An FDA Response on Alarm Systems Issues

Editor's note: Horizons separately posed the same list of questions to a group of experts from the U.S. Food and Drug Administration (FDA). Their responses follow.

What are some common problems seen with alarm systems for medical devices?
Based on medical device reports we have received in the past several years, it is often difficult to assign a root cause to problems reported concerning device alarm systems. The most commonly reported alarm system issue is that the device does not provide a critical alarm. Often, the alarms are not heard or they have been silenced or deactivated and never reset. Sometimes the lack of an alarm is due to mistaken disconnections from a central station or inoperable speakers.

What are the biggest obstacles to solving challenges related to alarms on medical devices?
- The challenging environment in which these alarm systems are used:
  - A vast number of potential alarms competing for a caregiver's attention in the typical hospital environment
  - Significant concurrent clinical demands on caregivers
  - Ensuring there is sufficient staffing to respond to all alarms
- Regulatory clearance to market typically applies to individual devices rather than entire systems—often for relatively minor modifications to devices that have been on the market for many years
- Lack of a systems approach to integrating alarms on devices from multiple vendors
- Differences between user interfaces related to alarms on various brands of systems
- Increasing complexity of monitor user interfaces
- Difficulty determining the optimum balance between sensitivity and specificity of alarms

What steps should healthcare facilities take to address problems with alarm systems?
FDA does not regulate healthcare facilities. However, we note that adverse event reports are very helpful to us in assessing problems with alarm systems and how to address them. We recommend that users and facilities submit adverse event reports that are as detailed as possible to the manufacturer and FDA regarding cases that involve alarm systems.

What steps should device designers and manufacturers be taking to address problems?
User interfaces for alarms should be as consistent as possible across vendors to minimize use errors. Alarm system user interfaces should be developed based on sound human factors principles and tested with representative end users to validate that the alarms are effective. Alarm design should take into account the other device alarms likely to be in the same environment. Intelligent alarm systems should be developed to improve the effectiveness and safety of alarm systems.

Standardization is most essential around the safety aspects of devices, of which alarm system design is a critical part. A consensus standard should be developed that describes appropriate approaches to the integration of alarms across vendors in a clinical setting. Manufacturers, healthcare providers, and regulators should work together in developing such a standard.

What efforts are needed or underway in the regulatory/standards front?
The FDA is looking closely at this problem to determine what role we can play in mitigating alarm-related hazards given that we do not regulate healthcare facilities where alarm system integration occurs. The FDA has recognized the following applicable standards and is promoting their use in pre-market submissions:
- IEC 60601-1-8[3]
- AAMI/ANSI HE75:2009, *Human factors engineering - Design of medical devices*
- IEC 62366, *Medical devices - Application of usability engineering to medical devices*.

We are also looking to open a dialogue with relevant standards organizations, manufacturers, and care providers to explore potential options.

What are the implications of current trends for alarm systems?
FDA is actively tracking a number of emerging trends in healthcare monitoring, including more personalized monitoring and targeted alarms as well as trends related to wireless technologies, interoperability, and home healthcare. As alarm technologies advance and alarm systems continue to become more distributed and complex, it is important to assess how their functionality impacts patient care and healthcare provider work processes (human factors). Device alarm systems need to be designed appropriately for each intended use environment, use, and type of user.

What comes next?
FDA is working to identify what else can be done to address the issues discussed and to develop additional guidance related to these issues. ■