4.4.2 Conceptual Model Rationale for the Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Complications Measure

The goal of risk adjustment is to adjust for case-mix differences across the hospitals. Risk adjustment supports fair and accurate comparison of outcomes across measured entities by including an adjustment for factors such as age, comorbid diseases, and indicators of patient frailty, which are clinically relevant and have relationships with the outcome.

In pursuing an approach that best leverages the data and analytical advancements since initial measure development, we developed and evaluated a framework to use individual ICD-10 codes for risk adjustment. The main advantage of leveraging ICD-10 codes in place of the prior method (that used an ICD-10 grouper, CMS's Condition Categories, or CCs) is the ability to address the clinical heterogeneity found in the broadly defined CCs. Our previous research indicates that the model performance of the mortality measures is significantly improved by using individual codes instead of CCs (Krumholz et al., 2019).

Selection of Clinical Risk Variables

For candidate risk variables, we included all secondary ICD-10 codes documented as present-on-admission (POA) during the index admission (except for the palliative care code of Z51.5, which, effective October 1, 2021, was considered POA-exempt), and both principal and secondary ICD-10 codes in the 12 months prior to admission from any inpatient, outpatient, and professional provider claims. We also considered the principal discharge diagnosis code for the index admission. In addition, we considered age, frailty, sex, an indicator for whether the admission was Medicare Advantage (MA) vs. Fee-for-Service (FFS), and other non-individual-ICD variables in the existing publicly reported THA//TKA Complications measure. The variable selection of individual ICD codes mainly relied on data-driven methodologies involving three key steps: 1) pre-processing, 2) evaluating association with outcome, and 3) consideration of associations between other non-individual-code variables, including frailty, with the outcome.

In pre-processing, we screened and included index and history (pre-index) codes if their prevalence exceeded 0.5% and 2.5%, respectively. Further, co-occurring index and pre-index codes with Pearson correlation coefficients greater than 0.8 were combined into one risk variable. Finally, pairs of identical index and pre-index ICD-10 codes with similar odds ratios that acted in the same direction (where the difference in association with the outcome, measured by odds ratio (OR), was less than 0.2) were merged.

In the second step, we included the remaining candidate variables including age in a multivariable logistic regression model that underwent variable selection through 1,000 iterations of bootstrapping. We selected variables that were statistically significantly associated with outcomes ($p<0.05$) in at least 70% of the bootstrapped samples. Additional variables were added if there was a resulting increase in c-statistic of at least 0.0005 for each additional variable or an increase of at least 0.005 for including additional variables within the next 5% of bootstrapped samples (e.g. moving from 70% to 65%). Lastly, we included other non-individual-ICD variables from the current FFS-only THA/TKA Complications measure if the regression coefficients were statistically significant when added to the models.

Lastly, based on evidence from the literature, expert input, guidance from the consensus-based entity for measure endorsement, the Assistant Secretary for Planning and Evaluation (ASPE, 2020), input from other stakeholders, as well as prior testing results, we included a claims-based indicator of frailty that was developed for CMS's Multiple Chronic Conditions measure (Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation [YNHHSC/CORE], 2019) in the final model for all measures. We did not include sex as a variable since sex can be considered a socio-demographic variable. After variable selection, we also added into the model the history of coronavirus disease 2019 (COVID-19) variable to be consistent with current CMS policy.

For the combined MA and FFS cohort, the risk adjustment model was updated to include an MA indicator (versus FFS) as a main effect. This was to adjust for the generally higher prevalence of comorbidities in the MA cohort, especially among the pre-index variables that were derived from services in the outpatient setting (e.g. physician visits).

Social Risk Factors

Although some recent literature evaluates the relationship between patient social risk factors and the complication outcome, few studies directly address causal pathways or examine the role of the hospital in these pathways (Trivedi et al., 2014; Buntin et al., 2017; Borza et al., 2019). Moreover, the current literature examines a wide range of conditions and risk variables with no clear consensus on which risk factors demonstrate the strongest relationship with complication.

The social risk factors that have been examined in the literature can be categorized into three domains: (1) patient-level variables, (2) neighborhood/community-level variables, and (3) hospital-level variables.

Patient-level variables describe the characteristics of individual patients and include the patient's race and ethnicity, income, or education level. For example, Black and Hispanic patients have been shown to experience higher rates of postoperative complications, longer lengths of stay, and more frequent non-home discharges (Rudisill et al., 2023; Usiskin and Misra, 2022; Brown, Paisner, and Sassoon, 2022). These disparities are often influenced by socioeconomic factors such as lower income or education levels, which can limit access to healthcare services, preventive care, or rehabilitation (Alvarez et al., 2022). Additionally, barriers such as language proficiency or health literacy may further exacerbate these challenges and contribute to poorer outcomes and higher rates of complications for patients with social risk factors (Suleiman et al., 2021).

Neighborhood/community-level variables use information from sources such as the American Community Survey as either a proxy for individual patient-level data or to measure environmental factors. Studies using these variables use one-dimensional measures such as median household income or composite measures such as the AHRQ-validated SES index score (Blum et al., 2014; Courtney et al., 2016; Martsolf et al., 2016; White et al., 2018). Some of these variables may include the local availability of clinical providers (Herrin et al., 2015; Herrin et al., 2016).

Hospital-level variables measure attributes of the hospital which may be related to patient risk. Examples of hospital-level variables used in studies are ZIP code characteristics aggregated to the hospital level or the proportion of Medicaid patients served in the hospital (Gilman et al., 2014; Joynt et al., 2013; Jha et al., 2013; Xu et al., 2018).

The conceptual relationship, or potential causal pathways by which these possible social risk factors influence the risk of complication following an acute illness or major surgery, like the factors themselves, are varied and complex. There are at least four potential pathways that are important to consider:

- **Patients with social risk factors may have worse health at the time of hospital admission**. Patients who have lower income/education/literacy or unstable housing may have a worse general health status and may present for their hospitalization or procedure with a greater severity of underlying illness. These social risk factors, which are characterized by patient-level or neighborhood/community-level (as proxy for patient-level) variables, may contribute to worse health status at admission due to competing priorities (for example, restrictions based on job), lack of access to care (e.g., geographic, cultural, or financial), or lack of health insurance. Given that these risk factors all lead to worse general health status, this causal pathway should be largely accounted for by current clinical risk adjustment.
- **Patients with social risk factors may receive care at lower-quality hospitals**. Patients of lower income, lower education, or unstable housing have inequitable access to high-quality facilities, in part because such facilities may be less likely to

be found in geographic areas with large populations of poor patients. Thus, patients with low income may be more likely to be seen in lower-quality hospitals, which can explain the increased risk of complications following hospitalization.

- **Patients with social risk factors may receive differential care within a hospital**. The third major pathway by which social risk factors may contribute to complications risk is that patients may not receive equivalent care within a facility. For example, patients with social risk factors such as lower education may require differentiated care (e.g. provision of lower literacy information – that they do not receive).
- **Patients with social risk factors may experience worse health outcomes beyond the control of the healthcare system.** Some social risk factors, such as income or wealth, may affect the likelihood of complications without directly affecting health status at admission or the quality of care received during the hospital stay. For instance, while a hospital may make appropriate care decisions and provide tailored care and education, a lower-income patient may have a worse outcome post-discharge due to competing financial priorities that don't allow for adequate recuperation or access to needed treatments, or a lack of access to care outside of the hospital.

We developed and used the conceptual framework described below to identify potential social risk factors. We analyzed two well-studied social risk factors that could best be operationalized in data, outlined below. We note that this measure already adjusts for age and note that the risk model already accounts for patient comorbidities which may differ among patients with social risk factors.

Dual-eligible (DE) Status

Dual eligibility for Medicare and Medicaid is available at the patient level in the Medicare Master Beneficiary Summary File. The eligibility threshold for Medicare beneficiaries aged 65 or older considers both income and assets. For the dual-eligible (DE) indicator, there is a body of literature demonstrating differential health care and health outcomes among beneficiaries (ASPE, 2020).

Area Deprivation Index (ADI)

While we previously used the AHRQ SES variable in these types of analyses, we now use the validated ADI (Forefront Group, 2023). We made this change to align with other CMS work on social risk factors that now use the ADI. We describe the ADI variable below.

The ADI, initially developed by the Health Resources & Services Administration, is based on 17 measures across four domains: income, education, employment, and housing quality (Kind et al., 2018; Singh, 2003).

The 17 components are listed below:

- Population aged ≥ 25 y with < 9 y of education, %
- Population aged ≥ 25 y with at least a high school diploma, %
- Employed persons aged ≥ 16 y in white-collar occupations, %
- Median family income, $
- Income disparity
- Median home value, $
- Median gross rent, $
- Median monthly mortgage, $
- Owner-occupied housing units, % (homeownership rate)
- Civilian labor force population aged ≥16 y unemployed, % (unemployment rate)

- Families below the poverty level, %
- Population below 150% of the poverty threshold, %
- Single-parent households with children aged < 18 y, %
- Households without a motor vehicle, %
- Households without a telephone, %
- Occupied housing units without complete plumbing, % (log)
- Households with more than 1 person per room, % (crowding)

ADI scores were derived using the beneficiary's 9-digit ZIP Code of residence, which is obtained from the Master Beneficiary Summary File and is linked to 2017-2021 US Census/American Community Survey (ACS) data. In accordance with the ADI developers' methodology, an ADI score is calculated for the census block group corresponding to the beneficiary's 9-digit ZIP Code using 17 weighted Census indicators. Raw ADI scores were then transformed into a national percentile ranking ranging from 1 to 100, with lower scores indicating lower levels of disadvantage and higher scores indicating higher levels of disadvantage. Percentile thresholds established by the ADI developers were then applied to the ADI percentile to dichotomize neighborhoods into more disadvantaged (high ADI areas=ranking equal to or greater than 85) or less disadvantaged areas (Low ADI areas= ranking of less than 85).

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