Impact Of Clinical Alarms On Patient Safety

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ABSTRACT

Clinical alarms warn caregivers of immediate or potential adverse patient conditions. Alarms must be accurate, intuitive, and provide alerts which are readily interpreted and acted on by clinicians in an appropriate fashion. Clinical alarms and their shortcomings have been the topic of numerous studies and analysis in the literature. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) established a National Patient Safety (NPS) goal in 2002 to improve the effectiveness of clinical alarms. This goal was removed for hospital organizations in 2004 and incorporated into the JCAHO standards. Despite the technological and healthcare improvements related to efforts to meet the NPS goal, adverse patient events continue to occur related to alarm system design and performance, care management and the complexity of the patient care environment.

In 2004, the ACCE Healthcare Technology Foundation started an initiative to improve clinical alarms. This paper reviews the literature related to clinical alarm factors and analyzes adverse event data-bases. Efforts to improve alarms through technological, standards, and regulatory means are reviewed and evaluated. Forums, meetings and a survey of 1,327 clinicians, engineers, technical staff and managers provided considerable feedback regarding alarm issues. Of particular value is the response from nursing who represented the majority of the respondents to the survey. Observations and recommendations have been developed to improve the impact of clinical alarms on patient safety. Future directions are aimed at awareness, a focused effort towards the reduction of false alarms, and soliciting all constituents involved in clinical alarms to meet and develop action plans to address key issues.

AHIT INITIATIVE

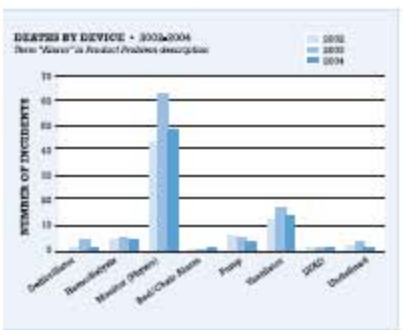
AHIT put forth an initiative in 2004:

- To improve patient safety by identifying issues and opportunities for enhancements in clinical alarm design, operation, response, communication, and appropriate actions to resolve alarm-related events.

To pursue this initiative a task force was formed to focus on clinical alarms management and integration. Activities have included open forums, audio conferences, literature and hazard reviews, the design, implementation and analysis of a clinical alarms survey, and development of educational materials including materials on the AHIT website http://www.acce-hf.org/ and the publication of this paper.

REPORTED PROBLEMS

As part of this study the FDA Manufacturer and User Facility Device Experience Database (MAUDE) and ECRI's Problem Report System were reviewed. These databases represent a subset of the total adverse events involving medical devices as has been stated in 2006 by the FDA. "Adverse events related to medical devices are widely under-reported by device users"[1] This under reporting denies the ability of healthcare providers and the medical device industry in taking appropriate corrective action to improve patient safety where clinical alarms are used.[2]



Clinical Alarm Survey Results

The survey was completed by 1,327 respondents, the large majority (84%) of which worked in acute care hospitals. Over half of respondents were Registered Nurses (51%), with a sizable portion of surveys completed by Respiratory Therapists (14%), Clinical Engineers and Biomedical Equipment Technicians (8% and 6%, respectively), and Clinical Managers (8%). Almost one-third of respondents (31%) work in an intensive care unit, with the remainder of respondents fairly dispersed among various other departments. 88% of respondents had more than 11 years of experience and only 8% had less than three years.

Answers to section E yielded some similarities and some differences between respondents. The large majority of respondents (>80%) agreed or strongly agreed with the statements, covering the purpose of clinical alarms, and the need for prioritized and easily-differentiated audible and visual alarms. Likewise, a large portion of respondents identified nuisance alarms as problematic, with the large majority agreeing or strongly agreeing that they occur frequently (81%), disrupt patient care (77%), and can reduce trust in alarms and cause caregivers to disable them (78%). 80% of respondents support smart alarms which can help minimize some types of nuisance alarms.

Responses were split on whether properly setting alarm parameters is overly complex on existing systems. 48% of respondents disagreed or strongly disagreed with this statement, while 32% agreed or strongly agreed and 32% responded as neutral on the issue. 72% of respondents agreed or strongly agreed that alarms are adequate to alert staff to changes in the patient's condition.

Two survey statements in section E addressed how alarms are conveyed to staff. 48% of respondents believe that a dedicated central alarm management staff (i.e., monitor watchers) for disseminating alarm information to caregivers is helpful, while 34% were neutral; 54% of respondents see utility in integrating alarm information with communications systems (e.g., pagers, cell phones), while 30% were neutral.

Two items showed more consistency among respondents. 60% of respondents consider "frequent false alarms reducing attention" and "response to alarms" as the most important of the presented issues, and 59% rated false alarms in the top four rankings. Conversely, 38% of respondents believe lack of training on alarms is the least important issue, and 62% rated it at the lowest ranking — 5 through 6.

OBSERVATIONS

The studies presented revealed several themes:

- The number and complexity of alarm systems in critical care environments challenge human limits for recognition and action.
- Alarms in critical care environments may not significantly affect care management decisions.
- In general, alarms are a tool in assessing patient conditions should be used in conjunction with direct clinical measurements and observations.
- The term "alarm" was found in the FDA MAUDE adverse event report Product Problem field most commonly for physiological monitoring systems along with ventilators and infusion pumps.
- Parameter acquisition improvements (e.g. pulse oximetry) are important in improving alarm accuracy and value.
- Remote alarm communication devices (e.g. pagers) if well designed can be of value but problems have occurred when used as the primary alert method.
- The IEC/ISO standards are viewed by many as a way to improve alarms by standardizing audible and visual alarms, priority and parameter differentiation.
- The alarm problem is a systems issue and actions toward specific areas must consider their impact on the system.
- There is disagreement about the role of user operation of alarm systems in alarm system performance. Caregivers de-emphasize the need for alarm configuration and operation training while adverse event analysts find many instances of improper setup and subsequent action when alarms do occur.
- False alarms have been consistently reported as a major issue with alarm systems. They reduce staff confidence in alarms which may result in deactivation of alarm systems and detract from care management.

RECOMMENDATIONS

Medical Device Industry

Manufacturers should consider the complexity of the healthcare environment in order to design alarm systems that are operationally intuitive, and effective given the care tasks of users, and which are focused on the true need for intervention. False alarms must be reduced for alarm systems to be effective. There must be additional emphasis on accurate parameter acquisition, human factors design, and a systems approach to alarm systems. The IEC/ISO standards for alarm systems represent an improvement in design and should be considered for implementation in the U.S. Standardization offers the opportunity to eliminate some elements of confusion over what different alarms mean, as well as how they are operated. The actual use of recognized standards by various manufacturers must become the norm rather than the exception. Additional standards and standardization are also necessary so that devices that are commonly used together operate as a system rather than as a collection of individual components. Furthermore, how devices are configured must also reach a greater level of commonality so that, for example, every manufacturer's monitor, or infusion pump, or ventilator does not require unique operator knowledge.

Healthcare

Healthcare organizations and clinicians should recognize the limitations of alarm systems and utilize them only as a tool in the overall assessment of patient condition. It should be recognized that improper configuration and operation can result in adverse events in the complex patient care environment. Effective education and training must take place to better understand proper operation, the implications of mis-configuration or defeating alarms, and the limitations of current alarm systems. False alarms will occur, but should not result in reduced alarm vigilance and disobedience of alarms. The care of patients where clinical alarms are used should be planned with input from clinical staff, biomedical/clinical engineers, facilities staff and others involved in the environment of care so that alarm use is well integrated with other procedures and requirements.

Healthcare institutions purchasing devices and systems with alarms should carefully evaluate the potential for devices to reduce false alarms and other cited problems through intelligent processing of incoming signals, the use of "smart alarm" technology, ease of use, usability and human factors design principles, and application of standardization and systems engineering measures. Consideration of the implications, interfacing and environmental factors in adding remote annunciator systems.

Education

Effective education for clinicians is a critical part of the process that needs to be considered when working to improve alarm-related safety. Clinicians need to be provided with plenty of opportunities to learn about the details of the alarm-based medical devices they are expected to operate. Such learning must reach the level of operational effectiveness rather than just intellectual knowledge. Planning for the education needs to start during the technology planning and procurement process. Specifically, the cost for training clinicians on how to use devices with alarms needs to be included in the budgeting and implementation timeline for new technology procurement. This needs to consider training of clinicians on devices once they arrive and an appropriate level of refresher courses, for example on an annual basis, and for training of per diem or other staff that miss the initial training. Training should be designed so that devices are operated in their normal clinical environments and should include information on the institution's alarm setting and response protocols.

FUTURE DIRECTIONS

The results of this study lay the groundwork for future efforts towards improving the area of clinical alarms. These efforts will include:

- Developing awareness of the need to improve clinical alarms through the publication of this report in media read by the various constituents – industry, regulatory, clinical, risk management, healthcare leadership, and clinical engineering.
- Soliciting the constituents to meet at focused forums to develop action plans to improve identified problem areas.
- Pressure to the medical device industry the critical need to reduce false alarms by:
  - enhanced parameter acquisition accuracy and employment of proven "smart alarms" technology to reduce false alarms.
  - better human factors engineering in alarm systems such as the use of more intuitive graphical user interfaces.
  - improved alarm integration and intelligence.
- Bringing forth the data to standards bodies to promote alarm standardization improvements including the use of scientific research data in developing alarm standards such as a uniform readout of annunciation (tone, display, etc.) for life critical versus other types of alarms.
- Developing a better awareness by clinical staff of the criticality of alarms and deleterious effects of operational problems so that there can be an enhanced emphasis of the importance of training and preparation in the area of alarms.
- Re-evaluate the area of clinical alarms in 1-2 years by administering a similar survey and other measures to determine progress in clinical alarm improvement.

MISSION:

Improving healthcare delivery by promoting the development and application of safe and effective healthcare technologies through the global advancement of clinical engineering research, education, practice and their related activities.

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