

# Neurology Spring 2021 Cycle: Public and Member Comments

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# Measure-Specific Comments on Neurology Spring 2021 Submissions

NQF #0507 Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports, Comment #7799

Standing Committee Recommendation: Consensus Not Reached

Comment ID#: 7799

Commenter: Submitted by Karen Orozco

Council / Public: HPR

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/23/2021

Developer Response Required? No

Level of Support: Member Does not support

Theme:

## Comment

The American College of Radiology (ACR) has completed data element empirical validity to support NQF 0507 reendorsement.

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 Meritbased 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

## Developer Response

N/A

NQF Response N/A

## NQF Committee Response

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

Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7756 Commenter: Submitted by David Morrill Council / Public: Public Comment Period: Post-Evaluation Public and Member Commenting Date Comment was Submitted: 9/7/2021 Developer Response Required? No Level of Support: N/A

Theme: N/A

#### Comment

As a patient who struggles with ongoing vestibular issues as a result of a missed stroke diagnosis, I am deeply invested in supporting efforts to improve the diagnostic performance of Emergency Department (ED) physicians in identifying strokes in patients who present with symptoms of dizziness and vertigo. I am writing to urge the NQF Neurology Standing Committee to reconsider its vote on the "Evidence" criteria for measure #3614"Hospitalization After Release with Missed Dizzy Stroke (H.A.R.M Dizzy-Stroke)".

Based on my work with the Vestibular Disorder Association (VeDA), I have been made aware of a number of diagnostic techniques that ED physicians can use to improve their performance in diagnosing patients that present with dizziness. These techniques include the Head Impulse, Nystagmus and Test of Skew (HINTS) exam; ordering MRIs instead of CT scans; and following published specialty guidelines (e.g SAEMS' GRACE3 guideline). As I understand the current healthcare landscape, these techniques have not been put into wide use.

Without a measure of diagnostic performance, the underlying assumption is that current diagnostic approaches are yielding an adequate result (and they're not!). Measure #3614 would provide the "feedback" loop this is currently missing on how well ED physicians recognize dizziness as "benign", as opposed to a symptom of a potentially devastating outcome, such as stroke.

My own misdiagnosis has left me with a life-long disability. Given the availability of interventions to improve diagnosis of dizzy patients, I would strongly urge the Standing Committee to reconsider its earlier vote on the "Evidence" associated with this measure and to support the measure's full endorsement.

David M Morrill Stroke Patient

Developer Response N/A

#### NQF 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.

NQF Committee Response N/A

Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7806

Commenter: Submitted by Koryn Rubin

Council / Public: Health Professional

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 9/24/2021

Developer Response Required? No

Level of Support: Member Does not support

Theme: N/A

## Comment

The American Medical Association (AMA) agrees with the concerns raised by the Standing Committee on this measure, particularly around the scientific acceptability of the measure. We support the Committee's recommendation to not endorse the measure at this time.

Developer Response N/A

## NQF 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.

NQF Committee Response N/A

Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7752 Commenter: Submitted by David Morrill Council / Public: Public Comment Period: Post-Evaluation Public and Member Commenting Date Comment was Submitted: 9/7/2021 Developer Response Required? No Level of Support: N/A

Theme: Supportive of measure

#### Comment

I am deeply invested in supporting efforts to improve the diagnostic performance of Emergency Department (ED) physicians in identifying strokes in patients who present with symptoms of dizziness and vertigo. I am writing to urge the NQF Neurology Standing Committee to reconsider its vote on the "Evidence" criteria for measure #3614"Hospitalization After Release with Missed Dizzy Stroke (H.A.R.M Dizzy-Stroke)".

Based on my work with the Vestibular Disorder Association (VeDA), I have been made aware of a number of diagnostic techniques that ED physicians can use to improve their performance in diagnosing patients that present with dizziness. These techniques include the Head Impulse, Nystagmus and Test of Skew (HINTS) exam; ordering MRIs instead of CT scans; and following published specialty guidelines (e.g SAEMS' GRACE3 guideline). As I understand the current healthcare landscape, these techniques have not been put into wide use.

Without a measure of diagnostic performance, the underlying assumption is that current diagnostic approaches are yielding an adequate result (and they're not!). Measure #3614 would provide the "feedback" loop this is currently missing on how well ED physicians recognize dizziness as "benign", as opposed to a symptom of a potentially devastating outcome, such as stroke.

My own misdiagnosis has left me with a life-long disability. Given the availability of interventions to improve diagnosis of dizzy patients, I would strongly urge the Standing Committee to reconsider its earlier vote on the "Evidence" associated with this measure and to support the measure's full endorsement.

# Developer Response

N/A

#### NQF 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.

NQF Committee Response N/A

Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7641

Commenter: Submitted by Donald May, Federation of American Hospitals

Council / Public: PRO

Comment Period: Post-Evaluation Public and Member Commenting

Date Comment was Submitted: 6/10/2021

**Developer Response Required? Yes** 

Level of Support: N/A

Theme: N/A

#### Comment

#3614, Hospitalization After Release with Missed Dizzy Stroke (H.A.R.M Dizzy-Stroke) The Federation of American Hospitals (FAH) appreciates the opportunity to comment on this measure. While FAH supports the measure's focus of driving improvements in diagnostic accuracy, we are concerned that the measure may require additional exclusions and question if case minimums to ensure adequate reliability and risk adjustment are needed and whether the measure scores produce sufficient variation to make the results meaningful for accountability purposes. The FAH asks the Standing Committee to consider whether some exclusions, delineation of a case minimum, and possible risk adjustment would be appropriate for inclusion in this measure. For example, is it appropriate to hold a facility accountable for a possible missed diagnosis when an individual leaves against medical advice (AMA)? We are also concerned that a minimum number of patients will be required to ensure that the measure produces acceptable reliability thresholds of 0.7 or higher, yet we were unable to identify any such requirement. Finally, while we appreciate the analyses completed to justify the lack of risk adjustment, we request that the committee discuss whether there are any clinical or social risk factors that could contribute to an individual presenting with a stroke within the 30-day window that is unrelated to the chief complaint of dizziness during the emergency department visit and as a result if there should be some adjustment based on those variables. The FAH also questions the usefulness of this measure given the limited variation in performance scores with no hospitals identified as statistically worse than the national average, only 8 were identified as having significant harm and the vast majority of the hospitals were no different or better than the national average. We do not believe that this measure provides any new information that would be useful to hospitals and patients. The FAH asks that the committee carefully consider these concerns during their review.

#### 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 1a/b), 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. From Medicare data using the method proposed (Figure 4, shown as the measured 30d rate above expected)...



**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 treat-and-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*.

## NQF 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.

# NQF Committee Response

N/A

NQF #3614 Hospitalization After Release with Missed Dizzy Stroke (H.A.R.M Dizzy-Stroke), Comment #7835 Standing Committee Recommendation: Measure Not Recommended for Endorsement

Comment ID#: 7835 Commenter: Submitted by J. Matthew Austin Council / Public: QMRI Comment Period: Post-Evaluation Public and Member Commenting Date Comment was Submitted: 9/27/2021 Developer Response Required? No Level of Support: N/A Theme: N/A

# NQF Comment Period Additional Evidence for Measure #3614

# **Contents of this Document**

Below the measure developers offer additional evidence to meet the NQF standard for "Evidence." 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. **Part I** below defines the logical links and accompanying evidence supporting the relationship between the measure and improved patient outcomes. **Part II** below shows how, in addition, the measure clearly meets the NQF standard for Evidence on purely technical grounds.

# Measure #3614

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

The measure denominator is ED treat-and-release with "benign" dizziness. The measure numerator is observed 30-day stroke hospitalizations post ED treat-and-release with "benign" dizziness, minus the expected number of stroke hospitalizations occurring during that same period.

## Part I. Logic Model and Supporting Evidence for Improved Quality and Patient Outcomes

#### A. Stepwise mechanism by which proposed measure will improve quality/safety for patients...

- 1. Measure #3614 reflects missed strokes in ED patients presenting with dizziness or vertigo
- 2. Accountability to the measure requires QI efforts that improve ED diagnosis of dizziness/vertigo (Figure 1)
- 3. These QI efforts will improve diagnosis both for patients with stroke and inner ear disease
- 4. Benefits to patients will then accrue from the prompt application of RCT-proven treatments
  - a. Those with stroke will benefit from tPA or early secondary prevention, as appropriate
  - b. Those with BPPV will benefit from prompt canalith repositioning and less CT radiation
- 5. These benefits to stroke patients (4a), in turn, will result in a "better" measure score (Figure 2)

#### STANDARD ED DIZZINESS DIAGNOSIS EVIDENCE-BASED ED DIZZINESS DIAGNOSIS S INNER EAR DISEASE (~25% of INNER EAR DISEASE (~25% of Т dizziness complaints in the ED) dizziness complaints in the ED) R Quality Improvement Prompt treatment of INNER EAR Unnecessary imaging and delayed treatment of INNER EAR DISEASE DISEASE with no excess imaging MRI CT >> MRI Neuroimaging (shaded area)

**CURRENT PRACTICE**: Search for stroke is mostly based on non-selective imaging (~90% by CT) of dizziness based on patient age and vascular risk rather than exam. Estimated ~45,000-75,000 missed strokes annually, many causing harms.

**NEW PRACTICE**: Bedside exams lead to selective imaging (MRI) to confirm stroke, pinpoint cause, and guide stroke treatments. Estimated ~25,000 harms prevented and ~\$1 billion in costs saved (half from unnecessary CTs, half admissions).

**Figure 1. Theory for ED practice change**. Standard practice in diagnosing dizziness now rests largely on CT to search for stroke in older patients with vascular risk factors. However, CT is ineffective for diagnosing vestibular strokes. Because inner ear causes are also more common among older populations with stroke risk factors, imaging is overused in inner ear diseases. Simultaneously, young patients (or old patients without vascular risk factors) who <u>do</u> have strokes as the cause may inadvertently be sent home untreated, sometimes with devastating consequences.<sup>1,2</sup> QI interventions such as teleconsultation will focus neuroimaging on directing stroke treatments, and more patients with inner ear disease will be correctly diagnosed and treated, preventing unnecessary imaging and admission.

Abbreviations: CT – computerized tomography; MRI – magnetic resonance imaging; QI – quality improvement



# Figure 2. Logic model by which proposed measure will improve quality and safety for patients.

Abbreviations:  $2^{\circ}$  – secondary; Dx – diagnosis; HRQoL – health related quality of life; MRI-DWI – magnetic resonance imaging with diffusion weighted images; PT – physical therapy; QI – quality improvement; Rx – treatment

# B. Logical validity of the evidence supporting positive impact of the measure on patient care...

1. SYSTEMATIC REVIEW EVIDENCE THAT BETTER EYE EXAMS INCREASE CLINICAL DIAGNOSTIC ACCURACY: There is strong evidence from multiple systematic reviews with meta-analyses of multiple prospective observational studies that bedside eye movement exams ("HINTS") in the hands of neurologists can more accurately diagnose stroke in patients with dizziness than even MRI scans.<sup>3-6</sup> Furthermore, the accuracy of these bedside exams far exceeds that of the more

commonly used imaging technique of CT (which misses over 90% of acute posterior fossa strokes presenting with dizziness [reviewed in Newman-Toker, 2016<sup>7</sup>]), as well as the overall accuracy of current ED care, in which 40% of strokes presenting with dizziness are missed.<sup>8</sup> Neurology consultation services directly to the ED have demonstrated dramatically improved diagnostic accuracy, while simultaneously reducing inappropriate imaging.<sup>9,10</sup> Reductions in inappropriate CT use eliminate unnecessary irradiation, thereby cutting cancer risk, so improving outcomes for patients.<sup>11</sup> And while untrained ED clinicians do not perform this bedside testing well, those who are trained using direct observation and feedback methods achieve similar diagnostic results to those obtained by specialists—(sensitivity: 92.9% [95% CI 70–100%]; specificity: 96.4% [95% CI 93–98%]; positive predictive value: 81.3% [95% CI 61–87%]; negative predictive value: 98.8% [95% CI 95–100%]).<sup>12</sup>

- FACE VALIDITY THAT BETTER DIAGNOSIS YIELDS BETTER TREATMENT: It is face valid that increasing correct diagnosis of posterior stroke in patients with dizziness and vertigo will lead to greater application of randomized trial and guideline approved stroke treatments in the ED. Likewise the same for inner ear diseases.
- 3. RCT EVIDENCE THAT EARLY TREATMENT OF MINOR STROKE/TIA IMPROVES OUTCOMES: It is proven through randomized clinical trials (CHANCE, POINT) that certain patients with TIA and minor stroke benefit from the application of early secondary prevention treatments, such as dual antiplatelet therapy. 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.<sup>13</sup> In our original application for measure #3614, we provided similar empirical evidence from other studies of the benefit of immediate stroke treatments: "Preventable adverse outcomes of misdiagnosis result from missed opportunities for thrombolysis,<sup>14,15</sup> early surgery for malignant posterior fossa edema,<sup>16,17</sup> or prevention of subsequent infarction.<sup>18-20</sup> Rapid treatment improves health outcomes<sup>21,22</sup> and prompt prophylaxis lowers repeat stroke risk by up to 80%.<sup>23,24</sup> Thus, patients generally benefit from early, correct diagnosis."
- 4. RCT EVIDENCE THAT EARLY TREATMENT OF INNER EAR DISEASES IMPROVES OUTCOMES: Benefits also accrue to patients with dizziness or vertigo who are correctly diagnosed with inner ear disease (benign paroxysmal positional vertigo and vestibular neuritis) who receive guidelinesupported treatments with randomized controlled trial evidence,<sup>25-31</sup> and direct harms of misdiagnosis<sup>32</sup> are reduced.
- 5. FACE VALIDITY THAT PREVENTING MAJOR STROKES WILL LOWER THE MEASURE SCORE: It is face valid that if there are fewer subsequent major strokes among those treated, then there will be fewer short-term hospitalizations for stroke, which is, in turn, reflected in the measure (i.e., by reducing the "n" in the numerator). Furthermore, properly identifying such patients in the first place will remove these higher risk patients from the denominator (by correctly diagnosing stroke rather than "benign" inner ear disease or non-specific dizziness); this will tend to lower the observed number of subsequent strokes towards the expected population base rate (which is included as part of the measure calculation, which is observed minus expected).

# *C. Evidence of improved diagnostic accuracy in clinical practice with consult-based quality improvement...*

Recent data (Table 1) from a quality improvement intervention (Tele-Dizzy) involving remote neurology consultations show dramatic <u>increases</u> in both stroke and specific inner ear diagnoses, along with dramatic <u>decreases</u> in inappropriate imaging among 287 patients who underwent consultation, relative to a matched emergency department population. These results provide compelling **empirical evidence** 

supporting the link between a *healthcare intervention/service* and the outcome of improved diagnosis, as well as better patient outcomes (reduction in unnecessary irradiation). It is inferentially logical and face valid, then, that these results, implemented more broadly, could be measured using #3614.

Category	Parameter	Baseline*	<b>Tele-Dizzy</b>	Improvement	p-value (χ²)
Diagnostic	Specific Vestibular Diagnosis Rate	77 (20.6%)	163 (56.8%)	↑176%	P<0.0001
Yield					
	Stroke Diagnosis Rate	1 (0.3%)	20 (7.0%)	↑ 2,506%	P<0.0001
	Non-Diagnosis Rate	235 (62.8%)	86 (30.0%)	↓52%	P<0.0001
Test	Neuroimaging (CT or MRI)	198 (52.9%)	70 (24.4%)	↓54%†	P<0.0001
Utilization					
Patient	Excess 30-day stroke	0.1%‡	0 (0.0%)‡	↓100%‡	NA
Outcomes	hospitalizations				

Table 1. Results of Tele-Dizzy Quality Improvement Intervention at Johns Hopkins Hospital (n=287 teleconsults).

\* Baseline rates for diagnostic accuracy and test utilization are from 374 ED patients with a presenting symptom of dizziness (seen outside of Tele-Dizzy consultation hours) who had mention of "nystagmus" in notes and were comparable on the variables age, sex, and ED triage acuity.

*†* CT scans were reduced by 96% (from 49.2% to 1.7%, p<0.0001) and MRIs for patients without strokes were unchanged (15.5% vs. 15.7%, p=0.95).

*‡* Baseline 30d stroke hospitalizations are calculated as in Measure #3614 (not using the comparator population for Tele-Dizzy, which was too small for a precise estimate). The Tele-Dizzy value is based on actual patients seen at the same hospital – thus far, there have been zero stroke returns.

# Part II. NQF Evidence Standard for Outcomes Measures (directly quoted from NQF documents, bold emphasis added)

**"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 [are] 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."

#### Technical Elements of NQF Evidence Standard Met by Measure #3614

- *A.* "...empirical data that demonstrate a relationship between the outcome and at least one healthcare *structure*..."
- **B.** "...empirical data that demonstrate a relationship between the outcome and at least one healthcare **process**..."
- C. "...data demonstrating wide variation in performance..."

NOTE – Only **ONE** of the three options is needed to meet the NQF Evidence standard, but all three are met. Also, only **ONE** structure OR **ONE** process is required, but FOUR structures and THREE processes are empirically shown below.

A. HEALTHCARE STRUCTURE (ED volume, population size, teaching status, % admitted from ED) From Medicare data using the method proposed (Figure 3, shown as incidence rate curve) ...



**Figure 3. Short-term stroke rates at large vs. small hospitals (based on ED visit volumes).** The graph at left shows stroke hospitalization incidence rates for the first 100 days after an ED treat-and-release visit (TRV) for "benign dizziness." Red represents larger hospitals and blue smaller hospitals. Shaded areas are 95% confidence intervals. These Medicare data reflect 5,472 facilities over a 10-year window from 2009-2018. A cutoff of 1,000 ED index visits over 10 years was used to define large vs. small facilities (1,472,612 ED TRVs occurred in large facilities, and 1,422,724 ED TRVs in small facilities). The Figure demonstrates that smaller facilities have higher short-term stroke incidence, mostly in the first 2 weeks after ED treat-and-release visit for "benign dizziness." These represent missed strokes in the ED.

Data element	Value	EST	SE	Z	Р	OR	LCL	UCL
Hospital Characteristics								
Region	Midwest	- 0.17	0.15	-1.1	0.27	0.84	0.62	1.14
	South	- 0.12	0.13	- 0.93	0.35	0.88	0.68	1.14
	West	- 0.03	0.12	- 0.24	0.81	0.97	0.77	1.22
	Northeast	*	*	*	*	*	*	*
Population size	Small metropolitan	- 0.26	0.09	- 2.94	0.003	<mark>0.77</mark>	<mark>0.65</mark>	<mark>0.92</mark>
	Micropolitan	0.21	0.15	1.41	0.16	1.23	0.92	1.64
	Rural	0.06	0.24	0.24	0.81	1.06	0.67	1.68
	Large metropolitan	*	*	*	*	*	*	*
Ownership	Public	- 0.01	0.12	- 0.10	0.92	0.99	0.78	1.25
	Private, for-profit	- 0.22	0.12	- 1.93	0.05	0.80	0.64	1.00
	Private, not-for- profit	*	*	*	*	*	*	*
Teaching Status	Nonteaching	0.37	0.11	3.24	< 0.001	1.45	<mark>1.16</mark>	<mark>1.82</mark>
	Teaching	*	*	*	*	*	*	*
Hospital workflow (annual average)								
Inpatient occupancy rate (annual)	Low <=0.5	0.00	0.13	0.03	0.98	1.00	0.78	1.29
	Moderate >0.5, <0.7	0.11	0.11	0.94	0.35	1.11	0.89	1.39
	High >=0.7	*	*	*	*	*	*	*
ED Volume (annual)	Low <=29,124	0.45	0.17	2.69	0.007	<b>1.57</b>	1.13	<mark>2.18</mark>
	Moderate 29-125- 64,434	0.10	0.10	1.02	0.31	1.11	0.91	1.36

From HCUP data (Newman-Toker, 2014<sup>33</sup>) using a similar method to that proposed...

Data element	Value	EST	SE	Z	Р	OR	LCL	UCL
ED Volume (annual)	High >=64,435	*	*	*	*	*	*	*
Percent admitted from ED (annual)	Low <=11.82%	0.44	0.15	2.88	.004	<mark>1.55</mark>	<mark>1.15</mark>	<mark>2.09</mark>
	Moderate >11.82, <19.46%	0.21	0.11	1.95	0.05	1.24	1.00	1.54
	High >=19.46%	*	*	*	*	*	*	*

\* Cell intentionally left empty

#### B. HEALTHCARE PROCESS (weekend visit, ED admit rate on day of visit, patient left AMA)

From HCUP data (Newman-Toker, 2014<sup>33</sup>) using a similar method to that proposed...

Data element	Value	EST	SE	Z	Р	OR	LCL	UCL
ED Visit characteristics (day of initial treat-and- release visit)								
Weekend	Monday-Friday	0.11	0.05	2.09	0.04	<mark>1.11</mark>	<mark>1.01</mark>	<mark>1.23</mark>
	Saturday-Sunday	*	*	*	*	*	*	*
ED Crowding on day of visit (percentile)	0-20 <sup>th</sup> percentile	-0.02	0.07	-0.33	0.75	0.98	0.84	1.13
	21-40 <sup>th</sup> percentile	0.04	0.07	0.5	0.62	1.04	0.90	1.19
	41-60 <sup>th</sup> percentile	0.04	0.07	0.52	0.60	1.04	0.90	1.20
	61-80 <sup>th</sup> percentile	0.08	0.07	1.18	.0.24	1.08	0.95	1.23
	81-100 <sup>th</sup> percentile	*	*	*	*	*	*	*
ED admit rate on day of visit (percentile)	0-20 <sup>th</sup> percentile	1.85	0.16	11.72	<0.001	<mark>6.34</mark>	<mark>4.66</mark>	<mark>8.63</mark>
	21-40 <sup>th</sup> percentile	0.91	0.11	8.03	<0.001	2.48	1.99	3.10
	41-60 <sup>th</sup> percentile	0.61	0.10	6.05	<0.001	1.85	1.51	2.25
	61-80 <sup>th</sup> percentile	0.34	0.08	4.04	<0.001	1.40	1.19	1.66
	81-100 <sup>th</sup> percentile	*	*	*	*	*	*	*
Patient left against medical advice	Against medical advice	1.08	0.14	7.50	<0.001	<mark>2.94</mark>	<mark>2.22</mark>	<mark>3.89</mark>
	Not against advice	*	*	*	*	*	*	*

187,188 of 198,819 trials used; number of events used =2088 of 2243 (records with missing data excluded); exchangeable correlation structure (working correlation = 0.002); 1016 clusters (facilities). EST, estimate; SE, standard error; Z, Z score; p, probability level; OR, odds ratio; LCL, lower confidence limit; UCL, upper confidence limit. <sup>a</sup>This is a patient-level analysis of inpatient stroke admissions, with and without a prior treat-and-release ED visit for dizziness or headache within 30 days of the stroke admission; only a single 'initial' ED visit (the most proximate to the 'index' stroke admission) is considered.

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#### WIDE VARIATION IN PERFORMANCE

From Medicare data using the method proposed (Figure 4, shown as the measured 30d rate above expected)...



**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**.

# SUMMARY

**Part I** above offers a set of valid logical links between the measure, quality improvement interventions, and improved patient outcomes. Each of the key steps is either supported by strong empirical evidence or is naturally face valid. Although none of this is required to meet the NQF "Evidence" standard for outcome measures, this, nevertheless, directly addresses the Neurology Standing Committee concerns regarding the strength of underlying evidence.

**Part II** above shows how the measure clearly meets the NQF "Evidence" standard on technical grounds. The measure must only demonstrate that it meets one such element, but we provide evidence that it meets the standard nine times.

Parts of the evidence presented here were submitted with the original NQF Evidence Attachment. This includes specific citations to randomized trials evidence of benefit to patients with early diagnosis and prompt treatments (quoted in Part I) and at least two components of the technical standard (Figure 3 and part of Figure 4). In accord with this, NQF staff, in their pre-review of the measure, concluded that the Evidence Criterion had been adequately passed by #3614.

Thus, in summary, we are confident that measure #3614 meets both the spirit and the letter of the standard.

Therefore, we hope that the Committee will reconsider its initial vote, and vote "pass" on the Evidence criterion.

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