

Using Middleware to Manage Smart Alarms for Patients Receiving Opioids

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Patient-controlled analgesia (PCA) and opioids are increasingly prescribed for postoperative pain management. The varied risks inherent in delivering opioids postoperatively poses significant risks and possibilities for sentinel events, particularly for patients diagnosed with or at-risk for obstructive or central sleep apnea. Patients diagnosed with chronic illnesses or comorbidities (e.g., sleep apnea, obesity) are of a population particularly vulnerable to respiratory depression.¹

Each year, more than one-half of medication-related deaths and 20,000 incidents of respiratory depression–related interventions are attributed to the delivery of opioids in a care setting at a cost of approximately \$2 billion per year to the U.S. healthcare system.² From 2004 to 2011, 29% of opioid-related adverse drug events were related to improper patient monitoring.³

The current practices for monitoring opioid patients are inadequate. For example, patients can be left largely unmonitored up to 96% of the time on a general care floor (GCF) when clinical care staff rely on periodic physical spot checks for monitoring.⁴

Healthcare advocates and governing agencies such as The Joint Commission, the Anesthesia Patient Safety Foundation, and the Association for the Advancement of Medical Instrumentation recommend the adoption of continuous respiratory monitoring of postsurgical and PCA patients as a best practice. However, continuous monitoring of these patient populations remains the exception to the rule, particularly

outside the critical care unit setting.⁵ Business and clinical challenges impede the adoption of this best practice, which may include implementing a costly physiologic monitoring technology, the addition of full-time, direct care clinical staff, and the difficulty of capturing holistic, real-time patient data in order to facilitate early intervention.

A major barrier to continuous monitoring is the disruption to direct care clinical staff workflow. The risk of alarm proliferation and fatigue increases when implementing a new or additional device technology with alarm capabilities.

This article seeks to raise awareness and focus on the unique and challenging clinical and technical aspects of opioid-induced respiratory depression (OIRD), increase safety for these patient populations, and suggest project strategies that promote a more efficient workflow for direct care clinical staff by using middleware to monitor real-time patient data.

Current State of Alarm Signals

Beyond conducting periodic physical spot checks of patients, surveillance monitoring can fall into three broad categories, which vary in complexity and comprehensiveness.

1. Vital signs monitoring devices send data and alarm signals to a central station, which may or may not be continuously monitored by clinical staff.
2. A telemetry room receives data and signals and is monitored by clinical staff or alarm

technicians. These technicians (i.e., “tele-techs”) can quickly become overwhelmed by the numerous alarm signals potentially generated by a single patient. An estimated 85% to 99% percent of these alarms are nonactionable and do not require intervention.^{6,7}

3. Smart alarms transmit to a secondary device held by direct care clinical staff.

Smart alarm technology represents arguably the most sophisticated continuous monitoring category. Smart alarms serve two primary purposes; they 1) provide an accurate and real-time picture of a patient’s condition, enabling direct care clinical staff and physicians to intervene before a patient begins to deteriorate, and 2) provide the flexibility to attenuate alarm signals in a way that balances communicating contextual patient safety-specific information and minimizes spurious and nonemergent events that do not indicate a threat to patient safety.⁷

Smart alarm strategies allow for more than just the analysis of the alarm signals themselves. Smart alarm signals can be based on the original high-fidelity physiological data, such as time trends, cross-parameter correlation, in-depth

alarm signal sensitivities, and statistical and predictive analytical techniques.

Smart Alarm Techniques

Separating clinically relevant from nonactionable alarm signals (e.g., a sensor on a patient momentarily detaches or a brief self-correcting physiological response occurs) is one of the major challenges in alarm signal management. This is compounded by the enormous number of alarm-enabled medical devices on the market today, default narrow alarm limits, and inaccurate default settings. More than 19 of 20 hospitals surveyed expressed concern over alarm fatigue, and almost 9 in 10 hospitals surveyed indicated they would increase use of pulse oximetry and capnography if it was possible to reduce false alarms.⁸

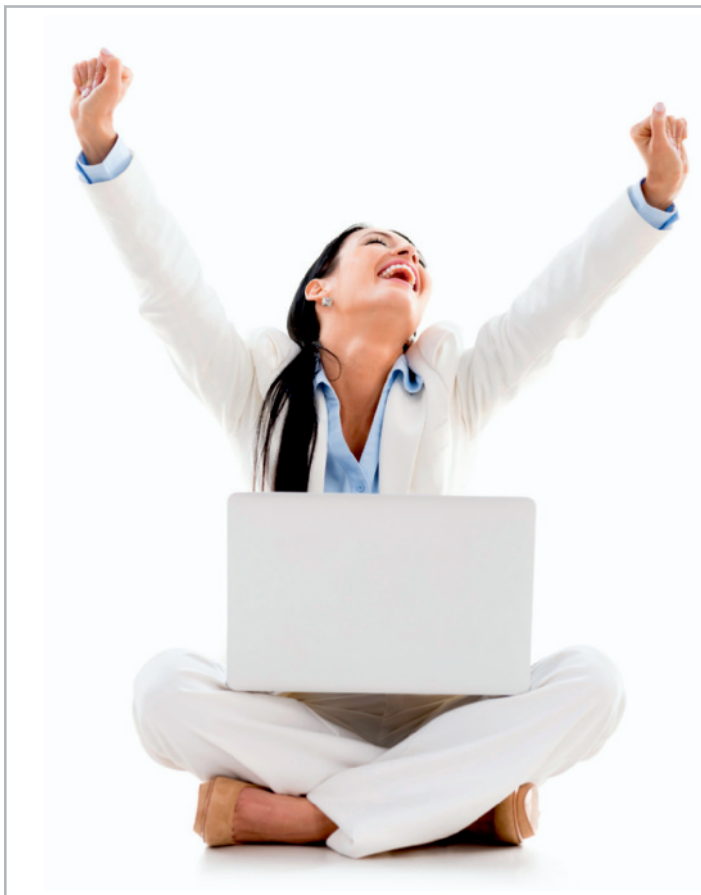
Several techniques and strategies work to reduce false, or nonactionable, alarm signals, including:

- **Trending alarms.** Parameter measurements that are evolving systematically towards a specific threshold can indicate an emergent condition.



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- **Consecutive alarms.** Periodic alarm signals or measured values occur within a predefined period (e.g., peak pressure alarm signals occur three times per minute or more on a given patient).
- **Sustained alarms.** Require setting a minimum time threshold that must be violated prior to sounding the alarm.
- **Combination alarms.** Multiple parameters from different devices meeting individual criteria simultaneously may together indicate a degraded patient condition.

The above strategies and others can be implemented individually or in concert to reduce nonactionable alarm signal notifications. The exact combination depends on the strategy developed with clinical staff. Leveraging smart alarm techniques requires middleware technology as well as a holistic understanding of the policies, training, and workflow of the hospital and affected care units.

A baseline alarm study is a critical tool for conducting evaluations that include time trends, in-depth examinations of alarm sensitivity, and statistical and predictive analysis. A baseline study enables hospitals to standardize alarm signal management and to develop evidence-based best practices that safeguard patient safety, increase efficiency, improve patient and staff satisfaction, and identify critical areas for improvement.

Hospitals must develop a standard approach to reduce the number of nonactionable alarm signals and maintain a strategy to address alarm fatigue, alarm reduction, and alarm noise. In addition, providers must guard against the overuse of monitoring when it is not indicated, as this just adds to the number of nonactionable alarm signals.

For example, the data generated by a baseline evaluation can guide clinical staff in developing a more effective alarm management process to measure improvements over time to meet their patient safety goals. Collecting high-resolution physiological data from medical devices (in addition to individual alarm signals) empowers clinical leadership to determine the effect of alarm signals on patient care before adjusting their settings.

Data Delivery, Communication, and Integrity

Multiparameter physiologic monitors are critical components for continuous patient monitoring and data capture. Capnography and continuous pulse oximetry monitoring provide a sensitive and early indicator of OIRD as long as the appropriate clinical indications are detected and the associated smart alarm signals communicated to clinical staff. Capnography measures respiratory rate and exhaled end-tidal carbon dioxide and inhaled carbon dioxide to determine whether a patient is experiencing respiratory distress over time. The capnography waveform together with the instantaneous values of end-tidal carbon dioxide are key indicators as to whether a patient is in respiratory failure or is trending towards respiratory failure, based on the shape of the capnogram and on the values of end-tidal carbon dioxide in concert with respiratory rate. The accuracy of these data, together with their timely delivery to clinical staff, are essential to patient safety.

Middleware Requirements and Technical Considerations

Smart alarm signals and techniques for generating smart alarm signals can be implemented using a device-agnostic middleware platform for interfacing with bedside devices. At a minimum, middleware should retrieve episodic data from a medical device and translate it to a standard format. Middleware should also include the capability to retrieve data at variable speeds to meet the requirements of various clinical operational settings (e.g., operating rooms, intensive care units, medical-surgical units).

Middleware can create a more holistic picture of the patient's current state by pulling data from medical devices and combining it with data from the patient health record. Combining analysis of retrospective and ancillary information with real-time data collection at the point of care provides a powerful tool for prediction and decision support.

Data collection and analysis are further enhanced when including methods for disseminating, exploiting, and distributing the data and the smart alarm signals. These features facilitate better patient care management and clinical workflow by providing the capability to notify clinicians of patient status throughout

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the hospital. This enables dynamically adding and removing medical devices and distributing real-time patient monitoring to dashboards and mobile devices. The healthcare enterprise's rollout plan must include the necessary technology (e.g., a robust wireless infrastructure) to ensure that smart alarms communicate to clinical stakeholders properly and effectively.

Using data for display, analysis, and predictive analytics, in addition to creating new information by processing data collected at the point of care for use in treatment and diagnosis requires demonstrated efficacy and technical capability from the middleware vendor, particularly as pertains to patient safety. To obtain Food and Drug Administration clearance, the middleware must demonstrate that it mitigates the risks associated with communicating higher frequency data for the purpose of interventional alarm signals and analysis. The data used for real-time intervention affects patient safety, and deleterious effects may result from any delay in delivery to the appropriate responder. Thus, understanding the implica-

tions of requirements on data delivery latency, response, and integrity is important as these requirements imply the ability to support active patient monitoring. The middleware system must receive clearance for active patient monitoring to transmit alarm signals for the purpose of intervention.

Vendors can achieve the appropriate clearance for active patient monitoring by demonstrating that their middleware mitigates the hazards of using the data in live interventions. This would be consistent with alarm signal communication or the creation of new data from raw data collected from medical devices. For a middleware vendor to claim clearance for active patient monitoring, they must implement checks and balances to ensure the receipt and delivery of all active patient data for intervention purposes from the collection point (medical device) to the delivery point (the clinician). Distinguishing between the ability to deliver on the timing and receipt of data necessary for interventions and active patient monitoring is important.

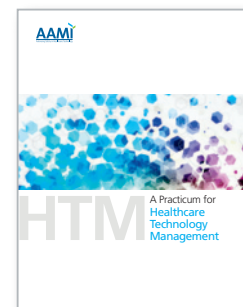
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Team Approach to Continuous Monitoring

Hospitals can mitigate many of the adverse events associated with failed technology adoption and implementation with adequate planning, training, and collaboration. The chances of success are dramatically increased by listening to, engaging with, and educating frontline staff. For example, nursing staff are responsible for properly setting alarm thresholds and responding when devices send an alarm signals. As the presence of alarm signal-generating patient care devices grows, nurses experience disruptions in their workflow and their ability to engage with patients as they chase down hundreds of often nonactionable alarm signals. Without proper education and implementation of alarm signal-generating devices, clinical staff may arbitrarily adjust alarm signal settings or even turn them off entirely.

Direct-care staff involvement is critical to the success of any new technology rollout. Two questions that need to be addressed are 1) How will this new technology impact how nurses deliver patient care? and 2) What adjustments in workflow and practice need to be made at go-live and beyond?

Clear and complete answers to these questions are often necessary when seeking needed buy-in from the clinical staff members who will be utilizing the equipment. If end-users are left out of equipment selection, adoption, and implementation, then they are less likely to feel enthusiastic about it.

For hospitals and healthcare systems (especially those breaking ground on a net-new technology integration), the first step is assessing need and the potential impact on clinical workflow. The formidable task list that comes with implementing any new technology requires the input and expertise of a project team. The ideal team includes many stakeholders, such as representatives from information technology networking, facilities, patient safety experts, educators, informatics nurses, laboratory staff, pharmacists, biomedical engineers, quality improvement specialists, vendors, and patient-facing clinical staff (e.g., physicians, nurses, and respiratory therapists). This team is responsible for every phase of deployment, including acquisition, rollout, implementation, and transition to live operations. The team validates and verifies the institutional objectives

and integration goals, business and clinical requirements, risk management concerns, and patient safety goals and is responsible for managing budget and vendor selection. The project team is also charged with identifying the departments or units affected by the integration. Large, enterprise-wide integrations are not unprecedented, but a phased rollout in a high-acuity department or set of departments (e.g., the surgical suite) allows more time and space for assessments, lessons learned, and best practices, which can be applied as the integration spreads to the rest of the enterprise.

The value of clinical workflow is an often-overlooked aspect of integration. Workflow considerations vary among hospitals and individual units. Effects on workflow largely define how data are collected and displayed, how alarm signals are communicated, and to whom. Hospitals should incorporate clinical workflow as quickly and as early as possible in the process. Designating an executive stakeholder, nursing champion, or empowered super-user at the outset allows other nurses and direct-care staff to receive information, training, and support during all phases of adoption, and these super-users work closely with the interdisciplinary team assembled from start to finish of the project.

Conclusion

The widespread use of PCA and the increasingly complex chronic conditions and comorbidities presented in patients receiving postoperative opioid pain medication raises considerable safety risks for hospitals and healthcare systems. It's possible to continuously monitor these patient populations (often in general care medical-surgical or other step-down units), but hospitals must evaluate and ensure a satisfactory clinical workflow and technical infrastructure before considering such an endeavor. Many hospital systems do not continuously monitor their patients on general care floors and would require upgrades in technology and changes in clinical workflow to do so. Furthermore, hospitals would need to employ smart technologies using middleware to ensure only actionable alarm signals are provided to clinical staff, else the possibility of flooding staff with nonactionable false alarms will result. The deployment of continuous monitoring for patient populations outside of critical care units requires a careful investment

of time and money in addition to workflow considerations for direct care clinical staff to ensure successful management of patients on general care floors. ■

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