CBE ID

4120e

Title

Hospital Harm – Falls with Injury

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Fall 2023

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

New

1.3 Electronic Clinical Quality Measure (eCQM)

Yes

1.6 Measure Description

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.

1.7 Composite Measure

No

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Hospital: Inpatient

1.10 Measure Rationale

N/A this is not a paired measure.

A website URL not available; Final measure specifications for implementation will be made publicly available on CMS' appropriate quality website, once finalized through the CBE endorsement and CMS rulemaking processes.

1.11 Measure Webpage

http://notavailable.com/seerationaleabove

1.12a Attach MADiE Output

CMS1017-v1-0-020-QDM-5-6_0.zip

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

Falls with Injury Value Set Directory 11 01 2023.zip

1.14 Numerator

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

1.14a Numerator Details

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)

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.

1.15 Denominator

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. Inpatient hospitalizations where the patient has a fall diagnosis present on admission are excluded from the denominator. Measure observation associated with the Denominator: The total number of eligible days across all encounters which match the initial population/denominator criteria.

1.15a Denominator Details

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.

1.15b Denominator Exclusions

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

1.15c Denominator Exclusions Details

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

Other

1.16a Other Scoring Method

Ratio

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

See attached.

1.18a Attach measure score calculation diagram

Falls with Injury_Measure Calculation Diagram 11 01 2023.pdf

1.19 Measure Stratification Details

N/A; this measure is not stratified.

1.20 Types of Data Sources

Electronic Health Records

1.25 Data Source Details

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.

1.26 Minimum Sample Size

N/A; this measure does not use a sample.

2.1 Attach Logic Model

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

2.2 Evidence of Measure Importance

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.

References:

1. AHRQ. (2019). Patient Safety Primer: Falls. Retrieved July 24, 2019, from AHRQ PSNet website: https://psnet.ahrq.gov/primers/primer/40/Falls
2. 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.
3. 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.
4. 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.
5. 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-chartbo...
6. 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-c...
7. 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-chartbo...
8. 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
9. 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 Anticipated Impact

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 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 (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.

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

See **Table 1 and Exhibit 2 in the logic model attachment** for a distribution of performance scores across sites.

References:

1. 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.
2. 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.
3. 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

2.5 Health Care Quality Landscape

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

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 from public comments, 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 member additionally stressed that the proposed measure has importance from a patient safety standpoint.

References:

1. 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
2. NICE. *Falls in Older People: Assessing Risk and Prevention*. London, UK; 2013
3. RNAO. *Preventing Falls and Reducing Injury from Falls*. 4th edition. Toronto, ON; 2017
4. 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

3.1 Contributions Towards Closing Care Gaps

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 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:

1. 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-adver...

4.1 Feasibility Assessment

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. 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.

4.2 Attach Feasibility Scorecard

Falls_COMBINED_Feasibility_Scorecard_EXTERNAL 11 01 2023.xlsx

4.3 Feasibility Informed Final Measure

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

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

4.4a Fees, Licensing, or Other Requirements

There are no fees associated with the use of this eCQM. Value sets are housed in the Value Set Authority Center (VSAC), which is provided by the National Library of Medicine (NLM), in coordination with the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services.

Viewing or downloading value sets requires a free Unified Medical Language System® (UMLS) Metathesaurus License, due to usage restrictions on some of the codes included in the value sets. Individuals interested in accessing value set content can request a UMLS license at https://uts.nlm.nih.gov/uts/.

5.1.1 Data Used for Testing

We recruited 4 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.

5.1.2 Differences in Data

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 3 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).

5.1.3 Characteristics of Measured Entities

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.

5.1.4 Characteristics of Units of the Eligible Population

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.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

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

References

1. Dickens, William T. "Error components in grouped data: is it ever worth weighting?." The Review of Economics and Statistics (1990): 328-333.
2. Landis, J. Richard, and Gary G. Koch. "The measurement of observer agreement for categorical data." biometrics (1977): 159-174.
3. 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

5.2.3 Reliability Testing Results

Signal-to-noise reliability was estimated as an intraclass correlation coefficient based on a two-way mixed model with facility random effects (C,1).

- Minimum: 0.195
- 25th percentile: 0.746
- Median: 0.826
- 75th percentile: 0.892
- Maximum: 0.948

Exhibit 3 in the logic model attachment shows the distribution of SNRs across test sites.

5.2.4 Interpretation of Reliability Results

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 2 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 HH-Falls, as currently specified, can distinguish the true performance in hospital acquired falls with major or moderate injury from one hospital to another.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.826	0.195											0.948
Mean Performance Score	12	1											1
N of Entities	193398	451											40286

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity), Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

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).
- **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.

To evaluate the empirical impact of each exclusion criterion:

1. 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.
2. 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.

5.3.4 Validity Testing Results

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' 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).

5.3.5 Interpretation of Validity Results

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.

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%.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

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-patie…).

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.

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.

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 1237 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 6090 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 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

1. 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-c…
2. Lackoff, A. S., Hickling, D., Collins, P. F., Stevenson, K. J., Nowicki, T. A., & Bell, J. J. (2020). The association of malnutrition with falls and harm from falls in hospital inpatients: Findings from a 5-year observational study. Journal of clinical nursing, 29(3-4), 429–436. https://doi.org/10.1111/jocn.15098
3. G R Neri S, S Oliveira J, B Dario A, M Lima R, Tiedemann A. Does Obesity Increase the Risk and Severity of Falls in People Aged 60 Years and Older? A Systematic Review and Meta-analysis of Observational Studies. J Gerontol A Biol Sci Med Sci. 2020;75(5):952-960. doi:10.1093/gerona/glz272
4. Bellanti, F., Lo Buglio, A., Quiete, S., & Vendemiale, G. (2022). Malnutrition in Hospitalized

Old Patients: Screening and Diagnosis, Clinical Outcomes, and Management. Nutrients, 14(4), 910. https://doi.org/10.3390/nu14040910

5. Vivanti, A., Ward, N. & Haines, T. Nutritional status and associations with falls, balance, mobility and functionality during hospital admission. J Nutr Health Aging 15, 388–391 (2011). https://doi.org/10.1007/s12603-010-0302-8
6. Sillner AY, Holle CL, Rudolph JL. The Overlap Between Falls and Delirium in Hospitalized Older Adults: A Systematic Review. Clin Geriatr Med. 2019;35(2):221-236. doi:10.1016/j.cger.2019.01.004
7. Stubbs, B., Mueller, C., Gaughran, F., Lally, J., Vancampfort, D., Lamb, S. E., Koyanagi, A., Sharma, S., Stewart, R., & Perera, G. (2018). Predictors of falls and fractures leading to hospitalization in people with schizophrenia spectrum disorder: A large representative cohort study. Schizophrenia research, 201, 70–78. https://doi.org/10.1016/j.schres.2018.05.010
8. AHRQ Patient Safety Indicators (PSI) Parameter Estimates, v2023 https://qualityindicators.ahrq.gov/Downloads/Modules/PSI/V2023/Paramete...
9. Homann B, Plaschg A, Grundner M, et al. The impact of neurological disorders on the risk for falls in the community dwelling elderly: a case-controlled study. BMJ Open. 2013;3(11):e003367. Published 2013 Nov 25. doi:10.1136/bmjopen-2013-003367
10. Jørgensen TS, Hansen AH, Sahlberg M, Gislason GH, Torp-Pedersen C, Andersson C, Holm E. Nationwide time trends and risk factors for in-hospital falls-related major injuries. Int J Clin Pract. 2015 Jun;69(6):703-9. doi: 10.1111/ijcp.12624. Epub 2015 Feb 24. PMID: 25707918.
11. Sterke CS, van Beeck EF, van der Velde N, et al. New insights: dose-response relationship between psychotropic drugs and falls: a study in nursing home residents with dementia. J Clin Pharmacol. 2012;52(6):947-955. doi:10.1177/0091270011405665
12. Oliver D, Connelly JB, Victor CR, et al. Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. BMJ. 2007;334(7584):82. doi:10.1136/bmj.39049.706493.55
13. Allen NE, Schwarzel AK, Canning CG. Recurrent falls in Parkinson's disease: a systematic review. Parkinsons Dis. 2013;2013:906274. doi:10.1155/2013/906274
14. Cameron MH, Nilsagard Y. Balance, gait, and falls in multiple sclerosis. Handb Clin Neurol. 2018;159:237-250. doi:10.1016/B978-0-444-63916-5.00015-X
15. Giannì C, Prosperini L, Jonsdottir J, Cattaneo D. A systematic review of factors associated with accidental falls in people with multiple sclerosis: a meta-analytic approach. Clin Rehabil. 2014;28(7):704-716. doi:10.1177/0269215513517575
16. Pati S, Kumaraswamy VM, Deep A, et al. Characteristics of falls in the epilepsy monitoring unit: a retrospective study. Epilepsy Behav. 2013;29(1):1-3. doi:10.1016/j.yebeh.2013.06.013
17. Spritzer SD, Riordan KC, Berry J, et al. Fall prevention and bathroom safety in the epilepsy monitoring unit. Epilepsy Behav. 2015;48:75-78. doi:10.1016/j.yebeh.2015.05.026
18. Djurovic, O., Mihaljevic, O., Radovanovic, S., Kostic, S., Vukicevic, M., Brkic, B. G., Stankovic, S., Radulovic, D., Vukomanovic, I. S., & Radevic, S. R. (2021). Risk Factors Related to Falling in Patients after Stroke. Iranian journal of public health, 50(9), 1832–1841. https://doi.org/10.18502/ijph.v50i9.7056
19. Forns J, Layton JB, Bartsch J, Turner ME, Dempsey C, Anthony M, Ritchey ME, Demos G. Increased risk of falls and fractures in patients with psychosis and Parkinson disease. PLoS One. 2021 Jan 27;16(1):e0246121. doi: 10.1371/journal.pone.0246121. PMID: 33503061; PMCID: PMC7840029.

20. Thurman DJ, Stevens JA, Rao JK; Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: Assessing patients in a neurology practice for risk of falls (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2008;70(6):473-479. doi:10.1212/01.wnl.0000299085.18976.20
21. Hodgson, G., Pace, A., Carfagnini, Q., Ayanso, A., Gardner, P., Narushima, M., Ismail, Z., & Faught, B. E. (2023). Risky Business: Factors That Increase Risk of Falls Among Older Adult In-Patients. Gerontology & geriatric medicine, 9, 23337214231189930. https://doi.org/10.1177/23337214231189930
22. https://www.ihi.org/resources/_layouts/download.aspx?SourceURL=%2fresou...
23. https://www.patientsafety.va.gov/docs/fallstoolkit14/falls_implementati...
24. Aryee E, James SL, Hunt GM, Ryder HF. Identifying protective and risk factors for injurious falls in patients hospitalized for acute care: a retrospective case-control study. BMC Geriatr. 2017;17(1):260. Published 2017 Nov 7. doi:10.1186/s12877-017-0627-9
25. Giorgio di Laura Frattura G, Filardo G, Giunchi D, Fusco A, Zaffagnini S, Candrian C. Risk of falls in patients with knee osteoarthritis undergoing total knee arthroplasty: A systematic review and best evidence synthesis [published correction appears in J Orthop. 2020 Dec 15;24:292]. J Orthop. 2018;15(3):903-908. Published 2018 Aug 24. doi:10.1016/j.jor.2018.08.026
26. Tanya M. Wildes, Priya Dua, Susan A. Fowler, J. Philip Miller, Christopher R. Carpenter, Michael S. Avidan, Susan Stark,Systematic review of falls in older adults with cancer,Journal of Geriatric Oncology,Volume 6, Issue 1,2015,Pages 70-83,SSN 1879-4068, https://doi.org/10.1016/j.jgo.2014.10.003.
27. Martí-Dillet, M. M., Fernández-Rodriguez, C., Ginesta-Guanter, A., & Suñer-Soler, R. (2023). Accumulated incidence of falls in people hospitalised with cancer and related factors. Nursing open, 10(8), 5571–5577. https://doi.org/10.1002/nop2.1799
28. Lorca LA, Sacomori C, Balagué-Ávila VP, Pino-Márquez LP, Quiroz-Vidal FA, Ortega L. Incidence and risk of falls in patients treated for hematologic malignancies in the Intensive Hematology Unit. Incidência e risco de quedas em pacientes tratados por neoplasias hematológicas na Unidade de Hematologia Intensiva. Rev Lat Am Enfermagem. 2019;27:e3145. Published 2019 Apr 29. doi:10.1590/1518-8345.2953-3145
29. Kong QH, Wang Y, Song CG, et al. Prospective analysis of the risk factors for falls in lymphoma patients. Eur J Oncol Nurs. 2014;18(5):540-544. doi:10.1016/j.ejon.2014.03.016
30. O'Leary JG, Greenberg CS, Patton HM, Caldwell SH. AGA Clinical Practice Update: Coagulation in Cirrhosis. Gastroenterology. 2019 Jul;157(1):34-43.e1. doi: 10.1053/j.gastro.2019.03.070. Epub 2019 Apr 12. PMID: 30986390.
31. Murphy SL, Tapper EB, Blackwood J, Richardson JK. Why Do Individuals with Cirrhosis Fall? A Mechanistic Model for Fall Assessment, Treatment, and Research. Dig Dis Sci. 2019;64(2):316-323. doi:10.1007/s10620-018-5333-8
32. Acharya C, White MB, Fagan A, et al. Liver Transplant Is Associated with Sustained Improvement in Tandem Gait and Risk of Falls. Dig Dis Sci. 2021;66(4):1360-1366. doi:10.1007/s10620-020-06261-y
33. Llompart-Pou JA, Pérez-Bárcena J, Chico-Fernández M, Sánchez-Casado M, Raurich JM. Severe trauma in the geriatric population. World J Crit Care Med. 2017 May 4;6(2):99-106. doi: 10.5492/wjccm.v6.i2.99. PMID: 28529911; PMCID: PMC5415855.
34. Pandya N, Bookhart B, Mody SH, Funk Orsini PA, Reardon G. Study of anemia in long-term care (SALT): prevalence of anemia and its relationship with the risk of falls in nursing home

residents. Curr Med Res Opin. 2008;24(8):2139-2149. doi:10.1185/03007990802215844
35. Callis N. Falls prevention: Identification of predictive fall risk factors. Appl Nurs Res. 2016 Feb;29:53-8. doi: 10.1016/j.apnr.2015.05.007. Epub 2015 May 22. PMID: 26856489.
36. Yoshikawa A, Ramirez G, Smith ML, et al. Opioid Use and the Risk of Falls, Fall Injuries and Fractures among Older Adults: A Systematic Review and Meta-Analysis. J Gerontol A Biol Sci Med Sci. 2020;75(10):1989-1995. doi:10.1093/gerona/glaa038
37. Cox, J., Thomas-Hawkins, C., Pajarillo, E., DeGennaro, S., Cadmus, E., & Martinez, M. (2015). Factors associated with falls in hospitalized adult patients. Applied nursing research : ANR, 28(2), 78–82. https://doi.org/10.1016/j.apnr.2014.12.003
38. Seppala LJ, Wermelink AMAT, de Vries M, Ploegmakers KJ, van de Glind EMM, Daams JG, van der Velde N; EUGMS task and Finish group on fall-risk-increasing drugs. Fall-Risk-Increasing Drugs: A Systematic Review and Meta-Analysis: II. Psychotropics. J Am Med Dir Assoc. 2018 Apr;19(4):371.e11-371.e17. doi: 10.1016/j.jamda.2017.12.098. PMID: 29402652.
39. Park H, Satoh H, Miki A, Urushihara H, Sawada Y. Medications associated with falls in older people: systematic review of publications from a recent 5-year period. Eur J Clin Pharmacol. 2015 Dec;71(12):1429-40. doi: 10.1007/s00228-015-1955-3. Epub 2015 Sep 26. PMID: 26407688
40. Shuto, H., Imakyure, O., Matsumoto, J., Egawa, T., Jiang, Y., Hirakawa, M., Kataoka, Y. and Yanagawa, T. (2010), Medication use as a risk factor for inpatient falls in an acute care hospital: a case-crossover study. British Journal of Clinical Pharmacology, 69: 535-542. https://doi.org/10.1111/j.1365-2125.2010.03613.x
41. O'Neil CA, Krauss MJ, Bettale J, et al. Medications and Patient Characteristics Associated With Falling in the Hospital. J Patient Saf. 2018;14(1):27-33. doi:10.1097/PTS.0000000000000163
42. Domingue, S., Morelock, S., Walsh, J., Newcomb, P., Russe, C., Nava, A., Jones, A., & John, J. R. (2018). Beyond fall risk assessment: A case-control study in an Urban Medical Center. Journal of clinical nursing, 27(21-22), 3894–3899. https://doi.org/10.1111/jocn.14635
43. Currie LM. Fall and Injury Prevention. In: Hughes RG, editor. Patient safety and quality: An evidence-based handbook for nurses. Rockville, MD: Agency for Healthcare Research and Quality; 2008. pp. 1–195.pp. 191–250.
44. Kahlaee, H.R., Latt, M.D. & Schneider, C.R. Comment on: A Systematic Review and Meta-Analyses of the Association Between Anti-hypertensive Classes and the Risk of Falls Among Older Adults. Drugs Aging 36, 93–94 (2019). https://doi.org/10.1007/s40266-018-0607-6
45. Shimbo D, Barrett Bowling C, Levitan EB, et al. Short-Term Risk of Serious Fall Injuries in Older Adults Initiating and Intensifying Treatment With Antihypertensive Medication. Circ Cardiovasc Qual Outcomes. 2016;9(3):222-229. doi:10.1161/CIRCOUTCOMES.115.002524
46. Seppala LJ, van de Glind EMM, Daams JG, Ploegmakers KJ, de Vries M, Wermelink AMAT, van der Velde N; EUGMS Task and Finish Group on Fall-Risk-Increasing Drugs. Fall-Risk-Increasing Drugs: A Systematic Review and Meta-analysis: III. Others. J Am Med Dir Assoc. 2018 Apr;19(4):372.e1-372.e8. doi: 10.1016/j.jamda.2017.12.099. Epub 2018 Mar 2. PMID: 29402646.
47. De Vries M, Seppala LJ, Daams JG, van de Glind EMM, Masud T, van der Velde N; EUGMS Task and Finish Group on Fall-Risk-Increasing Drugs. Fall-Risk-Increasing Drugs: A Systematic Review and Meta-Analysis: I. Cardiovascular Drugs. J Am Med Dir Assoc. 2018 Apr;19(4):371.e1-371.e9. doi: 10.1016/j.jamda.2017.12.013. Epub 2018 Feb 12. PMID: 29396189.

48. By the 2019 American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694. doi:10.1111/jgs.15767
49. Berry SD, Mittleman MA, Zhang Y, et al. New loop diuretic prescriptions may be an acute risk factor for falls in the nursing home. Pharmacoepidemiol Drug Saf. 2012;21(5):560-563. doi:10.1002/pds.3256
50. Lim LS, Fink HA, Blackwell T, Taylor BC, Ensrud KE. Loop diuretic use and rates of hip bone loss and risk of falls and fractures in older women. J Am Geriatr Soc. 2009;57(5):855-862. doi:10.1111/j.1532-5415.2009.02195.x
51. Woolcott, J. C., Richardson, K. J., Wiens, M. O., Patel, B., Marin, J., Khan, K. M., & Marra, C. A. (2009). Meta-analysis of the impact of 9 medication classes on falls in elderly persons. Archives of internal medicine, 169(21), 1952–1960. https://doi.org/10.1001/archinternmed.2009.357
52. De Jong MR, Van der Elst M, Hartholt KA. Drug-related falls in older patients: implicated drugs, consequences, and possible prevention strategies. Ther Adv Drug Saf. 2013;4(4):147-154. doi:10.1177/2042098613486829
53. Castaldi S, Principi N, Carnevali D, et al. Correlation between fall risk increasing drugs (FRIDs) and fall events at a rehabilitation hospital. Acta Biomed. 2022;92(6):e2021397. Published 2022 Jan 19. doi:10.23750/abm.v92i6.11340
54. 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
55. Dunne, T. J., Gaboury, I., & Ashe, M. C. (2014). Falls in hospital increase length of stay regardless of degree of harm. Journal of evaluation in clinical practice, 20(4), 396–400. https://doi.org/10.1111/jep.12144
56. Kim, J., Lee, E., Jung, Y., Kwon, H. & Lee, S. (2022). Patient-level and organizational-level factors influencing in-hospital falls. Journal of Advanced Nursing, 78(11), 3641–3651. https://doi.org/10.1111/jan.15254
57. Zecevic, A. A., Chesworth, B. M., Zaric, G. S., Huang, Q., Salmon, A., McAuslan, D., Welch, R., & Brunton, D. (2012). Estimating the cost of serious injurious falls in a Canadian acute care hospital. Canadian journal on aging = La revue canadienne du vieillissement, 31(2), 139–147. https://doi.org/10.1017/S0714980812000037
58. Morello, R. T., Barker, A. L., Watts, J. J., Haines, T., Zavarsek, S. S., Hill, K. D., Brand, C., Sherrington, C., Wolfe, R., Bohensky, M. A., & Stoelwinder, J. U. (2015). The extra resource burden of in-hospital falls: a cost of falls study. The Medical journal of Australia, 203(9), 367. https://doi.org/10.5694/mja15.00296
59. Najafpour, Z., Godarzi, Z., Arab, M., & Yaseri, M. (2019). Risk Factors for Falls in Hospital In-Patients: A Prospective Nested Case Control Study. International journal of health policy and management, 8(5), 300–306. https://doi.org/10.15171/ijhpm.2019.11
60. Noel SE, Santos MP, Wright NC. Racial and Ethnic Disparities in Bone Health and Outcomes in the United States. J Bone Miner Res. 2021 Oct;36(10):1881-1905. doi: 10.1002/jbmr.4417.

5.4.2a Attach Conceptual Model

Graphic for Falls RA Conceptual Model 11 01 2023.zip

5.4.3 Variable Distribution Across Measured Entities

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.

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

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.

1. Randomly partitioned the full denominator data into a 70% training set and a 30% hold-out (model performance or evaluation) test set.
2. 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.

3. 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.
4. 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.
5. 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.
6. 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.
7. The risk-adjustment model was also tested with additional social drivers of health variables (Medicaid insurance, Hispanic ethnicity, Race), considered individually and collectively.

References

1. T. Hastie, R. Tibshirani, J. Friedman, The Elements of Statistical Learning (Springer, 2001), vol. 1.
2. H. Zou and T. Hastie, "Regularization and variable selection via the elastic net," Journal of the Royal Statistical Society: Series B (Statistical Methodology), vol. 67, no. 2, pp. 301-320, 2005.

5.4.4a Attach Risk/Case-mix Adjustment Modeling and/or Stratification Specifications

FALLS WITH INJURY RISK MODEL 11 01 2023.xlsx

5.4.5 Calibration and Discrimination

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.
- 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).

References:

1. 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

5.4.5a Attach Calibration and Discrimination Testing Results

FALLS WITH INJURY CALIBRATION AND DISCRIMINATION TESTING_11 01 2023.pdf

5.4.6 Interpretation of Risk/Case-mix Factor Findings

See above.

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.2 Current or Planned Use(s)

Public Reporting, Payment Program

6.2.1 Actions of Measured Entities to Improve Performance

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 4 measured entities (hospital systems) on measure usability. All 4 measured entities (100%) agreed that the information produced by the performance measure is easy to understand and useful for decision making. Additionally, we polled 3 patients/family caregivers and all agreed that the measure outcome is important to know and can help improve care for patients.

References:

1. 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
2. RNAO. *Preventing Falls and Reducing Injury from Falls*. 4th edition. Toronto, ON; 2017
3. NICE. *Falls in Older People: Assessing Risk and Prevention*. London, UK; 2013
4. 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…. Accessed July 9, 2019.

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Measured/accountable entity (reliability and/or validity) methodology and results (if available)

Measured entity (reliability and validity) methodology and results (if available), Person or encounter-level (reliability and validity) methodology and results (if available)

Responder for Survey

Patient

Specify number of risk factors

5 (age, weight loss, delirium, dementia, other neurologic disorders)

The measure developer is different from the measure steward

Yes

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