R³ Report I Requirement, Rationale, Reference

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Published for Joint Commission accredited organizations and interested health care professionals, *R³ Report* provides the rationale and references that The Joint Commission employs in the development of new requirements. While the standards manuals also provide a rationale, the rationale provided in *R³ Report* goes into more depth. The references provide the evidence that supports the requirement. *R³ Report* may be reproduced only in its entirety and credited to The Joint Commission. To receive by e-mail, visit www.jointcommission.org.

Alarm system safety

Requirements

The requirement addressed in this issue of R³ Report is a National Patient Safety Goal (NPSG) that is effective January 1, 2014 for hospitals and critical access hospitals. As noted in the elements of performance below, the NPSG will be implemented in two phases. The first phase heightens awareness of the potential risks associated with clinical alarms, and the second phase introduces requirements to mitigate those risks.

This NPSG addresses clinical alarms that can compromise patient safety if they are not properly managed. This includes alarms from equipment such as cardiac monitors, IV machines, ventilators, etc. that have visual and/or auditory components. In general, this does not include items such as nurse call systems, alerts from computerized provider order entry (CPOE), or other information technology (IT) systems. Some psychiatric or rehabilitation hospitals may not use alarms that can present a serious safety issue because there is minimal use of medical devices that measure a patient's physiologic status. In these situations, it is acceptable if the hospital can demonstrate that the issue was considered but a limited number of such devices – or no devices at all – were identified as priorities.

NPSG.06.01.01: Improve the safety of clinical alarm systems.

EP 1: As of July 1, 2014, leaders establish alarm system safety as a hospital priority.

EP 2: During 2014, identify the most important alarm signals to manage based on the following:

- Input from the medical staff and clinical departments
- Risk to patients if the alarm signal is not attended to or if it malfunctions
- Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue
- Potential for patient harm based on internal incident history
- Published best practices and guidelines

(For more information on managing medical equipment risks, refer to Standard EC.02.04.01.)

EP 3: As of January 1, 2016, establish policies and procedures for managing the alarms identified in EP 2 above that, at a minimum, address the following:

- Clinically appropriate settings for alarm signals
- When alarm signals can be disabled
- When alarm parameters can be changed
- Who in the organization has the authority to set alarm parameters
- Who in the organization has the authority to change alarm parameters
- Who in the organization has the authority to set alarm parameters to "off"
- Monitoring and responding to alarm signals
- Checking individual alarm signals for accurate settings, proper operation, and detectability

(For more information, refer to Standard EC.02.04.03)

EP 4: As of January 1, 2016, educate staff and licensed independent practitioners about the purpose and proper operation of alarm systems for which they are responsible.

Rationale

One of the earliest NPSGs, in effect in 2003 and 2004, addressed the effectiveness of clinical alarm systems. The goal addressed preventive maintenance and testing of alarm systems and whether settings were appropriate and sufficiently audible. This goal was retired in 2005 because it was felt that sufficient attention had been brought to the issue.

Several years later, concerns were raised again about alarm safety. Clinical alarms have been at or near the top of the ECRI *Top 10 List of Technology Hazards* for several years.[1] Also, there have been a number of reports in the press of deaths attributed to "alarm fatigue." In some hospital units, alarm signals per patient per day can reach several hundred. Many of the signals do not require clinical intervention, but clinicians become overwhelmed by the volume of alarm signals and become desensitized or immune to the sounds. This is known as "alarm fatigue." In these cases, alarm volume may be turned down, alarms may be turned off inappropriately, or alarm settings may be adjusted outside of safe limits. These situations can have serious consequences.

The Joint Commission Sentinel Event database contains 98 reports of alarm events between January 2009 and June 2012. Eighty of those events resulted in patient death. In addition, a Food and Drug Administration (FDA) database contains 566 alarm-related patient deaths between January 2005 and June 2010.[2]

This situation led to a Summit on Medical Device Alarms in October 2011 that was co-convened by the Association for the Advancement of Medical Instrumentation (AAMI), the ECRI Institute, the American College of Clinical Engineering (ACCE), the Food and Drug Administration (FDA), and The Joint Commission. The Summit identified themes, challenges, and actions that can be taken immediately to improve safe use of clinical alarms. Also identified were priority actions requiring further study or longer timeframes to fully address; further study is in process on these longer-term issues.

Following the Alarms Summit, The Joint Commission conducted an environmental assessment on clinical alarm safety issues. A survey was sent out in March 2012 to assess the status of clinical alarm management in the field. Almost 1,600 responses were received, and 90 percent of hospital respondents agreed that clinical alarm management was a safety issue. Although 70 percent believed alarms were effectively managed, fewer than 50 percent of the respondents had an organization-wide process for alarm management.

Reference

The issues addressed in the elements of performance for the NPSG are consistent with the recommended actions that emerged from the Alarms Summit. These elements are also aligned with suggested practices that have been identified by professional organizations, including the ECRI Institute and AAMI.[3,4,5] During phase I, The Joint Commission will monitor emerging evidence about leading practices, will solicit feedback from hospitals on their experiences with the requirements of the NPSG, and will obtain feedback from surveyors about implementation issues and leading practices observed during surveys. The Joint Commission is aware of efforts currently underway that will support the field in implementing the second phase of the NPSG requirements. This includes an AAMI initiative to identify best practices in setting alarm parameters. It is important to note, therefore, that before they are implemented on January 1, 2016, the proposed phase II requirements may be enhanced based on new knowledge.

Feedback from the field

A field review of the proposed NPSG on safety of clinical alarm systems was conducted in January and February 2013; 2,700 individuals responded to the survey. There was some concern about the lack of agreed-upon solutions for alarm safety issues, but this should be mitigated by the ongoing work noted above and information learned in phase I. Approximately 88 percent of the respondents agreed that clinical alarm safety is an important safety issue and 75 percent agreed it should be a NPSG. The development of a goal on this topic was supported by The Joint Commission's Hospital Professional and

Technical Advisory Committee and the Patient Safety Advisory Group, as well as several professional organizations.

Select bibliography

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