**National Quality Forum—Measure Testing (subcriteria 2a2, 2b1-2b6)**

**Measure Number** (*if previously endorsed*)**:** 0230

**Measure Title**: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization

**Date of Submission**: 8/3/2020

**Type of Measure:**

|  |  |
| --- | --- |
| Outcome (*including PRO-PM*) | Composite – ***STOP – use composite testing form*** |
| Process *(including Appropriate Use)* | Efficiency |
| Structure |  |

|  |
| --- |
| **Instructions**   * Measures must be tested for all the data sources and levels of analyses that are specified. ***If there is more than one set of data specifications or more than one level of analysis, contact NQF staff*** about how to present all the testing information in one form. * **For all measures, sections 1, 2a2, 2b1, 2b2, and 2b4 must be completed.** * **For outcome and resource use measures**, section **2b3** also must be completed. * If specified for **multiple data sources/sets of specificaitons** (e.g., claims and EHRs), section **2b5** also must be completed. * Respond to all questions as instructed with answers immediately following the question. All information on testing to demonstrate meeting the subcriteria for reliability (2a2) and validity (2b1-2b6) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 25 pages (*incuding questions/instructions;* minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). * For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for version 7.1 of the Measure Testing Attachment. |

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| **Note:** The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF’s evaluation criteria for testing.  **2a2.** **Reliability testing** [**10**](#Note10) demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For **instrument-based measures** (including PRO-PMs) **and composite performance measures**, reliability should be demonstrated for the computed performance score.  **2b1.** **Validity testing** [**11**](#Note11) demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For **instrument-based measures (including PRO-PMs) and composite performance measures**, validity should be demonstrated for the computed performance score.    **2b2.** **Exclusions** are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure; [**12**](#Note12)  **AND**  If patient preference (e.g., informed decisionmaking) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately). [**13**](#Note13)  **2b3.** **For outcome measures and other measures when indicated** (e.g., resource use):   * **an evidence-based risk-adjustment strategy** (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; [**14**](#Note14)**,**[**15**](#Note15) and has demonstrated adequate discrimination and calibration   **OR**   * rationale/data support no risk adjustment/ stratification.   **2b4.** Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for **identification of statistically significant and practically/clinically meaningful** [**16**](#Note16) **differences in performance**;  **OR**  there is evidence of overall less-than-optimal performance.  **2b5.** **If multiple data sources/methods are specified, there is demonstration they produce comparable results**.  **2b6.** Analyses identify the extent and distribution of **missing data** (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias.  **Notes**  **10.** Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).  **11.** Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.  **12.** Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.  **13.** Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.  **14.** Risk factors that influence outcomes should not be specified as exclusions.  **15.** With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers. |

**1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE**

*Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.*

**1.1. What type of data was used for testing**? (*Check all the sources of data identified in the measure specifications and data used for testing the measure*. *Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

|  |  |
| --- | --- |
| **Measure Specified to Use Data From:**  **(*must be consistent with data sources entered in S.17*)** | **Measure Tested with Data From:** |
| abstracted from paper record | abstracted from paper record |
| claims | claims |
| registry | registry |
| abstracted from electronic health record | abstracted from electronic health record |
| eMeasure (HQMF) implemented in EHRs | eMeasure (HQMF) implemented in EHRs |
| other: Medicare Enrollment Data (including Master Beneficiary Summary File), VHA Administrative Data | other: Census Data/American Community Survey, VHA Administrative Data, Medicare Enrollment Data (including Master Beneficiary Summary File) |

**1.2. If an existing dataset was used, identify the specific dataset** (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

The data used for testing included Medicare Parts A and B claims as well as the Medicare Enrollment Database (EDB). Additionally, census as well as enrollment data were used to assess socioeconomic factors (dual eligible variable obtained through enrollment data; Agency for Healthcare Research and Quality [AHRQ] socioeconomic status [SES] index obtained through census data). Veterans’ Health Administration (VHA) data are also included in the testing dataset. The dataset used varies by testing type; see Section 1.7 for details.

**1.3. What are the dates of the data used in testing**? Click here to enter date range

The dates used for testing vary by testing type; see Section 1.7 for details.

**1.4. What levels of analysis** **were tested**? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

|  |  |
| --- | --- |
| **Measure Specified to Measure Performance of:**  **(*must be consistent with levels entered in item S.20*)** | **Measure Tested at Level of:** |
| individual clinician | individual clinician |
| group/practice | group/practice |
| hospital/facility/agency | hospital/facility/agency |
| health plan | health plan |
| other: Click here to describe | other: Click here to describe |

**1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)**? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

For this measure, hospitals are the measured entities. All non-federal, short-term acute care inpatient US hospitals (including territories) with Medicare fee-for-service (FFS) beneficiaries aged 65 or over are included. All Veteran’s Health Administration Hospitals are also included in the current public reported measure. The number of measured entities (hospitals) varies by testing type; see Section 1.7 for details.

**1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)**? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

The number of admissions/patients varies by testing type: see Section 1.7 for details.

**1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below**.

The datasets, dates, number of measured hospitals, and number of admissions used in each type of testing are in Table 1.

Measure Development

For measure development, we used Medicare administrative claims data (1998). The dataset also included administrative data on each patient for the 12 months prior to the index admission. The dataset contained inpatient and facility outpatient claims and Medicare enrollment database (EDB) data. We randomly split the data into two equal samples:the Development Dataset and Internal Validation Dataset.

**Measure Testing**

For analytical updates for this measure, we used three-years of Medicare administrative claims data (July 2016 – June 2019). The dataset also included administrative data on each patient for the 12 months prior to the index admission. The dataset contained inpatient and facility outpatient claims and Medicare enrollment database (EDB) data. The dataset also included administrative data from the VHA as these hospitals are currently publicly reported for this measure.

Table 1. Dataset Descriptions

| Dataset | Applicable Section in the Testing Attachment | Description of Dataset |
| --- | --- | --- |
| Development and Validation Datasets  (Medicare Fee-For-Service Administrative Claims Data) | Section 2b3 Risk Adjustment/Stratification  **2b3.6. Statistical Risk Model Discrimination Statistics**  **2b3.7. Statistical Risk Model Calibration Statistics** | Entire Cohort:  Dates of Data: 1998  Number of admissions = 134,661  Number of measured hospitals: 4,646 |
| Testing Dataset (Medicare Fee-For-Service Administrative Claims Data (July 1, 2016 – June 30, 2019) | Section 2a2 Reliability Testing  Section 2b1 Validity Testing  Section 2b2 Testing of Measure Exclusion  Section 2b3 Risk Adjustment/Stratification  2**b3.6. Statistical Risk Model Discrimination Statistics**  Section 2b4 Meaningful Differences | Dates of Data: July 2016 – June 2019  Number of admissions = 470,621  Patient Descriptive Characteristics: mean  age = 78.0 years; % male = 55.6  Number of measured hospitals: 4,246  This cohort was randomly split into two halves.  First half of split sample  Number of Admissions: 234,188.  Number of measured hospitals: 3,949.  Patient Descriptive Characteristics:  Mean age = 78.0; % Male = 55.5.  Second half of split sample  Number of Admissions: 236,433.  Number of measured hospitals: 4,246.  Patient Descriptive Characteristics:  Mean age = 78.0; % Male = 55.6 |
| The American Community Survey (ACS) | Section 2b3: Risk adjustment/Stratification for Outcome or Resource Use Measures | Dates of Data: 2013-2017  We used the AHRQ SES index score derived from the American Community Survey (2013-2017) to study the association between the 30-day mortality outcome and SRFs. The AHRQ SES index score is based on beneficiary 9-digit zip code level of residence and incorporates 7 census variables found in the American Community Survey. |
| Master Beneficiary Summary File (MBSF) | Section 2b3: Risk adjustment/Stratification for Outcome or Resource Use Measures | Dates of Data: July 2016 – June 2019  We used dual eligible status (for Medicare and Medicaid) derived from the MBSF to study the association between the 30-day measure outcome and dual-eligible status. |

**1.8** **What were the social risk factors that were available and analyzed**? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

We selected social risk factor (SRF) variables to analyze after reviewing the literature and examining available national data sources. We sought to find variables that are consistently captured in a reliable fashion for all patients in this measure. There is a large body of literature linking various SRFs to worse health status and higher mortality over a lifetime. Income, education, and occupation are the most commonly examined SRFs studied. The causal pathways for SRF variable selection are described below in Section 2b3.3a. Unfortunately, these variables are not available at the patient level for this measure. Therefore, proxy measures of income, education level and economic status were selected.

The SRF variables used for analysis were:

* Dual eligible status: Dual eligible status (i.e., enrolled in both Medicare and Medicaid) patient-level data is obtained from the CMS Master Beneficiary Summary File (MBSF).

Following guidance from ASPE and a body of literature demonstrating differential health care and health outcomes among dual eligible patients, we identified dual eligibility as a key variable (ASPE 2016; ASPE 2020). We recognize that Medicare-Medicaid dual eligibility has limitations as a proxy for patients' income or assets because it does not provide a range of results and is only a dichotomous outcome. However, the threshold for over 65-year-old Medicare patients is valuable, as it takes into account both income and assets and is consistently applied across states for the older population. We acknowledge that it is important to test a wider variety of SRFs including key variables such as education and poverty level; therefore, we also tested a validated composite based on census data linked to as small a geographic unit as possible.

* AHRQ-validated SES index score (summarizing the information from the following 7 variables): percentage of people in the labor force who are unemployed, percentage of people living below poverty level, median household income, median value of owner-occupied dwellings, percentage of people ≥25 years of age with less than a 12th grade education, percentage of people ≥25 years of age completing ≥4 years of college, and percentage of households that average ≥1 people per room)

Finally, we selected the AHRQ SES index score because it is a well-validated variable that describes the average SES of people living in defined geographic areas (Bonito et al., 2008). Its value as a proxy for patient-level information is dependent on having the most granular-level data with respect to communities that patients live in. We considered the area deprivation index (ADI) among many other potential indicators when we initially evaluated the impact of SDS indicators. We ultimately did not include the ADI at the time, partly due to the fact that the coefficients used to derive ADI had not been updated for many years. Recently, the coefficients for ADI have been updated and therefore we compared the ADI with the AHRQ SES Index and found them to be highly correlated. In this submission, we present analyses using the census block level, the most granular level possible using American Community Survey (ACS) data. A census block group is a geographical unit used by the US Census Bureau which is between the census tract and the census block. It is the smallest geographical unit for which the bureau publishes sample data. The target size for block groups is 1,500 and they typically have a population of 600 to 3,000 people. We used 2013-2017 ACS data and mapped patients’ 9-digit ZIP codes via vendor software to the census block group level. Given the variation in cost of living across the country, the median income and median property value components of the AHRQ SES Index were adjusted by regional price parity values published by the Bureau of Economic Analysis (BEA). This provides a better marker of low SES neighborhoods in high expense geographic areas. We then calculated an AHRQ SES Index score for census block groups that can be linked to 9-digit ZIP codes. We used the percentage of patients with an AHRQ SES index score equal to or below 42.7 to define the lowest quartile of the AHRQ SES Index.

References:

Adler NE, Newman K. Socioeconomic disparities in health: pathways and policies. Health affairs (Project Hope). 2002; 21(2):60-76.

Blum AB, Egorova NN, Sosunov EA, et al. Impact of socioeconomic status measures on hospital profiling in New York City. Circulation. Cardiovascular quality and outcomes. May 2014; 7(3):391-397.

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Mackenbach JP, Cavelaars AE, Kunst AE, Groenhof F. Socioeconomic inequalities in cardiovascular disease mortality; an international study. European heart journal. 2000; 21(14):1141-1151.

Pedigo A, Seaver W, Odoi A. Identifying unique neighborhood characteristics to guide health planning for stroke and heart attack: fuzzy cluster and discriminant analyses approaches. PloS one. 2011;6(7):e22693.

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**2a2. RELIABILITY TESTING**

***Note****: If accuracy/correctness (validity) of data elements was empirically tested*, *separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter “see section 2b2 for validity testing of data elements”; and skip 2a2.3 and 2a2.4.*

**2a2.1. What level of reliability testing was conducted**? (*may be one or both levels*)  
 **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)  
 **Performance measure score** (e.g., *signal-to-noise analysis*)  
  
**2a2.2. For each level checked above, describe the method of reliability testing and what it tests** (*describe the steps―do not just name a method; what type of error does it test; what statistical analysis was used*)

Measure Score Reliability

We performed two types of reliability testing. First, we estimated the overall measure score reliability by calculating the intra-class correlation coefficient (ICC) using a split sample (i.e. test-retest) method. Second, we estimated the facility-level reliability (signal-to-noise reliability).

Split-Sample Reliability

The reliability of a measurement is the degree to which repeated measurements of the same entity agree with each other. For measures of hospital performance, the measured entity is naturally the hospital, and reliability is the extent to which repeated measurements of the same hospital give similar results. Accordingly, our approach to assessing reliability is to consider the extent to which assessments of a hospital using different but randomly selected subsets of patients produce similar measures of hospital performance. That is, we take a "test-retest" approach in which hospital performance is measured once using a random subset of patients, and then measured again using a second random subset exclusive of the first, and the agreement of the two resulting performance measures compared across hospitals (Rousson, Gasser, and Seifert, 2002).

For split-sample reliability of the measure in aged 65 years and older, we randomly sampled half of patients within each hospital for a three year period, calculated the measure for each hospital, and repeated the calculation using the second half. Thus, each hospital is measured twice, but each measurement is made using an entirely distinct set of patients. To the extent that the calculated measures of these two subsets agree, we have evidence that the measure is assessing an attribute of the hospital, not of the patients. As a metric of agreement, we calculated the intra-class correlation coefficient (Shrout & Fleiss, 1979), and assessed the values according to conventional standards (Landis & Koch, 1977). Specifically, we used a combined 2016-2019 sample, randomly split it into two approximately equal subsets of patients, and calculated the RSMR for each hospital for each sample. The agreement of the two RSMRs was quantified for hospitals in each sample using the intra-class correlation as defined by ICC (2,1) (Shrout & Fleiss, 1979).

Using two non-overlapping random samples provides a conservative estimate of the measure’s reliability, compared with using two random but potentially overlapping samples which would exaggerate the agreement. Moreover, because our final measure is derived using hierarchical logistic regression, and a known property of hierarchical logistic regression models is that smaller volume hospitals contribute less 'signal', a split sample using a single measurement period would introduce extra noise. This leads to an underestimate in the actual test-retest reliability that would be achieved if the measure were reported using the full measurement period, as evidenced by the Spearman Brown prophecy formula (Spearman 1910, Brown 1910). We used this formula to estimate the reliability of the measure if the whole cohort were used, based on an estimate from half the cohort.

Signal-to-Noise

We estimated the signal to noise reliability (facility-level reliability), which is the reliability with which individual units (hospitals) are measured. While test re-test reliability is the most relevant metric from the perspective of overall measure reliability, it is also meaningful to consider the separate notion of “unit” reliability, that is, the reliability with which individual units (here, hospitals) are measured. The reliability of any one facility’s measure score will vary depending on the number of patients admitted for AMI. Facilities with more volume (i.e., with more patients) will tend to have more reliable scores, while facilities with less volume will tend to have less reliable scores. Therefore, we used the formula presented by Adams and colleagues (2010) to calculate facility-level reliability.

Where facility-to-facility variance is estimated from the hierarchical logistic regression model, n is equal to each facility’s observed case size, and the facility error variance is estimated using the variance of the logistic distribution (π^2/3). The facility-level reliability testing is limited to facilities with at least 25 admissions for public reporting.

Signal to noise reliability scores can range from 0 to 1. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real difference in performance.

Additional Information

In constructing the measure, we aim to utilize only those data elements from the claims that have both face validity and reliability. We avoid the use of fields that are thought to be coded inconsistently across providers. Specifically, we use fields that are consequential for payment and which are audited. We identify such variables through empiric analyses and our understanding of CMS auditing and billing policies and seek to avoid variables which do not meet this standard.

In addition, CMS has in place several hospital auditing programs used to assess overall claims code accuracy, to ensure appropriate billing, and for overpayment recoupment. CMS routinely conducts data analysis to identify potential problem areas and detect fraud, and audits important data fields used in our measures, including diagnosis and procedure codes and other elements that are consequential to payment.

Furthermore, we assessed the variation in the frequency of the variables over time. Detailed information is presented in the measure’s 2020 Condition-Specific Measure Updates and Specifications Report cited below.

References

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Spearman, Charles, C. (1910). Correlation calculated from faulty data. British Journal of Psychology, 3, 271–295.

**2a2.3. For each level of testing checked above, what were the statistical results from reliability testing**? (e*.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Measure Score Reliability Results

Signal-to-Noise

We calculated the signal-to-noise reliability score for each hospital with at least 25 admissions\* (see Table 2 below). The median reliability score was 0.59, ranging from 0.20 to 0.93. The 25th and 75th percentiles were 0.41 and 0.72, respectively. The median reliability score demonstrates moderate reliability.

Table 2. Signal-to-noise reliability distribution for AMI mortality

| **Mean** | **Std. Dev.** | **Min** | **5th Percentile** | **10th Percentile** | **25th Percentile** | **Median** | **75th Percentile** | **90th Percentile** | **95th Percentile** | **Max** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0.57 | 0.19 | 0.20 | 0.23 | 0.27 | 0.41 | 0.59 | 0.72 | 0.81 | 0.84 | 0.93 |

\*Hospital measure scores are calculated for all hospitals (including those that have fewer than 25 admissions) but only publicly reported for those that have at least 25 admissions to ensure hospital results are reliable.

Split-Sample Reliability

In total, 470,621 admissions were included in the analysis, using three years of data. After randomly splitting the sample into two halves, there were 234,188 admissions from 3,949 hospitals in one half and 236,433 admissions from 4,246 hospitals in the other half. As a metric of agreement, we calculated the ICC for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSMR for each hospital was 0.428.

**2a2.4 What is your interpretation of the results in terms of demonstrating reliability**? (i*.e., what do the results mean and what are the norms for the test conducted?*)

Measure Score Reliability Results

Using the approach used by Adams et. al. and Yu et al., we obtained the median signal-to-noise reliability score of 0.59, which demonstrates moderate agreement.

Our interpretation of the results is based on the standards established by Landis and Koch (1977):

< 0 – Less than chance agreement;

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; and

1 Perfect agreement

The split-sample reliability score of 0.428, discussed in the previous section, represents the lower bound of estimate of the true measure reliability.

In the absence of empirically supported standards, our position is that ‘acceptability’ depends on context. For simple concepts or constructs, such as a patient’s weight, the expectation is that the test-retest reliability of a measure of that construct should be quite high. However, for complex constructs, such as clinical severity, patient comorbidity, or symptom profiles used to identify a condition or clinical state, reliability of measures used to define these constructs is quite a bit lower.

Taken together, these results indicate that there is moderate reliability in the measure score.

References:

Landis J, Koch G. The measurement of observer agreement for categorical data, Biometrics 1977;33:159-174.

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**2b1. VALIDITY TESTING**

**2b1.1. What level of validity testing was conducted**? (*may be one or both levels*)  
 **Critical data elements** (*data element validity must address ALL critical data elements*)

**Performance measure score**

**Empirical validity testing** **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

**2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests** (*describe the steps―do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Empirical Validity

Stewards of NQF-endorsed measures going through the re-endorsement process are required to demonstrate external validity testing at the time of maintenance review, or if this is not possible, justify the use of face validity only. To meet this requirement for the AMI mortality measure, we identified and assessed the measure’s correlation with other measures that target the same domain of quality (e.g. complications, safety, or post-procedure utilization) for the same or similar populations. The goal was to identify if better performance in this measure was related to better performance on other relevant structural or outcomes measures. After literature review and consultations with measures experts in the field, there were very few measures identified that assess the same domains of quality. Given that challenge, we selected the following to use for validity testing.

1. Hospital Star Rating mortality group score: CMS’s Hospital Star Rating mortality group score assesses hospitals’ overall performance (expressed on Hospital Compare graphically, as stars) based on a weighted average of group scores from the mortality domain. The mortality group is comprised of the mortality measures that are publicly reported on Hospital Compare, including this measure. The mortality group score is derived from a latent-variable model that identifies an underlying quality trait for that group. For the validity testing presented in this testing form, we used mortality group scores from 4,246 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Rating can be found at: <https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources>.

2. Overall Hospital Star Rating: CMS’s Overall Hospital Star Rating assesses hospitals’ overall performance (expressed on Hospital Compare graphically, as stars) based on a weighted average of “group scores” from different domains of quality (mortality, readmissions, safety, patient experience, imaging, effectiveness of care, timeliness of care). Each group has within it, measures that are reported on Hospital Compare. Group scores for each individual group are derived from latent-variable models that identify an underlying quality trait for each group. Group scores are combined into an overall hospital score using fixed weights; overall hospital scores are then clustered, using k-means clustering, into five groups and are assigned one-to-five stars (the hospital’s Star Rating). For the validity testing presented in this testing form, we used hospital’s Star Ratings from 4,246 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Rating can be found at <https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources>.

We examined the relationship of performance the AMI mortality measure scores (RSMR) with each of the external measures of hospital quality. For the external measures, the comparison was against performance within quartiles of the mortality group score, or in the case of Star Ratings, to the Star Rating category (1-5 Stars). We predicted the AMI mortality scores would be more strongly associated with the Hospital Star Rating mortality group score than the Overall Star Ratings scores, with lower RSMRs associated with better Star Ratings.

Medical Record Model Validation

During original measure development, we validated the AMI mortality administrative model against a medical record model in the same cohort of patients for which hospital-level AMI mortality medical record data were available (Krumholz et al, 2006).

For the derivation of the chart-based model, we used cases identified through the Cooperative Cardiovascular Project (CCP) initiative and provided by the Health Care Financing Administration (now CMS). The CCP initiative included more than 200,000 admissions to non-governmental, acute care hospitals in the United States and Puerto Rico (Krumholz et al., 1998; Marciniak et al., 1998). In the CCP study, CMS sampled all claims from FFS Medicare patients during an approximately 8-month period (varying by state) in 1994 and 1995 who were discharged with a principal diagnosis of AMI (ICD-9-CM code 410, excluding 410.x2). These patients were matched to the Medicare enrollment database to determine survival and, where applicable, the date of death. Corresponding medical records were abstracted by 2 clinical data abstraction centers (DynKePRO [York, PA] and FMAS Corporation [Rockville, MD]), and the clinical data used to confirm the diagnosis of AMI.

The test sample contained 178,188 cases with an unadjusted mortality rate of 19.0%.

The medical record model validation included clinician and hospital outpatient data. The same coding and transfer rules described in the AMI administrative dataset were used in defining the AMI medical record dataset.

Validity Indicated by Established Measure Development Guidelines:

We developed this measure in consultation with national guidelines for publicly reported outcomes measures, with outside experts, and with the public. The measure is consistent with the technical approach to outcomes measurement set forth in NQF guidance for outcomes measures (National Quality Forum, 2010), CMS Measure Management System (MMS) guidance, and the guidance articulated in the American Heart Association scientific statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes” (Krumholz, Brindis, et al. 2006).

References:

Krumholz HM, Wang Y, Mattera JA, et al. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with an acute myocardial infarction. Circulation 2006;113(13):1683-92.

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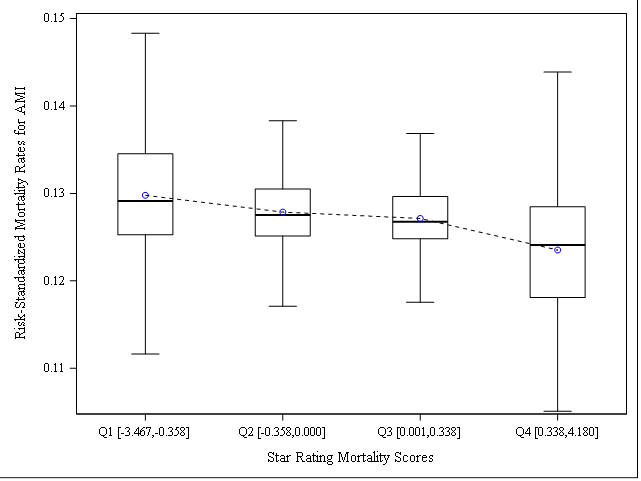
Krumholz HM, Brindis RG,Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation. January 24, 2006 2006;113(3):456-462.

**2b1.3. What were the statistical results from validity testing**? (*e.g., correlation; t-test*)

Comparison to Star-Rating Mortality Scores

Figure 1 shows the box-whisker plots of the AMI mortality measure RSMRs within each quartile of Star-Rating mortality scores. The blue circles represent the mean RSMRs of Star-Rating mortality score quartiles. The correlation between AMI RSMRs and Star-Rating mortality score is -0.409, which suggests that hospitals with lower AMI RSMRs are more likely to have higher Star-Rating mortality scores.

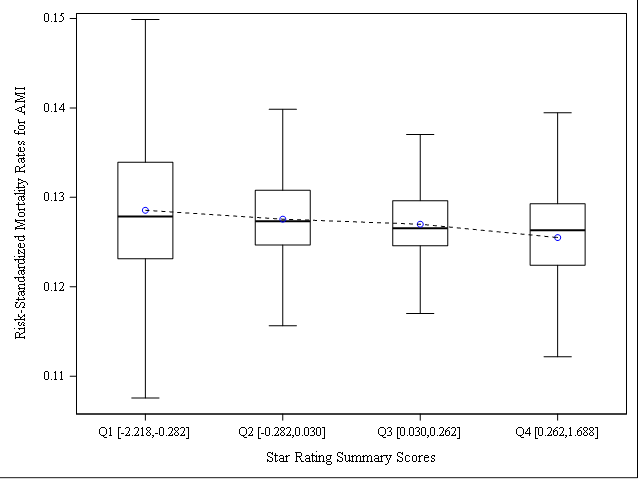
**Figure 1**



Comparison to Overall Star-Rating Scores

Figure 2 shows the Box-whisker plots of the AMI mortality measure RSMRs within each quartile of Star-Rating summary scores. The blue circles represent the mean RSMRs of Star-Rating summary score quartiles. The correlation between AMI RSMRs and Star-Rating summary score is -0.204, which suggests that hospitals with lower AMI RSMRs are more likely to have higher Star-Rating summary scores.

**Figure 2**

****

Medical-Record-Based Validation

CORE validated the performance of the claims-based model and a medical records-based model, as described above, and found the performance was similar. The areas under the receiver operating characteristic (ROC) curve were 0.69 and 0.77, respectively, for the two models. We estimated hospital-level RSMRs using the corresponding hierarchical logistic regression administrative and medical record models for the linked patient sample. We then examined the linear relationship between the two sets of estimates using regression techniques and weighting by the total number of cases in each hospital. The correlation coefficient of the standardized rates from the administrative and medical record models was 0.91 which shows that there was a strong correlation in rates calculated from the clinical and administrative models.

Reference:

Krumholz HM, Wang Y, Mattera JA, Wang Y, Han LF, Ingber MJ, Roman S, Normand SL. An administrative claims model suitable for profiling hospital performance based on 30-day mortality rates among patients with an acute myocardial infarction. Circulation. 2006 Apr 4;113(13):1683-92.

**2b1.4. What is your interpretation of the results in terms of demonstrating validity**? (i*.e., what do the results mean and what are the norms for the test conducted?*)

Empirical Validity Testing

This validation approach compares the 30-day AMI mortality measure results against the star rating mortality domain and overall summary scores. Figure 1 and 2 Box Plots results demonstrate an observed trend of lower risk-standardized mortality with higher star ratings score, especially at the extremes, which supports measure score validity. The correlation coefficients associated with the star rating mortality domain scores and the AMI mortality measure scores indicate a moderate association. A moderate association is also seen with the overall star ratings score, which is to be expected given the measures are calculated by complex statistical models. Overall, the results above show that the trend and direction of this association is in line with what would be expected.

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**2b2. EXCLUSIONS ANALYSIS**

**NA**  **no exclusions — *skip to section*** [***2b4***](#section2b4)

**2b2.1. Describe the method of testing exclusions and what it tests** (*describe the steps―do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

All exclusions were determined by careful clinical review and have been made based on clinically relevant decisions to ensure accurate calculation of the measure. To ascertain impact of exclusions on the cohort, we examined overall frequencies and proportions of the total cohort excluded for each exclusion criterion (**Testing Dataset**). These exclusions are consistent with similar NQF-endorsed outcome measures. Rationales for the exclusions are detailed in data field S.9 (Denominator Exclusions).

**2b2.2. What were the statistical results from testing exclusions**? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

In the **Testing Dataset (Table 3)**, below is the distribution of exclusions among hospitals with 25 or more admissions:

| **Exclusion** | **N** | **%** | **Distribution across hospitals N=3,854 (Min, 25th, 50th, 75th percentile, max)** |
| --- | --- | --- | --- |
| 1. Discharged alive on the day of admission or the following day who were not transferred to another acute care facility | 36,251 | 6.81% | (0.00, 3.38, 5.83, 9.25, 35.3) |
| 2. Inconsistent or unknown vital status or other unreliable demographic (age and gender) data | 23 | 0.00% | (0.00, 0.00, 0.00, 0.00, 1.56) |
| 3. Enrolled in the Medicare hospice program or used VA hospice services any time in the 12 months prior to the index admission, including the first day of the index admission | 3,694 | 0.69% | (0.00, 0.00, 0.42, 1.13, 37.2) |
| 4. Discharged against medical advice (AMA) | 3,302 | 0.62% | (0.00, 0.00, 0.34, 0.97, 11.8) |

**2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results?** (*i.e., the value outweighs the burden of increased data collection and analysis. Note:* ***If patient preference is an exclusion****, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

**Exclusion 1** (patients who were discharged alive on the day of admission or the following day who were not transferred to another acute care facility) accounts for 6.81% of all index admissions excluded from the initial index cohort. This exclusion represents the majority of all exclusions, and is meant to ensure a clinically coherent cohort. This exclusion prevents inclusion of patients who likely did not have clinically significant AMI.

**Exclusion 2** (patients with inconsistent or unknown vital status or other unreliable demographic [age and gender] data) accounts for less than 0.01% of all index admissions excluded from the initial index cohort. We do not include stays for patients where the age is greater than 115, where the gender is neither male nor female, where the admission date is after the date of death in the Medicare Enrollment Database, or where the date of death occurs before the date of discharge but the patient was discharged alive.

**Exclusion 3** (patients enrolled in the Medicare hospice program or used VA hospice services any time in the 12 months prior to the index admission, including the first day of the index admission) accounts for 0.69% of all index admissions excluded from the initial index cohort. These patients are likely continuing to seek comfort measures only; thus, mortality is not necessarily an adverse outcome or signal of poor quality care.

**Exclusion 4** (patients who are discharged AMA) accounts for 0.62% of all index admissions excluded from the initial index cohort. This exclusion is needed for acceptability of the measure to hospitals, who do not have the opportunity to deliver full care and prepare the patient for discharge. Given that a very small percentage of patients are being excluded, it is unlikely this exclusion affects the measure score.

After all exclusions are applied, the measure randomly selects one index admission per patient per year for inclusion in the cohort so that each episode of care is mutually independent with a similar probability of the outcome. For each patient, the probability of death may increase with each subsequent admission, and therefore, the episodes of care are not mutually independent. Similarly, for the three-year combined data, when index admissions occur during the transition between measure reporting periods (June and July of each year) and both are randomly selected for inclusion in the measure, the measure includes only the June admission. The July admissions are excluded to avoid assigning a single death to two admissions.

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**2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES**  
***If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section*** [***2b5***](#section2b5)***.***

**2b3.1. What method of controlling for differences in case mix is used?**

**No risk adjustment or stratification**

**Statistical risk model with** 27 **risk factors**

**Stratification by** Click here to enter number of categories **risk categories**

**Other,** Click here to enter description

**2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.**

See risk model specifications in Section 2b3.4a and the attached data dictionary.

**2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities**.

N/A. This measure is risk adjusted.

**2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk** (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any “ordering” of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

**Selecting Risk Variables**

Our goal in selecting risk factors for adjustment was to develop parsimonious models that included clinically relevant variables strongly associated with the risk of mortality in the 30 days following an index admission. We used a two stage approach, first identifying the comorbidity or clinical status risk factors that were most important in predicting the outcome, then considering the potential addition of social risk factors.

The original measure was developed with ICD-9. When ICD-10 became effective in 2015, we transitioned the measure to use ICD-10 codes as well. ICD-10 codes were identified using 2015 GEM mapping software. We then enlisted the help of clinicians with expertise in relevant areas to select and evaluate which ICD-10 codes map to the ICD-9 codes used to define this measure during development. A code set is attached in field S.2b. (Data Dictionary).

For risk model development, we started with Condition Categories (CCs) which are part of CMS’s Hierarchical Condition Categories (HCCs). The current HCC system groups the 70,000+ ICD-10-CM and 17,000+ ICD-9-CM codes into larger clinically coherent groups (201 CCs) that are used in models to predict mortality or other outcomes (Pope et al. 2001; 2011). The HCC system groups ICD- codes into larger groups that are used in models to predict medical care utilization, mortality, or other related measures.

To select candidate variables, a team of clinicians reviewed all CCs and excluded those that were not relevant to the Medicare population or that were not clinically relevant to the mortality outcome (for example, attention deficit disorder, female infertility). All potentially clinically relevant CCs were included as candidate variables and, consistent with CMS’s other claims-based mortality measures, some of those CCs were then combined into clinically coherent CC groupings.

To inform final variable selection, a modified approach to stepwise logistic regression was performed. The Development Sample was used to create 1,000 “bootstrap” samples. For each sample, we ran a logistic stepwise regression that included the candidate variables. The results (not shown in this report) were summarized to show the percentage of times that each of the candidate variables was significantly associated with mortality (p<0.01) in each of the 1,000 repeated samples (for example, 90 percent would mean that the candidate variable was selected as significant at p<0.01 in 90 percent of the times). We also assessed the direction and magnitude of the regression coefficients.

The clinical team reviewed these results and decided to retain risk adjustment variables above a predetermined cutoff, because they demonstrated a strong and stable association with risk of mortality and were clinically relevant. Additionally, specific variables with particular clinical relevance to the risk of mortality were forced into the model (regardless of percent selection) to ensure appropriate risk adjustment for AMI. These included variables representing markers for end of life/frailty, such as:

* Metastatic and other severe cancers (CC 8-CC 9)
* Hemiplegia, paraplegia, paralysis, functional disability (CC 70-CC 74, CC 103, CC 104, CC 189-CC 190)
* Stroke (CC 99-CC 100)
* Chronic kidney disease, stage 5 (CC 136)
* End-stage liver disease (CC 27)

This resulted in a final risk-adjustment model that included 27 variables.

Social Risk Factors

We weigh SRF adjustment using a comprehensive approach that evaluates the following:

* Well-supported conceptual model for influence of SRFs on measure outcome (detailed below);
* Feasibility of testing meaningful SRFs in available data (section 1.8); and
* Empiric testing of SRFs (section 2b3.4b).

Below, we summarize the findings of the literature review and conceptual pathways by which social risk factors may influence risk of the outcome, as well as the statistical methods for SRF empiric testing. Our conceptualization of the pathways by which patients’ social risk factors affect the outcome is informed by the literature cited below and IMPACT Act–funded work by the National Academy of Science, Engineering and Medicine (NASEM) and the Department of Health and Human Services Assistant Secretary for Policy and Evaluation (ASPE).

Causal Pathways for Social Risk Variable Selection

Although some recent literature evaluates the relationship between patient SRFs and the mortality outcome, few studies directly address causal pathways or examine the role of the hospital in these pathways (see, for example, Chang et al 2007; Gopaldas et al., 2009; Kim et al., 2007; LaPar et al., 2010; 2012; Bernheim et al., 2007; Lindenauer et al., 2013; Trivedi et al., 2014; Buntin et al., 2017; Kosar et al., 2020). 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 mortality.

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 characteristics of individual patients, and include the patient’s income or education level (Eapen et al., 2015). 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). 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 (Roshanghalb et al., 2019; Alghanem et al., 2020). 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; Jha et al., 2013).

The conceptual relationship, or potential causal pathways by which these possible social risk factors influence the risk of mortality 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:

1. **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 (restrictions based on job), lack of access to care (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.
2. **Patients with social risk factors often 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 are less likely to be found in geographic areas with large populations of poor patients. Thus, patients with low income are more likely to be seen in lower quality hospitals, which can explain increased risk of mortality following hospitalization.
3. **Patients with social risk factors may receive differential care within a hospital**. The third major pathway by which social risk factors may contribute to mortality 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).
4. **Patients with social risk factors may experience worse health outcomes beyond the control of the health care system.** Some social risk factors, such as income or wealth, may affect the likelihood of mortality 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 which don’t allow for adequate recuperation or access to needed treatments, or a lack of access to care outside of the hospital.

Although we analytically aim to separate these pathways to the extent possible, we acknowledge that risk factors often act on multiple pathways, and as such, individual pathways are complex to distinguish analytically. Further, some social risk factors, despite having a strong conceptual relationship with worse outcomes, may not have statistically meaningful effects on the risk model. They also have different implications on the decision to risk adjust or not.

Based on this model and the considerations outlined in section 1.8 – namely, that the AHRQ SES index and dual eligibility variables aim to capture the SRFs that are likely to influence these pathways (income, education, housing, and community factors) - the following social risk variables were considered for risk-adjustment:

* Dual eligible status
* AHRQ SES index

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**2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:**

**Published literature**

**Internal data analysis**

**Other (please describe)**

**2b3.4a. What were the statistical results of the analyses used to select risk factors?**

The table below shows the final variables in the model in the testing dataset with associated odds ratios (OR) and 95 percent confidence intervals (CI).

Table 4. Adjusted OR and 95% CIs for the AMI Mortality Hierarchical Logistic Regression Model over Different Time Periods in the **Testing Dataset**

| **Variable** | **07/2016-06/2017**  **OR (95% CI)** | **07/2017-06/2018**  **OR (95% CI)** | **07/2018-06/2019**  **OR (95% CI)** | **07/2016-06/2019**  **OR (95% CI)** |
| --- | --- | --- | --- | --- |
| Age minus 65 (years above 65, continuous) | 1.06 (1.05-1.06) | 1.06 (1.06-1.06) | 1.06  (1.06-1.06) | 1.06 (1.06-1.06) |
| Male | 1.10 (1.06-1.13) | 1.07 (1.04-1.11) | 1.04 (1.01-1.08) | 1.08 (1.05-1.10) |
| Anterior myocardial infarction | 2.62 (2.48-2.76) | 2.74 (2.60-2.90) | 2.89 (2.74-3.05) | 2.75 (2.66-2.84) |
| Non-anterior location of myocardial infarction | 2.52 (2.42-2.62) | 2.61 (2.50-2.72) | 2.63 (2.52-2.75) | 2.58 (2.52-2.65) |
| History of coronary artery bypass graft (CABG) surgery | 1.09 (1.04-1.14) | 1.11 (1.07-1.16) | 1.14 (1.09-1.19) | 1.11 (1.08-1.14) |
| History of percutaneous transluminal coronary angioplasty (PTCA) | 0.84 (0.81-0.88) | 0.78 (0.75-0.81) | 0.78 (0.74-0.81) | 0.80 (0.78-0.82) |
| Metastatic cancer, acute leukemia and other severe cancers (CC 8-9) | 1.89 (1.78-2.01) | 1.94 (1.83-2.07) | 1.78 (1.67-1.90) | 1.88 (1.81-1.95) |
| Diabetes mellitus (DM) or DM complications except proliferative retinopathy (CC 17-19, 123) | 1.11 (1.08-1.15) | 1.14 (1.11-1.18) | 1.13 (1.09-1.17) | 1.13 (1.10-1.15) |
| Protein-calorie malnutrition (CC 21) | 1.79 (1.70-1.88) | 1.79 (1.70-1.88) | 1.75 (1.66-1.84) | 1.79 (1.73-1.84) |
| Chronic liver disease (CC 27-29) | 1.77 (1.62-1.94) | 1.67 (1.52-1.83) | 1.69 (1.53-1.86) | 1.71 (1.63-1.81) |
| Dementia or other specified brain disorders (CC 51-53) | 1.53 (1.47-1.58) | 1.50 (1.45-1.56) | 1.48 (1.42-1.54) | 1.50 (1.47-1.54) |
| Major psychiatric disorders (CC 57-59) | 1.04 (0.98-1.10) | 0.97 (0.91-1.03) | 1.03 (0.96-1.09) | 1.02 (0.98-1.05) |
| Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190) | 1.36 (1.28-1.44) | 1.23 (1.16-1.32) | 1.24 (1.16-1.32) | 1.28 (1.23-1.32) |
| Cardio-respiratory failure and shock (CC 84 plus ICD-10-CM codes R09.01 and R09.02, for discharges on or after October 1, 2015; CC 84 plus ICD-9-CM codes 799.01 and 799.02, for discharges prior to October 1, 2015) | 1.21 (1.16-1.27) | 1.17 (1.11-1.23) | 1.18 (1.13-1.25) | 1.19 (1.16-1.23) |
| Congestive heart failure (CC 85) | 1.26 (1.21-1.31) | 1.22 (1.18-1.27) | 1.21 (1.16-1.26) | 1.23 (1.20-1.26) |
| Acute myocardial infarction (CC 86) | 1.01 (0.96-1.05) | 0.98 (0.93-1.02) | 1.03 (0.98-1.08) | 1.00 (0.97-1.03) |
| Unstable angina and other acute ischemic heart disease (CC 87) | 0.86 (0.81-0.91) | 0.90 (0.85-0.96) | 0.91 (0.85-0.97) | 0.89 (0.86-0.92) |
| Coronary atherosclerosis or angina (CC 88-89) | 0.70 (0.67-0.72) | 0.71 (0.68-0.74) | 0.74 (0.71-0.77) | 0.71 (0.70-0.73) |
| Valvular and rheumatic heart disease (CC 91) | 1.13 (1.09-1.17) | 1.11 (1.08-1.15) | 1.14 (1.10-1.18) | 1.13 (1.11-1.15) |
| Hypertension (CC 95) | 0.72 (0.70-0.75) | 0.72 (0.69-0.75) | 0.74 (0.71-0.77) | 0.73 (0.71-0.74) |
| Stroke (CC 99-100) | 0.94 (0.89-1.00) | 0.93 (0.87-0.99) | 1.01 (0.95-1.08) | 0.96 (0.92-0.99) |
| Cerebrovascular disease (CC 101-102, 105) | 1.01 (0.97-1.05) | 1.04 (1.00-1.09) | 1.05 (1.00-1.09) | 1.03 (1.01-1.06) |
| Vascular disease and complications (CC 106-108) | 1.11 (1.07-1.15) | 1.15 (1.10-1.19) | 1.08 (1.04-1.13) | 1.12 (1.09-1.14) |
| Chronic obstructive pulmonary disease (COPD) (CC 111) | 1.12 (1.08-1.16) | 1.17 (1.12-1.21) | 1.13 (1.09-1.18) | 1.13 (1.11-1.16) |
| Pneumonia (CC 114-116) | 1.47 (1.42-1.53) | 1.48 (1.42-1.54) | 1.44 (1.38-1.50) | 1.46 (1.43-1.49) |
| Renal failure (CC 135-140) | 1.39 (1.35-1.44) | 1.43 (1.38-1.48) | 1.45 (1.39-1.50) | 1.42 (1.39-1.45) |
| Trauma; other injuries (CC 166-168, 170-174) | 1.03 (0.99-1.06) | 1.05 (1.01-1.08) | 1.06 (1.02-1.10) | 1.04 (1.02-1.06) |

**2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors** *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Throughout this section, we present new SRF testing results based on the current testing dataset (2020); in addition, we show prior analyses included in the 2015 endorsement maintenance forms for comparison purposes.

Variation in prevalence of the factor across measured entities in 2020 and 2015 (Table 5)

|  |  |  |
| --- | --- | --- |
| **SRFs** | **2020 Prevalence**  **% (IQR)** | **2015 Prevalence**  **% (IQR)** |
| Dual | 11.4% (4.80-25.0%) | 10.8% (6.9-16.8%) |
| AHRQ Low SES | 16.5% (3.30-33.3%) | 16.4% (4.1-40.3%) |

The prevalence of social risk factors in the AMI cohort varies widely across measured entities in 2020. The median percentage of dual eligible patients was 11.4% (4.80%-25.0%) and the median percentage of patients with an AHRQ SES index score adjusted for cost of living at the census block group level equal to or below 42.7 (lowest quartile) was 16.5% (3.30%-33.3%) in 2020. These results are consistent with the 2015 results presented above. The increase in dually eligible patients may be due to a refinement in the definition that occurred since 2016.

Comparison of observed mortality rates in patients with and without social risk in 2020 and 2015 (Table 6)

|  |  |  |
| --- | --- | --- |
| **SRFs** | **2020 Observed Rate** | **2015 Observed Rate** |
| Dual (vs. Non-Dual) | 16.1% (vs. 12.2%) | 16.1% (vs. 14.0%) |
| AHRQ Low SES (vs. SES score above 42.7) | 13.3% (vs 12.7%) | 14.4% (vs. 13.9%) |

The patient-level observed AMI mortality rates are higher for dual-eligible patients (16.1%) compared with 12.2% for non-dual patients in 2020. Similarly, the mortality rate for patients with an AHRQ SES index score equal to or below 42.7 are 13.3% compared with 12.7% for patients with an AHRQ SES index score above 42.7 in 2020. For the AHRQ SES index, patient-level mortality rates have declined among all characteristic groups of patients; patient-level mortality rates have remained stable among dually eligible patients and have dropped for other characteristic groups of patients.

Incremental effect of SRF variables in a multivariable model in 2020 and 2015

We examined the strength and significance of the SRF variables in the context of a multivariable model. When we include these variables in a multivariable model that includes all of the claims-based clinical variables, the effect size of each of these variables is small. In 2020, dual eligibility and the AHRQ SES index have effect sizes (odds ratios) of 1.08 and 1.07 when added independently to the model, similar to 2016 findings. Furthermore, the effect size of each variable is slightly attenuated (1.07 and 1.06 for dual and SES, respectively) when both are added to the model simultaneously.

We also find that the c-statistic is essentially unchanged with the addition of any of these variables into the model (Table 7).

**Table 7**

| **AMI Mortality Models** | **2020 C-Statistic** |
| --- | --- |
| Base Model: risk-adjusted model using the original clinical risk variables selected for the 2020 CMS public report of the AMI mortality measure | 0.73 |
| Base Model plus AHRQ Low SES based on beneficiary residential 9-digit ZIP codes (SES9) as a social risk variable | 0.73 |
| Base Model plus dual eligibility (dual) as a social risk variable | 0.73 |
| Base Model plus SES9 and dual as social risk variables | 0.73 |

Furthermore, we find that the addition of any of these variables into the hierarchical model has little to no effect on hospital performance. We examined the change in hospitals’ RSMRs with the addition of any of these variables. The median absolute change in hospitals’ RSMRs when adding a dual eligibility indicator is 0.07% (interquartile range [IQR] -0.005% – 0.009%) with a correlation coefficient between RSMRs for each hospital with and without dual eligibility added of 0.999. The median absolute change in hospitals’ RSMRs when adding a low AHRQ SES Index score indicator to the model is 0.049% (IQR -0.021% – 0.068%) with a correlation coefficient between RSMRs for each hospital with and without an indicator for a low AHRQ SES Index score adjusted for cost of living at the census block group level is 0.978.

Summary

We find that the impact of any of these indicators is small to negligible on model performance and hospital-level results. Given the controversial nature of incorporating such variables into a risk-model, we do not support doing so in a case that is unlikely to affect hospital profiling. Given these empiric findings, ASPE’s recommendation to not risk adjust publicly reported quality measures for SRFs, and complex pathways which could explain the relationship between SRFs and mortality (and do not all support risk-adjustment), CMS chose to not incorporate SRF variables in this measure.

References:

Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). Second Report to Congress: Social Risk Factors and Performance in Medicare’s Value-based Purchasing Programs. 2020; <https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf>. Accessed July 2, 2020.

**2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach** (*describe the steps―do not just name a method; what statistical analysis was used*)

Approach to assessing model performance

We computed three summary statistics for assessing model performance (Harrell and Shih, 2001) for the expanded cohort:

***Discrimination Statistics***

(1) Area under the receiver operating characteristic (ROC) curve (the c-statistic) is the probability that predicting the outcome is better than chance, which is a measure of how accurately a statistical model is able to distinguish between a patient with and without an outcome)

(2) Predictive ability (discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects; therefore, we would hope to see a wide range between the lowest decile and highest decile.)

***Calibration Statistics***

(3) Over-fitting indices (over-fitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients)

We tested the performance of the model for **the development dataset** described in section 1.7.

References:

Harrell FE and Shih YC, Using full probability models to compute probabilities of actual interest to decision makers, *Int. J. Technol. Assess. Health Care* **17** (2001), pp. 17–26.

*Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below*.  
***If stratified, skip to*** [***2b3.9***](#question2b49)

**2b3.6. Statistical Risk Model Discrimination Statistics** (*e.g., c-statistic, R-squared*)**:**

Development and Validation Dataset:

**1st half of randomly split development sample**:

* c-statistic = 0.71
* Predictive ability (lowest decile %, highest decile %) = (4.0, 40.0)

**2nd half of randomly split development sample**:

* c-statistic = 0.70
* Predictive ability (lowest decile %, highest decile %) = (4.2, 40.1)

Results for the Testing Dataset

* C-statistic = 0.73
* Predictive ability (lowest decile %, highest decile %): (2.2, 33.7)

For comparison of model with and without inclusion of social risk factors, see above section.

**2b3.7. Statistical Risk Model Calibration Statistics** (*e.g., Hosmer-Lemeshow statistic*):

For the development cohort, the results are summarized below:

Development sample: Calibration: (0.0000, 1.0000)

Validation sample: Calibration: (-0.030, 0.994)

**2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves**:

The risk decile plot (Figure 3) is a graphical depiction of the deciles calculated to measure predictive ability. Below, we present the risk decile plot showing the distributions for Medicare FFS data from July 2016 – June 2019 (Testing Dataset).

Figure 3. Risk Decile Plot

The risk decile plot (Figure 3) is a graphical depiction of the deciles calculated to measure predictive ability. Below, we present the risk decile plot showing the distributions for Medicare FFS data from July 2016 – June 2020 (Testing Dataset).

**2b3.9. Results of Risk Stratification Analysis**:

N/A

**2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)?** (i*.e., what do the results mean and what are the norms for the test conducted*)

***Discrimination Statistics***

The c-statistic of 0.73 indicate moderate model discrimination. The model indicated a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects.

***Calibration Statistics***

*Over-fitting (Calibration γ0, γ1)*

If the γ0 in the validation samples are substantially far from zero and the γ1 is substantially far from one, there is potential evidence of over-fitting. The calibration value of close to 0 at one end and close to 1 to the other end indicates calibration of the model.

***Risk Decile Plots***

Higher deciles of the predicted outcomes are associated with higher observed outcomes, which show a good calibration of the model. This plot indicates good discrimination of the model and good predictive ability.

***Overall Interpretation***

Interpreted together, our diagnostic results demonstrate the risk-adjustment model adequately controls for differences in patient characteristics (case mix).

**2b3.11.** **Optional Additional Testing for Risk Adjustment** (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

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**2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE**

**2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified** (*describe the steps―do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

The measure score is hospital-specific risk-standardized mortality rates. These rates are obtained as the ratio of predicted to expected mortality, multiplied by the national unadjusted rate. The “predicted” mortality (the numerator) is calculated using the coefficients estimated by regressing the risk factors and the hospital-specific intercept on the risk of mortality. The estimated hospital-specific intercept is added to the sum of the estimated regression coefficients multiplied by the patient characteristics. The results are then transformed and summed over all patients attributed to a hospital to get a predicted value. The “expected” mortality (the denominator) is obtained in the same manner, but a common intercept using all hospitals in our sample is added in place of the hospital-specific intercept. The results are then transformed and summed over all patients in the hospital to get an expected value. To assess hospital performance for each reporting period, we re-estimated the model coefficients using the years of data in that period.

We characterize the degree of variability by:

1. Reporting the distribution of RSMRs.
   1. For public reporting of the measure, CMS characterizes the uncertainty associated with the RSMR by estimating the 95% interval estimate. This is similar to a 95% confidence interval but is calculated differently. If the RSMR’s interval estimate does not include the national observed mortality rate (because it is lower or higher than the rate), then CMS is confident that the hospital’s RSMR is different from the national rate, and describes the hospital on the Hospital Compare website as “better than the U.S. national rate” or “worse than the U.S. national rate.” If the interval includes the national rate, then CMS describes the hospital’s RSMR as “no different than the U.S. national rate” or “the difference is uncertain.” CMS does not classify performance for hospitals that have fewer than 25 cases in the three-year period.
2. Providing the median odds ratio (MOR) (Merlo et al, 2006)

The median odds ratio represents the median increase in the odds of mortality within 30 days of a AMI admission date on a single patient if the admission occurred at a higher risk hospital compared to a lower risk hospital. MOR quantifies the between hospital variance in terms of odds ratio, it is comparable to the fixed effects odds ratio.

Reference

Merlo J, Chaix B, Ohlsson H, Beckman A, Johnell K, Hjerpe P, Råstam L, Larsen K. (2006) A brief conceptual tutorial of multilevel analysis in social epidemiology: Using measures of clustering in multilevel logistic regression to investigate contextual phenomena. J Epidemiol Community Health, 60(4):290-7.

**2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities?** (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)  
Analyses of Medicare FFS data show substantial variation in RSMRs among hospitals.

Figure 4. Distribution (Histogram) Of Hospital-Level AMI RSMRs

Out of 4,246 hospitals in the measure cohort, 28 performed “better than the U.S. national rate,” 2,284 performed “no different from the U.S. national rate,” and 16 performed “worse than the U.S. national rate” and 1,918 were classified as “number of cases too small” (fewer than 25) to reliably tell how well the hospital is performing. 

Out of 4,246 hospitals in the measure cohort, 28 performed “better than the U.S. national rate,” 2,284 performed “no different from the U.S. national rate,” and 16 performed “worse than the U.S. national rate” and 1,918 were classified as “number of cases too small” (fewer than 25) to reliably tell how well the hospital is performing. There is considerable variation in RSMRs during the testing period, ranging from 8.8% to 18.1%.

The median odds ratio was 1.19.

**2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities?** (i*.e., what do the results mean in terms of statistical and meaningful differences?*)

The median odds ratio suggests a meaningful increase in the risk of mortality if a patient is admitted with AMI at a higher risk hospital compared to a lower risk hospital. A value of 1.19 indicates that a patient has a 19% increase in the odds of mortality at higher risk performance hospital compared to a lower risk hospital, indicating the impact of quality on the outcome rate is substantial.

The variation in rates and number of performance outliers suggests there remain differences in the quality of care received across hospitals for AMI. This evidence supports continued measurement to reduce the variation.

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**2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS**

***If only one set of specifications, this section can be skipped.***

**Note***: This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

**2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications** (*describe the steps―do not just name a method; what statistical analysis was used*)

N/A

**2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications?** (*e.g., correlation, rank order*)

N/A

**2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications?** (i*.e., what do the results mean and what are the norms for the test conducted*)

N/A

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**2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS**

**2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased** due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps―do not just name a method; what statistical analysis was used*)

The AMI mortality measure used claims-based data for development and testing. There was no missing data in the development and testing data.

**2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data?** (*e.g.,**results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

N/A

**2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased** due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i*.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

N/A