



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

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Executive Summary Checklist

Opioid induced respiratory depression is a leading cause of preventable patient death and serious patient harm events. Hospital leadership must understand, appreciate and commit to eliminating these events. Implementing an effective program to reduce opioid-induced respiratory depression will require an implementation plan to complete the following actionable steps:

- Implement continuous electronic monitoring on all floors where patients are being administered opioids and are in bed.
- Monitoring should consist of a minimum SET (Measure Through Motion and Low Perfusion) pulse oximetry with a central telemetry station; direct communication to the nurse on her "smart phone" is preferred.
- Patients receiving supplemental oxygen should also have ventilation monitored (e.g. capnography or acoustic rate monitoring).
- Set respiratory rate alarms to minimize alarm fatigue (e.g. 6 breaths per minute at the low end and 30 breaths per minute at the high end, with a 30 sec delay and a 15 sec notification delay.)
- A rapid response notification system should be in place to 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 preventable patient deaths and serious patient harm events over the previous 24 months where opioids were involved and may have contributed to the preventable event. A review of all previous closed malpractice claims related to opioid induced respiratory depression should also be undertaken.
 - Identifying and prioritizing common contributing factors from those serious preventable events.
 - Identifying continuous electronic monitoring technologies that notify staff of significant changes in a patient's respiratory condition which includes a rapid response approach that ensures appropriate interventions are initiated in a timely manner.
 - Providing the resources necessary to implement the chosen 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 as well as the implementation plan that strives to eliminate current risks associated with opioids.
 - Continuing to report and assess both near misses and patient harm events for additional learning opportunities and improvement.

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 a serious adverse event at a time that it is preventable by an intervention. The combination of training, technology 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.^{1,2,3,4} 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.⁵ Healthcare leadership is largely unaware of significant improvement in technology that can detect a patient who is deteriorating and alert the care givers prior to an adverse event occurring, such as post-operative 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.⁶ 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.⁷ 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, post-operative respiratory failure, post-operative sepsis. The study further identified that the cost associated with post-operative 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

¹ Alam, N., Hobbelenk, E.L., van Tienhoven, A.J. et al. The impact of the use of the Early Warning Score (EWS) on patient outcomes: a systematic review. *Resuscitation*. 2014;85:587–594.

² Ludikhuizen, J., Smorenburg, S.M., de Rooij, S.E., de, J.E. Identification of deteriorating patients on general wards; measurement of vital parameters and potential effectiveness of the Modified Early Warning Score. *J Crit Care*. 2012;27:424–513.

³ Fullerton JN., et al. Is the Modified Early Warning System (MEWS) superior to clinical judgement in detecting critical illness in the pre-hospital environment? *Resuscitation*. 2012;83(5):557-562.

⁴ Smith GB., et al. 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*. 2013;84:465-470.

⁵ Pearse RM et al. *Lancet* 2012; 380: 1059–65.

⁶ Committee on Quality of Health Care in America, Institute of Medicine, ed. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC, National Academy Press, 2001.

⁷ Reed and May, HealthGrades Patient Safety in American Hospitals Study, March 2011.

management.^{8,9,10,11,12} 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 post-operative 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.¹³ 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.¹⁴ 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.¹⁵ 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.¹⁶ 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,

⁸ Vila H Jr, Smith RA, Augustyniak MJ: 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 and Analgesia*, 2005;101:474-80.

⁹ Office of Applied Studies, Substance Abuse and Mental Health Services Administration. Substance abuse treatment admissions involving abuse of pain relievers: 1998 and 2008. Retrieved October 28, 2011 from <http://oas.samhsa.gov/2k10/230/230PainRelvr2k10.cfm>

¹⁰ McPherson ML: Strategies for the management of opioid-induced adverse effects. *Advanced Studies in Pharmacy*, 2008;5(2):52-57.

¹¹ Jarzyna D, et al: American Society for Pain Management Nursing guidelines on monitoring for opioid-induced sedation and respiratory depression. *Pain Management Nursing*, 2011;12(3): 118-145

¹² Pasero C, M McCaffery: Pain assessment and pharmacologic management. Chapter 12 – Key Concepts in Analgesic Therapy, and Chapter 19 – Management of opioid-induced adverse effects. St. Louis, Mosby Elsevier, 2011

¹³ Taenzer AH, Pyke JB, McGrath SP, et al. “Impact of Pulse Oximetry Surveillance on Rescue Events and Intensive Care Unit Transfers: A Before-and-After Concurrence Study.” *Anesthesiology*, February 2010, Vol. 112, Issue 2.

¹⁴ Taenzer A, Blike G, McGrath S, Pyke J, Herrick M, Renaud C, Morgan J. “Postoperative Monitoring – The Dartmouth Experience.” *Anesthesia Patient Safety Foundation Newsletter* Spring-Summer 2012.

¹⁵ Stoelting RK et al. APSF. 2011.

¹⁶ Joint Commission Sentinel Event Alert. Issue 49. August 8, 2012.

regardless of where they are in the hospital.¹⁷

In spite of the calls to address failure to rescue for post-operative 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 post-operative 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.¹⁸
- 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.”¹⁹
- 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 care givers. 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.
- Implement an effective system to accomplish continuous electronic monitoring and notification.
 - Continuous oxygenation monitoring (not spot check monitoring) with SET® measure through motion pulse oximetry through an adhesive sensor.
 - 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 at 80% with an alarm delay of 15 second (to reduce non-actionable alarms), plus a 15 second notification delay.

¹⁷ Centers for Medicare & Medicaid Services. Requirements for Hospital Medication Administration, Particularly Intravenous (IV) Medications and Post-operative Care of Patients Receiving IV Opioids. March 14, 2014. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-15.pdf>

¹⁸ NQF Safe Practices for Healthcare. 2010 Update.

¹⁹ Overview of the 100,000 Lives Campaign. Institute for Healthcare Improvement.

- Continuous ventilation monitoring for reduced respiratory rate for patients on supplemental oxygen.
- Set respiration rate alarms at 6 breaths per minute with a 30 second delay, plus a 15 second notification delay.
- 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 post-operative 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 post-operative respiratory depression.⁶
 - Since family members are often sensitive to changes in patients' condition, consider adding the option of family activation to the rapid response system.²⁰
 - Consider proactive rounding on high-risk patients by resource nurses with critical care training.²¹

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@patientsafetysummit.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).^{13,22}
- Continuous ventilation 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 Monitoring²³ or side-stream end-tidal carbon dioxide monitoring such as Oridion®, Masimo® or Respirationics®).
- Remote monitoring and notification system
 - Remote monitoring with direct clinician alert capability compatible with pulse oximetry technology compatible with recommended pulse oximetry technology (Masimo Patient SafetyNet™, or comparable multi-parameter monitoring system).

²⁰ Brady PW, Zix J, Brilli R, et al. Developing and evaluating the success of a family activated medical emergency team: a quality improvement report. *BMJ Qual Saf* 2015;24:203–211.

²¹ Hueckel R, Turi J, Kshitij M, et al. Beyond Rapid Response Teams: Instituting a “Rover Team” Improves the Management of At-Risk Patients, Facilitates Proactive Interventions, and Improves Outcomes. *Critical Care Medicine* 2006; 34(12):A54.

²² Shah N et al. *J Clinical Anaesthesia*. 2012.

²³ Mimos O et al. *BJA*. 2012.

- Direct clinician alert through dedicated paging systems or hospital 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:

$$\text{Lives} = (\text{PSI \#11 Rate}_{\text{baseline}} - \text{PSI \#11 Rate}_{\text{measurement}}) \times \text{Elective Surgical Discharges}_{\text{baseline}}$$

Notes:

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

Data Collection:

Data is collected through coding documentation.

Mortality:

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.²⁴

²⁴ Agency for Healthcare Research and Quality. Efforts to Improve Patient Safety Result in 1.3 Million Fewer Patient Harms: Interim Update on 2013 Annual Hospital-Acquired Condition Rate and Estimate of Cost Savings and Deaths Averted from 2010 to 2013. (Publication #15-0011-EF) Retrieved September 9, 2015 from <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html>.

Workgroup Members

Chair:

Michael Ramsay, MD, FRCA, President, Baylor Research Institute

Members:

Steven Barker, PhD, MD, Chief Science Officer, Masimo; Professor of Anesthesiology, University of Arizona

Jim Bialick, Immediate Past President, Patient Safety Movement Foundation

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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Paul Jansen	Initial Release	January 2013
Version 2	Michael Ramsay, Steven Barker, Thomas Corlett, Helen Haskell, Kelley Jaeger-Jackson, Pau Jansen, Maureen Leach, Ariana Longley, Tim O'Malley, Kenneth Rothfield, Joe Kiani	Workgroup Review	January 2016
Version 3	Michael Ramsay, David Mayer, Joe Kiani, Ariana Longley	Executive Review	April 2016