

State of Science in Alarm System Safety: Implications for Researchers, Vendors, and Clinical Leaders

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Abstract

Alarm fatigue is a complex phenomenon that needs to be assessed within the context of the clinical setting. Considering that complexity, the available information on how to address alarm fatigue and improve alarm system safety is relatively scarce. This article summarizes the state of science in alarm system safety based on the eight dimensions of a sociotechnical model for studying health information technology in complex adaptive healthcare systems. The summary and recommendations were guided by available systematic reviews on the topic, interventional studies published between January 2019 and February 2022, and recommendations and evidence-based practice interventions published by professional organizations. The current article suggests implications to help researchers respond to the gap in science related to alarm safety, help vendors design safe monitoring systems, and help clinical leaders apply evidence-based strategies to improve alarm safety in their settings. Physiologic monitors in intensive care units—the devices most commonly used in complex care environments and associated with the highest number of alarms and deaths—are the focus of the current work.

Nurses in intensive care units (ICUs) are exposed to as many as 350 alarms per bed per day, of which 85% to 99% are nonactionable.¹ This causes alarm fatigue, whereby nurses become insensitive and nonreactive to alarms. As a consequence, they may miss serious alarms, which may result in patient death.²

Alarm-equipped medical devices are not new to healthcare, but technological advances with a focus on liability have increased the sensitivity of the devices at the expense of specificity. Despite the presence of national guidelines and increased research

on alarm system safety, alarm fatigue remains a major healthcare burden.

Sentinel events and deaths attributed to alarm fatigue² led The Joint Commission (TJC) to issue National Patient Safety Goal (NPSG) 06.01.01 specific to alarm system safety.³ Moreover, the ECRI Institute ranked alarms, including inadequate alarm configuration practices and alarm fatigue, as the top technology hazard in four consecutive years (from 2012 to 2015)⁴ and ranked missed alarms among the top 10 technology hazards in 2016–2020.⁵

In 2014, TJC required hospitals to establish alarms as an organizational priority (phase 1) and develop policies, procedures, and training programs to manage alarms (phase 2).³ As a result, a remarkable increase has occurred in the number of research and quality improvement (QI) projects addressing alarm system safety and alarm fatigue. However, more work remains to be done to address alarm challenges. Alarm fatigue is a complex phenomenon that needs to be assessed within the context of the clinical settings. With that complexity in mind, little information is available on how to address alarm fatigue and improve alarm system safety.

Sittig and Singh⁶ developed a sociotechnical model for studying health information technology (IT) in complex adaptive healthcare systems. The model identifies eight interdependent and interrelated dimensions: (1) hardware and software computing infrastructure, (2) clinical content, (3) human-computer interface, (4) people, (5) workflow and communication, (6) internal organizational features (e.g., policies, procedures, culture), (7) external rules and regulations, and (8) measurement and monitoring.

The sociotechnical model depicts the position of technology within key complex

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contextual elements.⁷ The current article summarizes the state of science in alarm system safety based on the eight dimensions of the sociotechnical model and suggests implications to help (1) researchers respond to the gap in science regarding alarm safety, (2) vendors design safe monitoring systems, and (3) clinical leaders evaluate current practices and apply evidence-based strategies to improve alarm safety in their settings.

This article illustrates how the model of Sittig and Singh⁶ can be successfully applied to address alarm fatigue and improve alarm system safety within complex, adaptive healthcare settings. It focuses on physiologic monitors in ICUs, which are the most commonly used devices in complex care environments and are associated with the highest number of alarms and deaths in the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database and prior research studies.²

The current work seeks to provide the following for researchers, vendors, and clinical leaders:

- For **researchers**, it highlights key methodological and research considerations needed to improve alarm system safety and focuses on the value of log data in measuring the number of alarms, determining the priority of alarms, and tracking the alarm management practices of nurses.
- For **vendors**, it focuses on the need for built-in safety features and user-centered design.
- For **clinical leaders**, it addresses leading practices to mitigate alarm fatigue (while considering key contextual factors) and provides guidance for policies, procedures, and training programs on alarm system safety.

Methods

The state of science in alarm system safety was summarized, and the subsequent research and leadership implications were generated based on the eight dimensions of the sociotechnical model of Sittig and Singh.⁶ In addition to the authors' expertise in the field, the summary and recommenda-

tions were guided by a review of available systematic reviews and meta-analyses on the topic, a review of interventional studies published between January 2019 and February 2022, and a review of recommendations and evidence-based practice interventions published by professional organizations. The latter included a review of published toolkits, guides, position papers, and workbooks by TJC,⁸ the American Association of Critical-Care Nurses (AACN),⁹ ECRI,¹⁰ and the Association for the Advancement of Medical Instrumentation (AAMI).^{1,11,12}

Extraction and Analysis of Reviews and Meta-Analyses

A search identified systematic reviews and meta-analyses published on alarm fatigue and alarm system safety in PubMed, Scopus, TRIP, Cochrane, Google Scholar, and CINAHL. The key search terms used were *alarm*, *alarm fatigue*, *physiologic monitors*, *ICU*, and *systematic/meta-analysis* and their related MeSH terms. The only delimiter applied was English language.

Appendix A (available in the supplemental material for this article at www.aami.org/bit) provides an example of the search terminologies and the search results using PubMed. Appendix B (available in the supplemental material for this article at www.aami.org/bit) shows the results of the different phases of the search process based on the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) protocols.¹³

The 83 studies (Appendix B) were screened by two of the authors (A.K.S. and C.C.R.) for inclusion in the final analysis using the following eligibility criteria: (1) full text; (2) a systematic review or meta-analysis; and focused on (3) alarm system safety; and (4) use of physiologic monitors in (5) ICUs. The authors screened the titles and abstracts and excluded studies that did not meet all eligibility criteria. Disagreements were resolved by discussion and consensus. Five systematic reviews were included in the final analysis.^{14–18} No meta-analyses were found. The following data elements were extracted from the five systematic reviews: authors and year, objectives, databases screened, number of studies included in the final analysis, designs of the included studies, and results

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of the systematic review (Appendix C; available in the supplemental material for this article at www.aami.org/bit).

Extraction of Interventional Studies

The most recent systematic review found in the authors' search was published in 2020. Assuming that it takes one to two years to publish a systematic review suggests that studies published in 2019–2022 were not included among the published systematic reviews. Therefore, another search was conducted using PubMed to identify the single interventional studies that were published between January 2019 and February 1, 2022, using *ICU*, *alarm*, and *alarm fatigue* as the key search terminologies. The search yielded 29 studies.

Unrelated studies and studies that were conducted in non-ICUs ($n = 19$) and observational studies that focused on describing alarm rates and types or nurse perception of alarm fatigue ($n = 8$) were eliminated. This resulted in a total of two interventional studies related to alarm systems safety in ICUs. The two studies did not test new interventions but replicated interventions that were tested in previous reports.^{19,20}

Results

Summarizing the State of Science and Generating Recommendations

The results of the five systematic reviews and the two interventional studies were summarized under the eight dimensions of the sociotechnical model (Appendix D, column 1; available in the supplemental material for this article at www.aami.org/bit). The summary was augmented by our expertise in the field and by reviewing alarm-related toolkits, guides, position papers, and workbooks by TJC,⁸ AACN,⁹ ECRI,¹⁰ and AAMI.^{1,11,12} The summary helped generate recommendations for researchers, vendors, and clinical leaders (Appendix D, columns 2 and 3).

Approaching alarm system safety from the perspective of the sociotechnical model suggests addressing the interrelatedness and interdependence among the eight dimensions (Appendix D). Therefore, in addition to addressing the implications for each separate dimension, we demonstrated the interrelat-

edness among the dimensions by highlighting the name of the dimension in *italics* when it was listed under the implications of another dimension. For example, one of the leadership implications under dimension 3 (human-computer interface) is to “consider the number of parameter waves displayed (clinical content) on the monitor screen for optimal monitoring and to decrease information load on the user.” “The number of parameter waves displayed” is related to the “clinical content” dimension. However, displaying this “clinical content” in a usable format to end user is a “human-computer interface” feature.

In addition, some of the implications have hierarchical (interdependence) relationships. For example, it is essential to “understand the capabilities and limitations of the physiologic monitors based on brand and model” (a leadership implication under the hardware and software dimension) in order to “create patient profiles within the monitors based on most common diagnoses in the unit” (a leadership implication under the clinical content dimension). Similarly, the interdependence of the dimensions in research is related to conducting descriptive and observational research before moving to interventional studies.

Appendix D also includes implications for policies and procedures and training programs within each separate dimension. We grouped these implications based on the state of science (in the IMPLICATIONS FOR CLINICAL LEADERS section below) to help clinical leaders form policies and procedures and conduct training programs at the institution and/or unit levels.

Implications for Researcher

Appendix D, column 2, includes implications for future research to improve alarm system safety. Correct identification of the total number of alarms and most frequent alarm types is the foremost step to revealing the actual level of noise in clinical settings and guide research and QI initiatives to respond to NPSG.06.01.01 (dimensions 1, 6, and 8). With that said, a need exists to (1) use reliable and valid measures to quantify the number of alarms, (2) expand available measures beyond physiologic alarms to other

types of alarms, and (3) examine the effect of noise, reflected by the number of alarms, on nurse-, organization-, and patient-related outcomes. These commonly overlooked methodological considerations are critical to deepen our understanding of the real problem of alarm fatigue and to improve alarm system safety.

Sowan et al.²¹ highlighted the shortcomings of the current methods used to measure the number and types of alarms (i.e., real-time annotation using human observation or video cameras). They brought attention to the value of the built-in log data from physiologic monitors as the most objective, reliable, and comprehensive and least laborious and intrusive data source (Appendix D, dimension 1). In addition, these data can be obtained with minimal cost to measure alarm types and rates.²¹ Although the use of log data in research studies increased during the past couple of years, the majority of previous studies primarily focused on physiologic alarms. Nevertheless, other data are also pertinent. The information center or central station monitor has the capabilities to log three types of data: (1) alarm-related data (physiologic and technical alarms), (2) nurse-monitor navigation actions, and (3) system status messages. Most of the system status messages communicate the changes made by the nurse using the monitor (i.e., nurse-monitor navigation actions).

To date, little attention has been devoted to analyzing technical alarm data. Moreover, almost no attention has been given to the log data related to nurse-monitor navigation actions (e.g., nurse response time to alarms) (dimension 5, Appendix D). Therefore, future research should focus on physiologic alarms, technical alarms, and log data related to nurse-monitor navigation actions.

Nurse-monitor navigation actions' log data reflect alarm management practices and are a valuable source of information for investigating adverse events (dimension 6, Appendix D), inconsistent practice, adherence to policies and procedures in alarm management (dimensions 5 and 6, Appendix D), alarm fatigue, the need for education on alarm management, and the effect of interventions designed to improve alarm system safety (dimensions 6 and 8, Appendix

D). Nurse-monitor navigation and alarm management practices can also reflect issues related to the usability of the monitors^{22,23}—another area in which information is limited and research is needed (dimensions 3 and 8, Appendix D).

Our summary also shows that interoperability is needed between physiologic monitors and secondary devices (i.e., nurse call systems) to filter priority alarms and improve alarm response time (dimension 1, Appendix D). Studies also suggest the need for interoperability among physiologic monitors and essential medical devices in ICUs (e.g., ventilators, pulse oximeters, defibrillators) to create a smart care environment for alarm systems (dimension 1, Appendix D). More studies are needed to evaluate (1) the effectiveness of secondary devices and their downside of exacerbating alarm fatigue (dimension 1, Appendix D) and (2) the effect of interoperability between physiologic monitors and essential medical devices in ICUs on patient outcomes.

Other implications for research are related to cybersecurity. Security breaches related to physiologic monitors usually are reported by the FDA as case reports.²⁴ Dimension 1 (hardware and software) shows a lack of studies on assessing the monitoring of cybersecurity vulnerabilities. Similar to other medical devices, physiologic monitors are vulnerable to cyberattacks. Cyberattackers can control the monitoring system, manipulate associated parameters and alarm settings, and access patients' health information. These attacks not only endanger patients but also breach data confidentiality and patient privacy. Along with alarms, cyberthreats are one of the top 10 technology hazards in healthcare.⁶ In particular, cyberthreats will become an increasingly serious issue due to interoperability between physiologic monitors and other medical devices because vulnerabilities and threats are often pertinent to such interfaces. Therefore, research studies on this aspect are warranted.

Appendix D also highlights the need for a multidisciplinary collaboration in research and QI projects to investigate and improve alarm system safety (dimension 4). Within a multidisciplinary model, research is needed

to compare the fidelity of different interventions in response to the external rules and regulations related to alarm system safety and examine the effect of these interventions on patient-related outcomes (dimension 7, Appendix D). Finally, reporting alarm rates using a common measurement unit (e.g., per patient/day) is essential to enable comparison across settings and interventions (dimension 8, Appendix D).

Implications for Vendors

Designing safe alarm systems is a priority in healthcare. The high sensitivity of alarm systems at the expense of specificity, which is a major contributing factor to false alarms and alarm fatigue, has been attributed to poor quality and design of monitoring devices.^{14,23,25} Innovative methodological approaches to increase the specificity of monitoring devices include ones based on statistics and artificial intelligence (AI).^{25,26} Research suggests the need to replace the commonly used univariate-alarm-detection-algorithm approach with a multivariate-alarm-detection algorithm that is based on a concurrent analysis of multiple monitored parameters (dimension 2, Appendix D). Different AI-based algorithms have been proposed, tested, and/or validated to improve the detective value of monitoring devices.^{25,26} Once replicated and validated, vendors are encouraged to work collaboratively with other stakeholders to integrate AI-based, multivariate-alarm-detection algorithms into their systems as built-in safety features. Vendors of different medical devices, researchers, clinicians, accreditation and safety organizations, and other stakeholders are also encouraged to work collaboratively to build a smart care environment driven by machine learning and AI for safer monitoring and decision making.

In addition to AI-based algorithms, heuristic analysis of the chain reaction of alarms can also help stakeholders understand alarm behaviors and inform clinical decision making. For example, in a recent yet currently unpublished study by the authors, we investigated the chain reaction produced after a specific high-priority physiologic alarm was triggered and found “apnea” to be the “parent” alarm that triggers too many

arrhythmia- and vital signs-related alarms. Using such heuristics by vendors in collaboration with other stakeholders can help clinicians focus on preventing specific medical conditions or symptoms (such as apnea in the above example). The creation and integration of built-in algorithms and decision support tools to help prevent under- or overmonitoring is another implication for vendors to maximize the safety of the monitoring process.

In addition to its research implications, the body of limited available studies on usability testing (dimension 3, Appendix D) also calls for an end user-centered design for safe and efficient navigation of monitoring systems. A recent study showed that among 40 common monitoring tasks, only two were successfully completed by ICU nurses using the physiologic monitors.²³ The complexity of navigating physiologic monitors and its negative effects on timely recognition and response to lethal alarms and unsafe workarounds by nurses is supported by the literature.^{14,22} The availability of usable dashboards and reports is also important to improving safety.

Implications for Clinical Leaders

This state of science has leadership implications for IT infrastructure, policies and procedures, training programs, and implementation of evidence-based interventions (Appendix D). In terms of IT infrastructure, the use of advanced monitoring devices is recommended when possible for operation accuracy, enhanced tracking and monitoring (i.e., availability of log data, advanced data monitoring capabilities, interoperability with other devices), adherence to updated clinical guidelines to optimize clinical content, and enhanced security measures (dimensions 1 and 2, Appendix D). Understanding the capabilities and limitations of the physiologic monitors based on their brand and model is essential to guiding QI initiatives and interoperability across systems. In addition, Wi-Fi bandwidth of portable medical devices (e.g., portable monitors) and secondary communication devices (e.g., nurse pagers) should be tested when they are used to communicate and/or filter priority alarms.

Policies and procedures are recommended by safety professional organizations.^{12–18}

Based on the eight dimensions of the sociotechnical model (Appendix D), clinical leaders may want to consider addressing the following in their policies and procedures:

- Periodic maintenance and software updates of the monitors to maintain proper and secure operations (dimension 1). This is important because vulnerabilities may constantly be detected from the software running in the monitors, and therefore, the software needs to be patched to prevent exploitation of the vulnerabilities by cyberattackers.
- Optimizing clinical content and monitoring (dimensions 2 and 6). This can be achieved, for example, by (1) indications for monitoring certain parameters that contribute to the most frequent false or nonactionable alarms, (2) scrutinizing over- and undermonitoring of parameters based on available national guidelines (dimension 2), and (3) utilization of evidence-based data and multidisciplinary clinical judgment for daily customization of patient parameters and elimination of duplicate alarms.
- Defining clear roles and responsibilities (when, how, who) for troubleshooting technical alarm conditions (dimensions 3 and 6).
- Defining clear roles and responsibilities for responding to alarm signals at the bedside and central station monitors (dimension 5) and customizing parameters, including disabling alarms (dimension 6).
- Providing avenues at the unit level (e.g., huddles or shift reports for nurses) to communicate changes in parameters, excessive false alarms, and high-priority alarms (dimension 6).
- Using alarm escalation systems (dimension 6).
- Defining the information that nurses need to document in terms of alarms and parameter changes and where to document it (dimension 5).
- Creating leading alarm management practices based on national clinical guidelines (e.g., electrocardiogram leads change, over- and undermonitoring) (dimension 6).

- Auditing alarm data to investigate adverse events and best methods for communicating such events (dimension 6).
- Enforcing mandatory training programs and making support resources available to manage physiologic monitors and alarms (dimensions 1, 2, 3, 4, and 6).
- Tracking safety measures for continuous improvement (dimension 8).

Based on the eight dimensions of the sociotechnical model (Appendix D), clinical leaders could create and facilitate training programs that address the issues described below. Partnering with the device vendor in designing and delivering education programs, conducting multidisciplinary education, using superusers, and mandating training programs and assessing competencies in alarm management are recommended leading practices (dimensions 2, 4, and 6). Assessing the effectiveness of the training programs is essential to improve alarm system safety and their intended outcomes (dimension 6). Training programs could include the following areas:

- Appropriate connectivity of the hardware components (dimension 1)
- Terminologies used for alarm behaviors (dimension 2)
- Clinical and nonclinical conditions that are expected to display loss of signals/



Recommended practices for alarm management geared toward clinical leaders include partnering with the device vendor in designing and delivering education programs, conducting multidisciplinary education, identifying superusers, mandating training programs, and assessing competencies.

- weak signals and limitations in monitoring (dimension 2)
- Clinical content within the monitor (i.e., monitor configuration, parameter limits, customization) (dimension 2)
- Most common user-monitor navigation tasks (dimensions 3 and 6)
- Competency checklist for safe operation of the monitors and evidence-based alarm management practices (knowledge, skills, and attitude) (dimension 4)

Sowan et al.²⁷ developed and validated a nurse competence in physiologic monitor use instrument. Their tool targeted knowledge, skills, and attitude in four major areas in the context of physiologic monitors: (1) hardware and connectivity; (2) admission, discharge, and transfer of the patient; (3) alarm management; and (4) appropriate monitoring of the patient condition. Directions for tool administration and integration of the competencies within an education program in clinical settings are provided in a published toolkit.²⁸

Clinical leaders can also consider implementing evidence-based interventions and examining the effect of the interventions on nurse-, organization-, and patient-related outcomes in collaboration with multidisciplinary research and QI teams. Dimensions 2, 5, and 6 in Appendix D, column 1, summarize the interventions supported by the literature to improve alarm-related outcomes. Most studies implemented a range of interventions to improve alarm system safety.¹⁸ To achieve successful interventions, recommendations for clinical leaders include:

- Understanding data monitoring capabilities (i.e., availability of log data, capacity of log data in terms of retrieval and saving of alarm data, amount and type of logged data, availability of customizable reports, readability of report to clinical settings, frequency with which reports can be generated) (dimension 1) and other data that need to be collected (dimension 8).
- Identifying safety goals based on available measurement (dimension 6) and deciding on safety metrics (dimension 8).
- Establishing data-driven continuous monitoring of alarm system safety for adverse events and alarm rate (dimension 8).

- Continuously monitoring unacknowledged alarms (dimension 8).
- Communicating alarm-related data at the unit and organization level (dimension 8), disseminating successful strategies to tackle alarm fatigue and improve alarm system safety (dimension 5), and discussing incidents and events in collaboration with other units (dimension 7).

Appendix D also provides context-based modifications and interventions that leaders can implement to improve alarm system safety. These include:

- Creating patient profiles within the monitor in collaboration with the vendor based on most common diagnoses in the unit (dimension 2).
- Deciding whether all alarm signals from the patient room should go to the central station monitor (dimension 5).
- Assessing staff perceptions of the problem and suggestions for solutions (dimension 8).
- Ensuring the availability of an alarm escalation process (e.g., having a dedicated person at the central station monitor, determining whether alarms go to secondary alerting device) (dimension 5).
- Examining options for middleware in collaboration with IT and biomedical engineers to collect data if log data monitoring capabilities are not reliable/sufficient (dimension 1).
- Testing the volume of alarms and determining whether the volume is adjusted based on shift, if it is easily heard, and if clinicians can easily differentiate alarms from different devices (dimension 5).
- Assessing resources and infrastructure that are required to tackle alarm fatigue (dimension 7).
- Establishing an alarm system safety governance team at the organization level by involving all stakeholders (dimension 4).

Discussion

Physiologic monitors are the number one medical device contributing to alarms in ICUs.² This article summarizes the state of science in alarm system safety and, accordingly, provides implications for researchers, vendors, and clinical leaders guided by a sociotechnical model for studying health

IT in complex adaptive healthcare systems. It highlights the interrelatedness and interdependence of implications under different dimensions of the sociotechnical model to emphasize the complexity of alarm system safety within complex, adaptive healthcare systems.

TJC's NPSG.06.01.01 addresses the impact of noise generated by the excessive number of unnecessary alarms on hazardous alarm management practices, on nurse outcomes (e.g., alarm fatigue), and most importantly on adverse patient outcomes (e.g., death, adverse events, sleep deprivation, low satisfaction with care). Therefore, accurately identifying high-priority alarm rates and types should not be an end measure but rather a foundational step toward examining the effects of noise on the triad of nurse, organization, and patient outcomes.

To date, few interventional studies have examined the association between changes in alarm number and nurse, organization, or patient outcomes. For example, Sowan et al.²² were among the first to show that even a reduction of 25% in alarm rate (by customizing the threshold of 17 key parameters and establishing a standardized education program on alarm management practices) was insufficient in improving nurse perception of alarm fatigue, suggesting the need to assess other complex contextual factors that contribute to alarm fatigue and to focus attention on nurse and patient outcomes in alarm safety studies.

The current review has a number of limitations. First, our summary of the state of science was guided by the inclusion of systematic reviews that met certain eligibility criteria (i.e., focuses on alarm system safety using physiologic monitors in ICUs). Including systematic reviews on alarm system safety using other medical devices, such as pulse oximeters, ventilators, and infusion pumps, if available, could deepen our understanding of the complexity of alarm system safety. On the other hand, physiologic monitors are the devices associated with the highest number of alarm data. Similarly, our search for most recent interventional studies was limited to PubMed. Including other databases could have yielded other studies. Second, only three of the

available systematic reviews focused on interventions to mitigate alarm fatigue and improve alarm system safety.^{16–18} However, the inclusion of published toolkits, guides, position papers, and workbooks by safety organizations^{8–12} provided a broader understanding of leading practices in alarm system safety.

In summary, a comprehensive approach to mitigate alarm fatigue and improve alarm system safety is recommended given the interconnectedness and interdependence of the eight dimensions of the sociotechnical model of Sittig and Singh.⁶ Conducting studies to quantify the effect of the interactions of the eight dimensions in the sociotechnical model on alarm system safety would be valuable.

Conclusion

The complexity of healthcare systems and their interrelated components associated with technology use result in alarm fatigue, which is a challenging problem. Using available resources, including log data from physiologic monitors, and expanding our QI and research findings beyond alarm rate and type to the triad of patient, organization, and nurse outcomes are critical to effectively respond to TJC's mandate. By summarizing the state of science applied to the dimensions of the sociotechnical model, this article described root causes of the alarm fatigue problem; provided recommendations for leadership, policies and procedures, and training programs; and identified directions for future research and vendors of medical devices.

Funding

This work was supported by a grant from the San Antonio Life Sciences Institute.

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