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Clinical alarm hazards: a "top ten" health technology safety concern

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Abstract For the past several years ECRI Institute has published a list of Top Ten Health Technology Hazards. This list is based on ECRI's extensive research in health technology safety and on data provided to its problemreporting systems. For every year that the Top Ten list has been published, Alarm Hazards have been at or near the top of the list. Improving alarm safety requires a systematic review of a hospital's alarm-based technologies and analysis of alarm management policies like alarm escalation strategies and staffing patterns. It also requires careful selection of alarm setting criteria for each clinical care area. This article will overview the clinical alarm problems that have been identified through ECRI Institute's research and analysis of various problem reporting databases, including those operated by ECRI Institute. It will also highlight suggestions for improvement, particularly from a technology design and technology management perspective.

Keywords: Alarm safety; Alarm fatigue

Introduction

For the past five years ECRI Institute has published a list of Top Ten Health Technology Hazards. This list is based on ECRI's extensive research in health technology safety and on data provided to its problem-reporting systems. The list is designed to raise awareness about serious technology problems that ECRI Institute believes hospitals should be incorporating into their patient safety programs. For every year that the Top Ten list has been published, Alarm Hazards have been at or near the top of the list.

What's causing the problem and why is it such a safety concern? More and more alarm-based medical devices are being used in patient care. More and more patients are connected to one – or many – alarm-based devices. With the large number of alarm-based devices being used, the number of alarms that clinicians need to respond to has grown to an alarming number. Some reports suggest that in a critical care unit a caregiver can be subjected to 150–400 or more alarms per patient per day.[1] This can be overwhelming for clinical staff and dangerous for patients as many serious patient alarm events are being missed. Further complicating matters is that alarm-based devices are not standardized in many institutions. And many patient monitors have flexible alarm setting features that allow for inconsistent use of alarms.

Improving alarm safety requires a systematic review of a hospital's alarm-based technologies and analysis of alarm management policies like alarm escalation strategies and staffing patterns. It also requires careful selection of alarm setting criteria for each clinical care area.

This article will provide an overview of the clinical alarm problems that have been identified through ECRI Institute's research and analysis of various problem reporting databases, including those operated by ECRI Institute. It will also highlight suggestions for improvement, particularly from a technology design and technology management perspective. Also, for many years ECRI Institute has been the repository for a database of arrhythmias and normal electrocardiograms developed by the American Heart Association (AHA). The database has frequently been used to assist with the development of ECG arrhythmia detection equipment and for training of health professionals. This article will include a brief overview of the arrhythmia and electrocardiogram database.

ECRI institute background

ECRI Institute is a nonprofit health services research organization with an over forty year history of conducting comparative evaluations of medical devices and investigating risks associated with the use of medical devices. Its evaluations are published in ECRI Institute's monthly *Health Devices* journal. *Health Devices* also publishes results of its medical device incident investigations, typically in articles called Hazard Reports. The medical device investigations are based

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on reports submitted by healthcare professionals to ECRI Institute's problem reporting systems and on findings from its Accident and Forensic Investigation Services.

Alarm safety in the news

There's been quite a bit of very high-profile coverage of alarm-related deaths in the news over the last few years. In 2010, 2011, and 2012 the *Boston Globe*[2–7] published major articles on problems with clinical alarms. The first article in the series highlighted a problem at Massachusetts General Hospital where a patient died when the audible alarm for a patient monitor had been turned off. The Globe series was picked up by many other news outlets including the CBS News Morning Show.

And it's been getting attention at high levels of the US Government. US Congressman Ed Markey recently wrote a letter to Health and Human Services Secretary Kathleen Sebelius recommending that she commission the Institute of Medicine to conduct a study on how medical device manufacturers and healthcare organizations can better handle problems with clinical alarms.[8] The US Food and Drug Administration co-convened a 2011 Summit with the Association for the Advancement of Medical Instrumentation (AAMI), ECRI Institute, The Joint Commission, and the American College of Clinical Engineering to review ways that alarm safety can be improved.[9] The Joint Commission recently announced that it is collecting information through a survey of hospitals on current practices relative to clinical alarm management to determine how best to address the issue. Among the options it is considering include field education, Sentinel Event Alerts, and accreditation requirements.[10]

Typical problems

In 2008 the Pennsylvania Patient Safety Authority published a failure mode and effects analysis of alarm interventions during medical telemetry monitoring. It highlighted a typical patient monitor-related alarm incident. The report described a patient being admitted to a "monitored unit" with chest pain and shortness of breath. It noted that "at 3:25 a.m., the patient's nurse observed that the patient's leads were off and on checking on the patient found him in the bathroom unresponsive. Resuscitation efforts were unsuccessful." The patient's monitor showed that the leads had come off at 2:32 a.m.[11]

The first of the *Boston Globe* articles mentioned above referred to a database search that ECRI Institute conducted in support of the *Globe's* research. Our search included review of the FDA Manufacturer and User Device Experience (MAUDE) database, ECRI Institute's Health Devices Problem Reporting Network database, and ECRI Institute's Accident and Forensic Investigation files from 2005 to 2010. The key words "alarm" and "death" were used and the results were filtered to include only physiologic monitor-related events. We identified 216 deaths. In 73 of the cases, alarms sounded, but staff silenced them, did not hear them because the volume was too low, or did not respond for another reason. Some specific examples from the ECRI Institute search include:

- Failure of a patient monitor to detect a patient's ventricular tachycardia because its alarms were paused by the user. (ECRI Institute MAUDE reference ID 1629921)
- A new ward layout possibly contributing to the failure of nursing staff to hear a cardiac arrhythmia alarm. (ECRI Institute MAUDE reference ID 1635872)
- No alarm for an asystole event because the patient monitor was configured for its alarms to be in a permanent suspend mode. (ECRI Institute MAUDE reference ID 1636788)
- A telemetry monitor failed to provide an audible indication of low battery. Its low battery alarm feature was turned off. The reporting hospital stated that the lack of alarm contributed to a patient death. (ECRI Institute MAUDE reference ID 1644347)

The 216 events are considered to be a very small sampling of the actual number of alarm events. Although the Safe Medical Devices Act of 1990 requires that hospitals report medical device-related deaths and injuries, the actual amount of device reporting is very low. ECRI Institute has estimated that the number of alarm deaths is at least ten times higher than found in the database search conducted for the *Globe*.

Top ten considerations

The findings from our database analyses is one of the contributing factors to ECRI Institute's decision to place alarm hazards as number one on its list of Top Ten Health Technology Hazards for 2012. Other factors include the steady number of accident investigations ECRI institute is asked to perform each year and hospital surveys it has conducted asking about serious alarm-related events. A majority of survey respondents have reported that they have had problems. As mentioned in the introduction, the Top Ten List is part of an awareness raising initiative. Human factors, technology challenges and limitations, difficult patient conditions, a wide variety of environmental conditions, and even staffing cultures make alarm safety a complex problem to solve. This level of complexity needs high-level and focused attention which ECRI Institute determined its high Top Ten ranking could help initiate.[12]

Alarm fatigue

Alarm fatigue occurs when a caregiver can become overwhelmed by a large number of clinical alarms such that important alarms can be missed or ignored. Many of the alarm-related events reviewed by ECRI Institute's databases analyses can be attributed to alarm fatigue. Looking through the databases one can see report after report indicating that an alarm sounded for a serious condition but it was not heard or responded to by clinical staff in time to avert a bad outcome. Or, alarms are happening so often that