

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF#: 0468

Corresponding Measures:

De.2. Measure Title: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services (CMS)

De.3. Brief Description of Measure: The measure estimates a hospital-level 30-day risk-standardized mortality rate (RSMR). Mortality is defined as death for any cause within 30 days after the date of admission for the index admission, discharged from the hospital with a principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary diagnosis of pneumonia (including aspiration pneumonia) coded as present on admission (POA). CMS annually reports the measure for patients who are 65 years or older and are either Medicare fee-for-service (FFS) beneficiaries and hospitalized in non-federal hospitals or patients hospitalized in Veterans Health Administration (VA) facilities.

1b.1. Developer Rationale: The goal of this measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about hospital-level, risk-standardized mortality rates following hospitalization for pneumonia. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

Pneumonia mortality is a priority area for outcomes measure development as it is an outcome that is in part attributable to care processes and is an important outcome for patients. Measuring and reporting mortality rates will inform healthcare providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. The measure will also provide patients with information that could guide their choices, as well as increase transparency for consumers.

S.4. Numerator Statement: The outcome for this measure is 30-day all-cause mortality (including in-hospital deaths). We define mortality as death from any cause within 30 days of the index admission date from the date of admission for patients hospitalized with a principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary discharge diagnosis of pneumonia (including aspiration pneumonia) coded as POA and no secondary discharge diagnosis of severe sepsis.

S.6. Denominator Statement: This claims-based measure is used for a cohort of patients aged 65 years or over older.

The cohort includes admissions for patients aged 65 years and older discharged from the hospital with principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary discharge diagnosis of pneumonia (including aspiration pneumonia) coded as POA but no secondary discharge diagnosis of severe sepsis; and with a complete claims history for the 12 months prior to admission. The measure will be publicly reported by CMS for those patients 65 years or older who are Medicare FFS beneficiaries admitted to non-federal hospitals or patients admitted to VA hospitals.

Additional details are provided in S.9 Denominator Details.

- **S.8. Denominator Exclusions:** The mortality measure excludes index admissions for patients:
- 1. Discharged alive on the day of admission or the following day who were not transferred to another acute care facility;
- 2. With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;
- 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; or
- 4. Discharged against medical advice (AMA).

For patients with more than one admission for a given condition in a given year, only one index admission for that condition is randomly selected for inclusion in the cohort.

De.1. Measure Type: Outcome

S.17. Data Source: Claims, Enrollment Data, Other

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 09, 2007 Most Recent Endorsement Date: Aug 03, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? This measure is paired with a measure of hospital-level, all-cause, 30-day, risk-standardized readmission (RSRR) following pneumonia hospitalization.

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a health outcome measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

Evidence Summary or Summary of prior review in [year]

The developer submitted a logic model linking specific actions to this outcome.

Figure 1. PN Mortality Logic Model



Changes to evidence from last review

 \Box The developer attests that there have been no changes in the evidence since the measure was last evaluated.

☐ The developer provided updated evidence for this measure:

• Updates: The developer provided additional studies that demonstrate the importance of pneumonia mortality as well as specific interventions that can be performed to reduce pneumonia mortality.

Question for the Committee:

o Is there at least one thing that the provider can do to achieve a change in the measure results?

Guidance from the Evidence Algorithm

Box 1 – Outcome measure -> Box 2 – There is one ore more intervenetions that can be performed to reduce pneumonia mortality -> PASS

Preliminary rating for Evidence: ☐ Pass ☐ No Pass

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures - increased emphasis on gap and variation

- **1b. Performance Gap.** The performance gap requirements include demonstrating quality problems and opportunity for improvement.
 - Data were used from July 1, 2016 to June 30, 2019 for Medicare claims and VA administrative data (n= 1,310,984 admissions from 4,695 hospitals).
 - The three-year hospital-level risk standardized mortality rates (RSMRs) have a mean of 15.5% and range from 7.4-27.9% in the study cohort. The median risk-standardized rate is 15.4%. In 2019, the 20th percentile score was 14.0%, the median was 15.4% and the 80th percentile was 17.2%.

Disparities

- The distribution of 30-day PN RSMRs by Proportion of Dual Eligible Patients, was similar for the two strata of social risk proportion however somewhat higher on the upper board as well as lower on the lower bound for hospitals in the highest social risk scores.
- Using the AHRQ SES scores, the results were similar comparing Q1 and Q4.

Questions for the Committee:

- Is there a gap in mortality that warrants a national performance measure?
- Are there sufficient disparities to justify risk adjustment by SES?

Preliminary rating for opportunity for improvement:	\boxtimes	High	☐ Moderate	□ Low	☐ Insufficient
Committee Pre-evaluation Comments:					

Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures—are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- Pass
- Incredibly important to have focused communication at the time of discharge to the provider assuming care with timely follow up
- Strong evidence from literature to support measure focus; pneumonia is high risk and many modifiable risk factors may contribute to mortality rates.
- Evidence supports
- Relates adequately.
- Evidence exists and is applicable to the measures. Yes, at least one thing can be done to improve in each area.
- The rating is Pass. Agree evidence is present that one or more interventions can be used to reduce pneumonia mortality.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- No concerns.
- Yes. Continued need for measure given outcomes and disparities
- Absolute Gaps between 20th and 80th percentile of 3.2% are clinically meaningful. Social risk factors were assessed with negligible reported impact on overall hospital ratings
- Existing opportunity for improvement

- Fourfold range in performance suggests gap in care. No detailed data on disparities.
- Gaps have been demonstrated to exist and sufficient disparities to warrant risk adjustment by SES
- From 2016 to 2019 range of pneumonia mortality range from 9.7% to 27.9% with 10th percentile around 13% and 90th percentile around 18%. Agree that there is still room for improvement. Rating is High.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

2c. For composite measures: empirical analysis support composite approach

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if 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 enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel?
☐ Yes ☐ No

SMP Rates:

• R: H-4; M-4; L-0; I-0

• **V:** H-1; M-5; L-1; I-1

Evaluators: NQF Scientific Methods Panel

Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel and discussed on the call. A summary of the measure and the Panel discussion is provided below.

Reliability

- Two types of reliability testing at the level of the performance measure socre: 1) the intra-class correlation coefficient (ICC) using a split sample (i.e. test-retest) method, and 2) the facility-level reliability (signal-to-noise reliability).
- Split-Sample Reliability Results:

- In 1,310,984 admissions over 3 years of data, this was split into two samples. ICCs were calculated for hospitals with 25 admission or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of RSMR for each hospital was 0.668.
- Signal-to-Noise Results:
 - The median reliability score was 0.78, ranging from 0.31 to 0.98. The 25th and 75th percentiles were 0.59 and 0.88, respectively.

Validity

- The developer conducted empirical validity testing.
- Empirical validity results:
 - The developer validated the administrative model with a medical-record based model. Earlier work had shown rates to be highly correlated (Krumholz et al., 2006). When the developer reexamined the risk ratios for the risk variables used in the original (or current) measure, which showed that the variables remained predictive of the outcome (that is, mortality). Also, model performance characteristics were similar to those of the current pneumonia mortality measure.
 - The developer also mentioned a 2015 Reevaluation Report (Lindenauer et al., 2015), where the revision brings in a large portion of patients currently not included in the measure. The revised version of the measure according to the developer likely has greater validity in that it has mitigated biases introduced by hospital coding patterns. The developer confirmed that the approach to risk adjustment was effective, as hospital coding frequency was no longer associated with performance on the revised measure.
 - Two measures were the basis of comparison, the Hospital Star Rating Mortality group and the overall Hospital Star rating.
 - The correlation between PN RSMRs and Star-Rating mortality score is -0.653, which suggests that hospitals with lower PN RSMRs are more likely to have higher Star-Rating mortality scores
 - The correlation between PN RSMRs and Star-Rating summary score is -0.306, which suggests that hospitals with lower PN RSMRs are more likely to have higher Star-Rating summary scores.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability:	⊠ High	☐ Moderate	□ Low	☐ Insufficient
Preliminary rating for validity:	☐ High	⊠ Moderate	□ Low	☐ Insufficient

Committee Pre-evaluation Comments:

Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- High reliability
- OK
- High reliability indicated with signal to noise ratio of 0.78.
- reliable
- none
- No concerns or need to discuss or vote
- I do not have concerns

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- No
- No
- No
- no
- no
- No concerns or need to discuss or vote
- No concerns.

2b1. Validity -Testing: Do you have any concems with the testing results?

- No
- No
- Validity testing was moderate, correlated well with mortality star ratings but less strongly with overall star ratings. However, these results mostly point to a strong measure given the wide applicability.
- no
- no
- No concerns or need to discuss or vote
- No concerns.

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- No
- No concern
- The overall risk adjustment approach, using statistical and clinical input, seems appropriate. However, the model may under adjust for functional impairment by not taking into account where patients were admitted from (e.g. admissions from home health care would indicate homebound and higher risk),

admissions from SNF or long-term care may similarly indicate risk AND be disproportionately distributed among hospitals, especially those in rural areas. I also had a small concern with the AHRQSES application; a substantial body of literature is emerging to show poorer outcomes for adults in low neighborhood SES settings. Many of those approaches re-calculate the count of hospitals that may be impacted (through better star ratings or fewer penalties) by adjusting for SES status. The overall average model metrics may not be affected, but there may be subsets of highly vulnerable hospitals that are missed with this approach. Lastly, neighborhood poverty may have a threshold where the impacts are most likely to be feltextreme poverty rates (bottom 10-15%) may be more appropriate to use than the bottom quartile given the sample size.

- no concerns
- ok
- No concerns
- I agree that the exclusions and the rationale for risk adjustment are both sound.

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- No further discussion
- None
- No. Missing data was minimal and exclusions for hospice use and AMA discharges were appropriate.
- no concerns
- no
- No
- No concerns.

Criterion 3. Feasibility

Maintenance measures - no change in emphasis - implementation issues may be more prominent

- 3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
 - This measure comes from electronic claims data.

Questions for the Committee:

•	poes the SC	. nave any	concerns related	to the reasibilit	y of the measure?
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	• Does the SC have any cond	erns related	to the reasibility	or the meas	surer	
Prel	iminary rating for feasibility:		☐ Moderate	☐ Low	☐ Insufficient	
	Committee Pre-evaluation	n Comments	:			
	Criteria 3: Feasibility					

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- High feasibility. No concerns.
- No concerns
- Very feasible
- no concerns
- none
- Measure is feasible
- Already being implemented. High feasibility.

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

• 4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported?	⊠ Yes □	No	
Current use in an accountability program?	⊠ Yes □	No 🗆 UNCLEAR	
Accountability program details			

Public Reporting: Hospital Compare https://www.medicare.gov/hospitalcompare/search.html?

 $Payment\ Program: Hospital\ Value\ Based\ Purchasing\ Program\ (HVBP)$

https://www.qualitynet.org/inpatient/hvbp

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

Each hospital receives their measure results in the Spring of each calendar year through CMS's QualityNet website. The results are then publicly reported on CMS's Hospital Compare website in July of each calendar year. Since the measure is risk standardized using data from all hospitals, hospitals cannot independently calculate their score. Detailed reports are also provided each hospital, as well as a user guide and other resources.

Additional Feedback: Since the last endorsement cycle, there have been > 500 articles related to mortality following PN admissions. Some studies have argued that between 2006 – 2014, readmissions for PN decreased but post-discharge mortality increased, suggesting a potential unintended consequence that readmission measures may be incentivizing hospitals to not readily admit patients with PN, and as a result, mortality rates increased (Khera et al., 2018; Wadhera et al. 2018; Meyer et al., 2018). However, the same studies have acknowledged that PN mortality was increasing prior to HRRP implementation and that factors unrelated to HRRP could have caused this trend — for example, trends in PN volume during particularly potent influenza

years, or the increasing use of DNRs, could lead to an increase in mortality rates. These findings suggest that the increase in mortality (which, again, preceded HRRP) is not a result of denying admission to people seeking acute care services. Of note, other studies have found no apparent increase in PN mortality (Dharmarajan et al., 2017; MedPAC, 2018; Stensland, 2019).

Given the importance of this potential issue on patient outcomes, CMS commissioned an independent group to investigate whether there have been increases in mortality rates after HRRP implementation. CMS found through this investigation that no sufficient evidence exists to suggest that mortality has increased because of the HRRP readmission measures. CMS is committed to continuing to monitor trends in same-condition readmission and mortality rates through annual measure reevaluation and surveillance tasks.

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use	: ⊠ Pass	□ No Pass
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- 4b. Usability (4a1. Improvement; 4a2. Benefits of measure)
- **4b. Usability** evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.
- **4b.1 Improvement.** Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results. The median hospital 30-day, all-cause, RSRR for the pneumonia mortality measure for the 3-year period between July 1, 2016 and June 30, 2019 was 15.4%. The median RSRR decrease by 1 absolute percentage point from July 2016-June 2017 (median RSRR: 15.9%) to July 2018-June 2019 (median: RSRR: 14.9%).

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation None reported by the developer **Potential harms** None reported by the developer

Additional Feedback:

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

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Preliminary rating for Usability and use:	☑ High	□ Moderate	□ Low	☐ Insufficient	

• Committee Pre-evaluation Comments:

Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the

measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- No concerns
- Focus on timely follow up with PCP or other at the time of discharge, rather than concern over unintended outcome of "not" readmitting or putting the patient in observation
- Public reporting of data is ongoing, and currently being used in an accountability program.
- No concerns
- marginal
- Measure is actionable and useful
- Currently being used and publicly reported. Rating Pass.

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- 4b1. Usability Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2.
 Usability Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.
- No concerns
- Same as above
- Usability is good, and while there is the potential for financial harms to some hospitals serving more vulnerable populations the overall benefits to patients is likely higher.
- No concerns
- Details on specifically how low-performing hospitals may improve is not given; however, slow overall improvement in mean performance of hospitals is noted.
- Measure is relevant and useful
- Median mortality improved by 1% point so far. No identified unintended consequences. Rating high.

Criterion 5: Related and Competing Measures

Related or competing measures

0231: Pneumonia Mortality Rate (IQI #20)

0279: Community Acquired Pneumonia Admission Rate (PQI 11)

0506 : Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization

 $1891: Hospital\,30-day,\,all-cause,\,risk-standardized\,readmission\,rate\,(RSRR)\,following\,chronic\,\,obstructive\,\,pulmonary\,\,disease\,(COPD)\,hospitalization$

1893 : Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization

2579: Hospital-level, risk-standardized payment associated with a 30-day episode of care for pneumonia (PN)

3502: Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure

3504 : Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure

Harmonization

- The developer reports that the measure has been appropriately harmonized.
- Committee Pre-evaluation Comments: Criterion 5:
 Related and Competing Measures
- 5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?
- No concerns
- No concerns with IQI 20
- No major concerns
- Several, developer reports harmonization
- There is the claim that similar measures are 'harmonized.' I wonder if it is time to combine several related measures.
- No comment
- I find the explanations provided to differentiate this from other related measures to be satisfactory.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 01/15/2021

Comment by: American Medical Association

The American Medical Association (AMA) appreciates the opportunity to comment on #468, Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization. We are disappointed to see the minimum measure score reliability results of 0.31 using a minimum case number of 25 patients. We believe that measures must meet minimum acceptable thresholds of 0.7 for reliability.

In addition, the AMA is extremely concerned to see that the measure developer used the recommendation to not include social risk factors in the risk adjustment models for measures that are publicly reported as outlined in the recent report to Congress by Assistant Secretary for Planning and Evaluation (ASPE) on Social Risk Factors and Performance in Medicare's Value-based Purchasing program (ASPE, 2020). We believe that while the current testing may not have produced results that would indicate incorporation of the two social risk factors included in testing, this measure is currently used both for public reporting and value-based purchasing. A primary limitation of the ASPE report was that none of the recommendations adequately addressed whether it was or was not appropriate to adjust for social risk factors in the same measure used for more than one accountability purpose, which is the case for here. This discrepancy along with the fact that the additional analysis using the American Community Survey is not yet released must be addressed prior to any measure developer relying on the recommendations within this report.

We request that the Standing Committee evaluate whether the measure meets the scientific acceptability criteria.

Reference:

Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Department & Departme

Value-Based Purchasing Program. 2020. https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs

• Comment by: Federation of American Hospitals

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on Measure #468, Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization. The FAH is concerned that even though the median reliability score was 0.78 for hospitals with at least 25 cases, reliability ranged from 0.31 to 0.98 and believes that the developer must increase the minimum sample size to a higher number to produce a minimum reliability threshold of sufficient magnitude (e.g. 0.7 or higher)

In addition, the FAH is very concerned to see that the measure developer's rationale to not include social risk factors in the risk adjustment model was in part based on the recommendations from the report to Congress by Assistant Secretary for Planning and Evaluation (ASPE) on Social Risk Factors and Performance in Medicare's Value-based Purchasing program released in March of last year (ASPE, 2020). A fundament flaw within the ASPE report was the lack of any recommendation addressing how a single measure with multiple accountability uses should address inclusion of social risk factors as is the case with this measure, which is both publicly reported and included in the Hospital Value-Based Purchasing program. Regardless of whether the testing of social risk factors produced results that were sufficiently significant, the FAH believes that no developer should rely on the recommendations of this report until the question of how to handle multiple uses is addressed along with the additional analysis using the American Community Survey.

As a result, the FAH requests that the Standing Committee carefully consider whether the measure as specified meets the scientific acceptability criteria.

Reference:

Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs

- Of the 1 NQF member who have submitted a support/non-support choice:
 - o 0 support the measure
 - 1 does not support the measure
- Combined Methods Panel Scientific Acceptability Evaluation

Measure Number: 0468 Measure Title: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization Type of measure: □ Process □ Process: Appropriate Use □ Structure □ Efficiency □ Cost/Resource Use ☑ Outcome ☐ Outcome: PRO-PM ☐ Outcome: Intermediate Clinical Outcome ☐ Composite Data Source: ☐ Electronic Health Data ☐ Electronic Health Records ☐ Management Data ☐ Assessment Data ☐ Paper Medical Records ☐ Instrument-Based Data ☐ Registry Data **⊠** Enrollment Data **⊠** Other Level of Analysis: ☐ Clinician: Group/Practice ☐ Clinician: Individual □ Facility □ Health Plan ☐ Population: Community, County or City ☐ Population: Regional and State ☐ Integrated Delivery System ☐ Other Measure is: ☐ New ☐ Previously endorsed (NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.) **RELIABILITY: SPECIFICATIONS** 1. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? ⊠ Yes **Submission document:** "MIF xxxx" document, items S.1-S.22 **NOTE**: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation. 2. Briefly summarize any concerns about the measure specifications. Panel Member #1: No concerns Panel Member #2: None Panel Member #4: The documentation provided in the MIF file describing the numerator (S.5) and denominator (S.6) was a bit unclear and disorganized, especially in trying to reflect all of the different possible populations (FFS 65+, VA, all-payer). **Panel Member #5:** Overall, measure specifications are very clear. There is one general concern. The specifications include patients aged 18+. However, it seems that most testing was conducted using data from patients aged 65+. The only testing conducted for patients aged 18-64 vs. 65+ was for the risk-adjustment model (section 2b3.11) using data from 2006. I could not identify any other testing of reliability, validity, threats to validity, or performance that included data for the younger age group. This questions the reliability, and possibly also the validity of this measure for patients aged 18-64. This issue has been clarified, and measure developers decided to change the specifications to limit each of the measures to the Medicare FFS 65+ population. The ratings for reliability and validity were selected accordingly.

Panel Member #6: As with the other CMS measures, the wording is a bit ambiguous. Assuming that numerator includes both patients discharged alive and discharged dead, the metric otherwise is well

specified.

Scientific Acceptability: Preliminary Analysis Form

Panel Member #7: None Panel Member #8: None

RELIABILITY: TESTING

Submission document: "MIF xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2 3. Reliability testing level 4. Reliability testing was conducted with the data source and level of analysis indicated for this measure **⊠** Yes □ No 5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was empirical VALIDITY testing of patient-level data conducted? ☐ Yes ☐ No 6. Assess the method(s) used for reliability testing Submission document: Testing attachment, section 2a2.2 Panel Member #1: Developer used a split sample ICC and signal to noise approaches, which were appropriate. Panel Member #2: Split sample ICC (test/retest) and facility level signal/noise Panel Member #3: SNR of 0.78 is acceptable Split sample ICC score of 0.67 is acceptable Panel Member #4: Used two appropriate methods for testing – split sample and signal-to-noise. Panel Member #5: No concerns. Methods were appropriate and clearly described. A description of how the 25-case threshold for public reporting was determined would be useful. Panel Member #6: Split sample and signal to noise--appropriate Panel Member #7: "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. testretest) method. Second, we estimated the facility-level reliability (signal-to-noise reliability)."

Panel Member #8: Split sample ICC and signal to noise ratio

7. Assess the results of reliability testing

Submission document: Testing attachment, section 2a2.3

Panel Member #1: The STN analysis found a median facility (>25 admission) reliability estimate of 0.78. The split sample ICC demonstrated a reliability of 0.67. Both results indicate acceptable reliability for the pneumo mortality measure.

Panel Member #2: Signal to noise wide range of reliability scores: 0.31 to 0.98 – Q1 values is 0.59 – moderate by most scales.

Split sample ICC - 0.668 - moderate agreement

Panel Member #3: SNR of 0.78 is acceptable Split sample ICC score of 0.67 is acceptable

Panel Member #4: Median signal-to-noise score of 0.78, which demonstrates substantial agreement, as defined by Adams et al. Split-sample score was 0.668 and represents a lower bound of reliability.

Panel Member #5: I don't think the interpretation of SNR reliability estimate as an agreement statistic is appropriate. Results suggest acceptable reliability at the score level (>0.7), thus there is high/acceptable certainty that the performance measure scores are reliable. However, it is now known how the inclusion of patients below the age of 65 would have impacted these results.

It would be useful to report here the percent of hospitals included in the reliability results (25+cases), although this is reported in the performance section (10%).

Panel Member #6: Split sample 0.668; Signal to noise 0.73 (0.31 to 0.98) — moderate or better reliability **Panel Member #7:** Split sample \rightarrow 0.668.

SNR median reliability (hospitals with >25 admissions) was 0.78.

Panel Member #8: The split sample reliability analysis revealed that the overall reliability was 0.668. The signal to noise ratio analysis revealed that median reliability for hospitals with >25 admissions was 0.78 and the 25th percentile was 0.59. The reliability is quite good for the majority of entities but concerningly low for the botton 10% (r<0.45). Although the Landis modifiers are cited, I do not accept them as relevant to this context. The Landis modifiers pertain to the strength of evidence against the null hypothesis of no agreement between raters of a categorical classifier. Note that other modifiers exist: Koo 2016 - "values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively. Portney and Watkins are more conservative, particularly at the upper end, with <0.75 poor to moderate, >0.75 good, an >0.90 "reasonable for clinical measurements".

I think we really need to move beyond these modifiers and do some work on the implications of unreliability in different quality measurement contexts. Can the developers comment of the impact of the observed reliability on misclassification or other consequences?

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

	Submission document: Testing attachment, section 2a2.2
	□ No
	☐ Not applicable (score-level testing was not performed)
9.	Was the method described and appropriate for assessing the reliability of ALL critical data elements?
	Submission document: Testing attachment, section 2a2.2
	☐ Yes
	□ No
	☑ Not applicable (data element testing was not performed)
10.	OVERALL RATING OF RELIABILITY (taking into account precision of specifications and all testing results):
	☑ High (NOTE: Can be HIGH only if score-level testing has been conducted)
	☑ Moderate (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)
	\square Low (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)
	\square Insufficient (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)
11.	Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.

Panel Member #1: The results indicate acceptable but not excellent reliability based on most published

Panel Member #2: see #7

Panel Member #3: SNR of 0.78 is acceptable Split sample ICC score of 0.67 is acceptable

conventions for these tests of reliability.

Panel Member #4: Used two appropriate methods for testing; signal-to-noise produced a score that demonstrates 'substantial' agreement.

Panel Member #5: Results suggest acceptable reliability at the score level, thus there is high certainty that the performance measure scores are reliable.

Can developers elaborate on how the 25-case threshold was established in relation to the overall reliability results?

Panel Member #6: Appropriate tests with reasonably high level of reliability

Panel Member #7: By the numbers. Typical small numbers problem.

Panel Member #8: See my comments under #7

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. Please describe any concerns you have with measure exclusions.

Submission document: Testing attachment, section 2b2.

Panel Member #1: none
Panel Member #2: none
Panel Member #3: none
Panel Member #4: None.

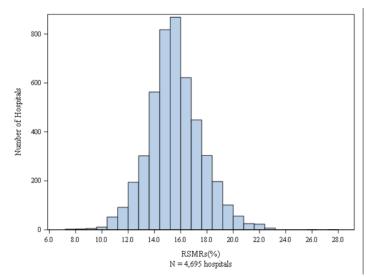
Panel Member #5: No concerns. Most cases excluded were due to being discharged alive on the day of admission or the following day who were not transferred to another acute care facility (2.9%) which is a criterion that has strong face validity and does not require additional testing. Other exclusions were less frequent (<2%) and also have strong face validity.

Panel Member #6: none Panel Member #7: None Panel Member #8: None

13. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

Submission document: Testing attachment, section 2b4.

Panel Member #1: none
Panel Member #3: None



Panel Member #4: There is variation in the calculated RSMRs; the statistical choice of how to categorize hospitals into 3 performance categories leaves 80% of hospitals in "no different from the U.S. national rate", which reflects some variation. Panel Member #5: As noted above, a clarification about the patient level performance transformation would be helpful: "The results are then transformed and...". As reported, 10% (483/4695) of hospitals had fewer than 25 cases therefor could not be reliably assessed for their RSMR (risk-standardized mortality rate). Can developers elaborate on how the 25-case threshold was established? Panel Member #6: Broad distribution demonstrated Panel Member #7: None Panel Member #8: None 14. Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified. **Submission document:** Testing attachment, section 2b5. Panel Member #1: N/A Panel Member #3: none Panel Member #4: Not applicable. Panel Member #6: Multiple data sources are used—claims plus eligibility plus vital status, etc. Ability to link these data sources well-established Panel Member #7: NA Panel Member #8: NA 15. Please describe any concerns you have regarding missing data. **Submission document:** Testing attachment, section 2b6. Panel Member #1: none Panel Member #2: Panel Member #3: none Panel Member #4: No missing data **Panel Member #5:** No concerns – no missing data reported. Panel Member #6: Issue appropriately addressed Panel Member #7: None Panel Member #8: None 16. Risk Adjustment □ None **⊠** Statistical model ☐ Stratification ☐ Yes □ No

16a. Risk-adjustment method □ None ☒ Statistical model □ Stratification

16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?
□ Yes □ No ☒ Not applicable

16c. Social risk adjustment:
16c. 1 Are social risk factors included in risk model? ☒ Yes ☒ No □ Not applicable
16c. 2 Conceptual rationale for social risk factors included? ☒ Yes □ No
16c. 3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☒ Yes □ No

16d. Risk adjustment summary:
16d. 1 All of the risk-adjustment variables present at the start of care? ☒ Yes □ No

16e. Assess the risk-adjustment approach

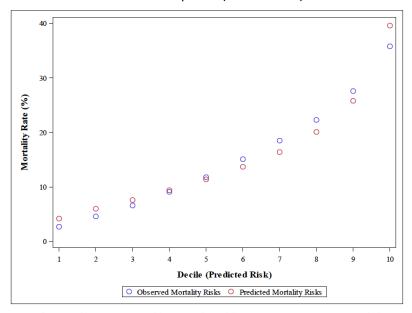
Panel Member #1: The risk adjustment approach is sound and results are acceptable, however I have a concern about the age of the data used to derive the coefficients in the model.

how inclusion might impact ratings of hospitals would be needed before decision not to include.

Panel Member #2: Methodology and results acceptable.

Panel Member #3: Standard approach based on hierarchical logistic regressionmodeling. Performance evaluated using PE ratio.

Model discrimination is acceptable (C stat = 0.72) and calibration is acceptable (0.05 0.95).



Panel Member #4: Used hierarchical logistic regression model; c-statistic of 0.72, which indicates moderate model discrimination

Panel Member #5: I have a few concerns, and would appreciate if developers could address the following issues:

- 1. Interpretation of Table 4 (Adjusted OR and 95% CIs for the AMI Mortality Hierarchical Logistic Regression Model over Different Time Periods in the Testing Dataset), especially for factors associated with lower risk of mortality. Could some of these 'protective' factors be due to collinearity with other risk-factors? Were results assessed for clinical plausibility (e.g., Asthma, Hypertension)?
- 2. I could not identify the results and interpretation of the estimation of average hospital and patient effects related to social risk factors described in section 2b3.3a ("To do this, we performed a

decomposition analysis to assess the independent effects of the SRF variables at the patient level and the hospital level.").

- 3. I do not understand why the summary states that: "the relationship between dual-eligible status and AHRQ low SES is in the opposite direction than what has been the expressed concern of stakeholders interested in adding such adjustment to the models". The odds ratios were >1, i.e., higher risk.
- 4. The decision to not include social risk factors in the model is supported mainly by testing results of no added predictive power and no change in hospital performance rankings. It would be useful to know the rate of hospitals that would have change rank if social-risk factors would have been included, which would provide information on the practical implication not informed by a correlation coefficient between RSRRs for each hospital with and without dual eligibility added. Regarding the result of no added predictive power, have similar considerations been applied to significant clinical factors included in the model, or even more, to non-significant clinical factors which are also expected to have no impact on the model's predictive power and hospital ranking?

Panel Member #7: C 0.721 with or without SES.

Panel Member #8: Good methodology, discrimination and calibration.

For cost/resource use measures ONLY:

	,									
17.	17. Are the specifications in alignment with the stated measure intent?									
	☐ Yes	□ Somewhat	☐ No (If "Some	what" or "No", pleas	se explain)					
18.	18. Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, of truncation (approach to outliers):									
VA	LIDITY: TI	ESTING								
19.	Validity	testing level: 🛛	Measure score	□ Data element	☐ Both					

- 20. Method of establishing validity of the measure score:

 - ☑ Empirical validity testing of the measure score
 - □ N/A (score-level testing not conducted)
- 21. Assess the method(s) for establishing validity

Submission document: Testing attachment, section 2b2.2

Panel Member #1: The developer used appropriate approach of correlating the measure score with CMS's Hospital Star Rating mortality group group score and the overall hospital star rating.

Panel Member #2: Facility-level correlations with the Star-Rating readmissions score, CMS's Overall Hospital Star Rating, and TJA Surgical Volume.

Panel Member #3: Standard approach. Compared new measure to existing measures.

Comparison to star-rating mortality scores: correlation coefficient -0.65

Comparison to star-rating for overall star rating: -0.36

Panel Member #4: For empirical validity testing, compared the hospital's performance on the PN mortality measure to the hospital's Mortality domain star rating and the hospital's overall Summary star rating. **Concerns with demonstrating validity by using a comparator measure that includes the measure being tested.** (we would expect there to be some correlation!)

Panel Member #5: Face validity was supported during the measure development phase based on national guidelines for publicly reported outcomes measures, and the inclusion of consultation with outside experts and with the public. Empirical testing against other similar measures were appropriate.

Panel Member #6: Correlation with Medicare Star ratings is somewhat problematic as this metric may be involved in those ratings. Slope of correlation but not R2 or p value are given. Validation with outside

source such as National Inpatient Sample might be more compelling. That said, the face validity of mortality as a metric is so strong that even without empirical testing measure has substantial validity.

Panel Member #7: Correlation with CMS Hospital Star Rating mortality and summary.

Panel Member #8: At the entity level, the measure score was correlated with the CMS's Hospital Star Rating mortality group score, which is derived from this measure and other related measures. In a sense, this is checking of the this measure is related to the latent valiable that is was used to to construct. It would be indeed suprising and concerning if this hypothesis wasn't supported. The measure was also correlated with the CMS's Overall Hospital Star Rating, which only indirectly contains the measure through the mortity score. It is reasonably hypothesized that the correlation would be positive but lower than the correlation with the mortalty score.

22. Assess the results(s) for establishing validity

Submission document: Testing attachment, section 2b2.3

Panel Member #1: The measure score correlation with star-rating mortality groups was moderately strong and in expected direction (-0.653), while the correlation with overall star rating group was weaker but still in the expected direction (-0.306). These findings provide support for the validity of the measures

Panel Member #2: Correlation with Star-Rating mortality score is -0.653

Correlation Star-Rating summary score is -0.306

Negative correlation is the desired direction in this case. Correlations with both star ratings is good.

Panel Member #3: Results suggest that hospitalsthis measure agrees with lower scoresother measures of hospital quality.

Panel Member #4: Moderate correlations (-0.653 and -0.306) with Mortality domain star rating and Summary star rating

Panel Member #5: Empirical testing results are more likelysatisfactory, supporting moderate to high evidence of validity against other related measures.

Panel Member #6: See comments to 21 above.

Panel Member #7: Negative correlations.

potential threats.

Panel Member #8: The correlation between this measure and the Star-Rating mortality score is -0.653, which suggests that hospitals with lower scores are more likely to have higher Star-Rating mortality scores. The correlation between this measure and Star-Rating summary score is -0.306, which suggests that hospitals with lower scores are more likely to have higher Star-Rating summary scores.

23. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?

	Submission document: Testing attachment, section 2b1.
	⊠ Yes
	⊠ No
	☐ Not applicable (score-level testing was not performed)
24.	. Was the method described and appropriate for assessing the accuracy of ALL critical data elements?
	NOTE that data element validation from the literature is acceptable.
	Submission document: Testing attachment, section 2b1.
	☐ Yes
	\square No
	☑ Not applicable (data element testing was not performed)
25.	OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of

\boxtimes	High (NOTE: Can be HIGH only if score-level testing has been conducted)
	Moderate (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been nducted)
	Low (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)
	Insufficient (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

26. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.

Panel Member #1: The validity testing results were acceptable, particularly the measure score correlation with mortality star-rating scores.

Panel Member #3: See above

Panel Member #4: Concerns with the choice of the two measures chosen (Mortality star rating & Summary star rating) to empirically test this measure's validity; a stronger choice would be measures that do not already include the measure under study.

Panel Member #5: Results suggest moderate to high correlation analysis with other similar measures at the score level, thus there is common, I would prefer to see an analysisa moderate certainty that the performance measure scores are valid.

Panel Member #6: Despite limitations of the methodology chosen for empiric testing, the face validity of mortality is so compelling that really nothing else should be needed.

Validation in >18 population based on 2009 data—should be updated to reflect same time frame as measure development.

Panel Member #7: Fine.

Panel Member #8: The hypothesized relationships were supported. Although the correlation analysis with other similar measures is common, I would prefer to see an analysis of the hypothesized relationships between hospital processes or structures and outcomes. The development, context, and accuracy of the risk model is good.

ADDITIONAL RECOMMENDATIONS

27. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.

Panel Member #1: For this measure and all the hospital risk standardized mortality measures submitted by this developer, we should consider whether it is acceptable for NQF endorsed measures to be based on out of date risk-models at the time of re-endorsement.

Developer Submission

NQF#: 0468

Corresponding Measures:

De.2. Measure Title: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services (CMS)

De.3. Brief Description of Measure: The measure estimates a hospital-level 30-day risk-standardized mortality rate (RSMR). Mortality is defined as death for any cause within 30 days after the date of admission for the index admission, discharged from the hospital with a principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary diagnosis of pneumonia (including aspiration pneumonia) coded as present on admission (POA). CMS annually reports the measure for patients who are 65 years or older and are either Medicare fee-for-service (FFS) beneficiaries and hospitalized in non-federal hospitals or patients hospitalized in Veterans Health Administration (VA) facilities.

1b.1. Developer Rationale: The goal of this measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about hospital-level, risk-standardized mortality rates following hospitalization for pneumonia. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

Pneumonia mortality is a priority area for outcomes measure development as it is an outcome that is in part attributable to care processes and is an important outcome for patients. Measuring and reporting mortality rates will inform healthcare providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. The measure will also provide patients with information that could guide their choices, as well as increase transparency for consumers.

- **S.4. Numerator Statement:** The outcome for this measure is 30-day all-cause mortality (including in-hospital deaths). We define mortality as death from any cause within 30 days of the index admission datefrom the date of admission for patients hospitalized with a principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary discharge diagnosis of pneumonia (including aspiration pneumonia) coded as POA and no secondary discharge diagnosis of severe sepsis.
- **S.6. Denominator Statement:** This claims-based measure is used for a cohort of patients aged 65 years or over older.

The cohort includes admissions for patients aged 65 years and older discharged from the hospital with principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary discharge diagnosis of pneumonia (including aspiration pneumonia) coded as POA but no secondary discharge diagnosis of severe sepsis; and with a complete claims history for the 12 months prior to admission. The measure will be publicly reported by CMS for those patients 65 years or older who are Medicare FFS beneficiaries admitted to non-federal hospitals or patients admitted to VA hospitals.

Additional details are provided in S.9 Denominator Details.

S.8. Denominator Exclusions: The mortality measure excludes index admissions for patients:

- 1. Discharged alive on the day of admission or the following day who were not transferred to another acute care facility;
- 2. With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;
- 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; or
- 4. Discharged against medical advice (AMA).

For patients with more than one admission for a given condition in a given year, only one index admission for that condition is randomly selected for inclusion in the cohort.

De.1. Measure Type: Outcome

S.17. Data Source: Claims, Enrollment Data, Other

S.20. Level of Analysis: Facility

 $\textbf{IF Endorsement Maintenance-Original Endorsement Date:} \ Mar\,09, 2007\, \textbf{Most Recent Endorsement Date:} \\$

Aug 03, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? This measure is paired with a measure of hospital-level, all-cause, 30-day, risk-standardized readmission (RSRR) following pneumonia hospitalization.

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. *Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.*

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF evidence PNmortality Fall2020 final 7.22.20.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

• 1a. Evidence (subcriterion 1a)

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 0468

Measure Title: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission: 11/2/2020

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- Outcome: 3 Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured intermediate clinical outcome leads to a desired health outcome.
- Process: ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- Efficiency: ⁶ evidence not required for the resource use component.
- For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- Process measures incorporating Appropriate Use Criteria: See NQF's guidance for evidence for measures, in general;
 guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

- 3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
- 4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.
- 5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.
- 6. Measures of efficiency combine the concepts of resource use and quality (see NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; AQA Principles of Efficiency Measures).

1a.1. This is a measure of: (should be consistent with type of measure entered in De. 1)

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Outcome: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization	
☐ Patient-reported outcome (PRO):	
PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)	
☐ Intermediate clinical outcome (<i>e.g., lab value</i>):	
Process:	
☐ Appropriate use measure:	

☐ Structure:☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Figure 1. PN Mortality Logic Model



The goal of this measure is to improve patient outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized mortality rates following hospitalization for pneumonia. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This mortality measure was developed to identify institutions, whose performance is better or worse than would be expected based on their patient case-mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome*, *process*, *or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A. This measure is not an intermediate outcome, process, or structure performance measure.

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

Pneumonia continues to be the most common infectious cause of hospitalization in the US, leading to more than 1 million hospitalizations a year and incurring billions of dollars in healthcare costs (Lindenauer et al., 2012; Jain et al., 2018; FastStats: pneumonia, CDC). The annual mortality rate (deaths per 100,000 population) is 15.1 (FastStats: pneumonia, CDC). Among patients 65 years [of age] or older in the United States, pneumonia is the leading infectious cause of death (Fry et al., 2005; Bratzler et al., 2011).

Pneumonia mortality is costly and represents an undesirable outcome of care from the patient's perspective, and highly disparate pneumonia readmission rates among hospitals suggest there is room for improvement.

Current hospital interventions have been shown to be associated with lower risk of mortality within 30 days of hospital admission (Lee et al., 2014; Radhakrishnan et al. 2018). Current process-based performance measures; however, cannot capture all the ways that care within the hospital might influence outcomes. Measurement of patient outcomes allows for a comprehensive view of quality of care that reflects complex aspects of care such as communication between providers and coordinated transitions to the outpatient environment. These aspects are critical to patient outcomes and are broader than what can be captured by individual process-of-care measures.

The diagram above indicates some of the many care processes that can influence mortality risk. Numerous studies have demonstrated that appropriate (guideline recommended care) and timely treatment for pneumonia patients can reduce the risk of mortality within 30 days of hospital admission (Gleason et al., 1999; Houck et al., 2001; Jha et al., 2007; Lee et al., 2014;). Evidence that hospitals have been able to reduce mortality rates through these quality-of-care initiatives illustrates the degree to which hospital practices can affect mortality rates (Lee et al., 2014; Radhakrishnan et al. 2018).

The pneumonia risk standardized mortality rate (RSMR) measure is thus intended to inform quality-of-care improvement efforts, as individual process-based performance measures cannot encompass all the complex and critical aspects of care within a hospital that contribute to patient outcomes. As a result, many stakeholders, including patient organizations, are interested in outcomes measures that allow patients and providers to assess relative outcomes performance for hospitals (Bratzler et al., 2007).

References:

Bratzler DW, Normand SL, Wang Y, et al. An administrative claims model for profiling hospital 30-day mortality rates for pneumonia patients. PLoS One. 2011; 6(4): e17401. [1]

Bratzler DW, Nsa W, Houck PM. Performance measures for pneumonia: are they valuable, and are process measures adequate. Current Opinion in Infectious Diseases. 2007; 20(2):182-189. [2]

Centers for Disease Control and Prevention. FastStats: pneumonia. Available at: http://www.cdc.gov/nchs/fastats/pneumonia.htm. Accessed March 13, 2020.

Fry AM, Shay DK, Holman RC, et al. Trends in hospitalizations for pneumonia among persons aged 65 years or older in the United States, 1988–2002. JAMA. 2005; 294:2712–2719.

Gleason PP, Meehan TP, Fine JM, et al. Associations between initial antimicrobial therapy and medical outcomes for hospitalized elderly patients with pneumonia. Arch Intern Med. 1999; 159(21):2562-2572.

Houck PM, MacLehose RF, Niederman MS, Lowery JK. Empiric antibiotic therapy and mortality among Medicare pneumonia inpatients in 10 western states: 1993, 1995, and 1997. Chest. 2001; 119(5):1420-1426.

Jain S, Khera R, Mortensen EM, Weissler JC. Readmissions of adults within three age groups following hospitalization for pneumonia: Analysis from the Nationwide Readmissions Database. *PLoS One*. 2018;13(9): e0203375. Published 2018 Sep 13. doi: 10.1371/journal.pone.0203375

Jha AK, Orav EJ, Li Z, Epstein AM. The inverse relationship between mortality rates and performance in the Hospital Quality Alliance measures. Health Aff (Millwood) 2007 Jul-Aug; 26(4):1104-10.

Lee JS, Nsa W, Hausmann LR, et al. Quality of care for elderly patients hospitalized for pneumonia in the United States, 2006 to 2010. JAMA Intern Med. 2014; 174(11):1806-1814.

Lindenauer PK, Lagu T, Shieh MS, et al. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003-2009. JAMA American Medical Association. 2012; 307(13):1405-1413.

Radhakrishnan K, Jones TL, Weems D, Knight TW, Rice WH. Seamless Transitions: Achieving Patient Safety Through Communication and Collaboration. J Patient Saf. 2018;14(1): e3-e5.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

•
Clinical Practice Guideline recommendation (with evidence review)
US Preventive Services Task Force Recommendation
\square Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center)
Other

Systematic Review

Evidence

Source of Systematic Review:

- Title
- Author
- Date
- Citation, including page number
- URL

Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.

Grade assigned to the evidence associated with the recommendation with the definition of the grade

Provide all other grades and definitions from the evidence grading system

Grade assigned to the recommendation with definition of the grade

Provide all other grades and definitions from the recommendation grading system

Body of evidence:

- Quantity how many studies?
- Quality what type of studies?

Estimates of benefit and consistency across studies

What harms were identified?

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

• 1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure (e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The goal of this measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about hospital-level, risk-standardized mortality rates following hospitalization for pneumonia. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

Pneumonia mortality is a priority area for outcomes measure development as it is an outcome that is in part attributable to care processes and is an important outcome for patients. Measuring and reporting mortality rates will inform healthcare providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. The measure will also provide patients with information that could guide their choices, as well as increase transparency for consumers.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. (This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Variation in mortality rates indicates opportunity for improvement. We conducted analyses using data from July 1, 2016 to June 30, 2019 Medicare claims and VA administrative data (n= 1,310,984 admissions from 4,695 hospitals).

The three-year hospital-level risk standardized mortality rates (RSMRs) have a mean of 15.5% and range from 7.4-27.9% in the study cohort. As shown below, the median risk-standardized rate is 15.4%. The distribution of mortality across hospitals is shown below:

Distribution of Hospital Pneumonia Mortality over Different Time Periods Results for each data year Characteristic//07/2016-06/2017//07/2017-06/2018//07/2018-06/2019//07/2016-06/2019

Number of Hospitals// 4,620 // 4,613 // 4,569 // 4,695

Number of Admissions// 424,866 // 455,286 // 430,832 // 1,310,984

Mean (SD) //16(1.6)//15.4(1.7)//15(1.4)//15.5(2)

Range (Min-Max) // 9.7 - 25.4 // 8.2 - 24.8 // 9.1 - 22.3 // 7.4 - 27.9

Minimum//9.7//8.2//9.1//7.4

10th percentile//14.2//13.5//13.4//13.1

20th percentile//14.9//14.2//14.0//14.0

30th percentile//15.2//14.7//14.4//14.6

40th percentile//15.6//15.0//14.7//15.0

50th percentile//15.9//15.3//14.9//15.4

60th percentile//16.2//15.7//15.2//15.9

70th percentile//16.6//16.1//15.6//16.4

80th percentile//17.2//16.6//16.1//17.2

90th percentile//17.9//17.6//16.9//18.2

Maximum//25.4//24.8//22.3//27.9

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

N/A

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Distribution of 30-day PN RSMRs by Proportion of Dual Eligible Patients:

Data Source: Medicare FFS claims, VA data, and Master Beneficiary Summary File (MBSF) data

Variation in RSMRs across hospitals (with at least 25 cases) by proportion of patients with social risk//

Description of Social Risk Variable//Dual Eligibility

Data Source: Medicare FFS claims, VA claims, and Medical Beneficiary Summary File (MBSF) data

Dates of Data: July 2016 through June 2019

Quartile//Q1//Q4

Social Risk Proportion (%)//(0-7.23)//(33.39-100)

of Hospitals//1052//1044

100%Max//22.8//27.9

90%//18.0//18.5

75%//16.5//17.0

50%//15.2//15.6

25%//14.1//14.2

10%//12.9//13.1

0%Min//9.5//7.4

Distribution of 30-day PN RSMRs by Proportion of Patients with AHRQ SES Index Scores:

Data Source: Medicare FFS claims, VA data, and the American Community Survey (ACS) data

Dates of Data: July 2016 through June 2019 (claims); 2013-2017 (ACS)

Variation in RSMRs across hospitals (with at least 25 cases) by proportion of patients in lower and upper social risk quartiles//

Description of Social Risk Variable //AHRQ SES Index

Quartile//Q1//Q4

SocialRiskProportion (%)//(0-14.25)//(29.77-97.44)

#ofHospitals //1053//1053

100%Max//22.5//23.0

90%//17.7//18.3

75%//16.3//16.8

50%//14.9//15.5

25%//13.6//14.2

10%//12.3//12.9

0%Min//8.3//7.4

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. *Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.*

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):

Respiratory: Pneumonia

De.6. Non-Condition Specific(check all the areas that apply):

Safety

De.7. Target Population Category (Check all the populations for which the measure is specified and tested if any):

Elderly, Populations at Risk

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

https://www.qualitynet.org/inpatient/measures/mortality/methodology

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure Attachment:

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment Attachment: NQF_datadictionary_PNmortality_Fall2020_final_7.22.20.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment**:

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

Updates consisted of updating the specifications to include new and modified ICD-10 CM/PCS codes.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The outcome for this measure is 30-day all-cause mortality (including in-hospital deaths). We define mortality as death from any cause within 30 days of the index admission datefrom the date of admission for patients hospitalized with a principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary discharge diagnosis of pneumonia (including aspiration pneumonia) coded as POA and no secondary discharge diagnosis of severe sepsis.

S.5. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The measure counts all deaths (including in-hospital deaths) for any cause within 30 days of the date of admission of the index pneumonia hospitalization.

Identifying deaths in the FFS measure

As currently reported, we identify deaths for FFS Medicare patients 65 years or over in the Medicare Enrollment Database (EDB) and for VA patients in the VA data.

S.6. Denominator Statement (Brief, narrative description of the target population being measured) This claims-based measure is used for a cohort of patients aged 65 years or over older.

The cohort includes admissions for patients aged 65 years and older discharged from the hospital with principal discharge diagnosis of pneumonia, including aspiration pneumonia or a principal discharge diagnosis of sepsis (not severe sepsis) with a secondary discharge diagnosis of pneumonia (including aspiration pneumonia) coded as POA but no secondary discharge diagnosis of severe sepsis; and with a complete claims history for the 12 months prior to admission. The measure will be publicly reported by CMS for those patients 65 years or older who are Medicare FFS beneficiaries admitted to non-federal hospitals or patients admitted to VA hospitals.

Additional details are provided in S.9 Denominator Details.

S.7. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excelor csv file in required format at S.2b.)

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

To be included in the measure cohort used in public reporting, patients must meet the following inclusion criteria:

- Principal discharge diagnosis of pneumonia, including aspiration pneumonia; or
 Principal discharge diagnosis of sepsis (not including severe sepsis), with a secondary discharge diagnosis of
 pneumonia (including aspiration pneumonia) coded as POA but no secondary discharge diagnosis of severe
 sepsis;
- 2. Enrolled in Medicare fee-for-service (FFS);
- 3. Aged 65 or over;
- 4. Not transferred from another acute care facility; and
- 5. Enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission and enrolled in Part A during the index admission.

We have explicitly tested the measure for those aged 65 years or over (see Testing Attachment for details).

S.8. Denominator Exclusions (Brief narrative description of exclusions from the target population)

The mortality measure excludes index admissions for patients:

- 1. Discharged alive on the day of admission or the following day who were not transferred to another acute care facility;
- 2. With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;
- 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; or
- 4. Discharged against medical advice (AMA).

For patients with more than one admission for a given condition in a given year, only one index admission for that condition is randomly selected for inclusion in the cohort.

- **S.9. Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)
- 1. The discharge disposition indicator is used to identify patients alive at discharge. Transfers are identified in the claims when a patient with a qualifying admission is discharged from an acute care hospital and admitted to another acute care hospital on the same day or next day. Patient length of stay and condition is identified from the admission claim.

Rationale: This exclusion prevents inclusion of patients who likely did not have clinically significant pneumonia.

2. Inconsistent vital status or unreliable data are identified if any of the following conditions are met 1) the patient's age is greater than 115 years; 2) if the discharge date for a hospitalization is before the admission date; or 3) if the patient has a sex other than 'male' or 'female'.

Rationale: Reliable and consistent data are necessary for valid calculation of the measure.

3. Hospice enrollment in the 12 months prior to or on the index admission is identified using hospice enrollment data.

Rationale: These patients are likely continuing to seek comfort measures only; thus, mortality is not necessarily an adverse outcome or signal of poor quality care.

4. Discharges against medical advice (AMA) are identified using the discharge disposition indicator.

Rationale: Providers did not have the opportunity to deliver full care and prepare the patient for discharge.

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 the 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. Also, 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.

S.10. Stratification Information (Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excelor csv file in required format with at S.2b.)

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

Statistical risk model

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)

The measure estimates hospital-level 30-day all-cause RSMRs following hospitalization for pneumonia using hierarchical logistic regression models. In brief, the approach simultaneously models data at the patient and hospital levels to account for variance in patient outcomes within and between hospitals (Normand and Shahian, 2007). At the patient level, it models the log-odds of mortality within 30 days of index admission using age, sex, selected clinical covariates, and a hospital-specific intercept. At the hospital level, it models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of a mortality at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution to account for the clustering (non-independence) of patients within the same hospital.

If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

The RSMR is calculated as the ratio of the number of "predicted" to the number of "expected" deaths at a given hospital, multiplied by the national observed mortality rate. For each hospital, the numerator of the ratio is the number of deaths within 30 days predicted on the basis of the hospital's performance with its observed case mix, and the denominator is the number of deaths expected based on the nation's performance with that hospital's case mix. This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus, a lower ratio indicates lower-than-expected mortality rates or better quality, and a higher ratio indicates higher-than-expected mortality rates or worse quality.

The "predicted" number of deaths (the numerator) is calculated by 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 transformed and summed over all patients attributed to a hospital to get a predicted value. The "expected" number of deaths (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 transformed and summed over all patients in the hospital to get an expected value. To assess hospital performance for each reporting period, we re-estimate the model coefficients using the years of data in that period.

This calculation transforms the ratio of predicted over expected into a rate that is compared to the national observed mortality rate. The hierarchical logistic regression models are described fully in the original methodology report posted on QualityNet:

https://qualitynet.org/inpatient/measures/mortality/methodology.

References:

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22(2): 206-226.

S.15. Sampling (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A. This measure is not based on a sample or survey.

S.16. Survey/Patient-reported data (If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.18.

Claims, Enrollment Data, Other

S.18. Data Source or Collection Instrument (*Identify the specific data source/data collection instrument* (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Data sources for the Medicare FFS measure:

Medicare Part A Inpatient and Part B Outpatient Claims: This data source contains claims data for FFS inpatient and outpatient services including: Medicare inpatient hospital care, outpatient hospital services, as well as inpatient and outpatient physician claims for the 12 months prior to an index admission.

Medicare Enrollment Database (EDB): This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This data source was used to obtain information on several inclusion/exclusion indicators such as Medicare status on admission as well as vital status. These data have previously been shown to accurately reflect patient vital status (Fleming et al., 1992). The Master Beneficiary Summary File (MBSF) is an annually created file derived the EDB that contains enrollment information for all Medicare beneficiaries including dual eligible status. Years 2016-2019 were used.

Veterans Health Administration (VA) Data: This data source contains data for VA inpatient and outpatient services including: inpatient hospital care, outpatient hospital services, skilled nursing facility care, some home health agency services, as well as inpatient and outpatient physician data for the 12 months prior to and including each index admission. Unlike Medicare FFS patients, VA patients are not required to have been enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission.

The American Community Survey (2013-2017): The American Community Survey data is collected annually and an aggregated 5-years data were used to calculate the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) composite index score.

Reference:

Fleming C., Fisher ES, Chang CH, Bubolz D, Malenda J. Studying outcomes and hospital utilization in the elderly: The advantages of a merged data base for Medicare and Veterans Affairs Hospitals. Medical Care. 1992; 30(5): 377-91.

S.19. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No data collection instrument provided

- **S.20. Level of Analysis** (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED) Facility
- **S.21. Care Setting** (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Inpatient/Hospital

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

N/A

3. Validity - See attached Measure Testing Submission Form

NQF_testing_PNmortality_Fall2020_final_10.27.20.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include

information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Yes - Updated information is included

• Measure Testing (subcriteria 2a2, 2b1-2b6)

NATIONAL QUALITY FORUM — Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (if previously endorsed): 0468

Measure Title: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia

hospitalization

Date of Submission: 8/3/2020

Type of Measure:

Measure	Measure (continued)
☑ Outcome (including PRO-PM)	☐ Composite – STOP – use composite testing form
☐ Intermediate Clinical Outcome	☐ Cost/resource
☐ Process (including Appropriate Use)	☐ Efficiency
☐ Structure	*

^{*}cell intentionally left blank

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:	Measure Tested with Data From:		
(must be consistent with data sources entered in S.17)			
abstracted from paper record	abstracted from paper record		
⊠ claims	⊠ claims		
□ registry	□ registry		
abstracted from electronic health record	abstracted from electronic health record		

Measure Specified to Use Data From:	Measure Tested with Data From:		
(must be consistent with data sources entered in S.17)			
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs		
☑ other: Medicare Enrollment Data, VHA Administrative Data	☑ other: Census Data/American Community Survey, VHA Administrative Data, 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 datasets used for testing included Medicare Parts A and B claims as well as the Medicare Enrollment Database (EDB). Veterans' Health Administration (VHA) data are also included in the testing dataset. Additionally, census as well as claims data were used to assess socioeconomic factors (dual eligible variable is obtained through enrollment data; Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index score obtained through census data). 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?** The dates used 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:	Measure Tested at Level of:		
(must be consistent with levels entered in item \$.20)			
☐ individual clinician	☐ individual clinician		
☐ group/practice	☐ group/practice		
☐ health plan	☐ health plan		
□ other:	□ other:		

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 years or over are included. In addition, for the testing period presented, VA hospitals and their 65 years and older patients are included in the 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 three-years of Medicare administrative claims data (July 2011– June 2014). The dataset also included administrative data on each patient for the 12 months prior to the index admission and the 30 days following it. The dataset contained inpatient and facility outpatient claims and Medicare enrollment database (EDB) data. We randomly split the three years of data (July 2011 – June 2014) 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.

Table 1. Dataset Descriptions

Dataset	Applicable Section in the Testing Attachment	Description of Dataset
Testing Dataset (Medicare Fee-For-Service Administrative Claims Data (July 1, 2015 – June 30, 2019)	Section 2a2 Reliability Testing Section 2b1 Validity Testing Section 2b2 Testing of Measure Exclusion Section 2b3 Risk Adjustment/Stratification 2b3.6. Statistical Risk Model Discrimination Statistics Section 2b4 Meaningful	Dates of Data: July 2016 – June 2019 Number of admissions = 1,310,984 Patient Descriptive Characteristics: mean age = 80.4 years; % male = 48.4 Number of measured hospitals:
The American Community Survey (ACS)	Section 2b3: Risk adjustment/Stratification for Outcome or Resource Use Measures	A,695 Dates of Data: 2013-2017 We used the AHRQSES index score derived from the American Community Survey (2013-2017) to study the association between the 30-day mortality outcome and SRFs. The AHRQSES 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 AHRQSES 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 AHRQSES 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 AHRQSES 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 AHRQSES index score equal to or below 42.7 to define the lowest quartile of the AHRQ SES Index.

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Tonne C, Schwartz J, Mittleman M, Melly S, Suh H, Goldberg R. Long-term survival after acute myocardial infarction is lower in more deprived neighborhoods. Circulation. Jun 14 2005; 111(23):3063-3070.

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 pneumonia. 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 ($\pi^2/3$). 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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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

Split-Sample Reliability

In total, 1,310,984 admissions were included in the analysis, using 3 years of data. After randomly splitting the sample into two halves, there were 654,330 admissions from 4,670 hospitals in one half and 656,654 admissions from 4,695 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 0.668.

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 0.78, ranging from 0.31 to 0.98. The 25th and 75th percentiles were 0.59 and 0.88, respectively. The median reliability score demonstrates moderate reliability.

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

Mean	Std. Dev.	Min	S5th Percentile	10th Percentile	25th Percentile	Median	75th Percentile	90th Percentile	95th Percentile	Max
0.73	0.18	0.31	0.38	0.45	0.59	0.78	0.88	0.93	0.94	0.98

^{*}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.

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

The split-sample reliability score of 0.668, discussed in the previous section, represents the lower bound of estimate of the true measure reliability.

Using the approach used by Adams et. al. and Yu et al., we obtained the median signal-to-noise reliability score of 0.78, which demonstrates substantial 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

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

References:

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

Adams J, Mehrota, A, Thoman J, McGlynn, E. (2010). Physician cost profiling – reliability and risk of misclassification. NEJM, 362(11): 1014-1021.

Yu, H, Mehrota, A, Adams J. (2013). Reliability of utilization measures for primary care physician profiling. Healthcare, 1, 22-29.

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
 - **I** 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 PN 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 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). The mortality group is comprised of the mortality measures that

are publicly reported on Hospital Compare, including this PN mortality 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 4,695 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Ratings 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 4,695 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Ratings can be found at https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources.

We examined the relationship of performance the PN 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 PN 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.

Clinical Validity

The measure's validity is demonstrated in three manners. The first is clinical and face validity of the cohort expansion. As discussed in the 2015 Reevaluation and Re-Specification Report of the Hospital-Level 30-Day Risk-Standardized Measures Following Hospitalization for Pneumonia (Mortality, version 9.2; Readmission, version 8.2) (Lindenauer et al., 2015), made publicly available to support the FY 2016 IPPS rule, the cohort expansion is based on changes in clinical and coding practices that have led to greater numbers of patients with pneumonia being coded with sepsis or aspiration pneumonia as a principal discharge diagnosis. These are patients that the measure is intended to assess, as they fit within the broad clinical category of pneumonia patients and are often treated by the same groups of physicians and staff, using similar treatment strategies. Moreover, virtually all patients hospitalized with pneumonia meet criteria for sepsis. The expansion was also supported by findings in the literature (Lindenauer et al., 2012; Rothberg et al., 2014).

Second, for a number of claims-based outcome measures, including the original version of this measure, we validated the administrative model with a medical-record based model. In this earlier study, we demonstrated that the rates calculated using the risk adjustment model with claims and medical record data were highly correlated (Krumholz et al., 2006). These analyses, though based on an earlier version of this measure, demonstrated that using comorbidity information from administrative claims data is a valid approach to risk adjustment and specifically, that claims-based risk adjustment adequately assesses the difference in case mix among hospitals. The claims-based measure produced results which were highly correlated with those produced through manual chart audit (Krumholz et al., 2006; Bratzler et al., 2011). The revised pneumonia mortality measure utilizes the same approach as the original (now, currently publicly reported) measure. When developing the expanded cohort for the mortality measure, we re-examined the risk ratios for the risk variables used in the original (or current) measure, which showed that the variables remained predictive of the outcome (that is, mortality). Also, model performance characteristics were similar to those of the current pneumonia mortality measure.

As we demonstrated in our analyses in the 2015 Reevaluation Report (Lindenauer et al., 2015), although the revision is bringing in a large portion of patients currently not included in the measure, the revised version of the measure likely has greater validity in that it has mitigated biases introduced by hospital coding patterns.

We confirmed that the approach to risk adjustment was effective, as hospital coding frequency was no longer associated with performance on the revised measure.

Finally, as part of measure validation, we tested the performance of the pneumonia mortality model developed in the first half of a randomly split sample of pneumonia hospitalizations from Dataset 1 (representing 687,838 admissions from 4,671 hospitals) against the second half of the randomly split sample of pneumonia hospitalizations (representing 690,151 admissions from 4,671 hospitals).

References:

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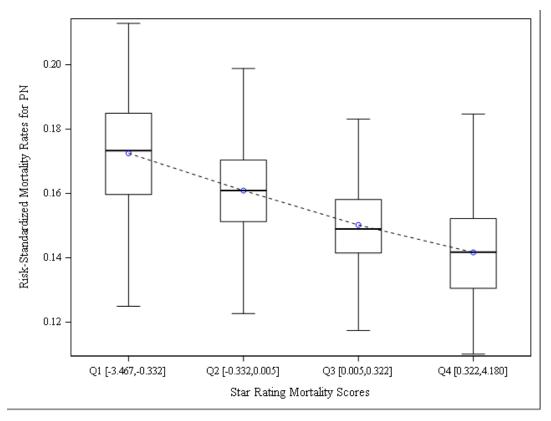
Rothberg M, Pekow P, Priya A, Lindenauer P. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: a cross-sectional analysis. Annals of internal medicine. Mar 18, 2014; 160(6):380-388.

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 PN 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 PN RSMRs and Star-Rating mortality score is -0.653, which suggests that hospitals with lower PN RSMRs are more likely to have higher Star-Rating mortality scores.

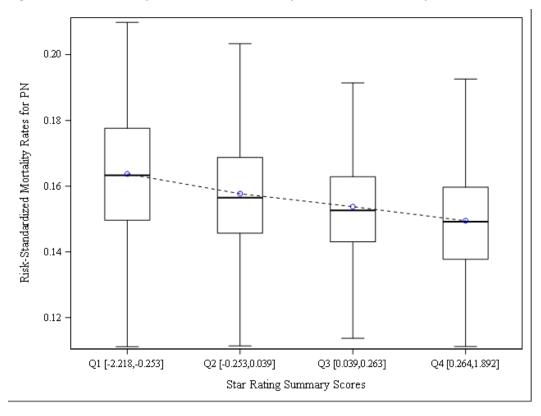
Figure 1 - Box whisker plots of the PN mortality RSMRs within each quartile of Star-rating mortality scores



Comparison to Star-Rating Summary Scores

Figure 2 shows the Box-whisker plots of the PN 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 PN RSMRs and Star-Rating summary score is -0.306, which suggests that hospitals with lower PN RSMRs are more likely to have higher Star-Rating summary scores.

Figure 2 - Box whisker plots of the PN mortality RSMRs within each quartile of Star-rating summary scores



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 PN 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 PN mortality measure scores indicate a strong association. A more moderate association is 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.

2b2. EXCLUSIONS ANALYSIS

NA □ no exclusions — *skip to section 2b4*

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:

Table 3. Frequency and Distribution of Exclusions

	Exclusion	N	%	Distribution across hospitals (N=4,287: Min, 25 th , 50 th , 75 th percentile, max
1.	Discharged against medical advice (AMA)	5,600	0.36	(0.00, 0.00, 0.00, 0.50, 9.68)
2.	Discharged alive on the day of admission or the following day who were not transferred to another acute care facility	44,997	2.91	(0.00, 1.35, 2.70, 4.71, 28.2)
3.	Inconsistent or unknown vital status or other unreliable demographic (age and gender) data	80	0.01	(0.00, 0.00, 0.00, 0.00, 2.86)
4.	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	30,128	1.95	(0.00, 0.67, 1.54, 2.67, 27.2)

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 are discharged AMA) accounts for 0.36% 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.

Exclusion 2 (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 2.91% 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 pneumonia.

Exclusion 3 (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 4 (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 **1.95**% 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.

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.

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. 2000; 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 PN. These included:

Markers for end of life/frailty:

- 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)
- Head injury (CC 166-168)
- Hip fracture/dislocation (CC 170)
- Major fracture, except of skull, vertebrae, or hip (CC 171)
- Traumatic amputations and complications (CC 173)

This resulted in a final risk-adjustment model that included 36 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; 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). 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., 2011).

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 AHRQSES 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
- AHRQSES 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
- ☐ 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 (Table 4) with associated odds ratios (OR) and 95 percent confidence intervals (CI).

Table 4. Adjusted Odds Ratios (ORs) and 95% Confidence Intervals (CIs) for the PN Mortality Hierarchical Logistic Regression Model Over Different Time Periods in the Testing Dataset

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Age minus 65 (years above 65, continuous)	1.05	1.05	1.05	1.05
	(1.05-1.05)	(1.05-1.05)	(1.04-1.05)	(1.05-1.05)
Male	1.19	1.18	1.17	1.19
	(1.17-1.21)	(1.16-1.20)	(1.15-1.20)	(1.18-1.20)
History of coronary artery bypass graft (CABG) surgery	1.02	1.06	1.04	1.04
	(0.99-1.05)	(1.03-1.09)	(1.01-1.07)	(1.02-1.06)
History of percutaneous transluminal coronary angioplasty (PTCA)	0.88	0.89	0.87	0.88
	(0.85-0.90)	(0.87-0.92)	(0.85-0.90)	(0.86-0.89)
Septicemia, sepsis, systemic inflammatory response syndrome/shock (CC 2)	0.86	0.87	0.87	0.87
	(0.83-0.88)	(0.85-0.89)	(0.85-0.90)	(0.85-0.88)

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Metastatic cancer, acute leukemia and other severe cancers (CC 8-9)	2.60	2.58	2.52	2.57
	(2.54-2.67)	(2.52-2.64)	(2.46-2.58)	(2.54-2.61)
Protein-calorie malnutrition (CC 21)	2.23	2.23	2.24	2.25
	(2.18-2.27)	(2.19-2.28)	(2.19-2.28)	(2.22-2.28)
Disorders of fluid/electrolyte/acid-base balance (CC 24)	1.13	1.14	1.13	1.14
	(1.11-1.16)	(1.12-1.16)	(1.11-1.16)	(1.12-1.15)
Chronic liver disease (CC 27-29)	1.43	1.47	1.38	1.43
	(1.36-1.50)	(1.41-1.54)	(1.32-1.45)	(1.39-1.47)
Severe hematological disorders (CC 46)	1.24	1.20	1.22	1.23
	(1.18-1.31)	(1.13-1.26)	(1.16-1.29)	(1.19-1.27)
Iron deficiency or other/unspecified anemias and blood disease (CC 49)	1.14	1.11	1.14	1.13
	(1.11-1.16)	(1.09-1.13)	(1.12-1.17)	(1.12-1.14)
Delirium and encephalopathy (CC 50)	1.02	1.06	1.08	1.05
	(0.99-1.04)	(1.04-1.09)	(1.05-1.11)	(1.04-1.07)
Dementia or other specified brain disorders (CC 51-53)	1.65	1.61	1.62	1.63
	(1.62-1.68)	(1.58-1.64)	(1.59-1.65)	(1.61-1.65)
Major psychiatric disorders (CC 57-59)	1.05	1.06	1.03	1.05
	(1.02-1.08)	(1.04-1.09)	(1.00-1.06)	(1.04-1.07)
Depression (CC 61)	0.95	0.95	0.95	0.95
	(0.93-0.97)	(0.93-0.97)	(0.93-0.97)	(0.94-0.96)
Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190)	1.18	1.19	1.14	1.17
	(1.15-1.22)	(1.16-1.22)	(1.10-1.17)	(1.15-1.19)
Parkinson's and Huntington's diseases (CC 78)	1.18	1.22	1.17	1.19
	(1.14-1.22)	(1.17-1.26)	(1.13-1.21)	(1.17-1.22)
Seizure disorders and convulsions (CC 79)	1.07	1.06	1.06	1.06
	(1.03-1.10)	(1.03-1.10)	(1.03-1.10)	(1.04-1.08)
Respirator dependence/tracheostomy status (CC 82)	0.73	0.70	0.73	0.72
	(0.68-0.79)	(0.65-0.76)	(0.68-0.78)	(0.69-0.75)
Respiratory arrest; cardio-respiratory failure and shock (CC 83-84 plus ICD-10-CM codes R09.01 and R09.02, for discharges on or after October 1, 2015; CC 83-84 plus ICD-9-CM diagnosis codes 799.01 and 799.02, for discharges prior to October 1, 2015)	1.18	1.20	1.19	1.19
	(1.15-1.21)	(1.17-1.22)	(1.16-1.22)	(1.17-1.20)
Congestive heart failure (CC 85)	1.17	1.14	1.15	1.15
	(1.15-1.19)	(1.12-1.16)	(1.12-1.17)	(1.14-1.16)
Acute myocardial infarction (CC 86)	1.17	1.14	1.11	1.14
	(1.13-1.21)	(1.10-1.18)	(1.07-1.15)	(1.11-1.16)
Unstable angina and other acute ischemic heart disease (CC 87)	0.95	0.95	0.99	0.97
	(0.91-0.99)	(0.92-0.99)	(0.95-1.04)	(0.95-0.99)

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Coronary atherosclerosis or angina (CC 88-89)	0.97	0.98	0.97	0.98
	(0.95-1.00)	(0.96-1.00)	(0.95-0.99)	(0.96-0.99)
Hypertension (CC 95)	0.85	0.83	0.85	0.84
	(0.83-0.87)	(0.81-0.85)	(0.83-0.87)	(0.83-0.85)
Stroke (CC 99-100)	1.05	1.04	1.06	1.05
	(1.02-1.08)	(1.01-1.07)	(1.03-1.09)	(1.03-1.07)
Cerebrovascular disease (CC 101-102, 105)	0.97	0.98	0.98	0.98
	(0.95-1.00)	(0.96-1.00)	(0.96-1.01)	(0.97-0.99)
Vascular disease and complications (CC 106-108)	1.00	1.01	1.02	1.01
	(0.98-1.02)	(0.99-1.03)	(1.00-1.04)	(1.00-1.02)
Chronic obstructive pulmonary disease (COPD) (CC 111)	1.04	0.98	0.94	0.98
	(1.02-1.06)	(0.96-1.00)	(0.93-0.96)	(0.97-0.99)
Fibrosis of lung or other chronic lung disorders (CC 112)	1.09	1.10	1.11	1.10
	(1.06-1.12)	(1.07-1.13)	(1.08-1.14)	(1.08-1.12)
Asthma (CC 113)	0.73	0.71	0.72	0.73
	(0.71-0.75)	(0.69-0.73)	(0.70-0.74)	(0.72-0.74)
Pneumonia; pleural effusion/pneumothorax (CC 114-117)	1.10	1.06	1.07	1.08
	(1.08-1.12)	(1.04-1.09)	(1.05-1.09)	(1.07-1.09)
Renal failure (CC 135-140)	1.12	1.11	1.10	1.11
	(1.10-1.14)	(1.09-1.13)	(1.08-1.12)	(1.10-1.12)
Decubitus ulcer of skin (CC 157-160)	1.34	1.36	1.37	1.36
	(1.30-1.38)	(1.32-1.40)	(1.33-1.41)	(1.34-1.38)
Trauma; other injuries (CC 166-168, 170-174)	1.05	1.05	1.04	1.05
	(1.03-1.07)	(1.03-1.07)	(1.03-1.06)	(1.04-1.06)
Vertebral fractures without spinal cord injury (CC 169)	1.12	1.13	1.11	1.12
	(1.08-1.16)	(1.09-1.17)	(1.07-1.15)	(1.09-1.14)

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 2016 endorsement maintenance forms for comparison purposes.

Table 5. Variation in prevalence of the factor across measured entities in 2020 and 2016

SRFs	2020 Prevalence % (IQR)	2016 Prevalence % (IQR)
Dual	20.9% (13.6-30.1%)	16.8% (11.1-24.6%)
AHRQLow SES	17.7% (6.40-33.9%)	16.2% (3.9-53.4%)

The prevalence of social risk factors in the PN cohort varies widely across measured entities in 2020. The median percentage of dual eligible patients was 20.9% (IQR 13.6%-30.1%) and the median percentage of patients with an AHRQSES index score adjusted for cost of living at the census block group level equal to or below 42.7 (lowest quartile) was 17.7% (IQR 6.40%-33.9%) in 2020. These results are relatively consistent with the 2016 results presented above. The increase in dually eligible patients may be due to a refinement in the definition that occurred since 2016.

Table 6. Comparison of observed mortality rates for patients with and without social risk in 2020 and 2016

SRFs	2020 Observed Rate	2016 Observed Rate
Dual (vs. Non-Dual)	17.6% (vs. 14.8%)	17.0% (vs. 16.1%)
AHRQ Low SES (vs. SES score above 42.7)	15.5% (vs 15.6%)	16.2% (vs. 16.3%)

The patient-level observed PN mortality rates are higher for dual-eligible patients (17.6%) compared with 14.8% for non-dual patients in 2020. Similarly, the mortality rate for patients with an AHRQSES index score equal to or below 42.7 are 15.5% compared with 15.6% for patients with an AHRQSES index score above 42.7 in 2020. Patient-level mortality rates have declined among AHRQlow SES patients but not among dual-eligible patients.

Incremental effect of SRF variables in a multivariable model in 2020 and 2016

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 AHRQSES index have effect sizes (odds ratios) of 1.07 and 1.02 when added independently to the model. Furthermore, the effect size of each variable is attenuated (1.06 and 1.01 for dual and AHRQSES) when both are added to the model together.

We also find that the c-statistic is essentially unchanged with the addition of any of these variables into the model (Table 7), which is consistent with 2016 results.

Table 7

PN Mortality Models	2020 C-Statistic	2016 C-Statistic
Base Model: risk-adjusted model using the original clinical risk variables selected for the 2020 CMS public report of the PN mortality measure	0.721	0.716
Base Model plus AHRQ Low SES based on beneficiary residential 9-digit ZIP codes (SES9) as a social risk variable	0.721	0.716
Base Model plus dual eligibility (dual) as a social risk variable	0.721	0.716
Base Model plus SES9 and dual as social risk variables	0.721	*

^{*}cell intentionally left blank

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 0.032%(interquartile range [IQR] -0.028% -0.037%) 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 0.176% (IQR -0.146% -0.193%) with a correlation coefficient between RSMRs for each hospital with and without an indicator for a low AHRQ SES Index score is 0.978.

Summary

We find that the impact of any of these SRF 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**

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

Development and Validation Dataset:

For the expanded measure cohort version 9.2 the results are summarized below:

c-statistic = 0.716

Predictive ability (lowest decile %, highest decile %) = (4.5, 40.3)

Results for the Testing Dataset

C-statistic = 0.72

Predictive ability (lowest decile %, highest decile %): (2.7, 35.8)

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 expanded cohort, the results are summarized below:

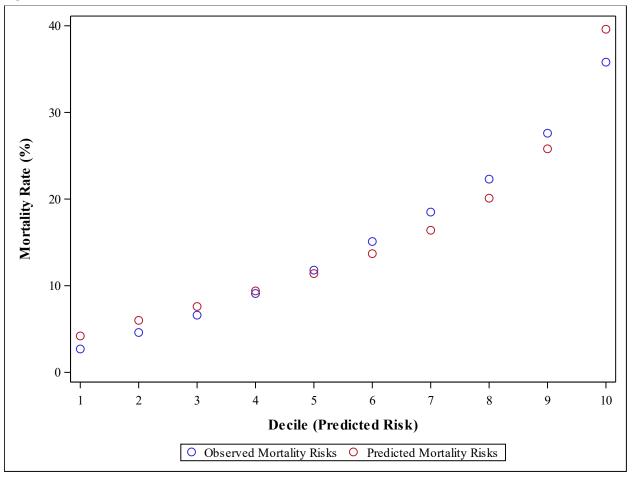
1st half of split sample: Calibration: (0.0457, 0.9526)

2nd half of split sample: Calibration: (0.0496, 0.9504)

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

The risk decile plot 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 the testing dataset (Figure 3).

Figure 3. Risk Decile Plot



2b3.9. Results of Risk Stratification Analysis:

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 0.72 indicate fair 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 $\gamma 0$ in the validation samples are substantially far from zero and the $\gamma 1$ 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) and is comparable to other (mortality) outcome measures.

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)

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" number of deaths (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" number of deaths (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.

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 a mortality within 30 days of a pneumonia 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.

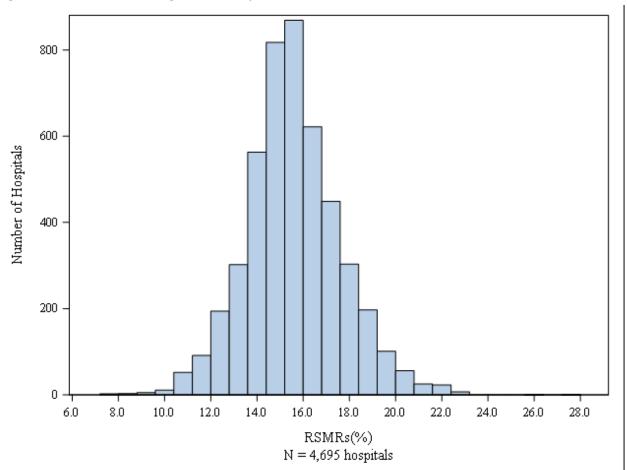


Figure 4. Distribution (Histogram) Of Hospital-Level PN RSMRs

Out of 4,695 hospitals in the measure cohort, 266 performed 'better than the U.S. national rate, '3,666 performed 'no different from the U.S. national rate, 'and 280 performed 'worse than the U.S. national rate.' 483 were classified as 'number of cases too small' (fewer than 25) to reliably tell how well the hospital is performing.

The median odds ratio was 1.26.

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 pneumonia at a higher risk hospital compared to a lower risk hospital. A value of 1.26 indicates that a patient's risk of mortality is 26% greater in a higher risk hospital than 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 PN. This evidence supports continued measurement to reduce the variation.

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)

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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 PN 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

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims) If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields) Update this field for maintenance of endorsement.

ALL data elements are in defined fields in electronic claims

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For maintenance of endorsement, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

N/A

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and

frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

This measure uses administrative claims and enrollment data and as such, offers no data collection burden to hospitals or providers.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).

N/A

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
*	Public Reporting
	Hospital Compare
	https://www.medicare.gov/hospitalcompare/search.html?
	Payment Program
	Hospital Value Based Purchasing (HVBP) Program
	https://www.qualitynet.org/inpatient/hvbp
	Hospital Value Based Purchasing (HVBP) Program
	https://www.qualitynet.org/inpatient/hvbp

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4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Public Reporting

Program Name, Sponsor: Hospital Compare, Centers for Medicare and Medicaid Services (CMS)

Purpose: Under Hospital Compare and other CMS public reporting websites, CMS collects quality data from hospitals, with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care provided to all patients.

The data collected are available to consumers and providers on the Hospital Compare website at:

https://www.medicare.gov/hospitalcompare/search.html. Data for selected measures are also used for paying a portion of hospitals based on the quality and efficiency of care, including the Hospital Value-Based Purchasing Program, Hospital-Acquired Condition Reduction Program, and Hospital Readmissions Reduction Program.

Payment Program

Program Name, Sponsor: Hospital Value-Based Purchasing (HVBP) Program, Centers for Medicare and Medicaid Services (CMS)

Purpose: The Hospital Value-Based Purchasing (VBP) Program is a CMS initiative that rewards acute-care hospitals with incentive payments for the quality of care they provide to people with Medicare. It was established by the Affordable Care Act of 2010 (ACA), which added Section 1886(o) to the Social Security Act. The law requires the Secretary of the Department of Health and Human Services (HHS) to establish a value-based purchasing program for inpatient hospitals. To improve quality, the ACA builds on earlier legislation—the 2003 Medicare Prescription Drug, Improvement, and Modernization Act and the 2005 Deficit Reduction Act. These earlier laws established a way for Medicare to pay hospitals for reporting on quality measures, a necessary step in the process of paying for quality rather than quantity.

Geographic area and number and percentage of accountable entities and patients included: More than 3,000 hospitals across the country are eligible to participate in Hospital VBP. The program applies to subsection (d) hospitals located in the 50 states and the District of Columbia and acute-care hospitals in Maryland. More details about the Hospital VBP program are online at https://www.qualitynet.org/inpatient/hvbp. The following hospitals are excluded from Hospital VBP:

- Hospitals and hospital units excluded from the Inpatient Prospective Payment System, such as psychiatric, rehabilitation, long-term care, children's, and cancer hospitals;
- Hospitals that are located in the state of Maryland participating in the Maryland All-Payer Model;
- Hospitals subject to payment reductions under the Hospital Inpatient Quality Reporting (IQR) Program;
- Hospitals cited by the Secretary of HHS for deficiencies during the performance period that pose an immediate jeopardy to patients' health or safety;
- Hospitals with an approved extraordinary circumstance exception specific to Hospital VBP; and
- Hospitals that do not meet the minimum number of cases, measures, or surveys required by Hospital VBP.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?) N/A. This measure is currently publicly reported.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

N/A. This measure is currently publicly reported.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

The exact number of measured entities (acute care hospitals) varies with each new measurement period. For the period between 2016 - 2019, all non-federal short-term acute care hospitals (including Indian Health Service hospitals), critical access hospitals, and VA hospitals (4,695 hospitals) were included in the measure calculation. Only those hospitals with at least 25 pneumonia admissions were included in public reporting.

Each hospital generally receives their measure results in the Spring of each calendar year through CMS's QualityNet website. The results are then publicly reported on CMS's public reporting websites in the summer

of each calendar year. Since the measure is risk standardized using data from all hospitals, hospitals cannot independently calculate their score.

However, CMS provides each hospital with several resources that aid in the interpretation of their results (described in detail below). These include Hospital-Specific Reports with details about every patient from their facility that was included in the measure calculation (for example, dates of admission and discharge, discharge diagnoses, outcome [died or not], transfer status, and facility transferred from). These reports facilitate quality improvement activities such as review of individual deaths and patterns of deaths; make visible to hospitals post-discharge outcomes that they may otherwise be unaware of; and allow hospitals to look for patterns that may inform quality improvement (QI) work (e.g. among patient transferred in from particular facilities). CMS also provides measure FAQs, webinars, and measure-specific question and answer inboxes for stakeholders to ask specific questions.

The Hospital-Specific Reports also provide hospitals with more detailed benchmarks with which to gauge their performance relative to peer hospitals and interpret their results, including comorbidity frequencies for their patients relative to other hospitals in their state and the country.

Additionally, the code used to process the claims data and calculate measure results is written in SAS (Cary, NC) and is provided each year to hospitals upon request.

4a2.1.2. Describe the process (es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

During the Spring of each year, hospitals have access to the following list of updated resources related to the measure which is provided directly or posted publicly for hospitals to use:

- 1. Hospital-Specific Reports (HSR): available for hospitals to download from QualityNet in April/May of each calendar year; includes information on the index admissions included in the measure calculation for each facility, detailed measure results, and state and national results.
- 2. HSR User Guide: available with the HSR and posted on QualityNet; provides instructions for interpreting the results and descriptions of each data field in the HSR.
- 3. Mock HSR: posted on QualityNet; provides real national results and simulated state and hospital results for stakeholders who do not receive an HSR.
- 4. HSR Tutorial Video: A brief animated video to help hospitals navigate their HSR and interpret the information provided.
- 5. Public Reporting Preview and Preview Help Guide: available for hospitals to view from QualityNet in Spring of each calendar year; includes measure results that will be publicly reported on CMS's public reporting websites.
- 6. Annual Updates and Specification Reports: posted in April/May of each calendar year on QualityNet with detailed measure specifications, descriptions of changes made to the measure specifications with rationale and impact analysis (when appropriate), updated risk variable frequencies and coefficients for the national cohort, and updated national results for the new measurement period.
- 7. Frequently asked Questions (FAQs): includes general and measure-specific questions and responses, as well as infographics that explain complex components of the measure's methodology, and are posted in April/May of each calendar year on QualityNet.
- 8. The SAS code used to calculate the measure with documentation describing what data files are used and how the SAS code works. This code and documentation are updated each year and are released upon request beginning in July of each year.
- 9. Measure Fact Sheets: provides a brief overview of measures, measure updates, and are posted in April/May of each calendar year on QualityNet.

During the summer of each year, the publicly-reported measure results are posted on CMS's public reporting websites, a tool to find hospitals and compare their quality of care that CMS created in collaboration with

organizations representing consumers, hospitals, doctors, employers, accrediting organizations, and other federal agencies. Measure results are updated in July of each calendar year.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Question and Answer Inbox (Q&A)

The measured entities (acute care hospitals) and other stakeholders or interested parties submit questions or comments about the measure through an email inbox (CMSmortalitymeasures@yale.edu). Experts on measure specifications, calculation, or implementation, prepare responses to those inquiries and reply directly to the sender. We consider issues raised through the Q&A process about measure specifications or measure calculation in measure reevaluation.

Literature Reviews

In addition, we routinely scan the literature for scholarly articles describing research related to this measure. We summarize new information obtained through these reviews every 3 years as a part of comprehensive reevaluation as mandated by the Measure Management System (MMS) Blueprint.

4a2.2.2. Summarize the feedback obtained from those being measured.

Summary of Questions or Comments from Hospitals submitted through the Q&A process:

For the PN mortality measure, we have received the following inquiries from hospitals since the last endorsement maintenance cycle:

- 1. Requests for detailed measure specifications including the ICD-9 and ICD-10 codes used to define the measure cohort or in the risk-adjustment model;
- 2. Requests for the SAS code used to calculate measure results;
- 3. Requests about the data source used to calculate the measure;
- 4. Questions about how transfers are handled in the measure calculation;
- 5. Requests for hospital-specific measure information such as HSRs; and
- 6. Requests for clarification of how inclusion and exclusion criteria are applied.

4a2.2.3. Summarize the feedback obtained from other users

Summary of Question and Comments from Other Stakeholders:

For the PN mortality measure, we have received the following feedback from other stakeholders since the last endorsement maintenance cycle:

- 1. Requests for detailed measure specifications including the narrative specifications for the measure, CC-to-ICD-9 code crosswalks, and ICD-9 and ICD-10 codes used to define the measure cohort or in the risk-adjustment model;
- 2. Requests for the data source and the SAS code used to calculate measure results;
- 3. Requests for clarification of how inclusion and exclusion criteria are applied;
- 4. Queries about how cohorts and outcomes are defined, including how planned readmissions are defined;
- 5. Questions about how transfers are handled in the measure calculation; and
- 6. Requests for clarification on measure national rates.

Summary of Relevant Publications from the Literature Review:

Since the last endorsement cycle, we have reviewed more than 500 articles related to mortality following PN admissions. Relevant articles shared key themes related to: spillover effects of the PN mortality measure on readmission rates for other conditions; considerations for additional risk adjustment variables, including social risk factors and other clinical comorbidities; association between public reporting of mortality rates and trends

in mortality rates; potential unintended consequences of readmission measures on mortality outcomes; and the clinical differences between different types of pneumonia.

Researchers have conducted considerable investigation of potential unintended consequences since the implementation of the Hospital Readmission Reductions Program. More specifically, the relationship between the implementation of the AMI, HF, and PN readmission measures in the Hospital Readmissions Reduction Program (HRRP) and subsequent trends in their respective mortality rates has been studied.

Some studies have argued that between 2006 – 2014, readmissions for PN decreased but post-discharge mortality increased, suggesting a potential unintended consequence that readmission measures may be incentivizing hospitals to not readily admit patients with PN, and as a result, mortality rates increased (Khera et al., 2018; Wadhera et al. 2018; Meyer et al., 2018). However, the same studies have acknowledged that PN mortality was increasing prior to HRRP implementation and that factors unrelated to HRRP could have caused this trend — for example, trends in PN volume during particularly potent influenza years, or the increasing use of DNRs, could lead to an increase in mortality rates. These findings suggest that the increase in mortality (which, again, preceded HRRP) is not a result of denying admission to people seeking acute care services. Of note, other studies have found no apparent increase in PN mortality (Dharmarajan et al., 2017; MedPAC, 2018; Stensland, 2019).

Given the importance of this potential issue on patient outcomes, CMS commissioned an independent group to investigate whether there have been increases in mortality rates after HRRP implementation. CMS found through this investigation that no sufficient evidence exists to suggest that mortality has increased because of the HRRP readmission measures. CMS is committed to continuing to monitor trends in same-condition readmission and mortality rates through annual measure reevaluation and surveillance tasks.

References:

Dharmarajan K, Wang Y, Lin Z, et al. Association of Changing Hospital Readmission Rates With Mortality Rates After Hospital Discharge. JAMA. 2017;318(3):270-278.

Khera R, Dharmarajan K, Wang Y, et al. Association of the Hospital Readmissions Reduction Program With Mortality During and After Hospitalization for Acute Myocardial Infarction, Heart Failure, and Pneumonia. JAMA Netw Open. 2018;1(5): e182777.

Medicare Payment Advisory Commission. Mandated report: The effects of the Hospital Readmissions Reduction Program. Washington, DC 07/18 2018.

Meyer N, Harhay MO, Small DS, et al. Temporal Trends in Incidence, Sepsis-Related Mortality, and Hospital-Based Acute Care After Sepsis. Crit Care Med. 2018;46(3):354-360.

Stensland J. MedPAC evaluation of Medicare's Hospital Readmission Reduction Program: Update. In: 2019.

Wadhera RK, Joynt Maddox KE, Wasfy JH, Haneuse S, Shen C, Yeh RW. Association of the Hospital Readmissions Reduction Program With Mortality Among Medicare Beneficiaries Hospitalized for Heart Failure, Acute Myocardial Infarction, and Pneumonia. JAMA. 2018;320(24):2542-2552.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

Each year, issues raised through the Q&A or in the literature related to this measure are considered by measure and clinical experts. Any issues that warrant additional analytic work due to potential changes in the measure specifications are addressed as a part of annual measure reevaluation. If small changes are indicated after additional analytic work is complete, those changes are usually incorporated into the measure in the next measurement period. If the changes are substantial, CMS may propose the changes through rulemaking and adopt the changes only after CMS receives public comment on the changes and finalizes those changes in the IPPS or other rule. There were no questions or issues raised by stakeholders requiring additional analysis or changes to the measure since the last endorsement maintenance cycle.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

The median hospital 30-day, all-cause, RSRR for the pneumonia mortality measure for the 3-year period between July 1, 2016 and June 30, 2019 was 15.4%. The median RSRR decrease by 1 absolute percentage point from July 2016-June 2017 (median RSRR: 15.9%) to July 2018-June 2019 (median: RSRR: 14.9%).

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

N/A

4b2.2. Please explain any unexpected benefits from implementation of this measure.

N/A

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0231: Pneumonia Mortality Rate (IQI #20)

0279: Community Acquired Pneumonia Admission Rate (PQI 11)

0506 : Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization

1891 : Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization

1893: Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization

2579: Hospital-level, risk-standardized payment associated with a 30-day episode of care for pneumonia (PN)

3502: Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure

3504: Claims-Only Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

We did not include in our list of related measures any non-outcome (for example, process) measures with the same target population as our measure. Because this is an outcome measure, clinical coherence of the cohort takes precedence over alignment with related non-outcome measures. Furthermore, non-outcome measures are limited due to broader patient exclusions. This is because they typically only include a specific subset of patients who are eligible for that measure (for example, patients who receive a specific medication or undergo a specific procedure). Lastly, this measure and the NQF Inpatient Pneumonia Mortality (AHRQ) Measure #0231 are complementary rather than competing measures. Although they both assess mortality for patients admitted to acute care hospitals with a principal discharge diagnosis of pneumonia, the specified outcomes are different. This measure assesses 30-day mortality while #0231 assesses inpatient mortality. Assessment of 30day and inpatient mortality outcomes have distinct advantages and uses which make them complementary as opposed to competing. For example, the 30-day period provides a broader perspective on hospital care and utilizes standard time period to examine hospital performance to avoid bias by differences in length of stay among hospitals. However, in some settings it may not be feasible to capture post-discharge mortality making the inpatient measure more useable. We have previously consulted with AHRQ to examine harmonization of complementary measures of mortality for patients with AMI and stroke. We have found that the measures are harmonized to the extent possible given that small differences in cohort inclusion and exclusion criteria are warranted on the basis of the use of different outcomes. However, this current measure includes patients with a principal discharge diagnosis of sepsis and a secondary discharge diagnosis of pneumonia that is present on admission. The cohort was also expanded to include patients with a principal discharge diagnosis of aspiration pneumonia. Thus, the current measure cohort is still not harmonized with measure #0231.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure); **OR**

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

N/A

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or

bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Available at measure-specific web page URL identified in S.1 Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services (CMS)

Co.2 Point of Contact: James, Poyer, James.poyer@cms.hhs.gov, 410-786-2261-

Co.3 Measure Developer if different from Measure Steward: Yale New Haven Health Services

Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE)

Co.4 Point of Contact: Doris, Peter, Doris.peter@yale.edu

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

The working group involved in the initial measure development is detailed in the original technical report available at www.qualitynet.org.

Our measure development team consisted of the following members:

Harlan M. Krumholz, M.D., S.M., Principal Investigator

Sharon-Lise T. Normand, Ph.D., M.Sc., Co-Investigator*

Dale W. Bratzler, D.O., M.P.H.**

Jennifer A. Mattera, M.P.H.

Amy S. Rich, M.P.H.

Yongfei Wang, M.Sc., Statistical Analyst

Yun Wang, Ph.D., Senior Biostatistician

*Harvard Medical School, Department of Health Care Policy

**Oklahoma Foundation for Medical Quality

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2006

Ad.3 Month and Year of most recent revision: 09, 2019

Ad.4 What is your frequency for review/update of this measure? Annual

Ad.5 When is the next scheduled review/update for this measure? 2020

Ad.6 Copyright statement: N/A

Ad.7 Disclaimers: N/A

Ad.8 Additional Information/Comments: N/A