of the State of Rio de Janeiro - UNIRIO. It was obtained the consent of professional nursing staff involved in the study. The research protocol CAAE: 07134912.0.0000.5285 was approved on 27 November 2011.

RESULTS AND DISCUSSION

During the observation period, it was found that the number of professionals within the unit during the morning and afternoon were between 18 and 35 people. In addition to health professionals and patients, two secretaries, a referral and two professional cleaning daily share the same physical space in the unit studied, contributing to high levels of noise along with the signal triggered alarms.

There were 129 audible alarms triggered by MV recorded, the most prevalent were the high respiratory rate (n=31), followed by low volume alarm (n=26), high airway pressure (n=24), low airway pressure (n=3), circuit disconnection (n=18) and alarm FiO2 (n=7).

The presence of a patient in invasive ventilator support completely lucid and sedation interruption protocol, in the period of field research, can explain the high number of alarms registered by the mechanical ventilator, especially those triggered by increased respiration and low volume.

Study[3] on fatigue of MV alarms showed a high number of audible alarm signals triggered by it (181 alarms in 32 hours of observation), of which the high ventilator rate (96 alarms) and high airway pressure (59) were the most prevalent.

About consistency or not audible alarms triggered of 129 MV registered, only 28% (n=36) were classified as consistent with 72% (n=93) of those considered the quantitative responses/visits by professionals, only five were promptly answered, against a lot of weary alarms or without the response to 124 alarms.

The high number of inconsistent alarms can cause a real life-threatening event lost in a cacophony of noise because of the multitude of devices with signals of competing alarms, all trying to get someone´s attention without proper clarity of why and what it is supposed to do. This constitutes a major cause of fatigue alarm[13].

The excess of inconsistent alarms, also called false positives, leading to an apathy team and not being sensitive that the actual events and consistent alarms are less likely to be met. This is a typical problem that usability can lead to adverse events, greatly compromising the efficiency/effectiveness and safety of clinical alarm systems[14].

The amount of alarms triggered by MV in this study has already been reported by another study conducted at ICU, which showed that over 30% of MHE alarm in the ICU, study scenario, are from MV, especially high alarm number of high frequency ventilation and high air pressure, which proved to be the variables that most triggered audible alarms signals[3].

The noise level in the environment achieved sound pressure values ranging from 48.1 dBA to 78 dBA, while the level of MV alarm noise isolation ranged between 40 and 50 dBA when the alarm volume level was set to gain 10% of its volume, and between 48 and 64 dBA when the volume was adjusted to 100% gain. It should be noted that at the time of measuring the noise level in the unit, the alarm volume level in each of the electrical equipment in operation and alarms triggered was unknown, including the MV.

Thus, it is clear from the above data that a ventilator alarm is perfectly capable of being covered by the noise levels recorded in the ICU setting of this study, and this fact is due to the cacophony of noise of this environment, although its volume is set to maximum gain (set to 100%).

Regarding the alarms of mechanical ventilators, the sound pressure level produced by them alone can range from 62,7dBA to 77.8 inconsistent. Among dBA, showing how the

alarm sound of the MHE can contribute to the noise level in the unit[3].

Figure 01 shows the maximum time recorded in the alarms triggered by MV remained sounding before being answered or silenced automatically.

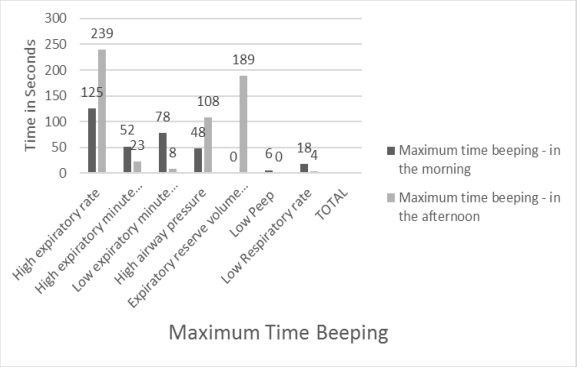

Figure 1. Distribution of audible alarms from the ventilator according to the maximum time they were sounding. Source: data collection instrument.

The data shows that the time when the MV alarms sounding remained until automatically be silenced or serviced by staff, was not more than four minutes, a time established as cut (upper limit) for an alarm to be considered fatigued. Even though it had not registered any wearied alarm due to the response time, the alarms are silenced automatically should be considered as fatigued as they were not answered by the professional.

In 2006, approximately 2,200 reports were received by the Emergency Care Research Institute, with approximately 12% included the word “alarm” in the problem description field. Reports related to alarm, 39% were on mechanical ventilators, 11% of multiparameter monitors and 14% of infusion pumps. Reports of the MV's and BI's indicate the occurrence of device failures that put the patient at risk, and that did not result in an alarm to alert the professionals[15].

The frequency of use of ventilatory support for patients in ICU was so high that approximately 58% of patients with heart failure had a diagnosis of impaired ventilation[16]. This situation shows the high use of this technology in this environment, which consequently contributes to increased frequency of alarms coming from mechanical ventilators.

FINAL CONSIDERATIONS

Even considering some limitations of the study, such as data production have been carried out in only one ICU and for a short period of observation, with few observed beds, some findings deserve attention and reflection by those who militate in these units, particularly concerning the usability of the alarm systems fitted to MV.

The findings of this study, even though they had not shown fatigued alarms, revealed a high number of alarms unanswered, because not only by the industry characteristics of alarm systems that equip the MV that allows them to be silent automatically but also because of its poor usability (settings, configuration and parameterization), suggesting that, at some point, consistent alarms may have been ignored by staff, thus compromising patient safety.

The results of this study reinforce the concern of the researchers of this study on the efficacy/effectiveness and safety of mechanical ventilator alarms, what makes them think that it is urgent to improve the usability of these features from programming and configuration of alarm and volume parameters the MV as practices that should be incorporated into the routine of intensive care units and responsibility of nurses, doctors, and physical therapists, including to care and critical judgment of triggered alarms.

The evolution of MV can enlarge the support possibilities and monitoring of critically ill patients in respiratory failure, while now requires professional a higher level of qualification and technical and scientific preparation, with a greater presence at the bedside, to handle the challenges and risks of this process.

As nursing professionals, we can and must use all the technological apparatus available following the assistance to patients in ICU not only for diagnostic and therapeutic purposes but also to improve the patient's protective barriers, with positive developments in quality of care and security, however, it is necessary to improve its usability.

RESUMO

Problemas inerentes a usabilidade de Equipamento Médico-Assistencial (EMA) e segurança do paciente em Unidades de Cuidados Intensivos (UCI) vão além daqueles descritos entre as seis metas internacionais de segurança do paciente do National Institutes of Health (NIH). Os Ventiladores Mecânicos (VM) geram muitos alarmes sonoros, alguns com dados pouco consistentes. Objetivou-se analisar a usabilidade de alarmes sonoros disparados por VM em UCI. Pesquisa observacional descritiva, do tipo estudo de caso, com abordagem quantitativa, desenvolvida na UCI de um hospital universitário localizado no Rio de Janeiro. Os dados foram analisados com estatística descritiva. Durante 30 horas de observação, foram registrados 129 alarmes disparados pelo VM, dos quais, somente cinco tiveram resposta e 124 fatigaram. Frequência respiratória alta (n=31), seguida do alarme de volume corrente baixo (n=26), pressão de via aérea alta (n=24), pressão de via aérea baixa (n=23), desconexão de circuito (n=18) e alarme de FiO2 (n=7) foram os mais prevalentes. Apenas 36 foram classificados como consistentes. Conclui-se que os alarmes passaram a ser cada vez mais banalizados pela equipe nas UCI. É necessário mudar a postura diante deles e melhorar sua efetividade.

Palavras-chave: Alarmes clínicos. Segurança do paciente. Cuidados intensivos.

USABILIDAD DE ALARMAS CLÍNICAS DE VENTILADORES MECÁNICOS EN CUIDADOS INTENSIVOS

RESUMEN

Los problemas inherentes a la usabilidad de Equipo Médico-Asistencial (EMA) y seguridad del paciente en Unidades de Cuidados Intensivos (UCI) van más allá de los descritos entre los seis objetivos internacionales de seguridad del paciente del National Institutes of Health (NIH). Los Ventiladores Mecánicos (VM) generan muchas alarmas sonoras, algunas con datos inconsistentes. El objetivo fue analizar la usabilidad de alarmas sonoras provocadas por VM de las UCI. Estudio descriptivo observacional, del tipo estudio de caso, con abordaje cuantitativo, desarrollado en la UCI de un hospital universitario ubicado en Rio de Janeiro. Los datos fueron analizados con estadística descriptiva. Durante 30 horas de observación, se registraron 129 alarmas activadas por VM, de las cuales solo cinco tuvieron respuesta y 124 fatigaron. Los más prevalentes fueron: Frecuencia respiratoria alta (n = 31), alarma de volumen de corriente bajo (n = 26), presión de la vía aérea alta (n = 24), presión de la vía aérea baja (n = 23), desconexión de circuito (n = 18), y alarma FiO2 (n = 7). Solo 36 fueron clasificados como consistentes. Se concluye que las alarmas se han vuelto cada vez más trivializadas por el equipo en las UCI. Es necesario cambiar esta actitud y mejorar su efectividad.

Palabras clave: Alarmas clínicas. Seguridad del paciente. Cuidados intensivos.

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