Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services (CMS)

Measure Justification Form

Falls with Major Injury

Task 2, Deliverable #3-4

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Version 3

DRAFT

SUBMITTED TO
Centers for Medicare & Medicaid Services (CMS)
Center for Clinical Standards and Quality (CCSQ)

ATTENTION
Annese Abdullah-Mclaughlin
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED BY
IMPAQ International, LLC
10420 Little Patuxent Parkway
Suite 300
Columbia, MD 21044
(443)256-5500
www.impaqint.com

PROJECT
Patient Safety Measure Development and Maintenance
Contract Number: 75FCMC18D0027

TASK & DELIVERABLE
Chapter 3 Information Gathering
Deliverable 3-4 Measure Justification Form

AUTHORS
Jaqueline Stocking, University of California-Davis
Michelle Lefebvre, IMPAQ International, LLC
Mia Nievera, IMPAQ International, LLC
Anna Michie, IMPAQ International, LLC

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Overview

PROJECT TITLE: Patient Safety Measure Development and Maintenance Project

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PROJECT OVERVIEW: The Centers for Medicare & Medicaid Services (CMS) has contracted with IMPAQ International to develop, maintain, reevaluate, and implement patient safety measures for CMS' hospital-level quality reporting programs. The contract name is Patient Safety Measure Development and Maintenance. The contract number is 75FCMC18D0027 (Task Order: 75FCMC19F0001).

1. Measure Name

Hospital Harm – Falls with Major Injury

2. Type of Measure

Outcome

3. Importance

3.1 EVIDENCE TO SUPPORT THE MEASURE FOCUS

Falls with injury in the hospital setting pose significant cause of patient harm for hospitalized patients. Each year, it has been estimated that between 700,000-1,000,000 patient falls occur in the U.S, and about one-third of these falls result in injury. Of those falls, approximately 11,000 of the result in patient death.[1–3] Recent studies also suggest that there are hospitals that contain specific units with persistently low and persistently high fall rates, suggesting that disparities in care exist between hospitals.[4]

Falls can also result in additional healthcare 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.[5,6]

Despite a significant amount of research on the effectiveness of falls risk assessments and falls intervention programs, and the clinical guidelines that support their use, the literature provides little conclusive evidence for effective fall reduction. While the effectiveness of various fall prevention programs can be variable, there are certain strategies that have been proven to be effective. These include performing fall risk assessments, tailoring patient care to individual fall risks, communication between care teams, devices to alert staff about patients' fall risks (e.g., bed posters, wrist bands, handouts), and hospital safety culture.[7,8] Additionally, clinical practice guidelines focus on the prevention of inpatient falls and inpatient falls with injury, and recommended practices include conducting environmental rounds; educating patients, caregivers, and staff on fall risks and best practices to prevent falls; implementing multifactorial interventions; using hip protectors to protect patients from hip fractures; tailoring interventions to individual patient's conditions and needs; implementing universal fall precautions in older patients; and collaborating with patients and prescribers to reduce, gradually withdraw, or

discontinue medications that increase fall risk when patients' condition allows (RNAO, ACS NSQIP/AGS, NICE).[9–11]

3.1.1 This is a Measure of:

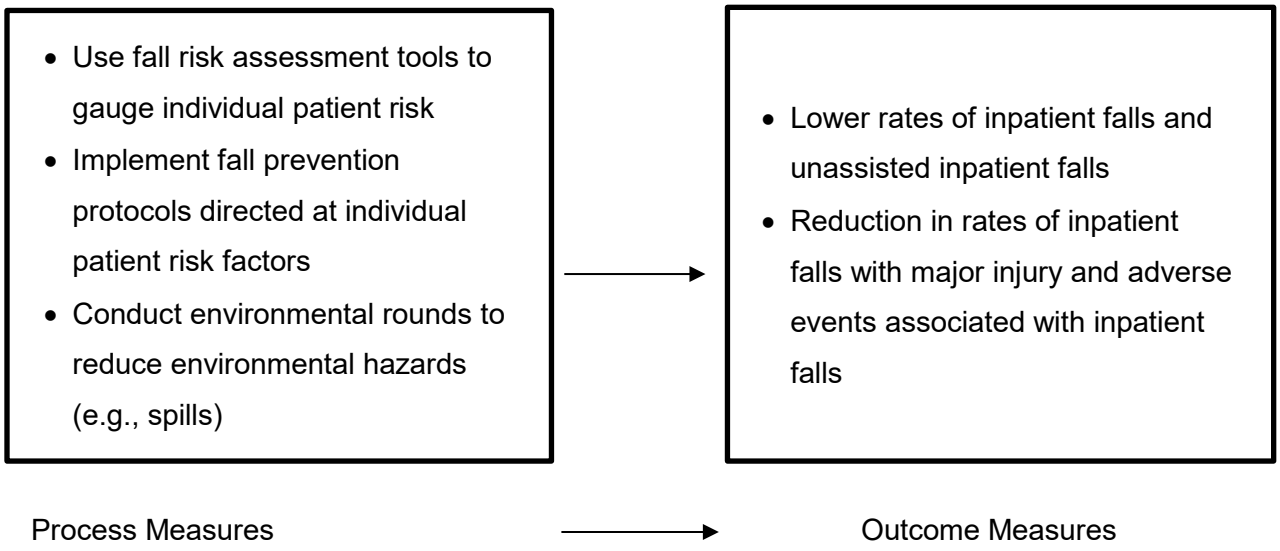
Outcome: Hospital Harm – Falls with Major Injury

3.1.2 Logic Model

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 NQF.[12]

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. The focus of this outcome electronic clinical quality measure (eCQM), however, is in-hospital falls with major injury. While even minor injuries (e.g., bruising, pain, minor wounds) resulting from in-hospital falls are indicative of significant patient harm, this measure assesses falls with major injury (e.g., fractures, closed head injuries, internal bleeding), as EHR-based documentation of these injuries is more consistent and reliable across hospital systems than documentation of less severe injuries. By focusing on falls with major injury, 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 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.

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 and tailoring interventions to individual patient's conditions and needs (RNAO, ACS NSQIP/AGS, NICE).[9–11] The scientific evidence and effectiveness on how certain falls prevention protocols impact falls with injury outcomes, however, is limited.[7,8] The intent and desired outcome for this eCQM is to work with existing falls prevention processes to track falls with major injury, and aim to reduce rates of inpatient falls resulting in major injury.



3.1.3 Value and Meaningfulness

Not applicable

3.1.4 Empirical Data (for outcomes measures) – as applicable

The NQF has identified "patient death or serious injury associated with a fall while being cared for in a health care setting" as a Serious Reportable Event.[12] Because falls are considered Serious Reportable Events and the potential for serious, preventable, harm associated with inpatient falls, many organizations—including AHRQ and the American Nurses Association-National Database of Nursing Quality Indicators (ANA-NDNQI)—have developed quality measures for patient falls with injury. There are no existing eCQM measures, however, to measure the outcome of falls with major injury.

Other studies, guidelines, and risk assessment tools have identified conducting environmental rounds to minimize environmental hazards, using fall risk assessment tools to gauge individual patient risks, and implementing fall prevention protocols directed at individual patient risk factors as evidence-based avenues for reducing falls with injury in the hospital setting.[7–10] However, evidence on many practices for reducing falls and falls with injury in the hospital setting—e.g., vitamin D supplementation, exercise, bed sensor alarms—is mixed, low-quality, or lacking.[13] Evidence for the effectiveness of in-hospital multifactorial interventions is mixed. For example, in a randomized trial, a multifactorial intervention in five geriatric rehabilitation wards, including medical, behavioral, cognitive, and environmental modifications was not associated with a significant difference in fall rates between intervention and control groups.[14] Additionally, there

was no change in fall rates and no evidence of effect on the rate of injurious falls in 24 acute medical or surgical wards following the implementation of a falls prevention program that included a nine item fall risk tool, a “falls alert” sign, supervision of patients in the bathroom, ensuring patients’ walking aids were within reach, establishment of a toileting regimen, use of a low-low bed, and use of a bed/chair alarm.[15] However, in hospital rehabilitation and geriatric wards, individualized multimedia education interventions reduced the rate of falls (adjusted RaR 0.60 [95% CI, 0.42-0.94]) and the rate of injurious falls (adjusted RaR 0.65 [95% CI, 0.42-0.88]).[16]

A recent publication by AHRQ has identified a downward trend in inpatient fall rates over time. In 2014, the measured baseline rate of inpatient falls was 239,000, compared to a preliminary 2016 normalized fall count of 218,000, for an overall 9% reduction in inpatient fall rates from 2014 to 2016.[17] Additionally, between 2014 and 2016, this reduction in inpatient falls was associated with an estimated cost savings of $137,670,000 and 1,000 fewer deaths due to inpatient falls.[17] AHRQ cited financial incentives created by CMS and other payers’ payment policies, public reporting of hospital-level results, technical assistance offered by the Quality Improvement Organization (QIO) program to hospitals, and technical assistance and catalytic efforts of the Department of Health and Human Services (HHS) Partnership for Patients (PfP) initiative led by CMS as likely contributing factors to downward trends in HACs over time. Despite this downward trend, more work is needed to reduce the hospital harm and healthcare costs associated with patient falls.

Knowledge of falls trends provides evidence that an outcome measure focused on measuring falls with major injury, along with established process-based falls interventions, will aim to reduce both falls and major injuries associated with inpatient falls. However, the literature is not clear, and remains grey, on whether there is a continuum between the falls with injury prevention processes and the outcome of a reduction of falls with injury. In the long-term, this measure provides a path to directly engage hospital staff and executives on the importance of inpatient fall prevention and reducing the risk of major injuries sustained from falls and will be a tool for quality improvement for staff to assess internal metrics. This eCQM additionally provides CMS with an instrument to assess the quality of care in reducing fall and fall-related major injury risk for patients across all acute care hospitals.

3.1.5 Systematic Review of the Evidence (for intermediate outcome, process, or structure performance measures, including those that are instrument-based) – as applicable

Not applicable

3.1.6 Other Source of Evidence – as applicable

3.1.6.1 Briefly Synthesize the Evidence

Not applicable

3.1.6.2 Process Used to Identify the Evidence

Not applicable

3.1.6.3 Citations for the Evidence

Not applicable

3.2 PERFORMANCE GAP AND OPPORTUNITY FOR IMPROVEMENT

Despite reductions in inpatient falls with injuries rates in recent years reported by AHRQ, the rate of inpatient falls resulting in injury or death remain high in the United States. Moreover, there are medical units with persistently low and persistently high fall rates, suggesting that disparities in care exist between hospitals.[4] One study of 800 medical units in 470 hospitals found that 87 percent of 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.[4] This suggests that there remains room for improvement in units with high fall rates.

At this time, this measure has not gone through the testing process. This measure will seek public comment in Summer 2021.

3.2.1 Rationale

This eCQM relates to falls with major injury in the hospital setting. Rates of in-hospital falls with major injury (e.g., fractures, closed head injuries, internal bleeding) can be considered an indicator of the quality of care provided by a hospital. Falls with injury are associated with a range of harms including poor clinical outcomes, increased length of hospital stay, and death in some cases.[2,3] The rate of falls varies across hospitals, which suggests that there are opportunities for improvement in fall prevention.[4]

The implementation of this eCQM will aim to achieve several improvements in quality, including encouraging providers to develop interventions aimed at reducing inpatient falls and injuries resulting from inpatient falls. In addition to avoiding direct patient harm from falls with major injury, lower rates of falls with major injury among hospital patients would be expected to result in lower rates of mortality and reduced lengths of hospital stays. Adoption of this eCQM has the potential to improve the quality of care for all patients and, therefore, advance the quality of care in patient safety, which is a priority area identified by the National Quality Strategy.[18] This will fill a gap in measurement and provide incentives for hospital quality improvement, as there is no existing falls with major injury outcome measure in any CMS program that is EHR-based, and there is no existing NQF-endorsed falls with major injury outcome measure with a target population of all hospital patients. With a systematic EHR-based patient safety measure in place, hospitals can more reliably assess harm reduction efforts and modify their improvement efforts in near real-time. In addition, greater achievements in reducing harms from falls with injury and enhancing hospital performance on patient safety outcomes can be expected.

3.2.2 Performance Scores

TBD

3.2.3 Summary of Data Indicating Opportunity

Despite reductions in inpatient falls with injuries rates in recent years reported by AHRQ, the rate of inpatient falls resulting in injury or death remain high 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.[1,3] Moreover, there are medical units with persistently low and persistently high fall rates, suggesting that disparities in care exist between hospitals.[4] One study of 800 medical units in 470 hospitals found that 87 percent of 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.[4] This suggests that there remains room for improvement in units with high fall rates.

At this time, this measure has not gone through the testing process and will seek public comment in Summer 2021.

3.2.4 Disparities

Not applicable

3.2.5 Provide summary of data if no or limited data

Not applicable

4. Scientific Acceptability

4.1 DATA SAMPLE DESCRIPTION

Electronic Health Records

4.1.1 What Type of Data Were Used for Testing?

Abstracted from Electronic Health Records. At this time, this measure is still being specified and has not gone through the testing process.

4.1.2 Identify the Specific Dataset

TBD

4.1.3 What Are the Dates of the Data Used in Testing?

TBD

4.1.4 What Levels of Analysis Were Tested?

Hospital/facility/agency

4.1.5 How Many and Which Measured Entities were Included in the Testing and Analysis?

TBD

4.1.6 How Many and Which Measured Patients Were Included in the Testing and Analysis?

TBD

4.1.7 Sample Differences If applicable

TBD

4.1.8 What are the social risk factors that were available and analyzed?

Not applicable

4.2 RELIABILITY TESTING (FOR REFERENCE ONLY)

4.2.1 Level of Reliability Testing

TBD. At this time, this measure is still being specified and has not gone through the testing process. The measure will seek public comment in Summer 2021.

4.2.2 Method of Reliability Testing

TBD

4.2.3 Statistical Results from Reliability Testing

TBD

4.2.4 Interpretation

TBD

4.3 VALIDITY TESTING (FOR REFERENCE ONLY)

TBD. At this time, this measure is still being specified and has not gone through the testing process. The measure will seek public comment in Summer 2021.

4.3.1 Level of Validity Testing

TBD

4.3.2 Method of Validity Testing

TBD

4.3.3 Statistical Results from Validity Testing

TBD

4.3.4 Interpretation

TBD

4.4 EXCLUSION ANALYSIS (FOR REFERENCE ONLY)

TBD

4.4.1 Method of Testing Exclusions

TBD

4.4.2 Statistical Results from Testing Exclusions

TBD

4.4.3 Interpretation

TBD

4.5 RISK ADJUSTMENT OR STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURE (FOR REFERENCE ONLY)

TBD. At this time, this measure is still being specified and has not gone through the testing process. The measure will seek public comment in Summer 2021.

4.5.1 Methods of Controlling for Differences

TBD

4.5.2 Rationale Why Risk Adjustment is Not Needed

TBD

4.5.3 Conceptual, Clinical, and Statistical Methods

TBD

4.5.4 Conceptual Model of Impact of Social Risks

TBD

4.5.5 Statistical Results

TBD

4.5.6 Analyses and Interpretation in Selection of Social Risk Factors

TBD

4.5.7 Methods Used to Develop the Statistical Model or Stratification Approach

TBD

4.5.8 Statistical Risk Model Discrimination Statistics

TBD

4.5.9 Statistical Risk Model Calibration Statistics

TBD

4.5.10 Statistical Risk Model Calibration – Risk decile plots or calibration curves

TBD

4.5.11 Results of Risk Stratification Analysis

TBD

4.5.12 Interpretation

TBD

4.5.13 Optional Additional Testing for Risk Adjustment

TBD

4.6 IDENTIFICATION OF MEANINGFUL DIFFERENCES IN PERFORMANCE (FOR REFERENCE ONLY)

TBD. At this time, this measure is still being specified and has not gone through the testing process. The measure will seek public comment in Summer 2021.

4.6.1 Method

TBD

4.6.2 Statistical Results

TBD

4.6.3 Interpretation

TBD

4.7 COMPARABILITY OF MULTIPLE DATA SOURCES/METHODS (FOR REFERENCE ONLY)

Not applicable

4.7.1 Method

Not applicable

4.7.2 Statistical Results

Not applicable

4.7.3 Interpretation

Not applicable

4.8 MISSING DATA ANALYSIS AND MINIMIZING BIAS (FOR REFERENCE ONLY)

TBD. At this time, this measure is still being specified and has not gone through the testing process. The measure will seek public comment in Summer 2021.

4.8.1 Method

TBD

4.8.2 Missing Data Analysis

TBD

4.8.3 Interpretation

TBD

5. Feasibility

5.1 DATA ELEMENTS GENERATED AS BYPRODUCT OF CARE PROCESSES

Data elements are from the electronic health record. At this time, this measure is still being specified and has not gone through the testing and feasibility process. The measure will seek public comment in Summer 2021.

5.2 ELECTRONIC SOURCES

Data elements are generated for the measure scores through the electronic health record during the provision of care. At this time, this measure is still being specified and has not gone through the testing and feasibility process. The measure will seek public comment in Summer 2021.

5.2.1 Data Elements Electronic Availability

All data elements are in defined fields in EHRs. The list of data elements can be found in Section 3.3 of the Measure Information Form.

5.2.2 Path to Electronic Capture

TBD

5.2.3 eCQM Feasibility

TBD. At this time, this measure is still being specified and has not gone through the testing and feasibility process. The measure will seek public comment in Summer 2021.

5.3 DATA COLLECTION STRATEGY

TBD

5.3.1 Data Collection Strategy Difficulties (optional)

TBD

5.3.2 Fees, Licensing, Other Requirements

TBD

6. Usability and Use

6.1 USE

At this time, this measure is still being specified and has not gone through the testing and feasibility process. The measure will seek public comment in Summer 2021.

6.1.1 Current and Planned Use

Public reporting - TBD

- Purpose - TBD
- Geographic area - Nationwide
- Number and percentage of accountable entities and patients included - TBD
- Level of measurement – Facility
- Setting – Hospital

Payment program – TBD

- Purpose- TBD
- Geographic area - Nationwide
- Number and percentage of accountable entities and patients included - TBD
- Level of measurement – Facility
- Setting – Hospital

Quality improvement internal to a specific organization

- Purpose - TBD
- Geographic area - Nationwide
- Number and percentage of accountable entities and patients included - TBD
- Level of measurement – Facility
- Setting – Hospital

6.1.1.1 Reasons for Not Publicly Reporting or Use in Other Accountability Application

Not applicable

6.1.1.2 Plan for Implementation

TBD. At this time, this measure is still being specified and has not gone through the testing and feasibility process. The measure will seek public comment in Summer 2021.

6.1.2 Feedback on the measure by those being measured or others

TBD. The measure will seek public comment in Summer 2021.

6.1.2.1 Technical Assistance Provided During Development or Implementation

TBD

6.1.2.2 Technical Assistance with Results

TBD

6.1.2.3 Feedback on Measure Performance and Implementation

TBD

6.1.2.4 Feedback from Providers being Measure

TBD

6.1.2.5 Feedback from Other Users

TBD

6.1.2.6 Consideration of Feedback

TBD

6.2 USABILITY

At this time, this measure is still being specified and has not gone through the testing and feasibility process. The measure will seek public comment in Summer 2021.

6.2.1 Improvement

TBD

6.2.2 Unexpected Findings

TBD

6.2.2.1 Unexpected Benefits

TBD

7. Related and Competing Measures

7.1 RELATION TO OTHER NQF-ENDORSED MEASURES

There is only one existing NQF-endorsed falls with injury measure – "PSI 08: In Hospital Fall with Hip Fracture Rate" (NQF #0531, endorsed as part of PSI 90 composite). PSI 08 identifies patients with a claim for hip fracture repair that suffered a fall during a patient encounter. PSI-08 is a claims-based measure, and as such is focused solely on the Medicare/Medicaid population. Additionally, the numerator for this measure includes only patients with a procedure code for hip fracture. Therefore, the Hospital Harm – Falls with Major Injury measure provides the opportunity to assess the rate of falls with injury in a much larger patient population.

7.2 HARMONIZATION

The Hospital Harm – Falls with Major Injury measure has a different focus than the existing falls with injury NQF-endorsed measure, "PSI 08: In Hospital Fall with Hip Fracture Rate" (NQF #0531, endorsed as part of PSI 90 composite). The target population for PSI-08 includes medical and surgical patient populations, but the outcome currently only focuses on hip fracture. The proposed measure includes all hospital patients over 18 years of age who suffer any of the listed major injuries. Additionally, the proposed measure identifies falls with injury over patient days, while PSI 08 measures falls with hip fracture over patient discharges. This proposed Falls with Major Injury measure would be the first NQF-endorsed falls with major injury eCQM.

7.3 COMPETING MEASURES

Not applicable

8. Appendix

TBD

Co.1.—Measure Steward Point of Contact
Co.1.1. Organization
Co.1.2. First Name
Co.1.3. Last Name
Co.1.4. Email Address
Co.1.5. Phone Number ( ) ext.
Co.2.—Developer Point of Contact (indicate if same as Measure Steward Point of Contact)
Co.2.1. Organization
Co.2.2. First Name
Co.2.3. Last Name
Co.2.4. Email Address
Co.2.5. Phone Number ( ) ext.

Other Additional Information
Ad.1. Working Group/Expert Panel Involved in Measure Development
List the working group/panel members' names and organizations
Describe the members' role in measure development
Measure Developer/Steward Updates and Ongoing Maintenance
Ad.2. Year the Measure Was First Released
Ad.3. Month and Year of Most Recent Revision
Ad.4. What is your frequency for review/update of this measure?
Ad.5. When is your next scheduled review/update for this measure?
Ad.6. Copyright Statement
Ad.7. Disclaimers
Ad.8. Additional Information/Comments

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