Memo



October 27, 2021

- To: Neurology Standing Committee
- From: NQF staff
- Re: Post-comment web meeting to discuss public comments received and NQF member expressions of support

Introduction

NQF closed the public commenting period on the measures submitted for endorsement consideration to the Neurology Standing Committee. NQF received three comments that require the Standing Committee's review and consideration during the Neurology post-comment meeting.

The Standing Committee's recommendations will be reviewed by the Consensus Standards Approval Committee (CSAC) on November 30, 2021. The CSAC will determine whether or not to uphold the Standing Committee's recommendation for each measure submitted for endorsement consideration. All Standing Committee members are encouraged to attend the CSAC meeting to listen to the discussion.

Purpose of the Call

The Neurology Standing Committee post-comment web meeting is scheduled for October 27, 2021 from 10:00am – 1:00pm ET. The purpose of the post-comment call is to:

- Re-vote on a Consensus Not Reached measure;
- Review and discuss comments received during the post-evaluation public and member comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expression of support of the measures 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 draft report.
- 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 measures.
- 4. Be prepared to re-vote and to 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: <u>https://nqf.webex.com/nqf/j.php?MTID=m8d89d582d3b9ce22a1725f2143190bb0</u> Meeting Number: 2336 690 0143 Meeting Password: QMEvent Join by phone: 1-844-621-3956 Passcode: 2336 690 0143

Background

The Global Burden of Disease Study found the three most burdensome neurological conditions in the United States (U.S.) to be stroke, Alzheimer's disease and other dementias, and migraine headache.¹ Additionally, due to an aging population, neurological disorders are increasing in prevalence, incidence, mortality, and disability-adjusted life years (DALYs).² The National Quality Forum (NQF) Neurology Standing Committee oversees the measurement portfolio used to improve the quality of care for neurological conditions. To date, the NQF has endorsed 14 measures that address neurological conditions such as stroke, subarachnoid and intracerebral hemorrhage, dementia, and carotid stenosis. For the spring 2021 cycle, the Standing Committee evaluated measures related to stroke and carotid stenosis.

For the spring 2021 cycle, the 22-member Standing Committee evaluated one newly submitted measure and one measure undergoing maintenance review against NQF's standard evaluation criteria.

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

• NQF #0507 Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports (American College of Radiology)

The Standing Committee did not recommend the following new measure:

• NQF #3614 Hospitalization After Release With Missed Dizzy Stroke (Johns Hopkins Armstrong Institute of Patient Safety and Quality)

Comments Received

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

Pre-evaluation Comments

NQF accepts comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from April 22 to June 3, 2021 for the measures under review. The majority of the comments received focused on concerns over the lack of exclusions, insufficient reliability results, and lack of risk adjustment. All of these pre-evaluation comments were provided to the Standing Committee prior to the measure evaluation meeting.

¹ GBD 2017 US Neurological Disorders Collaborators, Feigin VL, Vos T, et al. Burden of Neurological Disorders Across the US From 1990-2017: A Global Burden of Disease Study. JAMA Neurol. 2021;78(2):165. ² Ibid.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on August 11, 2021 for 30 calendar days. During this commenting period, NQF received four comments from four member organizations:

Member Council	# of Member Organizations Who Commented
Health Professional	2
Provider Organization	1
QMRI	1

NQF staff have included all comments that were 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.

In order to facilitate discussion, the post-evaluation comments have been summarized below, along with the developer's response. Although all comments are subject to discussion, the intent is not to discuss each individual comment during the post-comment call. Instead, NQF staff will spend the majority of the time considering the themes discussed below 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

NQF #0507: Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports

The American College of Radiology (ACR) has completed data element empirical validity to support NQF 0507 re-endorsement. According to the Blueprint for the Centers for Medicare & Medicaid Services (CMS) Measures Management System, data element validity is the "extent to which the information represented by the data element or code used in the measure reflects the actual concept or event intended." The ACR performed random audits using the groups that submitted Qualified Clinical Data Registry (QCDR) records for the measure to CMS for their Merit-based Incentive Payment System (MIPS) program, over a four-year period. The auditors compared the numerator data element registry submissions used in measure calculation with actual exam records from the submitters' systems. The audit confirmed a high level of agreement and concordance between the data shown on exam records and what was submitted to the registry. The records where exam data did not match the registry data represent human error in collection or submission of data.

Year	# Groups	# Records Audited	# Records Without Issue	% Records Without Issue
2017	11	108	106	98%
2018	22	128	126	98%
2019	17	130	130	100%
2020	15	69	69	100%

Summary of NQF 0507 in 2017-2020 Audit by Year

Measure Steward/Developer Response:

N/A

Proposed Committee Response:

Thank you for your comment. The Standing Committee will review and consider this information in the upcoming meeting.

Action Item:

Review the comments received and re-vote on validity.

NQF #3614 Hospitalization After Release with Missed Dizzy Stroke (H.A.R.M Dizzy-Stroke)

During the post-comment meeting, the Standing Committee will review the reconsideration request submitted by the developer and determine whether to reconsider NQF #3614. Public comments received on NQF #3614 will only be reviewed by the Standing Committee if the measure is reconsidered.

The measure developer provided additional evidence to support the submission. The developer suggests that some members of the Neurology Standing Committee, in their initial review of Evidence, did not see a clear link between the measure, the quality improvements that would be induced, and the outcomes for patients. The developer's full comment (contained within the separate Comment Narrative document) first defines the logical links and accompanying evidence supporting the relationship between the measure and improved patient outcomes, and follows by demonstrating how they believe the measure clearly meets the NQF standard for Evidence on purely technical grounds.

Measure Steward/Developer Response:

N/A

Proposed Committee Response:

Thank you for your comment. If the Standing Committee chooses to reconsider this measure, this comment will be reviewed and discussed in full during the upcoming meeting.

Action Item:

Review the comment received and determine whether to accept the proposed Standing Committee response.

The Federation of American Hospitals submitted a comment in support of this concept but raising concerns that the measure may require the addition of exclusions, case minimums to ensure adequate reliability, and risk adjustment. The commenter notes that there may be clinical or social risk factors that could contribute to an individual presenting with a stroke within the 30-day window that are unrelated to the chief complaint of dizziness during the emergency department visit and adjustment based on

those variables may be needed. The commenter also questions whether the measure scores produce sufficient variation to make the results meaningful for accountability purposes.

Measure Steward/Developer Response:

We appreciate the opportunity to respond to The Federation of American Hospitals' (FAH) comments on measure #3614 under review by the NQF Neurology Standing Committee.

The concerns raised by FAH primarily relate to the scientific acceptability of the measure. These aspects of the measure have already been reviewed and discussed by the NQF Scientific Methods Panel, where the panel voted to pass the measure on Scientific Acceptability. We will address FAH's comments in brief below and would urge Standing Committee members and other interested parties to review the Scientific Methods Panel meeting notes for additional detail about these topics.

Lack of exclusions: Patients who left against medical advice (AMA) were excluded. We apologize for any lack of clarity on this point in the documentation. We are happy to provide additional information on this issue if the Committee so desires.

Minimum sample size for reliability: As described in our submitted testing documentation, we restricted our sample to those hospital EDs that had at least 250 "benign dizziness" discharges from the ED during the 3-year performance period (i.e., the measure denominator needs to be 250 or higher). The median reliability score for the entire 967 hospital sample was 0.590, with an interquartile range of 0.414-0.951. These values closely mirror the reliability statistics that describe many NQF-endorsed measures. We would encourage a potential user of the measure to use a similar denominator threshold. We note there are other measures (e.g., 30-day stroke mortality) used by the Centers for Medicare and Medicaid Services (CMS) for accountability where public reporting is reserved for larger hospitals; smaller hospitals receive their (less precise) results as a quality improvement tool, rather than for public accountability. We envision that the same sort of procedure would occur for this measure once implemented.

Risk adjustment: The risk-adjustment approach used for this measure in unique in that it compares the same patient population at two different points in time. In short, it compares the patient's short-term risk of stroke (1-30d post-discharge) to their underlying baseline risk (91-360d post-discharge). As noted in the measure documentation, there are disparities in how well hospital EDs diagnosis strokes in different subgroups (women, younger patients, and people of color are more likely to experience a misdiagnosed stroke). It is these very disparities in diagnosis that our measure aims to highlight. Adjusting for clinical risk factors or social risk factors would result in these variations being adjusted away.

Sufficient variation: As discussed with the Scientific Methods Panel, our ability to distinguish "good" from "bad" performers on this measure is exclusively a function of the limited data set that we had available for testing the measure. The data set included only Medicare fee-for-service patients, which typically represents only about 20% of hospital ED discharges. In real-world applications, where more complete data sets are likely available, the ability to distinguish "good" from "bad" will be substantially more precise. As can be seen in the data presented as part of our measure developer comments (reproduced below as Figure 4), the true practice variation is substantial, with hospital performance ranging from 0 to over 150 per 10,000 discharges, with hundreds of hospitals having measured rates ranging from 20 to 200 per 10,000. These data reflect a 10-year window, so this level of precision or greater is what one would expect from a complete 100% ED sample (5x the 20% Medicare sample) from each hospital when using the proposed 3-year rolling window of analysis. This could be accomplished

using HCUP data from states with linkable SEDD-SID records (now nearly half). In other words, this problem noted by the FAH is a problem related to data availability, not the measure itself.



Figure 4. Excess short-term stroke rates at all hospitals by ED visit volume, with descriptive overlay separating true variation from measure imprecision. These Medicare data reflect 5,472 facilities over a 10-year window from 2009-2018. Each circle represents a single facility. The Figure demonstrates that smaller facilities have higher 30-day stroke hospitalization rates above the expected base rate after ED treat-and-release visit (TRV) for "benign dizziness." Optimal measure performance is to have a zero rate above baseline (0 on the Y axis). The graph shows wide variation in ED performance on the measure (from less than zero to 500 excess stroke hospitalizations per 10,000 TRVs). Although not all of this variation reflects actual clinical performance, the vast majority of US hospitals have non-zero (>0) rates. The regression trend line shows the association between facility size and measure performance, with the larger facilities having the best performance (zero excess strokes over expected). The **red shaded area** reflects measure instability at the smallest hospitals. For hospitals with fewer than ~20 treatand-release visits (TRV) for "benign dizziness" each year, the measure would be used only for quality improvement and **not** public accountability. The **purple shaded area** shows mild measure imprecision at hospitals with 20-200 dizziness TRVs each year; maximum imprecision is +/- ~20 per 10,000 TRVs at the smaller EDs. The **yellow shaded area** shows true clinical performance variability (from rates of 0 excess strokes per 10,000 TRVs to >150 excess strokes – i.e., 1.5% of all "benign" discharges). **This is strong evidence of wide practice variation around the US**.

Proposed Committee Response:

Thank you for your comment. If the Standing Committee chooses to reconsider this measure, this comment will be reviewed and discussed in full during the upcoming meeting.

Action Item:

Review the comments received and determine whether to accept the proposed Standing Committee response.

David Morrill, a member of the public, submitted a comment in disagreement with the Standing Committee's decision. The commenter states that this measure would provide feedback to aid emergency department physicians to differentiate dizziness as a symptom of a critical health condition, such as stroke, as compared to a more benign condition. The commenter raises concerns that there are diagnostic techniques that are not in wide use and could be addressed by the implementation of this measure.

Measure Steward/Developer Response:

N/A

Proposed Committee Response:

Thank you for your comment. If the Standing Committee chooses to reconsider this measure, this comment will be reviewed and discussed in full during the upcoming meeting.

Action Item:

Review the comments received and determine whether to accept the proposed Standing Committee response.

The American Medical Association (AMA) submitted a comment in agreement with the concerns raised by the Standing Committee on this measure, particularly around scientific acceptability. The AMA states it supports the Committee's recommendation to not endorse the measure at this time.

Measure Steward/Developer Response:

N/A

Proposed Committee Response:

Thank you for your comment. If the Standing Committee chooses to reconsider this measure, this comment will be reviewed and discussed in full during the upcoming meeting.

Action Item:

Review the comments received and determine whether to accept the proposed Standing Committee response.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members have the opportunity to express their support ('Support' or 'Do Not Support') for each measure to inform the Standing Committee's recommendations during the commenting period. This expression of support (or not) during the commenting period replaces the member voting opportunity that was previously held subsequent to Standing Committee deliberations. One NQF member provided their expression of non-support: See <u>Appendix A</u>.

Appendix A: NQF Member Expression of Support Results

One NQF member provided their expression of nonsupport. No measures under consideration received support from NQF members. Results for each measure are provided below.

NQF #0507 Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports (American College of Radiology)

No expressions of support or nonsupport provided.

NQF #3614 Hospitalization After Release with Missed Dizzy Stroke (H.A.R.M Dizzy-Stroke) (Johns Hopkins Armstrong Institute of Patient Safety and Quality)

Member Council	Commenter Name, Organization	Support	Do Not Support	Total
Health Professional	Koryn Rubin, American Medical Association	0	1	1

Appendix B: Reconsideration Request

The developer submitted a request for the Standing Committee to reconsider its vote for evidence.

In the reconsideration request, the developer raised concerns that because the measure's evidence is of a type that has not been seen before at NQF, and the developer was not able to sufficiently organize the initial submission to make this evidence sufficiently digestible. The developer noted that the evidence provided in the submission was sufficient, but has also provided additional documentation in the comment above for the Standing Committee's consideration. The developer also raised concerns regarding adherence to the Consensus Development Process during the Measure Evaluation meeting. During the meeting, one member of the developer team who is a member of the Neurology Standing Committee was not permitted to present the measure to the Committee. The developer cited an example from 2015 in which a Standing Committee member who was also one of the measure's developers was able to present during the measure evaluation meeting. The developer also noted that due to loss of quorum multiple times during the original Measure Evaluation Meetings, the discussion of the measure was fragmented and much of the voting was conducted asynchronously. Finally, the developer noted that there were inconsistencies in voting for this measure compared to the other measure reviewed this cycle. The other measure reviewed did not initially pass the scientific acceptability vote (reliability) one of the must-pass criteria but received a revote. The developer asserts that if the Standing Committee applied the same standard to NQF #3614 for evidence as it applied to NQF #0507 on scientific acceptability, NQF #3614 would have passed.

RE: Petition for a Revote on Evidence for Measure #3614 before the Neurology Standing Committee

Dear NQF Neurology Standing Committee Members:

We appreciate the committee's thoughtful review of our measure during the July 2021 meeting. We would like to petition the committee for a revote on the "Evidence" criterion with the opportunity for

Dr. Newman-Toker (developer) to provide an additional brief summary of the evidence for the measure, re-present the measure to the group, and answer questions. The grounds for this appeal are threefold:

(1) On the merits, we believe that the measure does, in fact, meet the NQF Evidence Criterion, and that our initial submission materials support that contention. This contention is supported by the fact that the *NQF staff, in their pre-review of the measure, concluded that the Evidence Criterion had been adequately passed*. Our submission was for a new type of measure that has not been seen before at NQF. As such, we did not know how best to focus and organize our initial submission, and we believe we may have presented an overwhelming amount of information for Committee members to review and from which to answer the Evidence question, leading (in combination with #2 below) to a flawed result. In addition, as part of the NQF comment period, we have provided additional documentation that hopefully clarifies the link between existing interventions and the outcome measure (in particular, two large, randomized clinical trials [CHANCE, POINT] that show patient benefit of dual antiplatelet therapy for prevention of major stroke after minor stroke and TIA – combined results in over 10,000 patients show that treatment in the first 24 hours cuts the risk of a major stroke by 34% in the next 21 days).

(2) The live Committee process was highly fragmented, and Dr. Newman-Toker (lead developer) was not permitted to present the measure to the Committee. The meeting had barely a quorum of committee members to begin with, and this led to a stop-start fragmentation of the meeting. The meeting was paused when one member dropped off, started again when the quorum was reached again, and then stopped again for lack of quorum. The discussion was therefore derailed and curtailed. The subsequent online vote was via email, and it is unclear whether individuals who voted were able to view even the fragmented discussion prior to voting. Furthermore, despite requesting to present in advance of the meeting, Dr. Newman-Toker was denied the opportunity to do so by NQF staff for the Neurology Committee on the grounds that he had a conflict of interest as a member of the Committee. However, we have since learned that *developers who are members of other Standing Committees have previously been granted the opportunity to present their measures*, and merely be recused from voting. Specifically, based on NQF transcripts, we know that this occurred at the Patient Safety Standing Committee Meeting (June 17-18, 2015). On Day #1 of the meeting, Jason Adelman, a Committee member, introduced himself and announced his conflict for Day #2. On Day #2, Jason went on to present his measure with no objections from NQF staff, then recused himself from voting.

(3) We believe that it would be a sign of fairness and consistency across measures for the Committee to take a re-vote. In the same July, 2021 Neurology Committee meeting at which our measure (#3614) was reviewed, another measure for carotid artery imaging reporting standards (#0507) was reviewed. This measure initially failed a vote on one of the required criteria (Scientific Acceptability of Measure Properties); the initial vote was 0 high, 7 moderate, 5 low, 3 insufficient. The Chair called for a re-vote on the grounds of the adverse ruling, and several members changed their votes without any new information, so that the measure could progress. In addition, this measure provided no evidence of the link between the measure and improved patient outcomes, impact on the real-world accuracy of carotid artery measurement, or even whether those self-reporting that they were using a specific technique to measure the carotid artery thickness were actually doing so. They simply surveyed experts to ask if the measure would support quality, and 23 of 28 experts said that it would. The NQF staff stated the following, "Based on staff review, there is not a clear link between outcomes/quality of care with accurate vs. inaccurate carotid measurement." However, the Committee took as sufficient for the Evidence criterion that it was logical that if (a) measurement of the carotid artery was standardized, (b) it would have to be more accurate, and, (c) as a result, it would lead to more correctly applied carotid artery surgeries. The Committee then relied upon the strong evidence from the NASCET trial (and others) showing benefit of carotid endarterectomy to patients in prevention of major strokes. No direct

evidence of logical conclusions "a" "b" or "c" was provided by measure developers or Committee members to support the measure. If the Committee were to apply the same standard to measure #3614 as was applied to measure #0507, which passed, we believe that ours would pass as well.

Measure #3614 has support from patients and professional societies. It has been developed in partnership with both the Vestibular Disorders Association and the American College of Emergency Physicians as part of an AHRQ-funded measure development process. The Society of Academic Emergency Medicine is currently creating a guideline to improve diagnosis of dizziness in the emergency department (GRACE3 – <u>https://www.saem.org/publications/academic-emergency-medicine/grace</u>). We believe there is strong evidence that supports exiting interventions can drive improved performance on this measure. We hope the committee reaches that same conclusion.

Thank you for your thoughtful consideration of this request.

Sincerely,

David Newman-Toker & Matt Austin on behalf of the Center for Diagnostic Excellence at Johns Hopkins