National Healthcare Safety Network (NHSN)
Medication Safety Component Manual

Introduction

Medications are among the top causes of adverse events in U.S. hospitals and are long-standing targets of quality improvement and patient safety efforts [1-5]. Surveillance of adverse drug events (ADEs) in inpatient settings has taken several forms over the years, but quantification of ADEs to inform rigorous, standardized national benchmarking and targeted prevention efforts remains challenging for several reasons; these include lack of consensus in ADE definitions, variability in data collection methods, and reliance on manual and voluntary reporting [5-8]. The NHSN Medication Safety Component (MSC) leverages NHSN's decades of experience in surveillance of patient-safety events along with emerging interoperability pathways to improve the approach to surveillance of ADEs in inpatient settings. The MSC incorporates modules that rely on Healthcare Level Seven International® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) to enable automated reporting of digital quality measures (dQMs) to support facility-level quality improvement and national benchmarking [9]. The MSC currently focuses on the following three medication-safety areas:

- Glycemic Control: Hyperglycemia and Medication-Related Hypoglycemia (in early adoption phase)
- Opioid-Related Adverse Events (ORAE) (under development)
- Hospital-Onset Acute Kidney Injury (HAKI) (under development)

The MSC includes these areas based on their clinical importance, amenability to prevention or quality improvement, feasibility of capture by automated data exchange, and alignment with the Centers for Medicare & Medicaid Services (CMS) quality-reporting mandates. As NHSN gains more experience with the MSC, we will identify new areas of focus that can be supported by digital quality measurement.

Settings and Patient Locations

All inpatient facilities enrolled in NHSN are eligible to enroll and participate in the MSC. Long-term care facilities (LTCFs) and outpatient dialysis facilities are not yet eligible to participate in the Medication Safety Component.

Facilities are required to map all facility locations in which surveillance is performed according to the guidance in the CDC Locations and Descriptions Manual. Facilities newly enrolled in NHSN must map locations according to the CDC Locations and Descriptions manual; for facilities already enrolled in NHSN, MSC uses the locations that have been mapped in other NHSN components.

Data for all inpatient areas that qualify for the NHSN MSC Module measure denominators, including procedural areas like operating rooms, will be analyzed. This is different than NHSN Facility-wide Inpatient (FacWideIN) in some NHSN modules that exclude procedural areas, such as the laboratory-Identified (LabID) event reporting for the Multidrug-Resistant Organism & Clostridioides difficile Infection module. Data from CMS-certified inpatient rehabilitation facilities (IRFs) units and from inpatient psychiatric facilities (IPFs) units that have a different

CMS Certification Number (CCN) than their acute-care facility are analyzed separately from the acute-care facility's data.

The primary measures in the MSC modules are intended to align with CMS electronic clinical quality measure (eCQM) specifications. Data from stays in emergency departments (ED) and observation units that end within one hour of the inpatient encounter are included in the denominator for Glycemic Control modules to align with CMS eCQM specifications. Data reported to the MSC do not currently fulfill any reporting requirement for CMS accountability programs; reporting to the MSC by acute care facilities is currently optional.

Data-Reporting Requirements

All participating inpatient facilities reporting data to the NHSN MSC module must be able to report data electronically in adherence to HL7 FHIR US Core FHIR R4.0.1 data standards and specifications and NHSN instructions for reporting dQMs [9-11]. Facility personnel responsible for reporting data to NHSN must coordinate with their information-systems providers to allow generation of standard formatted files that are imported into NHSN according to these standards and instructions. The MSC does not support manual data entry or Clinical Document Architecture (CDA) submission. NHSN performs FHIR queries on the 20th day of the calendar month; a monthly report reflects measures for the previous month.

Minimum Requirements for Reporting dQMs

1. All information required for facility enrollment in NHSN is on file, including mapping of facility locations according to the CDC Locations and Descriptions Manual.
2. A completed NHSN Medication Safety Component Annual Hospital Survey is on file.
3. FHIR files containing all data fields outlined in the CDC NHSN dQM Content Package Implementation Guide.
4. A completed Digital Measure Reporting Plan, which indicates the facility has committed to:
    a. Agreement the facility will permit access to data on the FHIR server for the required data elements.
    b. Conformance of the data transmitted by the facility to the NHSN Medication Safety Component protocol.
    c. Adherence to technical specifications for value sets, including mapping local or non-standardized codes in the facility EHR to established value sets (CDC NHSN dQM Content Package Implementation Guide). This includes mapping of any local codes used for medications to RxNorm and laboratory or point of care (POC) laboratory tests to LOINC (NHSN Glycemic Control Valueset Package), and location codes to CDC location codes (HSLOC). Facilities must work with their EHR vendors to download all the required value

sets for mapping local or non-standardized codes to established value sets (CDC NHSN dQM Content Package Implementation Guide).

5. An acceptable minimal month of data required for generating a monthly intra-facility analytic report, including all the following:
    a. Patient identifiers (patient medical record number and encounter number, patient date of birth, patient sex).
    b. FHIR "MedicationRequest" and "MedicationAdministration" resources results with medication identifiers, including date/time of request (order) and administration [12,13].
    c. For the Glycemic Control module, FHIR "Observation" resource results with blood glucose orders and results, including specimen collected date and time [14].

Measures are calculated only for submissions meeting the minimum requirements listed above.

Reporting medication exposure in the NHSN Medication Safety Component

Medication-administration data, which is data sourced directly from the electronic medication-administration record) is considered the gold standard and "source of truth" for medication exposure in inpatient settings. While medication orders (e.g., from a pharmacy, from a physician, or a standing order) provide additional sources of information on medications used in inpatient settings, they are suboptimal sources regarding medication exposure [15,16]. Medications can be ordered for patients but never administered; for example, medications often appear on standing orders that are never executed, and medication orders can be stopped or cancelled before being administered.

The NHSN Medication Safety Component requires data on medication **administration** for calculation of all metrics in the MSC modules (medication-related hypoglycemia, ORAE, and HAKI). To effectively participate in MSC, hospitals must work with their electronic health record (EHR) vendors to enable the "MedicationAdministration" FHIR resource for reporting to NHSN [13].

Definitions

Inpatient encounter – includes all encounters in inpatient or with inpatient location status. One (1) patient visit equals one (1) encounter.

Emergency department (ED)/Observation (Obs) encounter – Any patient visit to an ED or observation location. One (1) patient visit equals one (1) encounter. ED/Observation encounters are considered outpatient locations. The Glycemic Control module includes a metric (metric 1) that counts events in ED/Obs encounters that occur within 1 hour or less of an inpatient admission.

Patient-day – Any day during the measurement period during which a patient is cared for/housed in an inpatient location. A patient-day is counted as of the first day of each calendar month through the last day of the calendar month.

Glycemic Control, Hyperglycemia, and Medication-Related Hypoglycemia

Inpatient hypoglycemia can be severe and life-threatening and is associated with longer hospital stays and increased medical costs [17-21]. The prevalence of inpatient hypoglycemia varies with patient, hospital unit, timing of episodes, and glycemic threshold. Severe hypoglycemia (<40 mg/dL) occurs in 2%-5% of hospitalized patients with diabetes mellitus (DM) while hypoglycemia <70 mg/dL has been reported in up to 10% of all patients in the intensive care unit [22]. Patients with DM comprise more than 25% of all U.S. inpatient stays and medication-related hypoglycemia events are common causes of adverse drug events (ADEs) that occur in inpatient settings [1,23]. Rates of severe hypoglycemia events vary across hospitals, suggesting opportunities for improvement in glycemic-control quality of care [24, 25]. Inpatient hyperglycemia can increase morbidity, prolong hospital stays, and increase the risk of mortality [27-31]. The prevalence of inpatient hyperglycemia varies depending upon glycemic threshold and setting, but blood glucose >140 mg/dL likely occurs in approximately one-eighth to one-quarter of hospitalized patients [31-33]. Tracking patient blood-glucose levels and implementing appropriate interventions may reduce complications associated with both hyperglycemia and hypoglycemia [26,27-37].

The primary objective of the NHSN Glycemic Control module is to measure and benchmark medication-related hypoglycemia and hyperglycemia events within a facility. NHSN uses line-level data on medications and blood glucose reported by facilities to provide analytic reports to inform quality-improvement efforts for glycemic control and track patient safety events. As NHSN collects additional data, an additional objective will be to allow inter-facility benchmarking and evaluate national-level trends of medication-related hypoglycemia over time.

Glycemic Control Definitions

Blood glucose: Blood-glucose data refers to data from random, periprandial, or fasting tests; from capillary, serum, plasma, interstitial fluid, or whole-blood sources; using central laboratory device (CLD), point-of-care (POC) testing, or continuous glucose monitors (CGM). Blood glucose data from CGM devices can only be captured if data are integrated into laboratory sources, exposed in FHIR, and codified in HL7 standard terminology (NHSN Glycemic Control Valueset Package). Post-glucose administration tests are excluded. Events are based on the day/time the laboratory test was **collected** (drawn). Refer to the NHSN Glycemic Control Valueset Package for a complete list of blood glucose tests and corresponding value sets used in the NHSN Glycemic Control module uses. Reported data include the day and time that the laboratory test was **collected** (drawn). If day/time collected is not available, we use the day/time the lab was ordered. Blood glucose data from both central laboratory and prescription POC blood glucose

monitoring systems (BGMSs) are included (i.e., both CLD and POC sources of blood glucose data are used to identify events that meet numerator criteria).

Note*:* It is recognized that not all commercial BGMS used POC testing in hospitals conform to accuracy standards identified by the U.S. Food and Drug Administration (FDA) guidance regarding BGMSs' precision, linearity, user performance, inference, and other related aspects to system performance, including accuracy of glucose results relative to a CLD comparator method [38,39]. However, POC testing is considered the standard of care for recognizing and managing inpatient hypoglycemia episodes [39]. Additionally, the ability to distinguish between laboratory and POC testing in EHR data sources is limited owing to variability in how LOINCs are used to designate CLD versus POC specimen sources. For these reasons, the NHSN Glycemic Control module does not distinguish between CLD and POC data sources. Once an adequate number of representative hospitals have contributed data to the NHSN Glycemic Control module, we will re-evaluate the necessity for stratification of glycemic control Measures by testing source (CLD versus POC).

Hypoglycemic medication: All current or previously commercially available oral or injectable hypoglycemic medications in the United States. Refer to the NHSN Glycemic Control Valueset Package for a complete list of hypoglycemic medications and corresponding value sets used in the NHSN Glycemic Control module. This list will evolve as new agents become commercially available.

Hypoglycemic medication day: An inpatient day during which at least one injectable or oral hypoglycemic medication was administered. A hypoglycemic medication day is eligible to contribute to the metric denominator, regardless of whether the patient experienced a hypoglycemia event. Hospitalizations for partial days count towards the full hypoglycemic medication day.

Hypoglycemia day: An inpatient day (for patients of all ages) with at least one documented hypoglycemia event (mild, moderate, or severe).

> **Mild hypoglycemia event**: Blood glucose 54.0 mg/dL to 69.9 mg/dL as identified on CLD or prescription POC device with no subsequent repeat test for blood glucose with a result > 80 mg/dL within 5 minutes of the start of the initial low blood glucose test.

> **Moderate hypoglycemia event**: Blood glucose 40.0 mg/dL to 53.9 mg/dL as identified on CLD or prescription POC device with no subsequent repeat test for blood glucose with a result > 80 mg/dL within 5 minutes of the start of the initial low blood glucose test.

Severe hypoglycemia event: Blood glucose < 40.0 mg/dL as identified on CLD or prescription POC device with no subsequent repeat test for blood glucose with a result > 80 mg/dL within 5 minutes of the start of the initial low blood glucose test.

Hyperglycemia event: Blood glucose >180.0mg/dL as identified on CLD or prescription POC device.

Hyperglycemia day: An inpatient day (for patients of all ages) with at least one documented blood glucose >180.0 mg/dL as identified on CLD or prescription POC device. 33

Glycemic Control Measures

Tables 1 and 2 show the medication-related hypoglycemia and hyperglycemia measures that will be reported monthly in the NHSN Glycemic Control module. For Metric 1, only the first qualifying severe hypoglycemia event is counted in the numerator and only one severe hypoglycemia event is counted per encounter. A single patient may contribute to more than one encounter if admitted more than one time during the measurement period. Emergency department (ED) and observation (Obs) encounters are included only if they ended within one hour of an inpatient hospitalization.

Table 1: Description of Hypoglycemia Measures Reported in the NHSN Glycemic Control Module

	Numerator	Denominator
Metric 1, Hypoglycemia Events Aligned with eCQM CMS816v4, Hospital Harm – Severe Hypoglycemia (40)	Number of adult (≥ 18 years of age) inpatient and ED/Obs encounters (hospitalizations) that include (all the following criteria must be met):[i] 1. A severe hypoglycemia event during the encounter AND 2. Hypoglycemic medication administered during the encounter and within 24 hour prior to the start of the severe hypoglycemia event,[ii] AND 3. No subsequent repeat test for blood glucose with a result > 80 mg/dL within 5 minutes of the start of the initial low blood glucose test. [ii]	Number of adult (≥ 18 years of age) inpatient encounters (hospitalizations) where at least one hypoglycemic medication was administered during the encounter. The measure includes instances of administration of hypoglycemic medication in the ED or in observation status that end within one hour of the inpatient encounter.

	Numerator	Denominator
Metric 2, Hypoglycemia Days[iii]	Number of hypoglycemia days per month for patients of all ages	Number of hypoglycemic medication days per month for patients of all ages
Metric 3, Recurrent Hypoglycemia Days[iv]	Number of recurrent hypoglycemia days per month for patients of all ages	Number of hypoglycemic medication days per month for patients of all ages

[i]ED/Obs stays are counted when the transition between the ED encounter, observation encounter, and the inpatient encounter are within an hour or less of each other.

[ii]The 24-hour and 5-minute timeframes are based on the time the blood glucose was collected (drawn) as this reflects the time the patient was experiencing that specific blood glucose level. The 24-hour timeframe extends from the end of the medication administration to the time of the glucose test. The five-minute timeframe extends from the start of the severe hypoglycemic test to the time of the repeat hypoglycemic test.

[iii]A "Hypoglycemia day" is categorized as "severe", "moderate" or "mild" as per the Definitions above and assigned in hierarchical fashion based on the lowest BG value. For example, a hypoglycemia day during which a patient experienced a severe and moderate hypoglycemia event, the "hypoglycemia day" would be considered "severe" for the purpose of metric calculation by threshold." Metrics 2 will be evaluated at the following BG thresholds: <40 mg/dL, 40-53 mg/dL, and 54-69 mg/dL.

[iv]A "recurrent hypoglycemia day" is a hypoglycemic medication day (for patients of all ages) with at least one documented hypoglycemia event that is preceded by another inpatient day with a hypoglycemia event (defined by a 24-hour period in between). Metric 3 will be evaluated at the following BG thresholds: <40 mg/dL, 40-53 mg/dL, and 54-69 mg/dL. The metric will be qualified by the BG level of the *first* event during the *original* day.

Description of Metric 4, Severe Hypoglycemia Resolution

Severe Hypoglycemia Resolution is the median time between a hypoglycemia event <40.0 mg/dL and the first BG ≥70.0 mg/dL thereafter (for patients of all ages).

Table 2: Description of Hyperglycemia Measures Reported in the NHSN Glycemic Control Module

	Numerator	Denominator
Metric 5, Hospital Harm, Severe Hyperglycemia Aligned with eCQM CMS871v4 Hospital Harm – Severe Hyperglycemia (41)	Number of adult (≥ 18 years of age) inpatient encounters (hospitalizations) with:[i] (1) a day with at least one BG >300.0 mg/dL, or (2) a day on which BG test and results are not found, and immediately preceded by two contiguous, consecutive calendar days on which at least one BG value was ≥200.0 mg/dL	Number of adult (≥ 18 years of age) inpatient encounters (hospitalizations) with:[ii] (1) a diagnosis of DM that starts before the end of the encounter, or (2) at least one administration of insulin or any hypoglycemic medication that starts during the encounter, or (3) at least one BG value ≥200 mg/dL at any time during the encounter
Metric 5b, Percent Hospital Harm, Severe Hyperglycemia-Modified	Number of adult (≥ 18 years of age) inpatient encounters[i] (hospitalizations) with a day with at least one BG >300.0 mg/dL	Number of inpatient encounters (hospitalizations)[ii]
Metric 6, Percent Hyperglycemia Days	Number of patient-days with hyperglycemia (>180.0 mg/dL, >200.0 mg/dL, >300.0 mg/dL, and >400.0 mg/dL)	Number of patient-days

[i]Numerator exclusions: Inpatient hospitalizations for patients with a glucose result of >=1000 mg/dL anytime between 1 hour prior to the start of the encounter to 6 hours after the start of the encounter; patients who have comfort care measures ordered or provided during the encounter; patients who have a discharge disposition to home or to a health care facility for hospice care.

[ii]Denominator exclusions: Inpatient hospitalizations for patients with a glucose result of >=1000 mg/dL anytime between 1 hour prior to the start of the encounter to 6 hours after the start of the encounter; patients who have comfort care measures ordered or provided during the encounter; patients who have a discharge disposition to home or to a health care facility for hospice care.

Glycemic Control Intra-facility Analytic Reports

Based on a monthly transmission of FHIR data, NHSN reports metrics for all qualifying NHSN-defined inpatient locations from which the numerator and denominator data can be accurately captured. This allows a facility to optimize intra-facility comparisons among specific wards, combined wards, and facility-wide data. Table 3 summarizes the analytic reports for each month for the NHSN Glycemic Control module.

Table 3: Proposed Analytic Reports for the NHSN Glycemic Control Module

Metric	Analytic Report	Calculations[i]
Metric 1, Hospital Harm - Severe Hypoglycemia[ii]	• Rate table (summary statistic) • Line listing of qualifying events	$\frac{\text{Number of qualifying encounters with severe hypoglycemia}}{\text{Number of qualifying encounters with } \geq 1 \text{ hypoglycemic medications administered per month}} \times 100$
Metric 2, Hypoglycemia Days[ii]	• Rate table (summary statistic) • Line listing of qualifying events	$\frac{\text{Number of qualifying hypoglycemia encounter days per month}}{\text{Number of hypoglycemic medication days per month}} \times 100$
Metric 3, Recurrent Hypoglycemia Days[iii]	• Rate table (summary statistic) • Line listing of qualifying events	$\frac{\text{Number of recurrent hypoglycemia days per month}}{\text{Number of hypoglycemic medication days per month}} \times 100$
Metric 4, Severe Hypoglycemia Resolution	• Table of median and range, in minutes (summary statistic)	$\text{Median (Time of BG} \geq 70.0 \text{ mg/dL immediately following BG result} < 40.0 \text{ mg/dL)} - \text{(Time of hypoglycemia event BG} < 40.0 \text{ mg/dL)}$
Metric 5, Hospital Harm - Severe Hyperglycemia[iv]	• Rate Table (summary statistic) • Line Listing of qualifying events	$\frac{\text{Number of encounters with severe hyperglycemia event}}{\text{Number of qualifying encounters}} \times 100$
Metric 5b Percent Hospital Harm Severe Hyperglycemia Modified	• Rate Table (summary statistic) • Line Listing of qualifying events.	$\frac{\text{Number of encounters with severe hyperglycemia event}}{\text{Number of inpatient encounters}} \times 100$
Metric 6, Percent Hyperglycemia Days[v]	• Rate Table (summary statistic) • Line Listing of qualifying events	$\frac{\text{Number of patient days per month with BG at defined threshold}}{\text{Number of patient days per month}} \times 100$

[i] Hypoglycemia event refers to mild, moderate, or severe hypoglycemia events preceded by administration or order of hypoglycemic medication within 24 hours prior to the start of the event and no subsequent repeat test for blood glucose with a result > 80 mg/dL within five minutes of the start of the initial low blood glucose test. See Table 2 for numerator and denominator definitions.

[ii] Metric 1 and 2 rates will be stratified by a) hypoglycemic medication class, including separate aggregate measures for inpatients receiving metformin as the only hypoglycemic medication; b) patient age group, sex, race, ethnicity; c) patient location as per HSLOC associated with the low blood glucose event; and d) discharge disposition (e.g., discharged, transferred, died). Metric 2 will be analyzed at the following BG thresholds: <40.0 mg/dL, 40.0-53.9 mg/dL, and 54.0-69.9 mg/dL.

[iii] Metric 3 rate will be stratified by patient location as per the HSLOC associated with the low blood glucose event. Metric 3 will be qualified by the BG level of the first event during the original day and analyzed at the following BG thresholds: <40.0 mg/dL, 40.0-53.9 mg/dL, and 54.0-69.9 mg/dL.

[iv] Metric 5 defines severe hyperglycemic event as meeting either of the numerator criteria (criterion 1 or criterion 2) provided in Table 2.

[v] Metric 6 rate will be analyzed at the following BG thresholds: >180.0 mg/dL, >200.0 mg/dL, >300.0 mg/dL, and >400.0 mg/dL.

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