Chapter 2: Risk Adjustment Summary Report: Hospital Harm – Falls with Injury

Patient Safety Measure Development and Maintenance

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Task & Deliverable

Chapter 6 Measure Testing
Deliverable 6-4 Risk Adjustment Methodology Report

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1. Introduction

This project, titled Patient Safety Measure Development and Maintenance, is performed under the Measure & Instrument Development and Support (MIDS) contract for the Centers for Medicare & Medicaid Services (CMS).

The goal of the project is to develop, maintain, re-evaluate, and implement patient safety measures for CMS's hospital-level quality reporting programs. Broadly, these programs range from the Hospital Inpatient Quality Reporting (IQR) Program to Hospital-Acquired Condition (HAC) Reduction Program, and the Promoting Interoperability (PI) Program.

This report is an independent chapter of the overall measure testing report and describes the rationale and methodology for a risk adjustment model for the Hospital Harm – Falls with Injury (HH-Falls) electronic clinical quality measure (eCQM). In this report, we explain risk factors selection, provide the model specification, summarize empirical findings, and present coefficient estimates.

We note that the baseline risk adjustment model presented in this chapter welcomes future update and refinement, as the number of hospitals (or test sites) participating in testing and model development is small. We aim to improve the model by augmenting hospitals and hence enlarging sample size to improve the model's generalizability to the full population in the future (during measure implementation).

2. Measure Description

HH – Falls 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. The initial population (IP) 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 measure denominator population is a subset of the IP, where encounters meeting denominator exclusion criteria are excluded. The measure numerator population is, in turn, a subset of denominator population where the patient has a fall that results in moderate or major injury. To qualify for the measure numerator, one harm event suffices.

Table 1 summarizes the measure's core components without delving into the technical details. For an in-depth review of the measure specification, please refer to **Chapter 1: Measure Testing Summary Report.**

Table 1: Measure Initial Population, Denominator Exclusion, Denominator, and Numerator

Population	Description
Measure IP	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.
Denominator Exclusion	Inpatient hospitalizations where the patient has a fall diagnosis present on admission.
Denominator	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.
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.

3. Rationale For Risk Adjustment

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 (e.g., adverse events due to immobility such as increased risk of pressure injury, functional decline, and venous thromboembolism) that are likely to exceed fall-related harms.[1,2] In order to permit fair comparisons among hospitals that serve very different patient populations, risk-adjustment is used in the HH-Falls eCQM.

4. Streamlined Conceptual Model

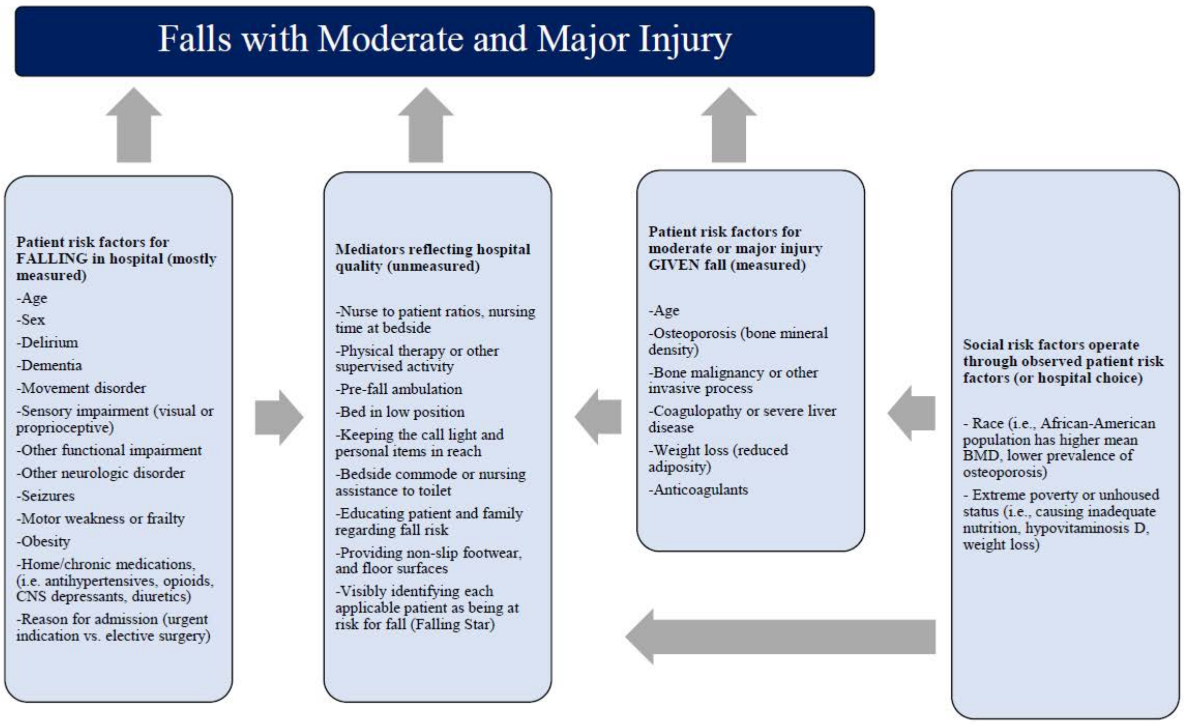
Exhibit 1 is a simplified conceptual framework that guided our risk model development. Conceptually, risk factors for in-hospital falls with injury can be separated into two categories: 1) risk factors for falling, given hospitalization; and 2) risk factors for moderate or serious injury, given a fall. 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.

[1] Resnick, B., & Boltz, M. (2023). *Failure to ensure patient safety leads to patient falls in nursing homes.* Patient Safety Network. https://psnet.ahrq.gov/web-mm/failure-ensure-patient-safety-leads-patient-falls-nursing-homes
[2] Healey, F. (2011). *Implementing a fall prevention program.* Patient Safety Network. https://psnet.ahrq.gov/perspective/implementing-fall-prevention-program

Below, we discuss how patient risk factors for falling, patient risk factors for an injury given a fall, social risk factors, and mediators reflecting each component relates to the outcome of interest and whether they below to the risk model, and if so in what forms.

Exhibit 1. Simplified Conceptual Model That Guided the Risk Adjustment Model Development



Note: This eCQM logic model is adopted from The World Falls Guidelines (WFG) Task Force, World guidelines for falls prevention and management for older adults: a global initiative. Age and Ageing, 51(9), 1–36. https://doi.org/10.1093/ageing/afac2

4.1 Social Factors

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 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."[3] Social factors, such as race and ethnicity, were not coded consistently across a large proportion of the data to be considered for inclusion in the risk model. Additionally, 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.

[3] Noel SE, Santos MP, Wright NC. Racial and Ethnic Disparities in Bone Health and Outcomes in the United States. *J Bone Miner Res*. 2021;36(10):1881-1905. doi:10.1002/jbmr.4417.

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.

4.2 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.[4] 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).[4] 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.

4.3 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).[5,6,7] 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).[8] 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.

4.4 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.[9] The risk of falling was lower in

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

[5] 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

[6] 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

[7] 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

[8] 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.

[9] 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.

the comparison group without delirium in all studies (median 2%, range 1% to 47%).Accordingly, the relative risk (RR) for falls with delirium was elevated and significant in all studies but one (median RR = 4.5, range 1.4–12.6)."[9] 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.

4.5 Dementia

Patients with dementia have increased risk of falls during hospitalization.[10,11,12,13,14] 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).[15] 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).[16] 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.

4.6 Depression

Depression has been identified as one of the risk factors for falls.[10,12,17] 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."[17] 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).[18] The current risk

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[10] 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.

[11] 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.

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[13] 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.

[14] 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

[15] 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.

[16] 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

[17] 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.

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.

4.7 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.[18,19] 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).[19] 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.

4.8 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[10,12,17] epilepsy, including seizure disorder,[12,20,21] Parkinson disease, multiple sclerosis, stroke, and other neurological disorders[10,15,18,22,23,24] 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.**Error! Bookmark not defined.** 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.

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[18] 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.

[19] 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.

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[24] 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.

4.9 Sex

In papers by Aryee (2017) and Hodgson (2023), male sex was associated with increased risk of falls.[25,26] 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.

4.10 Surgery

Aryee (2017) reported that surgery was a statistically significant protective risk factor.[26] 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.[27,28] 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.

4.11 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.[29,30] 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%."[30] 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).[15]

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[25] 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.

[26] 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.

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[30] 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.

4.12 Leukemia/lymphoma

Several studies found hematological and other cancers to be a risk factor for falls Lorca, 2019, Kong, 2014).[31,32] 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.[31] 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.

4.13 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.[33,34,35] 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."[35] 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.

4.14 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.[27,28] "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."[36] "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."[37] The current risk

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[31] 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

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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.

4.15 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 [38,39,40,41,42]
- CNS depressants:
    - Antipsychotics, hypnotics, opioids, benzodiazepines, antiepileptics[40]
    - Active treatment on CNS agents[26]
    - Antipsychotics, antidepressants, TCAs, SSRIs, benzodiazepines, short-acting benzodiazepines, long-acting benzodiazepines, antiepileptic[38]
    - Sedatives, hypnotics, antidepressants including tricyclic antidepressants, selective serotonin reuptake inhibitors, and serotonin norepinephrine reuptake inhibitors[39]
    - Antiparkinsonian agents, anti-anxiety agents and hypnotic agents[43]
    - Anticonvulsant, benzodiazepine anticonvulsant, haloperidol, tricyclic antidepressant[44]

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[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

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        - Lorazepam[45]
        - Sedatives, hypnotics, psychotropics, antiepileptics[46]
- Antihypertensives[47,48]
    - Alpha blockers, alpha agonist, angiotensin-converting enzyme inhibitors (ACE-i), angiotensin receptor blockers (ARB), calcium channel blockers (CCB), beta blockers (BB), vasodilators[43,49,50]
- Diuretics (increase bone loss on loop diuretics[38,44,47,51,52]
- Antidepressants[39,50,53,54,55]

4.16 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.**Error! Bookmark not defined.** Assistance during

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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 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).

5. Methodology

5.1 Data Sources

The final risk-adjustment model was estimated using 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. 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;
- 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.

5.2 Model Development

Guided by the conceptual model, we developed the baseline risk adjustment model for HH-Falls using a 2-step sequential process (A) feature selection followed by (B) risk adjustment (RA) model development as explained below.

1. Created contingency tables (**see Table 2**) for all the categorical features to identify any that had zero cells for either the positive or negative outcome. These features were not considered for feature selection due to anticipated model convergence problems (i.e., quasi-complete separation) in the RA model. 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 (see **Exhibit 2**).
2. Obtained summary statistics such as event rate by facility, overall event rate, overall event rate based on encounter days, and unadjusted observed event rates by facility.
3. Randomly partitioned the full denominator data into a 70% training set and a 30% hold-out test set. The hold out test set was used to evaluate the generalizability of the

features chosen. The feature selection algorithm was applied to the training set with 100-fold cross-validation (CV).

4. Elastic net was developed by Zou and Hastie in 2005 by combining the advantages of least absolute shrinkage and selection operator (LASSO) and ridge regression[56]. 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. We ran elastic net feature selection algorithm using all the clinically justifiable features on the training set using 100-fold cross-validation (CV) (see **Exhibit 3**). This step helped understand how many features get selected at different values of the regularization parameter (lambda) and to assess model fit on the training set. We extracted the final set of features chosen by the 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 on hold-out test set (unseen data).
5. The elastic net model (where lambda is equal to lambda1se) with the selected features was evaluated on the hold-out test set and performance metrics obtained (see **Exhibit 4**).

Table 2: Contingency Table of Risk Factors

Categorical Feature[57]	# Negative events	# Positive Events	Event Rate (%)
Male	80499	49	0.03%
Female	112813	37	0.02%
Obese (no)	163668	77	0.04%
Obese (yes)	29644	9	0.00%
Coag (no)	147016	52	0.03%
Coag (yes)	46296	34	0.02%
Weight loss (no)	173153	47	0.02%
Weight loss (yes)	20159	39	0.02%
Antidep (no)	174193	70	0.04%
Antidep (yes)	19119	16	0.01%
Anthyp (no)	119594	39	0.02%
Anthyp (yes)	73718	47	0.02%
CNS (no)	155740	56	0.03%
CNS (yes)	37572	30	0.02%
coagdis (no)	177511	67	0.03%
coagdis (yes)	15801	19	0.01%
delir (no)	189199	78	0.04%

[56] 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.
[57] Variables with zero cells or small cell sizes, for either the positive or negative outcome, were not considered for feature selection due to anticipated model convergence problems (i.e., quasi-complete separation) in the RA model.

Categorical Feature[57]	# Negative events	# Positive Events	Event Rate (%)
delir (yes)	4113	8	0.00%
demen (no)	182285	70	0.04%
demen (yes)	11027	16	0.01%
depress (no)	176432	71	0.04%
depress (yes)	16880	15	0.01%
diur (no)	171631	70	0.04%
diur (yes)	21681	16	0.01%
epil (no)	185661	79	0.04%
epil (yes)	7651	7	0.00%
leuk (no)	188902	79	0.04%
leuk (yes)	4410	7	0.00%
liver (no)	190503	82	0.04%
liver (yes)	2809	4	0.00%
bone (no)	190917	84	0.04%
bone (yes)	2395	2	0.00%
movement (no)	190755	85	0.04%
movement (yes)	2557	1	0.00%
neuroother (no)	177568	64	0.03%
neuroother (yes)	15744	22	0.01%
Opiods (no)	171932	65	0.03%
Opiods (yes)	21380	21	0.01%
Osteo (no)	189751	83	0.04%
Osteo (yes)	3561	3	0.00%
Neuropathy (no)	183177	78	0.04%
Neuropathy (yes)	10135	8	0.00%
Psychosis (no)	190017	83	0.04%
Psychosis (yes)	3295	3	0.00%
Stroke (no)	184678	79	0.04%
Stroke (yes)	8634	7	0.00%
Suicide (no)	193284	86	0.04%
Suicide (yes)	28	0	0.00%
Surgery (no)	164572	75	0.04%
Surgery (yes)	28740	11	0.01%

Exhibit 2: Lowess Smoothing; Patient Age (x-axis) and Falls with Injury

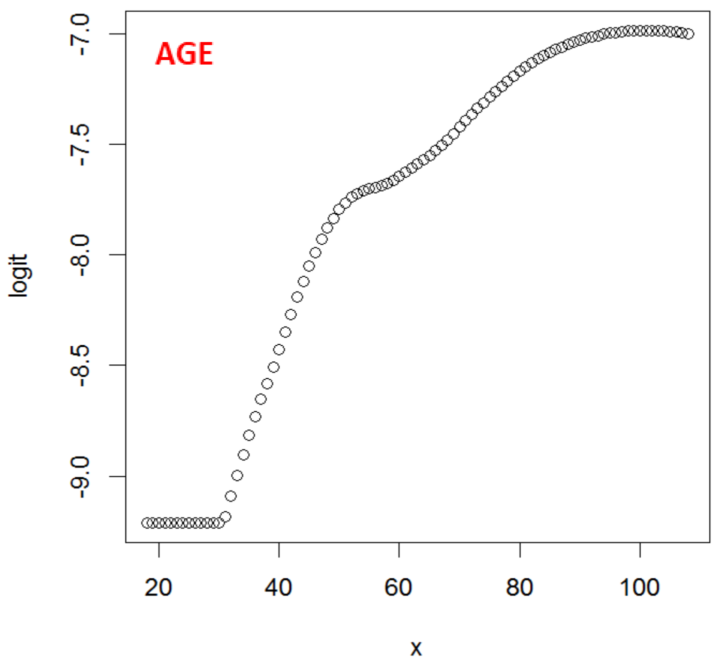


Exhibit 3: Elastic net model feature selection (100-fold CV on 70% Training Set)

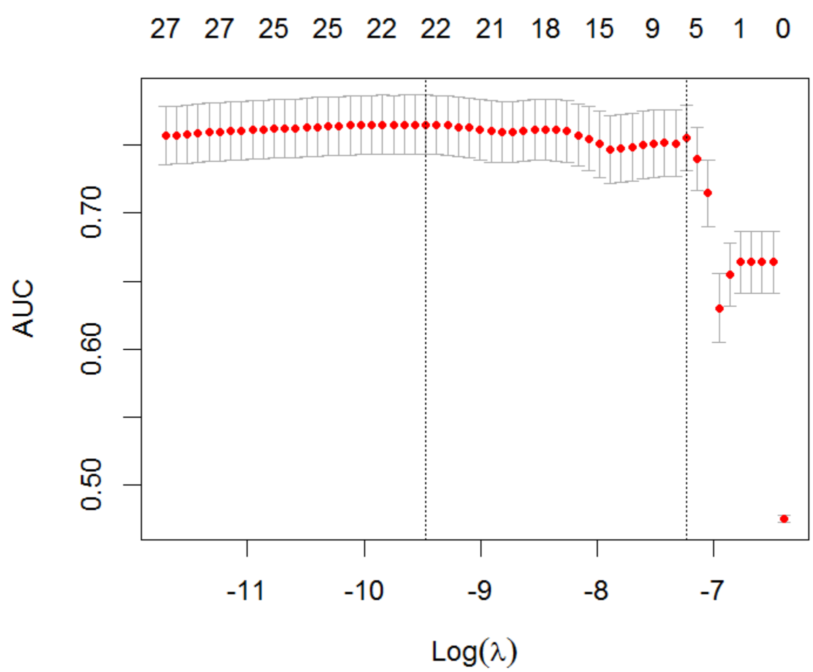
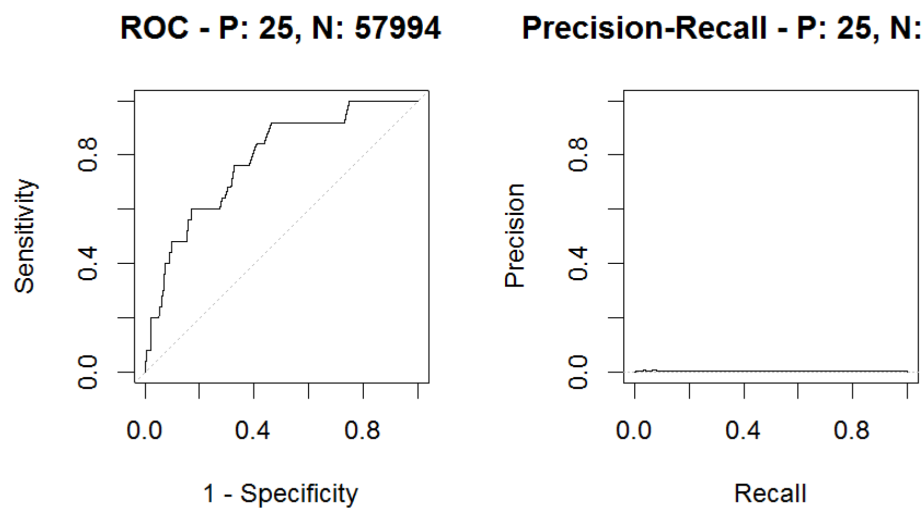


Exhibit 4: Performance of elastic net model with selected features (Test Data)



6. We also ran a least absolute shrinkage and selection operator (LASSO) on the split data for feature selection. LASSO selected more features and had poorer performance on the hold-out test set. The clinical team reviewed the features selected by LASSO and noticed that several features were collinear. Therefore, we decided to use the features selected by elastic net for the RA model.
7. The final risk-adjustment model was a 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 RA model coefficients were estimated on the entire dataset using the set of features selected by elastic net through 100-fold CV and testing on the hold-out test set. Feature selection and RA model performance were evaluated using a variety of metrics such as C-statistics, area under the precision-recall curve and calibration plots.
8. The risk-adjustment model was also tested with additional social drivers of health variables (race, Medicaid insurance, Hispanic ethnicity, race), considered individually and collectively. See **Section 7** for results.
9. After feature selection with 100-fold cross-validation and testing on the hold-out test set, the final RA model only included these risk factors - age (in linear form), weight loss or malnutrition POA, delirium POA, dementia POA, and other neurological disorders POA. We tested RA models, without performing feature selection, by including all the clinical factors and found three statistically significant features which were age, weight loss and home opioid medication but no meaningful improvement in any metric of model performance (e.g., AUC, Brier score, AIC/BIC).

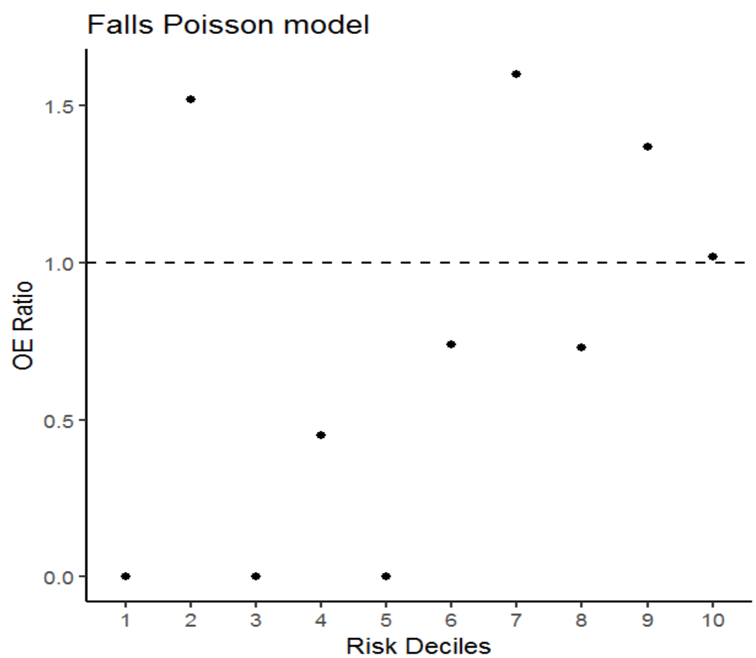
5.3 Model Performance

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 model. 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 for the elastic net was 0.781 on the hold-out test set and 0.852 for the final Poisson RA model run on the entire data. 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. Given the low overall event rate for this measure, it was advisable to check the values of AUPRC. The AUPRC was 0.00166 on the hold-out test set (elastic net), indicating poor prediction at the individual patient level but reasonable performance relative to a random classifier with AUPRC=0.00043.

The RA model calibration was assessed across deciles of patient risk using Hosmer-Lemeshow plots (see **Exhibit 5**). 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.

Exhibit 5: Hosmer-Lemeshow Decile Calibration Plot (Final Risk Adjustment Model)

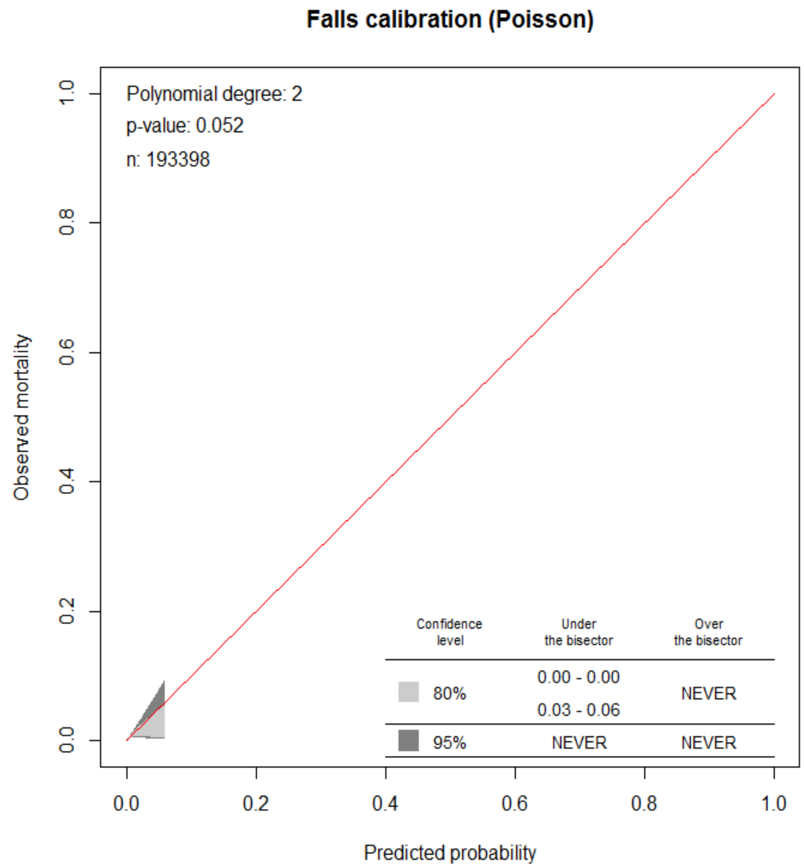


A preferred approach in this situation is to estimate calibration belts suggested by Nattino et al. (2017).[58] Calibration belts are an advance over the conventional Hosmer-Lemeshow plot, as the latter has the limitation of undue sensitivity to the choice of bins and extreme fluctuations in the

[58] 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.

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) (see **Exhibit 6**).

Exhibit 6: Calibration belt (Final Risk Adjustment Model)



6. Risk Adjustment Model Specification

Table 3 shows the coefficient estimates, standard errors, and 95% confidence interval using data points from the full denominator population.

Table 3: Final Risk Model Coefficient Estimates, Standard Error, and Odds Ratios

Risk Adjuster	Estimate	Standard Error	Odds Ratio (95% CI)	
Age	0.019**	0.007	1.019	(1.006, 1.034)
Weight Loss	0.740**	0.226	2.096	(1.341, 3.257)
Delirium	0.194	0.383	1.214	(0.530, 2.424)
Dementia	0.338	0.305	1.403	(0.750, 2.501)
Other neurological disorders	0.240	0.261	1.271	(0.747, 2.087)

Notes: *** p<0.0001; ** p < 0.001; *p < 0.01; Cstat = 0.8522; BrierScore = 0.0004

Table 4 shows the denominator count as well as observed and risk-adjusted measure performance rates for every hospital included in the analysis. We calculated risk-adjusted measure rate as:

$$\frac{Observed\ measure\ rate}{Expected\ measure\ rate} \times sample\ average,$$

where the expected measure rate came from the risk-adjustment model and the sample average stands in for the observed measure rate in the reference population.

Table 4: Denominator Count and Observed and Risk-adjusted Measure Rates Per 1000 Qualified Inpatient Encounters

Facility	Number of Events	Denominator Count (sum of days in hospital)	Observed Measure Rate (per 1000 encounter days)	Risk-adjusted Measure rate
1	16	73,597	0.2174	0.2575
2	7	121,102	0.0578	0.0650
3	2	55,458	0.0361	0.0451
4	0	3,597	0.0000	0.0000
5	11	229,966	0.0478	0.0497
6	4	67,844	0.0590	0.0530
7	2	43,412	0.0461	0.0375
8	11	108,704	0.1012	0.0935
9	17	269,922	0.0630	0.0585
10	1	12,655	0.0790	0.0708
11	5	128,945	0.0388	0.0428
12	10	43,742	0.2286	0.1861

Note: risk-adjusted measure rate = observed measure rate / expected measure rate sample averages. Expected measure rate was resulted from the risk-adjustment model and sample average serves as the proxy for the observed measure rate in the reference population.

7. Social Risk Factors

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.[59] 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 the 12 test sites, we conducted a social disparities analysis. Our results align with the literature as we found:

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

- 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.

See **Tables 5 - 8** below for results (individually and collectively).

Table 5: Social Drivers of Health Analysis - Race

Variable	Estimate	Std. Error	z value	Pr(>|z|)	Odds Ratio	U CL	L CL
Age	0.015	0.007	2.131	0.033*	1.015	1.001	1.029
Weight Loss	0.755	0.225	3.350	0.001***	2.128	1.362	3.307
Delirium	0.179	0.382	0.468	0.640	1.196	0.523	2.387
Dementia	0.360	0.306	1.177	0.239	1.433	0.766	2.556
Other neurological disorders	0.251	0.261	0.961	0.337	1.285	0.755	2.109
Race: White	REF						
Race: Black	-0.682	0.330	-2.069	0.039*	0.506	0.251	0.926
Race: Other	-1.014	0.330	-3.074	0.002**	0.363	0.180	0.665
Race: Unknown	-0.328	0.720	-0.456	0.648	0.720	0.118	2.306

Notes: *** p<0.0001; ** p < 0.001; *p < 0.01; Cstat = 0.8603; BrierScore = 0.0004; AIC: 1340.7***

Table 6: Social Drivers of Health Analysis - Medicaid Insurance

Variable	Estimate	Std. Error	z value	Pr(>|z|)	Odds Ratio	U CL	L CL
Age	0.017	0.007	2.363	0.018*	1.017	1.003	1.032
Weight Loss	0.747	0.226	3.305	0.001***	2.110	1.350	3.282
Delirium	0.188	0.383	0.490	0.624	1.206	0.527	2.410
Dementia	0.358	0.306	1.170	0.242	1.431	0.764	2.555
Other neurological disorders	0.248	0.261	0.951	0.342	1.282	0.753	2.106
Medicaid	-0.241	0.267	-0.900	0.368	0.786	0.455	1.303

Notes: *** p<0.0001; ** p < 0.001; *p < 0.01; Cstat = 0.8498; BrierScore = 0.0004; AIC: 1349.4***

Table 7: Social Drivers of Health Analysis – Hispanic Ethnicity

Variable	Estimate	Std. Error	z value	Pr(>|z|)	Odds Ratio	U CL	L CL
Age	0.016	0.007	2.371	0.018*	1.017	1.003	1.031
Weight Loss	0.744	0.226	3.292	0.001***	2.104	1.345	3.271
Delirium	0.176	0.383	0.461	0.645	1.193	0.521	2.381

Variable	Estimate	Std. Error	z value	Pr(>|z|)	Odds Ratio	U CL	L CL
Dementia	0.341	0.305	1.115	0.265	1.406	0.752	2.506
Other neurological disorders	0.252	0.261	0.967	0.334	1.287	0.756	2.114
Hispanic	-1.276	0.514	-2.481	0.013*	0.279	0.085	0.673

Notes: *** p<0.0001; ** p < 0.001; *p < 0.01; Cstat = 0.8586; BrierScore = 0.0005; AIC: 1336.0***

Table 8: Social Drivers of Health Analysis – Combined (Race, Medicaid Insurance, Hispanic Ethnicity)

Variable	Estimate	Std. Error	z value	Pr(>|z|)	Odds Ratio	U CL	L CL
Age	0.013	0.007	1.807	0.071†	1.013	0.999	1.028
Weight Loss	0.756	0.226	3.344	0.001***	2.129	1.362	3.311
Delirium	0.171	0.382	0.447	0.655	1.186	0.518	2.367
Dementia	0.355	0.307	1.159	0.247	1.426	0.761	2.549
Other neurological disorders	0.266	0.261	1.020	0.308	1.305	0.767	2.145
Medicaid	-0.006	0.273	-0.022	0.982	0.994	0.569	1.667
Hispanic	-1.033	0.538	-1.922	0.055†	0.356	0.105	0.910
Race: White	REF						
Race: Black	-0.739	0.332	-2.228	0.026*	0.478	0.236	0.878
Race: Other	-0.756	0.346	-2.188	0.029*	0.469	0.226	0.887
Race: Unknown	0.447	0.720	0.620	0.535	1.563	0.256	5.015

Notes: *** p<0.0001; ** p < 0.001; *p < 0.01; † p < 0.05; Cstat = 0.8630; BrierScore = 0.0005; AIC: 1333.6***

8. Conclusion

Using EHR data from 12 hospitals with varying bed size, geographic location, and EHR system, we developed a baseline risk adjustment model for HH-Falls. Importantly, the risk model developed is still in its preliminary stage due to the small sample of hospitals. Risk-adjusted measure rates move closer to a state where comparison of hospital performance is affected as little as possible by factors other than the quality of care.

Acknowledging these limitations, we consider this exercise an important innovation in hospital outcome measures using EHR data on two fronts:

1. Developing a risk adjustment methodology for eCQMs responds to the preference of care providers and stakeholders that physiological data captured at the start of encounter can be valuable for adjusting patient-level risk factors in hospital outcome measures. In this sense, we took a step toward developing a risk-adjusted eCQM that takes full advantage of the rich physiological information existent in the medical record and recorded at the beginning of the episode of care. These data are used by clinicians to evaluate how sick patients are and to guide their treatment plans in real time. The face validity of these data and their use for risk adjustment are well-justified.
2. Use of EHR data in risk adjustment provides new efficiencies in future eCQM development and implementation, in that EHR data are already documented during the process of care and hence, data collection incurs minimal burden on providers. Maximizing the utility of EHR data elements for risk adjustment improves feasibility and data element reliability, and potentially improves harmonization across measures.