



**Actionable Patient Safety Solution (APSS) #4:
FAILURE TO RESCUE: MONITORING FOR OPIOID INDUCED RESPIRATORY DEPRESSION**

Executive Summary Checklist

Opioid induced respiratory depression is a leading cause of totally preventable patient death.^{1,2,3} It also causes serious patient harm. Patients receiving opioids in the hospital have almost twice the incidence of cardiorespiratory arrest compared to other patients.⁴ Establishing an effective program to reduce opioid-induced respiratory depression will require full hospital administration support to complete the following actionable steps:

- Implement continuous electronic monitoring on all floors where patients are receiving opioid medications.
- Make continuous (not spot-check) monitoring of oxygenation the care standard. At a minimum, monitoring should include continuous measure through motion and low perfusion pulse oximetry (i.e. SET, until another technology is proven to be equivalent) with a central monitoring station with direct, immediate communication to the nurse on a mobile device.
- Monitor ventilation in patients receiving supplemental oxygen with either continuous capnography or acoustic respiration rate monitoring are technologies that can achieve this.
- Set appropriate respiratory rate (RR) alarms and apnea alarms to minimize alarm fatigue based on the patient population and individual risk of respiratory compromise. For example, RR between 6 and 30 breaths per minute, pulse rate (PR) between 40 and 100 for adults, PR between 70-120 for pediatric patients and a lower limit of 84% for SpO₂⁵)
- Institute a rapid response notification system, which will alert staff if the patient is deteriorating. A plan for escalation of rapid response alarm to another staff member should also be in place.
- Hospital governance should commit to a plan that includes:
 - Reviewing all reported patient deaths and serious patient harm events over the previous 24 months where opioids were involved and may have contributed to the event. A review of all previous closed malpractice claims related to opioid induced respiratory depression should also be undertaken.
 - Monitor and review all patients where naloxone was administered.
 - Identifying and prioritizing common contributing factors from those serious preventable events.
 - Identify and institute continuous electronic monitoring technologies that notify staff of significant changes in a patient's respiratory condition, and ensure appropriate interventions are initiated in a timely manner.
 - Providing the resources necessary to implement the action plan.
 - Identifying a hospital "champion" who will be accountable for successful implementation, education and evaluation of the chosen plan.
 - Developing an educational plan for all staff, patients and family members that shares common contributing factors leading to opioid induced respiratory depression.
 - Implementation of a plan that eliminates current risks associated with opioids.
 - Continuing to report and assess both near misses and patient harm events for additional learning opportunities and improvement.
- Develop a multimodal analgesic pain management program utilizing non-opioid adjuncts.

¹ Joint Commission. (2012). Sentinel Event Alert. Safe use of opioids in the hospital. Issue 49.

² Institute for Safe Medication Practices. (2007). ISMP 2007 survey on HIGH-ALERT medications. Retrieved from: <http://www.ismp.org/survey/Survey200702W.asp>

³ Weinger, M. B., & Lee, L. A. (2011). No patient shall be harmed by opioid-induced respiratory depression. APsF Newsletter, 26, 21-26.

⁴ Overdyk, F. J., Dowling, O., Marino, J., Qiu, J., Chien, H. L., Erslon, M., ... & Gan, T. J. (2016). Association of Opioids and Sedatives with Increased Risk of In-Hospital Cardiopulmonary Arrest from an Administrative Database. PloS one, 11(2), e0150214.

⁵ McGrath, S. P., Pyke, J., & Taenzer, A. H. (2016). Assessment of continuous acoustic respiratory rate monitoring as an addition to a pulse oximetry-based patient surveillance system. Journal of Clinical Monitoring and Computing, 1-9.

- Patients and caregivers should be educated to recognize potential side effects of opioids and sedatives, and notify caregivers immediately if they occur.

The Performance Gap

Complications are inevitable and they are not always avoidable or the result of errors. However, when a patient dies because of a complication that was not recognized in a timely manner or treated appropriately, that death is preventable and is called "Failure to Rescue." Technology and knowledge now exist to anticipate and head off a serious adverse event at a time that it is preventable by an intervention. The combination of training, technology, notification and computerized data analysis will allow early intervention before a patient reaches a critical life threatening status.

Monitors now exist to detect respiratory depression as well as sepsis, hemodynamic instability, bleeding, cardiac threats, and even the risk of patient fall at a time that an intervention can be made in time to avert a potential disaster. The development of early warning systems (EWS) has been well studied and validated in Europe and Australia.^{6,7,8,9} The technology to support EWS is now robust and can be instituted very easily into any institution. Even patients that have been discharged home can be monitored remotely.

In-hospital mortality after surgery is higher than anticipated and has multiple factors that can be systematically addressed.¹⁰ Healthcare leadership is largely unaware of significant improvement in technology that can detect a patient who is deteriorating and alert the caregivers prior to an adverse event occurring, such as postoperative respiratory depression.

After the Institute of Medicine described failure to rescue as a key issue in healthcare quality in 2001, failure to rescue was identified as a key area for improvement in patient safety.¹¹ 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 implemented systems that facilitate patient safety.¹² The following patient safety indicators accounted for 68% of all failure-to rescue patient safety events: death among surgical inpatients with serious treatable complications, pressure ulcer, postoperative respiratory failure, postoperative sepsis. The study further identified that the cost associated with postoperative respiratory failure alone in the U.S. Healthcare System is \$2 billion.

While opioid use is safe for most patients, opioid analgesics are associated with adverse effects and cause respiratory depression in significant number of post-surgical patients, who often receive them for pain

⁶ Alam, N., Hobbelink, E. L., Van Tienhoven, A. J., Van de Ven, P. M., Jansma, E. P., & Nanayakkara, P. W. B. (2014). The impact of the use of the Early Warning Score (EWS) on patient outcomes: A systematic review. *Resuscitation*, 85(5), 587-594.

⁷ Ludikhuijze, J., Smorenburg, S. M., de Rooij, S. E., & de Jonge, E. (2012). Identification of deteriorating patients on general wards; measurement of vital parameters and potential effectiveness of the Modified Early Warning Score. *Journal of Critical Care*, 27(4), 424-e7.

⁸ Fullerton, J. N., Price, C. L., Silvey, N. E., Brace, S. J., & Perkins, G. D. (2012). Is the Modified Early Warning Score (MEWS) superior to clinician judgement in detecting critical illness in the pre-hospital environment?. *Resuscitation*, 83(5), 557-562.

⁹ Smith, G. B., Prytherch, D. R., Meredith, P., Schmidt, P. E., & Featherstone, P. I. (2013). The ability of the National Early Warning Score (NEWS) to discriminate patients at risk of early cardiac arrest, unanticipated intensive care unit admission, and death. *Resuscitation*, 84(4), 465-470.

¹⁰ Pearse, R. M., Moreno, R. P., Bauer, P., Pelosi, P., Metnitz, P., Spies, C., ... & Rhodes, A. (2012). Mortality after surgery in Europe: A 7 day cohort study. *The Lancet*, 380(9847), 1059-1065.

¹¹ Institute of Medicine (US). Committee on Quality of Health Care in America. (2001). *Crossing the quality chasm: A new health system for the 21st century*. National Academy Press.

¹² Reed, K., May, R., Nicholas, C., Taylor, H., & Brown, A. (2011). *HealthGrades patient safety in American hospitals study*. US: HealthGrades.



management.^{13,14,15,16,17} Of opioid-related adverse drug events – including deaths – that occurred in hospitals and were reported to The Joint Commission’s Sentinel Event database (2004-2011), 47% were wrong dosing medication errors, 29% were related to improper monitoring of the patient, and 11% were related to other factors including excessive dosing, medication interactions, and adverse drug reactions.

Failure to Rescue postoperative respiratory depressions can be prevented through appropriate pain management and dosing approaches, surveillance to identify patients at risk for Failure to Rescue, notification to providers of significant changes in patient condition, and automated decision support to ensure appropriate therapies are initiated in a timely manner. A landmark study published in January 2010 by Dartmouth-Hitchcock Medical Center demonstrated that clinicians using Masimo SET® measure through motion and low perfusion pulse oximetry and Patient SafetyNet™ 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.¹⁸ 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 thoracovascular post-surgical units produced similar results to those seen in the original orthopedic unit.¹⁹ They also reported savings of \$58,459 saved per patient who was not transferred to the ICU in 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 2011, the Anesthesia Patient Safety Foundation recommended that all patients receiving parenteral narcotics be monitored continuously and a notification system be used to indicate to caregivers when alarming conditions occur.²⁰ In August 2012, the Joint Commission issued a sentinel event alert, urging all healthcare systems to introduce measures to improve safety for patient receiving opioids, including systematic protocols to assess pain and appropriate opioid dosing, as well as continuous monitoring of oxygenation and ventilation.²¹ In 2014 the Center for Medicare and Medicaid Services (CMS) clarified the surgical services CoP requirement for hospitals to have adequate provisions for immediate postoperative care, to emphasize the need for postoperative monitoring for patients receiving IV opioid medications, regardless of where they are in the hospital.²²

¹³ Vila Jr, H., Smith, R. A., Augustyniak, M. J., Nagi, P. A., Soto, R. G., Ross, T. W., ... & Miguel, R. V. (2005). The efficacy and safety of pain management before and after implementation of hospital-wide pain management standards: Is patient safety compromised by treatment based solely on numerical pain ratings?. *Anesthesia & Analgesia*, 101(2), 474-480.

¹⁴ Substance Abuse and Mental Health Services Administration. Substance abuse treatment admissions involving abuse of pain relievers: 1998 and 2008. Retrieved from: <http://oas.samhsa.gov/2k10/230/230PainRelvr2k10.cfm>

¹⁵ McPherson, M. L. (2008). Strategies for the management of opioid-induced adverse effects. *Advanced Studies in Pharmacy*, 5(2), 52-57.

¹⁶ Jarzyna, D., Jungquist, C. R., Pasero, C., Willens, J. S., Nisbet, A., Oakes, L., ... & Polomano, R. C. (2011). American Society for Pain Management Nursing guidelines on monitoring for opioid-induced sedation and respiratory depression. *Pain Management Nursing*, 12(3), 118-145.

¹⁷ Ferrell, B. R., Pasero, C., & McCaffery, M. (2010). *Pain assessment and pharmacologic management*. Elsevier Health Sciences.

¹⁸ Taenzer, A. H., Pyke, J. B., McGrath, S. P., & Blike, G. T. (2010). Impact of Pulse Oximetry Surveillance on Rescue Events and Intensive Care Unit Transfers: A Before-and-After Concurrence Study. *The Journal of the American Society of Anesthesiologists*, 112(2), 282-287.

¹⁹ Taenzer, A. H., Blike, G. T., McGrath, S., Pyke, J., Herrick, M., Renaud, C., & Morgan, J. (2012). Postoperative monitoring-the Dartmouth experience. *APSF Newsletter Spring-Summer*, 27(1), 1-28.

²⁰ Weinger, M. B., & Lee, L. A. (2011). No patient shall be harmed by opioid-induced respiratory depression. *APSF Newsletter*, 26, 21-26.

²¹ The Joint Commission. (2012, August 8). Safe use of opioids in hospitals. The Joint Commission Sentinel Event Alert (49). Retrieved from: https://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf

²² Centers for Medicare & Medicaid Services. (2014, March 14). Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-operative Care of Patients Receiving IV

In spite of the calls to address failure to rescue for postoperative respiratory depression, pain assessment and opioid dosing approaches are variable, and a high percentage of post-surgical patients on parenteral narcotics are not monitored continuously. 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. Closing the performance gap will require hospitals and healthcare systems to commit to action in the form of specific leadership, practice, and technology plans.

Leadership Plan

- The plan should include fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action.²³
- Hospital governance and senior administrative leadership must commit to become aware of this major performance gap in their own healthcare system.
- Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gap by implementing a comprehensive approach to addressing the performance gap.
- A goal date should be set to implement the plan to address the gap with measurable quality indicators.
 - “Some is not a number. Soon is not a time.”²⁴
- Specific budget allocations for the plan should be evaluated by governance boards and senior administrative leaders.
- Clinical/safety leadership should endorse the plan and drive implementation across all providers and systems.

Practice Plan

- Formally address opportunities to improve electronic detection of deteriorating patients and the early notification of the caregivers. This includes the prevention of adverse events due to respiratory depression from pain medications.
- Implement systematic protocols to assess pain management protocols and unify order sets where possible.
- Implement multi-modality pain strategies.²⁵
- Implement an effective system to accomplish continuous electronic monitoring and notification and escalation.
 - Continuous oxygenation and/or respiratory monitoring (not spot check monitoring) with pulse oximetry through an adhesive sensor. Pulse Oximetry with measure through motion and low perfusion technology is preferred.
 - Remote notification system that provides alarm notification to the care provider.
 - A system of alarm escalation if the primary nurse does not respond in a timely manner.
 - Set SpO2 alarms to reduce non-actionable alarms
 - Depending on the institution and patient populations within that institution, lower alarm limits may be set to be conscious of alarm fatigue. Each institution should set limits to fit their specific patient population.

Opioids. Retrieved from: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-15.pdf>

²³ National Quality Forum. (2010). Safe practices for better healthcare—2010 update. Retrieved from: http://www.qualityforum.org/publications/2010/04/safe_practices_for_better_healthcare_%E2%80%932010_update.aspx

²⁴ Institute for Healthcare Improvement. Overview of the 100,000 lives campaign. Retrieved from: <https://www.ihl.org/Engage/Initiatives/Completed/5MillionLivesCampaign/Documents/Overview%20of%20the%20100K%20Campaign.pdf>

²⁵ American Society of Anesthesiologists Task Force on Acute Pain Management. (2012). Practice guidelines for acute pain management in the perioperative setting: An updated report by the American Society of Anesthesiologists Task Force on Acute Pain Management. *Anesthesiology*, 116(2), 248.

- Continuous ventilation monitoring (e.g. capnography or respiratory acoustic rate monitoring) for reduced respiratory rate in patients on supplemental oxygen.
- Set respiration rate alarms to reduce non-actionable alarms
 - Depending on the institution and patient populations within that institution, lower alarm limits may be set to be conscious of alarm fatigue. Each institution should set limits to fit their specific patient population.
- Continuous electronic monitoring systems should integrate multiple physiologic parameters in the form of an index to identify clinically significant changes earlier and more reliably.
- Formalize transfer protocols from surgery and intensive care unit to postoperative general floor unit.
- Formalize workflows for patient admits and discharges from continuous monitoring.
- Rapid response team
 - Identify the opportunities for implementation of rapid response teams and protocol for initiating a rapid response call for postoperative respiratory depression.⁶
 - Since family members are often highly sensitive to changes in a patient's condition, it is advisable to allow families to ask the nurse to activate the rapid response system. Families should be educated regarding this option.²⁶
 - Consider proactive rounding on high-risk patients by resource nurses with critical care training.²⁷

Technology Plan

Suggested technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. Other technology options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

- Continuous pulse oximetry
 - 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, with added importance in care areas without minimal direct surveillance of patients (ie: Masimo SET® pulse oximetry, in a standalone bedside device or integrated in one of over 100 multi-parameter bedside monitors, until another technology is proven to be equivalent).^{13,28}
- 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 (e.g. Masimo rainbow® Acoustic Monitoring²⁹, EarlySense Contact Free Monitoring System, or sidestream end-tidal carbon dioxide monitoring such as Oridion®, Masimo® or Respironics®).
- Remote monitoring and notification system
 - Remote monitoring with direct clinician alert capability compatible with recommended pulse oximetry technology or other respiratory rate monitoring technologies (Masimo Patient

²⁶ Brady, P. W., Zix, J., Brilli, R., Wheeler, D. S., Griffith, K., Giaccone, M. J., ... & Tegtmeier, K. (2014). Developing and evaluating the success of a family activated medical emergency team: A quality improvement report. *BMJ Quality & Safety*, *bmjqs-2014*.

²⁷ Hueckel, R. M., Turi, J. L., Cheifetz, I. M., Mericle, J., Meliones, J. N., & Mistry, K. P. (2008). Beyond rapid response teams: Instituting a "Rover Team" improves the management of at-risk patients, facilitates proactive interventions, and improves outcomes.

²⁸ Shah, N., Ragaswamy, H. B., Govindugari, K., & Estanol, L. (2012). Performance of three new-generation pulse oximeters during motion and low perfusion in volunteers. *Journal of Clinical Anesthesia*, *24*(5), 385-391.

²⁹ Mimosz et al. Accuracy of Respiratory Rate Monitoring using a Non-Invasive Acoustic Method after General Anaesthesia. *Br J Anaesth*. 2012 May;108(5):872-5.



SafetyNet™, EarlySense Contact Free Monitoring System or comparable multi-parameter monitoring system).

- 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, a wired network can be used which allows surveillance of patients while they are in bed but not while they are ambulating.



Metrics

Topic:

Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) #11 Postoperative Respiratory Failure Rate

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-9-CM or ICD-10-CM diagnosis code for acute respiratory failure; or
- any-listed ICD-9-CM or ICD-10-PCS procedure codes for a mechanical ventilation for 96 consecutive hours or more that occurs zero or more days after the first major operating room procedure code (based on days from admission to procedure); or
- any-listed ICD-9-CM or ICD-10-PCS procedure codes for a mechanical ventilation for less than 96 consecutive hours (or undetermined) that occurs two or more days after the first major operating room procedure code (based on days from admission to procedure); or
- any-listed ICD-9-CM or ICD-10-PCS procedure codes for a reintubation that occurs one or more days after the first major operating room procedure code (based on days from admission to procedure)

Denominator: Elective surgical discharges, for patients ages 18 years and older, with any-listed ICD-9-CM or 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:

- with a principal ICD-9-CM or ICD-10-CM diagnosis code (or secondary diagnosis present on admission) for acute respiratory failure (see above)
- where the only operating room procedure is tracheostomy
- where a procedure for tracheostomy occurs before the first operating room procedure†
- with any-listed ICD-9-CM or ICD-10-CM diagnosis codes for neuromuscular disorder
- with any-listed ICD-9-CM or ICD-10-PCS procedure codes for laryngeal or pharyngeal, nose, mouth or pharynx surgery
- with any-listed ICD-9-CM or ICD-10-PCS [if appropriate] procedure codes involving the face and any-listed ICD-9-CM or ICD-10-CM diagnosis codes for craniofacial anomalies
- with any-listed ICD-9-CM or ICD-10-PCS procedure codes for esophageal resection
- with any-listed ICD-9-CM or ICD-10-PCS procedure codes for lung cancer
- any-listed ICD-9-CM or ICD-10-CM diagnosis codes for degenerative neurological disorder
- MDC 4 (diseases/disorders of respiratory system)
- MDC 5 (diseases/disorders of circulatory system)
- MDC 14 (pregnancy, childbirth, and puerperium)
- with missing gender, age, quarter, year, or principal diagnosis

† If day of procedure is not available in the input data file, the rate may be slightly lower than if the information was available.

* Rate is typically displayed as Patients/1000 Elective surgical discharges

Metric Recommendations:

Direct Impact:

All elective surgical patients

**Lives Spared Harm:**

$Lives = (PSI\ #11\ Rate_{baseline} - PSI\ #11\ Rate_{measurement}) \times Elective\ Surgical\ Discharges_{baseline}$

Notes:

For detailed information regarding specific diagnosis codes and DRGs for inclusion, please see [AHRQ's PSI #11 Specification document](#).

Data Collection:

Data is collected through coding documentation.

Mortality (will be calculated by the Patient Safety Movement Foundation):

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.³⁰

³⁰ Agency for Healthcare Research and Quality. (2015). Efforts to improve patient safety result in 1.3 million fewer patient harms. Retrieved from <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>



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Conflicts of Interest Disclosure:

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.