Actionable Patient Safety Solutions (APSS) #4: Monitoring for opioid-induced respiratory depression

How to use this guide
This guide gives actions and resources for creating and sustaining safe practices for monitoring for opioid-induced respiratory depression. In it, you’ll find:

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APSS #4: Monitoring for opioid-induced respiratory depression

Executive summary checklist

Opioid-induced respiratory depression is a leading cause of preventable patient death (Weinger) and causes serious patient harm.

To create a culture of safety and prevent serious harm, health care providers must take steps to prevent opioid-induced respiratory depression and carefully monitor a patient if it happens.

Create an action plan

☐ Find and prioritize factors in common with serious preventable events:
  ☐ Review all reported patient deaths and serious patient harm events over the previous 24 months for patients given opioids and opioids with sedatives, such as benzodiazepines
  ☐ Review all closed malpractice claims related to opioid-induced respiratory depression
  ☐ Monitor and review all patients given naloxone

☐ Develop an action plan for your institution based on the data collected from serious preventable events and the strategies within this APSS:
  ☐ Include guidelines for continuous electronic monitoring to notify staff of significant changes in a patient’s respiratory condition, and ensure that staff respond correctly and promptly
  ☐ Appoint a staff “champion” to be in charge of your plan’s implementation, education, and evaluation
  ☐ Provide the resources necessary to implement your action plan

☐ Educate all staff, patients, and family members on the common contributing factors leading to opioid-induced respiratory depression and side effects of opioids and sedatives

☐ Continue to report and assess both near-misses and patient harm events for more opportunities to learn and improve

☐ Use written and recorded patient stories to help staff find gaps between their care and a patient’s experience

☐ Complete a community needs assessment and act on overused opioids within substance abuse and mental health

☐ Create a community based approach to alternatives to opioids to opioids when appropriate

Ensure best patient care

☐ Use continuous electronic monitoring in all hospital units where patients receive opioids:
  ☐ Include continuous monitoring of blood oxygen levels in your care standard, which should include motion and low perfusion pulse oximetry
  ☐ Monitor respiratory rate in patients receiving oxygen with either continuous capnography or acoustic respiration rate monitoring
  ☐ Use a system to alert staff early if a patient’s health is deteriorating, and set an escalation plan to include another staff member
☐ Lower alarm fatigue for staff by setting proper respiratory rate (RR), pulse rate (PR), SpO2, and apnea alarms based on the patient’s risk

☐ Develop a pain management program that uses various methods, including non-opioid adjuncts, Opioid Free Analgesia (OFA), and safe opioid tapering protocols
What we know about opioid-induced respiratory depression

Opioid induced respiratory depression is a serious patient safety issue and only a multidisciplinary approach can improve outcomes. It is a problem that involves the emergency department, hospitalization floor, operating room, postanesthesia care unit, intensive care unit and even home care facilities, and all the professionals involved in those areas.

When a patient has somnolence or appears to be sedated is at high risk to develop OIVI. If not on continuous monitoring this needs to applied immediately and/or the patient transferred to an area where continuous monitoring can occur. OIVI has been reported within 15 minutes of a nursing check (Lee et al 2015). The critical time period for use of continuous monitoring is the first 24 hours postoperatively as demonstrated by the Closed Claims Project that revealed that 88% of events occurred in that time frame. (Lee et al 2015). Regular visits by nurse, medical or administrative staff can trigger alarms about the risk of OIVI, and assessments should include blood pressure, temperature, pulse, respiratory rate, pain level, respiratory status, and especially sedation level. These visits cannot replace continual monitoring.

A greater emphasis on monitoring the first 24 hours is likely to be helpful in reducing adverse events from opioids.

Patients receiving opioids in the hospital have almost twice the incidence of cardiac arrest compared to other patients (Overdyk et al., 2016). The cost associated with respiratory failure after surgery alone in the U.S. Healthcare System is $2 billion (Reed, May, Nicholas, Taylor, & Brown, 2011).

Improper monitoring can lead to opioid-induced respiratory depression

While opioid use is safe for most patients, opioid analgesics are associated with adverse effects, including respiratory depression in many post-surgical patients (Vila et al., 2005; Jarzyna et al., 2011)

Adverse effects associated with opioids not only include the above mentioned respiratory depression, but also hyperalgesia, early development of tolerance and dependence, ileus (inability of the intestine to move food or waste), nausea and vomiting, and delayed recovery (Kane-Gill et al., 2014).

Administration of supplemental oxygen complicates the monitoring issue because it can delay detection of depression ventilation and further impair hypoxic respiratory drive. Another challenge is to accurately measure the incidence of OIVI, because without sequentially acquired measures any new monitoring system or protocol can’t be evaluated. There are some surrogates for identifying respiratory depression, like: Hypercapnic hypoventilation, Hypopnea, Decreased ventilatory rate, Hypoexmia and others. After the Institute of Medicine (IOM) described failure to rescue as a key issue in healthcare quality in 2001, they identified it as a key area for improvement in patient safety (“Crossing the Quality Chasm: A New Health System for the 21st Century”, 2001).

A decade later, a study looked at patient safety indicators for 40 million hospitalized patients and concluded that many deaths and permanent disabilities could still be avoided if healthcare systems adopted safe practices and put systems in place that help patient safety (Reed, et al., 2011). Reports by hospitals to the Joint Commission’s Sentinel Event database (2004-2011) show that the causes of opioid-related adverse events and deaths include:
• 47% from dosing errors
• 29% related to improper monitoring of the patient
• 11% related to other factors including excessive dosing, medication interactions, and adverse drug reactions

This document focuses on the 29% of patients that were improperly monitored.

In-hospital mortality after surgery is higher than expected and has multiple factors that institutions can address systematically (Pearse et al., 2012). This document provides solutions to reduce postoperative opioid-induced respiratory depression, including:
• Properly monitor and identify patients at risk for “failure to rescue”
• Create systems to notify staff of important changes in patient condition
• Ensure proper pain management and opioid dosing
• Use automated decision support to ensure staff use the right therapy at the right time

Proper monitoring can prevent opioid-induced respiratory depression

In 2011, the Anesthesia Patient Safety Foundation recommended continuous monitoring for all patients receiving parenteral (usually administered Intravenously) opioids, and using a system to notify caregivers when alarming conditions occur (Weinger).

In August 2012, the Joint Commission issued a sentinel event alert (a change in policy based on death or serious harm to a patient), urging all healthcare systems to introduce measures to improve safety for patients receiving opioids, including systematic protocols to assess pain and proper opioid dosing, as well as continuous monitoring of oxygenation and ventilation (Joint Commission, 2012). In 2014, the Center for Medicare and Medicaid Services (CMS) clarified the surgical services Condition of Participation (CoP) for hospitals to have adequate provisions for immediate postoperative care and to emphasize the need for monitoring after surgery for patients receiving parenteral opioid medications, regardless of where they are in the hospital (Centers for Medicare & Medicaid Services, 2014).

The evidence for proper monitoring

Research has studied the development of early warning systems (EWS) and validated EWS in Europe and Australia (Alam et al., 2014; Ludikhuize, Smorenburg, De Rooji, and De Jonge, 2012; Fullerton et al., 2012; Smith et al., 2013). Your institution can easily incorporate the technology to support EWS, such as remotely monitoring discharged patients. Recently newer EWS have been developed, like NEWS and NEWS 2, which improve sensitivity and specificity to activate Fast Response Teams (FRT (RCP London, 2017).

A landmark study published in January, 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using motion-resistant and low perfusion pulse oximetry and remote monitoring and clinician notification system identified patient distress earlier, which decreased rapid response team activations by 65%, ICU transfers by 48%, and reduce ICU days by 135 days annually (Taenzer, Pyke, McGrath, and Blike, 2010).

A follow-up report by Dartmouth in 2012 reported that, since December, 2007, no patients have died or had serious brain injuries as a result of respiratory depression from opioids. In addition, expanding monitoring to all general and thoracic vascular post-surgical units produced similar results to those seen in the original orthopedic unit (Taenzer). They also reported savings of $58,459 saved per patient who was not transferred to the ICU from the original orthopedic unit ($76,044 vs. $17,585), equating to $1.48 million in annual
opportunity cost savings in this one unit alone.

In spite of the calls to address failure to rescue for postoperative respiratory depression, pain assessment and opioid dosing approaches are still variable, and a high percentage of postsurgical patients on parenteral opioids are not continuously monitored. A combined approach with clinical skills and technology helps to provide additional information for detection of respiratory depression. The lack of a systematic approach to prevent failure to rescue from postoperative respiratory depression poses significant patient safety, quality, and cost of care implications. Healthcare institutions must commit to action with specific leadership, action, and technology plans to close their performance gap on this issue.

In the future no patients will be harmed by postoperative OIVI. We need to make the commitment to provide safe prescription, to reach for alternative analgesics, and to use technology and clinical skills to monitor every patient with opioid analgesia.

Leadership plan
- Hospital governance, senior administrative leadership, and clinical/safety leadership should close their performance gap through a comprehensive approach that addresses the problem
- Hospital governance and senior administrative leadership should commit to be aware of this major performance gap in their healthcare system
- Clinical/safety leadership should:
  - Endorse the plan
  - Drive implementation across their institution
  - Include fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action (National Quality Forum, 2010)
  - Set measurable quality indicators
  - Set a goal date to implement the plan
  - Have hospital governance and senior administrative leadership evaluate the budget
- Use patient stories – in written and video form – to find gaps and inspire change in your staff

Action plan
Create protocols for opioid treatment (refer to APSS #3G: Opioid Safety Stewardship)
- Assess pain management protocols and standardized order sets where possible
- Create standard transfer protocols from surgery and intensive care unit to postoperative general floor unit
- Use a tapering protocol for opioid and/or combination of opioids with sedatives based on patient’s alertness, respiratory rate, and pain control
- Store naloxone in every Code Blue crash cart tray on every hospital unit
- Create standard workflows for continuous monitoring from patient admits through discharges

Use opioid alternatives in your pain management protocols (refer to APSS #3G: Opioid Safety Stewardship)
• Enact opioid-free analgesia (OFA) protocols as routine surgical/anesthesia practice as recommended by the Enhanced Recovery After Surgery (ERAS) organizations – evidence shows less cancer recurrence if cancer surgeries use OFA protocols
• Include the following alternatives in your protocols: multimodal therapy with regional anesthetic blocks (such as TAP Blocks with liposomal bupivacaine), non-steroids - acetaminophen, low dose ketamine, dexmedetomidine, intravenous lidocaine, and intravenous magnesium (ASA, 2016)

Create protocols for continuous electronic monitoring
• Improve electronic detection of deteriorating patients and the early notification of the caregivers, including the prevention of adverse events due to respiratory depression from pain medications
• Continuous oxygenation and/or respiratory monitoring (not spot check monitoring) with pulse oximetry through an adhesive sensor. Ideally use pulse oximetry with measure through motion and low perfusion technology
• Use a remote notification system with an alarm to notify the care provider
• Use a system of alarm escalation if the primary nurse does not respond promptly
• Set respiratory rate (RR), pulse rate (PR), and blood oxygen (SpO2) alarms to reduce alarm fatigue, based on your specific patient population. Examples:
  o For most adults:
    • Set RR alarm for below 6 and above 30 breaths per minute
    • Set PR alarm for below 40 and above 100 beats per minute (Taenzer, Pyke, McGrath, and Blike, 2010).
  o For children (use clinical judgement appropriate for age):
    • Set SpO2 alarm for below 84% (McGrath, Pyke, and Taenzer, 2016)
• Use continuous ventilation monitoring (such as capnography or respiratory acoustic rate monitoring) for reduced respiratory rate in patients on supplemental oxygen
• Continuous electronic monitoring systems should use multiple physiologic measures in the form of an index to help identify clinically significant changes earlier and more reliability

Update rapid response team protocols
• Use rapid response teams and a protocol for starting a rapid response call for postoperative respiratory depression (Alam, et al., 2014)
• Allow families to ask the nurse to activate the rapid response system. Educate families about this option (Brady et al., 2014)
• Consider using proactive rounding on high-risk patients by resource nurses with critical care training (Hueckel et al., 2006)

Technology plan
These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: http://patient.sm/dgQogJ
Consider using the following technologies:

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<tr>
<th>System or Practice</th>
<th>Available technology</th>
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| ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities:  
  • Computerized Provider Order Entry (CPOE)  
  • Drug-drug interaction check  
  • Drug-allergy interaction check  
  • Clinical Decision Support tools (CDS) | CCHIT-certified EHR systems |
| Continuous pulse oximetry  
  • direct surveillance of patients | Adhesive pulse oximetry sensor connected with pulse oximetry technology proven to measure-through-motion and low perfusion to avoid false alarms and detect true physiologic events |
| Continuous respiratory rate monitoring  
  • Ability to accurately measure changes in respiratory rate and cessation of breathing with optimal patient tolerance and staff ease of use in order to avoid false alarms, with added importance in care areas without minimal direct surveillance of patients | |
| Remote monitoring and notification system  
  • Remote monitoring with direct clinician alert capability compatible with recommended pulse | Multi-parameter monitoring system which includes direct clinician alert through dedicated paging systems or existing hospital mobile device notification system. |
| Network |  
  • Medical-grade wireless network suitable to permit reliable, continuous remote monitoring and documentation during ambulation and/or transport  
  • Alternatively, use a wired network which allows surveillance of patients while they are in bed, but not while they are in an ambulance |
Measuring outcomes

Key performance indicator
If your organization uses the Safety Event Classification system, the following metric specifications apply (If not, consider adapting this model as a template):

Rate of patients with postoperative respiratory failure per 1,000 elective surgical discharges for patients 18 years and older as defined by the Agency for Healthcare Quality and Research (AHRQ)

Outcome measure formula

**Numerator:** Discharges, among cases meeting the inclusion and exclusion rules for the denominator, with either:
- Any secondary ICD-10-CM diagnosis code for acute respiratory failure
- Any listed ICD-10-PCS procedure codes for:
  - A mechanical ventilation for 96 consecutive hours or more that occurs 0 or more days after the first major operating room procedure code (based on days from admission to procedure)
    - A mechanical ventilation for less than 96 consecutive hours (or undetermined) that occurs 2 or more days after the first major operating room procedure code (based on days from admission to procedure)
    - A reintubation that occurs 1 or more days after the first major operating room procedure code (based on days from admission to procedure)
    - Narcan use
  - MDC 4 (diseases/disorders of respiratory system)

**Denominator:** Elective surgical discharges, for patients ages 18 years and older, with any-listed ICD-10-PCS procedure codes for an operating room procedure. Elective surgical discharges are defined by specific DRG or MS-DRG codes with admission type recorded as elective.

Exclude cases:
- Where the only operating room procedure is tracheostomy
- Where a procedure for tracheostomy occurs before the first operating room procedure (If day of procedure is not available in the input data file, the rate may be slightly lower than if the information was available).
- With missing gender, age, quarter, year, or principal diagnosis
- With a principal ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for acute respiratory failure (see above)
- With any listed ICD-10-CM diagnosis codes for:
  - Neuromuscular disorder
  - Degenerative neurological disorder
- With any listed ICD-10-PCS procedure codes:
  - That involve the face (when appropriate) and any-listed ICD-10-CM diagnosis codes for craniofacial anomalies
  - For laryngeal or pharyngeal, nose, mouth, or pharynx surgery
  - For esophageal resection
  - For lung cancer
- MDC 4 (diseases/disorders of respiratory system)
Metric recommendations

Direct Impact: All elective surgical patients

Lives Spared Harm:
\[ \text{Lives Spared Harm} = (\text{PSI #11 Rate}_{\text{baseline}} - \text{PSI #11 Rate}_{\text{measurement}}) \times \text{Elective Surgical Discharges}_{\text{baseline}} \]

Notes
For detailed information regarding specific diagnosis codes and DRGs for inclusion, please see AHRQ’s PSI #11 Specification document.

Data collection
Collect data through coding documentation.

Mortality (Patient Safety Movement Foundation will calculate):
The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patient’s grant funded Hospital Engagement Networks (HEN). The program targeted 10 hospital acquired conditions to reduce medical harm and costs of care. “At the outset of the PfP initiative, HHS agencies contributed their expertise to developing a measurement strategy by which to track national progress in patient safety—both in general and specifically related to the preventable HACs being addressed by the PfP. In conjunction with CMS’s overall leadership of the PfP, AHRQ has helped coordinate development and use of the national measurement strategy. The results using this national measurement strategy have been referred to as the “AHRQ National Scorecard,” which provides summary data on the national HAC rate (AHRQ, 2019).

Conflicts of interest disclosure
The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Some of the APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

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