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

**Measure Number** (*if previously endorsed*): Previously endorsed as 2363e, now submitted as 3503e

**Measure Title**: Hospital Harm – Severe Hypoglycemia

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Not applicable

**Date of Submission**: 4/2/2019

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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: Severe Hypoglycemia

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 enter measure title

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 Severe Hypoglycemia Electronic Clinical Quality Measure (eCQM) is to improve patient safety and prevent severe hypoglycemia in patients who are at risk. The focus of this outcome measure is inpatient hypoglycemia. The purpose of measuring hypoglycemic events is to reduce the frequency of these adverse patient outcomes and to improve hospitals’ practices for appropriate dosing of medication and adequate monitoring of patients receiving glycemic control agents. Rates of inpatient hypoglycemic events can be reduced with high quality of care provided by a hospital.1,2 Severe hypoglycemic events are largely avoidable by careful use of antihyperglycemic medication, monitoring of patient blood glucose levels, enhanced use of technology, and implementation of evidence-based best practices.3,4,5,6,7,8

Several important benefits related to quality improvement are envisioned with the implementation of this measure. Specifically, the measure will help providers identify individuals who develop severe hypoglycemia in the hospital inpatient setting. Furthermore, this eCQM will encourage providers to develop interventions to improve glycemic control for hospital inpatients, before a patient becomes hypoglycemic. In addition to avoiding direct patient harm from the hypoglycemic event, lower rates of hypoglycemia among hospitalized individuals would be expected to result in shorter lengths of stay and lower mortality. Moreover, the rate of severe hypoglycemia varies across hospitals indicating an opportunity for improvement in care. Hypoglycemic rates have been reported from 2.3% to 5% of hospitalized patients,1,9 and from 0.4% of non-ICU patient days to 1.9% of ICU patient days.3

Hypoglycemic events are an adverse outcome that causes patients to experience a range of symptoms. The first signs of hypoglycemia include increased heart rate, sweating, uncontrollable trembling, confusion, anxiety, and irritability. As blood glucose levels further decrease, the severity of symptoms increase, resulting in drowsiness, weakness, loss of consciousness, seizure, and coma.8,10 Measuring this adverse event can improve hospitals’ practices and reduce the occurrence of hypoglycemic events.

* Lower rates of hypoglycemic events
* Fewer adverse drug symptoms such as dizziness, confusion, coma due to hypoglycemia
* Appropriate dosing of antihyperglycemic medications2
* Appropriate timing of medications in relation to meals2,4
* Appropriate frequency and timing of glucose monitoring2
* Awareness of comorbid conditions or medications that exacerbate hypoglycemia2,4
* Modification and monitoring protocols when dosing as indicated2

References:

1. Wexler DJ, Meigs JB, Cagliero E, Nathan DM, Grant RW. Prevalence of hyper- and hypoglycemia among inpatients with diabetes: a national survey of 44 U.S. hospitals. *Diabetes Care.* 2007;30(2):367-369.

2. American Diabetes Association. 14. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. *Diabetes Care.* 2018;41(Supplement 1):S144.

3. Cook CB, Kongable GL, Potter DJ, Abad VJ, Leija DE, Anderson M. Inpatient glucose control: a glycemic survey of 126 U.S. hospitals. *J Hosp Med.* 2009;4(9):E7-E14.

4. Moghissi ES, Korytkowski MT, DiNardo M, et al. American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control. *Diabetes Care.* 2009;32(6):1119-1131.

5. Office of the Inspector General (OIG), US Department of Health and Human Services. *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries.* 2010.

6. American Diabetes Association. Hypoglycemia (Low Blood Glucose). 2015; http://diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html. Accessed August 20, 2018.

7. Milligan PE, Bocox MC, Pratt E, Hoehner CM, Krettek JE, Dunagan WC. Multifaceted approach to reducing occurrence of severe hypoglycemia in a large healthcare system. *Am J Health Syst Pharm.* 2015;72(19):1631-1641.

8. Jeffrey Schnipper CL, Chima Ndumele, and Merri Pendergrass. Effects of a Computerized Order Set on the Inpatient Management of Hyperglycemia: A Cluster-Randomized Controlled Trial. *Endocrine Practice.* 2010;16(2):209-218.

9. Nirantharakumar K, Marshall T, Kennedy A, Narendran P, Hemming K, Coleman JJ. Hypoglycaemia is associated with increased length of stay and mortality in people with diabetes who are hospitalized. *Diabet Med.* 2012;29(12):e445-448.

10. Classen DC, Jaser L, Budnitz DS. Adverse drug events among hospitalized Medicare patients: epidemiology and national estimates from a new approach to surveillance. *Jt Comm J Qual Patient Saf.* 2010;36(1):12-21.

**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.**

Severe hypoglycemic events are largely avoidable by careful use of antihyperglycemic medications, monitoring of patient blood glucose levels, enhanced use of technology, and a hypoglycemia reduction bundle that includes creation of an internal hypoglycemia prevention task force to raise awareness of hypoglycemia risks and rates, with the development of data analytics.11,12,13 The Joint Commission and Johns Hopkins Hospital’s Glucose Steering Committee outlined policies for inpatient glucose management, revolving around educating staff on the importance of glycemic management, disseminating best practices, and evaluating intervention effectiveness by using process and outcome measures.14 The American Diabetes Association (ADA) guidelines call for frequent blood glucose monitoring to properly implement diabetes therapy.15

This Hospital harm – Severe Hypoglycemia eCQM provides a path to directly engage staff and hospital executives in the importance of glycemic measurement and will be a tool for quality improvement staff to assess internal metrics, along with providing CMS an instrument to assess the quality of care delivered to patients at risk for severe hypoglycemia across all acute care hospitals. Measuring hypoglycemic events in the hospital setting can help improve quality of care by identifying patients who develop hypoglycemia and incentivize hospitals to implement clinical workflows that facilitate evidence-based management to reduce the likelihood of severe hypoglycemic events.16 This eCQM has the potential to make care safer by reducing harm caused in the delivery of care, which is a National Quality Forum (NQF) healthcare priority.17

References:

11. Milligan PE, Bocox MC, Pratt E, Hoehner CM, Krettek JE, Dunagan WC. Multifaceted approach to reducing occurrence of severe hypoglycemia in a large healthcare system. *Am J Health Syst Pharm.* 2015;72(19):1631-1641.

12. Jeffrey Schnipper CL, Chima Ndumele, and Merri Pendergrass. Effects of a Computerized Order Set on the Inpatient Management of Hyperglycemia: A Cluster-Randomized Controlled Trial. *Endocrine Practice.* 2010;16(2):209-218.

13. Greg Maynard KK, Pedro Ramos, Diana Childers, Brian Clay, Meghan Sebasky, Ed Fink, Aaron Field, Marian Renvall, Patricia S. Juang, Charles Choe, Diane Pearson, Brittany Serences, and Suzanne Lohnes. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. *Endocrine Practice.* 2015;21(4):355-367.

14. Munoz M, Pronovost P, Dintzis J, et al. Implementing and Evaluating a Multicomponent Inpatient Diabetes Management Program: Putting Research into Practice. *The Joint Commission Journal on Quality and Patient Safety.* 2012;38(5):195-AP194.

15. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care. 2018; Supp 1: S1-S15. http://care.diabetesjournals.org/content/41/Supplement\_1.

16. Aloi JA, Mulla C, Ullal J, Lieb DC. Improvement in Inpatient Glycemic Care: Pathways to Quality. *Current Diabetes Reports.* 2015;15(4):18.

17. National Quality Forum. *Prioritization of High-Impact Medicare Conditions and Measure Gaps: Measure Prioritization Advisory Committee Report.* Washington, DC: NQF;2010.

**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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| **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.**