

Patient Safety Alert

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ENSURING ALARMS ARE AUDIBLE

Many medical devices (vital sign monitors, infusion pumps, ventilators, etc.) used in the delivery of patient care have built in alarms to notify clinicians that attention to the patient is required. On some devices, the alarms can be disabled. Disabling alarms on monitors can pose a risk to patient safety when staff are not alerted to respond to the patient's needs.

RECOMMENDATIONS

The Ministry of Health recommends that regional health authorities and health care organizations:

- **Have standard work in place for safe alarm management and response in all areas;**
- **Assess the current inventory of alarm equipped medical devices used in high-risk areas and identify the default alarm settings;**
- **Establish guidelines for modifying alarm settings and the extent to which alarms can be modified.**

Supporting Documents

1. The Joint Commission 2014 National Patient Safety Goal on Alarm Management – *Joint Commission Perspectives July 2013 Volume 33 Issue 7*
2. A Work Plan for the Joint Commission National Patient Safety Goal on Alarm Management – *article Journal of Clinical Engineering Volume 39 Number 1 January/March 2014*

Background of the Critical Incident

A 55 year old patient underwent a day surgery procedure. Following the procedure, the patient was taken to the post anesthetic care unit for recovery, then transferred to day surgery for completion of recovery.

When transferred to day surgery, a vital signs monitor was attached to the patient. As per standard practice vital signs were to be recorded every 30 minutes. The staff member went to reassess vital signs and found the patient unresponsive and near respiratory arrest. The oxygen saturation level was reading 36% (normal levels are 95-100%). There was no audible alarm sounding on the vital signs monitor. The staff initiated resuscitation, administered oxygen therapy and called the anesthetist and respiratory therapist to the bed side. The anesthetist administered Narcan and the patient's level of consciousness began to improve. A second dose of Narcan was given and the patient regained full consciousness. Vitals signs returned to normal limits with oxygen therapy.

The patient was weaned off low flow oxygen and normal oxygen saturation was achieved. The patient recovered and was discharged home.

Analysis and Contributory Factors

1. The alarm on the vital signs monitor used while the patient recovered in day surgery had previously been silenced. As a result no alarm sounded to alert staff to the low oxygen saturation.
2. There were no current work standards in place to check the alarm thresholds and functionality of the monitor prior to the monitor being used. This contributed to the disabled alarm not being recognized.
3. Staff had the ability to disable the audio alarms on vital signs monitors in patient care areas.

Regional Health Authority's Response to the Critical Incident

1. The region's Clinical Engineering Department eliminated the ability for staff to disable the audio alarms on vital signs monitors.
2. Work standards were implemented in the Day Surgery Department to ensure that default vital signs alarm parameters are programmed into all monitors by clinical engineering staff.

Patient safety alerts may be issued by the Ministry of Health following the review of at least one critical incident reported to the Ministry. A critical incident is defined as a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority, Saskatchewan Cancer Agency or health care organization.

The purpose of a patient safety alert is to recommend actions that will improve the safety of patients who may be cared for under similar circumstances. Recommendations are intended to support the development of best practices and to act as a framework for improvement and can be adapted to fit the needs of the health service organization. When possible, policies or initiatives that have been developed by RHAs or the Saskatchewan Cancer Agency will be shared, to encourage adoption of similar policies or actions.

The Joint Commission Announces 2014 National Patient Safety Goal

In June 2013, The Joint Commission approved new National Patient Safety Goal NPSG.06.01.01 on clinical alarm safety for **hospitals** and **critical access hospitals**. The box on page 3 displays the new goal and its four elements of performance (EPs). The implementation for NPSG.06.01.01 will occur in two phases:

- In Phase I (beginning January 2014), hospitals will be required to establish alarms as an organization priority and identify the most important alarms to manage based on their own internal situations.
- In Phase II (beginning January 2016), hospitals will be expected to develop and implement specific components of policies and procedures. Education of those in the organization about alarm system management will also be required in January 2016.

The Joint Commission plans to publish the Phase I and II requirements at the same time to provide the field with complete information about the ultimate requirements of NPSG.06.01.01. However, due to changes that could arise from newly emerging evidence about best practices, the field's experience with Phase I requirements, and other developmental work, the Phase II requirements may be enhanced before they are implemented. Any changes to Phase II requirements will be communicated to the field through Joint Commission channels such as field

reviews, *Perspectives*, *Joint Commission Online*, and the *Joint Commission Connect*TM extranet.

In their review of the National Patient Safety Goal, Joint Commission advisory committee members noted that the goal helps focus the field's attention on the safety issue and solutions will be evolving over many years. In fact, The Joint Commission is aware of efforts currently underway that will


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The Joint Commission Announces 2014 National Patient Safety Goal (continued)

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Joint Commission



Requirement

Official Publication of Joint Commission Requirements

National Patient Safety Goal on Alarm Management

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective January 1, 2014

National Patient Safety Goal (NPSG)

NPSG.06.01.01
Improve the safety of clinical alarm systems.

Rationale for NPSG.06.01.01
Clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multi-faceted problem. In some situations, individual alarm signals are difficult to detect. At the same time, many patient care areas have numerous alarm signals and the resulting noise and displayed information tends to desensitize staff and cause them to miss or ignore alarm signals or even disable them. Other issues associated with effective clinical alarm system management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow. These issues vary greatly among hospitals and even within different units in a single hospital.

There is general agreement that this is an important safety issue. Universal solutions have yet to be identified, but it is important for a hospital to understand its own situation and to develop a systematic, coordinated approach to clinical alarm system management. Standardization contributes to safe alarm system management, but it is recognized that solutions may have to be customized for specific clinical units, groups of patients, or individual patients. This NPSG focuses on managing clinical alarm systems that have the most direct relationship to patient safety. As alarm system management solutions are identified, this NPSG will be updated to reflect best practices.*

* Additional information on alarm safety can be found on the AAMI website <http://www.aami.org/htsi/alarms/>. Also, the ECRI Institute has identified alarm hazards as one of the top technology hazards for 2013; more information on this hazard list can be found at http://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx.

Elements of Performance for NPSG.06.01.01

A 1. As of July 1, 2014, leaders establish alarm system safety as a [critical access] hospital priority. **R**

A 2. During 2014, identify the most important alarm signals to manage based on the following: **R**

- 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.)

A 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: **R**

- 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)

C 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. **R**

support the field in implementing the second phase of the goal's requirements. For example, the Association for the Advancement of Medical Instrumentation's (AAMI) Healthcare Technology Safety Institute (HTSI) is engaged in several activities intended to promote safe alarm system

management, including the following:

- Conducting a survey of hospital practices in setting alarm parameters, followed by a study of alarm parameters
- Posting literature (reviewed in advance by a work group)

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The Joint Commission Announces 2014 National Patient Safety Goal (continued)

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on best practices on alarm system management on the HTSI website at <http://www.aami.org/htsi/alarms/library.html>

- Offering webinars on safe alarm management

ECRI Institute also offers information (such as articles, policies, and webinars) on safely managing alarm systems at http://www.ecri.org/Forms/Pages/Alarm_Safety_Resource.aspx. In addition, The Joint Commission published *Sentinel Event Alert* Issue 50 on alarm management in April 2013 (see May 2013 *Perspectives*, page 1). The *Alert*, which contains sugges-

tions for the field on assessing and managing risks associated with alarms, complements the expectations of the new National Patient Safety Goal on alarm management.

The new goal will appear in the *2013 Update 2* to the *Comprehensive Accreditation Manual* for the hospital and critical access hospital programs as well as their fall 2013 E-dition® updates.

For more information, contact Maureen Carr, project director, Department of Standards and Survey Methods, at mcarr@jointcommission.org or 630-792-5969. 

A Work Plan for The Joint Commission Alarm National Patient Safety Goal

William A. Hyman, ScD

The effective use of medical device alarms continues to be a challenging area. In addition to whatever internal efforts an organization may have currently underway, The Joint Commission–accredited institutions must now comply with the specific elements of the new National Patient Safety Goal on Alarm Management. Completing these elements before the specified deadlines will require considerable effort. A documented and functional plan of work will likely be necessary in order to achieve success in this endeavor.

The effective use of alarms continues to be a challenge in the clinical setting with respect to how they are selected, set up, and responded to. The Joint Commission (TJC) has specifically addressed alarm management in the past and more recently with its April 2013 Sentinel Event Alert¹ (SE) and June 2013 National Patient Safety Goal² (NPSG). The latter includes a number of specific steps that TJC-accredited organizations must undertake, along with deadlines ranging from July 1, 2014, through January 1, 2016. There have been a number of educational programs available to explain the NPSG including the no-cost Association for the Advancement of Medical Instrumentation and multiple coconveners webinar series, which began on September 25, 2013.³

It is fair to say that these steps are relatively complex and therefore potentially time consuming and human resource intensive. It is therefore imperative that affected organizations establish a compliance development plan with realistic estimates of how long it will take them to undertake and complete the multiple parts of this NPSG. Subcomponents and supporting activities can also be defined, along with the task sequencing necessary to move through the necessary steps. With this detailed task definition and associated time estimates, with an appropriate inefficiency multiplier, necessary start dates can in turn be estimated by working backward from the deadlines.

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Of course, one does not have to wait until the deadline to implement the requirements, and waiting could create risk management issues. For example, if a required element is not due until, say, December 2014, but an adverse incident occurs before then that is related to that element, saying that you did not do it because it was not yet required may not be a satisfactory argument. For example, it might be hard to explain why the obvious necessity of educating staff and others about the operation of the alarm systems for which they are responsible was not put into place because it was not required until January 2016. Similarly, even for hospitals that are not TJC accredited, this new NPSG still provides guidance that can be pointed to as to what constitutes reasonable safety efforts.

The NPSG, as do all TJC standards, sets minimum requirements for accreditation. This minimum does not limit what else might need to be done based on an institution's own self-assessment and experience. In this particular case of alarms, the NPSG does not emphasize the challenges of communicating alarms to the right caregiver at the right time and ensuring that that caregiver is available and responsive or that the alarm communication is escalated if not responded to. The NPSG also does not address preventive (planned) maintenance activities relative to alarms, nor does it address ongoing monitoring of alarm utilization and close calls or adverse events. Nonetheless, what is called for is sensible and, for the most part, what probably should have already been in place.

Requirements

Table 1 recasts the elements of the NPSG into a working document that includes the TJC text, a short summary statement, and the TJC deadline. Given that most organizations would want to have the element completed in advance of the deadline, Table 1 calls for the establishment of an earlier internal or working deadline. For each part of the TJC requirement, Table 1 also contains suggestions for a subset of tasks.

These subtasks are not unique, and they can be adjusted and combined to suit the organization's plans. However, in one form or another, it is important to recognize that each part, and the respective subparts, of the NPSG is itself a complex undertaking. Thus, for part 1, even establishing alarm safety as a priority can require a sequence of steps, especially if the establishment is going

TABLE 1. NPSG Work Plan

TJC Text	In brief	Deadline	Task	Assigned to
Part 1. As of July 1, 2014, leaders establish alarm system safety as a [critical access] hospital priority.	Establish alarm safety as a priority	TJC: July 1, 2014	Set and track milestones	
		Working deadline:	Create approval document	
			Obtain approval	
			Disseminate	
			Implement	
			Track milestones	
Review				
Part 2. During 2014, identify the most important alarm signals to manage based on the following:	Identify most important alarm signals	TJC: December 2014	Set and track milestones	
		Working deadline:	Develop written assessment of all alarms relative to their relative importance.	
			Review.	
• Input from the medical staff and clinical departments	Medical/clinical input	Working deadline:	Format and use survey mechanism to obtain necessary medical/clinical input.	
			Document.	
			Review.	
• Risk to patients if the alarm signal is not attended to or if it malfunctions	Risk analysis	Working deadline:	Create alarm risk tool and use it to assess each alarm.	
			Document.	
			Review.	
• Whether specific alarm signals are needed or unnecessarily contribute to alarm noise and alarm fatigue	Establish alarm necessity	Working deadline:	Create alarm necessity survey tool and use it to assess necessity for each alarm.	
			Document.	
			Review.	
• Potential for patient harm based on internal incident history	Use internal incident history	Working deadline:	Review internal alarm incident history.	
			Document.	
			Review.	
• Published best practices and guidelines	Review available best practices	Working deadline:	Identify and review best practices.	
			Document.	
			Review.	

continues

TABLE 1. NPSG Work Plan, Continued

TJC Text	In brief	Deadline	Task	Assigned to
Part 3. As of January 1, 2016, establish policies and procedures (P&P) for managing the alarms identified in Part 2 above that, at a minimum, address the following:	Establish alarm P&P, including	TJC: January 1, 2016	Set and track milestones	
		Working deadline:	Establish task force to create alarms P&P	
			Review	
			Document	
• Clinically appropriate settings for alarm signals	Establish settings	Working deadline:	Subtask: settings	
• When alarm signals can be disabled	Establish disablement rules	Working deadline:	Subtask: disabling	
• When alarm parameters can be changed	Establish change rules	Working deadline:	Subtask: changing	
• Who in the organization has the authority to set alarm parameters	Who can set	Working deadline:	Subtask: setting	
• Who in the organization has the authority to change alarm parameters	Who can change	Working deadline:	Subtask: changing	
• Who in the organization has the authority to set alarm parameters to "off"	Who can turn off	Working deadline:	Subtask: turning off	
• Monitoring and responding to alarm signals	Signal response systems	Working deadline:	Subtask: signal monitoring	
• Checking individual alarm signals for accurate settings, proper operation, and detectability	Settings check controls	Working deadline:	Subtask: settings checks	
Part 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	Educate staff	TJC: January 1, 2016	Set and track milestones	
		Working deadline:	Identify areas of alarm responsibilities	
			Develop training	
			Deliver and track training	
			Document	

to have real meaning and not just be a platitude from management. In this regard, simply saying that it is a priority is not the same as providing the resources necessary to see that the stated priority is translated into real action.

Establishing a new priority activity also raises the question of how many priorities you can have, especially given the dictionary definition of priority as "something that is more important than other things and that needs to be done or dealt with first." If something new is made a

priority, then something else that used to be the priority must be made at least secondary, and everything below it pushed down the list in turn. There is also a fundamental problem in externally created priorities. Something that is perceived as a national issue may or may not be a local issue, whereas something that is a local issue may or may not have generated a national priority. Of course, the glib answer is to do it all, with equal priority, but this ignores the reality of limited time and resources.

Feature Article

The final column of Table 1 suggests that there be a named individual responsible for seeing each part to its conclusion. This is a common component of good task management in that it requires that we know who it is that is supposed to be getting a task done, or at least seeing to it that it gets done. It is also necessary in most cases to have periodic progress reports on each task and subtask so that there can be a measure of progress.

Although Table 1 is intended to capture the overall work required, it is not a schedule-based document aside from the ultimate due dates. Setting additional operational tasks and deadlines can be presented in another table such as in Table 2. Here, the task is expanded to show all of the TJC called-out parts and internally created subparts, with their associated necessary completion dates in order to reach the ultimate deadline.

In general, these require identifying not only what the objective is but how the work is going to get done, and then doing the work, analyzing the results, documenting the results, and having appropriate review and sign-off, and then final documentation and action. Each of these steps has a time element that must be accumulated to determine the latest possible start date in order to achieve the goal by the end date. As given, the table is moved

TABLE 3. SE Elements (in Brief)

Primary	Components
Leadership ensures process	Focus on high-risk areas
Inventory of alarm-equipped devices	For high-risk areas and clinical conditions
Alarm settings	For high-risk areas and clinical conditions
	Identify where alarms are not necessary
Individualizing alarm settings	When can settings be adjusted from default
Preventive maintenance	Operation and detectability

through from bottom to top to maintain focus on the final deadline. This could certainly be reversed as desired.

It must be noted where necessary that some subtasks must be completed before others can be begun. For example, in part 2, the input from the medical staff must be obtained before there can be an effective risk analysis. However, how the risk analysis is going to be done and by whom could be developed before all of the input from the medical staff is available. Appropriate parallel tasking of course saves calendar time, but not effort hours.

Moreover, depending on who is doing the work parallel tasks can overwhelm the people who are supposed to be doing the work. In this regard, the establishment of the NPSG as a priority must mean that the people who are doing this work have had as necessary a reduction in their other duties. Everything being an add-on is not likely to be possible, nor does it reflect prioritization. The milestone chart is a classic way to present and monitor task scheduling and record progress, especially when tasks are of necessity linked with respect to their start and end dates.

Mapping From the Earlier Sentinel Event

The 2011 SE called for a number of tasks that if completed and maintained should serve as input to the NPSG process. For example, leadership commitment to the SE supports the priority commitment of the NPSG. Similarly the inventory process of the SE is a basis for the NPSG steps that require identification of the most important clinical alarms, and the guidelines for tailoring alarm settings should map into the alarm setting components of part 7 of the NPSG. Note here that while the SE called for a focus on high-risk alarms, the language of the NPSG is arguably less specific, calling for identification of the most important alarms (Table 3).

TABLE 2. Schedule Development

Component: _____ Deadline: _____
1. TJC deadline
2. Dissemination completed
3. Internal completion deadline
Revisions
4. Ready for final review
Revisions
5. Ready for committee final review
6. Component readiness
Part A
Part B
Etc
7. Start A
8. Start B
9. Start X
10. Assign tasks
11. Establish work plan

Some parts of the SE are not found expressly in the NPSG. For example, the preventive/panned maintenance of the SE has no direct relationship to any specific part of the NPSG, although the settings check at the end of part 3 is related. This of course does not mean that the maintenance part of SE is no longer applicable, in part because the SE has not been withdrawn, and also because proper maintenance is an existing part of TJC standards, even if an alarm focus is not called out elsewhere.

CONCLUSION

Although presented in less than 2 pages, the TJC NPSG on alarm management has a considerable scope of requirements that involves study of the environment, development and implementation of plans, and education of personnel.

These are no simple or quick activities, and a realistic plan of action and associated deadlines needs to be developed—and followed—in order to reach the end point in a timely and effective manner.

References

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