Partnership for Quality Measurement
Powered by Battelle

WHAT GOOD LOOKS LIKE – OUTCOME MEASURE EXAMPLE

Note: *The information provided in this form is intended to aid the committee and other interested parties in understanding to what degree the items in the measure submission form addresses each of the five PQM Measure Evaluation Rubric domains.*

This document is based on a submission provided by Centers for Medicare & Medicaid Services (measure steward) and American Institutes for Research (former measure developer). The measure is maintained by Mathematica (current measure developer).

Intent to Submit

Endorsement and Maintenance (E&M) Cycle*

Select the intended measure review cycle for endorsement consideration.

Spring 2024	**Fall 2024**	**Spring 2025**
ITS deadline: Monday, April 1, 2024 Full Submission deadline: Wednesday, May 1, 2024	ITS deadline: Tuesday, October 1, 2024 Full Submission deadline: Friday, November 1, 2024	ITS deadline: Tuesday, April 1, 2025 Full Submission deadline: Thursday, May 1, 2025
☒ Spring 2024	☐ Fall 2024	☐ Spring 2025

Measure Information

1.1 New or Maintenance*

Select whether this is a new measure or maintenance measure. If this is a maintenance measure, provide the consensus-based entity (CBE) ID number as "0123" or "0123e" for an eCQM. Measures seeking initial endorsement will be assigned a CBE ID after ITS.

☒ New ☐ Maintenance

[If a maintenance measure] **1.1a Provide CBE ID***

Start by typing CBE ID or measure title and select an autocomplete option.

4120e

1.2 Measure Title*

The measure title should include the type of score (e.g., rate, count, composite), the measure focus, and the target population. Title example: The rate [type of score] of 30-day all-cause mortality [measure focus] among patients discharged from an acute inpatient

Reminder

If the measure has a short name or abbreviation often included in the title (e.g., at the end in parentheses), please include in the submission.

facility with a diagnosis of acute myocardial infarction [target population].

Hospital Harm – Falls with Injury

1.3 Measure Description*

Briefly describe the type of score, measure focus, target population, and timeframe. Note: There are separate fields below for the numerator and denominator.

This ratio measure assesses the number of inpatient hospitalizations where at least one fall with a major or moderate injury occurs among the total qualifying inpatient hospital days for patients aged 18 years and older.

Quick Tip

Include the type of score in the measure description.

Quick Tip

Include the target population in the description. Here, the developer describes the population as adults that experience at least one fall with a major or moderate injury during their hospital stay.

1.4 Project*

Choose the project that you expect to review the measure. To see the project descriptions and examples of project-related measures, please refer to the E&M projects page on the PQM website. Note: Battelle may reassign the measure to a different project following internal review. Choose one.

- ☐ Advanced Illness and Post-Acute Care
- ☐ Cost and Efficiency
- ☐ Initial Recognition and Management
- ☒ Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health
- ☐ Primary Prevention

Quick Tip

Review the five project descriptions to determine which committee may be the best fit for your measure topic.

This measure aligns best with the Management of Acute Events. Chronic Disease, Surgery, and Behavioral Health as it focuses on a patient safety event.

1.5 Measure Type*

Choose one. If "Other," please specify.

- ☐ Cost/Resource use
- ☐ Efficiency
- ☐ Intermediate Outcome
- ☒ Outcome
- ☐ Population Health
- ☐ Process
- ☐ Patient-reported Outcome Performance Measure (PRO-PM)
- ☐ Structure
- ☐ Other (**1.5a** *Please specify**)

1.6 Composite Measure*

Is this a composite measure?

☒ No ☐ Yes

1.7 Electronic Clinical Quality Measure (eCQM)*

Is this measure an eCQM (i.e., based on the Quality Improvement Core [QI-Core], the Quality Data Model [QDM], Clinical Quality Language [CQL], and specified using value sets)? Includes hybrid measures.

☐ No ☒ Yes

Reminder

A hybrid measure is a quality measure that uses more than one source of data for measure calculation. Current hybrid measures use claims data and electronic clinical data from electronic health records to calculate measure results.

1.8 Level of Analysis*

Select the level(s) of analysis for which the measure is specified and tested. Choose all that apply. If "Population of Geographic Area" or "Other," please specify.

☐ Accountable Care Organization
☐ Clinician: Group/Practice
☐ Clinician: Individual
☒ Facility
☐ Health Plan
☐ Population or Geographic Area (**1.8a** *Specify Population or Geographic Area Level of Analysis**)

Reminder

Measures with multiple levels of analysis have the same CBE ID. The level(s) of analysis should be consistent across the specifications and testing items within the application.

1.9 Care Setting*

Select the care setting(s) for which the measure is specified and tested. Choose all that apply. If "No Applicable Care Setting" or "Other Care Setting," please explain.

☐ Ambulatory Care: Clinic
☐ Ambulatory Care: Clinician Office
☐ Ambulatory Care: Office
☐ Ambulatory Surgery Center
☐ Behavioral Health: Inpatient (e.g., Inpatient Psychiatric Facility)
☐ Behavioral Health: Outpatient
☐ Birthing Center
☐ Clinician Office/Clinic
☐ Emergency Department
☐ Emergency Medical Services/Ambulance
☐ Home Health
☐ Hospice
☐ Hospital: Acute Care Facility
☐ Hospital: Critical Access
☒ Hospital: Inpatient
☐ Hospital: Outpatient
☐ Imaging Facility
☐ Inpatient Rehabilitation Facility
☐ Long-Term Acute Care Facility
☐ Nursing Home/Skilled Nursing Facility
☐ Outpatient Rehabilitation
☐ Pharmacy

☐ Urgent Care: Ambulatory
☐ No Applicable Care Setting (**1.9a** *Please explain**)

☐ Other Care Setting (**1.9b** *Please specify**)

*[**Note:** Responses to items 1.10-1.13 and other measure specification details are to be provided in the Full Measure Submission.]*

1.14 Numerator*

Provide the numerator (i.e., the measure focus). Do not include the measure rationale.

Inpatient hospitalizations where the patient has a fall that results in moderate or major injury. The diagnosis of a fall and of a moderate or major injury must not be present on admission.

Quick Tip

Clearly state the measure focus and relevant timeframes. The measure focus is a fall that occurred during the inpatient hospitalization and resulted in a major or moderate injury.

1.15 Denominator*

Provide the denominator (i.e., the target population).

Inpatient hospitalizations for patients aged 18 and older with a length of stay less than or equal to 120 days that ends during the measurement period.

Quick Tip

Include relevant timeframes, as applicable. Here, the developer notes that a patient's length of stay in the hospital must be 120 days or less to be in the target population.

1.15d Age Group*

Select the age group(s) that are reflected in your measure's target population (choose all that apply). Choose an age group only if the entire range is included in your measure's target population. If only part of one or more listed age ranges applies, select "Other" and enter the correct age range (e.g., 14-50).

☐ Children (0-17 years)
☒ Adults (18-64 years)
☒ Older Adults (65 years and older)
☐ Other (1.15e Provide age range in years*)

Quick Tip

Remember to select all age ranges that apply to the measure population. Here, the developer selected both Adults (18-64 years) and Older Adults (65 years and older) as the measure population is all adults 18 years and older.

6.1 Use

6.1.1. Current Status*

Is this new or maintenance measure currently in use?

☐ No ☒ Yes

Quick Tip

There should be a plan for use in at least one accountability application after initial endorsement but before the measure's first maintenance review.

6.1.2 *[If initial endorsement]* Current or Planned Use(s)*

Choose all that apply.

☒ Public Reporting
☐ Public Health/Disease Surveillance

☒ Payment Program
☐ Regulatory and Accreditation Programs
☐ Professional Certification or Recognition Program
☒ Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
☐ Quality Improvement (Internal to the specific organization)
☐ Other

6.1.2a Please specify other use*

6.1.4 *[If Current Status = Yes (6.1.1)]* **Program Details***

Please provide the following information describing the program(s) in which the measure is currently used:

Name of the program and sponsor

CMS Hospital Inpatient Quality Reporting Program

URL of the program

https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/inpatient-reporting-program

Purpose of the program

The Hospital Inpatient Quality Reporting (IQR) Program is a pay-for-reporting program for acute care hospitals. Under this program, CMS requires subsection (d) hospitals to submit data on quality measures to CMS each year. Subsection (d) hospitals are acute care hospitals that are paid under the Inpatient Prospective Payment System (IPPS).

Geographic area and percentage of accountable entities and patients included

The CMS IQR Program includes acute care hospitals across the United States. These hospitals are required to submit data on quality measures to CMS annually. The program covers a wide geographic area, encompassing hospitals in various states and regions.

Regarding the percentage of accountable entities and patients included, the program primarily involves subsection (d) hospitals, which are paid under the IPPS. This excludes certain types of hospitals like children's, inpatient psychiatric, long-term care, rehabilitation hospitals, and the 11 Prospective Payment System-Exempt cancer hospitals (CMS, Hospital Inpatient Quality Reporting Program).

Reference:

Hospital Inpatient Quality Reporting Program | CMS. https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/inpatient-reporting-program.

Applicable level of analysis and care setting

Level of Analysis: Hospital

Care Setting: Hospital: Inpatient

Name of the program and sponsor

Medicare Promoting Interoperability Program

URL of the program

https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs

Purpose of the program

The Medicare Promoting Interoperability Program is a pay-for-reporting program. Eligible hospitals and critical access hospitals (CAHs) are required to report on measures from each of the program's four scored objectives: electronic prescribing, health information exchange, provider-to-patient exchange, and public health and clinical data exchange. Participants are also required to report (yes/no) on the Protect Patient Health Information objective: Security Risk Analysis measure and Safety Assurance Factors for EHR Resilience (SAFER) Guides measure. Beginning in calendar year 2024, participants will be required to attest "Yes" to having completed the SAFER Guides measure. Selecting "no" or not completing the requirement will result in automatic failure. There is also a required attestation: Actions to Limit or Restrict Interoperability of CEHRT Attestation.

Eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program must score a minimum of the total required points as specified by CMS to satisfy the scoring requirement and successfully attest. Eligible hospitals or CAHs scoring below the required minimum points will not be considered meaningful EHR users and could be subject to a downward payment adjustment.

Geographic area and percentage of accountable entities and patients included

The Medicare Promoting Interoperability Program is open to eligible hospitals and CAHs that receive federal funds from Medicare across the United States. These hospitals are required to submit data on quality measures to CMS annually. The program covers a wide geographic area, encompassing hospitals in various states and regions.

Reference:

Promoting Interoperability Programs | CMS. https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs

Applicable level of analysis and care setting

Level of Analysis: Hospital

Care Setting: Hospital: Inpatient

Attestations: Preparing for Full Measure Submission for Endorsement Consideration

Check the boxes to attest this information will be available and submitted to Battelle by the Full Measure Submission (FMS) deadline of the intended review cycle. The measure may be insufficient for endorsement review if this information is not available by the FMS deadline. Please review the PQM E&M Rubric [Endorsement and Maintenance (E&M) Guidebook] for full measure submission evaluation criteria.

Reminder

If there are questions about what is required for your measure for endorsement review, please reach out to PQMSupport@battelle.org prior to the Full Measure Submission deadline.

☒ **A.1 Detailed Measure Specifications***
I will provide detailed measure specifications, including how to calculate the measure, data dictionaries, and code sets.

☒ **A.2 Logic Model***
I will provide a logic model and evidence that support the link between structures/processes/intermediate outcomes and the desired outcome.

☒ **A.3 Impact and Gap***

- For initial endorsement, I will provide a description of the measure's anticipated impact on important outcomes supported by the scientific literature and other sources (e.g., functional improvement, disease prevented, or adverse events or costs avoided).
- For maintenance endorsement, I will supply evidence of a continued performance or measurement gap by providing performance scores on the measure as specified (current and over time) at the specified level of analysis.

☒ **A.4 Feasibility Assessment Methodology and Results** *
I will provide feasibility assessment methodology and results. I will show how the assessment considered the people, tools, tasks, and technologies necessary to implement the measure, and if submitting an eCQM, I will provide the completed feasibility scorecard.

Quick Tip

As this measure is an eCQM, a completed Feasibility Scorecard is required for Full Measure Submission. The feasibility scorecard must include testing within EHR systems from at least two EHR vendors.

A.5 Measure Testing (reliability and validity)
Check the boxes to attest to which testing (person/encounter-level or accountable entity-level) for reliability and validity will be available and submitted for each level of analysis by the FMS deadline of the intended review cycle. ***Note:*** *For initial endorsement, you must provide a rationale if empirical person or encounter-level will not be presented in the FMS. For maintenance endorsement, you must provide a rationale if measured/accountable entity testing will not be presented in the FMS.*

A.5a Empirical Person or Encounter Level[1] *
Will empirical person- or encounter-level evidence, testing, methodology, and results be presented for this endorsement?

☐ No ☒ Yes

Quick Tip

For initial endorsement, person- or encounter-level empirical testing is required or existing evidence (e.g., prior research, literature) must be presented to support testing of all critical data elements (numerator, denominator, exclusions).

A.5b Empirical Accountable Entity Level *
Will empirical accountable entity-level evidence, testing, methodology, and results be presented for this endorsement?

☐ No ☒ Yes

Quick Tip

Accountable entity-level empirical testing is required for maintenance measures, but can be submitted for measures undergoing initial endorsement review if the information is available.

[1] For patient- or encounter-level testing, prior evidence of reliability and validity of data elements for the data type specified in the measure (e.g., hospital claims) can be used as evidence for those data elements. Prior evidence could include published or unpublished testing that: includes the same data elements, uses the same data type (e.g., claims, chart abstraction), and is conducted on a sample as described above (i.e., representative, adequate numbers, and randomly selected, if possible).

☒ **A.6 Address Health Equity (optional)**
I will describe how this measure contributes to efforts to address inequities in health care. This is an optional criterion for FMS.

Reminder

Equity will be a required domain beginning with the Spring 2025 cycle.

☒ **A.7 Measure's Use or Intended Use** *
I will provide the measure's use or intended use and actions measured entities must take to improve performance on this measure. For a maintenance measure, I will provide a summary of any progress improvement.

A.8 Risk Adjustment or Stratification *

Choose the correct option to attest to whether the measure is risk-adjusted and/or stratified, and to attest that each component of the respective information will be available and submitted by the FMS deadline of the intended review cycle, as applicable.

☐ No, neither risk-adjusted nor stratified

☒ Yes, risk-adjusted only

☒ **Conceptual model for risk adjustment**

I will present the conceptual model for risk adjustment, including supporting evidence from literature, internal analyses, and/or expert panels, AND

☒ **Risk-adjustment approach**

I will present the risk adjustment approach, including the methodology, specifications, results, and interpretation of results

☐ Yes, stratified only

☐ **All information required to stratify the measure results**

I will present all information required to stratify the measure results, including the stratification variables, definitions, specific data collection items/responses, and code/value sets

☐ Yes, both risk-adjusted and stratified

☐ **Conceptual model for risk adjustment**

I will present the conceptual model for risk adjustment, including supporting evidence from literature, internal analyses, and/or expert panels, AND

☐ **Risk-adjustment approach**

I will present the risk-adjustment approach, including the methodology, specifications, results and interpretation of results, AND

☐ **All information required to stratify the measure results**

I will present all information required to stratify the measure results, including the stratification variables, definitions, specific data collection items/responses, and code/value sets, and the risk-model covariates and coefficients for the adjusted version of the measure

A.9 Quality Measure Developer and Steward Agreement (QMDSA) Form *

The QMDSA and Additional and Maintenance Measures Forms are contractual agreements that must be signed by Battelle Memorial Institute (Battelle) and any measure steward that is submitting one or more measures to be evaluated for endorsement via the consensus endorsement process. If the measure is not owned by a government entity, the measure steward will also complete and submit a QMDSA Form. For more information about QMDSA requirements, please see the QMDSA Submission Instructions. Choose one.

Reminder

If the measure is stewarded by a non-government entity, prioritize having the QMDSA Form completed as soon as possible by submitting the QMDSA to Battelle prior to or by the Intent to Submit deadline.

☐ I already submitted a QMDSA Form to Battelle.

Provide the date submitted

☐ I would like to submit the QMDSA Form now.

Attach form; One file only; 256 MB limit; Allowed types: PDF.

☒ The measure is owned by a government entity; therefore, the QMSDA Form is not applicable at this time.

Quick Tip

As the measure steward is the Centers for Medicare & Medicaid Services (a government entity), a QMDSA Form is not applicable.

A.10 Additional and Maintenance Measures Form*

Choose one. Note: Measure stewards with current measures endorsed by Battelle who wish to add additional measures to their current QMDSA will need to complete this form.

☐ I have submitted or will submit an Additional and Maintenance Measures Form

☒ The Additional and Maintenance Measures Form is not applicable at this time.

☒ **A.11 508 Compliance***

I will ensure that the measure information that will be submitted at FMS, including all attachments, will be prepared in accordance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194).

Reminder

Appendix E in the E&M Guidebook includes guidance for making submissions 508 compliant.

Measure Points of Contact Information

The user account completing this form is the Measure Developer Point of Contact (POC)

☒ Do you have a secondary **measure developer** point of contact?
Secondary POC email: sampleuser@domain.com
Secondary POC phone number: 555-123-4567
Country: United States
First Name: Jane
Last Name: Doe
Organization: Battelle
Street Address: 505 King Avenue
City, State, ZIP: Columbus, Ohio 43201

☒ The measure developer is NOT the same as **measure steward**
Steward organization URL: https://www.cms.gov/
Steward POC email: sampleuser@domain.com
Steward POC phone number: 555-123-4567
Steward organization: Centers for Medicare & Medicaid Services
Country: United States
First Name: Jane
Last Name: Doe
Street Address: 7500 Security Boulevard
City, State, ZIP Windsor Mill, Maryland 21244
Steward Organization Copyright: Not Applicable

Reminder

At any point when a point of contact changes, please inform Battelle by contacting PQMsupport@battelle.org so our can update this information in the system.

Full Measure Submission

Section 1. Measure Specifications

[NOTE: Items 1.1-1.9, 1.14, and 1.15 were entered in the ITS, and can be edited in the FMS]

1.10 Measure Rationale *

Provide a rationale for why measured entities should report this measure, including how the measure will improve the quality of care for patients and/or any associated health care costs, and what are the benefits or improvements in quality envisioned by use of this measure.

Inpatient falls are among the most common incidents reported in hospitals and can increase length of stay and patient costs. Due to the potential for serious harm associated with patient falls, “patient death or serious injury associated with a fall while being cared for in a health care setting” is considered a Serious Reportable Event by the National Quality Forum (NQF).

Quick Tip

The rationale should explain the benefits or improvements in quality envisioned by the measure, including any associated health care costs or savings.

Inpatient falls are noted as a common event that can increase length of stay and patient costs. This measure aims to raise hospitals’ awareness of their fall rates, improve hospitals’ practices for monitoring patients at high risk for falls with injury and, improve patient safety by preventing falls with injury in hospitalized patients.

Falls (including unplanned or unintended descents to the floor) can result in patient injury ranging from minor abrasion or bruising to death as a result of injuries sustained from a fall. While major injuries (e.g., fractures, closed head injuries, internal bleeding) (Mintz, 2022) have the biggest impact on patient outcomes, 2008-2021 data findings from The 2022 Network of Patient Safety Databases (NPSD) demonstrated that 41.8 % of falls resulted in moderate injuries such as skin tear, avulsion, hematoma, significant bruising, dislocations, and lacerations requiring suturing. Moderate injury is, as defined by NDNQI, that resulted in suturing, application of steri-strips or skin glue, splinting, or muscle/joint strain (Press Ganey, 2020). NPSD findings also demonstrated that mild to moderate level of harm represent 24.2.%, 0.4% - severe harm, and 0.1% - death (levels of harm definitions developed by WHO, 2009).

By focusing on falls with major and moderate injuries, the goal of this hospital harm eCQM is to raise awareness of fall rates and, ultimately, to improve patient safety by preventing falls with injury in all hospital patients. The purpose of measuring the rate of falls with major and moderate injury events is to improve hospitals' practices for monitoring patients at high risk for falls with injury and, in so doing, to reduce the frequency of patient falls with injury.

References:

National Quality Forum. Serious Reportable Events. http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx. Accessed July 24, 2019

Mintz, J., Duprey, M. S., Zullo, A. R., Lee, Y., Kiel, D. P., Daiello, L. A., Rodriguez, K. E., Venkatesh, A. K., & Berry, S. D. (2022). Identification of Fall-Related Injuries in Nursing Home Residents Using Administrative Claims Data. The journals of gerontology. Series A, Biological sciences and medical sciences, 77(7), 1421–1429. https://doi.org/10.1093/gerona/glab274

Network of Patient Safety Databases Chartbook, 2022. Rockville, MD: Agency for Healthcare Research and Quality; September 2022. AHRQ Pub. No. 22-0051

WHO. (2009). Conceptual Framework for the International Classification for Patient Safety, Version 1.1. https://apps.who.int/iris/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf

Quick Tip

Provide supportive empirical evidence to shed light on the quality care gap.

1.11 Measure Webpage *

Provide a URL to a webpage, specific for this measure, containing current detailed specifications, including code lists, risk model details, and supplemental materials. Do not enter a URL to a home page or to general information. The webpage must be publicly accessible. If no URL is available, copy and paste this example: http://example.com.

Hospital Harm – Falls with Injury | eCQI Resource Center (healthit.gov)

Quick Tip

URLs should go directly to the measure specification. Here, the developer includes a link to the measure specification posted on the eCQI Resource Center.

1.13 Attach Data Dictionary

Attach a data dictionary, code table, and/or value sets (include variables in the final risk model or stratification plan, if applicable). Attachment should include variables used in the final risk model and/or stratification, if applicable.

One file only; 256 MB limit; Allowed file type: .xls; .xlsx; .csv (please clearly label sheets).

Falls with Injury Value Set Directory 11 01 2023.zip

Reminder

If a data dictionary is not attached, submitters are asked to attest that all information will be provided in relevant fields (e.g., 1.14a-1.15b) where code and/or value sets are needed.

1.14a Numerator Details *

Provide details needed to calculate the numerator. All information required to identify and calculate the cases from the target population (denominator) with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets. If your list of codes with descriptors is greater than will fit in this text box, you must attach an Excel or csv file in the previous question. If the numerator includes a list (or lists) of individual codes with descriptors that exceeds one page, please provide this information in an xls; .xlsx; .csv file as part of the data dictionary attachment.

The numerator is inpatient hospitalizations where the patient has a fall that results in moderate or major injury. The diagnosis of a fall and of a moderate or major injury must not be present on admission.

Examples of moderate injuries include lacerations, open wounds, dislocations, sprains, and muscle strains. Examples of major injuries include fractures, closed head injuries, and internal bleeding.

The time period for data collection is during an inpatient hospitalization, which are defined as beginning at hospital arrival including time in the emergency department or observation when the transition between these encounters (if they exist) and the inpatient encounter are within an hour or less of each other.

All data elements necessary to calculate this numerator are defined within value sets available in the Value Set Authority Center (VSAC) and listed below:
Fall diagnoses are represented by the value set Inpatient Falls (2.16.840.1.113762.1.4.1147.171)
Moderate injury diagnoses are represented by the value set Moderate Injuries (2.16.840.1.113762.1.4.1248.205)
Major injury diagnoses are represented by the value set Major Injuries (2.16.840.1.113762.1.4.1147.120)
The not present on admission indicators are represented by the value set Not Present on Admission or Documentation Insufficient to Determine (2.16.840.1.113762.1.4.1147.198)

Quick Tip

The numerator is the primary focus of the measure. Clearly describe details that are needed in order to calculate the numerator, including definitions and relevant time periods for data collection.

The developer clearly states the measure focus and provides illustrative examples of moderate and major injuries and defines the associated time periods for data collection during an inpatient hospitalization.

Quick Tip

Provide a list of codes required to calculate the numerator. The developer provides the OIDs for value sets necessary to calculate the numerator. The user can access the list of codes within the value sets by visiting the VSAC at https://vsac.nlm.nih.gov/.

To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

The measure observation associated with the numerator is the total number of inpatient hospitalizations where a fall with moderate or major injury occurred, across all eligible encounters.

1.15a Denominator Details *

Provide details needed to calculate the denominator. All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets. If the list(s) of individual codes with descriptors exceeds one page, please provide this information in an Excel or .csv file as part of the data dictionary attachment.

This measure includes all inpatient hospitalizations with a length of stay less than or equal to 120 days ending during the measurement period for patients aged 18 years and older at the time of admission, and all payers. The time period for data collection is inpatient hospitalizations, which are defined as beginning at hospital arrival and including time in the emergency department and observation when the transition between these encounters (if they exist) and the inpatient encounter are within an hour or less of each other.

Measurement period is one year. This measure is at the hospital-by-admission encounter level.

All data elements necessary to calculate this denominator are defined within value sets available in the Value Set Authority Center (VSAC) and listed below:

Inpatient encounters are represented using the value set of Encounter Inpatient (2.16.840.1.113883.3.666.5.307)
Emergency department visits are represented using the value set of Emergency Department Visit (2.16.840.1.113883.3.117.1.7.1.292)
Observation encounters are represented using the value set of Observation Services (2.16.840.1.113762.1.4.1111.143)

To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

The measure observation associated with the denominator is the total number of eligible days across all encounters which match the initial population/denominator criteria.

Quick Tip

The denominator represents the target population for the measure (patients 18 years or older who had an inpatient hospitalization of 120 days or less).

Quick Tip

Provide definitions where necessary. The submission outlines the criteria for an inpatient hospitalization, clarifying the start time (arrival at the hospital) and any additional time to consider (such as time spent in the emergency department or under observation)

Quick Tip

Clearly state the time period for data collection in the denominator. Here, the developer explains that the measurement period is 1 year.

Quick Tip

Provide a list of codes required to calculate the denominator. The developer provides the OIDs for value sets necessary to calculate the denominator. The user can access the list of codes within the value sets by visiting the VSAC at https://vsac.nlm.nih.gov/.

1.15b Denominator Exclusions *

Briefly describe exclusions from the denominator cases, if any. Enter "None" if the measure does not have denominator exclusions.

Inpatient hospitalizations where the patient has a fall diagnosis present on admission.

1.15c Denominator Exclusions Details *

Provide details needed to calculate denominator exclusions. Enter "None" if the measure does not have denominator exclusions. All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets. If the list(s) of codes with descriptors exceeds one page, please provide this information in an Excel or .csv file as part of the data dictionary attachment.

The denominator exclusion is inpatient hospitalizations where the patient has a fall diagnosis present on admission.

The time period for data collection is during an inpatient hospitalization, which is defined as beginning at hospital arrival including time in the emergency department or observation when the transition between these encounters (if they exist) and the inpatient encounter are within an hour or less of each other.

All data elements necessary to calculate this numerator are defined within value sets available in the Value Set Authority Center (VSAC) and listed below:

Fall diagnoses are represented by the value set Inpatient Falls (2.16.840.1.113762.1.4.1147.171)
The present on admission indicators are represented by the value set Present on Admission or Clinically Undetermined (2.16.840.1.113762.1.4.1147.197)

To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at https://vsac.nlm.nih.gov/.

1.16 Type of Score *

Select the most relevant type of score.

☐ Categorical, e.g., yes/no
☐ Continuous variable, e.g., average
☐ Count
☐ Rate/proportion
☐ Composite scale
☒ Other scoring method

1.16a Describe other scoring method *

Ratio

1.17 [If Measure Type (1.5) IS NOT "Cost/Resource Use"] **Measure Score Interpretation** *

Select the appropriate interpretation of the measure score

☐ Better quality = Higher score
☒ Better quality = Lower score
☐ Better quality = Score within a defined interval
☐ Passing score defines better quality

☐ Other

1.17a Describe Other measure score interpretation *

1.18 Calculation of Measure Score *

Diagram or describe the calculation of the measure score as an ordered sequence of steps. Identify the denominator, denominator exclusions (if any), numerator, time period of data collection, risk adjustment and/or stratification, and any other calculations.

The developer provided a Measure Calculation Diagram: Falls with Injury_Measure Calculation Diagram 11 01 2023.pdf

Quick Tip

The measure calculation diagram clearly describes the calculation of the measure score as an ordered sequence of steps using "Yes/No" decision points.

1.19 Measure Stratification Details*

Provide all information required to stratify the measure results, if necessary. Include the stratification variables, definitions, code/value sets, and, if appropriate, the risk-model covariates and coefficients for the clinically adjusted version of the measure. If the list(s) of codes with descriptors exceeds one page, please provide this information in an Excel or .csv file as part of the data dictionary attachment. If the measure is not stratified, please state, "The measure is not stratified." If the information is included within the data dictionary attachment, please state, "See data dictionary attachment."

The measure is not stratified.

1.20 Testing Data Sources*

Select the data sources for which you have tested and specified the measure. Choose all that apply.

☐ Administrative Data
☐ Claims Data
☒ Electronic Health Records
☐ Paper Patient Medical Records
☐ Registries
☐ Standardized Patient Assessments
☐ Patient-Reported Data and/or Survey Data *[Answer questions 1.21-1.24]*
☐ Non-Medical Data
☐ Other Data Source

1.20a Specify other data source*

1.25 Data Sources*

Identify the specific data source(s) other than or in addition to any patient-reported data and/or survey data collection instrument(s) indicated for the measure. For example, provide the name of the database, clinical registry, etc. and describe how the data are

collected. Please discuss any data feasibility, reliability, and/or validity challenges and how they have been mitigated.

Hospitals collect EHR data using certified electronic health record technology (CEHRT). The MAT output, which includes the human readable and XML artifacts of the clinical quality language (CQL) for the measure are contained in the eCQM specifications attached. No additional tools are used for data collection for eCQMs.

Quick Tip

The developer identifies one data source (electronic health record data), which aligns with the selection in question 1.20 (Testing Data Sources).

As an eCQM, the data are electronically extracted from the electronic health record and require no additional tools for data collection.

1.26 Minimum Sample Size*

Indicate whether the measure has a minimum sample size to calculate the performance score and provide any instructions needed for obtaining the sample and guidance on minimal sample size.

The measure does not include a minimum sample size to calculate the measure.

Section 2. Importance

2.1 Attach Logic Model *

Attach a logic model depicting the relationship between structures and processes and the desired outcome. Briefly describe the steps between the health care structures and processes (e.g., interventions, or services) and the desired health outcome(s). Identify the relationships among the inputs and resources available to create and deliver an intervention, the activities the intervention offers, and the expected results (i.e., desired outcome). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process, or outcome being measured.

One file only; 256 MB limit; Allowed file types: .pdf; .doc; .docx.

Inpatient falls are among the most common incidents reported in hospitals and can increase length of stay and patient costs. Due to the potential for serious harm associated with patient falls, “patient death or serious injury associated with a fall while being cared for in a health care setting” is considered a Serious Reportable Event by the National Quality Forum (NQF, 2019). Certain protocols and prevention measures to reduce patient falls with injury include using fall risk assessment tools to gauge individual patient risk, implementing fall prevention protocols directed at individual patient risk factors, and implementing environmental rounds to assess and correct environmental fall hazards. Recommended clinical guidelines and practices to reduce falls and injuries from falls in hospitals support many prevention activities including implementing multifactorial interventions (see Tables 11-27 in the clinical practice guidelines section of this document) and tailoring interventions to individual patient’s conditions and needs (WFG, 2022, RNAO, 2017; ACS NSQIP/AGS, 2016; NICE, 2013). The scientific evidence and effectiveness on how certain falls prevention protocols impact falls with injury outcomes, however, is limited (Dykes et al., 2010; Gu et al., 2016). The intent and desired outcome for this eCQM is to work with existing falls prevention processes to track falls and aim to reduce rates of inpatient falls resulting in major and moderate injuries. This eCQM logic model is adopted from The World Falls Guidelines (WFG) Task Force, World guidelines for falls prevention and management for older adults: a global initiative. Age and Ageing, 51(9), 1–36. https://doi.org/10.1093/ageing/afac205

Figure 1: Falls Logic Model

Inputs (resources)	Activities (what the program does)	Outputs (direct results of the activities)	Outcomes	Impact (broad, systemic changes influenced by the quality program)
EHR Hospital staff (nurses, doctors, and others who care for the patient and input data into the EHR) Staff training (on both prevention activities and how to properly record falls/ injuries in EHR) Falls risk assessment tools and prevention protocols Clinical practice guidelines for falls prevention and management (NICE, RNAO, ACS NSQIP/AGS, WFG Task Force)	Multifactorial falls risk assessment and stratification Implementing practices to reduce falls and injuries from falls (e.g., environmental rounds to assess and correct environmental fall hazards) Personalized single or multidomain falls prevention strategies (i.e., patient education, fall-prevention protocols based on best practice guidelines, medications review, adaptation of the environment)	Data showing how many falls with major or moderate injuries occurred during hospital stay Increased monitoring of patients at risk for falls Reduced falls resulting in major or moderate injury during hospitalization	<u>Short-term</u> Increased awareness of fall rates, improvements in hospital practices for monitoring patients at high risk for falls <u>Intermediate term</u> Lower rates of falls-associated injuries, improved patient quality of life (reduced pain and discomfort, reduced immobility and its consequences, such as deep vein thrombosis and pressure injuries) <u>Long-term</u> Improvements in patient safety by preventing falls with injury in all hospital patients	Improved patient safety and patient confidence: safer environment for all patients and increased patient satisfaction Health care costs/ resources: Reducing the incidence of falls with major/moderate injury can decrease the need for additional treatments and prolonged hospital stays, lowering health care-associated costs Resource allocation: Implementing this measure may lead hospitals to allocate resources more effectively, such as investing in better safety equipment or more staff training programs, which can optimize hospital operations and patient care services
Feedback Mechanisms				
Hospitals that submit eCQM data for this measure to the CMS Hospital Inpatient Quality Program will receive annual performance results.				
Assumptions (underlying beliefs about the quality program and context)				
Falls Prevention: Monitoring patients at high risk for falls with injury and implementing best practices for prevention in high-risk patients can prevent falls with injury in hospitalized patients. **Resource Availability:** Hospitals have or can obtain the resources (e.g., staff, training) needed to address falls prevention effectively. **Measurement Drives Improvement:** There is an assumption that by measuring and reporting on fall rates, hospitals will be motivated to implement changes and improvements to reduce these incidents. This is based on the belief that what gets measured gets managed and improved. **Adherence to Latest Guidelines and Patient Compliance:** Health care providers follow the latest evidence-based guidelines in fall prevention and patients comply with provider instructions.				
External Factors (conditions outside the quality program's control)				
Regulations: Changes in regulations, compliance requirements, and government policies. **Technological Advancement:** Emerging technologies can both create new opportunities to streamline processes and pose challenges.				

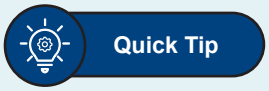
2.2 Evidence of Measure Importance*

Summarize evidence of the measure's importance from the literature, linking the structure/process/intermediate outcome to the desired health outcome. Please provide references for supporting evidence.

This eCQM captures the number of patients who experience harm in the form of major and moderate injuries during their inpatient hospitalization. Inpatient falls are among the most common incidents reported in hospitals and can increase length of stay and patient costs. Falls (including unplanned or unintended descents to the floor) can result in patient injury ranging from minor abrasion or bruising to death.

Despite reductions in rates of inpatient falls with injury in recent years, these events remain common in the United States. It has been estimated that there are 700,000-1,000,000 inpatient falls in the U.S. annually, with more than one-third resulting in injury and up to 11,000 resulting in patient death (AHRQ, 2019; Currie, 2008). Moreover, there are medical units with persistently low and persistently high fall rates, suggesting that disparities in care exist among hospitals (Staggs et al., 2015). One study of 800 medical units in 470 hospitals found that 87 percent of the variation in 24-month fall rates was due to between-unit differences, and with the exception of patient days, low- and high-fall units did not differ on nurse staffing or any other unit or hospital characteristic variable (Staggs et al., 2015). This finding suggests that there remains room for improvement in units with high fall rates.

While major injuries (e.g., fractures, closed head injuries, internal bleeding) (Mintz et al., 2022) have the biggest impact on patient outcomes, data from the Network of Patient Safety Databases (NPSD) between 2014 and 2022 showed that in-hospital falls more frequently result in moderate injuries, as defined by National Database of Nursing Quality Indicators (2010). These injuries, including skin tears, avulsions, hematomas, significant bruising, dislocations, and lacerations requiring suturing, affected 35.9%, 45.2%, 49.8%, and 51% of adults (18-64 years), mature adults (65-74 years), older adults (75-84 years), and aged adults (85+years) who fell, respectively. The residual harm to the patient, after discovery of the fall and after any attempts to minimize adverse consequences, also increased with age. For example, 38.7% of adults who fell in the hospital experienced residual harm compared to 56.8% of older adults and 61% of aged adults. Levels of harm can be categorized following WHO definitions (2009); the NPSD Chartbook reported that 24.2% of falls were followed by mild to moderate levels of harm, 0.4% by severe harms, and 0.1% by death. By focusing on falls with major and moderate injuries, the goal of this hospital harm eCQM is to raise awareness of fall rates and, ultimately, to improve patient safety by preventing falls with injury in all hospital patients.



The developer presents a thorough literature review, citing relevant studies related to the need for and benefits of appropriate care in the context of falls during hospitalization.

In addition, relevant clinical practice guidelines from the National Institute for Health and Care Excellence (NICE), Registered Nurses' Association of Ontario (RNAO), American College of Surgeons National Surgical Quality Improvement Program / American Geriatrics Society (ACS NSQIP/AGS), World Falls Guidelines (WFG) Task Force, including the strength of the recommendation and level of the evidence, are included on pages 9-24 in the attachment, Hospital Harm – Falls with Injury_Logic Model and Tables_11 01 2023.pdf

Quick Tip

When including clinical practice guidelines, also include any context around the strength of the recommendation, quality of evidence, and applicable grading scale.

References:

AHRQ. (2019). Patient Safety Primer: Falls. Retrieved July 24, 2019, from AHRQ PSNet website: https://psnet.ahrq.gov/primers/primer/40/Falls

Currie, L. (2008). Fall and Injury Prevention. In E. Hughes RG (Ed.), Patient Safety and Quality: An Evidence-Based Handbook for Nurses (pp. 195–250). Rockville: Agency for Healthcare Research and Quality.

National Database of Nursing Quality Indicators. (2010). Guidelines for data collection on the American Nurses Association's National Quality Forum endorsed measures. Kansas City: University of Kansas Medical Center.

Mintz, J., Duprey, M. S., Zullo, A. R., Lee, Y., Kiel, D. P., Daiello, L. A., Rodriguez, K. E., Venkatesh, A. K., & Berry, S. D. (2022). Identification of Fall-Related Injuries in Nursing Home Residents Using Administrative Claims Data. The journals of gerontology. Series A, Biological sciences and medical sciences, 77(7), 1421–1429.

Network of Patient Safety Databases Chartbook, 2022. Rockville, MD: Agency for Healthcare Research and Quality; September 2022. AHRQ Pub. No. 22-0051. https://www.ahrq.gov/sites/default/files/wysiwyg/npsd/data/npsd-chartbook-2022.pdf

Network of Patient Safety Databases Chartbook, 2023. Rockville, MD: Agency for Healthcare Research and Quality; September 2023. AHRQ Pub. No. 23-0090. https://www.ahrq.gov/sites/default/files/wysiwyg/npsd/data/npsd-falls-chartbook-2023.pdf

Network of Patient Safety Databases Chartbook, 2023. Rockville, MD: Agency for Healthcare Research and Quality; September 2023. AHRQ Pub. No. 23-0082 https://www.ahrq.gov/sites/default/files/wysiwyg/npsd/data/npsd-chartbook-2023.pdf

Staggs, V. S., Mion, L. C., & Shorr, R. I. (2015). Consistent differences in medical unit fall rates: Implications for research and practice. Journal of the American Geriatrics Society, 63(5), 983–987. https://doi.org/10.1111/jgs.13387

World Health Organization & WHO Patient Safety. (2010) Conceptual framework for the international classification for patient safety version 1.1: final technical report January 2009. World Health Organization. https://apps.who.int/iris/handle/10665/70882

2.3 *[If initial endorsement]* **Anticipated Impact***

If implemented, what is the measure's anticipated impact on the desired outcomes, such as those listed in the logic model? Please cite evidence to identify adverse events and costs avoided and provide references. Describe how the benefits of the measure's impact will outweigh any potential unintended consequences.

This eCQM captures the number of patients who experience harm in the form of major and moderate injuries during their inpatient hospitalization. Inpatient falls are among the most common incidents reported in hospitals and can increase length of stay and patient costs. Falls (including unplanned or unintended descents to the floor) can result in patient injury ranging from minor abrasion or bruising to death.

Falls can result in additional health care costs due to increased length of stay and use of additional resources, such as diagnostic imaging. Falls with injury also result in higher patient costs in the inpatient setting. The estimated additional patient costs associated with inpatient falls are $2,680-$15,491 per inpatient stay (Bysshe, 2017). A multi-site prospective cohort study demonstrated that "patients who had an in-hospital fall had a mean increase in LOS of 8 days (95% CI, 5.8-10.4; P < 0.001) compared with non-fallers and incurred mean additional hospital costs of $6,669 (95% CI, $3,888-$9,450; P < 0.001). Patients with a fall-related injury had a mean increase in LOS of 4 days (95% CI, 1.8-6.6; P = 0.001) compared with those who fell without injury" (Morello, 2015).

A multi-center study conducted in two US health care systems by Dykes, et al, 2023, demonstrated that "the average total cost of a fall was $62, 521 ($36,776 direct costs), and the average total cost of a fall with any injury was $64,526." The implementation of evidence-based falls prevention program, Fall TIPS Program (Tailoring Interventions for Patient Safety), was associated with $22 million in savings at study sites across the 5-year study period or $14,600 in net avoided costs per 1000 patient-days.

By focusing on falls with major and moderate injuries, the goal of this hospital harm eCQM is to improve patient safety by preventing falls with injury in all hospital patients and increase hospital monitoring of fall rates. The purpose of measuring the rate of falls with major and moderate injury events is to improve hospitals' practices for monitoring patients at high risk for falls with injury, implement best practices for prevention in high-risk patients and, in so doing, to reduce the frequency of patient falls with injury.

Quick Tip

Explain the measure's anticipated impact on costs. Here, the developer notes the additional health care and patient costs associated with inpatient falls with injuries.

References:

Morello RT, Barker AL, Watts JJ, et al. The extra resource burden of in-hospital falls: A cost of falls study. Med J Aust. 2015;203(9):367.e1-367.e8. doi:10.5694/mja15.00296.

Bysshe T, Yue Gao M, Krysta Heaney-Huls M, et al. Draft Final Report Estimating the Additional Hospital Inpatient Cost and Mortality Associated with Selected Hospital Acquired Conditions.; 2017. www.ahrq.gov.

Dykes PC, Curtin-Bowen M, Lipsitz S, et al. Cost of Inpatient Falls and Cost-Benefit Analysis of Implementation of an Evidence-Based Fall Prevention Program. JAMA Health Forum. 2023;4(1):e225125. doi:10.1001/jamahealthforum.2022.5125.

2.4 Performance Gap

If available, provide evidence of performance gap or measurement gap by providing performance scores on the measure as specified at the specified level(s) of analysis. Please include mean, minimum, maximum, and scores by deciles by using the table below or upload an attachment. In the text field here, describe the data source, including number of measured entities, number of patients, dates of data. If a sample was used, provide characteristics of the entities included. If performance scores are unavailable for the measure, please explain.

Performance Results from Beta Testing: Risk-adjusted rates showed substantial variation in performance scores from 0.0 to 0.257 (95% CI, 0.111-0.324) falls per 1,000 hospital encounter days across the 12 test hospitals. Performance scores were as follows:

Minimum: 0

Median: 0.053

Mean: 0.08

Maximum: 0.2575

Decile analysis was not possible with only 12 facilities reporting complete data. However, Table 1 and Exhibit 2 in the logic model attachment show the distribution of performance scores across sites.

Quick Tip

For initial endorsement, reporting performance gap information is optional. If available, developers can include the information in Table 1 or include as a separate attachment in 2.4a (as this developer did). Data should be provided, if available.

Quick Tip

If the decile analysis in Table 1 is not feasible and performance scores will be provided in a different way (e.g., separate attachment), please explain why.

2.4a Attach Performance Gap Results

If needed, you may attach additional performance gap results here. If submitting an attachment rather than entering results in Table 1 above, please enter the overall mean, minimum, maximum, and mean scores by decile. Enter the number of measured entities and persons/encounters/episodes overall and within each decile. Please ensure all attachments are 508 compliant and all tables and figures are labeled with alternative

text, as appropriate. Please clearly refer to any results within your attachment within the relevant text fields of this measure submission form.

One file only; 256 MB limit; allowed types: .zip, .pdf, .docx, .xls, .xlsx

Hospital Harm – Falls with Injury_Logic Model and Tables_11 01 2023.pdf

2.5 *[If initial endorsement]* **Health Care Quality Landscape***

Please explain why existing measures/quality improvement programs are insufficient for addressing this health care need.

There is only one existing outcome consensus-based entity (CBE) - endorsed falls with injury measure for acute care setting – "PSI 08: In Hospital Fall-Associated Fracture Rate (CBE #0531, endorsed as part of PSI 90 composite). PSI 08 identifies patients with a claim for a fall-associated fracture during an inpatient encounter. PSI 08 is a claims-based measure, and as such is focused solely on the Medicare fee-for-service population. Additionally, the numerator for this measure is limited to fractures, and does not include fall-associated moderate injuries such as lacerations. Therefore, the Hospital Harm – Falls with Injury measure provides the opportunity to assess the rate of falls with injury in a much larger patient population, and it will ultimately enable CMS to replace PSI 08 in the CMS programs where it is currently used.

2.6 Meaningfulness to Target Population*

Provide evidence the target population (e.g., patients) values the measured outcome, process, or structure, and finds it meaningful. Please describe how and from whom you obtained input.

The guidelines developed by Schoberer et al. (2022), the National Institute for Health and Care Excellence (NICE), and the Registered Nurses' Association of Ontario included patients, patient advocates, and caregivers on their development panels. The World Falls Group (WFG) guidelines development process included feedback from older adults obtained through early and meaningful involvement in the consensus process. The RNAO guideline development process also included consideration of a survey questionnaire sent to key stakeholders, which included patients and caretakers.

Based on the feedback collected from public comment, patient/caregiver representatives agreed that the rate of hospital-acquired falls resulting in major or moderate injury is important to measure and can help improve care for patients. During an additional technical expert panel (TEP) meeting, one patient member additionally stressed that the proposed measure has importance from a patient safety standpoint.

Quick Tip

The developer demonstrates that the target population values the measured outcome and finds it meaningful, as evidenced by direct input from patients and caregivers. The description of how and from whom the input was obtained is clear.

References:

Montero-Odasso, M., van der Velde, N., Martin, F. C., Petrovic, M., Tan, M. P., Ryg, J., Aguilar-Navarro, S., Alexander, N. B., Becker, C., Blain, H., Bourke, R., Cameron, I. D., Camicioli, R., Clemson, L., Close, J., Delbaere, K., Duan, L., Duque, G., Dyer, S. M., … Rixt Zijlstra, G. A. (2022). World guidelines for falls prevention and management for older adults: a global initiative. Age and Ageing, 51(9), 1–36

NICE. Falls in Older People: Assessing Risk and Prevention. London, UK; 2013

RNAO. Preventing Falls and Reducing Injury from Falls. 4th edition. Toronto, ON; 2017

Schoberer, D., Breimaier, H. E., Zuschnegg, J., Findling, T., Schaffer, S., & Archan, T. (2022). Fall prevention in hospitals and nursing homes: Clinical practice guideline. Worldviews on Evidence-Based Nursing, 19, 86-93

Public Comment Summary Report: Falls with Major Injury (2021). Available at: https://mmshub.cms.gov/sites/default/files/Public-Comment-Summary-Report-Falls-Major-Injury.pdf

Section 3. Feasibility

3.1 Feasibility Assessment*

Describe the feasibility assessment conducted, showing you considered the people, tools, tasks, and technologies necessary to implement this measure. For maintenance measures, describe whether feasibility issues due to implementation might have arisen and the near-term (i.e., within one year) mitigation approaches.

The feasibility assessment should address:

- *Whether all required data elements are routinely generated and used during care delivery*
- *The extent of any missing data, measure susceptibility to inaccuracies, and the ability to audit data to detect problems*
- *Estimates of the costs or burden of data collection, data entry, and analysis, including the impact on clinician workflow, diagnostic thought processes, and patient-physician interaction*
- *Barriers encountered or that could be encountered in implementing the measure specifications, data abstraction, measure calculation, or performance reporting*
- *Ability to collect information without violation of patient confidentiality, including circumstances in which measures based on patient surveys or the small number of patients may compromise confidentiality*
- *Identification of unintended consequences*

Quick Tip

Testing of eCQMs should be conducted within EHR systems from at least two EHR vendors. Beyond this minimum requirement, developers/stewards should test on the number of health systems/facilities they deem appropriate.

The developer tested the measure in two EHR systems and clearly identified those here and within the eCQM Feasibility Scorecard.

Thirteen hospitals participated in the evaluation of feasibility—four Epic and nine Allscripts users. All hospital sites confirmed that the data elements used in the measure are captured within the EHR in a structured and codified manner either using nationally accepted terminology standards or local system codes that could be easily mapped. However, one Epic hospital did not always use their structured fields to capture a fall that occurred during hospitalization. For this reason, the site opted to not proceed with reliability and validity phases of testing. The one Epic hospital is aware of the documentation challenges and will work on these improvements moving forward. Of note, three other Epic sites used in all testing phases did not encounter the same workflow challenges. Please see Table 2 in logic model attachment for combined feasibility scores for data availability, data accuracy, data standards, and workflow across all 13 hospitals.

3.2 *[If an eCQM]* **Attach Feasibility Scorecard***

Attach your completed feasibility scorecard; please create the scorecard using the approved template.

One file only; 256 MB limit; allowed type: xlsx.

Falls_COMBINED_Feasibility_Scorecard_EXTERNAL 11 01 2023.xlsx

3.3 Feasibility-Informed Final Measure*

Describe how the feasibility assessment informed the final measure specifications, indicating any decisions made to adjust the measure in response to feasibility assessment.

There were no changes to the measure specification as a result of feasibility testing. Any issues identified were site specific (as described above).

3.4 Proprietary Information*

Indicate whether your measure or any of its components are proprietary, with or without fees (choose one).

Quick Tip

The measure uses EHR data, ensuring all required data elements are available without additional collection efforts. Data were structured and codified in a manner either using nationally accepted terminology standards or local system codes that could be easily mapped.

Quick Tip

Feasibility challenges among tests sites should be reported along with a rationale as to why and a plan for readdressing the data element. The developer does that here and also within the eCQM Feasibility Scorecard, noting that the one Epic hospital did not consistently use the structured fields and that the single test site is aware of the documentation challenges and will work on these improvements moving forward.

Quick Tip

This eCQM Feasibility Scorecard clearly describes the two EHR systems used for testing (Epic and Allscripts) and the systems used by each of the 13 hospitals; lists all the key data elements used to calculate the measure; identifies clearly data availability, data accuracy, data standards, and workflow issues; and describes a plan to overcome the data challenges.

☐ Proprietary measure or components (e.g., risk model, codes), without fees
☐ Proprietary measure or components with fees
☒ Not a proprietary measure and no proprietary components

Section 4. Scientific Acceptability

4.1 Data and Samples

4.1.1 Data Used for Testing*
Describe the data used for testing (include dates, sources).

We recruited four health systems consisting of 13 individual hospital sites. One hospital in the Northeast region only participated in alpha (feasibility) testing. We collected data for calendar year 2021 (January 1, 2021-December 31, 2021) from 12 hospitals.

4.1.2 Differences in Data*
If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), clearly identify which data source/sample is used for each aspect of testing, including the years of data used in each. If there are no differences to report, enter "None."

Hospital 13 (located in the Northeast region) only participated in alpha (feasibility) testing. This was due to inconsistent workflows around clinical documentation that a fall occurred during hospitalization. Of note, this was an Epic site, and three other Epic sites used in all testing phases did not encounter the same workflow challenges.

Measure score-level reliability testing used data from the full denominator population in Hospitals 1-12. Measure data element-level validity testing, on the other hand, were based on subsamples drawn from the measure initial population using the approach of random sampling without replacement. These subsamples served as the foundation upon which clinical abstractors compared data exported from the EHR (eData) to data manually abstracted from patients' medical charts (mData, or "gold standard"). This process is commonly known as the parallel-form comparison. When drawing the subsamples, we held constant the distribution of patient characteristics exhibited in the initial population to the extent possible (e.g., % of male, % of white, % of Black, etc. in the abstraction sample are comparable to those in the initial population to the extent possible).

Quick Tip

Identify any differences in the data used for testing. Here, the developer notes that Hospital 13 only participated in alpha (feasibility) testing.

Quick Tip

Identify any differences in the sample used for testing. Here, the developer notes that the full denominator population was used for measure-score reliability testing and a random subsample was used for data-element validity testing.

4.1.3 Characteristics of Measured Entities*
Describe characteristics of measured entities included in the analysis (e.g., number, size, location, type). If you used a sample, describe how

you selected measured entities for inclusion in the sample and the representativeness of the sample.

Hospital test site characteristics are shown in Table 3 in the logic model attachment.

Vendor and location: Nine used Allscripts as their EHR and are headquartered in the Northeastern region of the United States. Four used Epic as their EHR and are headquartered in various regions (Northeast, Southeast, and West).

Bed size: Three hospitals had between 100-199 beds, eight hospitals had between 200-499 beds, and two hospitals had >499 beds.

Teaching status: Three hospitals were major teaching hospitals and nine were community teaching hospitals. Teaching intensity is often measured by the ratio of interns and residents to beds. In this report, major teaching hospitals are those with an intern- and resident-to-bed ratio (IRB) of 0.25 (one resident for every four beds) or above and at least 50 beds, while community teaching hospitals include hospitals with an IRB of less than 0.25 or teaching hospitals with fewer than 50 beds.

Quick Tip

Describe the number, size, location, and type of measured entities. In addition to describing the EHR vendor, geographic location, bed size, and teaching status of the hospitals used in measure testing, the developer references an attachment with more information.

4.1.4 Characteristics of Units of the Eligible Population*

Describe characteristics of the patients, encounters, episodes, etc., including numbers and percentages by factors such as age, sex, race, or diagnosis. Provide descriptive statistics separately by each specified level of analysis and data source. If you used a sample, describe how you selected the patients for inclusion in the sample and the representativeness of the sample. If there is a minimum case count used for testing, you must reflect that minimum in the specifications in Minimum Sample Size in Section 1.

We collected data for calendar year 2021 (January 1, 2021-December 31, 2021) from 12 test sites. Tables 4 and 5 in the logic model attachment provide information on measure denominator population including age, sex, race, ethnicity, primary payer, comorbidity, and medications. The number of encounters in the measure denominator ranged from a low of 451 to a high of 40,286 across test sites. Note that while the measure is inpatient based, the measure denominator includes emergency department visits and observation stays that were eventually admitted.

4.2 Reliability

4.2.1 Level(s) of Reliability Testing Conducted*

Choose all that apply.

☐ Patient or Encounter Level (e.g., inter-abstractor reliability)
☒ Accountable Entity Level (e.g., signal-to-noise analysis)
☐ Not applicable/reliability testing not conducted

4.2.2 *[If reliability testing was conducted]* **Method(s) of Reliability Testing***

For each level of reliability testing conducted, describe the method(s) of reliability testing and explain what each tests. Describe the steps; do not just name a method. What type of error does it test? Provide the type of statistical analysis used. Describe proportion of missing data, how missing data were analyzed and/or excluded, and any sensitivity analysis conducted.

Note: Testing at the patient or encounter level requires that all critical data elements be tested (not just agreement of one final overall computation for all patients). At a minimum, the numerator, denominator, and exclusions must be assessed and reported separately. Prior evidence of reliability of data elements for the data type specified in the measure (e.g., hospital claims) can be used as evidence for those data elements. Prior evidence could include published or unpublished testing that includes the same data elements, uses the same data type (e.g., claims, chart abstraction), and is conducted on a sample as described above (i.e., representative, adequate numbers, and randomly selected, if possible).

Quick Tip

Explain why the selected reliability method was chosen and why it's appropriate for the measure.

We applied split-half and test-retest approaches to estimate the reliability of this risk-adjusted measure at the accountable entity (hospital) level, using the intracluster correlation coefficient (ICC) as an estimator. As formulas are not allowed in the online form, see logic model attachment pg. 6-7 for the methodology.

The higher the ICC, the greater the statistical reliability of the measure, and the greater the proportion of variation that can be attributed to systematic differences in performance across hospitals (i.e., signal as opposed to noise). We used the rubric established by Landis and Koch (1977) to interpret ICCs: 0 – 0.2: slight agreement, 0.21 – 0.39: fair agreement, 0.4 – 0.59: moderate agreement, 0.6 – 0.79: substantial agreement, 0.8 – 0.99: almost perfect agreement, 1: perfect agreement

We applied this methodology to hospital subsamples that were formed by randomly dividing the available year of patient data from each hospital into two, then executing the measure code separately on each split-half, to yield two estimates per hospital. Because the reliability of the measure is assumed to be dependent on denominator size, we used an application of the Spearman-Brown prophecy formula to estimate the reliability of each hospital based on the ICC estimator.

References:

Dickens, William T. “Error components in grouped data: is it ever worth weighting?.” The Review of Economics and Statistics (1990): 328-333.

Landis, J. Richard, and Gary G. Koch. “The measurement of observer agreement for categorical data.” biometrics (1977): 159-174.

Spearman-Brown Prophecy Formula” in: Frey, B. (2018). The SAGE encyclopedia of educational research, measurement, and evaluation (Vols. 1-4). Thousand Oaks, CA: SAGE Publications, Inc. doi: 10.4135/9781506326139

4.2.3 *[If reliability testing was conducted]* **Reliability Testing Results***

Provide the statistical results from reliability testing for each level and type of reliability testing conducted. Where applicable, include results from accountable entity-level reliability testing (e.g., signal-to-noise testing) in the table below.

Signal-to-noise reliability was estimated as an intraclass correlation coefficient based on a two-way mixed model with facility random effects (C,1). Exhibit 3 in the logic model attachment shows the distribution of SNRs across test sites.

Minimum: 0.195

25th percentile: 0.746

Median: 0.826

75th percentile: 0.892

Maximum: 0.948

4.2.3a *[If reliability testing was conducted]* **Attach Additional Reliability Testing Results**

If needed, you may attach additional reliability testing results here. Please ensure all attachments are 508 compliant and that all tables and figures are labeled with alternative text, as appropriate. Please clearly refer to any results within your attachment within the relevant text fields of this measure submission form.

One file only; 256 MB limit; allowed types: .zip, .pdf, .docx, .xls, .xlsx

Table 2. *[If accountable entity-level testing was conducted, i.e., if 4.2.1 includes “Accountable Entity-Level”)]* **Accountable Entity-Level Reliability Testing Results**

Enter the overall reliability, minimum, maximum, and mean reliability by decile. Enter the number of measured entities and persons/encounters/episodes overall and within each decile. If a sample, provide characteristics of the entities included.

Description	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean STNR (Reliability)	0.826	0.195	-	-	-	-	-	-	-	-	-	-	0.948
Mean Performance Score	12	1	-	-	-	-	-	-	-	-	-	-	1
Entities	193398	451	-	-	-	-	-	-	-	-	-	-	40286

4.2.4 *[If reliability testing was conducted]* **Interpretation of Reliability Results***

Provide your interpretation of the results in terms of demonstrating reliability for each level and type of reliability testing conducted. How do the results support an inference of reliability for the measure?

HH-Falls demonstrates high signal-to-noise reliability at most test facilities. ICC estimates ranged from 0.195 to 0.948 across test sites, with a mean and median equal to 0.762 and 0.826, respectively. ICCs at 10 of the 12 hospitals were at least 0.6 with two hospitals having lower values (0.46 and 0.195) due to very small numerators and denominators (i.e., site 4 is a children's hospital but was evaluated since patients aged 18-20 years were included in their population). Decile analysis was not possible with only 12 facilities reporting complete data. Overall, testing results showed that at least 60% of the variation in the measure scores among 10 of the 12 tests sites was due to true differences in performance. Thus, HH-Falls, as currently specified, can distinguish the true performance in hospital-acquired falls with major or moderate injury from one hospital to another.

Quick Tip

Reliability testing results at the entity-level (not the mean or median across all entities) is used to determine if results meet the minimum reliability threshold of 0.6.

Quick Tip

The developer provided rationale provided as to why decile analysis was not possible due to the low number of test sites. The developer provided a narrative summary of the number of test sites that achieved a 0.6 reliability estimate.

Quick Tip

The interpretation should explain what the reliability results mean in the context of the measure.

4.3 Validity

4.3.1 Level(s) of Validity Testing Conducted*

Choose all that apply.

☒ Patient or Encounter Level (e.g., sensitivity and specificity)
☒ Accountable Entity Level (e.g., criterion validity)
☐ Not applicable/validity testing not conducted

4.3.2 Type of Accountable Entity Level Validity Testing Conducted*

Choose all that apply.

☒ Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)
☐ Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use (i.e., the score is an accurate reflection of the effect of performance on quality or resource use and can distinguish good from poor performance)
☐ Not applicable/accountable entity-level validity testing not conducted

4.3.2a *[If a maintenance measure]* **Provide a rationale for why accountable entity-level validity testing was not conducted.**

4.3.3 *[If validity testing was conducted]* **Method(s) of Validity Testing***

For each level of testing conducted, describe the method(s) of validity testing and what each tests. Describe the steps (do not just name a method) and explain what was tested (e.g., accuracy of data elements compared with authoritative source, relationship to another measure as expected). What statistical analysis did you use? Describe proportion of missing data, how missing data were analyzed and/or excluded, and any sensitivity analysis conducted.

Note: Testing at the patient or encounter level requires that all critical data elements be tested (not just agreement of one final overall computation for all patients). At a minimum, the numerator, denominator, and exclusions must be assessed and reported separately. For patient- or encounter-level testing, prior evidence of validity of data elements for the data type specified in the measure (e.g., hospital claims) can be used as evidence for those data elements. Prior evidence could include published or unpublished testing that: includes the same data elements, uses the same data type (e.g., claims, chart abstraction), and is conducted on a sample as described above (i.e., representative, adequate numbers, and randomly selected, if possible).

For empirical accountable entity-level testing, the following should be included:

- *Narrative describing the hypothesized relationships*
- *Narrative describing why examining these relationships (e.g., correlating measures) would validate the measure*
- *Expected direction of the association*
- *Expected strength of the association*

To empirically assess data element validity, we compared data exported from the EHR (eData) to data manually abstracted from patients' medical charts (mData) for a subsample of measure initial population. We then quantified the validity by calculating four statistics that tell us if the measure is subject to false positives and false negatives:

Positive Predictive Value (PPV)—describes the probability that a patient who experienced the harm during hospitalization, per the EHR, is confirmed as a positive case per the clinical abstractor.
Sensitivity—describes the probability that an encounter where the patient experienced the harm per the mData was correctly classified as having the same in the eData.
Negative Predictive Value (NPV)—describes the probability that a patient who did not experience the harm per the eData is confirmed as a negative case with mData (either because the encounter is excluded from the denominator or numerator negative).

Quick Tip

Clearly explain methods used for each level of validity testing. To assess data element (patient- or encounter-level) validity, the developer compared EHR data to manually abstracted medical charts, gleaning evidence of false positives and false negatives.

Specificity—describes the probability that a patient who did not experience a harm per clinical abstraction was correctly classified as not experiencing the harm by the eData.

This process of data comparison is frequently known as the parallel-form comparison. As formulas are not allowed in the online form, see logic model attachment p.7-8 for methodology.

To assess measure score validity, we used face validity. Specifically, we reviewed the measure specification and results with members from our Hospital Harm Technical Expert Panel (TEP) and Technical Advisory Group (TAG). We collected feedback on the precision of the measure specifications, importance of the measure outcome, and whether the performance scores can be used to distinguish good from poor hospital-level quality. The TEP and TAG was comprised of individuals that hold various roles in the health care and academic sectors, including professors of medicine and health care, physicians, quality, analytics and informatics directors, nursing specialists, and patient advocates.

To evaluate the empirical impact of each exclusion criterion:
Using the full denominator data, we removed exclusion criteria one at a time from the measure logic and calculated the marginal and relative increase in the number of numerator and denominator encounters as a result.

Using the abstraction data, we compared each excluded sample case to the electronic information stored in the patient's medical record to assess whether the automated exclusion truly met the clinical criteria for exclusion.

Quick Tip

Clearly explain methods used for each level of validity testing.

The developer assessed measure score validity via face validity (i.e., reviewed the measure specification and results with a technical expert panel and technical advisory group to collect feedback on the precision of the measure specifications, importance of the measure outcome, and whether the performance scores can be used to distinguish good from poor hospital-level quality). Importantly, face validity is adequate for initial endorsement review but for maintenance measures, empirical validity testing is required.

Quick Tip

Describing the stakeholder composition of technical expert panels or advisory groups provides additional context for reviewers.

Quick Tip

Empirically assess exclusions by evaluating frequency of occurrence, variability of exclusions across measured entities, and/or sensitivity analyses with and without the exclusion.

4.3.4 *[If validity testing was conducted]* **Validity Testing Results***

Provide the statistical results from validity testing for each level and type of validity testing conducted.

As shown in table 6 in the logic model attachment, across all sites there is a 4.6% increase in the denominator and a 3.6% increase in the numerator when removing the one measure exclusion. This, along with the face validity in excluding present on admissions falls, is evidence that the exclusion occurs frequently enough to justify its use in the measure. See tables 7-10 in the logic model attachment for PPV, sensitivity, NPV, and specificity values across sites.

Face validity results are as follows:

16 of 16 members (100%), including 3 patient and family caregiver representatives, voted "yes" that the measured outcome (rate of in-hospital falls resulting in major or moderate injury) was important to measure and can improve care for patients.

15 of 16 members (94%), including 3 patient and family caregiver representatives, voted "yes" that measure specifications were precise and that it appears to measure what it is supposed to (i.e., face validity). The individual who voted "no" questioned the need for any risk adjustment (in response to which our team explained that risk adjustment only accounts for patient characteristics present on admission, is designed to support fair comparisons across hospitals that treat very different types of patients, and does not reduce hospitals' motivation to prevent falls with injury).

14 of 16 members (88%), including 3 patient and family caregiver representatives, voted "yes" that the measure's performance scores provide an accurate reflection of hospital-level quality, and scores resulting from the measure (Hospital Harm: Falls with Injury) can be used to distinguish good from poor hospital-level quality related to hospital-acquired falls with major or moderate injury. Of the two members who voted "no:" 1) one felt that hospital-level quality needs to be measured by more than just one element (in response to which our team indicated CMS's intent to use this measure as part of a patient safety composite eCQM that will add to a comprehensive portfolio of other quality measures already implemented into CMS programs); and 2) another individual indicated that the improvement opportunity for moderate injury is less than for serious injury and requested to see a breakdown of the various types of falls (which was provided in a follow-up email).

Quick Tip

The degree of consensus and any areas of disagreements should be discussed when providing face validity results.

4.3.5 *[If validity testing was conducted]* **Interpretation of Validity Results***

Provide your interpretation of the results in terms of demonstrating validity for each level and type of validity testing conducted. How

do the results support an inference of validity for the measure? For accountable entity-level testing, discuss how the results relate to the hypothesis. If the results are not what were expected, why?

HH-Falls excludes inpatient hospitalizations where the patient has a fall diagnosis present on admission. This criterion uses the structured diagnosis information and its POA status to determine if patients had a fall prior to the start of the encounter. Overall, the measure exclusion is necessary to reduce the measure's false positive rate and to prevent hospitals from being penalized by including falls that occurred prior to the encounter, when injuries resulting from these falls may be diagnosed later in a hospital stay. As shown in Table 6 in the logic model attachment, the percent change in the denominator and numerator is minimal.

Testing results indicate strong concordance and inter-rater agreement between data exported from the EHR and data in the patient chart. For the measure numerator, PPV denotes the probability that an EHR-reported fall with injury is a valid fall with injury based on the clinical review of patients' medical records. Numerator PPV across all test sites was 98.77%. For measure denominator exclusions, PPV denotes the probability that cases excluded from the measure per the EHR truly met the clinical rationale for exclusion. Denominator exclusion PPV across all test sites was 100%.

Quick Tip

The developer explains what the data-element validity results mean in the context of the measure, which helps to simplify statistical concepts.

4.4 Risk Adjustment

4.4.1 Methods Used to Address Risk Factors*

What methods or approaches were used to explore the effects of risk factors on this measure? (Note: If you tested for the effects of risk factors and ultimately determined that risk adjustment or stratification was not warranted, please select the method(s) used and provide details of the testing and your rationale in 4.4.2 through 4.4.6; the measure's ultimate status will be reported in 4.4.7).

Choose all that apply.

☒ Statistical risk-adjustment model with risk factors
☐ Stratification by risk factor category
☐ Other

4.4.1a Describe other method(s) used

4.4.2. *[If risk factors are addressed by any method (4.4.1)]*
Conceptual Model Rationale*

Explain the rationale for the risk approach, including reasons for risk adjustment and/or stratification. Describe the sources that inform the conceptual model, e.g., scientific literature, unpublished findings, TEP. Consider age, gender, race, ethnicity, urbanicity/rurality, Medicare/

Medicaid dual eligibility status, indices of social vulnerability (e.g., Centers for Disease Control and Prevention Social Vulnerability Index), and markers of functional status-related risk (e.g., cognitive or physical function) in the conceptual model, using evidence to support the model, with references. If risk factors (e.g., social, functional status-related, clinical) are included in the conceptual model but data are not available for all factors, describe any potential bias as a result of not including the risk factor(s) in the final risk-adjustment model or stratification. Address the validity of the measure in light of this bias.

4.4.2a *[If risk factors are addressed by any method (4.4.1)]*
Attach Conceptual Model *

Attach a figure of the conceptual model that illustrates the hypothesized pathway between the social and/or functional status-related risk factors, patient clinical factors, quality of care, and the measured outcome.

One file only; 256 MB limit; allowed types: .pdf, .jpg, .png, .zip

Graphic for Falls RA Conceptual Model 11 01 2023.zip

Quick Tip

The graphic of the conceptual model effectively categorizes patient risk factors into distinct groups such as those for falling, those for moderate or major injury given a fall, and mediators reflecting hospital quality. This clear segmentation helps in understanding the different dimensions of risk and their respective influences.

It is well understood that there are major risk factors for falls with injury, many of which are outside hospitals' control (e.g., age, frailty), which is why current practice guidelines emphasize risk assessment and mitigation. It is also well understood that misguided efforts to reduce fall rates to zero (i.e., by limiting patient activity or movement, installing bed or chair alarms) may cause other harms that are likely to exceed fall-related harms (see, for example, https://psnet.ahrq.gov/perspective/implementing-fall-prevention-program and https://psnet.ahrq.gov/web-mm/failure-ensure-patient-safety-leads-patient-falls-nursing-homes).

Conceptually, risk factors for in-hospital falls with injury can be separated into two categories: risk factors for falling, given hospitalization; and risk factors for moderate or serious injury, given a fall. Some personal characteristics are risk factors for falling but are unlikely to affect the risk of injury given a fall, whereas other personal characteristics are risk factors for injury given a fall, but are unlikely to affect the risk of falling. Our review below focuses on risk factors for falls with injury in the inpatient setting; a much larger literature describes risk factors for falls in ambulatory settings (over several years). Patient attributes (demographics, comorbid conditions, clinical signs and symptoms, functional risk factors, and others) present at the start of care are integral components of the risk model, in that they directly influence the measured outcome and hospitals have less control.

Quick Tip

The response delineates the risk factors into two categories: those that increase the likelihood of falling and those that increase the risk of injury given a fall. This distinction is crucial for understanding the different patient-level characteristics that influences these fall categories. The detailed discussion on how specific conditions like delirium, dementia, and depression, etc., influence these categories of falls adds depth to the model's rationale.

Quick Tip

Patient-level characteristics to be considered for a risk model should be present at the start of care.

Social factors have been shown to have relatively little marginal impact on the risk of falls with injury in inpatient settings, except as shown in the attached conceptual model. As summarized by Noel (2021), non-Hispanic Black "(NHB) adults have higher bone mineral density (BMD), lower prevalence of osteoporosis, and lower rates of fracture compared with NHW adults. Research on Hispanic adults, however, is less clear, with conflicting evidence regarding BMD, osteoporosis, and fractures. Although Asian populations generally show lower BMD, higher prevalence of osteoporosis, and lower fracture rates compared with NHW adults, data are limited... there is considerable variation within these groups based on origin for genetic, lifestyle, social, cultural, and environmental factors." Because the impact of social factors on the risk of inpatient falls with injury appears to be mediated through clinical characteristics such as osteoporosis and other comorbidities, we adjust for those latter factors (rather than social factors) in our final model. Some of the factors described below were tested but proved not to be independent risk factors for falls with injury in the available data. The risk-adjustment model will be updated annually (from the existing feature set) and additional risk factors will be added to the model as needed.

Age

Advanced age is recognized as a risk factor for falling and for fall-related injuries among hospitalized patients, although it may serve largely as a proxy for frailty and related concepts that cannot be measured directly. For example, the Network of Patient Safety Databases (NPSD) Falls Chartbook 2023 analyzed patient safety events from 2014 to 2022 and demonstrated that the residual harm after a fall, defined by the extent of harm to the patient after discovery of the incident and after any attempts to minimize adverse consequences, increased with age. Specifically, 38.7% of adults (18-64 years) experienced residual harm compared to 56.8% of older adults (75-84 years) and 61% of aged adults (85+ years). The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates a nearly linear effect of age from <40 years to >85 years.

Weight Loss

Several studies have reported increased risk of harmful falls in patients with malnutrition and low BMI (Lackoff, 2019), especially in the older elderly population (>80 years) (Vivanti, 2010, Bellanti, 2022). Based on a systematic review and meta-analysis by Neri et al. (2020), obesity increases the risk of falls but is a protective factor for injury, given falls (due to greater bone mineral density and less kinetic energy transmission to bone). The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.51 (95% CI: 1.44-1.58) for comorbid weight loss.

Quick Tip

Social risk factors should also be considered in the conceptual model phase. This does not mean they must be included in the final risk model, but developers should consider risk factors other than just clinical risks, such as social and/or functional patient-level risks.

Quick Tip

Highlighting the commitment to annually updating the risk model based on new data and additional risk factors as needed is crucial for responding to evolving health care landscapes and emerging research findings.

Quick Tip

The developer supports the identification of risk factors in this conceptual model with literature.

Delirium
Delirium is common among hospitalized older adults, "with studies suggesting that up to 31% of older adults have delirium on hospital admission." In a systematic review, Sillner et al. (2019) reported that "the median risk of falling with delirium among the studies was 12% (range from 6% to 67%) with smaller studies on the higher end of the range. The risk of falling was lower in the comparison group without delirium in all studies (median 2%, range 1% to 47%). Accordingly, the RR for falls with delirium was elevated and significant in all studies but one (median RR = 4.5, range 1.4–12.6)." The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.28 (95% CI: 1.20-1.37) for comorbid psychotic delirium.

Dementia
Patients with dementia have increased risk of falls during hospitalization (Jørgensen, 2015, Morello, 2015, Thurman, 2008, Homann, 2013, Sterke, 2012, Oliver, 2007). For example, a study by Jørgensen, et. al. (2015) demonstrated significantly increased odds of in-hospital fall-related major injuries among individuals with dementia, compared with patients without dementia (OR = 2.34, CI: 1.87–2.92). The use of psychotropic drugs, even at low defined daily dose (0.25 DDD), to treat symptoms of dementia further increases the risk of in-hospital falls (Sterke, 2012). The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.72 (95% CI: 1.64-1.81) for comorbid dementia.

Depression
Depression has been identified as one of the risk factors for falls (Homann, 2013, Thurman, 2008, Djurovic, 2021). For example, the retrospective case-control study by Djurovic, 2021, confirmed that depression is a statistically significant risk factor for falls (P<0.001), recognizing "a causal link between depressive symptoms and the falls." Antidepressants are considered to be an independent risk factor for falls. For example, in the retrospective case-control study by Castaldi (2022), antidepressants had a significant correlation with increased risk of falls (OR: 2.18; CI 95%: 1.32-3.59). The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.34 (95% CI: 1.28-1.39) for comorbid depression.

Psychosis/Psychotic Disorders
Psychosis and psychotic disorders have been found risk factors for falls. Study findings demonstrate increased immobility as well as bone density loss associated with psychotic disorders (Forns et al., 2021; Stubbs et al., 2018). For example, in the multivariable analysis of predictors of fractures by Stubbs (2018), psychosis was an independent and significant predictor for fall-related fractures requiring hospitalization (HR: 2.05, 95% CI 1.53-2.73). The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.28 (95% CI: 1.20-1.37) for comorbid psychosis.

Other Neurologic Disorders
Neurological disorders put patients at a higher risk for injurious falls during hospitalization. These conditions include peripheral neuropathy, disorders of gait and balance (Homann, 2013, Thurman, 2008, Djurovic, 2021), epilepsy, including seizure disorder (Homann, 2013, Spritzer 2015, Pati, 2013), Parkinson disease, multiple sclerosis, stroke, and other neurological disorders (Gianni, 2014, Forns, 2021, Cameron, 2018, Jørgensen, 2015, Allen, 2013, Thurman, 2008, Homann, 2013). For example, a study by Forns, et al. (2021) comparing patients with Parkinson disease with (PDP) and without psychosis (PD), found that PDP patients had higher risk for falls and fractures than those without psychosis. This effect was noted separately for falls (IRR = 1.48; 95% CI, 1.43–1.54) and any fractures (IRR = 1.17; 95% CI, 1.08–1.27) as well as for specific types of fracture, including pelvis and hip fractures. The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates

adjusted odds ratios of 1.13 (95% CI: 1.07-1.19) for comorbid other neurologic disorders and 1.23 (95% CI: 1.14-1.31) for seizures.

Sex
In papers by Aryee (2017) and Hodgson (2023), male sex was associated with increased risk of falls. The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, suggests that male sex is associated with higher risk of these adverse events up to 54 years, but lower risk above that age.

Surgery
Aryee (2017) reported that surgery was a statistically significant protective risk factor. Patients after a recent lower limb amputation may be at increased risk of falling, compared with other surgical and medical patients, according to IHI and VA Fall Prevention Group. The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 0.063 (95% CI: 0.059-0.068) for medical patients, relative to surgical patients. However, this estimate must be interpreted in the context of other features in the model.

Bone Disorders
In systematic reviews by Wildes (2015) and Frattura (2022), bone disorders including cancers involving bones were found to be significant risk factors for falls and falls with injuries. For example, Frattura's review of 11 papers on 1,237 patients with osteoporosis undergoing TKA found "pre-operative fall prevalence ranged from 23% to 63%, while post-operative values ranged from 12% to 38%." In Jørgensen's (2015) analysis of administrative data on patients 65 years and older with in-hospital falls causing fractures or head injuries with need for surgery or intensive observation, osteoporosis was a significant risk factor for falls with injuries (OR = 1.68, CI: 1.43-1.99).

Leukemia/lymphoma
Several studies found hematological and other cancers to be a risk factor for falls (Martí-Dillet, 2023, Lorca, 2019, Kong, 2014). For example, in the prospective study by Martí-Dillet (2023) of 6,090 patients hospitalized with cancer, patients with hematological cancers had the second highest incidence of falls (24.8%), after lung cancer. The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.44 (95% CI: 1.23-1.68) for leukemia and 1.22 (95%CI: 1.06-1.39) for lymphoma.

Liver Disease
Severe liver disease as well as management of severe liver disease increases risk of falls and bleeding due to injuries associated with falls (O'Leary, 2019, Murphy, 2019, Acharya,2021). Acharya (2021) described gait abnormalities among patients with liver cirrhosis listed for deceased solitary liver transplant from 2011 to 2015: "abnormal tandem gait (TG) trended towards increased falls (OR 3.3, P=0.08). 49% had abnormal TG, 61% had cognitive dysfunction (CD), 32.7% had CD plus abnormal TG, 62% had prior overt hepatic encephalopathy (OHE), and 14.7% had falls." The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.45 (95% CI: 1.30-1.63) for severe and 1.13 (95%CI: 1.05-1.21) for mild liver disease.

Coagulopathy
Coagulation disorders and anticoagulant medications put patients at a higher risk for developing bleeding after a fall. IHI and VA Fall Prevention Group identify coagulation issues that put the patient at risk for injury in the event of a fall such as bleeding, anticoagulant use, and abnormal platelet count. "Anticoagulants are commonly used in elderly patients to reduce the risk of potential stroke, but this potential benefit must be weighed against the risk of falls with potentially fatal bleeds" (Llompart-Pou, 2017). "In the regression

model for the dependent variable of falling, anemia (OR=2.26, p<0.001) was associated with more than twice the risk of falling." (Pandya, 2008). The current risk model for AHRQ PSI 08, based on 11,536 in-hospital fall-associated fractures among over 58 million patients, estimates an adjusted OR of 1.08 (95% CI: 1.02-1.15) for comorbid coagulopathies.

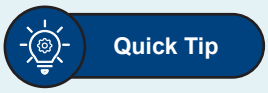
Medications POA

There are several classes of medications, referred to as a fall-risk increasing drugs (FRIDs), especially in adults who are greater than 65 years or older, that increase risks of falls. If these medications were administered at home, with persisting effects at admission to the hospital, then they are appropriate for risk-adjustment.

Opioids: Seppala, 2018; Park, 2015; Callis, 2016; Yoshikawa, 2020; Cox, 2014.
CNS depressants: Callis, 2016 (antipsychotics, hypnotics, opioids, benzodiazepines, antiepileptics); Aryee, 2017 (active treatment on CNS agents); Seppala, 2018(antipsychotics, antidepressants, TCAs, SSRIs, benzodiazepines, short-acting benzodiazepines, long-acting benzodiazepines, antiepileptic); Park, 2015 (sedatives, hypnotics, antidepressants including tricyclic antidepressants, selective serotonin reuptake inhibitors, and serotonin norepinephrine reuptake inhibitors); Shuto, 2010 (antiparkinsonian agents, anti-anxiety agents and hypnotic agents); O'Neill, 2019 (anticonvulsant, benzodiazepine anticonvulsant, haloperidol, tricyclic antidepressant); Dominigue, 2018 (lorazepam); Currie, 2008 (sedatives, hypnotics, psychotropics, antiepileptics).
Antihypertensives: Kahlaee, 2018; Shimbo, 2016 (ACE-i,ARB,CCB,BB, vasodilators); Shuto, 2010 (ARB); De Vries, 2018; 2019 American Geriatrics Society (AGS) Beers criteria (alpha blockers, Alpha agonist, calcium channel blockers)
Diuretics: Kahlaee, 2018; O'Neill, 2019; Seppala, 2018; Berry, 2012; Lim, 2009 (increase bone loss on loop diuretics).
Antidepressants: Woolcott, 2009; 2019 AGS Beers criteria; De Jong, 2013; Castaldi, 2021; Park, 2015.

Mediating Factors

Several care processes and intermediate factors (or mediators) may also contribute to the occurrence of falls with injuries. These factors are largely within the hospital's control and are therefore not considered as risk factors. For example, in the NPSD Falls Chartbook 2023 analysis of patient safety reports from 2014 through 2022, 22.9% of in-hospital falls were associated with injury or residual harm among patients ambulating without assistance prior to falling, versus only 6.4% among patients ambulating with assistance. Assistance during ambulation may not decrease the risk of falling, but it appears to reduce the risk of injury as the patient is assisted to the ground. Other process factors are summarized in the Importance section. Other mediating factors include keeping the bed in low position, keeping the



Mediating factors are elements that the accountable entity, in this case hospitals, can influence directly. By identifying and addressing these factors, the response underscores the hospital's role in actively managing and reducing the risk of falls. This is crucial because it shifts some focus from patient-specific risk factors, which may not be as easily modifiable and thus included in the risk model, to actionable hospital practices that can be adjusted to improve the outcome of falls.

call light and personal items in reach, educating the patient and family regarding fall risk, providing non-slip footwear, and visibly identifying each applicable patient as being at risk for fall (e.g., Falling Star).

References

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Quick Tip

The response is well-supported by a wide array of scientific literature and studies, which not only lends credibility but also shows a thorough research process. References to studies and data, such as the Network of Patient Safety Databases (NPSD) and various systematic reviews, provide a solid evidence base for the risk factors included in the conceptual model. Other types of evidence may also come from focus groups or expert panels.

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4.4.3 *[If risk factors are addressed by any method (4.4.1)]* **Risk Factor Characteristics Across Measured Entities***

Provide descriptive statistics showing how the risk variables identified from the conceptual model are distributed across the measured entities. Indicate which risk factors were tested in the risk-adjustment model and which were tested for stratifying the measure, as applicable.

Tables 4 and 5 in the logic model attachment show substantial variation in the distribution of risk variables across the 12 measured entities. For example, mean age varied from 20.1 (SD=3.0) years at Site 4 (a children's hospital that admits young adults) to 69.3 (SD=18.2) years at Site 7. The percentage of Black patients varied from 5.3% at Site 7 to 34.3% at Site 1. The percentage of Hispanic patients varied from 3.0% at Site 1 to 86.3% at Site 9. The percentage of Medicaid-enrolled patients varied from 10.4% at Site 1 to 54.8% at Site 4. Most comorbidities and home medication-related variables also demonstrated substantial variation across sites; for example, the prevalence of obesity varied across non-children's hospitals from 10.5% at Sites 5 and 6 to 51.1% at Site 1.

Quick Tip

The response not only provides descriptive statistic tables but also summarizes the results, identifying where there are variations in these risk factors across the accountable entities.

4.4.4 *[If risk factors are addressed by any method (4.4.1)]* **Risk-Adjustment Modeling and/or Stratification Results***

Describe the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model and/or stratification, as applicable. Clearly indicate the risk factors included in the final risk model and/or used in the final stratification approach.

4.4.4a *[If risk factors are addressed by any method (4.4.1)]* **Attach Risk-Adjustment Modeling and/or Stratification Specifications** *

Provide detailed risk-adjustment model and/or stratification specifications, including the method(s), risk factor data sources, and equations, as applicable. Please list all risk factors in your conceptual model, clearly indicating which factors were available/tested and which (if any) were retained in final model and/or stratification plan. Also include the data source, code with descriptor, and coefficient for each risk factor in the final risk-adjustment model or stratification plan, as appropriate.

One file only; 256 MB limit; allowed types: .xls; .xlsx; .csv

FALLS WITH INJURY RISK MODEL 11 01 2023.xlsx

Quick Tip

The response clearly outlines the use of advanced statistical techniques such as cluster-adjusted Poisson regression, 100-fold cross-validation, LASSO (Least Absolute Shrinkage and Selection Operator), and Elastic Net modeling. This detailed explanation demonstrates a rigorous approach to model development and ensures that the model is both robust and reliable.

The final risk-adjustment model was estimated using cluster-adjusted Poisson regression with an exposure time offset term (Stay_days) run on the entire dataset. All risk factors were dichotomous (0/1) except for age, as described above. Data sources included:

ICD-10-CM diagnosis codes for comorbidities present on admission, including Obesity, Weight loss or malnutrition, Coagulation disorder, Delirium, Dementia, Depression, Seizures and epilepsy, Leukemia or lymphoma, Liver disease (moderate or severe), Malignant bone disease, Neurological movement disorders, Other neurological disorders, Osteoporosis, Neuropathy, Psychosis, and Stroke (POA);
Anesthesia record for surgery (CHECK);
EHR home medication list for Antidepressants, Antihypertensives, CNS depressants, Diuretics, and Opioids;

EHR hospital medication record for Anticoagulants; and
EHR demographic fields for age, sex, race, ethnicity, and primary payer.

After feature selection with 100-fold cross-validation and testing on the hold-out test set, the only retained risk factors were age (in linear form), weight loss or malnutrition POA, delirium POA, dementia POA, and other neurological disorders POA. We tested models forcing in other factors and found only one statistically significant effect at the $p<0.1$ level (i.e., home opioid medication) and no meaningful improvement in any metric of model performance (e.g., AUC, Brier score, AIC/BIC).

Guided by the conceptual model, we developed the baseline risk-adjustment model for Falls with injury using the following process.

Randomly partitioned the full denominator data into a 70% training set and a 30% hold-out (model performance or evaluation) test set.

Created contingency tables for all categorical features to identify any that had zero cells for either the positive or negative outcome. These features were not considered further due to anticipated model convergence problems (i.e., quasi-complete separation). For continuous variables, such as age, we ran locally weighted bivariate regressions (i.e., locally weighted scatterplot smoothing, or LOWESS) to understand the functional form of the relationship. This analysis confirmed that the risk of fall with injury was linearly related to age through nearly all the age distribution, from about 30 to 90 years of age.

Fit one model using the least absolute shrinkage and selection operator (LASSO) on the training set using 100-fold cross-validation (CV). This step helped to assess model fit on the training set, while facilitating parameter tuning (e.g., the lambda regularization parameter in the cross-validation [CV]-based LASSO). We chose the final model where the regularization parameter (lambda) was set to lambda1se, i.e., “one-standard-error” (i.e., the largest lambda at which the mean squared error (MSE) is within one standard error of the minimum MSE.). This rule is standard practice for improving generalization, and its suitability was confirmed using the hold-out test set.

Fit an Elastic net model with the set of initial features on the training set using a 100-fold cross-validation (CV) and finally assessing generalizability on the hold-out test set. The final model selected was the one where the regularization parameter was lambda1se. Elastic net was developed by Zou and Hastie in 2005 by combining the improvements of LASSO and ridge regression. Its main advantage is in handling multicollinearity. It outperforms LASSO in prediction accuracy and provides a unique solution due to the ridge regression penalty term.

Quick Tip

By splitting the data into a training set and a test set, the model can be trained on one subset of the data and then tested on a completely independent subset. This process helps to evaluate how well the model generalizes to new, unseen data, which is crucial for assessing the model’s real-world applicability and robustness. This also helps prevent overfitting. Overfitting occurs when a model learns not only the underlying patterns in the training data but also the noise, leading to excellent performance on the training set but poor performance on new data. By using a separate test set, it’s possible to check for overfitting by ensuring that the model performs well on both the training data and the test data.

Compared selected features (or risk factors) across the two models by consulting with clinicians to confirm that no feature was included incorrectly from a clinical standpoint. We eventually decided to use the features chosen by Elastic net.

The final risk-adjustment model was a cluster-adjusted Poisson model with an offset for patient stay days, accounting for the fact that in-hospital falls followed a Poisson distribution with stay days as an indicator of exposure time. The model was estimated on the entire dataset using the set of features selected by Elastic net through 100-fold cross-validation and testing on the hold-out test set.
The risk-adjustment model was also tested with additional social drivers of health variables (Medicaid insurance, Hispanic ethnicity, Race), considered individually and collectively.

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Quick Tip

The response mentions consulting with clinicians to ensure that no feature was incorrectly included from a clinical standpoint. This collaboration is essential for maintaining the clinical relevance of the risk model and ensuring that it aligns with practical health care settings and patient care standards.

4.4.5 *[If 4.4.1 includes "Statistical risk adjustment model with risk factors"]* **Calibration and Discrimination***

Describe the approach and results of calibration and discrimination testing. Describe any over- or under-prediction of the model for important subgroups.

Quick Tip

The model's testing with additional social drivers of health variables like Medicaid insurance, Hispanic ethnicity, and race shows an understanding of the broader factors that can influence health outcomes. This approach is aligned with current trends in health care toward more holistic and inclusive models of care.

4.4.5a *[If 4.4.1 includes "Statistical risk adjustment model with risk factors"]* **Attach Calibration and Discrimination Testing Results***

Attach results of calibration and discrimination testing.

One file only; 256 MB limit; allowed types: .pdf; .zip

FALLS WITH INJURY CALIBRATION AND DISCRIMINATION TESTING_11 01 2023.pdf

We summarize model performance using the following measures:

Overall model discrimination as assessed by C-statistic. The C-statistic is the area under the receiver-operator curve (i.e., AUC) that measures the discriminative ability of a regression model across all levels of risk. It also describes the probability that a randomly selected patient who experienced a fall with injury had a higher expected value than a randomly selected patient who did not experience that event. The AUC was 0.781 in the holdout test set (based on Elastic net) and 0.852 for the final Poisson model. These values indicate strong discrimination performance, relative to a random classifier with AUC=0.5.

Quick Tip

The C-statistic (AUC) values reported for both the Elastic net model and the final Poisson model are significantly above 0.5. This indicates that the models have strong discriminative abilities. Specifically, the AUC of 0.781 for the Elastic net model and 0.852 for the Poisson model suggest that the models are effective in distinguishing between patients who will and will not experience a fall with injury.

- The precision-recall (PR) curve and the area under the curve (AUPRC). The PR curve and AUPRC are less sensitive to data imbalance or class imbalance (i.e., very rare events) than the AUC. The AUPRC was 0.00166 in the holdout test set (based on Elastic net), indicating poor prediction at the individual patient level but reasonable performance relative to a random classifier with AUPRC=0.00043.
- Model calibration was assessed across deciles of patient risk using Hosmer-Lemeshow plots. The deciles of risk are ten mutually exclusive groups containing equal numbers of discharges, ranging from very low-risk patients (according to the model) to high-risk patients. We do not provide Hosmer-Lemeshow test statistics because, given the large sample size of our data, the null hypothesis is almost always rejected. Moreover, the plots provide more detail on model fit than the overall Hosmer-Lemeshow statistic. Because over 53% of events occurred in the highest-risk decile, and nearly 76% occurred in the highest-risk quintile, the decile analysis is statistically unstable.
- A preferred approach in this situation is to estimate calibration belts suggested by Nattino et al. (2017). Calibration belts are an advance over the conventional Hosmer-Lemeshow plot, as the latter has the limitation of undue sensitivity to the choice of bins and extreme fluctuations in the observed-to-expected ratios in bins with few harm events. The null hypothesis of perfect calibration is never rejected at the 95% confidence level (p=0.052).

Reference:

Nattino, G., Lemeshow, S., Phillips, G., Finazzi, S., & Bertolini, G. (2017). Assessing the calibration of dichotomous outcome models with the calibration belt. The Stata Journal, 17(4), 1003-1014

Quick Tip

The use of the Precision-Recall (PR) curve and the area under the PR curve (AUPRC) is an appropriate test, given any imbalance in the dataset (i.e., falls with injury are relatively rare events). The AUPRC provides a more relevant measure of model performance in such scenarios.

Quick Tip

The use of deciles of risk and calibration provides a nuanced view of how well the predicted probabilities match the observed outcomes across different levels of risk. This detailed approach helps in understanding the model's performance across the spectrum of patient risk, which is crucial for ensuring that the model performs well not just on average but across all risk levels.

Quick Tip

The decision not to rely solely on the Hosmer-Lemeshow test statistic due to its limitations with large sample sizes is prudent. This approach avoids misleading conclusions that could arise from the automatic rejection of the null hypothesis in large datasets. The response clearly provides an explanation and reasoning for not using Hosmer-Lemeshow statistics.

Quick Tip

The adoption of calibration belts, as suggested by Nattino et al. (2017), represents an advanced methodological approach that overcomes some of the limitations of traditional Hosmer-Lemeshow plots. This method is less sensitive to the choice of bins (i.e., groups or categories into which the data are divided based on the predicted probability of an outcome) and provides a more stable assessment of calibration, especially in the presence of few harm events in certain bins.

4.4.6. *[If risk factors are addressed by any method (4.4.1)]* **Interpretation of Risk Factor Findings***

Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix). Clearly describe the rationale for why each risk factor tested WAS or WAS NOT included in the final model. Describe what the results mean, including what is normally expected in relation to the test conducted.

After feature selection with 100-fold cross-validation and testing on the hold-out test set, the only retained risk factors were age (in linear form), weight loss or malnutrition POA, delirium POA, dementia POA, and other neurological disorders POA. We tested models forcing in other factors and found only one statistically significant effect at the $p<0.1$ level (i.e., home opioid medication) and no meaningful improvement in any metric of model performance (e.g., AUC, Brier score, AIC/BIC).

Rationale for Inclusion of Risk Factors

Age (in linear form)
Rationale: Age is a fundamental predictor in many health-related models due to its strong association with physiological changes, disease prevalence, and overall health risk. The linear form suggests that the risk associated with age increases continuously without thresholds or cutoffs.
Expected Outcome: Typically, older age is associated with increased risk for many adverse health outcomes, making its inclusion and linear modeling justified.

Weight Loss or Malnutrition POA
Rationale: Malnutrition or significant weight loss is a critical indicator of poor health status and can exacerbate vulnerability to diseases and injuries. Including this factor helps to adjust for the severity of patient condition at admission.
Expected Outcome: Patients with poor nutritional status are often at higher risk for complications, justifying its inclusion.

Delirium POA
Rationale: Delirium is an acute change in mental status that is often linked with higher morbidity and mortality in hospitalized patients. It is a marker of acute illness severity and can influence patient outcomes significantly.
Expected Outcome: Delirium is associated with an increased risk of falls and other adverse events in hospital settings.

Dementia POA
Rationale: Dementia is a chronic condition that affects cognitive function and can severely impact a patient's ability to manage their health. Including dementia adjusts for the cognitive impairment that might not be captured by other medical diagnoses.
Expected Outcome: Patients with dementia are known to have higher risks of hospitalization complications, including falls.

Other Neurological Disorders POA
Rationale: Neurological disorders can affect multiple aspects of health, from motor function to cognitive abilities, and are critical to consider in any model predicting health outcomes in a clinical setting.

Quick Tip

The response describes a risk factor selection process demonstrating a robust approach to model building, ensuring that only factors that provide significant predictive power and improve model performance are included. This method helps in adequately controlling for differences in patient characteristics, ensuring that the model is both efficient and effective in predicting the outcomes based on the most relevant and impactful factors.

Expected Outcome: Such conditions often complicate patient care and increase the risk of adverse outcomes.

Rationale for Exclusion of Other Factors

Other Tested Factors (e.g., home opioid medication)
Rationale for Exclusion: While home opioid medication showed a statistically significant effect, it did not lead to meaningful improvement in model performance metrics such as AUC, Brier score, AIC, or BIC. This suggests that while opioids have an effect, their inclusion does not enhance the model's predictive accuracy or reliability significantly compared to the included factors.
Expected Outcome: Normally, significant predictors that improve model performance are retained. However, if their inclusion does not enhance or potentially complicates the model without clear benefits, they are not included.

4.4.7 *[If risk factors are addressed by any method (4.4.1)]* **Final Approach to Address Risk Factors***

After testing, what methods or approaches were ultimately used to control for the effects of risk factors? (Note: The final approach should be supported by the testing and the rationale provided in 4.4.2-4.4.6). Choose all that apply.

☒ Statistical risk-adjustment model with risk factors
☐ Stratification by risk factor category
☐ Other

4.4.1a Describe other method(s) used

☐ No risk adjustment or stratification.

Section 5. Equity

5.1 Contributions Toward Advancing Health Equity *(optional)*.

Describe how this measure contributes to efforts to advance health equity. Provide a description of your methodology and approach to empirical testing of differences in performance scores across multiple socio-contextual variables (e.g., race, ethnicity, urbanicity/rurality, socioeconomic status, sex, gender identity, sexual orientation, age). Provide an interpretation of the results, including interpretation of any identified differences and consideration of negative impact or unintended consequences on subgroups.

There may exist disparities in the rate of in-hospital falls. According to a report from the Leapfrog Group, the rate of in-hospital falls with hip

Quick Tip

Developer identified disparities in the rate of in-hospital falls with hip fracture based on patient characteristics identified from existing literature.
The developer conducted a disparities analysis using odds ratios to determine the degree of association between the patient characteristic and the outcome of in-hospital falls and compared findings to the existing literature.

fracture is significantly higher for patients insured by Medicare and Medicaid than for privately insured patients. This analysis also found the rate of in-hospital fall with hip fracture is also significantly lower for Non-Hispanic Black and Hispanic patients than for white patients.

Using data from 12 hospitals we conducted a social disparities analysis. Our results align with the literature as we found:

Hispanic patients have significantly lower risk of fall with injury (OR=0.36; 95% CI, 0.10-0.91) than non-Hispanic patients, after adjusting for age and other factors in the risk-adjustment model.

Black patients (OR=0.48; 36; 95% CI, 0.24-0.88) and patients of "other" race (OR=0.47; 95% CI, 0.23-0.89) have significantly lower risk of fall with injury than patients of white or "unknown" race, after adjusting for age and other factors in the risk-adjustment model.

Racial/ethnic differences are likely to reflect known variation in the prevalence of osteoporosis, as we find very few false negative cases (see above).

Risk of fall with injury is unrelated to Medicaid or uninsured status (OR=0.99), or dual eligibility among Medicare beneficiaries, after adjusting for age and other factors in the risk-adjustment model.

Reference:
Gangopadhyaya, A., Pugazhendhi, A., Austin, M., Campione, A., & Danforth, M. (2023) Racial, ethnic, and payer disparities in adverse safety events: Are there differences across Leapfrog Hospital Safety Grades? The Leapfrog Group. https://www.leapfroggroup.org/racial-ethnic-and-payer-disparities-adverse-safety-events-are-there-differences-across-leapfrog

Section 6. Use & Usability

6.2 Usability

6.2.1 Actions of Measured Entities to Improve Performance*

What are the actions measured entities must take to improve performance on this measure? How difficult are those actions to achieve and how can measured entities overcome those difficulties?

Certain protocols and prevention measures to reduce patient falls with injury include using fall risk assessment tools to gauge individual patient risk, implementing fall prevention protocols directed at individual patient risk factors, and implementing environmental rounds

to assess and correct environmental fall hazards. Recommended clinical guidelines and practices to reduce falls and injuries from falls in hospitals support many prevention activities including implementing multifactorial interventions (see clinical practice guidelines tables 11 to 27 in logic model attachment) and tailoring interventions to individual patient's conditions and needs (WFG, 2022, RNAO, 2017; ACS NSQIP/AGS, 2016; NICE, 2013). The proposed measure would enable hospitals to track and trend the number and rate of falls with major and moderate injuries to assess and improve fall intervention efforts over time and compare their performance with that of other organizations. We collected feedback from four measured entities (hospital systems) on measure usability. All four measured entities (100%) agreed that the information produced by the performance measure is easy to understand and useful for decision making. Additionally, we polled three patients/family caregivers and all agreed that the measure outcome is important to know and can help improve care for patients.

References:

Montero-Odasso, M., van der Velde, N., Martin, F. C., Petrovic, M., Tan, M. P., Ryg, J., Aguilar-Navarro, S., Alexander, N. B., Becker, C., Blain, H., Bourke, R., Cameron, I. D., Camicioli, R., Clemson, L., Close, J., Delbaere, K., Duan, L., Duque, G., Dyer, S. M., Rixt Zijlstra, G. A. (2022). World guidelines for falls prevention and management for older adults: a global initiative. Age and Ageing, 51(9), 1–36

RNAO. Preventing Falls and Reducing Injury from Falls. 4th edition. Toronto, ON; 2017

NICE. Falls in Older People: Assessing Risk and Prevention. London, UK; 2013

ACS National Surgical Quality Improvement Program (NSQIP)/ American Geriatrics Society (AGS). Optimal Perioperative Management of the Geriatric Patient: Best Practices Guideline from ACS NSQIP/AGS.; 2016. https://www.facs.org/-/media/files/quality-programs/geriatric/acs-nsqip-geriatric-2016-guidelines.ashx?la=en. Accessed July 9, 2019.

Quick Tip

Explain the actions that measured entities can take to improve their measure scores. The developer notes clinical practice guidelines and prevention activities that the entity can implement to reduce falls with injuries in the hospital. The developer also explains feedback collected from measure entities on the usability of the measure.

Quick Tip

If available, include references to supporting literature.

Section 7. Supplemental Attachment

7.1 Supplemental Attachment

If needed, you may attach additional measure information here. Please ensure that all included files are 508 compliant, including labeling all tables and figures with alternative text, as appropriate. Clearly label all components of the attachment with the field number(s) their contents refer to, and, likewise, clearly refer to any results in this attachment within the relevant text fields of the FMS.

One file only; 256 MB limit; allowed file types: .zip, .pdf, .docx, .xlsx

Hospital Harm – Falls with Injury_Logic Model and Tables_11 01 2023.pdf (p4qm.org)