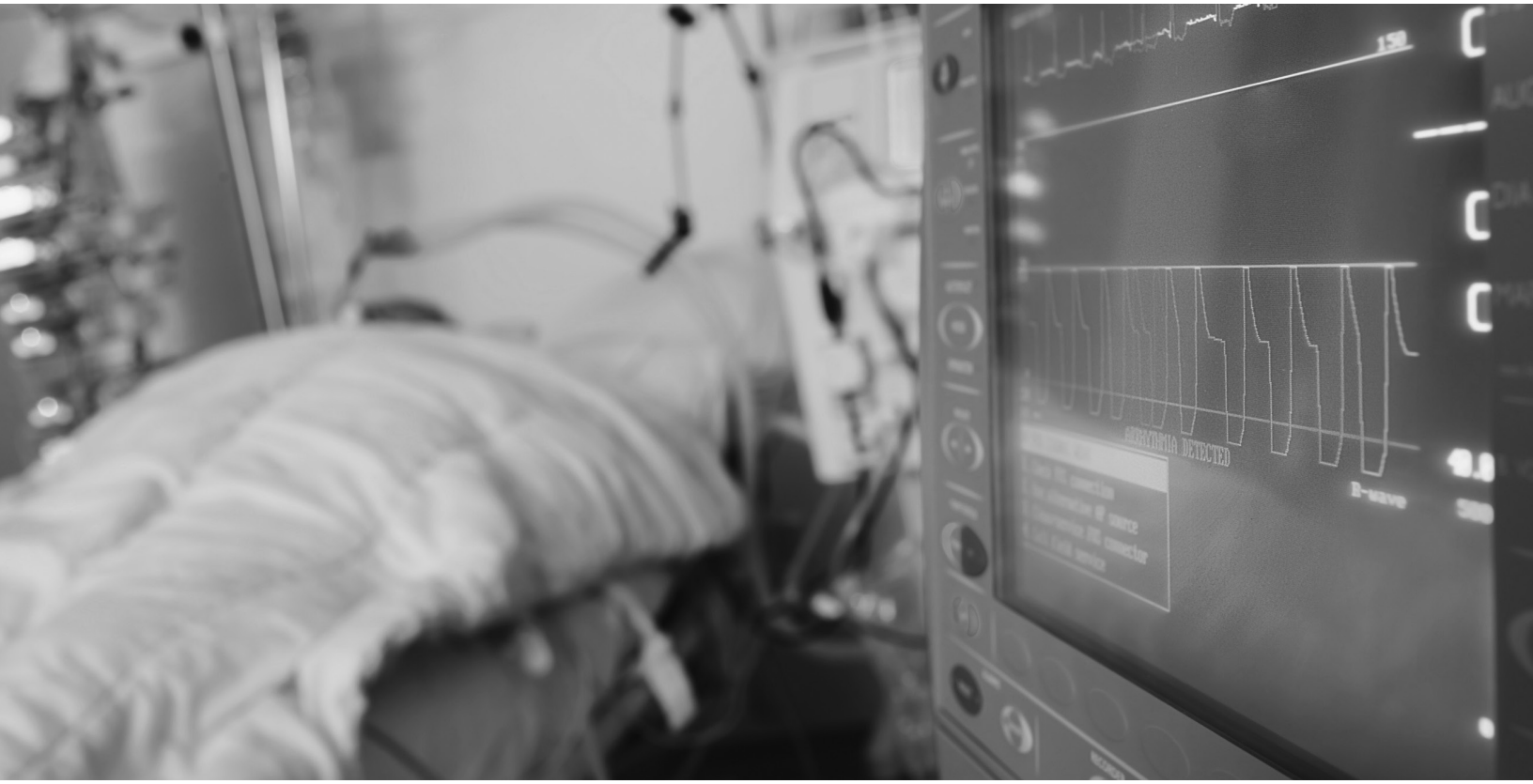
A Bernoulli White Paper

DEAD IN BED

How Continuous Clinical Surveillance Can Prevent Respiratory Depression



Executive Summary

Opioids are integral to most post-surgical pain management strategies. However, post-operative patients at risk for obstructive or central sleep apnea are particularly vulnerable to undetected respiratory depression.

Analysis of site claims reviews suggest that improved surveillance techniques could prevent most opioid-induced respiratory depression (OIRD) events. Continuous clinical surveillance is a powerful tool for prediction, mitigates alarm fatigue and facilitates the distribution of real-time data to centralized dashboards or mobile devices.

As such, continuous clinical surveillance has been recommended as a best practice by prominent healthcare advocates and governing agencies.

The purpose of this white paper is to:

- Define the inherent risks associated with undetected OIRD in patients with obstructive or central sleep apnea
- Identify the short-comings of current surveillance tactics
- Describe the key elements of continuous clinical surveillance
- Demonstrate the efficacy of continuous clinical surveillance.

Respiratory Depression is Preventable

Injuries or death due to OIRD has become an increasingly urgent[1]—and public[2]—concern for hospitals and health systems.

According to the Association for the Advancement of Medical Instrumentation (AAMI), more than 20,000 opioid-induced respiratory depression interventions occur annually. This estimated cost for these interventions to the U.S. healthcare system are about $2 billion per year.[3] According to the Joint Commission's Sentinel Event database, 29 percent of adverse events are related to improper patient monitoring.[4]

However, the overwhelming majority of respiratory depression cases—97 percent[5]—could have been prevented with the appropriate surveillance practices.

In an analysis of the Anesthesia Closed Claims Project database of patients at risk for respiratory depression over a 20-year period, Lee, et al., noted

> ...a growing consensus that opioid-related adverse events are multifactorial and potentially preventable with improvements in assessment of sedation level, monitoring of oxygenation and ventilation, and early response and intervention, particularly within the first 24 [hours] postoperatively.[6]

The Joint Commission, Anesthesia Patient Safety Foundation, AAMI and others recommend the adoption of continuous respiratory depression surveillance as a best practice. However, this practice remains the exception to the rule[7], particularly outside critical care settings.

Current State of Patient Surveillance

Current practices for monitoring patients receiving opioids are neither adequate nor comprehensive for early intervention. The most common practices include visual spot checks by clinical staff and responding to alarms by physiologic devices.

However, beneath these strategies lie potentially lethal assumptions. Clinicians won't always be present when respiratory depression occurs. Pulse oximeters and capnographs are often set to pre-determined thresholds, which can cause false alarms.

In truth, spots checks can leave patients unmonitored 96 percent[8] of the time, leaving them vulnerable to advanced deterioration. In addition, neither method consistently identifies gradual deterioration; only that respiratory depression is already in progress.[9]

Jungquist, et al., note that in 42 percent of confirmed OIRD events, "the interval between the last nursing assessment and the detection of respiratory depression was less than two hours, and in 16 [percent] of the cases, it was within 15 minutes."[10]

The inability to identify respiratory depression early is not just a patient safety problem. Rescuing these patients is also costly in terms of resource utilization, morbidity and mortality.[11]

In contrast, continuous clinical surveillance utilizes real-time data to help clinicians quickly recognize and respond to signs of respiratory distress. A rules-based analytics engine and multi-parameter physiological monitoring devices can identify, capture and distribute clinically actionable data to remote clinicians in real time while also eliminating nuisance alarms.

There also is growing evidence that continuous clinical surveillance facilitates interventions long before OIRD degrades to a life-threatening event.

Key Elements of Continuous Clinical Surveillance

Continuous clinical surveillance allows clinicians to surveil multiple patients from a centralized location or via mobile alarm notifications. Continuous clinical surveillance uses multi-variate rules to correlate data and create new early warning alarms. This helps clinicians to quickly recognize and respond to signs of respiratory distress before the patient's health is compromised.

The solution is broken into three main buckets—medical device integration (MDI), smart alarms and data distribution and communication capabilities.

Medical Device Integration. Smart alarms can be implemented using device-agnostic middleware for interfacing with bedside devices. Most medical device integration solutions gather and filter data to support documentation in an EHR. To achieve real-time surveillance, a more clinically significant capability, MDI should be able to collect data at variable speeds to meet the requirements of various clinical operational settings. The ability to retrieve data at variable rates (including at the sub-second level) requires advanced technical capabilities.

Data collection and analysis are further enhanced when including methods for disseminating, analyzing, and distributing the data and the smart alarm signals. These features facilitate better patient care management and clinical workflow by allowing patients to be monitored remotely. This enables dynamically adding and removing medical devices and distributing real-time patient monitoring to dashboards and mobile devices.

Smart Alarms. An underlying factor that produces alarm fatigue is that the simplistic threshold limits in pulse oximeters and capnographs are highly susceptible to false alarms. Optimization of the alarm limits on these devices and silencing of non-actionable alarms is not enough to eliminate the risk of alarm fatigue. The challenge of attenuating alarm data is achieving the balance between communicating essential patient information while minimizing spurious and non-emergent events.

Continuous clinical surveillance solutions that analyze real-time patient data can generate smart alarms. Identifying clinically relevant trends, sustained conditions, reoccurrences and combinatorial indications may indicate a degraded patient condition prior to the violation of any individual parameter. In addition, clinicians can leverage settings and adjustments data from bedside devices to evaluate adherence to or deviation from evidence-based care plans and best-practice protocols.

Data Distribution. Clinicians can't be everywhere at once. Even the most aggressive rounding protocols will leave patients alone for a significant period of time. In addition, the physical layout of the care unit can impair a clinician's ability to move quickly from patient to patient.

Continuous clinical surveillance allows clinical staff to monitor patients remotely. Networked laptop and desktop computers as well as scrolling message bars can provide clinical staff with access to data and alarms from all surveilled patients. In addition, alarms can easily be routed to central stations via dashboards or mobile devices and pagers.

Continuous Clinical Surveillance at Work

Bernoulli recently collaborated with Virtua Health System to determine if selectively delayed notifications using adjustable, multi-variable thresholds could identify clinically-actionable events and reduce false alarms without risking patient safety.[12]

The study measured pulse (HR), oxygen saturation (SpO_2), respiratory rate (RR), and end-tidal carbon dioxide (ETCO2) continuously. It then compared alarms received through the bedside monitoring devices with remote alerts annunciated through the Bernoulli system, designed to trigger only after a selective delay.

Using only sustained alarms as the filter for notifications reduced alerts from 22,812 to 13,272, which was still high enough to risk alarm fatigue. Passing multiple data time series through a multi-variate rules engine that monitored the values of HR, RR, SPO2 and $ETCO_2$ reduced the number alerts sent to the nurse-call phone system to 209—a 99 percent reduction. In addition, that it was independently verified that no actual clinical events were missed and several patients received Naloxone to counteract OIRD.

An important observation made during this study was that remote alarm communication was an important aide to in-room monitoring alarm annunciation. A key argument that is made for in-room annunciation in the case of conscious or waking sleep apnea patients is the room audible alert. Yet, in every observed case of OIRD, the in-room audible annunciation had no effect on waking or stirring the patients. Hence, remote monitoring capability to catch such instances is necessary to ensure patients do not slip through the cracks.

Beyond high-acuity areas, healthcare systems are creating a foundation for other real-time healthcare innovations, including clinical surveillance modules, MDI with the EHR and virtual ICUs.

Conclusion

Healthcare organizations face a steep climb to significantly reduce OIRD events. The inadequacy of spot-checks and the medical community's consensus on the superiority of continuous surveillance point to an urgent need for new best practices.

However, concerns over adding to clinician alarm fatigue and contributing to an increasingly noisy hospital environment are significant obstacles. Hospitals need to take a system-wide inventory of alarms, apply analytics to understand their value and convene project teams to embark on a technology transformation.

This transformation should include the perspectives of frontline clinicians and should respect the significance of disrupting workflows. Hospitals should employ smart technologies to ensure only actionable alarm signals are sent to clinical staff. The deployment of continuous clinical surveillance requires a careful investment of time and money in addition to workflow considerations to ensure the highest level of patient safety.

About Bernoulli

The mission of Bernoulli® Health is to improve patient safety in real time. Since 1989, Bernoulli has developed solutions including the all-inclusive Bernoulli One™ platform. A single solution for continuous patient health monitoring and clinical surveillance, medical device integration, and real-time data analytics, there are no other solutions as advanced as Bernoulli One. The Bernoulli software helps save patient lives as it continuously detects deteriorating patient conditions and notifies clinicians of potential events. This results in improved patient observation and provider workflows. Bernoulli has achieved FDA Class II clearance for use in both patient monitoring and secondary alarm management. Bernoulli headquarters are in Milford, CT. For more information visit BernoulliHealth.com, email info@BernoulliHealth.com, or call 800-337-9936.

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