**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** N/A

**Measure Title**: Hospital Harm - Opioid-Related Adverse Events

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** N/A

**Date of Submission**: 4/2/2021

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Opioid-Related Adverse Event

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Click here to name what is being measured

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.**

The goal of the Opioid-Related Adverse Events electronic clinical quality measure (eCQM) is to improve safety for patients who receive opioids during their hospitalization. Patients who receive excessive doses of opioids (overdose) in the hospital experience confusion, altered consciousness, delirium, respiratory depression, anoxia, anoxic organ damage, and even death as a result.1-4 The reversal of opioid overdose using an antagonist like naloxone, while necessary to avoid severe effects, in itself causes patients to experience symptoms such as sudden and severe return of pain, nausea, vomiting, tachycardia, seizures, and even cardiac arrest.5 For these reasons, opioid-related adverse events resulting from opioids administered in the hospital by clinicians are outcomes that should be avoided. Most opioid-related adverse events are preventable with appropriate dosing, patient monitoring, and early response which allows clinicians to reduce opioid dosage before antagonist reversal is necessary.6

This eCQM captures the proportion of hospitalized patients aged 18 years and older who suffer the harm of an opioid-related adverse event, defined as receiving a narcotic antagonist (naloxone), with evidence of hospital administration of opioids prior to administration of naloxone. Naloxone administration has been used in studies of computerized adverse drug event surveillance as an indicator of severe opioid-related adverse events.7,8 By encouraging hospitals to implement evidence-based practices such as routine patient monitoring for potential adverse effects of opioids, this eCQM can lead to better quality of care associated with excessive opioid administration in the hospital setting.9,10

* Assess patients for opioid-induced respiratory depression risk factors, such as age, pulmonary disease, or sleep disordered breathing2,9
* Proper dosing of opioids and proper drug selection9
* Monitor patients for adequacy of ventilation (such as respiratory rate and depth of respiration), oxygenation, and level of consciousness9
* Frequent and continuous monitoring of patients receiving opioids as indicated by type of opiate2,9
* Fewer opioid-related adverse events
* Reduced need to administer naloxone to patients with respiratory depression and oversedation related to opioids

References:

1. Kessler ER, Shah M, Gruschkus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. *Pharmacotherapy.* 2013;33(4):383-391.
2. Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs. 2020 Feb;21(1):7-25. Epub 2019 Jul 31.
3. Ramachandran SK, Haider N, Saran KA, et al. Life-threatening critical respiratory events: a retrospective study of postoperative patients found unresponsive during analgesic therapy. *Journal of Clinical Anesthesia.* 2011;23(3):207-213.
4. Dahan A, Aarts L, Smith TW. Incidence, Reversal, and Prevention of Opioid-induced Respiratory Depression. *Anesthesiology*. 2010;112(1):226-238.
5. Wermeling DP. Review of naloxone safety for opioid overdose: practical considerations for new technology and expanded public access. *Ther Adv Drug Saf.* 2015;6(1):20-31.
6. Lee, L. A., Caplan, R. A., Stephens, L. S., Posner, K. L., Terman, G. W., Voepel-Lewis, T., & Domino, K. B. Postoperative opioid-induced respiratory depression: a closed claims analysis. *Anesthesiology*. 2015;122(3), 659-665.
7. Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S. E., & Coleman, J. J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. *Eur J Clin Pharmacol*. 2013;69(2), 255-259.
8. Eckstrand, J. A., Habib, A. S., Williamson, A., Horvath, M. M., Gattis, K. G., Cozart, H., & Ferranti, J. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. *Patient Saf Surg*. 2009;3(1), 18.
9. Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535-52. .
10. Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015;122(3):659-665.

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

Best practices to prevent opioid-related adverse events in hospitals have been a major focus by The Joint Commission (TJC), the Institute for Healthcare Improvement (IHI), and the Centers for Medicaid and Medicare Services (CMS).1-3 Of the opioid-related adverse drug events reported to the Joint Commission’s Sentinel Event database, 47% were due to a wrong medication dose, 29% to improper monitoring, and 11% to other causes (for example, medication interactions and drug reactions).6 Additionally, in a closed-claims analysis, 97% of adverse events were judged preventable with better monitoring and response.7 Clinical practice guidelines recommend better patient monitoring to improve the measure outcome and reduce the number of opioid-related adverse events.

While monitoring is key to the prevention of opioid-related adverse events, there is considerable variability in hospital monitoring practices. A 2013 study surveyed nurses from 90 institutions in the U.S. and found that pulse oximetry monitoring was more common than other monitoring methods for opioid-induced sedation and respiratory depression.8 Nonetheless, only about 58% reported using intermittent pulse oximetry and only 25% used continuous monitoring for patient controlled analgesia (PCA). End-tidal carbon dioxide (ETCO2) monitoring was only used for 2.2% of patients on epidural therapy and 1.5% for PCA patients.8 One hospital found a fivefold reduction in opioid-induced over sedation and respiratory depression cases after implementing targeted interventions such as enhanced monitoring for sedation, improved clinical decision support in the electronic medical record (EMR), and various adjustments to dosing for high-risk patients that included clinician education.9 Thus, there is room for improvement in monitoring hospitalized patients taking opioids to avoid unintended over sedation and possible opioid-related adverse events.

One study evaluated monitoring practices for patients receiving intravenous (IV) opioids via PCA and found that none of the patients monitored frequently (at least every 2.5 hours) received naloxone in the hospital.10 Thus, better patient monitoring and response is linked to reduced naloxone administration, signaling avoidance of opioid-related adverse events in the hospital.

References:

1. The Joint Commission. Joint Commission enhances pain assessment and management requirements for accredited hospitals. 2017;37 (7) 1-4.

https://www.jointcommission.org/-/media/tjc/documents/standards/jc-requirements/2018-requirements/joint\_commission\_enhances\_pain\_assessment\_and\_management\_requirements\_for\_accredited\_hospitals1.pdf?db=web&hash=1DFAA78F3C6EDD8AA2A1A152D18D4409

1. Institute for Healthcare Improvement. (2012). How to guide: Prevent harm from high alert medications. Cambridge, MA. <http://www.ihi.org/resources/Pages/Tools/HowtoGuidePreventHarmfromHighAlertMedications.aspx>
2. Centers for Medicare and Medicaid Services. (2014). Requirements for hospital medication administration, particularly intravenous (IV) medications and postoperative care of patients receiving IV opioids. Baltimore, MD. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-15.pdf>
3. Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs. 2020 Feb;21(1):7-25. Epub 2019 Jul 31.
4. Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535-52
5. The Joint Commission. Safe use of opioids in hospitals. Sentinel Event Alert. 2012(49):1-5.
6. Lee LA, Caplan RA, Stephens LS, et al. Postoperative opioid-induced respiratory depression: a closed claims analysis. *Anesthesiology*. 2015;122(3):659-665.
7. Willens JS, Jungquist CR, Cohen A, Polomano R. ASPMN survey--nurses' practice patterns related to monitoring and preventing respiratory depression. *Pain Management Nursing.* 2013;14(1):60-65.
8. Meisenberg B, Ness J, Rao S, Rhule J, Ley C. Implementation of solutions to reduce opioid-induced oversedation and respiratory depression. Am J Health Syst Pharm. 2017;74:162-169.
9. Jungquist CR, Correll DJ, Fleisher LA, et al. Avoiding Adverse Events Secondary to Opioid-Induced Respiratory Depression: Implications for Nurse Executives and Patient Safety. *Journal of Nursing Administration.* 2016;46(2):87-94.

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation** with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**