



May 25, 2021

- To: Neurology Standing Committee
- From: NQF staff
- **Re:** Post-comment web meeting to discuss public comments received and revote on the evidence criteria for NQF #3596 Consensus Not Reached (CNR)

Introduction

NQF closed the public commenting period on the measure submitted for endorsement consideration to the fall 2020 measure review cycle on April 30, 2021.

Purpose of the Call

The Neurology Standing Committee will meet via web meeting on May 25, 2021 from 11:00 am – 2:00 pm ET. The purpose of this call is to:

- Discuss the evidence criteria for measure #3596 and revote on evidence and overall suitability for endorsement, if needed;
- Review and discuss comments received during the post-evaluation member and public comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expression of support of the measure under consideration; and
- Determine whether reconsideration of any measures or other courses of action are warranted.

Standing Committee Actions

- 1. Review this briefing memo and <u>draft report</u>.
- 2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments (see comment table and additional documents included with the call materials).
- 3. Review the NQF members' expressions of support of the submitted measure.
- 4. Be prepared to discuss evidence and revote on this criteria as well as provide feedback and input on proposed post-evaluation comment responses.

Conference Call Information

Please use the following information to access the conference call line and webinar:

Meeting link: https://nqf.webex.com/nqf/j.php?MTID=mfde12ee1b6574a24bad5448fb27bac5f

Meeting number: 173 455 0109; Password: QMEvent Join by phone: 1-844-621-3956; Access code: 173 455 0109

Background

In 2017, the Global Burden of Disease study found the three most burdensome neurological conditions in the United States (U.S.) with regard to absolute numbers of disability-adjusted life years (DALY):

- 1. Stroke (3.58 million DALYs)
- 2. Alzheimer's and other dementias (2.55 million DALYs)
- 3. Migraine headache (2.40 million DALYs)

Additionally, stroke is the fifth leading cause of death in the U.S., leading to 146,383 deaths in 2017. It is a condition which has historically had few treatments, yet today, treatments including intravenous and intra-arterial thrombolysis, clot retrieval, and other technologies have revolutionized care. Stroke prevalence increases with advanced age and reveals disparities among different racial/ethnic groups (e.g., stroke is more common among Blacks as compared to Whites) and among people with lower socioeconomic status and with fair or poor perceived health status. Stroke is also the leading cause of long-term serious disability in the U.S.

The 17-member <u>Neurology Standing Committee</u> has been charged with overseeing the NQF Neurology measure portfolio. The Standing Committee evaluates both newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifies gaps in the measurement portfolio, provides feedback on how the portfolio should evolve, and serves on any ad hoc or expedited projects in its designated topic areas.

During the February 5, 2021 and February 24, 2021 web meetings, the Neurology Standing Committee evaluated one new measure during the fall 2020 cycle related to stroke care, specifically a measure of risk-adjusted inpatient mortality for stroke. The risk adjustment is based on the National Institutes of Health (NIH) Stroke Scale, which is used to assess stroke severity upon hospital arrival.

The Standing Committee did not reach consensus on the following measure:

 #3596 Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization [Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (Yale CORE)/Centers for Medicare & Medicaid Services (CMS)]

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments during a 16-week comment period via an online tool on the project webpage.

Pre-evaluation Comments

NQF solicits comments prior to the evaluation of measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from December 3, 2020 to January 5, 2021 for the measure under review. NQF received two comments on NQF 3596: *Hospital 30day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Acute Ischemic Stroke Hospitalization* concerning reliability score performance at the minimum size threshold of 25 cases. All pre-evaluation comments were provided to the Standing Committee prior to the measure evaluation meeting.

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Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on April 1, 2021 for 30 calendar days. During this commenting period, NQF received nine comments from four member organizations and five non-member organizations:

Member Council	# of Member Organizations Who Commented	
Health Professional	2	
Provider Organization	2	

We have included all comments that we received (both pre- and post-evaluation) in the comment table (excel spreadsheet) posted to the Standing Committee SharePoint site. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses (including measure steward/developer responses) for the Standing Committee's consideration. Please review this table in advance of the meeting and consider the individual comments received and the proposed responses to each.

Although all comments are subject to discussion, the intent is not to discuss each individual comment on the May 25 post-comment call. Instead, we will spend most of the time considering the overall themes and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit Standing Committee discussion. Additionally, please note measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Standing Committee to consider.

Comments and Their Disposition

Measure-Specific Comments

3596 Hospital-30 Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization

We are a comprehensive stroke center, offering care to a mixed rural and small city population, with a large uninsured and underserved population. Risk stratifying measures of mortality would be a step in the right direction. One important measure would be to look at comorbidities identified after admission, as patients often come in without any prior medical care, with diabetes, hypertension, heart failure, but without diagnoses for any of this, because of lack of prior medical care.

Functional outcomes would also be a welcome addition to outcomes grading. However, follow up outcomes vary, with patients from more disadvantaged settings having difficulties with follow up including loss of phone access, fear of being called for bill collection, loss of follow up while indigent care is established. We would suggest moving to the risk adjusting mortality model and keeping the conversation going regarding outcomes.

Measure Steward/Developer Response:

Thank you for your comments in support of endorsing measure #3596. We appreciate your suggestions for evaluating comorbidities identified after admission. Our technical specifications and risk variable selection strategies are outlined in our methodology report. Yale-CORE is committed to continued re-evaluation activities to ensure the reliability and validity of our measures and our risk adjustment approaches.

Notably, this measure adjusts for select clinical comorbidities reported in administrative claims within the preceding 12 months leading up to the index admission, as well as at the index admission. Secondary diagnoses on the index claim of chronic conditions like diabetes, hypertension, heart failure, etc. would be adjusted for within the risk model. For example, if a patient arrives with a principal discharge diagnosis of acute ischemic stroke but a secondary discharge diagnoses that could be consequences of care and are only on the index claim (and not in the prior 12 months) would not be adjusted for in the risk model. Please refer to the submission form for further details.

We acknowledge and agree with your suggestion to measure alternative outcomes, including functional outcomes, as well as limitations of follow-up methods. At this time, CMS is currently limited by the data available within administrative claims but is continuously moving toward improved quality measurement and is actively evaluating the availability and validity of variables, such as functional status, through electronic health records and other data sources. Proposed Committee Response:

Thank you for your comment and for the developer's response to the themes identified in the comment. The Committee will review the comment at the post-comment web meeting on May 25, 2021.

Proposed Committee Response:

Thank you for your comments. The Committee will review and discuss them during the Post-Comment Meeting.

Action Item:

The Committee should review the comments and be prepared to discuss any recommendations for the developer to consider.

[abridged comment] The AHA/ASA agrees with the Standing Committee that measuring 30-day mortality in isolation has potential unintended consequences, such as incentivizing efforts to prolong life through invasive interventions without considering functional outcomes. We also agree that it may not be the best approach to measuring the quality of stroke care or of driving improvement. However, reporting 30-day mortality inaccurately can also lead to serious adverse consequences for hospitals and for patients. The AHA/ASA has and will continue to strongly advocate that 30-day mortality should be balanced with measures such as functional status or healthy days at home. However, it is undeniable that mortality is also an outcome that is important to all patients and their families. As such, we expect that CMS is very likely to continue reporting it, even if the measure is imperfect. It is therefore critical that risk-adjusted mortality be reported as accurately as possible.

The standing committee and commenters also expressed concerns about the reliability of the measure and the impact of missing data, given that the uptake of the new ICD-10 codes is still not universal. CMS has indicated that initially they will impute the NIHSS when it is missing, which we acknowledge is a suboptimal approach, however, it is reasonable as a starting point. Once missingness rates decline, they can revise their approach. We would suggest that the standing committee consider revisiting this issue when the measure undergoes maintenance of endorsement after it has been in widespread use for a period of time.

Measure Steward/Developer Response:

Thank you for supporting the NQF endorsement of measure #3596. We agree with the commenter that "Measure 3596 will incentivize hospitals to routinely document the NIHSS, as required by good clinical practice and evidence-based guidelines and would appropriately penalize those who do not. This alone would represent a tremendous advance in the quality of stroke care."

Proposed Committee Response:

Thank you for your comments. The Committee will review and discuss them during the Post-Comment Meeting.

Action Item:

The Committee should review the comments and be prepared to discuss any recommendations for the developer to consider.

The Federation of American Hospitals (FAH) remains concerned with the less than desirable reliability threshold at the minimum sample size. In addition, FAH agrees with the Standing Committee's concerns that mortality may not be the best outcome to track in this population, rather measures that ensure that treatment decisions are aligned with patient preferences and emphasize improved functional outcomes would be more appropriate.

Measure Steward/Developer Response:

Thank you for your comments. The reliability of this measure is consistent with other measures endorsed by NQF, and the Scientific Methods Panel voted to pass the measure on both reliability and validity. Variation in volume can impact reliability. However, consistent with CMS's other mortality and readmission outcome measures, measure scores would only be assigned and publicly reported for hospitals with at least 25 cases. This ensures quality information be available for most hospitals while maintaining reliable measure scores.

The results presented in our testing attachment show that the reliability of the measure score is sufficient, based on current standards. We used signal-to-noise approach described by Adams and colleagues (2010) to calculate the facility-level reliability. The median signal-to-noise reliability score was 0.75, ranging from 0.24 to 0.95. The 25th and 75th percentiles were 0.59 and 0.83, respectively. We also report confidence intervals for measure results that account for volume.

As stated in previous responses, we agree with the committee that other outcomes beyond functional status should be considered to more holistically measure stroke outcomes. To your concern that measuring mortality in isolation could lead to unintended consequences, we agree that stroke mortality is not the only outcome that should be assessed; other outcomes, such as functional status, should be explored as well. However, measuring functional status in isolation could similarly lead to unintended consequences in which death is perversely incentivized over life with impairments, despite patient care preferences.

At this time, CMS is currently limited by the data available within administrative claims but is continuously moving toward improved quality measurement and is actively evaluating the availability and validity of variables, such as functional status, through electronic health records and other data sources. We continue to believe mortality is an important outcome from the patients' perspective and an important piece of the quality picture. Further, we believe that this revised stroke measure that adjusts for stroke severity provides incremental improvements in

accurately measure stroke mortality performance compared to the measure currently in publicly reporting.

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

Proposed Committee Response:

Thank you for your comments. The Committee will review and discuss them during the Post-Comment Meeting.

Action Item:

The Committee should review the comments and be prepared to discuss any recommendations for the developer to consider.

BJC HealthCare ("BJC") is comprised of fourteen acute care hospitals, a large multi-specialty physician practice, and post-acute, corporate, and behavioral health services, with a service area spanning the St. Louis metropolitan region, as well as parts of mid and southeastern Missouri and southwest Illinois.

BJC appreciates the opportunity to comment on Measure #3596, Hospital 30-day, all-cause, riskstandardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity.

BJC supports the updated version of the Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke hospitalization measure to include the initial NIH Stroke Scale, a validated measure of stroke severity in its risk adjustment model. We fully support the additional commentary and support of this metric offered by the American Heart Association, and American Stroke Association. We also offer the following comments regarding measure implementation and future quality metrics:

- CMS will need to ensure 100% compliance with NIHSS documentation by all stroke centers. If
 not, severe stroke patients that are transferred to higher acuity centers from lower acuity
 centers, may lack of the adequate risk adjustment. This could paint a very inaccurate picture of
 stroke care and suggest the best care is mainly given at smaller centers and worst care at larger
 centers.
- NIHSS scores documented earlier in the stay may not be as accurate as those documented after evaluation and initial recovery. CMS should be careful of the timing of NIHSS assessment and use later documentation to abstract the appropriate value.
- Stroke severity alone outperforms all other variables in models predicting stroke mortality, even when these other variables are combined.
- BJC historically has always supported more robust and clinically relevant risk adjustment in the CMS outcome measures. We have also advocated for inclusion of adjustment for social determinants of health in risk-adjusted outcome measures and encourage CMS to continue to evaluate the inclusion of these variables in their metrics, in addition to the clinically relevant indicators such as the NIHSS score.
- There are some concerns from the literature that measuring mortality in isolation could lead to unintended consequences of prolonging life through invasive interventions without considering functional outcomes. We would urge CMS to be cognizant of this concern and to consider the

development of metrics that look at functional outcomes in addition to mortality and continue to promote advance care planning.

In summary, BJC supports the use of new ICD-10 codes for initial NIHSS, represents a significant improvement over the measure that is currently reported. We strongly urge the Standing Committee to vote to endorse it to relieve providers of some of the regulatory burden associated with public programs.

Measure Steward/Developer Response:

Thank you for BJC's comments supporting the endorsement and use of measure #3596. We appreciate your feedback on the implementation of this measure and offer the following additional points for your consideration.

We agree that it is important for all hospitals to consistently report the NIH Stroke Scale within administrative claims, a Class I guideline according to the American Heart Association/American Stroke Association (AHA/ASA). Notably, hospital reporting of the NIH Stroke Scale has increased considerably since ICD-10 implementation in 2016.

In response to your concern regarding adequate risk adjustment for transferred patients, please note that the outcome (mortality) is attributed to the admitting hospital.

Thank you for the suggestion to ensure NIH Stroke Scale score documentation and compliance. The aim of the measure is to identify the first NIH Stroke Scale and will be implemented with the following logic for multiple NIH Stroke Scale scores:

- If there are multiple NIH Stroke Scale scores, use the scores coded as present on admission (POA) for risk adjustment
- If there are multiple NIH Stroke Scale scores with more than one coded as POA, randomly select one POA score to use for risk adjustment
- If there are multiple NIH Stroke Scale scores and none of them are coded as POA, randomly select one score to use for risk adjustment

As to your concern about social risk factors, while there is a conceptual pathway by which patients with social risk factors (SRFs) could experience worse outcomes, the empiric evidence does not support risk adjustment at the hospital level.

As presented in the testing attachment of the NQF submission for this measure, our main empiric finding is that adjusting for social risk has little impact on measure scores – mean changes in measure scores are small, and correlations between measure scores calculated with and without adjustment for social risk are near 1.

In additional analyses we have shown that there is little correlation between measure scores and hospitals' proportion of patients with social risk (dual-eligible and low AHRQ SES) across all hospitals, and in the fifth quintile we see no significant association.

The decision to not include social risk factors in the risk model is consistent with recommendations from ASPE that quality measures should not be adjusted for social risk factors¹. Given these empiric findings, ASPE's latest recommendations, and the fact that this is a hospital quality measure, CMS chose to not include these two social risk factors in the final risk model at this time.

We agree that stroke mortality is not the only outcome that should be assessed and that other outcomes, such as functional status, should be explored. However, measuring functional status in isolation could similarly lead to negative unintended consequences in which death is perversely incentivized over life with impairments, despite patient care preferences. At this time, CMS is currently limited by the data available within administrative claims but is continuously moving toward improved quality measurement and is actively evaluating the availability and validity of variables, such as functional status, through electronic health records and other data sources. We continue to believe mortality is an important outcome from the patients' perspective and an important piece of the quality picture. Further, we believe that this revised stroke measure that adjusts for stroke severity provides incremental improvements in accurately measuring stroke mortality performance compared to the measure currently in publicly reporting, which lacks adjustment for stoke severity.

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

Proposed Committee Response:

Thank you for your comments. The Committee will review and discuss them during the Post-Comment Meeting.

Action Item:

The Committee should review the comments and be prepared to discuss any recommendations for the developer to consider.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for the measure submitted for endorsement consideration to inform the Committee's recommendations. Two NQF members provided their expressions of support: See <u>Appendix A</u>.

Appendix A: NQF Member Expression of Support Results

One NQF member provided their expression of support. The measure under consideration received support from NQF members. Results for the measure are provided below.

3596: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity

Member Council	Support	Do Not Support	Total
Health Professional	1	0	1